Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • September 2022

Cleveland Clinic Laboratories is dedicated to keeping you updated and informed about recent testing changes. This Technical Update is provided on a monthly basis to notify you of any changes to the tests in our catalog.

Recently changed tests are bolded, and they could include revisions to methodology, reference range, days performed, or CPT code. Deleted tests and new tests are listed separately. For your convenience, tests are listed alphabetically and order codes are provided.

To compare the new information with previous test information, refer to the online Test Directory at clevelandcliniclabs.com. Test information is updated in the online Test Directory on the Effective Date stated in the Technical Update. Please update your database as necessary.

For additional detail, contact Client Services at 216.444.5755 or 800.628.6816, or via email at clientservices@ccf.org.

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
3	AFP, Serum (Tumor Marker)						■							
3	Albumin, Fluid											■		
3	Amylase, Body Fluid											■		
9	Beta Globin (HBB) Sequencing												■	■
3	Bilirubin, Fluid											■		
13	BK Virus Quantitation, Urine													■
9	BRAF V600E Mutation Detection Blood			■										
9	BRAF V600E Mutation Detection Bone Marrow			■										
10	BRAF V600E Mutation Detection Other			■										
3	CA 19-9						■							
3	CA 27.29						■							
3	CEA						■							
3	Cholesterol, Body Fluid											■		
3	Chromogranin A						■							
3	Creatinine, Fluid											■		
4	Cryptococcus Ag Detection							■	■			■		
4	F-Actin (Smooth Muscle) Antibody, IgG ELISA						■		■	■				
10	FISH for CRLF2 and CRLF2/IGH Panel Blood		■	■										
10	FISH for CRLF2 and CRLF2/IGH Panel Bone Marrow			■										
11	FISH for CRLF2 Blood			■										

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
11	FISH for CRLF2 Bone Marrow			■										
11	FISH for CRLF2/IGH Blood			■										
11	FISH for CRLF2/IGH Bone Marrow			■										
4	Gastric Parietal Cell IgG Serum		■			■		■	■		■			
4	Gastrin					■								
4	Glucose, Body Fluid											■		
5	Hepatitis B Surface Ab, Immunity					■								
5	Hepatitis B Surface Ab, Qual.					■								
5	Hepatitis B Surface Ab, Quant					■								
6	Histoplasma galactomannan Antigen, Urine		■			■		■		■	■	■		
6	Human Epididymis Protein 4					■								
6	JC Virus DNA, Ultrasensitive (LLOQ 10 copies/mL), Quantitative, Real-Time PCR, CSF						■	■		■		■		
6	Kappa, Free, Serum					■								
7	Kappa/Lambda, Free, Serum					■								
12	KIT D816V Mutation Detection Blood			■										
12	KIT D816V Mutation Detection Bone Marrow			■										
12–13	Kit D816V Mutation Detection Other			■										
7	Kleihauer Betke Stain									■				
7	Lactate Dehydrogenase, Body Fluid											■		
7	Lambda, Free, Serum					■								
7	Lipase, Fluid											■		
13	Meningitis Encephalitis Panel			■										
13	Mitochondrial Antibody Panel				■									
7	Mitochondrial M2 IgG Serum		■			■		■	■					
13	Myeloma Prognostic Risk Signature (MyPRS)				■									
13	Parietal Cell Antibody Panel				■									
7	pH, Body Fluid						■					■		
8	pH Urine by pH Meter						■					■		
8	Routine, Prenatal Group B Strep PCR						■							
13	Smooth Muscle Antibody Panel				■									
8	Thyroglobulin					■								
8	Thyroglobulin Antibody					■								
8	Thyroid Cancer (Thyroglobulin) Monitoring					■								
8	Titanium, Serum or Plasma										■			
8	Triglyceride, Body Fluid											■		
8	Urea Nitrogen, Fluid											■		

