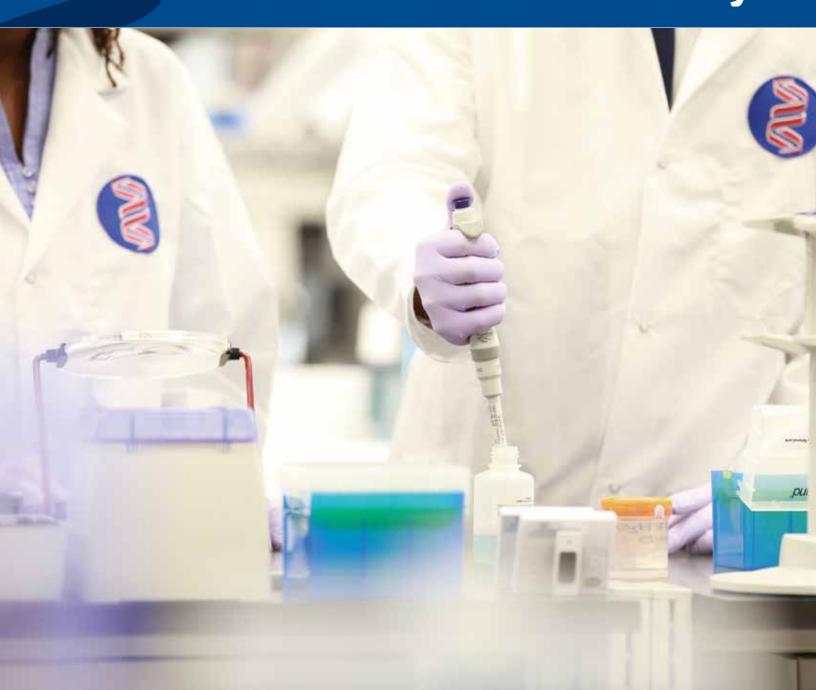


A Sonic Healthcare Company

Laboratory Test Directory



Overview

We are pleased to provide you with our CBLPath test directory. We have tried to provide comprehensive information on test ordering. If you need additional information or have questions about test results or ordering, our Client Services staff will be happy to assist you.

CBLPath, a Sonic Healthcare USA laboratory, is a leading diagnostic, molecular and informatics reference laboratory that combines anatomic pathology with advanced molecular diagnostics and multi-platform testing systems. We're committed to helping our clients deliver better medicine, faster. At our core we're pathologists; excited about technology and innovation and its promise of helping patients. We integrate comprehensive diagnoses with prognostic and therapeutic recommendations to deliver personalized medicine and the most effective patient care.

At CBLPath, Quality is in our DNA™. Our mission at CBLPath is quality and service. We welcome your suggestions about how we can continue to improve our service to you and your patients.

Visit us at www.cblpath.com

Certification and Accreditation:

New York: CLIA ID # 33D0653618

Florida: CLIA ID # 10D2056505

New York: CAP LAP # 7184143, AU-ID # 1402616

Lab Location:

760 Westchester Avenue Rye Brook, NY 10573

Phone: 877.225.7284

General Information

CPT Codes

The CPT Codes provided are based on AMA Guidelines and are for informational purposes only. CPT Coding is the sole responsibility of the billing party. Please direct any questions regarding CPT Coding to the billing department of the pay being billed.

Inappropriate Submissions

All specimens must be collected, labeled, transported, and processed according to procedure. Review the appropriate container type, volume, and special handling requirements needed for test before the specimen is collected. The specimen may be rejected of the test canceled if the guidelines are not met.

The Quality Control Department will contact the client for resolution. The list (on the following page) represents some possible causes which would generate a QA flag which may delay a specimen or lead to a specimen rejection or test cancellation:

- Inappropriate specimen type
- Insufficient volume for analysis
- Improperly labeled specimen
- Improper specimen container
- Improper specimen transport
- Specimen has leaked in transit

- Incorrect or expired transport media
- Incomplete or incorrect test request form
- Specimen without a test order
- No specimen type provided
- Compromised specimen (e.g., hemolyzed, lipemic, or clotted specimens)

Panels, Profiles and Reflex Tests

Tests offered in any panel or profile are available individually. Panels and profiles are constructed to meet best practices and adhere to medical necessity criteria. Components of these panels may be ordered individually, unless otherwise indicated. If you have any questions regarding the individual components of a panel of profile, please contact Client Services or your local Representative.

Test Menu

Our Test Menu provides general reference information on most of the tests offered by CBLPath such as:

- CPT Codes
- General specimen requirements for specific methodologies
- Specimen transport considerations
- Methodology information

Our aim is to provide the most current testing. This test list is a work in progress and will be updated periodically. For additional information, or with questions about tests which are not included on this list, please contact our client services department, or contact your local Sales representative.

Site changes will require you to refresh when you access the Test Menu site.

Test Turnaround Time

Turnaround time is defined as the usual number of hours or days between the time a specimen is received at CBLPath and the time a test result is released. Testing schedules may change.

Observed Holidays

CBLPath recognizes the following as official holidays. As a result, specimens will not be picked up or shipped to referral laboratories on the following holidays:

- New Year's Day January 1
- Memorial Day Last Monday in May
- Independence Day July 4
- Labor Day First Monday in September
- Thanksgiving Fourth Thursday in November
- Christmas December 25

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Cytogenetic Studies

Methodology: Cytogenetics/karyotype (G-banding)

Test Description: Routine cytogenetics (karyotype) is used to identify structural and numerical

chromosomal abnormalities, providing valuable diagnostic and prognostic

information in a variety of tumor types.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube

Peripheral blood: Minimum 5 ml in green top (sodium heparin) tubeFresh tissue+:

1 cm³ tissue completely immersed in RPMI.

Storage & Transportation:Bone marrow aspirate/peripheral blood: Store and transport at room temperature.

Fresh tissue: Store refrigerated but not frozen. Use a cold pack for transport,

making sure the cold pack is not in direct contact with the specimen.

CPT Code(s): 88237, 88264, 88280

Level of Service:Global **Turnaround Time:**5-7 days

DIF

Methodology: (DIF) (Panel (IgG, IgM, IgA, C3 and Fibrin)

Test Description:Cutaneous Direct Immunofluorescence Testing Direct immunofluorescence (DIF)

test can be performed on skin or mucosa obtained in the physician's office. All biopsy specimens are examined for the presence of bound immunoglobulins (IgG, IgM, IgA), complement C3 and fibrinogen. IF testing is particularly useful for confirmation of the following: immunobullous diseases (pemphigus, IgA dermatitis, bullous pemphigoid, pemhigoid gestationis, epidermolysis bullosa acquisita, dermatitis herpetiformis), connective tissue diseases (lupus, dermatomyositis), and vasculitis. IF tests may be diagnostic when dermatopathologic studies are only

suggestive, nonspecific, or negative.

Specimen Requirements: Selection of biopsy sites:

Immunobullous Diseases- Perilesional skin with the exception of skin to rule out/in

dermatitis herpertiformis (DH). For DH- non-lesioned skin is preferred

Connective Tissue Diseases- Established lesional skin (best an active 6 month or

older lesion)

Vasculitis - Lesional skin less than 24 Hours old.

Storage & Transportation Specimens for DIF should be places in Michel's Solution. They should not be

placed in formalin.

All jars must have two (2) identifiers clearly written and match exactly with the

specimen identifier and specimen labelling on accompanying req.

Storage & Transportation The specimen can be transported at room temperature. For best results it should

be received (and frozen) within 5 days of biopsy. Do not place on ice, dry

ice, or freeze the Michel's Solution.

CPT Code(s): 88346, 88350

Level of Service: Global

Turnaround Time: 48 days. Test processed Tuesday, Thursday & Saturday



Acute Lymphoblastic Leukemia (ALL) FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: BCR/ABL1 t(9;22), MLL

(11q23), ETV6(TEL)/RUNX1(AML1) t(12;21)

Test Description: The ALL FISH Panel uses probes to detect several translocations seen in B

lymphoblastic leukemia/lymphoma with recurrent genetic abnormalities: BCR/ABL1, MLL, and ETV6(TEL)/RUNX1(AML1). The ETV6/RUNX1 translocation is often undetectable by routine cytogenetics, making FISH a particularly important

tool to exclude this abnormality.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top

(EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Acute Myeloid Leukemia (AML) FISH Panel

Methodology: FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: RUNX1T1/RUNX1 t(8;21),

PML/RARA t(15;17), inv16 (CBFB), 11q23(MLL)

Test Description: The AML FISH Panel uses probes to detect several abnormalities seen in AML with

recurrent genetic abnormalities: RUNX1T1/RUNX1, PML/RARA, CBFB, and MLL. Abnormalities of CBFB and MLL are often undetectable by routine cytogenetics, making

FISH a particularly important tool for detection.

Specimen Requirements:Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or purple top

(EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

ALK FISH for NSCLC

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: ALK (2p23)

Test Description: This ALK FISH analysis is used to detect ALK rearrangements in non-small cell

lung cancer (NSCLC) to aid in identifying patients eligible for treatment with Xalkori® (crizotinib). See "ALK (2p23) FISH" for ALK testing recommended in

anaplastic large cell lymphoma.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block label with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation:Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

ALK (2p23) FISH

Specimen Requirements:

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: ALK (2p23)

Test Description: The ALK Dual Color, Break Apart Rearrangement Probe is designed to detect the

known ALK (2p23) rearrangements that occur in anaplastic large cell lymphoma

including t(2;5) and its variants.

See "ALK FISH for NSCLC" for ALK testing recommended in non-small cell lung cancer.

Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block label with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

RUNX1/RUNX1T1 (AML1/ETO) t(8;21) FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: RUNX1/RUNX1T1 (AML1/ETO) t(8;21)

Test Description: This test is used to aid in the diagnosis of acute myeloid leukemia with t(8:21

(q22;q22.1);RUNX1-RUNX1T1. This probe is also available as part of the AML FISH Panel.

Specimen Requirements:Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

MLL (11q23) FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: MLL (11q23)

Test Description: This probe is used to detect abnormalities in MLL (11q23), which are seen

in MDS, AML, and ALL. Translocations involving MLL are often undetectable by routine cytogenetics, making FISH a particularly important tool for detection. This probe is also available as part of the AML, MDS, and ALL FISH Panels.

Bone marrow aspirate: Minimum 2 ml in green top (sodium benarin) tube or

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

PML/RARA t(15;17) FISH

Storage & Transportation:

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: PML/RARA t(15;17)

Test Description:This test is used to aid in the diagnosis of acute promyelocytic leukemia with PML-RARA.

This probe is also available as part of the AML FISH Panel.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377 Level of Service: Global

Turnaround Time: Performed as STAT with preliminary results available 24 Hours from receipt in lab.

CBFB inv(16) FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: CBFB inv(16)

Test Description: This test is used to aid in the diagnosis of acute myeloid leukemia with inv(16)

(p13.1q22) or t(16;16)(p13.1;q22);CBFB-MYH11. This probe is also available as

part of the AML FISH Panel.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 Hours

IGH Gene Rearrangement FISH *

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: IGH (14q32)

Test Description: The IGH Dual Color, Break Apart Rearrangement Probe is designed to detect

chromosomal breakage of the immunoglobulin heavy chain (IGH) locus that is

associated with 14q32 translocations involving multiple other loci.

IGH rearrangements are seen in a variety of lymphoid neoplasms of B-cell origin. This probe is also available as part of the Non-Hodgkin Lymphoma, Large B-Cell

Lymphoma, and Multiple Myeloma Panels.

Specimen Requirements:Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Bladder Cancer Profile FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: CEP 3, CEP 7, 9p21, CEP 17 **Test Description:** UroVysion Bladder Cancer FISH Analysis is designed to detect aneuploidy for

UroVysion Bladder Cancer FISH Analysis is designed to detect aneuploidy for chromosomes 3, 7, 17, and/or loss of the 9p21 locus in urine specimens from patients suspected of having bladder cancer. Results from the UroVysion test are intended for use in conjunction with, but not in lieu of, current standard diagnostic procedures for initial diagnosis of bladder carcinoma in patients with

hematuria and for monitoring for tumor recurrence in patients previously

diagnosed with bladder cancer.

Specimen Requirements: ≥33 ml voided urine, fresh or in PreservCyt vial **Storage & Transportation:** Refrigerate until transport. Frozen unacceptable.

CPT Code(s): 88377

Level of Service:Global Tech Only **Turnaround Time:**48-72 Hours

MYC (8q24) FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: MYC (8q24)

Test Description:The MYC Dual Color Break Apart Rearrangement Probe is intended to detect

chromosomal rearrangements involving the MYC gene on chromosome 8q24. Translocations involving MYC have diagnostic and prognostic importance in B-cell lymphomas including Burkitt lymphoma and high-grade B-cell lymphoma, with MYC and BCL2 and/or BCL6 rearrangements (double/triple-hit lymphomas). This probe is also available as part of the Non-Hodgkin Lymphoma and Large B-Cell

Lymphoma Panels.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E stained slide with tumor encircled. Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns. Clearly label with patient name and ID number. BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Chronic Lymphocytic Leukemia (CLL) FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: 11q22.3 ATM,

Test Description: 13q14.3/D13S25, 17p13.1 P53, CEP12, t(11;14) CCND1/IGH, 6q23.3 MYB
This FISH Panel includes probes to detect various recurrent abnormalities seen in chronic lymphocytic leukemia (CLL) and the CCND1/IGH rearrangement seen

in the vast majority of mantle cell lymphomas. This panel is useful to help establish an initial diagnosis of CLL and exclude mantle cell lymphoma and to assess

important prognostic markers in CLL.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377, 88367 Level of Service: Global Turnaround Time: 48-72 Hours

BCR/ABL1 t(9;22) FISH

Test Description:

Storage & Transportation:

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: BCR/ABL1/ASS1 t(9;22)

The BCR/ABL1/ASS1 Tri-Color Dual Fusion FISH Probe Kit is used to detect the t(9;22)(q34;q11.2) reciprocal translocation involving the BCR and ABL1 genes . The t(9;22) translocation is the diagnostic hallmark of chronic myeloid leukemia (CML), BCR-ABL1+ but is also seen in a subset of cases of B lymphoblastic leukemia/lymphoma. This analysis includes a probe for the ASS1 gene on chromosome 9, which can help distinguish true rearrangement from random

signal overlap in a subset of cases.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

EGFR FISH*

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: EGFR/CEP7

Test Description:This analysis is used to detect abnormalities in the EGFR gene including increased

copy number and amplification, which have been correlated with the development of many solid tumors including non-small cell lung cancer (NSCLC) and colorectal cancers. Assessment of EGFR amplification may be indicated in some tumors to

predict response to anti-EGFR therapy.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Eosinophilia FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: PDGFRA, PDGFRB

Test Description: This Panel is used to aid in the diagnosis or exclusion of myeloid and lymphoid

neoplasms with eosinophilia and abnormalities of PDGFRA or PDGFRB. The PDGFRA translocation is often undetectable by routine cytogenetics, making FISH

a particularly important tool to exclude this abnormality.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88374 x 2
Level of Service: Global
Turnaround Time: 48-72 Hours

EWSR1 FISH⁺

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: EWSR1

Test Description: The EWSR1 Dual Color Break Apart Rearrangement Probe is used to aid in the

diagnosis of Ewing sarcoma and other malignancies with EWSR1 rearrangements.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E stained slide with tumor encircled. Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns. Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

IGH/BCL2 t(14;18) FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: IGH/BCL2, t(14;18)

Test Description: The IGH/BCL2 Dual Color, Dual Fusion Translocation Probe is designed to detect

the translocation involving IGH at 14q32 and BCL2 at 18q21, t(14;18)(q32;q21). This rearrangement is found in the majority of follicular lymphomas and in a subset of diffuse large B-cell lymphomas and high-grade B-cell lymphomas, with MYC and BCL2 and/or BCL6 rearrangements (double/triple-hit lymphomas). This probe

is also available as part of the Non-Hodgkin Lymphoma and Large B-Cell

Lymphoma Panels.

Specimen Requirements:Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

FOXO1 FISH⁺

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: FOX01 (13q14)

Test Description: The FOX01 Dual Color Break Apart Rearrangement Probe is intended to

detect chromosomal rearrangements involving the FOX01 gene on chromosome

13q14, which are characteristic of alveolar rhabdomyosarcoma.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation:Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

HER2 FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: CEP 17, HER2

Test Description: HER2 testing in breast cancer is used to assess prognosis and eligibility for

trastuzumab (Herceptin®) treatment. In gastric cases, it is also used to determine

eligibility for anti-HER2 treatments.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns

Clearly label with patient name and ID number.

Storage & Transportation:Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

HER2 Equivocal FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: CEP 17, RARA, TP53

Test Description: The HER2 Equivocal FISH test is a reflex test utilized when a patient has double

equivocal HER2 results (IHC and FISH). Following current CAP HER2 Testing guidelines, this test uses alternative chromosome 17 probes to recalculate the

HER2 ratio.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns. Clearly label with patient name and ID number. If sending solely as a reflex test, please provide original HER2 FISH results with corresponding H&E to ensure the

analysis is performed on the same tumor area.

Fixation Requirements: 6-72 Hours fixation recommended as per CAP-ASCO guidelines.

Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

BIRC3/MALT1 t(11;18) FISH

Storage & Transportation:

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: BIRC3/MALT1, t(11:18)

The API2(BIRC3)/MALT1 Dual Color, Dual Fusion Translocation Probe is designed to detect the translocation involving API2(BIRC3) at 11q21 and MALT1 at 18q21, t(11;18)(q21;q21). This translocation is seen in a subset of extranodal marginal zone lymphomas of mucosa-associated lymphoid tissue (MALT lymphomas) and has been associated with advanced-stage disease and lack of response to H.

pylori eradication in gastric MALT lymphoma. This probe is also available as part of the Non-Hodgkin Lymphoma Panel.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

IGH/MALT1 t(14;18) FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: IGH/MALT1, t(14;18)

Test Description: The IGH/MALT1 Dual Color, Dual Fusion Translocation Probe is designed to

detect the translocation involving IGH at 14q32 and MALT1 at 18q21, t(14;18) (q32;q21). This translocation is seen in a subset of extranodal marginal zone lymphomas of mucosa-associated lymphoid tissue (MALT lymphomas). This probe is also available as part of the Non-Hodgkin Lymphoma Panel.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CCND1 (BCL1)/IGH t(11;14) FISH

Test Description:

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: CCND1 (BCL1)/IGH t(11;14)

The CCND1(BCL1)/IGH Dual Color, Dual Fusion Translocation Probe is designed to detect the translocation involving CCND1(BCL1) at 11q13 and IGH at 14q32, t(11;14)(q13;q32). This translocation is seen in the vast majority of mantle cell lymphomas but is generally not seen in other B-cell lymphomas. This translocation is also seen in a subset of plasma cell myelomas. This probe is also available as

part of the CLL and Non-Hodgkin Lymphoma Panels.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Large B-Cell Lymphoma FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: MYC (8q24), IGH/BCL2 t(14;18),

BCL6 (3q27), IGH (14q32)

Test Description: This panel can detect several common translocations seen in large B-cell

lymphomas and is useful to evaluate for high-grade B-cell lymphoma, with MYC

and BCL2 and/or BCL6 rearrangements (double/triple-hit lymphomas),

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Melanocytic Differentiation FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: RREB1, CEP 6, MYB, CCND1

Test Description:This panel is used to detect copy number gains of the RREB1 (6p region) and CCND1 (11q region) genes as well as copy number loss of the MYB (6q region).

Detection of these abnormalities can help distinguish melanomas from nevi.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

Multiple Myeloma FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: D5S23, CEP 9, CEP 15,

CEP11, TP53, 13q14.3/D13S25, IGH

Test Description: This panel is used to detect common abnormalities seen in multiple myeloma

(plasma cell myeloma), which are often undetectable by routine cytogenetics. Detection of one or more of these abnormalities can help to establish a diagnosis of myeloma and provide prognostic information. The Multiple Myeloma Reflex Panel is recommended when IGH rearrangement is detected to determine the

specific fusion partner and prognostic implications.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Multiple Myeloma Reflex FISH Panel (IGH Fusions)

Methodology: Fluorescence In Situ Hybridization (FISH)

Probe: CCND1 (BCL1)/IGH, FGFR3/IGH, IGH/MAF

Test Description: This panel is mainly used to help determine the specific fusion partner and

prognostic implications when an IGH rearrangement is detected in the Multiple Myeloma FISH Panel, although the panel can also be ordered as a stand-alone test if clinically indicated. The common IGH fusion partners that can be detected

include CCND1 (11q13), FGFR3 (4p16.3), and C-MAF (16q23).

Specimen Requirements:Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Myelodysplastic Syndrome (MDS) FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH)

Probes: EGR1, 7q31/del7q, CEP8, 20q12, MLL

Test Description: This panel is used to detect common abnormalities seen in myelodysplastic

syndromes (MDS) and other myeloid neoplasms, including gain of chromosome 8, deletion of chromosome 7/7q, deletion of chromosome 5/5q, deletion of chromosome 20q, and deletion of chromosome 11q. Detection of one or more of

these abnormalities can help to establish a diagnosis of MDS and provide

prognostic information.

Specimen Requirements:Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

BCL6 (3q27) FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: BCL6

Test Description: The BCL6 Dual Color, Break Apart Rearrangement Probe is used to detect

translocations involving the BCL6 gene. BCL6 translocations are seen in

diffuse large B-cell lymphoma; high-grade B-cell lymphoma, with MYC and BCL2 and/or BCL6 rearrangements; and other B-cell lymphoproliferative disorders. This probe is also available as part of the Non-Hodgkin Lymphoma and Large B-Cell

Lymphoma Panels.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E stained slide with tumor encircled. Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns. Clearly label with patient name and ID number. BM/PB, block or unstained slides: Store and transport at room temperature.

Storage & Transportation:BM/PB, block or unstained slides: Store and transport at room Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Non-Hodgkin Lymphoma FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH)

Probes: ALK, IGH, BCL6, MYC, CCND1/IGH, IGH/BCL2, BIRC3/MALT1, IGH/MALT1, Test Description:

The Non-Hodgkin Lymphoma FISH Panel includes probes to detect a range of

The Non-Hodgkin Lymphoma FISH Panel includes probes to detect a range of recurrent genetic abnormalities seen in non-Hodgkin lymphoma that are useful for

diagnosis and subclassification.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: Min14 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

PDGFRA FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: FIP1L1/CHIC2/PDGFRA

Test Description: The FIP1L1/CHIC2/PDGFRA FISH Deletion/Fusion Probe is used to aid in the

diagnosis or exclusion of myeloid and lymphoid neoplasms with PDGFRA rearrangement, which are associated with eosinophilia. The PDGFRA rearrangement is often undetectable by routine cytogenetics, making FISH a particularly important tool for detection. This probe is also available as part of the

Eosinophilia Panel.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

PDGFRB FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: PDGFRB

Test Description: This analysis is used to aid in the diagnosis or exclusion of myeloid neoplasms

with PDGFRB rearrangement, which are associated with eosinophilia. This probe

is also available as part of the Eosinophilia Panel.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377 Level of Service: Global **Turnaround Time:** 48-72 hrs

Prostate FISH Panel (PROSTACOMP)

Methodology: Fluorescence In Situ Hybridization (FISH)

Probes: PTEN, TMPRSS2/ERG

Test Description: This analysis is used to detect PTEN deletion and TMPRSS2:ERG rearrangement,

which have been associated with adverse prognosis in prostate cancer...

Fresh tissue: 1 cm3 tissue completely immersed in RPMI. **Specimen Requirements:**

> Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E stained slide with tumor encircled. Unstained slides: Minimum 4 unstained charged slides and 1 H&E Slide cut at 4 microns. Clearly label with patient name

and ID number.

