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.
Storage & Transportation	Use 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

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 & Transportation	Use 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

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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 & Transportation	Use 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

Human Papilloma Virus Wide Spectrum (HPV-WS)

Methodology:	In Situ Hybridization (ISH)
Test Description:	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 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 & Transportation	Use 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

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Kappa

Methodology:	In Situ Hybridization (ISH)
Test Description:	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 req.
Storage & Transportation	Use 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

Lambda

Methodology:	In Situ Hybridization (ISH)
Test Description:	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 the specimen identifies 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):	88365
Level of Service:	Global Tech Only
Turnaround Time:	48 Hours

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