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 & Transportation	Room 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: ≥ 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

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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.
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):	81264
Level of Service:	Global
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

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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.
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

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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™).
Specimen Requirements:	FFPE tissue: 1-10 sections of 10 µm 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.
Storage & Transportation	Store and transport at room temperature. Transport with cool pack in extreme heat.
CPT Code(s):	81210
Level of Service:	Global
Turnaround Time:	7 days. Test processed Tuesday & Friday

BRAF Mutation Analysis

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.
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. 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 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

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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	Store and transport at room temperature. Transport with cool pack in extreme heat.
CPT Code(s):	81301, 88381
Level of Service:	Global
Turnaround Time:	

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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.
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.
Storage & Transportation	Store and transport at room temperature. Transport with cool pack in extreme heat.
CPT Code(s):	81275, 81276
Level of Service:	Global
Turnaround Time:	2-7 days. Test processed Tuesday & Friday

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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

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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. vIf 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.
Storage & Transportation	Store and transport at room temperature. Transport with cool pack in extreme heat.
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

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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:	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.
Storage & Transportation	Store and transport at room temperature. Transport with cool pack in extreme heat.
CPT Code(s):	81479
Level of Service:	Global
Turnaround Time:	2-7 days, Test processed Monday - Friday

ThyroSeq+

Methodology:	Next Generation, semiconductor-based sequencing.
Test Description:	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. ThyroSeq 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 ThyroSeq v2. Today, ThyroSeq v3 is available for clinical use
Specimen Requirements:	FNA (Fine Needle Aspiration)- FNA collected into ThyroSeqPreserve 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
Storage & Transportation	After the sample is collected, the specimen should be kept at -20 C, Dry Ice
CPT Code(s):	Varies by payer
Level of Service:	Global
Turnaround Time:	

7-10 Days

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