Storage & Transportation: Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377 Level of Service: Global **Turnaround Time:** 48-72 hrs

ROS1 FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: ROS1

Test Description: This analysis is used to detect rearrangement of the ROS1 gene, which occurs in

1-2% of non-small cell lung cancer and is associated with responsiveness to

treatment with Xalkori® (crizotinib).

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

> Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E stained slide with tumor encircled. Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns. Clearly label with patient name and ID number.

Storage & Transportation: Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377 Level of Service: Global **Turnaround Time:** 48-72 hrs

Synovial Sarcoma SS18 (SYT) FISH+

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: SS18 (SYT)

Test Description: The SS18 Dual Color Break Apart Rearrangement Probe is intended to detect

chromosomal rearrangements involving the SS18 (SYT) gene on chromosome

18g11.2, which are characteristic of synovial sarcoma. Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Specimen Requirements: Paraffin block: FFPE block labeled with patient name & ID number and

1 H&E stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

Cervical Cancer TERC FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: TERC/CEN3

Test Description:This analysis is used to detect increases in the copy number of the telomerase

component gene (TERC) in cervical cytology specimens. Detection of such abnormalities can help determine which patients with low-grade or atypical Pap test results have an increased risk of high-grade cervical intraepithelial neoplasia

or invasive carcinoma.

Specimen Requirements: Cervical brushing: Submit sample in Thinprep Cytolyt collection container.

Unstained slides: Minimum 2 ThinPrep slides.

Storage & Transportation: Cervical brushing: Store refrigerated, and ship with cool pack .Unstained slides:

Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

TOP2A FISH (Breast Carcinoma) +

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: TOP2A

Test Description: The topoisomerase II-α (TOP2A) FISH test is used to detect amplifications and

deletions of the TOP2A gene. These abnormalities have been associated with responsiveness to anthracycline-based chemotherapy in breast carcinoma.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E

Storage & Transportation:
Slide cut at 4 microns. Clearly label with patient name and ID number.
Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

Flow Cytometry

Acute Myeloid Leukemia (AML) Panel

Specimen Requirements:

Storage & Transportation

Methodology: Flow Cytometry Markers: CD34, CD41a, CD45, CD235a, Myeloperoxidase **Test Description:** The Acute Myeloid Leukemia (AML) Panel by flow cytometry is used to

The Acute Myeloid Leukemia (AML) Panel by flow cytometry is used to characterize the immunophenotype of a myeloblast population to aid in the diagnosis and subclassification of AML and other myeloid neoplasms.

This panel is best used in combination with the Leukemia/Lymphoma Panel.

Bone marrow aspirate: 2-3 ml in green top (sodium heparin) or purple top (EDTA) tube

Peripheral blood: 5-7 ml in green top (sodium neparin) or purple top (EDTA) tube

Specimens should be received within 24-48 Hours from collection to ensure acceptable cell viability. Peripheral blood and bone marrow aspirate specimens can be stored and transported at room temperature. Other tissue biopsies and body fluids should be refrigerated but not frozen; please use a cold pack to

transport these specimens, making sure the cold pack is not in direct contact with the specimen.

CPT Code(s): +88184, 88185, 88189

Level of Service:Global **Turnaround Time:**1 day

DNA Ploidy⁺

Methodology: Flow Cytometry

Test Description: DNA stain propidium iodide is used to determine S-phase cell cycle fraction and

DNA index as indicators of DNA ploidy. Clinical Significance DNA analysis is, after immunofluorescence, the second most important application of flow cytometry. By measuring the DNA content of individual cell, we can obtain information about their ploidy, of particular relevance in tumors, and, for a population, the distribution

of cells across the cell cycle.

Specimen Requirements: Flow cytometry testing can be performed on bone marrow aspirate, peripheral

blood, fresh bone marrow core biopsy, unfixed tissue, and body fluids.

Please see full specimen requirements for either Standard Leukemia/Lymphoma

Analysis or Extended Leukemia/Lymphoma Analysis.

Storage & Transportation Specimens should be received within 24-48 Hours from collection to ensure

acceptable cell viability. Peripheral blood and bone marrow aspirate specimens can be stored and transported at room temperature. Other tissue biopsies and body fluids should be refrigerated but not frozen; please use a cold pack to transport these specimens, making sure the cold pack is not in direct contact with

the specimen.

CPT Code(s): +88182 Level of Service: Global Turnaround Time: 1 day

Hairy Cell Leukemia Panel

Storage & Transportation

Methodology: Flow Cytometry Markers: CD11c, CD20, CD25, CD45, CD103

Test Description: The Hairy Cell Leukemia Panel by flow cytometry is used to aid in the initial

diagnosis of hairy cell leukemia or hairy cell leukemia variant or to assess for the presence of residual/relapsed disease. This panel is best used in combination with

the Leukemia/Lymphoma Panel.

Specimen Requirements:Bone marrow aspirate: 2-3 ml in green top (sodium heparin) or purple top (EDTA) tube

Peripheral blood: 5-7 ml in green top (sodium heparin) or purple top (EDTA) tube Specimens should be received within 24-48. Hours from collection to ensure acceptable cell viability. Peripheral blood and bone marrow aspirate specimens can be stored and transported at room temperature. Other tissue biopsies and

body fluids should be refrigerated but not frozen; please use a cold pack to transport these specimens, making sure the cold pack is not in direct contact with

the specimen.

CPT Code(s): +88184, 88185, 88187

Level of Service: Global **Turnaround Time:** 1 day

Immune Deficiency Panel

Storage & Transportation

Test Description:

Methodology: Flow Cytometry Markers: CD3, CD4, CD8, CD19, CD45, CD56

Test Description: Clinical Significance

The Immune Deficiency Panel by flow cytometry is used to quantify the relative proportions and absolute numbers of T, B, and NK cells in the peripheral blood. This data can help to evaluate the status of a patient's immune system and assess degree of immunodeficiency, for example, by measuring absolute CD4

counts in patients with HIV infection.

Specimen Requirements: Peripheral blood: 5-7 ml in purple top (EDTA) tube (preferred) or green top

(sodium heparin) tube

Storage & Transportation Specimens should be received within 24 Hours from collection to ensure sample

integrity and acceptable cell viability. Specimens should be transported at room

temperature.

CPT Code(s): 86359, 86360, 86357, 86355

Level of Service: Global **Turnaround Time:** 12-24 Hours

Leukemia/Lymphoma Panel for Peripheral Blood and Bone Marrow

Methodology: Flow Cytometry Markers: CD2, CD3, CD4, CD5, CD7, CD8, CD10 CD11b, CD13,

CD14, CD16, CD19, CD20, CD22, CD23, CD25, CD34, CD38, CD45, CD56,

CD64, CD117, CD138, HLA-DR, sKappa, sLambda

Test Description: This is a general panel used to screen peripheral blood or bone marrow

specimens for the presence of hematolymphoid neoplasms.

Specimen Requirements: Bone marrow aspirate: 2-3 ml in green top (sodium heparin) or purple top (EDTA) tube

Peripheral blood: 5-7 ml in green top (sodium heparin) or purple top (EDTA) tube Specimens should be received within 24-48 Hours from collection to ensure

sample integrity and acceptable cell viability. Specimens should be stored and

transported at room temperature.

CPT Code(s): +88184, 88185, 88189

Level of Service:Global
Turnaround Time: 24-36 Hours

Leukemia/Lymphoma Panel for Lymph Node/Tissue Biopsies

Methodology: Flow Cytometry Markers: CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD16, CD19,

CD20, CD22, CD23, CD25, CD38, CD45, CD56, CD138, FMC7, sKappa, sLambda This is a general panel used to screen lymph node and other tissue biopsies for

the presence of lymphoproliferative disorders.

Specimen Requirements: Incisional/excisional or core needle biopsy: Ideally, 1 cm3 of tissue completely

immersed in RPMI. Testing can be successfully performed on smaller specimens if the tissue has adequate cellularity. The number of markers tested may be reduced if cellularity is insufficient. If RPMI is unavailable, tissue can be submitted

wrapped in saline-moistened gauze but not submerged in saline.

Fine needle aspirate (FNA): 1:1 ratio of aspirate and RPMI; minimum 2 ml total Storage & Transportation Specimens should be received within 24-48 Hours from collection to ensure

sample integrity and acceptable cell viability. Specimens should be refrigerated but not frozen. Please use a cold pack for transport, making sure the cold pack is

not in direct contact with the specimen

CPT Code(s): +88184, 88185, 88189

Level of Service:Global **Turnaround Time:**1 day

Paroxysmal Nocturnal Hemoglobinuria (PNH) Panel⁺

Methodology: Flow Cytometry Markers: CD14, CD15, CD24, CD33, CD45, CD59, FLAER

Test Description: The PNH Panel by flow cytometry is used to diagnose and monitor patients with

paroxysmal nocturnal hemoglobinuria (PNH).

Specimen Requirements: Peripheral blood: 3 ml in purple top (EDTA) tube

Storage & Transportation Specimens should be received within 24 Hours of draw time to ensure sample

integrity and acceptable cell viability.

CPT Code(s): 88184, 88185, 88187

Level of Service:GlobalTurnaround Time:72 Hours

Plasma Cell Neoplasm Panel

Storage & Transportation

Methodology: Flow Cytometry Markers: CD19, CD38, CD45, CD56, CD138, cKappa, cLambda **Test Description:** The Plasma Cell Neoplasm Panel by flow cytometry is used to aid in the initial

The Plasma Cell Neoplasm Panel by flow cytometry is used to aid in the initial diagnosis of plasma cell neoplasms (i.e., plasma cell myeloma, plasmacytomas, and monoclonal gammopathy of undetermined significance) or to assess for the presence of residual/relapsed disease. This panel is best used in combination with

the Leukemia/Lymphoma Panel.

Specimen Requirements:Bone marrow aspirate: 2-3 ml in green top (sodium heparin) or purple top (EDTA) tube

Peripheral blood: 5-7 ml in green top (sodium heparin) or purple top (EDTA) tube Incisional/excisional or core needle biopsy: Ideally, 1 cm3 of tissue completely immersed in RPMI. Testing can be successfully performed on smaller specimens if the tissue has adequate cellularity. If RPMI is unavailable, tissue can be submitted wrapped in saline-moistened gauze but not submerged in saline. Fine needle aspirate (FNA): 1:1 ratio of aspirate and RPMI; minimum 2 ml total Specimens should be received within 24-48 Hours from collection to ensure

sample integrity and acceptable cell viability. Specimens should be stored and

transported at room temperature.

CPT Code(s): +88184, 88185, 88187

Level of Service:GlobalTurnaround Time:1 day

T-Cell Panel

Methodology: Flow Cytometry Markers: CD1a, CD3, CD45, TCRαβ, TCRγδ, TdT

Test Description: The T-Cell Panel by flow cytometry is used to aid in the diagnosis of T-cell

leukemias/lymphomas. This panel is best used in combination with the Leukemia/

Lymphoma Panel.

Specimen Requirements:Bone marrow aspirate: 2-3 ml in green top (sodium heparin) or purple top (EDTA) tube

Peripheral blood: 5-7 ml in green top (sodium heparin) or purple top (EDTA) tube Incisional/excisional or core needle biopsy: Ideally, 1 cm3 of tissue completely immersed in RPMI. Testing can be successfully performed on smaller specimens if the tissue has adequate cellularity. If RPMI is unavailable, tissue can be submitted wrapped in saline-moistened gauze but not submerged in saline.

Fine needle aspirate (FNA): 1:1 ratio of aspirate and RPMI; minimum 2 ml total Storage & Transportation Specimens should be received within 24-48 Hours from collection to ensure

sample integrity and acceptable cell viability. Peripheral blood and bone marrow aspirate specimens should be stored and transported at room temperature. Other tissue biopsies and body fluids should be refrigerated but not frozen; please use a cold pack to transport these specimens, making sure the cold pack is not in

direct contact with the specimen.

CPT Code(s): +88184, 88185, 88187

Level of Service:GlobalTurnaround Time:1 day

ZAP-70 Panel

Storage & Transportation

Methodology: Flow Cytometry Markers: CD5, CD19, CD45, ZAP-70

Test Description: Clinical Significance

The ZAP-70 Panel by flow cytometry is used to assess for the presence of ZAP-70 expression on chronic lymphocytic leukemia/small lymphocytic lymphoma. The presence of ZAP-70 expression has been associated with an adverse prognosis and correlates with unmutated IGHV status. This panel is best used in

combination with the Leukemia/Lymphoma Panel.

Specimen Requirements: Peripheral blood: 5-7 ml in green top (sodium heparin) or purple top (EDTA) tube

Specimens should be received within 24 Hours of draw time.

Specimens should be stored and transported at room temperature.

CPT Code(s): +88184, 88185, 88187

Level of Service: Global Turnaround Time: 1 day

Flow TC- Contact CBLPath for the current menu

GENERAL HISTOLOGY/ MORPHOLOGY

Anatomic Pathology (Breast Pathology, Dermatopathology, Gastrointestinal Pathology, General Surgical Pathology, Uropathology)

Methodology: Histology Microscopy

Test Description: H&E

Specimen Requirements: Specimen received in formalin fixative (10 %NBF preferred) or paraffin embedded specimen

All jars, blocks and slides must have two (2) identifiers clearly written and matching exactly with the specimen identifiers and specimen labeling on the

accompanying requisition

Storage & Transportation Ambient, refrigerated. Use cold pack for transport if necessary.

Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): ⁺88302, 88304, 88305, 88307, 88309 - varies by Level of Service

Level of Service: Global

Tech Only

Turnaround Time: 48 hrs

SLIDE PREPARATION

H&E ONLY

Cytopathology

Fluid and Brushing Cytology

Methodology: Microscopy

Test Description: Preparation of slide(s) from submitted fluid or brushing sample utilizing liquid

based techniques to include ThinPrep or cytospin and Cell Block preparation (as

needed) for microscopic interpretation.

Preparation of direct smears for microscopic interpretation

Specimen Requirements: Fluid Collection: 1ml-200ml fresh or fixed fluid

Nipple Discharge: 1-2 direct smears, spray fixed

Brushing sample: collected in 30 ml Cytolyt tube And/or Direct smears immediately spray fixed or fixed in ethanol and brush collected in ethanol or Cytolyt tube

Anal specimen: Brushing collected in Preservcyt Jar

All jars, tubes and slides must be labeled with two (2) patient identifiers clearly written and matching exactly with the specimen identifiers and specimen labeling

on the accompanying requisition

Storage & Transportation Sterile plastic container or Cytolyt tube or Preservcyt jar

Fresh samples: Are to be refrigerated after 1hr of collection.

If delay of more than 24 Hours is expected add an equal amount of Cytolyt or ethanol to the sample. Use cold pack for transport. Cold pack shouldn't come in

direct contact with specimen.

Fixed samples: Room temperature and shipped routinely

CPT Code(s): 88108, 88112, 88305, 88104, 8817326

Level of Service: Global

Tech Only; Professional Only **Turnaround Time:**48-72 hrs

Urine Cytology

Methodology: Microscopy

Test Description: Preparation of slide(s) from submitted urine sample utilizing liquid based

techniques to include ThinPrep or Surepath and cytospin for microscopic interpretation. Clinical Significance, utilized for the initial detection or recurrence of high grade

urothelial carcinoma

Specimen Requirements: Minimum 30-40 ml of voided (second-morning void) or catherized urine;

instrumented samples to include washings or brushings of bladder, urethra, ureters or renal pelvis 'Additional 33 ml of urine required for Bladder Cancer FISH profile- UroVysion® All jars must be labeled with two (2) patient identifiers clearly written and matching exactly with the specimen identifiers and specimen labeling on the accompanying requisition

Storage & Transportation Sterile plastic container

Ambient, are to be refrigerated after 1hr of collection.

If delay of more than 24 Hours is expected add an equal amount of ethanol (50%) to the sample (urine samples for microbiology/culture are to remain unfixed/fresh). Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88112, 8811226

Level of Service: Global

Tech Only; Professional Only

Turnaround Time: 48-72 hrs

FNA Cytology

CPT Code(s):

Methodology: Microscopy

Test Description: Preparation of slide(s) from submitted FNA sample utilizing either liquid

based techniques to include ThinPrep and/or cytospin methodologies and/or review of submitted direct smears for microscopic interpretation. Preparation and review of Cell Block material as needed. Clinical Significance utilized for the detection of normal/benign and reactive, infectious and/or inflammatory processes and identification of atypical, premalignant and malignant entities in

cellular samples

Specimen Requirements: Liquid based preparation: 2-4 FNA passes into 30ml prefilled Cytolyt tube per nodule/site

Direct Smear Collection: Direct smears immediately fixed in 95% ethanol for Papanicolaou (PAP) staining. Needle rinse and designated pass into Cytolyt,

ethanol or formalin for cell block preparation as needed. Diff-Quik staining (if needed): Air-dried direct smears

+For specimens in which a hematopoietic disorder cannot be excluded or Lymphoma is suspected

additional FNA material to be collected in RPMI for flow cytometry testing

All jars, tubes and slides must be labeled with two (2) patient identifiers clearly written and matching exactly with the specimen identifiers and specimen labeling

on the accompanying requisition

Storage & Transportation 30 ml Cytolyt tube Or 1-2, Air-dried direct smears in cardboard holder And/or

2-4, Direct smears (ethanol fixed) in coplin jar And 15ml Cytolyt, ethanol or formalin jar for needle rinse/cellblock Ambient, refrigerated. Use cold pack for transport if necessary. Cold pack shouldn't come in direct contact with specimen.

88173, 88313, 88305, 88172, 88177, 88321

Level of Service: Glob

Tech Only; Professional Only

Turnaround Time: 48-72 hrs

IHC

A-AT/a-1 Antitrypsin (AAT)

Methodology: Immunohistochemistry (IHC)

Test Description: Alpha-1-Antitrypsin (AAT) is useful in the study of inherited AAT deficiency, benign

and malignant hepatic tumors and yolk sac carcinoma. Sensitivity and specificity of the results have made this antibody a useful tool in the screening of patients with cryptogenic cirrhosis or other forms of liver disease with portal fibrosis of

uncertain etiology.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifier and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 2-4 days

ACTH/Adrenocorticotropin Hormone

Methodology: Immunohistochemistry (IHC)

Test Description: Anti-adrenocorticotropic hormone (ACTH) is a useful marker in the classification

of pituitary tumors and the study of pituitary disease. It reacts with ACTH-producing cells (corticotrophs). It also may react with other tumors (e.g., some small cell carcinomas of the lung) causing paraneoplastic syndromes by secreting ACTH. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

Specimen Requirements:

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cu at 4-5 microns for H&E staining (required) and three (3) positively charged

unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifier and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Actin-HHF-35

Methodology: Test Description:

Specimen Requirements:

Storage & Transportation

Storage & Transportation

CPT Code(s):

Level of Service:

Immunohistochemistry (IHC)

Four muscle actins have been identified; skeletal alpha, cardial alpha, vascular smooth muscle alpha and enteric alpha actin. This antibody recognizes the alpha and gamma isotypes of skeletal, cardiac, and smooth muscle cells. It is non-reactive with other mesenchymal cells and all epithelial cells except for myoepithelium. MSA antibody is useful in the identification of tumors with muscle differentiation and detection of myoepithelial cells. Actin is one of two major cytoskeletal proteins involved in cell motility. Smooth muscle actin binds to smooth muscle cells and myoepithelial cells. It stains the muscularis and muscularis mucosae of the gastrointestinal tract, the uterine myometrium, medial layer of blood vessels, myoepithelial cells of salivary glands and other organs. The antibody does not stain skeletal and cardiac muscle, endothelium, connective tissue, epithelium or nerve. The antibody can be used to identify smooth muscle tumors. It stains leiomyomas and leiomyosarcomas but does not stain carcinomas.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifier and specimen labeling on accompanying req.

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

 CPT Code(s):
 88342

 Level of Service:
 Global

 Tech Only
 24-48 Hours

Adenovirus

Methodology: Immunohistochemistry (IHC)

Test Description: Adenovirus infection. Useful in identification of adenovirus.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifier and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 (or 88341 if not the first single antibody per specimen)

Global Tech Only

Adipophilin

Methodology: Test Description: Immunohistochemistry (IHC)

Sebaceous carcinoma is a relatively uncommon cutaneous malignancy and mimics other malignant neoplasms, such as basal and squamous cell carcinomas, and benign processes, such as chalazions and blepharitis, sometimes resulting in delayed diagnosis and suboptimal treatment. 1 Adipophilin is present in milk fat globule membranes and on the surface of lipid droplets in various normal cell types.. 2 Expression of adipophilin with a membranous pattern of staining was not seen in any of the other clear cell lesions of the skin, including basal and squamous cell carcinomas, trichilemmomas, clear cell hidradenomas, or balloon cell nevi. Interestingly, a nonspecific granular uptake of anti-adipophilin was seen in adjacent macrophages, keratohyalin granules of epithelial squamous cells, and some tumor cells. Therefore, this anti-adipophilin is suitable for immunostaining formalin-fixed, paraffin-embedded tissue and is helpful in the identification of intracytoplasmic lipids, as seen in sebaceous lesions. It is especially helpful in identifying intracytoplasmic lipid vesicles in poorly differentiated sebaceous carcinomas in challenging cases such as small

periocular biopsy specimens.

Specimen Requirements:

Storage & Transportation

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match

exactly with the specimen identifier and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only
Turnaround Time: 24-48 Hours

AE1/AE3

Methodology: Test Description:

CPT Code(s):

Level of Service:

Immunohistochemistry (IHC)

Useful in distinguishing and classifying epithelial carcinoma from non-epithelial

malignancies, metastatic malignant tumors.

Specimen Requirements:

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & TransportationUse colCPT Code(s):88342Level of Service:Global

Global Tech Only

AFP

Methodology: Immunohistochemistry (IHC)

Test Description: Useful in the detection of hepatocellular carcinomas, germ cell neoplasms, volk

sac tumors Alpha-1-fetoprotein (AFP) is a 64 kD tumor-associated embryonal antigen produced by fetal liver, hepatoma, yolk sac tumor and several germ cell tumors of testicular and ovarian origin. About 70% of non-seminomatous germ cell tumors produce AFP. AFP is of importance in diagnosing hepatocellular carcinoma. Occasionally, a slight AFP elevation is found in other cancers as a result of metastasis to the liver resulting in regeneration of hepatic parenchyma.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying reg. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service:

88342 Global Tech Only

Turnaround Time: 24-48 Hours

ALK 1

Methodology: Immunohistochemistry (IHC)

Reacts with Anaplastic Large Cell Lymphomas **Test Description:**

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut **Specimen Requirements:**

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered

or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying reg. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

Alpha-1-Antichymotrypsin

Storage & Transportation

Methodology: Immunohistochemistry (IHC)

Test Description:

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

> at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying reg. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88342 (or 88341 if not the first single antibody per specimen) Level of Service:

Global Tech Only

Amyloid A

Methodology:

Specimen Requirements:

Storage & Transportation

Test Description:

CPT Code(s):

Level of Service:

Immunohistochemistry (IHC)

This antibody reacts with amyloid deposits in all tissues including kidney and rectum. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying reg. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 (or 88341 if not the first single antibody per specimen)

Global Tech Only

Turnaround Time: 24-48 Hours

Amyloid P

Methodology:

Specimen Requirements:

Storage & Transportation

Immunohistochemistry (IHC) **Test Description:** Amyloid subtyping. The antibody reacts with amyloid P component in all tissues.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 (or 88341 if not the first single antibody per specimen)

Global Tech Only

Turnaround Time: 24-48 Hours

Androgen Receptor

CPT Code(s):

Level of Service:

Methodology: Immunohistochemistry (IHC)

Test Description: Androgen receptor is responsible for the regulation of the growth of the prostate

> epithelial cells. In untreated prostate carcinoma, androgen receptor positive cells are more likely to be responsive to hormonal therapy. In patients with hormone refractory prostate carcinoma, the presence of androgen receptor has a

negative prognostic impact.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

> at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying reg. Use cold pack for transport. Cold pack shouldn't not come in direct contact with specimen.

Storage & Transportation 88342, 88360

CPT Code(s): Level of Service: Global

Tech Only

Anti-Pancreatic Polypeptide

Methodology: Immunohistochemistry (IHC)

Test Description: PPY / Pancreatic Polypeptide belongs to the NPY family and it encodes a protein

that is synthesized as a 95 aa polypeptide precursor in the pancreatic islets of Langerhans. It is cleaved into two peptide products; the active hormone of 36 aa and an icosapeptide of unknown function. PP is produced by pancreatic islet F-cells and released to the circulation following a meal. It slows stomach emptying

time and insulin secretion and is thought to inhibit further food intake. It stains the periphery of islets, exocrine pancreatic parenchyma and the

epithelium of small and medium sized ducts and acinar cells.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

BCA-225

Methodology: Immunohistochemistry (IHC)

Test Description: Indicates breast cancer metastatic lesions, adenocarcinoma. This antibody

recognizes a human breast carcinoma associated glycoprotein BCA-225 (220-225kD). This protein differs in size and distribution from other breast carcinoma antigens. It does not react with benign or malignant gastrointestinal tissues. It can be used to identify skin carcinomas with sweat gland and sebaceous differentiation.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req.

Storage & TransportationUse cold pack for transport.

Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88342
Level of Service: Global
Tech Only

Tech Only 24-48 Hours

Turnaround Time: 24-48 Hou

BCL-2

Methodology: Immunohistochemistry (IHC)

Test Description:Useful in distinguishing reactive and neoplastic follicular proliferation and between

follicular lymphomas expressing bcl-2 protein. Useful in the identification of follicular lymphomas. Overexpression of BCL2 is in higher grade tumors and may

predict disease progression.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service:

Turnaround Time:

88342 Global

Tech Only 24-48 Hours

The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party.

Please direct any questions regarding coding to the pay or being billed. *Tests are sent to CBLPath's preferred laboratory.

BCL-6

Methodology:

Immunohistochemistry (IHC)

Test Description:

Specimen Requirements:

Storage & Transportation

Lymphoma typing, BCL6 is a transcriptional regulator gene that codes for a 706-amino-acid nuclear zinc finger protein. Antibodies to this protein stain the germinal center cells in lymphoid follicles, the follicular cells and interfollicular cells in follicular lymphoma, diffuse large B-Cell lymphomas, and Burkitt

lymphoma, the majority of Reed-Sternberg cells in nodular lymphocyte predominant Hodgkin lymphoma. In contrast, BCL6 rarely stains mantle cell lymphoma and MALT lymphoma. BCL6 expression is seen in approximately 45% of CD30+ anaplastic large cell lymphomas but is absent in other peripheral T-cell lymphomas. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying reg. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global Tech Only 24-48 Hours

Level of Service: **Turnaround Time:**

CPT Code(s):

Ber-EP4

Methodology: Immunohistochemistry (IHC)

Test Description: Epithelial antigen is a transmembrane glycoprotein functioning as a cellular

adhesion molecule. This epithelium-specific antigen is broadly distributed in epithelial cells, and displays a highly conserved expression in carcinomas. The antibody is useful in the differential diagnosis of adenocarcinoma versus malignant mesothelioma. Anti-Epithelial Antigen may also aid in detection of micrometastases in lymph nodes of patients with esophageal carcinoma as well

as in differentiation between basal and squamous cell carcinomas of the skin. Specimen

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut Requirements: at 4-5 microns for H&E staining (required) and three (3) positively charged

unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88342 Level of Service: Global

Tech Only

Turnaround Time:

Storage & Transportation

Beta-Catenin

Methodology: Immunohistochemistry (IHC)

Test Description: b-Catenin is an important regulator of cellcell adhesion and embryogenesis and

there is evidence that mutations of b-catenin could lead to some human cancers. Beta-catenin binds to the cytoplasmic domain of E-cadherin, forming a component of cell-cell adhesion. Normal cells show membrane staining for

b-catenin, while cytoplasmic and/or nuclear staining is abnormal. Dysregulation of b-catenin occurs in Gardners syndrome, where it leads to both familial adenomatous polyposis and fibromatosis. Nuclear location of b-catenin also occurs in colon and endometrioid ovarian carcinomas as well as in synovial

sarcoma, osteosarcoma, liposarcoma and malignant fibrous histiocytoma. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut **Specimen Requirements:** at 4-5 microns for H&E staining (required) and three (3) positively charged

> unstained slides cut at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and on accompanying req.

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only

24-48 Hours **Turnaround Time:**

BOB-1

Methodology:

Test Description:

Specimen Requirements:

Storage & Transportation

CPT Code(s):

Level of Service:

Immunohistochemistry (IHC)

BOB.1/OBF.1 is a transcriptional coactivator that interacts with the transcription factors Oct1 or Oct2 in regulating transcription of immunoglobulin genes. In

ractors Oct1 or Oct2 in regulating transcription of immunoglobulin genes. In normal tonsil, the germinal center B cells all express BOB.1, while only scattered cells in the mantle zone express this protein. On immunohistochemistry, there is strong nuclear staining and weak cytoplasmic staining. Expression of BOB.1/OBF.1, Oct2, and PU.1 transcription factors are often down-regulated in classical

Hodgkin lymphomas, in contrast to many cases of nodular lymphocytepredominant Hodgkin lymphoma. This property can be useful in the diagnosis of

nodular lymphocyte predominant Hodgkin lymphoma (both markers expressed). One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only
Turnaround Time: 24-48 Hours

CA 125

Methodology: Immunohistochemistry (IHC)

Test Description:Useful in the detection of ovarian tumors of serous, endometroid and clear cell types.

Breast cancer and adenocarcinoma. CA-125 reacts with approximately 80% of epithelial ovarian neoplasms of serous, endometrioid, clear cell and

undifferentiated types. Several studies have shown that CA-125 is useful tumor marker for ovarian carcinomas; however, CA-125 has also been described in other neoplasms such as seminal vesicle and anaplastic lymphomas. No reactivity has been shown for mucinous ovarian tumors. It reacts with both normal tissues and neoplasms of fallopian tube, endometrium, endocervix and mesothelioma. It does not react with colon cancer. Normal tissues such as breast, liver, skin, kidney

and spleen are negative.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation Use co CPT Code(s): 88342

CPT Code(s): Level of Service:

Global Tech Only

CA 19.9

Methodology: Test Description: Immunohistochemistry (IHC)

Gastrointestinal, pancreatic adenocarcinomas, salviary gland mucoepidermiod carcinomas. Mucin secreting cells and squamous cell CA may also be labeled. In normal

tissues, the CA19-9 antigen has been demonstrated in ductal epithelium of the breast, kidney, salivary gland and sweat glands, respiratory epithelium of the lung, colon epithelium, pancreatic acini and ducts, biliary epithelium in the liver and prostate epithelium. Gastrointestinal carcinomas are positive as well as transitional cell carcinomas of the bladder, endometrial adenocarcinomas, thyroid papillary, gallbladder carcinomas and lung carcinomas, including adenocarcinomas, bronchoalveolar cell carcinomas, squamous and small cell carcinomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service:

Global Tech Only 24-48 Hours

88342

Turnaround Time: 24-48 Hours

Calcitonin

Methodology: Test Description: Immunohistochemistry (IHC)

Calcitonin producing cells in the thyroid, medullary thyroid carcinomas Calcitonin is secreted by thyroidal parafollicular cells of neuroectodermal origin, probably in response to hypercalcemia. Both in C-cell hyperplasia and medullary thyroid carcinoma (MTC), individual secretory granules exhibit considerable variations in size, shape and density. The IHC demonstration of calcitonin is important: (1) For identification of early or microscopic MTC, (2) To identify an MTC in the absence of amyloid deposits, (3) To distinguish non-typical forms of MTC (e.g., predominantly spindle cell or small cell patterns) from anaplastic carcinoma or malignant lymphoma, (4) To differentiate MTC with microfollicular or papillary patterns from thyroid follicular and papillary neoplasms and (5) To identify C-cell

hyperplasia in association with hypercalcemia of diverse etiologies.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged

unstained slides cut at 3-4 microns for each test/antibody ordered

or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation CPT Code(s):

Level of Service:

88342 Global Tech Only

Caldesmon

Methodology: Immunohistochemistry (IHC)

Test Description: Caldesmon is a developmentally regulated protein involved in smooth muscle

> and non-muscle contraction. Two closely related variants of human caldesmon have been identified. The h-caldesmon variant (120-150kDa) is predominantly expressed in smooth muscle and subset of myoepithelial cells whereas

> I-caldesmon (70-80kDa) is found in non-muscle tissue and cells. Neither of the

two variants has been detected in skeletal muscle.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only **Turnaround Time:** 24-48 Hours

Calponin

Methodology: Immunohistochemistry (IHC)

Test Description: Developing smooth muscles of various phenotype. Calponin, a calmodulin, is

> involved in the regulation of smooth muscle contraction. The expression of calponin is restricted to smooth muscle cells. Two isoforms of calponin exist with molecular weights of 34kDa and 29kDa. Expression of the 29kDa form is primarily restricted to muscle of the urogenital tract. Calponin also labels myoepithelial cells and can be useful in distinguishing in situ from infiltrating breast carcinoma. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

Specimen Requirements: at 4-5 microns for H&E staining (required) and three (3) positively charged

unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only

Turnaround Time:

24-48 Hours

Calretenin

Methodology: Immunohistochemistry (IHC)

Test Description: Useful in distinguishing mesothelioma from adenocarcinomas Calretinin is the

> most specific and reproducible positive marker of epithelial mesothelioma. Calretinin is a calcium-binding protein similar to \$100 protein. It is found in the central and peripheral nervous system and in a wide spectrum of non-neural cells, including steroid-producing cells of ovaries and testes, fat cells, renal tubular epithelial cells, eccrine glands, thymic epithelial cells and mesothelial cells.

> Calretinin immunostaining was found in 95-100% of epithelial mesotheliomas and 3-9% of adenocarcinomas.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut **Specimen Requirements:**

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered

or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying reg. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service:

88342 Global

Tech Only

CAM 5.2

Methodology: Immunohistochemistry (IHC)

Test Description: The keratin antibody clone CAM 5.2 reacts with the low-molecular-weight (LMW)

> cytokeratins CK8 and CK7. All simple (one-layered, polar) epithelial cells contain the paired CK8 and CK18, representing the primary (constitutive) CKs of simple epithelia. These LMW CKs are the only CKs found in some simple epithelium (hepatocytes, pancreatic acini, most endocrine cells and proximal renal tubules). CAM 5.2 reacts with cells in a filamentous pattern within the cytoplasm. Useful in

distinguishing carcinomas from non -epithelial tumors

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut **Specimen Requirements:**

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying reg. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service:

88342 Global Tech Only

Turnaround Time: 24-48 Hours

CAM 5.2/AE1

Methodology: Immunohistochemistry (IHC)

Test Description: Useful in distinguishing carcinomas from non -epithelial tumors

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut **Specimen Requirements:** at 4-5 microns for H&E staining (required) and three (3) positively charged

unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying reg. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD10

Methodology: Immunohistochemistry (IHC)

Test Description: Lymohoma/Leukemia typing. CD10, also known as Common Acute Lymphocytic

Leukemia Antigen (CALLA), is expressed in early lymphoid progenitors and normal germinal center cells. It is almost always present on the surface of precursor B-lymphoblastic and Burkitt lymphomas and much less frequently on precursor T-lymphoblastic leukemia-lymphoma. Many follicular lymphoma and some diffuse large B-cell lymphomas, along with multiple myeloma are positive. CD10 is also present on breast myoepithelial cells, bile canaliculi, fibroblasts and with especially

high expression on the brush border of kidney and gut epithelial cells.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

> at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only

CD117/c-kit

Methodology: Immunohistochemistry (IHC)

Test Description: c-kit is a transmembrane receptor tyrosine kinase. c-kit is expressed in many

tissues and cells. c-kit is involved in the development of several lineages of stem cells, such as germ cells, neural crest derived melanocytes and hematopoietic precursor cells. This antibody can be used in the identification of gastrointestinal

stromal tumors (Gist tumor).

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service:

88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD138

Methodology: Immunohistochemistry (IHC)

Test Description: Plasma cells. CD138 (Syndecan-1) mediates cell adhesion, growth factors.

Positive staining (normal): B-cell precursors, plasma cells. Positive staining (tumors): myeloma, primary effusion lymphoma. Negative staining: mature B-cells,

lymphomas (even plasmacytoid lymphomas).

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD15

Methodology: Immunohistochemistry (IHC)

Test Description: CD15 (X-Hapten) plays a role in mediating phagocytosis, bactericidal activity,

and chemotaxis. It is present on >95% of granulocytes including neutrophils and eosinophils and to a lesser degree on monocytes. CD15 is also expressed in Reed-Sternberg cells and some epithelial cells. CD15 antibody is very useful in the identification of Hodgkin lymphoma. CD15 is occasionally expressed in large cell lymphomas of both B- and T- phenotypes that otherwise have a quite distinct

histological appearance.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only
Turnaround Time: 24-48 Hours

Methodology: Immunohistochemistry (IHC)

Test Description: CD19 is the broadest lineage-specific surface marker for B cells. CD19 is present

on the surface of virtually all B lymphocytes, including early B-progenitor cells, but it is lost upon terminal differentiation to plasma cells. CD19 is also expressed on follicular dendritic cells. Results aid in the classification of B-lineage leukemias

and lymphomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service:

88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD163

Methodology: Immunohistochemistry (IHC)

Test Description: CD163 antigen is restricted in its expression to the monocytic/macrophage lineage. It

is present on all circulating monocytes and most tissue macrophages except those found in the mantle zone and germinal centres of lymphoid follicles,

interdigitating reticulum cells and Langerhans cells.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service:

88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD1a

Methodology: Immunohistochemistry (IHC)

Test Description: Useful in distinguishing leukemias and lympomas At least five CD1 genes

(CD1a, b, c, d, and e) have been identified. CD1a is expressed on cortical thymocytes, Langerhans cells, and dendritic cells. It is absent on mature peripheral blood T-cells, but cytoplasmic expression is detected on activated T-lymphocytes. CD1a is found on a subset of T-lymphoblastic lymphoma-leukemia. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

Specimen Requirements:

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slid at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party.

Please direct any questions regarding coding to the pay or being billed. *Tests are sent to CBLPath's preferred laboratory.

Methodology:

Specimen Requirements:

Immunohistochemistry (IHC)

Test Description: Lymphoma/Leukemia typing. CD2, the E-rosette receptor, is an extremely broad

> T-cell marker. This antibody immunolabels the vast majority of T-cells and a subset of natural killer (NK)- cell malignancies. Some thymic B-cells (50%) are also CD2 positive. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only 24-48 Hours

Turnaround Time:

CD20

Methodology: Immunohistochemistry (IHC)

Test Description: Lymohoma/Leukemia typing. Positive staining (normal): Most B-cells (after CD19

and CD10 expression, before CD21/22 expression and surface immunoglobulin

expression), retained on mature B-cells until plasma cell development;

also follicular dendritic cells. Positive staining (disease): 90% of B-cell lymphomas, 40% of pre B-ALL/LBL; 80% of lymphocyte predominant Hodgkin lymphoma, dimly expressed in T-cells (benign and neoplastic), spindle cell thymomas. Negative staining: non-hematopoietic cells, most T-cells and plasma cells.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

Specimen Requirements:

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time:

24-48 Hours

CD21

Methodology: Immunohistochemistry (IHC)

Test Description: CD21 (CR2, C3d receptor and EBV receptor) is expressed strongly on mature

B-cells, follicular dendritic cells (FDC) and weakly on immature thymocytes and T-lymphocytes. In B-cell ontogeny, CD21 appears after the pre-B-stage, is maintained during peripheral B-cell development and is lost upon terminal differentiation into plasma cells. Immunohistological analysis of FDC in paraffin sections of NHL with this antibody demonstrates a nodular and usually dense and sharply defined FDC meshwork in follicular lymphomas and a loose, ill-defined FDC of varying size in some diffuse lymphoma types. Precursor B-cell lymphoma (lymphoblastic lymphomas), Burkitt lymphomas, plasmacytomas and hairy cell

leukemias constantly lack FDC.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut **Specimen Requirements:**

> at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying reg. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

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Storage & Transportation

CPT Code(s): Level of Service:

Turnaround Time:

88342 Global

Tech Only 24-48 Hours

The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party.

Methodology: Immunohistochemistry (IHC)

Test Description: CD22 expression is restricted to normal and neoplastic B-cells and is absent

from other hemopoietic cell types. In B-cell ontogeny, CD22 is first expressed in the cytoplasm of pro-B and pre-B-cells and on the surface as B-cells mature to become IgD+. It is not expressed by plasma cells. CD22 is found highly expressed in follicular, mantle and marginal zone B-cells, while germinal center B-cells are relatively weak. Its expression roughly parallels that of CD19. It is

strongly expressed in hairy cell leukemia.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD23

Methodology: Immunohistochemistry (IHC)

Test Description: Lymohoma/Leukemia typing. CD23 is identical to low affinity IgE receptor

found on B-cells. CD23 is expressed on a subpopulation of peripheral blood cells, B-lymphocytes and on EBV transformed B-lymphoblastoid cell lines. CD23 is most useful in distinguishing B-cell chronic lymphocytic leukemia/small

lymphocytic lymphoma (CLL/SLL) from other entities and remains present in CLL/

SLL that has undergone large cell transformation.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD25

Methodology: Immunohistochemistry (IHC)

Test Description: The interleukin-2 receptor is designated CD25. Originally isolated from

T-lymphocytes, it is now known to be expressed on hairy cell leukemia and adult

T-cell leukemia/lymphoma.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only

Methodology: Immunohistochemistry (IHC)

Test Description: Lymphoma/ Leukemis typing. Labels T cell neoplasms. The CD3 antigen is first

detectable in early thymocytes and its appearance probably represents one of the earliest signs of commitment to the T-cell lineage. It has a cytoplasmic expression at early T-cell differentiation, then membranous expression. CD3 is the most specific T-cell antibody. Positive staining (normal): thymocytes, peripheral T-cells, NK cells; also Purkinje cells of cerebellum. Positive staining (disease): 80% of T-cell lymphomas. Negative staining: gamma/delta T-cell receptors and most

B-cell lymphomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD30

Methodology: Immunohistochemistry (IHC)

Test Description: Lymohoma/Leukemia typing. CD30 is a lymphocyte activation antigen, related to

tumor necrosis factor. Positive staining (normal): granulocytes, plasma cells,

activated B-, T- and NK cells. Positive staining (disease): infectious

mononucleosis, lymphocytes infected with HIV, HTLV-1, EBV, HHV8 or hepatitis B; Reed-Sternberg cells, 90% of anaplastic large cell lymphomas, lymphomatoid papulosis, peripheral T-cell lymphomas, germ cell tumors and some melanomas. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged

unstained slides cut at 3-4 microns for each test/antibody ordered

or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation CPT Code(s):

Specimen Requirements:

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD31

Methodology: Immunohistochemistry (IHC)

Test Description: CD31 is a 130-kd transmembrane glycoprotein that is shared by vascular lining

cells, megakaryocytes and platelets. This marker is highly restricted to endothelial neoplasms among all tumors of the soft tissue and its sensitivity is excellent. 100% of angiosarcomas and hemangiomas are CD31 positive. However, KS is labeled more consistently by CD34 than by CD31. CD31 has also been used as a

prognostic marker measuring tumor angiogenesis.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only
Turnaround Time: 24-48 Hours

Methodology: Immunohistochemistry (IHC)

Test Description: CD34, a single chain transmembrane glycoprotein, is selectively expressed on

human lymphoid and myeloid hematopoietic progenitor cells and endothelial cells.

CD34 antibody labels all gastrointestinal stromal tumors (GIST),

dermatofibrosarcoma protuberans, solitary fibrous tumor and a subset of sarcomas. CD34 staining has been also used to measure angiogenesis. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cu

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service:

88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD35

Methodology: Immunohistochemistry (IHC)

Test Description: CD35 antigen is a transmembrane protein of 160-250 kD that binds complement

components C3b and C4b. It mediates phagocytosis by neutrophils and monocytes. CD35 is found on erythrocytes, B-cells, a subset of T-cells,

monocytes, macrophages cultured in vitro, neutrophils, eosinophils, glomerular podocytes and follicular dendritic cells. CD35 antibody is useful in the diagnosis of

MALT lymphoma and in the study of inflammatory disorders.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

Specimen Requirements:

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD38

Methodology: Immunohistochemistry (IHC)

Test Description: CD38 is a transmembrane protein, that is highly expressed on thymocytes. It is

also present on activated T-cells and terminally differentiated B-cells (plasma cells). Other reactive cells include NK cells, monocytes, macrophages and dendritic cells. CD38 may be detected on cells from multiple myeloma, ALL (B and T) and some AML. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation
CPT Code(s):

Level of Service:

88342 Global

Tech Only Turnaround Time: 24-48 Hours

Methodology: Immunohistochemistry (IHC)

Test Description: Lymphoma/Leukemia typing. CD4, a single chain transmembrane glycoprotein,

is found on a T-cell subset (helper/inducer). It is also present on a variety of monocyte-derived cells, including Langerhans and other dendritic cells. The CD4 epitope is absent from immature thymocytes and is expressed during T-cell development. Precursor T-lymphoblastic lymphomas are therefore variable in their expression of CD4, but most mature T-cell lymphomas are positive, with the exception of aggressive NK-cell leukemia, extranodal NK-cell lymphoma, gamma

delta T-cell lymphomas and enteropathy-type T-cell lymphoma.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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88342 Global

Tech Only
Turnaround Time: 24-48 Hours

Storage & Transportation

Storage & Transportation

CPT Code(s):

Level of Service:

CD43

Methodology: Immunohistochemistry (IHC)

Test Description: Lymohoma/Leukemia typing CD43 (leukosialin, sialophorin, or leukocyte

sialoglycoprotein) is a cell surface glycoprotein that is expressed on all thymocytes, T-cells and cells of myeloid lineage. CD43 antibody can be useful in

diagnosis of T-cell lymphoma and a subset of B-cell lymphoma. CD43 expression in lymphomas is highly correlated with CD5; thus, most of T-cell malignancies and a group of small lymphocyte B-cell malignancies (CLL/SLL, mantle cell lymphoma, prolymphocytic leukemia (PLL)) are often positive, whereas follicular lymphoma is

rarely positive.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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CPT Code(s): 88342

Level of Service: Global Tech C

Tech Only 24-48 Hours

Methodology: Immunohistochemistry (IHC)

Test Description: It is a transmembranous glycoprotein (80 kDa) present on T lymphocytes,

granulocytes, red blood cells, brain, and epithelial cells. The standard isoform, CD44s, is expressed in a wide range of normal tissues such as tonsil, skin, bladder, and cervical squamous epithelium. In breast cancer studies, CD44 expression, demonstrated a favorable prognostic factor in patients with nodenegative invasive breast carcinoma. Further studies have shown a subpopulation of CD44+/CD24- cells in breast cancer have stem/progenitor cell properties. Anti-CD44 may be useful in discrimination of urothelial carcinoma in-situ from non-

neoplastic changes in the urothelium.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD45RO

Methodology: Immunohistochemistry (IHC)

Test Description: Lymohoma/Leukemia typing. CD45RO (an isoform of leukocyte common antigen)

reacts with mature activated T-cells, most thymocytes, and a sub-population of resting T-cells within both CD4 and CD8 subsets. CD45RO antibody marks many T-cell lymphomas but also identifies granulocytes, histiocytes and some B-cells. It

rarely stains B-cell lymphomas

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation CPT Code(s):

Level of Service:

88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD₅

Methodology: Immunohistochemistry (IHC)

Test Description: Lymphoma/Leukemia typing, CD5, a transmembrane protein, is found on most

thymocytes and immature peripheral T-cells. Positive staining (normal): B-cells of mantle zone of spleen and lymph nodes; B-cells in peritoneal and pleural cavities; almost all T-cells; In fetus, most B-cells in spleen and cord blood are CD5 positive. Positive staining (disease): B-cell CLL/SLL, mantle cell lymphoma (MCL), hairy cell loukemia (HCL), most T-malignancies, thymic carcinomas (most). Negative

leukemia (HCL), most T-malignancies, thymic carcinomas (most). Negative staining: Spindle cell thymomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Global Tech Only

CD56/Leu 6

Methodology: Immunohistochemistry (IHC)

Test Description: Lymohoma/Leukemia typing. CD56 recognizes two proteins of the neural

cell adhesion molecule, the basic molecule expressed on most neuroectodermally derived cell lines, tissues and neoplasms (e.g. retinoblastoma, medulloblastomas, astrocytomas, and neuroblastomas). It is also expressed on some mesodermally derived tumors (rhabdomyosarcoma) and on natural killer cells. CD56 could be used as a marker for NK-like T-Cell Lymphoma. Some benign and malignant

plasma cells are also positive.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD57

Methodology: Immunohistochemistry (IHC)

Test Description: CD57 is expressed on a subpopulation of 15-20% of peripheral blood

mononuclear cells, about 60% of NK active cells and on a subset of T-cells. Hematopoietic malignancies that are CD57+ include a minority of T-lymphoblastic leukemias, roughly three quarters of the indolent T-cell large granular lymphocytic

leukemias and small portion of NK-cell lymphomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation CPT Code(s):

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD61

Methodology: Immunohistochemistry (IHC)

Test Description: CD61 (GPIlla) is a glycoprotein found on megakaryocytes, platelets and their precursors.

CD61 antigen plays a role in platelet aggregation and also as a receptor for fibrinogen, fibronectin, von Willebrand factor and vitronectrin. This antibody is useful in detecting neoplastic platelet precursors, normal platelets and most cases

of megakaryocytic leukemias.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

CD63(NKI/C3)

Methodology: Immunohistochemistry (IHC)

Test Description: Its reactivity is seen in the cytoplasm of many cell types including lymphoid,

myeloid, endothelial cells and the majority of malignant melanomas. CD63 is a 53kDa lysosomal membrane protein in the family of tetraspan moieties, and characterized as an activation dependent platelet surface antigen. It is a useful

marker for the identification of malignant melanoma.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD68

Methodology: Immunohistochemistry (IHC)

Test Description: CD68 is important for identifying macrophages in tissue sections. It stains macrophages

in a wide variety of human tissues, including Kupffer cells and macrophages in the red pulp of the spleen, in lamina propria of the gut, in lung alveoli, and in bone marrow. This antibody reacts with myeloid precursors and peripheral blood granulocytes. It shows strong granular cytoplasmic staining of chronic and acute myeloid leukemia and also reacts with rare cases of true histiocytic neoplasia. Tumors of lymphoid origin are usually

not stained.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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CPT Code(s): 88342

Level of Service:Global
Tech Only

Turnaround Time: 24-48 Hours

CD7

Methodology: Immunohistochemistry (IHC)

Test Description: Lymphoma/Leukemia typing. CD7 is expressed on the majority of immature and mature

T-lymphocytes and T-cell leukemia. It is also found on natural killer cells, a small subpopulation of normal and malignant B-cells. CD7 antibody can be useful for

detection of T-cell leukemias and myeloid leukemias.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only
Turnaround Time: 24-48 Hours

CD79a

Methodology: Immunohistochemistry (IHC)

Test Description: Lymohoma/Leukemia typing. CD79a first appears at the pre B-cell stage and persists

until the plasma cell stage where it is found as an intracellular component. CD79a is found in the majority of acute leukemias of precursor B-cell type, in B- cell lines, B-cell

lymphomas, and in some myelomas. It is not present in myeloid or T-cell.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

Specimen Requirements:

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD8

Methodology: Immunohistochemistry (IHC)

Test Description:CD8 is a T-cell marker for the detection of cytotoxic/suppressor T-cells. CD8 is also

detected on NK cells, most thymocytes, a subpopulation of null cells and bone marrow

cells. This antibody is useful in evaluating T-cell lymphomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CD99/MIC2/P30

Methodology: Immunohistochemistry (IHC)

Test Description: CD99 (MIC2 gene product, E2) antigen is strongly expressed by Ewings sarcoma cells,

primitive peripheral neuroectodermal tumors and lymphoblastic leukemia/lymphoma.

Specimen Requirements:One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged

unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation Use CPT Code(s): 883

Level of Service:

88342 Global Tech Only

CDX2

Methodology: Immunohistochemistry (IHC)

Test Description: CDX2 is an intestine specific transcription factor that regulates both the proliferation and

the differentiation in intestinal epithelial cells. It is expressed in the nuclei of epithelial cells throughout the intestine, from duodenum to rectum. The CDX2 protein is expressed in primary and metastatic colorectal carcinomas and has also been demonstrated in the intestinal metaplasia of the stomach and intestinal-type gastric cancer, while it is not expressed in the normal gastric mucosa. CDX2-88 may be used in identifying metastatic

carcinoma of colonic origin in the setting of an unknown primary tumor.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CDX2/CK7

Methodology: Immunohistochemistry (IHC)

Test Description: CDX2 protein is expressed in primary and metastatic colorectal carcinomas and has also

been demonstrated in the intestinal metaplasia of the stomach and intestinal-type gastric cancer. It is not expressed in the normal gastric mucosa. Cytokeratin 7 is a basic cytokeratin and is expressed in epithelial cells of ovary, lung, and breast, but not of the colon or gastrointestinal tract. This antibody cocktail of CDX2 and CK7 can be used simultaneously to distinguish stomach and colon cancers from breast, lung and

ovarian cancers.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service:

Global Tech Only 24-48 Hours

88342

Turnaround Time: 24-48 Hours

CEA (Mono)

Methodology: Immunohistochemistry (IHC)

Test Description: The antibody shows a strong reaction with CEA and CEA-like proteins, such as

CEACAM1 (biliary glycoprotein, BGP1) and CEACAM6 (non-specific cross-reacting

antigen, NCA).

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only
Turnaround Time: 24-48 Hours

CEA (Poly)

Methodology: Immunohistochemistry (IHC)

Test Description: Carcinoembryonic antigen (CEA) is a heterogeneous cell surface glycoprotein produced

> by cells of fetal colon. Low levels are also found on normal mucosal epithelia of the adult colon and a variety of other normal tissues. CEA is encoded by the CEA gene that is located on chromosome 19. It is a member of the CEA gene family, which in turn is a subfamily of the immunoglobulin superfamily. Cell adhesion properties are now well recognized for CEA. It is believed that the expression of this glycoprotein in conjunction

with other known adhesion molecules will influence the cell-cell interaction. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut **Specimen Requirements:**

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying reg. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service:

88342 Global Tech Only 24-48 Hours

Turnaround Time:

Chromogranin A

Immunohistochemistry (IHC) Methodology:

Neuroendocrine differentiation. Chromogranin is present in several elements of the **Test Description:**

> diffuse neuroendocrine system (DNES), including anterior pituitary, thyroid perifollicular C cells, parathyroid chief cells, pancreatic islet cells, intestinal enterochromaffin cells and tumors derived from these cells. Chromogranin immunoreactivity was also seen in thymus, spleen, lymph nodes, fetal liver, neurons, the inner segment of rods and cones, the submandibullar gland and the central nervous system. This marker is useful in

evaluating neuroendocrine tumors.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut **Specimen Requirements:**

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation CPT Code(s): 88342

Level of Service:

Global Tech Only

Turnaround Time: 24-48 Hours

CK 5/6

Methodology: Immunohistochemistry (IHC)

Test Description: CK5/6 positivity is seen in nearly 100% of malignant mesotheliomas and in almost no

lung adenocarcinomas. CK5/6 positivity can be seen in undifferentiated large cell carcinoma as well as squamous carcinoma. Less than 10% of carcinomas of the breast,

colon and prostate stain positively for this marker.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut **Specimen Requirements:**

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only

Turnaround Time:

24-48 Hours

CK19

Methodology: Immunohistochemistry (IHC)

Test Description: Cytokeratin 19 is a member of type I acidic subfamily of keratins. It is expressed in

various different human tissues. CK19 labels ductal and glandular epithelia, prostatic epithelia, and non-keratinizing squamous epithelia. This antibody is useful in the diagnosis of breast and cervical carcinoma. CK19 is not expressed in hepatocytes, therefore antibody to keratin 19 is also useful in the distinction of liver metastasis from

hepatocellular carcinomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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88342 Global Tech Only

Turnaround Time: 24-48 Hours

Storage & Transportation

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CPT Code(s):

Level of Service:

CPT Code(s): Level of Service:

CK20

Methodology: Immunohistochemistry (IHC)

Test Description: CK20 positivity is seen in the majority of adenocarcinomas of the colon, mucinous

ovarian carcinomas, transitional cell and Merkel cell carcinomas and frequently in adenocarcinomas of the stomach, bile system and pancreas. The primary sites of adenocarcinoma causing the most cancer deaths are the lung and colon. However, pathological differentiation of these two neoplasms can be difficult. Cytokeratin 7 is usually present in pulmonary but not colonic adenocarcinomas. CK7/CK20 immunostaining patterns may be helpful in separating pulmonary from colonic

adenocarcinomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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88342 Global Tech Only

Turnaround Time: 24-48 Hours

CK34BE12

Methodology: Immunohistochemistry (IHC)

Test Description: CK 903 (34betaE12) is a high molecular weight cytokeratin that reacts with all squamous

epithelium and their carcinomas. This antibody recognizes cytokeratins 1, 5, 10 and 14 that are found in complex epithelia. CK903 shows no reactivity with hepatocytes, pancreatic acinar cells, proximal renal tubes or endometrial glands. There has been no reactivity with cells derived from simple epithelia. Mesenchymal tumors, lymphomas, melanomas, neural tumors and neuroendocrine tumors are unreactive with this antibody. One useful application is the identification of basal cell layer in prostate tissue in the

determination of carcinoma.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): 88342
Level of Service: Global
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Tech Only 24-48 Hours

CK5

Methodology: Test Description: Immunohistochemistry (IHC)

It is a type II cytokeratin. CK5 is expressed in many non-keratinizing stratified squamous epithelia as well as basal cells in prostate glands and myoepithelial cells in mammary glands. It has been useful in the differential diagnosis of metastatic carcinoma in the pleura versus epithelial mesothelioma. Anti-Cytokeratin 5, along with anti-cytokeratin 14, has been found to have an application in identifying the basal-like phenotype of breast carcinoma Helps defines a basal-like subtype of invasive ductal carcinoma of the breast

that is usually CK5/6+, ER-, PR-, HER2-, EGFR+ with poorer prognosis

Distinguish breast usual ductal hyperplasia (strong staining) from solid papillary DCIS (negative), p63+ and CK5/6+ poorly differentiated metastatic carcinomas are likely to have

squamous carcinoma primaries

Distinguish epithelioid mesothelioma (CK5/6+ cytoplasmic staining with perinuclear

enhancement) from lung adenocarcinoma (usually CK5/6 negative).

Distinguish cutaneous spindled squamous cell carcinoma (CK5/6+ in 100%) from

superficial epithelioid sarcoma (rare focal positivity).

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Tech Only
Turnaround Time: 24-48 Hours

CK7

Methodology: Test Description:

CPT Code(s):

Level of Service:

Storage & Transportation

Immunohistochemistry (IHC)

This antibody reacts with proteins that are found in most ductal, glandular and transitional epithelium of the urinary tract and bile duct epithelial cells. Cytokeratin 7 distinguishes between lung and breast epithelium that stain positive, and colon and prostate epithelial cells that are negative. It also reacts with many benign and malignant epithelial lesions, e.g. adenocarcinomas of the ovary, breast and lung. Transitional cell carcinomas are positive and most prostate cancers are negative. This antibody does

not recognize other intermediate filament proteins.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

CK8 - 18

Methodology: Immunohistochemistry (IHC)

Test Description: Cytokeratin 8, 35betaH11 antibody, is reactive with the majority of epithelium and

epithelial tumors and stains positive in non-squamous epithelial tumors and is negative in squamous cell carcinomas. This antibody stains positive for adenocarcinomas of the breast, ovary, gastrointestinal tract, thyroid, pancreas, bile duct, and salivary glands. It does not react with skeletal muscle or nerve cells. Stains most epithelial-derived tumors.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

CMV

Methodology: Immunohistochemistry (IHC)

Test Description: Reacts with CMV immediate early antigen and early antigen. The antibody shows no

cross-reaction with other herpesviruses or with adenovirus. In CMV-infected cells, the antibody gives a nuclear staining pattern early during the infection; at a later stage, a

diffuse nuclear and apparent cytoplasmic staining is observed.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. 88342

Global Tech Only

Turnaround Time: 24-48 Hours

Collagen IV

Methodology: Immunohistochemistry (IHC)

Test Description: Collagen IV is a major constituent of the basement membranes along with laminins and

enactins. In kidney, the antibody reacts with glomerular and tubular basement

membranes, parts of mesenchymal matrix and the Bowmans capsule. It also reacts with basal lamina of capillaries as well as basement membranes in a variety of tissues.

Antibody to collagen IV is useful in detecting the loss of parts of basement membrane in

carcinomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global Tech Only

Cyclin D1

Methodology: Immunohistochemistry (IHC)

Test Description: Cyclin D1, one of the key cell cycle regulators, is a putative proto-oncogene

overexpressed in a wide variety of human neoplasms. Cyclins are proteins that govern transitions through distinct phases of the cell cycle by regulating the activity of the cyclin-dependent kinases. In mid to late G1, Cyclin D1 shows a maximum expression following growth factor stimulation. Cyclin D1 has been successfully employed and is a promising tool for further studies in both cell cycle biology and cancer associated abnormalities. This antibody is useful for separating mantle cell lymphomas (Cyclin D1 positive) from

SLLs and small cleaved cell lymphomas (Cyclin D1 negative).

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

Cytokeratin (AE1)

Methodology: Immunohistochemistry (IHC)

Test Description: Its reactivity is seen mostly in normal and neoplastic cells of epithelial origin. It is useful

for distinguishing between poorly differentiated carcinomas and non-epithelial

neoplasms. Diagnostically, antikeratin antibodies are usually applied as part of a panel to

determine cell lineage of poorly differentiated malignant tumors.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only
Turnaround Time: 24-48 Hours

Cytokeratin (AE3)

Methodology: Immunohistochemistry (IHC)

Test Description: Recognize all basic keratins. It is a broadly reactive antibody staining most epithelia and

their neoplasms. It is used to observe the distribution of keratin- containing cells in normal epithelia and to identify neoplasm derived from such epithelium. Diagnostically, antikeratin antibodies are usually applied as part of a panel to determine cell lineage of

poorly differentiated malignant tumors.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation

CPT Code(s): Level of Service: 88342

Global

Tech Only

c-MYC(Y69)

Methodology: Immunohistochemistry (IHC)

Test Description: Proto-oncogene at 8q24.1 produces short lived nuclear phosphoprotein. It activates

the transcription of growth related genes. It has a crucial role in cellular metabolism and

apoptosis and is associated with variety of tumors.

Overexpressed by t(8;14)(q24;q32.3), t(8;22);(q24;11) and t(2;8);(p11-12;q24), which translocate c-myc gene next to immunoglobulin genes in Burkitt's lymphoma. The antibody stains also this protein from colorectal adenocarcinoma, breast invasive ductal carcinoma, prostate adenocarcinoma, neuroblastoma, AIDS-related lymphomas,

diffuse large-cell lymphomas, posttransplant lymphoproliferative disease, B-ALL

(leukemic counterpart of Burkitt's lymphoma)

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only **Turnaround Time:** 24-48 Hours

D2-40

Methodology: Immunohistochemistry (IHC)

Test Description: D2-40 identifies a 40 kDa O-linked sialoglycoprotein expressed by a variety of tissues,

including fetal testes and testicular germ cell tumors. Anti-D2-40 has also been demonstrated to label lymphatic endothelium whereas it is unreactive with vascular endothelium. In neoplastic tissue, immunostaining of lymphatic endothelium by Anti-D2-40 can be useful in identifying lymphatic invasion of primary tumors

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 **Specimen Requirements:**

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88342 Level of Service: Global

Tech Only

Turnaround Time: 24-48 Hours

DESMIN

Methodology: Immunohistochemistry (IHC)

Test Description: Desmin is an intermediate filament protein of both smooth and striated muscles.

Antibody to desmin reacts with striated (skeletal and cardiac) as well as smooth muscle cells. Anti-desmin antibody is useful in identification of tumors of myogenic origin. It reacts with leiomyosarcomas (smooth muscle) as well as rhabdomyosarcomas

(striated muscle).

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 **Specimen Requirements:**

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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CPT Code(s): 88342

Level of Service: Global Tech Only

DOG₁

Methodology: Immunohistochemistry (IHC)

Test Description: Anti-DOG1 antibody has been shown to be highly specific and sensitive in the diagnosis

of Gastrointestinal Stromal Tumors. Approximately 4-15% of GIST, stain weakly or are negative for c-kit by immunohistochemistry. In the vast majority of these cases, DOG1 is expressed by IHC. Such testing has important implications regarding treatment

via imatinib therapy.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

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88342 Global Tech Only

Turnaround Time: 24-48 Hours

E Cadherin

Methodology: Immunohistochemistry (IHC)

Test Description:

E-Cadherin is an adhesion protein that is expressed in cells of epithelial lineage. It stains positively in glandular epithelium as well as adenocarcinomas of the lung and G.I. tract and ovary. It is useful in distinguishing adenocarcinoma from mesothelioma. It has also been shown to be positive in some thyroid carcinomas. Breast carcinomas

with ductal and lobular features show two staining patterns: (1) complete or almost complete lack of membrane staining in lobular carcinomas and (2) uniform membrane expression throughout the tumor in ductal carcinomas. Immunohistochemical detection of E-Cadherin expression can be a useful diagnostic tool for the differentiation of ductal

and lobular carcinomas of the breast.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

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CPT Code(s): Level of Service:

Turnaround Time:

88342 Global

Tech Only 24-48 Hours

EGFR

Methodology: Immunohistochemistry (IHC)

Test Description: EGFR (H11) reacts with a 170 kDa (wild type) and 145 kDa (VIII variant), identified as

the first member (EGR-Receptor) of type I family of growth factor receptors. It shows no cross-reaction with c-erbB-2, c-erbB-3 or c-erbB-4. Over-expression of EGFR is reported in tumors of breast (25%), brain, bladder, lung, gastric, esophagus, cervix,

ovary and endometrium.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global Tech Only

Epithelial Membrane Antigen (EMA)

Methodology: Immunohistochemistry (IHC)

Test Description: EMA antibody is a useful marker for staining many carcinomas. It stains normal and

neoplastic cells from various tissues, including mammary epithelium, sweat glands and squamous epithelium. Hepatocellular carcinoma, adrenal carcinoma and embryonal carcinomas are consistently EMA negative, therefore keratin positivity with negative EMA favors one of these tumors. EMA is frequently positive in meningioma, which can be useful when distinguishing it from other intracranial neoplasms, e.g. Schwannomas. The absence of EMA can also be of value since negative EMA is characteristic of tumors

such as adrenal carcinoma, seminomas, paraganglioma and hepatoma.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service:

Tech Only Turnaround Time: 24-48 Hours

ERG

Methodology: Immunohistochemistry (IHC)

88342

Global

Test Description: Anti-ERG (EPR3864) Rabbit Monoclonal Primary Antibody (anti-ERG (EPR3864))

is directed against the C-terminus of the ETS transcription regulator, ERG, and is capable of detecting both wildtype ERG, and truncated ERG resulting from ERG gene rearrangement. This antibody exhibits a nuclear staining pattern and may be used to sid in the identification of prostote advances in a part of the identification of prostote advances in the identification of the identification of prostote advances in the identification of prostote advances in the identification of the ide

to aid in the identification of prostate adenocarcinomas through the detection of

truncated ERG. **Specimen Requirements:**One (1) formalin

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): 88342
Level of Service: Global
Tech Only

Turnaround Time: 24-48 Hours

Estrogen Receptor (ER) - Quantitative

Methodology: Immunohistochemistry (IHC)

Test Description:Anti-ER (SP1) is directed against an epitope present on human ER protein located in the nucleus of ER positive normal and neoplastic cells. Anti-ER (SP1) is indicated as an aid

in the management, prognosis, and prediction of therapy outcome of breast cancer One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

Specimen Requirements:

 CPT Code(s):
 88360

 Level of Service:
 Global

 Tech Only
 24-48 Hours

Factor XIIIA

Methodology: Immunohistochemistry (IHC)

Test Description: Factor XIIIa is a blood proenzyme that has been identified in platelets, megakaryocyte,

and fibroblast-like mesenchymal or histiocytic cells present in the placenta, uterus, and prostate; it is also present in monocytes and macrophages and dermal dendritic cells. Anti- Factor XIIIa has been found to be useful in differentiating between

dermatofibroma (90% (+)), dermatofibrosarcoma protuberans (25%(+)) and desmoplastic

malignant melanoma (0%(+)). Factor XIIIa positivity is also seen in capillary

hemagioblastoma (100%(+)), hemangioendothelioma (100%(+)), hemangiopericytoma (100%(+)), xanthogranuloma (100%(+)), xanthoma (100(+)), hepatocellular carcinoma

(93%(+)), glomus tumor (80%(+)), and meningioma (80 % (+)).

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only

Turnaround Time: 24-48 Hours

Factor VIII

Methodology: Immunohistochemistry (IHC)

Test Description: Factor VIII-related antigen is a component of Factor VIII complex. Factor VIII-related

antigen is one of the available immunohistochemical markers of endothelial cells. It has also been demonstrated in platelets and megakaryocytes. IHC staining of Factor VIII-related antigen is useful for diagnosis of vascular neoplasms and for identification of

vascular invasion by neoplasms.

Specimen Requirements: Formalin fixed paraffin-embedded tissue block; 1 H&E slide

plus 3 unstained charged slides; fine needle aspirate in RPMI; bone marrow core fixed in

formalin; bone marrow clot fixed in formalin.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

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88342 Global

Tech Only

Turnaround Time: 24-48 Hours

FASCIN

Methodology: Immunohistochemistry (IHC)

Test Description: Human fascin is a highly conserved actin-bundling protein. It is expressed predominantly

in dendritic cells. Lymphoid cells, myeloid cells and plasma cells are negative. However, Reed-Sternberg cells in Hodgkin lymphoma are positive for fascin staining. Epstein-Barr

virus may induce expression of fascin in B-cells

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only

Turnaround Time: 24-48 Hours

The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party.

Please direct any questions regarding coding to the pay or being billed. *Tests are sent to CBLPath's preferred laboratory.

FLI-1

Methodology: Immunohistochemistry (IHC)

Test Description:Labels Ewing's Kaposis sarcoma, Hemangiomas Angiosarcomas and Merkel cell carcinoma. **Specimen Requirements:**One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only
Turnaround Time: 24-48 Hours

Galectin-3

Methodology: Immunohistochemistry (IHC)

Test Description: Galectin-3 has been associated with binding to the basement membrane glycoprotein

laminin. Anti-Galectin-3 has been demonstrated to be valuable in differentiating between benign and malignant thyroid neoplasms in both histologic sections and fine needle aspiration biopsy material. Anti-Galectin-3 antibody has also been useful in identifying

anaplastic large cell lymphoma.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & TransportationUse cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88342 Level of Service: Global

Tech Only

Turnaround Time: 24-48 Hours

Gastrin

Methodology: Immunohistochemistry (IHC)

Test Description: Gastrin, a polypeptide hormone, occurs naturally in three forms: gastrin-14, gastrin-17

and gastrin-34. This antibody labels gastrin or gastrin-analogue producing cells in

gastrin-secreting tumors and G cell hyperplasia.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation Us CPT Code(s): 88

Level of Service:

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. 88342

Global Tech Only

GATA3

Methodology: Immunohistochemistry (IHC)

Test Description: GATA3 (GATA binding protein 3) is a member of the GATA family of transcription factors.

> Among several other roles, GATA3 is involved in luminal cell differentiation in the mammary gland and appears to control a set of genes involved in the differentiation and proliferation of breast cancer. The expression of GATA3 is associated with the expression of estrogen receptor-alpha (ER) in breast cancer. GATA3 has been shown to be a useful in the characterization of carcinomas, including primary bladder and breast

carcinomas, and some types of mesenchymal and neuroectodermal tumors

(ie, paragangliomas).

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

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Storage & Transportation

CPT Code(s): Level of Service:

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. 88342 Global

Tech Only

Turnaround Time: 24-48 Hours

GLUCAGON

Methodology: Immunohistochemistry (IHC)

Test Description: Glucagon is used for the identification of tumors and hyperplasias of pancreatic islets.

Antibody labels A cells of the endocrine mammalian pancreas. It reacts with glucagon in

a large number of mammalian species.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

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Storage & Transportation

CPT Code(s): Level of Service:

88342 Global

Tech Only **Turnaround Time:** 24-48 Hours

Glycophorin-A

Methodology: Immunohistochemistry (IHC)

Glycophorin A (sialoglycoprotein alpha) is one of two transmembrane proteins exposed **Test Description:**

> on the outer surface of normal human erythrocytes. This monoclonal antibody reacts with an epitope located on the extracellular domain of glycophorin A and does not cross-react with glycophorin D (glycophorin delta). In normal human erythrocytes. glycophorin A is expressed during all stages of differentiation, from the normoblast to the mature erythrocyte. Once maximally expressed, the quantity of glycophorin A in each red blood cell remains constant. Glycophorin A has also been located in the blast cells of cases of erythroleukemia. Cases of acute lymphoblastic and myeloblastic leukemia

are not reactive.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 **Specimen Requirements:**

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only

Glypican-3

Methodology: Immunohistochemistry (IHC)

Test Description: A useful marker to differentiate between benign (negative) and malignant (positive) liver

diseases (HCCs).

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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88342 Global Tech Only

Turnaround Time: 24-48 Hours

Granzyme-B

Methodology: Immunohistochemistry (IHC)

Test Description: Granzyme B, a 29 kDa monomer protein, labels activated human cytotoxic

T-lymphocytes (CTL) and natural killer (NK) cells and is a useful tool for the identification

of anaplastic large cell lymphoma (ALCL), large granular lymphocytic leukemias,

hepatosplenic T-cell lymphomas, intestinal T-cell lymphomas, NK-like T-cell lymphomas, NK-cell lymphomas, nasal T/NK-cell lymphomas, subcutaneous T-cell lymphomas and pulmonary angiocentric lymphomas of T or NK phenotype. Labels activated human

cytotoxic T-lymphocytes (CTL) and natural killer (NK) cells.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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88342 Global Tech Only

Turnaround Time: 24-48 Hours

Gross Cystic Fluid Protein 15(GCDF15)

Methodology: Immunohistochemistry (IHC)

Test Description: This antibody is specific to a 15 kDa monomer protein called Gross Cystic Disease Fluid

Protein-15 (GCDFP-15). GCDFP15 is expressed in apocrine epithelia, lacrimal, ceruminous and Molls glands as well as in numerous serous cells of the submand

ceruminous and Molls glands as well as in numerous serous cells of the submandibular, tracheal, bronchial, sublingual and minor salivary glands. It can be of use in the identification of breast carcinoma, salivary duct carcinoma and apocrine epithelia.

Specimen Requirements:

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only Turnaround Time: 24-48 Hours

Helicobacter Pylori

Methodology: Immunohistochemistry (IHC)

Test Description: This antibody reacts with H. pylori on the surface and in the cytoplasm of epithelial

> cells of stomach biopsies. Studies have shown that H. pylori plays an important role in the etiology of chronic active gastritis and the development of peptic ulcer disease.

Immunohistochemistry is a good choice for rapid detection of these bacteria. **Specimen Requirements:** One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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> 88342 Global Tech Only

Turnaround Time: 24-48 Hours

HEPPAR-1 (hepatocyte)

CPT Code(s):

Level of Service:

Methodology: Immunohistochemistry (IHC)

Test Description: Anti-Hepatocyte Specific Antigen (HepPar1) recognizes both benign and malignant liver

derived tumors such as hepatoblastoma, hepatocellular carcinoma and hepatic adenoma. It recognizes both adult and fetal liver tissue. The typical pattern is a granular

cytoplasmic staining. This antibody is useful in differentiating hepatocellular

carcinomas from adenocarcinomas, either primary or metastatic. HepPar1 also can be used in differential diagnostic separation of hepatoblastoma versus other small round

cell tumors. HepPar1 is also expressed in a subset of gastric carcinoma.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

88342 CPT Code(s): Level of Service: Global Tech Only

Turnaround Time: 24-48 Hours

HER2 (4B5))

Methodology: Immunohistochemistry (IHC)

The HER2 oncogene is over-expressed in some breast carcinomas. The expected **Test Description:**

> over-expression rate varies based on the grade and type of breast cancer. Tumors showing 3+ over-expression of HER2 may benefit from trastuzumab therapy. Borderline results (2+) show a significantly reduced response rate to trastuzumab therapy. Assessment of the HER2 gene status may provide additional therapeutic information in some cases. Known artifacts such as edge artifact, tissue retraction and tissue crush may give the false impression of over-expression. Care should be taken to avoid assessing these areas, especially in needle core biopsies that generally harbor all of

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 Specimen Requirements:

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. CPT Code(s): 88360 Level of Service:

Global

Tech Only

24-48 Hours **Turnaround Time:**

Herpes Simplex, Type 1 (HSV 1)

Methodology: Immunohistochemistry (IHC)

Test Description: Antibody reacts with HSV type 1 specific antigens and with antigens common for HSV

types 1 and 2. The antibody reacts with all the major glycoproteins present in the viral

envelope and at least one core protein as determined by crossed

immunoelectrophoresis. This antibody does not cross-react with cytomegalovirus and Epstein-Barr virus. It is well suited for detection of HSV in human cellular material obtained from superficial lesions or biopsies and for the early identification of HSV in

infected tissue cultures.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only
Turnaround Time: 24-48 Hours

Herpes Simplex, Type 2 (HSV 2)

Methodology: Immunohistochemistry (IHC)

Test Description: This antibody reacts with HSV type 2 specific antigens and with antigens common for

HSV types 1 and 2. The antibody reacts with all the major glycoproteins present in

the viral envelope and at least one core protein as determined by crossed

immunoelectrophoresis. It does not cross react with cytomegalovirus and Epstein-Barr virus. The antibody is well-suited for detection of HSV in human cellular material obtained from superficial lesions or biopsies and for the early identification of HSV in infected tissue cultures. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

Specimen Requirements:One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut

microns for H&E staining (required) and three (3) positively charged unstained slides cat 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

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88342 Global

Tech Only
Turnaround Time: 24-48 Hours

HMB-45

Methodology: Immunohistochemistry (IHC)

Test Description:Clone HMB45 recognizes a melanoma-specific antigen by reacting with melanoma

cells, nevus cells and neonatal melanocytes. HMB45 expresses on the majority of malignant melanoma cases as well as on tumors of melanocytic differentiation.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. 88342

Global Tech Only

Human Chorionic Gonadotropin (hCG)

Methodology: Immunohistochemistry (IHC)

Test Description: hCG is secreted in large quantities by the placenta and normally is found in maternal

> circulation during early fetal development. The presence of hCG in maternal blood and urine provides a convenient basis for early recognition of pregnancy. hCG has been detected in several cases of germ cell tumors of the ovary and testis. Furthermore, gestational trophoblastic tumors (hydatidiform mole and choriocarcinoma) derived from

the placenta are invariably associated with abnormally high levels of hCG.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. 88342 Global

CPT Code(s): Level of Service:

Tech Only 24-48 Hours

Turnaround Time:

Human Herpes Virus, Type 8 (HHV-8)

Methodology: Immunohistochemistry (IHC)

Test Description: Human herpesvirus type 8 (HHV-8) is the likely etiological agent of Kaposi's sarcoma (KS). HHV-8 DNA sequences have been found in Kaposi's sarcoma lesions, primary

effusion lymphoma, and multicentric Castleman's disease via polymerase chain reaction and in situ hybridization. Latent nuclear antigen (LNA-1, LNA, LANA-1), also known as ORF73, is a 222- or 234 kD protein that is consistently expressed in HHV-8 infected cells.

Anti-HHV-8 labels the latent nuclear antigen protein via immunohistochemistry.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342

Global Tech Only

Turnaround Time: 24-48 Hours

IGG4

CPT Code(s):

CPT Code(s):

Level of Service:

Level of Service:

Methodology: Immunohistochemistry (IHC)

Test Description: Autoimmune pancreatitis typically produces an enlarged pancreas with narrowing of

> the pancreatic duct, and can mimic carcinoma. It was shown that the pancreatic tissue from patients with autoimmune pancreatitis often shows moderate or marked infiltration by IgG4-positive plasma. IgG4 staining in patients with chronic alcoholic pancreatitis and pancreatic ductal adenocarcinoma was rarely observed. IgG4-positive plasma cells are a useful marker for the tissue diagnosis of autoimmune pancreatitis. Elevated IgG4+ to IgG+ plasma cell ratio (IgG4/IgG ratio) is helpful in distinguishing IgG4-related from

non IgG4-related inflammatory conditions.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 Specimen Requirements:

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

> 88342 Global

Tech Only

24-48 Hours **Turnaround Time:**

Immunoglobulin A (IgA)

Methodology: Immunohistochemistry (IHC)

Test Description: IgA antibody reacts with immunoglobulin Ig alpha chains. It is useful in identifying

leukemias, plasmacytomas and B-cell lineage derived lymphomas.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 **Specimen Requirements:**

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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88342 Global Tech Only

Turnaround Time: 24-48 Hours

Immunoglobulin D (IgD)

Specimen Requirements:

Storage & Transportation

CPT Code(s):

Level of Service:

Methodology: Immunohistochemistry (IHC)

Test Description: IgD antibody reacts with immunoglobulin Ig delta chains. This antibody is useful when

identifying leukemias, plasmacytomas and B-cell lineage derived lymphomas (in particular Marginal Zone Lymphoma). Cytoplasmic staining is easily identified on paraffin tissue. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): 88342 Level of Service: Global Tech Only

Turnaround Time: 24-48 Hours

Immunoglobulin G (IgG)

Methodology: Immunohistochemistry (IHC)

Test Description: IgG antibody reacts with immunoglobulin Ig gamma chains. This antibody is useful when

identifying leukemias, plasmacytomas and B-cell lineage derived lymphomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation

CPT Code(s): 88342 Level of Service: Global Tech Only **Turnaround Time:** 24-48 Hours

Immunoglobulin M (IgM)

Methodology: Immunohistochemistry (IHC)

Test Description: IgM antibody reacts with immunoglobulin Ig mu chains. This antibody is useful when

identifying leukemias, plasmacytomas and B-cell lineage derived lymphomas.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 **Specimen Requirements:**

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global Tech Only

Turnaround Time: 24-48 Hours

Inhibin Alpha

CPT Code(s):

Level of Service:

Methodology: Immunohistochemistry (IHC)

Test Description: Anti-Inhibin alpha is an antibody against a peptide hormone which has a demonstrated

> utility in differentiation between adrenocortical tumors and renal cell carcinoma. This antibody stains about 100% of adrenal tumors but no cases of renal cell carcinomas. Sex Cord Stromal tumors of the ovary as well as trophoblastic tumors also demonstrate

cytoplasmic positivity with this antibody

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 **Specimen Requirements:**

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. 88342

Global Tech Only

Turnaround Time: 24-48 Hours

INSULIN

CPT Code(s): Level of Service:

Methodology: Immunohistochemistry (IHC)

Test Description: Insulin is composed of a and b chains connected through the C-peptide. The main

storage site for insulin is the pancreatic islets. Antibodies to insulin are important as a

marker of islet cell tumor of pancreas (insulinoma).

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 **Specimen Requirements:**

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

> 88342 Global

Tech Only **Turnaround Time:** 24-48 Hours

Kappa

Methodology: Immunohistochemistry (IHC)

Test Description:Antibody to the kappa light chain of immunoglobulin is reportedly useful in the

identification of leukemias, plasmacytomas and certain non-Hodgkin lymphomas. Demonstration of monotypism in lymphoid infiltrates is a surrogate for clonality, and

therefore malignancy.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88342
Level of Service: Global
Tech Only

Turnaround Time: 24-48 Hours

Storage & Transportation

Specimen Requirements:

Ki67

Methodology: Immunohistochemistry (IHC)

Test Description: Ki-67 is a nuclear protein that is expressed in proliferating cells. Ki-67 is preferentially

expressed during late G1-, S-, M-, and G2-phases of the cell cycle, while cells in the G0 (quiescent) phase are negative for this protein. Increased proliferative activity is

associated with more aggressive tumor and decreased disease-free survival period.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88342, 88361 Level of Service: Global

Tech Only

Turnaround Time: 24-48 Hours

KI67/AE1-AE3

CPT Code(s):

Methodology: Immunohistochemistry (IHC)

Test Description: Ki-67 is a nuclear protein that is expressed in proliferating cells. Ki-67 is preferentially

expressed during late G1-, S-, M-, and G2-phases of the cell cycle, while cells in the G0 (quiescent) phase are negative for this protein. Increased proliferative activity is associated with more aggressive tumor and decreased disease-free survival period. AE1-AE3 Useful in distinguishing and classifying epithelial carcinoma from non-epithelial

malignancies, metastatic malignant tumors.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & TransportationUse cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342, 88344

Level of Service: Global

Tech Only

KI67/MART-1

Methodology: Immunohistochemistry (IHC)

Test Description: Ki-67 is a nuclear protein that is expressed in proliferating cells. Ki-67 is preferentially

expressed during late G1-, S-, M-, and G2-phases of the cell cycle, while cells in the G0 (quiescent) phase are negative for this protein. Increased proliferative activity is associated with more aggressive tumor and decreased disease-free survival period. MART-1 (Melanoma Antigen Recognized by T cells 1) recognizes a protein of 18 kDa, a subcellular fraction found in melanosomes. The antibody labels melanomas and tumors showing melanocytic differentiation. It does not mark neoplasms of epithelial origin.

lymphomas or mesenchymal tumors.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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88342, 88344

Global Tech Only

Turnaround Time: 24-48 Hours

Lambda

Storage & Transportation

CPT Code(s):

Level of Service:

Level of Service:

Methodology: Immunohistochemistry (IHC)

Test Description: Antibody to the lambda light chain of immunoglobulin is reportedly useful in the

identification of leukemias, plasmacytomas and certain non-Hodgkin lymphomas. Demonstration of monotypism in lymphoid infiltrates is a surrogate for clonality, and

therefore malignancy.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & TransportationUse cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s):

88342

Global Tech Only

Turnaround Time: 24-48 Hours

LCA

Methodology: Immunohistochemistry (IHC)

Test Description: CD45, Leucocyte Common Antigen (LCA), is expressed on most nucleated cells of

haematopoietic origin and has various isoforms.CD45 is routinely used to aid the differential diagnosis of undifferentiated neoplasms, whenever malignant lymphoma is suspected by the morphologic clinical data. Certain types of lymphoid neoplasms may lack CD45 expression (Hodgkins disease, some T-cell lymphomas, some leukemias). One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

Specimen Requirements:One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only
Turnaround Time: 24-48 Hours

Mammaglobin

Methodology: Immunohistochemistry (IHC)

Test Description: Mammaglobin is a breast-associated glycoprotein. Mammaglobin mRNA expression

> is breast specific and has shown to be a very sensitive marker of occult breast cancer cells in sentinel lymph nodes and peripheral blood. In normal breast tissue, this antibody labels breast ductal and lobular epithelial cells. In tumor cells, they are reactive with all types of breast adenocarcinoma regardless of tumor differentiation and type. Adenocarcinomas from other organs rarely express mammaglobin. Overall sensitivity of mammaglobin for breast cancers was reported to be about 80%. Mammaglobin can

metastatic sites.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

play a contributing role in the identification of primary sites of carcinomas presenting at

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only **Turnaround Time:** 24-48 Hours

Mart-1

Methodology: Immunohistochemistry (IHC)

Test Description: MART-1 (Melanoma Antigen Recognized by T cells 1) recognizes a protein of 18 kDa, a

subcellular fraction found in melanosomes. The antibody labels melanomas and tumors showing melanocytic differentiation. It does not mark neoplasms of epithelial origin,

lymphomas or mesenchymal tumors.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

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88342 Global

Tech Only **Turnaround Time:** 24-48 Hours

Melan-A

Methodology: Immunohistochemistry (IHC)

Test Description: Melan-A (MART-1, Melanoma Antigen Recognized by T-cells 1), is a differentiation

> melanoma cell lines. Melan A recognizes a subcellular fraction found in melanosomes. Melan-A is a useful addition to melanoma panels since it is specific for melanocytic lesions. Both HMB-45 and Melan-A are coexpressed in the majority of melanomas, as well as uniquely expressed in certain cases. Studies have shown that Melan-A is more sensitive than HMB-45 when labeling metastatic melanomas. Melan-A antibody labels the tumor cells of a subset of adrenocortical carcinomas and sex cord tumors of

antigen that is expressed in 100% of melanocytes, most melanomas and 50-60% of

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only

Turnaround Time: 24-48 Hours

The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the pay or being billed. *Tests are sent to CBLPath's preferred laboratory

Mesothelial Cell (HBME-1)

Methodology: Immunohistochemistry (IHC)

Test Description: HBME-1 is an antimesothelial monoclonal antibody that recognizes an unknown antigen

> on microvilli of mesothelioma cells. It stains normal mesothelial cells as well as epithelial mesotheliomas in a thick membrane pattern. This antibody also reacts with some (20-

30%) carcinomas showing cytoplasmic immunostaining.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 **Specimen Requirements:**

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

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Turnaround Time: 24-48 Hours

Microphthalmia transcription factor (MITF)

Methodology: Immunohistochemistry (IHC)

Test Description: MITF (microphthalmia transcription factor) is a transcription factor that regulates the

development and survival of melanocytes. MITF is restricted to the melanocyte cell lineage. Anti-MITF recognizes a nuclear protein that is expressed in the majority of primary and metastatic epithelioid malignant melanomas as well as in normal

melanocytes, benign nevi and dysplastic nevi.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

Specimen Requirements:

Level of Service:

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. CPT Code(s): 88342 Level of Service: Global Tech Only

Turnaround Time: 24-48 Hours

MLH₁

Methodology: Immunohistochemistry (IHC)

Test Description: Mismatch repair genes perform an essential cellular function by repairing DNA

> mismatches that may occur during cellular replication. A number of these genes have been identified in human genome, including hMLH1, hMSH2, hMSH3, hMSH6, hPMS1, and hPMS2. MLH1 and MSH2 proteins are normally expressed in the nucleus of cells. The absence of nuclear expression of one or both of these proteins has been found to correlate with the presence of a mismatch repair gene defect in the respective gene. Recent studies have been found that 50-70% of patients with hereditary non-polyposis colorectal cancer syndrome (HNPCC) have a deficient DNA mismatch repair. Patients with HNPCC have an 80-90% lifetime risk of colorectal carcinoma, and typically have an

earlier onset (mean age of onset 42: vs. 65 years for conventional colon cancer). One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

microns for H&E staining (required) and three (3) positively charged unstained slides cut

the specimen identifier and specimen labeling on accompanying reg.

Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. CPT Code(s): 88342

Global Tech Only

MOC31

Specimen Requirements:

Storage & Transportation

Specimen Requirements:

Storage & Transportation

CPT Code(s):

CPT Code(s):

Level of Service:

Level of Service:

CPT Code(s):

Level of Service:

Methodology: Immunohistochemistry (IHC)

Test Description:Anti-MOC-31 reacts with a transmembrane glycoprotein present on most glandular

epithelium and tumors originating from such epithelium. This antibody has been used to distinguish adenocarcinoma from mesothelioma and hepatocellular carcinoma. This antibody is also useful in distinguishing serous carcinomas of the ovary from mesothelioma. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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88342 Global Tech Only

Turnaround Time: 24-48 Hours

MSH₂

Methodology:Immunohistochemistry (IHC)Test Description:Mismatch repair genes perform an essential cellular function by repairing DNA

mismatches that may occur during cellular replication. A number of these genes have been identified in human genome, including hMLH1, hMSH2, hMSH3, hMSH6, hPMS1, and hPMS2. MLH1 and MSH2 proteins are normally expressed in the nucleus of cells. The absence of nuclear expression of one or both of these proteins has been found to correlate with the presence of a mismatch repair gene defect in the respective gene. Recent studies have been found that 50-70% of patients with hereditary non-polyposis colorectal cancer syndrome (HNPCC) have a deficient DNA mismatch repair. Patients with HNPCC have an 80-90% lifetime risk of colorectal carcinoma, and typically have an

earlier onset (mean age of onset: 42 vs. 65 years for conventional colon cancer).

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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88342 Global Tech Only

Turnaround Time: 24-48 Hours

MSH₆

Methodology: Immunohistochemistry (IHC)

Test Description: Mismatch repair (MMR) genes results in failure to repair errors in repetitive sequences

that occur during DNA replication. The defects in DNA repair pathways have been related to tumor carcinogenesis. Studies have shown the mutations of MLH-1, MSH2 and MSH6 genes contribute to the development of sporadic colorectal carcinoma. MSH6 is a heterodimer of MSH2 and binds to DNA containing G/T mismatches. Germ-line mutations of MLH1 and MSH2 account for 90% of all known MMR mutations in HNPCC and mutation of MSH6 account for another 5-10%, whereas

mutations of other genes are rare.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

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88342 Global Tech Only

MUC 1

Methodology: Immunohistochemistry (IHC)

Test Description: MUC1 is a high molecular weight glycoprotein that is found on the apical surface of

many glandular epithelia including the gastrointestinal, respiratory, urinary, reproductive tracts and some hematopoietic cell lineages. MUC1 has been implicated in progression of numerous types of cancer including breast, colon, lung, gastric and pancreatic cancers. MUC1 expression in tumors is greatly increased and accompanied by altered aberrant expression patterns that become more diffuse when compared to the normal

apically restricted pattern.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only
Turnaround Time: 24-48 Hours

MUC 2

Methodology: Immunohistochemistry (IHC)

Test Description: MUC2 expression is detected in such human tissues as normal colon, breast, prostate,

salivary gland as well as in gastrointestinal, colonic, breast and prostate neoplasia. This antibody labels MUC2 in normal colon and colonic carcinomas where it produces

intense perinuclear staining in goblet cells.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only
Turnaround Time: 24-48 Hours

MUC 5ac

Methodology: Immunohistochemistry (IHC)

Test Description: Mucins are high molecular weight glycoproteins with 80% carbohydrates and 20%

core protein. Gastric Mucin 5AC antigen is found in columnar mucus cells of surface gastric epithelium and in goblet cells of the fetal and precancerous colon but not in normal colon. Resurgence of gastric mucin during colonic carcinogenesis is suggestive of either re-expression of the peptide core of gastric mucin in the adult colon or due to changes in the glycosylation pattern of mucin, which expose the hidden Mucin 5AC antigen.

Specimen Requirements:One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global Tech Only

MUC 6

Methodology: Immunohistochemistry (IHC)

Test Description:A marker of the gastric epithelial cell phenotype

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying reg.

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global Tech Only

Turnaround Time: 24-48 Hours

MUM₁

Methodology: Immunohistochemistry (IHC)

Test Description: MUM1 is specific for the MUM1/IRF4 protein that is overexpressed in late plasma-cell-

directed stages of B-cell differentiation. The morphologic spectrum of MUM1 expression ranges from the stage of a centrocyte to that of a plasmablast. MUM1 is useful in identification of the transition from BCL6 positivity to CD138 expression, and in combination with these two markers, MUM1 is a powerful tool for understanding the histogenesis of B-cell lymphomas. MUM1 protein is an excellent marker for Hodgkin and Reed-Sternberg cells of classical Hodgkin lymphoma in combination with CD30. Furthermore, MUM1 seems to be a marker of prognostic value since it has been found that the expression of MUM1 is associated with poor prognosis of patients with diffuse

large B-cell lymphoma (DLBCL).

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying reg.

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global Tech Only

Turnaround Time: 24-48 Hours

Myeloperoxidase

Level of Service:

Methodology: Immunohistochemistry (IHC)

Test Description: Myeloperoxidase is an important enzyme used by granulocytes during phagocytic lysis

of foreign particles engulfed. In normal tissues and in a variety of myeloproliferative disorders, myeloid cells of both neutrophilic and eosinophilic types, at all stages of maturation, exhibit strong cytoplasmic reactivity for MPO. Erythroid precursors, megakaryocytes, lymphoid cells, mast cells and plasma cells are nonreactive. MPO is not observed in the neoplastic cells of a wide variety of epithelial tumors and

sarcomas. MPO is useful in differentiating between myeloid and lymphoid leukemias.

Specimen Requirements:

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88342 (or 88341 if not the first single antibody per specimen)

Global Tech Only

MYOD-1

Methodology: Immunohistochemistry (IHC)

Test Description: Nuclear expression of myogenic differentiation 1 (MyoD1) is restricted to skeletal muscle

tissue and has been demonstrated to be a sensitive marker of myogenic differentiation. The antibody strongly labels the nuclei of myoblasts in developing skeletal muscle tissue, whereas the majority of adult skeletal muscle is negative. MyoD1 immunostaining has been demonstrated in the majority of rhabdomyosarcomas of various histological

subtypes.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

 CPT Code(s):
 88342

 Level of Service:
 Global

 Tech Only
 7

 Turnaround Time:
 24-48 Hours

Myogenin

Methodology: Immunohistochemistry (IHC)

Test Description: Restricted to cells of skeletal muscle origin.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

the specimen identifier and specimen labeling on accompanying reg.

Storage & Transportation

CPT Code(s): 88342 Level of Service: Global Tech C

Tech Only
Turnaround Time: 24-48 Hours

Myoglobin

Level of Service:

Methodology: Immunohistochemistry (IHC)

Test Description: Immunostaining with anti-myoglobin provides a specific, sensitive and practical

procedure for the identification of tumors of muscle origin. Since myoglobin is found exclusively in skeletal and cardiac muscle and is not present in any other cells of the human body, it may be used to distinguish rhabdomyosarcoma from other soft tissue tumors. Anti-myoglobin staining is also useful when demonstrating rhabdomyoblastic differentiation in other tumors, e.g. neurogenic sarcomas, and malignant mixed

mesodermal tumors of the uterus and ovary.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying req.

Storage & TransportationUse cold pack for transport. Cold pack shouldn't come in direct contact with specimen. **CPT Code(s):**88342

Global Tech Only

Myosin Smooth Muscle (SMM)

Methodology: Immunohistochemistry (IHC)

Test Description: Smooth Muscle Myosin, Heavy Chain (SMMS-1) is an antibody to smooth muscle

myosin, heavy chain that reacts with human visceral and vascular smooth muscle cells. The antibody also reacts with human myoepithelial cells. It is very helpful in distinguishing between benign sclerosing breast lesions and infiltrating carcinomas in difficult cases since it strongly stains the myoepithelial layer in the benign lesions while it is negative in

the infiltrating carcinomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

the specimen identifier and specimen labeling on accompanying reg.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only

Turnaround Time: 24-48 Hours

NAPSIN A

Methodology: Immunohistochemistry (IHC)

Test Description: Napsin A has a specific function in normal alveolar epithelium and is proposed to

play a role in the proteolytic processing of surfactant precursors. Napsin A is reported to be predominantly expressed in lamellar bodies of type II pneumocytes, secondary lysosomes of alveolar macrophages, respiratory epithelium of terminal and respiratory bronchioles, plasma cells, and within a subset of lymphocytes in normal lung as well as in epithelial cells of renal tubules in normal kidney. It is weakly expressed in normal spleen. Past studies have also reported that Napsin A is expressed in most primary lung adenocarcinomas. Napsin A expression may also be seen in renal carcinoma and

ovarian clear cell adenocarcinoma.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only

Turnaround Time: 24-48 Hours

Neurofilament

Methodology: Immunohistochemistry (IHC)

Test Description: Anti-neurofilament stains an antigen localized in a number of neural, neuroendocrine,

and endocrine tumors. Neuromas, ganglioneuromas, gangliogliomas,

ganglioneuroblastomas, and neuroblastomas stain positively for anti-neurofilament. Neurofilaments are also present in paragangliomas as well as adrenal and extra-adrenal pheochromocytomas. Carcinoids, neuroendocrine carcinomas of the skin, and

oat cell carcinomas of the lung also express neurofilament.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying reg.

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global Tech Only

Neuron-specific enulase (NSE)

Methodology: Immunohistochemistry (IHC)

Test Description: In normal tissue, most neurons and their axonal and dendritic processes stain strongly

positive for NSE, with the exception of Purkinje cells. Schwann cells, cells of the adrenal medulla and paraganglia also contain NSE. Endocrine cells of the skin (Merkel cells). respiratory and GI tract epithelium, pituitary parathyroid, pancreatic islets and C

cells of thyroid all stain positively for NSE. NSE has been demonstrated in

ganglioneuromas, neuroblastomas, Schwannomas and malignant melanomas. It is also present in pheochromocytomas and paragangliomas. Carcinoids, medullary thyroid carcinomas, pituitary adenomas and endocrine tumors of the pancreas and GI tract all show positive immunoreactivity for NSE. NSE is found in neuroendocrine carcinoma

of the skin (Merkel cell tumor) and small cell carcinoma of the lung.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 CPT Code(s): Level of Service: Global Tech Only

P120

Turnaround Time:

Methodology: Immunohistochemistry (IHC)

Useful in the diagnostic distinction between lobular (cytoplasmic staining pattern) and **Test Description:**

ductal (membranous) breast neoplasia.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88342 Level of Service: Global Tech Only **Turnaround Time:**

24-48 Hours

24-48 Hours

P16

Methodology: Immunohistochemistry (IHC)

Test Description: P 16 is a marker for dysplasia in squamous epithelium especially in those lesions

associated with high risk HPV. It helps in distinguishing an atypical epithelium from

reactive to precancerous by decorating the latter.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation

88342 CPT Code(s): Level of Service: Global Tech Only **Turnaround Time:** 24-48 Hours

P40

Methodology:

Test Description: The mouse monoclonal antibody p40 [BC28] recognizes an epitope unique to the p40

Immunohistochemistry (IHC)

protein and may have applications in cases where p63 has traditionally been used. p63 [4A4] recognizes both the p63 and p40 proteins. As a result, p63 suffers from specificity limitations due to reactivity in a subset of lung adenocarcinomas (ADC). In contrast, p40 is selectively expressed in lung Squamous cell carcinoma (SqCC), offering an opportunity for improved specificity. p40 antibody (M) [BC28] recognizes an epitope unique to p40, which may result in diminished reactivity in lung ADC and increased specificity. Studies have supported routine use of p40 as an alternative for p63. In contrast to the rabbit polyclonal p40, p40 [BC28] does not stain macrophages.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only

Turnaround Time: 24-48 Hours

P53

Methodology: Immunohistochemistry (IHC)

Test Description: The product of the p53 gene is a nuclear phosphoprotein that regulates cell

> proliferation. Excess accumulation of the mutant p53 gene product results in inactivation of its tumor suppressor function and cellular transformation. Overexpression of mutant p53 gene has also been associated with high proliferative rates and poor prognosis in breast, colon, lung, and brain cancer, as well as in some leukemias and lymphomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut

> at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying reg.

Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342, 88361

Global Tech Only

Turnaround Time: 24-48 Hours

P63

CPT Code(s):

CPT Code(s):

Level of Service:

Level of Service:

Methodology: Immunohistochemistry (IHC)

Test Description: p63 is a homologue of the p53 gene and is necessary for normal breast and prostate

development. Unlike other markers of myoepithelial cells and basal cells, p63 immunoreactivity is localized to the nucleus of the cells, which can offer distinct advantages over cytoplasmic labeling in certain types of cases. P63, as a marker of myoepithelial and basal cells, is extremely useful in diagnostic surgical pathology,

particularly when examining difficult breast biopsies and prostate biopsies. **Specimen Requirements:**

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying reg.

Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

> 88342 Global Tech Only

PAN MELANOMA 2 (MART-1, Tyrosinase)

Methodology: Immunohistochemistry (IHC)

Test Description: Pan Melanoma 2 antibody is a cocktail of MART-1 and Tyrosinase antibodies. MART-1 is

a useful addition to melanoma panels as it is apparently specific for melanocytic lesions. Studies show that MART-1 is more sensitive than HMB45 when labeling metastatic melanomas. These MART-1 clones do not stain steroid tumors unlike Melan A .Tyrosinase has also been shown to be a more sensitive marker when compared to HMB45 and MART-1 and to label a higher percentage of desmoplastic melanomas than HMB45. The combination of MART-1 and Tyrosinase may aid in identifying metastatic

melanoma in sentinel lymph nodes.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying reg.

Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): Level of Service: 88342, 88344 Global

Tech Only Turnaround Time: 24-48 Hours

Pan Melanoma Cocktail (HMB45, MART-1, Tyrosinase)

Methodology: Immunohistochemistry (IHC)

Test Description: The combination of HMB45, MART-1 and Tyrosinase make this antibody combination

a first-order pan melanoma screener. HMB45 has been shown to label the majority of melanomas. MART-1/Melan A is specific to melanocytic lesions. Studies have shown that MART-1 is more sensitive than HMB45 when labeling metastatic melanomas. Tyrosinase has also been shown to be a more sensitive marker when compared to HMB45 and MART-1 and to label a higher percentage of desmoplastic melanomas than HMB45. HMB45 + MART-1 + Tyrosinase Antibody may prove to be a valuable marker for melanoma metastasis in sentinel lymph nodes. Staining of melanomas with this

antibody showed tyrosinase in melanotic as well as amelanotic variants.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88344 Global

Tech Only
Turnaround Time: 24-48 Hours

Parathyroid Hormone (PTH)

Methodology:

Immunohistochemistry (IHC)

Test Description:

The parathyroid glands are small, oval, endocrine glands closely associated with the thyroid gland. The parathyroid glands regulate serum calcium and phosphate levels via parathyroid hormone (parathormone). Parathyroid hormone raises serum calcium levels directly, by increasing the rate of osteoclastic reabsorption and promoting breakdown of the bone matrix, and indirectly, by increasing the renal tubular reabsorption of calcium ions and inhibiting the reabsorption of phosphate ions from the glomerular filtrate, and finally, by promoting the absorption of calcium from the small intestine. Parathyroid hormone is the most important regulator of blood calcium levels and is essential to life, whereas calcitonin appears only to provide a complementary mechanism for fine adjustment. Chief cells are the most abundant cells in the parathyroid gland and are responsible for the secretion of parathyroid hormone.

Antibodies to parathyroid hormone together with antibodies to thyroglobulin are useful in studies to differentiate parathyroid-derived lesions from thyroid-derived lesions.

Specimen Requirements:

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifier and specimen labeling on accompanying reg.

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation CPT Code(s):

 CPT Code(s):
 88342

 Level of Service:
 Global

 Tech Only
 24-48 Hours

PAX 8

CPT Code(s):

Level of Service:

Methodology: Immunohistochemistry (IHC)

Test Description: The PAX8 gene is a member of the paired box (PAX) family of transcription factors.

This family plays critical roles during fetal development and cancer growth. PAX8 is involved in kidney cell differentiation, and thyroid development. PAX8 has been shown to be expressed in three of the most common types of renal cell carcinoma including clear cell, chromophobe and papillary carcinoma. PAX8 stains nuclei exclusively and performs well in formalin-fixed paraffin-embedded (FFPE) tissues. PAX8 has been shown to be

positive in thyroid and ovarian carcinomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global Tech Only

PAX-5

Methodology: Immunohistochemistry (IHC)

Test Description: PAX-5 is a B-cell specific activator protein (BSAP). In early stages of B-cell development,

> PAX-5 influences the expression of several B-cell specific genes, such as CD19 and CD20. PAX-5 is expressed primarily in pro-, pre-, and mature B-cells, but not in plasma cells. There is an excellent correlation between CD20 and PAX-5 expression; however, anti-PAX-5 exceeds the specificity and sensitivity of L26 (CD20) because of its earlier expression in B-cell differentiation and its ability to detect all committed B-cells, including classic Hodgkin lymphoma. It is very specific to B-cell lineage and does not

stain T-cells.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying reg.

Storage & Transportation

CPT Code(s): Level of Service:

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. 88342 Global Tech Only

Turnaround Time: 24-48 Hours

PCAT (P-504s, 34B12, P-63)

Methodology: Immunohistochemistry (IHC)

Test Description: In IHC, P504S has been shown to be a valuable marker of prostatic adenocarcinoma.

Additionally, prostate glands involved in PIN have been found to express P504S,

whereas P504S was nearly undetectable in benign glands.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying reg.

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88344 Global

Tech Only **Turnaround Time:** 24-48 Hours

PD-L1-KEYTRUDA(22C3)

Methodology: Immunohistochemistry (IHC)

Test Description: PD-L1 IHC 22C3 pharm Dx is the only companion diagnostic indicated as an aid in

identifying patients with NSCLC for treatment with KEYTRUDA® (pembrolizumab)

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88360 Global Tech Only

PD-L1 28-8 (Opdivo®)

Methodology: Immunohistochemistry (IHC)

Test Description: PD-L1 IHC 28-8 pharmDx is a qualitative immunohistochemical assay using Monoclonal

Rabbit Anti-PD-L1, clone 28-8 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-squamous non-small cell lung cancer

(NSCLC) and melanoma

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 **Specimen Requirements:**

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. 88360 Global Tech Only

Turnaround Time: 24-48 Hours

PD-L1 SP142 (Tecentriq™)⁺

Methodology: Immunohistochemistry (IHC)

The VENTANA PD-L1 (SP142) Assay is a qualitative immunohistochemical assay using **Test Description:**

rabbit monoclonal anti-PD-L1 clone SP142 intended for use in the assessment of the PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) urothelial carcinoma and non-small cell lung cancer (NSCLC) tissue on a VENTANA BenchMark ULTRA

instrument. Determination of PD-L1 status is indication-specific, and evaluation is based on either the proportion of tumor area occupied by PD-L1 expressing tumor-infiltrating immune cells (% IC) of any intensity or the percentage of PD-L1 expressing tumor cells (% TC) of any intensity. Primary or metastatic urothelial carcinoma (bladder cancer) or

NSCLC (lung cancer) tissues may be submitted.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying reg.

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88360 Global

Tech Only **Turnaround Time:** 24-48 Hours

PLAP

Methodology: Immunohistochemistry (IHC)

Test Description: Normally human Placental Alkaline Phosphatase (PLAP) is produced by

> syncytiotrophoblasts after the twelfth week of pregnancy. PLAP is expressed by both malignant somatic and germ cell tumors. PLAP can be useful in distinguishing seminoma and embryonal carcinomas from undifferentiated malignant tumors.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. 88342

Global Tech Only

PMS2

Methodology: Immunohistochemistry (IHC)

Test Description: Mismatch repair (MMR) genes result in failure to repair errors in repetitive sequences

that occur during DNA replication. This failure leads to microsatellite instability (MSI) of the tumor, which is the hallmark of HNPCC. Increased risk for malignancy in HNPCC is caused by a mutation in one of the following DNA mismatch repair (MMR) genes; MLH1, MSH2, MSH3, MSH6, PMS1, and PMS2. Germ-line mutations of MLH1 and MSH2 account for 90% of all known MMR mutations in HNPCC and mutation of MSH6 account for another 5-10%, whereas mutations of other genes are rare. PMS2 protein forms a heterodimer with the MLH1 protein. Due to this, the absence of the MLH1

protein due to germ-line mutation also leads to loss of PMS2 protein.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only
Turnaround Time: 24-48 Hours

Progesterone Receptor (PR)

Methodology: Immunohistochemistry (IHC)

Test Description: Anti-PR (1E2) Primary Antibody is a rabbit monoclonal antibody (IgG) that is intended

for laboratory use for the qualitative detection of progesterone receptor (PR) antigen in

sections of formalin fixed, paraffin embedded tissue.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation

CPT Code(s): Level of Service:

Turnaround Time:

88360, 88361 Global

Tech Only 24-48 Hours

Prostate Specific Antigen (PSA)

Methodology: Immunohistochemistry (IHC)

Test Description: Prostate specific antigen (PSA) is a glycoprotein with a molecular weight of 33-34 kD.

It is restricted to the cytoplasm of acinar and ductal epithelia of normal, benign or malignant prostate tissue. Furthermore, PSA from prostatic cancers has been shown to be immunologically and biochemically similar to that of normal prostate tissue. The antibody reacts against primary and metastatic prostatic neoplasms, but not against tumors of nonprostatic origin. This antibody is useful for determining if an isolated

metastasis is of prostatic origin.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation

CPT Code(s): Level of Service: 88342

Global Tech Only

PSAP

Methodology: Immunohistochemistry (IHC)

Test Description: Prostate specific acid phosphatase/human prostatic acid phosphatse (PSAP/HPAP)

is a 100kDa glycoprotein present in high concentration in the prostate gland and its secretions. PSAP is specific to the benign or malignant epithelial cells of the prostate gland. Prostatic stroma, urethra and the basal cells stain negatively. Also, epithelial cells injured due to inflammation, infarction, etc. and areas of squamous metaplasia of the prostatic acini show loss of PSAP activity. Nearly all metastases of prostatic carcinoma,

irrespective of site, demonstrate PSAP immunoreactivity.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global

Tech Only
Turnaround Time: 24-48 Hours

PTEN

Methodology: Immunohistochemistry (IHC)

Test Description:Controls cell proliferation, apoptosis and cell migration. A tumor suppressor gene

implicated in a wide variety of cancers, especially in glioblastomas endometrial

carcinomas, prostate and breast cancer.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only
Turnaround Time: 24-48 Hours

Renal Cell Carcinoma (RCC)

Methodology: Immunohistochemistry (IHC)

Test Description: In normal kidney, RCC (gp200) is localized along the brush border of the proximal tubule.

Of other normal tissues, the RCC is also localized along the luminal surfaces of breast lobules and ducts, the luminal surface of the epididymal tubular epithelium, within the cytoplasm of parathyroid parenchymal cells and focally within the colloid of thyroid follicles. Other normal tissues do not express similar or cross-reacting antigens. RCC is

expressed by 93% of primary and 84% of metastatic renal cell carcinomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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the specimen identifier and specimen labeling on accompanying req.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only

S100

Methodology: Immunohistochemistry (IHC)

Test Description: S100 belongs to the family of calcium binding proteins. Antibody to S100 stains

> Schwannomas, ependymomas, astrogliomas, almost all benign melanocytic lesions, melanomas and their metastases. S100 protein is also expressed in the Langerhans cells in skin and interdigitating reticulum cells in the paracortex of lymph nodes.

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 **Specimen Requirements:**

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation CPT Code(s): 88342 Level of Service: Global Tech Only **Turnaround Time:** 24-48 Hours

Smooth Muscle Actin (SMA)

Methodology: Immunohistochemistry (IHC)

Test Description: Actin is one of two major cytoskeletal proteins involved in cell motility. Smooth muscle

actin binds to smooth muscle cells and myoepithelial cells. It stains the muscularis and muscularis mucosae of the gastrointestinal tract, the uterine myometrium, medial layer of blood vessels, myoepithelial cells of salivary glands and other organs. The antibody does not stain skeletal and cardiac muscle, endothelium, connective tissue, epithelium or nerve. The antibody can be used to identify smooth muscle tumors. It

stains leiomyomas and leiomyosarcomas but does not stain carcinomas

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

the specimen identifier and specimen labeling on accompanying reg.

Storage & Transportation

88342 CPT Code(s): Level of Service: Global Tech Only

Turnaround Time: 24-48 Hours

SOMATOSTATIN

Methodology: Immunohistochemistry (IHC)

Test Description: Somatostatin is a useful marker of D-cells of pancreatic islet cells. D-cells are used

> to identify hyperplasia of the pancreatic islets. Most of these tumors are malignant, giving rise to somatostatinomas. Somatostatin suppresses gastric acid secretion, gallbladder contractions and pancreatic insulin secretion; therefore, the most common clinical

manifestations of patients with these tumors are mild diabetes.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. CPT Code(s): 88342 Level of Service: Global

Tech Only

SOX 10

Methodology: Immunohistochemistry (IHC)

Test Description: SOX10 is a sensitive marker of melanoma, including conventional, spindled, and

desmoplastic subtypes. It is also a useful marker in detecting both the in situ and invasive components of desmoplastic melanoma. SOX10 is diffusely expressed in schwannoma, neurofibroma, and granular cell tumor. SOX10 was not identified in any other mesenchymal and epithelial tumors except for myoepitheliomas and diffuse

astrocytomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

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Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88342
Level of Service: Global
Tech Only

Turnaround Time: 24-48 Hours

SOX11

Methodology: Immunohistochemistry (IHC)

Test Description: Nuclear protein expression of SOX-11 is highly associated with both cyclin D1-positive

and negative mantle cell lymphoma (MCL). SOX-11 IHC is useful for identifying true cyclin D1-negative MCL and further defining pathologic features of CD5+ DLBCL. Routine use of anti-SOX-11 in cases of suspected CD5+ DLBCL might help identify additional cases of cyclin D1-negative blastoid MCL. SOX-11 can also be detected in some BL, LBL, and T-PLL, although the different morphological and phenotypic features of these malignancies allow easy recognition of the cases of cyclin D1-negative MCL.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service:

Global Tech Only 24-48 Hours

88342

Turnaround Time: 24-48 Hours

SOX₂

Methodology: Immunohistochemistry (IHC)

Test Description: SOX2 stains all embryonal carcinomas and is highly specific for squamous cell carcinoma.

Specimen Requirements:One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation CPT Code(s):

Level of Service:

88342 Global Tech Only

Spirochetes

Methodology: Immunohistochemistry (IHC)

Test Description: Useful in identification of Spirochete (Treponema Pallidum).

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req.

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. 88342 Global

Tech Only

Turnaround Time: 24-48 Hours

Synaptophysin

Methodology: Immunohistochemistry (IHC)

Test Description: Antibody to synaptophysin reacts with neuroendocrine neoplasms of neural as well as

epithelial types. In combination with anti-chromogranin A and anti-NSE, antibody to synaptophysin is very useful in the identification of normal neuroendocrine cells and

neuroendocrine neoplasms.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

Turnaround Time: 24-48 Hours

T Cell Intracytoplasmic antigeng (TIA-1)

Methodology: Immunohistochemistry (IHC)

Test Description: TIA-1 (T-cell intracytoplasmic antigen) monoclonal antibody reacts with a 15 kDa

cytoplasmic granule-associated protein, expressed in lymphocytes processing cytolytic potential. About 60-70% of anaplastic large cell lymphoma react with TIA-1. TIA-1 also reacts with most large granular lymphocytic leukemias, hepatosplenic T-cell lymphomas, intestinal T-cell lymphomas, NK-like T-cell lymphomas, NK-cell lymphomas, nasal T/NK-cell lymphomas, subcutaneous T-cell lymphomas and pulmonary

angiocentric lymphomas of T or NK phenotype. All B-cell lymphomas, Hodgkin and

lymphoblastic leukemias are negative for TIA-1.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

TB (Mycobacterium Tuberculosis)

Methodology: Immunohistochemistry (IHC)

Test Description: Mycobacterium tuberculosis is the most common cause of tuberculosis.

Immunohistochemical demonstration of mycobacterial antigens is not only useful in establishing mycobacterial etiology, but can also be used as an alternative method to

the conventional Ziehl-Neelsen method.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): 88342
Level of Service: Global
Tech Only

Turnaround Time: 24-48 Hours

Terminal Deoxynucleotidyl Transferase (TdT)

Methodology: Immunohistochemistry (IHC)

Test Description: TdT is considered to be a highly specific marker for the diagnosis and classification of

acute lymphoblastic lymphoma/leukemias. The determination of TdT expression is most valuable when it is important to differentiate histologically between lymphoblastic

lymphoma and Burkitt lymphoma.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): 88342
Level of Service: Global
Tech Only

Turnaround Time: 24-48 Hours

Thyroid Transcription Factor 1 (TTF1)

Methodology: Immunohistochemistry (IHC)

Test Description: TTF-1 is found only in thyroid and thyroid tumors regardless of histologic type, as well

as in lung carcinomas, including adenocarcinomas (75%), non-small cell carcinomas (63%) neuroendocrine and small cell carcinomas (>90%) and squamous cell carcinomas (10%). The utility of TTF-1 becomes apparent in the differential diagnosis of primary versus metastatic carcinomas, especially in the lung. CK7 and CK20, along with TTF-1 and CEA, are the antibodies that best discriminate primary lung carcinomas from

metastatic carcinoma to the lung.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): 88342 Level of Service: Global

Tech Only Turnaround Time: 24-48 Hours

THROMBOMODULIN

Methodology: Immunohistochemistry (IHC)

Test Description: Thrombomodulin is a plasma membrane-related glycoprotein that has anticoagulant

activity. TM antigen is found in several cell types, including megakaryocytes, mesangial cells, synovial cells, mesothelial cells, endothelial cells and some squamous epithelial cells and their associated tumors. TM antibody labels most of mesotheliomas with thick membranous staining pattern and about half of pulmonary adenocarcinomas, showing

cytoplasmic immunostaining

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & TransportationUse coCPT Code(s):88342Level of Service:Global

Global Tech Only

24-48 Hours

Turnaround Time: 24-48 Hours

Thyroglobulin (TG)

Methodology: Immunohistochemistry (IHC)

Test Description: Thyroglobulin is the precursor of thyroid hormones. It is synthesized by thyrocytes and

transported to the apical surface where it is secreted into the lumen of thyroid follicles and stored as the major component of colloid. The antibody is useful for the detection of

thyroglobulin in thyroid tissue and is a useful tool for the identification of welldifferentiated thyroid carcinomas.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): 88342
Level of Service: Global
Tech Only

Turnaround Time:

TOXOPLASMA – Gondii

Methodology: Immunohistochemistry (IHC)

Test Description:Toxoplasma is a crescent shaped sporozoan that lives as an intracellular parasite in

various tissues of vertebrates and completes its life cycle in a single host. It is transmitted via raw/undercooked meat, contaminated soil, or by direct contact. Infection

due to Toxoplasma gondii usually occurs in pregnant women where a variable degree of immunosuppression may exist or in patients receiving immunosuppressive drug therapy following organ transplant. Toxoplasma infects tissue of the GI tract where an active infection is accompanied by fever and enlargement of the spleen. Symptoms of toxoplasmosis are generally mild but severe infection of lymph nodes may occur. Congenital toxoplasmosis, in which the maternal infection is transmitted during

pregnancy, can produce blindness or mental retardation in the newborn. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block All blocks and slides must have two (2) identifiers clearly written and match

exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

Specimen Requirements:

CPT Code(s): 88342 Level of Service: Global Tech C

Tech Only

Tryptase

Methodology: Immunohistochemistry (IHC)

Test Description: This antibody labels a mast cell tryptase. It will also show reactivity to basophils, but to a

lesser degree.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & TransportationUse cold page 20CPT Code(s):88342Level of Service:Global Tech Only

24-48 Hours

Tyrosinase

Turnaround Time:

Methodology: Immunohistochemistry (IHC)

Test Description: Tyrosinase is a copper-containing metalloglycoprotein that catalyzes several steps in

the melanin pigment biosynthetic pathway. Mutations of the tyrosinase gene occur in various forms of albinism. Tyrosinase is one of the targets for cytotoxic T-cell recognition in melanoma patients. Staining of melanomas with this antibody showed

tyrosinase in melanotic as well as amelanotic variants.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service:

88342 Global Tech Only

Turnaround Time: 24-48 Hours

UBIQUITIN

Methodology: Immunohistochemistry (IHC)

Test Description:Ubiquitin, isolated from cow erythrocytes and coupled to chicken gammaglobulin, has

been used for immunization. The antibody cross-reacts strongly with human ubiquitin, and is well-suited for the demonstration of ubiquitinated filamentous inclusions in human chronic, neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global Tech Only

URO3 (CK-20, CD-44, P-53)

Methodology: Immunohistochemistry (IHC)

Test Description: CD44 + p53 + CK20 can be used to differentiate urothelial reactive atypia from CIS

(carcinoma in situ) in bladders. In normal urothelium, superficial umbrella cell layer shows reactivity for CK20 only, whereas CD44 staining is limited to the basal and parabasal urothelial cells and p53 nuclear staining is absent to focal. For urothelium with reactive atypia, particularly in cases with marked atypia, CD44 shows increased reactivity in all layers of the urothelium and is often absent in neoplastic cells. CK20 and p53 staining remain identical to those seen in normal urothelium. In cases of CIS, diffuse, strong cytoplasmic reactivity for CK20 and diffuse nuclear reactivity for p53 is observed

throughout the urothelium.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88344 Global Tech Only 24-48 Hours

Turnaround Time:

Specimen Requirements:

Storage & Transportation

Storage & Transportation

CPT Code(s):

Level of Service:

Varicella Zoster Virus (VZV)

Methodology: Immunohistochemistry (IHC)

Test Description: The Varicella zoster virus (VZV) is one of the eight herpes viruses known to affect

humans (and other vertebrates). Primary VZV infection results in chickenpox (varicella), which may rarely result in complications including VZV encephalitis or pneumonia. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 (or 88341 if not the first single antibody per specimen)

Global Tech Only

Turnaround Time: 24-48 Hours

VILLIN

Methodology: Immunohistochemistry (IHC)

Test Description: This antibody recognizes villin, a cytoskeletal filament protein of 58 kD found in human

renal epithelial cells. Villin antibody is useful for the study of gastrointestinal cells in normal and tumor tissues. This antibody is often used in the study of cellular origin in

human renal cell carcinoma.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88342 Level of Service: Global

Global Tech Only

Vimentin

Methodology: Immunohistochemistry (IHC)

Test Description:Vimentin is the major intermediate filament in a variety of mesenchymal cells including

endothelial cells, all fibroblastic cells, macrophages, Sertoli cells, melanocytes, lymphocytes and ovarian granulosa cells. Vimentin is found in all types of sarcomas and lymphomas. Positive staining for vimentin is seen in most cells of fibrosarcomas, liposarcomas, malignant fibrous histocytomas, angiosarcomas, chondrosarcomas and

lymphomas. All melanomas and Schwannomas are strongly vimentin-positive. One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88342 Global Tech Only

Turnaround Time: 24-48 Hours

Wilms Tumor (WT-1)

CPT Code(s):

Level of Service:

Specimen Requirements:

Storage & Transportation

Methodology: Immunohistochemistry (IHC)

Test Description: Wilms tumor susceptibility gene 1 protein (WT1) has diagnostic utility in the distinction of

mesothelioma from adenocarcinoma in tissue sections of pleural tumors. WT1 diffusely stains most ovarian serous carcinomas and all (100%) renal cell carcinomas and

Wilms tumors.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88342 Global

Tech Only
Turnaround Time: 24-48 Hours

ISH

Epstein-Barr Virus (EBV)

Methodology: In Situ Hybridization (ISH)

Test Description: This probe set labels all latent EBV-infected cells, including EBV-positive lymphoblastoid

cell lines and EBV infected B-cell immunoblasts in infectious mononucleosis. It also reacts with EBV-associated undifferentiated nasopharyngeal carcinomas and with Reed-Sternberg cells in almost all EBV-associated Hodgkin lymphoma cases. Global interpretation is available on head and neck specimens only; tech-only testing is available for all samples. Clinical Significance The Epstein-Barr virus (EBV) probe demonstrates latent EBV infection by hybridizing to abundantly expressed EBER

transcripts which are concentrated in the nuclei of latently infected cells. The Epstein–Barr virus (EBV) belongs to the human herpesvirus family (HHV-4), and infects approximately 90% of the world's adult population asymptomatically [1, 2].

EBV is the causative agent of infectious mononucleosis, and is associated with hairy leukoplakia (HL) and certain lymphoid and epithelial cancers such as Burkitt's lymphoma,

immunoblastic lymphoma, Hodgkin's lymphoma, and nasopharynx

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut

at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with the specimen identifies and specimen labeling on accompanying req. Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation

CPT Code(s): Level of Service: 88365 Global Tech Only 48 Hours

Turnaround Time: 48 Hours

Human Papilloma Virus High Risk (HPV-H)

Methodology:In Situ Hybridization (ISH)Test Description:16/18 High Risk

In situ hybridization on FFPE tissues for qualitative detection of E6/E7 mRNA in up to 28

HPV subtypes with the complete panel: low risk (10 subtypes: 6, 11, 40, 43, 44, 54, 69, 70, 71, 74) plus high risk (18 subtypes: 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82). Testing with the complete panel is recommended, but orders for partial panels are accepted. Orderable components are (1) 16/18 High Risk; (2) High Risk Cocktail with all of the previously-named high risk subtypes; and (3) Low Risk Cocktail with all previously-named low risk subtypes. Reports will identify which component or cocktail is positive, but will not identify specific subtypes as positive.

Testing is performed only on a global or consult basis at this time

Clinical Significance Infection with human papillomavirus (HPV) is a major risk factor for the development of precancerous and cancerous cervical lesions. HPV DNA is found in more than 90% of cervical cancers, but it can also be detected in low-grade lesions. Human papillomavirus-16 (HPV16) is the causative agent in a biologically distinct subset of oropharyngeal squamous cell carcinoma (OPSCC) with highly favorable prognosis. In clinical trials, HPV16 status is an essential inclusion or stratification parameter,

highlighting the importance of accurate

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and six (6) positively charged unstained slides cut at

3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Storage & TransportationUse cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88365, Global Tech Only

Turnaround Time: 48 Hours

CPT Code(s):

Level of Service:

Human Papilloma Virus Low Risk (HPV-L)

Methodology:In Situ Hybridization (ISH)Test Description:6/11 High Risk

In situ hybridization on FFPE tissues for qualitative detection of E6/E7 mRNA in up to 28 HPV subtypes with the complete panel: low risk (10 subtypes: 6, 11, 40, 43, 44, 54, 69, 70, 71, 74) plus high risk (18 subtypes: 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82). Testing with the complete panel is recommended, but orders for partial panels are accepted. Orderable components are (1) 16/18 High Risk; (2) High Risk Cocktail with all of the previously-named high risk subtypes; and (3) Low Risk Cocktail with all previously-named low risk subtypes. Reports will identify which component or cocktail is positive, but will not identify specific subtypes as positive.

Testing is performed only on a global or consult basis at this time

Clinical Significance Infection with human papillomavirus (HPV) is a major risk factor for the development of precancerous and cancerous cervical lesions. HPV DNA is found in more than 90% of cervical cancers, but it can also be detected in low-grade lesions. Human papillomavirus-16 (HPV16) is the causative agent in a biologically distinct subset of oropharyngeal squamous cell carcinoma (OPSCC) with highly favorable prognosis. In clinical trials, HPV16 status is an essential inclusion or stratification parameter,

highlighting the importance of accurate

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and six (6) positively charged unstained slides cut at

3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Storage & TransportationUse cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88365,
Level of Service: Global
Tech Only
Turnaround Time: 48 Hours

Test Description:

Human Papilloma Virus Wide Spectrum (HPV-WS)

Methodology: In Situ Hybridization (ISH)

HPV RNA ISH 16/18, HPV RNA ISH High Risk Cocktail, HPV RNA ISH Low Risk Cocktail In situ hybridization on FFPE tissues for qualitative detection of E6/E7 mRNA in up to 28 HPV subtypes with the complete panel: low risk (10 subtypes: 6, 11, 40, 43, 44, 54, 69, 70, 71, 74) plus high risk (18 subtypes: 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82). Testing with the complete panel is recommended, but orders for partial panels are accepted. Orderable components are (1) 16/18 High Risk; (2) High Risk Cocktail with all of the previously-named high risk subtypes; and (3) Low Risk Cocktail with all previously-named low risk subtypes. Reports will identify which component or cocktail is positive, but will not identify specific subtypes as positive.

Testing is performed only on a global or consult basis at this time

Clinical Significance Infection with human papillomavirus (HPV) is a major risk factor for the development of precancerous and cancerous cervical lesions. HPV DNA is found in more than 90% of cervical cancers, but it can also be detected in low-grade lesions. Human papillomavirus-16 (HPV16) is the causative agent in a biologically distinct subset of oropharyngeal squamous cell carcinoma (OPSCC) with highly favorable prognosis. In clinical trials, HPV16 status is an essential inclusion or stratification parameter,

highlighting the importance of accurate

Specimen Requirements:One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microps for H&E staining (required) and six (6) positively charged unstained slides cut at

microns for H&E staining (required) and six (6) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88365 Global Tech Only

Turnaround Time: 48 Hours

Storage & Transportation

CPT Code(s): Level of Service:

Kappa

Methodology: Test Description: In Situ Hybridization (ISH)

Each test contains a set of oligonucleotide probes. The intended target is the kappa light chain immunoglobulin messenger RNA (mRNA) in the cytoplasm of immunoblastic cells, plasma cells and plasmacytoid cells. Assessing the light chain immunoglobulin restriction is important in malignant lymphoma diagnosis. The relationship between monoclonal B-cell proliferation and light chain mRNA restriction aids in the distinction between neoplastic and reactive lymphoid proliferations and the evaluation of multiple myeloma, plasmacytoma, lymphomas with plasmacytoid features, immunoblastic lymphomas and reactive plasma cell proliferations.

Clinical Significance Kappa and lambda probes are used to detect antibody producing B-cells or plasma cells in formalin-fixed, paraffin-embedded tissue. Restriction of light chain production to either kappa or lambda (monoclonality) can help distinguish between

reactive and neoplastic B-cell and plasma cell proliferations.

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and six (6) positively charged unstained slides cut at

3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying reg.

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88365 Global Tech Only 48 Hours

Storage & Transportation CPT Code(s): Level of Service:

Turnaround Time:

Lambda

Methodology: Test Description: In Situ Hybridization (ISH)

Each test contains a set of oligonucleotide probes. The intended target is the lambda light chain immunoglobulin messenger RNA (mRNA) in the cytoplasm of immunoblastic cells, plasma cells and plasmacytoid cells. Assessing the light chain immunoglobulin restriction is important in malignant lymphoma diagnosis. The relationship between monoclonal B-cell proliferation and light chain mRNA restriction aids in the distinction between neoplastic and reactive lymphoid proliferations and the evaluation of multiple myeloma, plasmacytoma, lymphomas with plasmacytoid features, immunoblastic lymphomas and reactive plasma cell proliferations.

Clinical Significance Kappa and lambda probes are used to detect antibody producing B-cells or plasma cells in formalin-fixed, paraffin-embedded tissue. Restriction of light chain production to either kappa or lambda (monoclonality) can help distinguish between reactive and neoplastic B-cell and plasma cell proliferations.

Specimen Requirements:

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and six (6) positively charged unstained slides cut at

3-4 microns for each test/antibody ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

the specimen identifies and specimen labeling on accompanying req.

Storage & Transportation

CPT Code(s): Level of Service: 88365 Global Tech Only

Turnaround Time:

1ech Only 48 Hours

MOLECULAR/PCR

(All PCR testing is global)

ABL Kinase Mutation Analysis⁺

Methodology: PCR, Sequencing

Test Description: RT-PCR and sequencing of the BCR-ABL1 fusion transcript for qualitative detection

of mutations associated with resistance to Gleevec (imatinib) and other tyrosine kinase

inhibitors. Analysis includes detection of the common T315I mutation.

Clinical Significance Testing is recommended in CML with poor initial response to Gleevec (imatinib), relapse, or progression to accelerated/blast phase. Presence and identity of mutation may direct management to alternative drugs or stem cell transplant.

Specimen Requirements: 1 Lavender/EDTA tube peripheral blood or bone marrow (3-5 ml)

Storage & TransportationRoom temp. or 2-8°C within 48 Hours after collection.

CPT Code(s): 81401
Level of Service: Global
Turnaround Time: 7-10 days

B-Cell Gene Rearrangement/Clonality (IGH)

Methodology: PCR and fragment analysis

Test Description: Gene rearrangement analysis of the immunoglobulin heavy chain (IGH) gene is

used to evaluate clonality in B-cell proliferations. Monoclonal IGH gene rearrangements are detectable in the majority of B-cell lymphoproliferative disorders, while polyclonal results are seen in the majority of reactive (non-neoplastic) B-cell proliferations. This analysis can be useful to establish an initial diagnosis of a B-cell lymphoproliferative disorder and to evaluate for residual disease in cases with a prior monoclonal result. This analysis is most effective when combined with gene rearrangement analysis of the

immunoglobulin kappa (IGK) gene, which significantly increases the sensitivity.

Specimen Requirements: Peripheral blood: ≥ 1 ml in EDTA tube.

Bone marrow: \geq 0.5 ml in EDTA tube.

FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10

unstained slides cut at 5 or more microns.

Fresh tissue: ≥ 0.2 cm3 in RPMI.⁺ If other gene rearrangement assays have been

requested, a single specimen can be used for all tests.

Storage & Transportation Peripheral blood, bone marrow, FFPE tissue: Store and transport at room temperature.

Transport with cool pack in extreme heat conditions.

Fresh tissue: Refrigerate until shipping. Use cold pack for transport. Make sure cold

pack is not in direct contact with specimen.

CPT Code(s): 81261 Level of Service: Global

Turnaround Time: 2 - 7 days. Test processed Monday & Thursday

B-Cell Gene Rearrangement/Clonality (IGK)

Methodology: PCR and fragment analysis

Test Description: Gene rearrangement analysis of the immunoglobulin kappa (IGK) gene is used

to evaluate clonality in B-cell proliferations. Monoclonal IGK gene rearrangements are detectable in the majority of B-cell lymphoproliferative disorders, while polyclonal results are seen in the majority of reactive (non-neoplastic) B-cell proliferations. This analysis can be useful to establish an initial diagnosis of a B-cell lymphoproliferative disorder and to evaluate for residual disease in cases with a prior monoclonal result. This analysis

is most effective when combined with gene rearrangement analysis of the

immunoglobulin heavy chain (IGH) gene, which significantly increases the sensitivity.

Peripheral blood: ≥ 1 ml in EDTA tube. Bone marrow: ≥ 0.5 ml in EDTA tube.

FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10

unstained slides cut at 5 or more microns.

Fresh tissue: ≥ 0.2 cm3 in RPMI.⁺ If other gene rearrangement assays have been

requested, a single specimen can be used for all tests.

Storage & Transportation Peripheral blood, bone marrow, FFPE tissue: Store and transport at room temperature.

Transport with cool pack in extreme heat conditions.

Fresh tissue: Refrigerate until shipping. Use cold pack for transport. Make sure cold

pack is not in direct contact with specimen.

CPT Code(s): 81264 **Level of Service:** Global

Specimen Requirements:

Turnaround Time: 2-7 days. Test processed Monday & Thursday

T-Cell Gene Rearrangement/Clonality (TCRG)

Methodology: PCR and fragment analysis

Test Description: Gene rearrangement analysis of the T-cell receptor gamma (TCRG) gene is used

to evaluate clonality in T-cell proliferations. Monoclonal TCRG gene rearrangements are detectable in the majority of T-cell lymphoproliferative disorders, while polyclonal results are seen in the majority of reactive (non-neoplastic) T-cell proliferations. This analysis can be useful to establish an initial diagnosis of a T-cell lymphoproliferative disorder and to evaluate for residual disease in cases with a prior monoclonal result. This analysis is most effective when combined with gene rearrangement analysis of the T-cell receptor

beta (TCRB) gene, which significantly increases the sensitivity.

Specimen Requirements: Peripheral blood: ≥ 1 ml in EDTA tube.

Bone marrow: ≥ 0.5 ml in EDTA tube.

FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10

unstained slides cut at 5 or more microns.

Fresh tissue: ≥ 0.2 cm3 in RPMI.⁺ If other gene rearrangement assays have been

requested, a single specimen can be used for all tests.

Storage & Transportation Peripheral blood, bone marrow, FFPE tissue: Store and transport at room temperature.

Transport with cool pack in extreme heat conditions.

Fresh tissue: Refrigerate until shipping. Use cold pack for transport. Make sure cold

pack is not in direct contact with specimen.

CPT Code(s): 81342 Level of Service: Global

Turnaround Time: 2-7 days. Test processed Monday & Thursday

T-Cell Gene Rearrangement/Clonality (TCRB)

Methodology: PCR and fragment analysis

Test Description:Gene rearrangement analysis of the T-cell receptor beta (TCRB) gene is used to evaluate

clonality in T-cell proliferations. Monoclonal TCRB gene rearrangements are detectable in the majority of T-cell lymphoproliferative disorders, while polyclonal results are seen in the majority of reactive (non-neoplastic) T-cell proliferations. This analysis can be useful to establish an initial diagnosis of a T-cell lymphoproliferative disorder and to evaluate for residual disease in cases with a prior monoclonal result. This analysis is most effective when combined with gene rearrangement analysis of the T-cell receptor

gamma (TCRG) gene, which significantly increases the sensitivity.

Specimen Requirements: Peripheral blood: ≥ 1 ml in EDTA tube.

Bone marrow: ≥ 0.5 ml in EDTA tube.

FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10

unstained slides cut at 5 or more microns.

Fresh tissue: ≥ 0.2 cm3 in RPMI.⁺ If other gene rearrangement assays have been

requested, a single specimen can be used for all tests.

Storage & Transportation Peripheral blood, bone marrow, FFPE tissue: Store and transport at room temperature.

Transport with cool pack in extreme heat conditions.

Fresh tissue: Refrigerate until shipping. Use cold pack for transport. Make sure cold

pack is not in direct contact with specimen.

CPT Code(s): 81340 Level of Service: Global

Turnaround Time: 2-7 days. Test processed Monday & Thursday

BCR/ABL (Quantitative PCR)

Methodology: Quantitative real-time PCR, Mbcr ratio reported with International Scale

Test Description: This analysis is primarily used to diagnose and monitor chronic myeloid leukemia (CML),

BCR-ABL1+ and is capable of detecting both the Mbcr (p210 protein) and mbcr (p190 protein) breakpoints. The analytical sensitivity (limit of detection) of this analysis is as high as 1:100,000, capable of detecting a 5-log reduction in BCR/ABL fusion transcripts. Detection of mbcr BCR/ABL fusion transcripts can also aid in the diagnosis and

monitoring of B lymphoblastic leukemia/lymphoma.

Specimen Requirements: Peripheral blood: ≥ 5 mL in EDTA tube.

Bone marrow: ≥ 2.5 mL in EDTA tube. Store and transport at room temperature.

Storage & Transportation Store and transport at room temperature.

Transport with cool pack in extreme heat conditions.

CPT Code(s): 81206, 81207 Level of Service: Global

Turnaround Time: 2-7 days. Test processed Tuesday & Friday

BluePrint+

Methodology: 80-Gene Molecular Subtyping Assay

Test Description:The BluePrint analysis is designed to determine the gene activity of specific genes in

a tissue sample. BluePrint assesses the molecular subtype of breast cancer and informs if tumors are Basal-Type, Luminal-Type or HER2-Type. Clinical Significance BluePrint is performed for the breast cancer patients, with Stage I or Stage II disease with a tumor size of < 5.0 cm and lymph node negative. The BluePrint FFPE result is indicated for use by physicians as a prognostic marker only, along with other clinicopathological factors.

Specimen Requirements: FFPE - Specimen Block with invasive tumor OR

10 unstained slides with a 5 micron section on each slide

at least 30% of invasive tumor

Storage & Transportation 10 glass slides in a sturdy outer box or container, slidemailer box, zip-lock bag

CPT Code(s): 81599
Level of Service: Global
Turnaround Time: 10 Days

BRAF Melanoma cobas 4800

Methodology: Real-time PCR

Test Description: The cobas® 4800 BRAF V600 Mutation Test is used to detect BRAF V600E mutations

in melanoma and thereby aid in selecting patients for treatment with vemurafenib (ZELBORAF $^{\text{TM}}$). FFPE tissue: 1-10 sections of 10 μ m thickness are needed depending on the size of the

tissue. Sections should contain at least 50% tumor cells. Specimens containing less than 50% tumor cells will be microdissected to enrich tumor cell content before analysis.

Store and transport at room temperature. Transport with cool pack in extreme heat.

Storage & TransportationStore atCPT Code(s):81210Level of Service:Global

Turnaround Time: 7 days. Test processed Tuesday & Friday

BRAF Mutation Analysis

Specimen Requirements:

Storage & Transportation

Specimen Requirements:

Methodology: PCR and pyrosequencing

Test Description: This analysis is used to detect mutations in the BRAF gene including the V600E

mutation. BRAF mutations are seen in various tumor types including melanoma, colorectal carcinoma, papillary thyroid carcinoma, non-small cell lung cancer, hairy cell leukemia, Langerhans cell histiocytosis, and others. The BRAF V600E mutation has been associated with a lack of response to EGFR targeted therapies in colorectal carcinomas.

FFPE tissue: 4-10 sections of 10 µm thickness are needed depending on the size of the tissue. Sections should contain at least 25% tumor cells. Specimens containing less

than 25% tumor cells will be microdissected to enrich tumor cell content before analysis. Peripheral blood: 1 ml in EDTA tube.

Bone marrow: 0.5 ml in EDTA tube.
Store and transport at room temperature.

Transport with cool pack in extreme heat conditions.

CPT Code(s): 81210 **Level of Service:** Global

Turnaround Time: 2-7 days. Test processed Tuesday & Friday

CALR Mutation Analysis

Methodology: PCR and fragment analysis

Test Description: CALR mutations occur in 49-67% of JAK2-negative, MPL-negative essential

thrombocythemia cases and in 88% of JAK2-negative, MPL-negative primary myelofibrosis cases. CALR mutations are not associated with polycythemia vera. CALR testing is thus a useful tool for the diagnosis of essential thrombocythemia and primary myelofibrosis and is part of the WHO diagnostic criteria for these entities.

Specimen Requirements: Peripheral blood: 1 mL in EDTA tube.

Bone marrow: 0.5 mL in EDTA tube.

If the specimen is being tested initially or concurrently for JAK2 V617F mutation, no

additional specimen is required.

Storage & Transportation Store and transport at room temperature.

Transport with cool pack in extreme heat conditions.

CPT Code(s): 81219 Level of Service: Global

Turnaround Time: 7 days, Test processed Wednesday

EGFR Mutation Analysis

Methodology: PCR, pyrosequencing

Test Description: This analysis is used to detect mutations in exons 18, 19, 20 (Codons 768 and 790),

and 21 of the EGFR gene. EGFR mutations are found in a subset of lung

adenocarcinomas and other carcinomas and may predict response to EGFR-targeted therapies. This analysis can also detect mutations associated with resistance to therapy,

such as the T790M mutation.

Specimen Requirements: FFPE tissue: 4-10 sections of 10 µm thickness are needed depending on the size of the

tissue. Sections should contain at least 35% tumor cells. Specimens containing less than 35% tumor cells will be microdissected to enrich tumor cell content before analysis.

Storage & Transportation Store and transport at room temperature.

Transport with cool pack in extreme heat conditions.

CPT Code(s): 81235 **Level of Service:** Global

Turnaround Time: 2-7 days. Test processed Tuesday & Friday

HRAS Mutation Analysis⁺

Methodology: Molecular

Test Description: Bi-directional sequencing of HRAS exons 2 and 3 which includes sites of common

activating mutations in codons 12, 13, 59 and 61 Clinical Significance Samples are accepted for somatic and germline HRAS mutation testing. HRAS is highly homologous with KRAS and NRAS; all are members of the most frequently mutated family of oncogenes. HRAS mutations are found in a wide variety of solid tumors, including cancers of the bladder, thyroid, upper digestive tract, and melanoma. Germline HRAS mutations are associated with Costello syndrome, which confers a lifetime risk of approximately 15% for malignant tumors including rhabdomyosarcoma and

neuroblastoma in childhood and bladder cancer in adolescence and young adulthood

Specimen Requirements: Peripheral blood: 5 mL in EDTA tube.

Bone marrow: 2 mL in EDTA tube.

FFPE solid tumor tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and

10% NBF fixative. Do not use zinc fixative.

Storage & Transportation Use cold pack for transport, making sure cold pack is not in direct contact.

CPT Codes: 81403 Level of Service: Global Turnaround Time: 7 Days

IGHV +

Methodology: PCR and Sanger sequencing

Test Description: Clonal IGHV gene hypermutation status provides important prognostic information for

patients with CLL and small lymphocytic lymphoma (SLL). The presence of IGH SHM is defined as greater than 2% difference from the germline VH gene sequence identity (mutated), whereas less than or equal to 2% difference is considered no SHM (unmutated). The status of SHM has clear influence on the median survival of CLL patients. Hypermutation of the IGH variable region is strongly predictive of a good

prognosis, while lack of mutation predicts a poorer prognosis.

Specimen Requirements: Peripheral blood: ≥ 1 ml in EDTA tube.

Bone marrow: ≥ 0.5 ml in EDTA tube.

FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10

unstained slides cut at 5 or more microns.

Fresh tissue: ≥ 0.2 cm3 in RPMI.+ If other gene rearrangement assays have been

requested, a single specimen can be used for all tests.

Storage & Transportation: FFPE samples: Store and transport at room temperature. Fresh tissue like bone marrow

and blood: Transport with cool pack.

CPT Code(s): Level of Service: Sent out CGI

Turnaround Time: 10-12 days

MLH1 Promoter Methylation assay⁺

Methodology: PCR

Test Description:This analysis is used to detect microsatellite instability (MSI), which indicates defective mismatch repair (MMR). Defective MMR can occur as a result of germline (hereditary)

mutation in one of the MMR genes or sporadic MLH1 promoter methylation. The finding of MSI in a patient suspected to have Lynch syndrome strongly indicates the presence of mismatch repair (MMR) mutations and the need for further genetic testing. Defective MMR occurs in approximately 15% of sporadic colorectal carcinomas. Colorectal carcinomas with defective MMR (MSI-high) have a better prognosis than

those with intact mismatch repair (microsatellite stable or MSI-low).

Specimen Requirements: FFPE tissue: 4-10 sections of 10µm thickness are needed depending on the size of the

tissue. Sections should contain at least 50% tumor cells. Specimens containing less than 50% tumor cells will be microdissected to enrich tumor cell content before analysis. If the submitted tumor tissue does not contain a substantial amount of normal tissue that can be easily microdissected away from the tumor, a normal tissue sample from the

same patient must also be submitted.

Storage & Transportation

CPT Code(s): Level of Service: Turnaround Time: Store and transport at room temperature. Transport with cool pack in extreme heat.

81301, 88381

Global

JAK2 Exon 12 Mutation Assay

Methodology: PCR and fragment analysis

Test Description: This analysis is used to detect mutations in exon 12 of the JAK2 gene. The JAK2

V617F mutation is found in the majority of cases of the myeloproliferative neoplasm, polycythemia vera (PV). However, not all cases harbor this mutation. Most of the JAK2 V617F-negative PV cases are associated with JAK2 Exon 12 mutations. The World Health Organization includes JAK2 Exon 12 mutation as a diagnostic criterion for PV in

addition to JAK2 V617F.

Specimen Requirements: Peripheral blood: 1 ml in EDTA tube.

Bone marrow: 0.5 ml in EDTA tube.

If the specimen is being tested initially for JAK2 V617F mutation, no additional specimen

is required.

Storage & Transportation

Store and transport at room temperature. Transport with cool pack in extreme heat.

CPT Code(s): 81403 Level of Service: Global

Turnaround Time: 2-7 days. Test processed Tuesday & Friday

JAK2 V617F Mutation Assay

Methodology: PCR, pyrosequencing

Test Description: This assay is used to detect the V617F mutation in the JAK2 gene. This mutation is

seen in the majority of cases of polycythemia vera and in a substantial proportion of cases of primary myelofibrosis and essential thrombocythemia, but it is not present in non-neoplastic conditions. Thus, detection of this mutation can be highly useful in establishing the diagnosis of one of these myeloproliferative neoplasms. It is

recommended to combine this analysis with CALR, MPL, JAK2 Exon 12, and/or BCR/

ABL analyses in order to cover the majority of mutations associated with

myeloproliferative neoplasms. The CALR, MPL, and/or JAK2 Exon 12 analyses can be ordered as reflex tests and only run if there is no evidence of JAK2 V617F mutation, as

these mutations are mutually exclusive.

Peripheral blood: 1 ml in EDTA tube.

Specimen Requirements:Peripheral blood: 1 ml in EDTA tube.
Bone marrow: 0.5 ml in EDTA tube.

Storage & Transportation Store and transport at room temperature. Transport with cool pack in extreme heat.

CPT Code(s): 81270 **Level of Service:** Global

Turnaround Time: 2-7 days. Test processed Tuesday & Friday

KRAS Mutation Analysis

Methodology: PCR, pyrosequencing

Test Description:This analysis is used to detect mutations in the KRAS gene, specifically those affecting

codons 12, 13, and 61. Activating mutations of KRAS are seen in many carcinomas, including non-small cell lung, colorectal, pancreatic, thyroid, liver and kidney, as well as a subset of seminomas, melanomas, myelodysplastic syndromes and acute myeloid leukemias. These mutations have been associated with resistance to treatment with

EGFR-targeted therapies.

Specimen Requirements: FFPE tissue: 4-10 sections of 10 µm thickness are needed depending on the size of the

tissue. Sections should contain at least 25% tumor cells. Specimens containing less than 25% tumor cells will be microdissected to enrich tumor cell content before analysis. Store and transport at room temperature. Transport with cool pack in extreme heat.

Storage & Transportation Store and trans **CPT Code(s):** 81275, 81276

CPT Code(s): 81275. Level of Service: Global

Turnaround Time: 2-7 days. Test processed Tuesday & Friday

MammaPrint+

Methodology: Gene expression profile

Test Description: Mammaprint FFPE is a qualitative in vitro diagnostic test, performed in a central

laboratory, using the gene expression profile obtained from FFPE breast cancer tissue samples to assess a patient's risk for distant metastatis within 5 years. Clinical Significance The test is performed for breast cancer patients, with Stage I or Stage II disease, with a tumor size of < 5.0 cm and lymph node negative. The mammaprint FFPE result is indicated for use by physicians as a prognostic marker only, along with other

clinicopathological factors.

Specimen Requirements: FFPE - Specimen Block with invasive tumor OR

10 unstained slides with a 5 micron section on each slide at least 30% of invasive tumor

Storage & Transportation 10 glass slides in a sturdy outer box or container, slidemailer box, zip-lock bag

CPT Code(s): 84999
Level of Service: Global
Turnaround Time: 10 Days

MPL Mutation Analysis

Methodology: PCR, pyrosequencing

Test Description: This analysis is used to detect mutations in codons 505 and 515 of the MPL gene.

MPL mutations are detectable in a minor subset of cases of primary myelofibrosis and essential thrombocythemia that are negative for JAK2 and CALR mutations. MPL mutations are not associated with polycythemia vera. MPL testing is thus a useful tool for the diagnosis of essential thrombocythemia and primary myelofibrosis and is part of

the WHO diagnostic criteria for these entities.

Specimen Requirements: Peripheral blood: 1 ml in EDTA tube.

Bone marrow: 0.5 ml in EDTA tube.

If the specimen is being tested initially or concurrently for JAK2 V617F mutation, no

additional specimen is required.

Storage & Transportation Store and transport at room temperature. Transport with cool pack in extreme heat.

CPT Code(s): 81402 Level of Service: Global

Turnaround Time: 2-7 days. Test processed Tuesday & Friday

MLH+

Methodology: PCR and fragment analysis

Test Description: This analysis is used to detect microsatellite instability (MSI), which indicates defective

mismatch repair (MMR). Defective MMR can occur as a result of germline (hereditary) mutation in one of the MMR genes or sporadic MLH1 promoter methylation. The finding of MSI in a patient suspected to have Lynch syndrome strongly indicates the presence of mismatch repair (MMR) mutations and the need for further genetic testing. Defective MMR occurs in approximately 15% of sporadic colorectal carcinomas. Colorectal carcinomas with defective MMR (MSI-high) have a better prognosis than

those with intact mismatch repair (microsatellite stable or MSI-low).

Specimen Requirements: FFPE tissue: 4-10 sections of 10µm thickness are needed depending on the size of the

tissue. Sections should contain at least 50% tumor cells. Specimens containing less than 50% tumor cells will be microdissected to enrich tumor cell content before analysis. If the submitted tumor tissue does not contain a substantial amount of normal tissue that can be easily microdissected away from the tumor, a normal tissue sample from the

same patient must also be submitted.

Storage & Transportation

Store and transport at room temperature. Transport with cool pack in extreme heat.

CPT Code(s): 81301, 88381

Level of Service: Global

Turnaround Time: 4-10 days, Test processed Wednesday

MSI (Microsatellite Instability)

Methodology: PCR and fragment analysis

Test Description:This analysis is used to detect microsatellite instability (MSI), which indicates defective

mismatch repair (MMR). Defective MMR can occur as a result of germline (hereditary) mutation in one of the MMR genes or sporadic MLH1 promoter methylation. The finding of MSI in a patient suspected to have Lynch syndrome strongly indicates the presence of mismatch repair (MMR) mutations and the need for further genetic testing. Defective MMR occurs in approximately 15% of sporadic colorectal carcinomas. Colorectal carcinomas with defective MMR (MSI-high) have a better prognosis than

those with intact mismatch repair (microsatellite stable or MSI-low).

Specimen Requirements: FFPE tissue: 4-10 sections of 10µm thickness are needed depending on the size of the

tissue. Sections should contain at least 50% tumor cells. Specimens containing less than 50% tumor cells will be microdissected to enrich tumor cell content before analysis. vlf the submitted tumor tissue does not contain a substantial amount of normal tissue that can be easily microdissected away from the tumor, a normal tissue sample from the

same patient must also be submitted.

Storage & Transportation Store and transport at room temperature. Transport with cool pack in extreme heat.

CPT Code(s): 81301, 88381 Level of Service: Global

Turnaround Time: 4-10 days, Test processed Wednesday

NRAS Mutation Detection

Methodology: PCR, pyrosequencing

Test Description: This analysis is used to detect mutations in codons 12, 13, and 61 of the NRAS gene.

NRAS mutations are found in various tumor types including melanoma, colorectal carcinoma, thyroid carcinoma, and acute myeloid leukemia. NRAS mutational status may be predictive of BRAF inhibitor response in metastatic melanoma patients and anti-

EGFR therapy response in metastatic colorectal carcinoma.

Specimen Requirements: FFPE tissue: 4-10 sections of 10 µm thickness are needed depending on the size of the

tissue. Sections should contain at least 25% tumor cells. Specimens containing less than 25% tumor cells will be microdissected to enrich tumor cell content before analysis. Store and transport at room temperature. Transport with cool pack in extreme heat.

Storage & Transportation Store a

CPT Code(s): 81311 Level of Service: Global

Turnaround Time: 2-7 days. Test processed Tuesday & Friday

PML/RARA (AML-M3)+

Methodology: Reverse Transcription Polymerase Chain Reaction

Test Description: Real-time RT-PCR for quantitative detection of the t(15;17) PML-RARA fusion transcript.

Both long and short isoforms of the fusion transcript are detected. Positive results identify the isoform and quantify it as a ratio with the amount of transcript from a normal control gene. Analytical sensitivity is 1 tumor cell in 100,000 normal cells Clinical Significance Provides genetic confirmation of APL. Predict relapse risk and monitor for

minimal residual disease post-consolidation therapy

Specimen Requirements: Lavender EDTA or Bone marrow EDTA 5 mL whole blood (Min: 1 mL). OR 3 mL bone

marrow (Min: 1 mL

Storage & Transportation Specimens must be received within 48 Hours of collection due to lability of RNA,

Refrigerated

CPT Code(s): 81315
Level of Service: Global
Turnaround Time: 2-7 Days

MYD88 Mutation Assay

Methodology:

Real time PCR

Test Description:

This analysis is used to detect the MYD88 L265P mutation. This mutation is present in greater than 90% of lymphoplasmacytic lymphomas (Waldenstrom macroglobulinemia) but absent, or only rarely present, in marginal zone lymphomas. Thus, testing for this mutation can be highly useful in differentiating these entities. Distinguishing lymphoplasmacytic lymphoma from other B-cell lymphomas with plasmacytic

differentiation, particularly marginal zone lymphoma, is often challenging as these entities have similar morphologic and immunophenotypic features. Furthermore, most cases do not show distinctive abnormalities by routine cytogenetics or FISH analysis.

Differentiating these entities is of great clinical importance, as they have unique clinical

features and biology, and patients may be managed differently.

Specimen Requirements:

Storage & Transportation

Peripheral blood: 1 ml in EDTA tube. Bone marrow: 0.5 ml in EDTA tube.

FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10

unstained slides cut at 5 or more microns.

Store and transport at room temperature. Transport with cool pack in extreme heat.

81479 Global

Turnaround Time: 2-7 days, Test processed Monday - Friday

ThyroSeq⁺

Methodology: **Test Description:**

CPT Code(s):

Level of Service:

Next Generation, semiconductor-based sequencing.

Targeted mutation detention by next generation sequencing in Thyroid (FNA) and tissue samples, Thyroseq v.2 next generation sequencing panel offers simultaneous sequencing and detention in >1000 hotspots of 14 thyroid cancer-related genes and for 42 types of gene fusions known to occur in thyroid cancer. Clinical Significance ThyroSeq® Genomic Classifier (GC) is a test for the pre-operative assessment of thyroid nodules with indeterminate cytology, which offers accurate assessment of cancer probability in a given nodule and additionally provides information on cancer prognostication, helping to select the most optimal patient management.

ThyroSeg incorporates all major scientific advances in thyroid cancer genetics and has more than 10-years experience serving physicians and their patients with thyroid nodules and cancer. The first version of ThyroSeq was launched for clinical use at the University of Pittsburgh Medical Center as a seven-gene panel (ThyroSeq v0) in April of 2007. Until recently, the test was offered as ThyroSeg v2. Today, ThyroSeg v3 is

available for clinical use

Specimen Requirements: FNA (Fine Needle Aspiration)- FNA collected into ThyroSegPreserve solution

FNA Cell Block - Submit two H&E slides and 10 unstained slides.

Resected Tumors - FFPE Tissue Specimens-1 H&E and 6 unstained slides containing at

least 3 mm of tumor cut at 4-5 microns

After the sample is collected, the specimen should be kept at -20 C, Dry Ice

Varies by payer

Global

Storage & Transportation CPT Code(s): Level of Service: **Turnaround Time:**

7-10 Days

SPECIAL STAINS

Alcian Blue (AB/PAS)

Methodology: Special stain

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. 88313
Global

Tech Only
Turnaround Time: 24 Hours

Alcian Blue 2.5

Methodology: Special stain

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying reg.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Storage & Transportation

CPT Code(s): Level of Service:

Turnaround Time:

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88313 Global Tech Only

24 Hours

Congo Red

Methodology: Special stain

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 8 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88313 Global

Tech Only
Turnaround Time: 24 Hours

Copper

Methodology: Special stain

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88313 Global Tech Only

Turnaround Time: 24 Hours

Crystal Violet

CPT Code(s):

Level of Service:

Storage & Transportation

Methodology: Special stain

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 8 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88313
Level of Service: Global
Tech Only

Turnaround Time: 24 Hours

Elastic Verhoeff-Van Gieson (EVG)

Methodology: Special stain

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Storage & TransportationUse cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88313
Level of Service: Global
Tech Only
Turnaround Time: 24 Hours

Fite

Methodology: Special stain

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying reg.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88312 Global Tech Only

Turnaround Time: 24 Hours

Storage & Transportation

CPT Code(s):

Level of Service:

Fontana

Methodology: Special stain

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88313 Level of Service: Global Tech Only

24 Hours

Giemsa

Turnaround Time:

Methodology: Special stain

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying reg.

Note: When submitting samples for consultations, please provide (suspected) diagnosis Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

on the requisition (and/or attach pathology reports).

Storage & Transportation

CPT Code(s): 88312 Level of Service: Global Tech Only **Turnaround Time:** 24 Hours

Grocott Methenamine Silver stain (GMS)

Methodology:

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying reg.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88312 Global Tech Only

Turnaround Time: 24 Hours

Storage & Transportation

Storage & Transportation

Turnaround Time:

CPT Code(s):

Level of Service:

Gram +/-

Methodology: Special stain

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88312 Level of Service: Global

Tech Only 24 Hours

Iron (Pearls)

Methodology: Special stain

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying reg.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

on the requisition (and/or attach pathology reports).

Storage & Transportation

CPT Code(s): 88313 Level of Service: Global Tech Only 24 Hours

Turnaround Time:

Masson's Trichrome

Methodology: Special stain

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying reg.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88313 Level of Service: Global Tech Only

Turnaround Time: 24 Hours

Mucicarmine

Methodology: Special stain

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

Storage & Transportation CPT Code(s): 88312 Level of Service: Global Tech Only

Turnaround Time: 24 Hours

Periodic Acid Schiff (PAS)

Special stain Methodology:

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying reg.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Storage & Transportation

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen. CPT Code(s): 88312 Level of Service: Global Tech Only **Turnaround Time:** 24 Hours

Periodic Acid Schiff with digestion (DPAS)

Methodology:

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Storage & Transportation Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

CPT Code(s): 88312 Level of Service: Global

Tech Only

Reticulin

Methodology:

Specimen Requirements:

Storage & Transportation

Special stain

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88313 Global

Tech Only

Turnaround Time:

Level of Service:

CPT Code(s):

24 Hours

Van Kossa

Methodology:

Specimen Requirements:

Special stain

One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88313 Global Tech Only

Turnaround Time: 24 Hours

Warthin Starry

Methodology:

Special stain

Specimen Requirements: One (1) formalin-fixed, paraffin-embedded (FFPE) unbaked, unstained slide cut at 4-5

microns for H&E staining (required) and three (3) positively charged unstained slides cut

at 4-5 microns for each test ordered or

A formalin-fixed, paraffin-embedded (FFPE) tissue block

All blocks and slides must have two (2) identifiers clearly written and match exactly with

the specimen identifies and specimen labeling on accompanying req.

Note: When submitting samples for consultations, please provide (suspected) diagnosis

on the requisition (and/or attach pathology reports).

Storage & Transportation

CPT Code(s): Level of Service: Use cold pack for transport. Cold pack shouldn't come in direct contact with specimen.

88312 Global Tech Only

Turnaround Time:

24 Hours