Test Changes

Test Name	Order Code	Change	Effective Date
AFP, Serum (Tumor Marker)	AFP	**Special Information: The Alpha-Fetoprotein test was performed using the Siemens Centaur XP chemiluminometric immunoassay method. Results obtained with different assay methods or kits cannot be used interchangeably.** **Clinical Limitation: This test is not to be used for maternal screening.** **Clinical Information: The test is intended for follow up of patients undergoing treatment for hepatocellular carcinoma or testicular or ovarian cancers, among others.**	9/20/22
Albumin, Fluid	FLALB	**Stability:** Ambient: **7 days** Refrigerated: **7 days** Frozen: **Unacceptable**	10/13/22
Amylase, Body Fluid	FAMYL	**Stability:** Ambient: 7 days Refrigerated: **7 days** Frozen: Unacceptable **Days Performed:** Sun–Sat; **24** hours	10/13/22
Bilirubin, Fluid	FLBIL	**Stability:** Ambient: 1 day if care is taken to prevent exposure to light. Refrigerated: 7 days if care is taken to prevent exposure to light. Frozen: **Unacceptable** **Days Performed:** Sun–Sat; **24** hours	10/13/22
CA 19-9	CA199	**Special Information: The CA 19-9 Antigen test was performed using the Beckman Coulter Unicel DXI paramagnetic particle chemiluminescent immunoassay method. Results obtained with different assay methods or kits cannot be used interchangeably.** **Clinical Limitation: Patients taking a Biotin dose of up to 5 mg/day should refrain from taking Biotin for 1 hour prior to sample collection. Patients taking a Biotin dose > 5 mg/day to 10 mg/day should refrain from taking Biotin for 2 hours prior to sample collection. Patients taking a Biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.** **Clinical Information: Cancer antigen 19-9 test is used as an aid in monitoring response to treatment or recurrence in patients with established pancreatic, hepatobiliary, or gastrointestinal malignancies.**	9/20/22
CA 27.29	CA2729	**Special Information: The CA27.29 test was performed using the Siemens Centaur XP chemiluminometric immunoassay method. Results obtained with different assay methods or kits cannot be used interchangeably.** **Clinical Information: CA 27.29 test is used as aid in monitoring disease recurrence or response to treatment in patients with previous diagnosis of breast cancer.**	9/20/22
CEA	CEA	**Special Information: The Carcinoembryonic antigen test was performed using the Beckman Coulter Unicel DXI paramagnetic particle chemiluminescent immunoassay method. Results obtained with different assay methods or kits cannot be used interchangeably.** **Clinical Limitation: This test is not recommended as a screening test.** **Clinical Information: Carcinoembryonic antigen test is used as an aid in monitoring response to treatment or recurrence in patients with established colorectal, breast, lung, prostatic, pancreatic, and ovarian carcinomas.**	9/20/22
Cholesterol, Body Fluid	FCHOL	**Stability:** Ambient: 7 days Refrigerated: 7 days Frozen: **Unacceptable** **Days Performed:** Sun–Sat; **24** hours	10/13/22
Chromogranin A	CHROMA	**Special Information:** Plasma is not acceptable. Grossly hemolyzed samples will be rejected. **The Chromogranin A test was performed using the Cisbio CGA ELISA method. Results obtained with different assay methods or kits cannot be used interchangeably.**	9/20/22
Creatinine, Fluid	FCRE	**Stability:** Ambient: 7 days Refrigerated: 7 days Frozen: **Unacceptable**	10/13/22

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cryptococcus Ag Detection	CAD	**Clinical Information:** The Cryptococcal Antigen test is used to determine the presence of Cryptococcus neoformans antigen in CSF or serum using **lateral flow** methodology. Cryptococcal disease is known to occur more frequently in immunosuppressed patients and may follow exposure to bird droppings. False positives may occur in patients with **T. beigelii infections or high levels of Human anti-mouse antibodies (HAMA).** Positive specimens are titered. **Specimen Requirement:** 10 mL serum from Serum Separator (Gold) tube; **Transport recommendations: Refrigerated: 72 hrs, Frozen: indefinitely** *OR* 2 mL Cerebrospinal fluid (CSF) in sterile container; Transport recommendations: **Refrigerated: 72 hrs**, Frozen: indefinitely. **Stability:** Refrigerated: Serum separated from clot: 1 week; Serum not separated from clot: **72** hours; CSF: **72** hours Frozen: Serum: Indefinitely; CSF: Indefinitely **Methodology: Line Immunoassay (INNO-LIA)**	9/20/22
F-Actin (Smooth Muscle) Antibody, IgG ELISA	SMTHS	**For interface clients only–Test build may need to be modified** **Test Name:** Previously Smooth Muscle Antibody Screen **Clinical Information: F-Actin (Smooth Muscle) IgG test is** used as an aid in diagnosing autoimmune hepatitis. **They can also be detected with less prevalence in primary biliary cholangitis. Weak positive antibodies, where present, can be seen in healthy individuals.** Clinical correlation is required. **Methodology: Semi Quantitative Enzyme Linked Immunosorbent Assay** **Reference Range:** **Actin Smooth Muscle IgG Qualitative (ACTNQL): Negative** **Actin Smooth Muscle IgG Quantitative (ACTIN): < 20 Units**	10/11/22
Gastric Parietal Cell IgG Serum	PARIES	**For interface clients only–Test build may need to be modified** **Test Name:** Previously Parietal Cell Antibody Screen **Clinical Information: Gastric Parietal Cell IgG test** is used as an aid in diagnosing autoimmune gastritis. **Positive results, where present, can be seen in healthy individuals and especially in patients with autoimmune hypothyroidism.** Clinical correlation is required. **Methodology: Semi Quantitative Enzyme Linked Immunosorbent Assay** **Reference Range:** **Gastric Parietal Cell IgG Qualitative (GPARQL): Negative** **Gastric Parietal Cell IgG Quantitative (GPARIT): ≤ 20 Units** **Days Performed: Tue,** Fri **Reported:** 1–**5** days	10/11/22
Gastrin	GAST	**Special Information:** Patient preparation: Preferably fasting for 12 hours or more. Patients taking a Biotin dose of up to 5 mg/day should refrain from taking Biotin for 4 days prior to sample collection. Patients taking a Biotin dose > 5 mg/day to 10 mg/day should refrain from taking Biotin for 7 days prior to sample collection. Patients taking a Biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result. **The Gastrin test was performed using the Siemens Immulite chemiluminescent immunometric method. Results obtained with different assay methods or kits cannot be used interchangeably.**	9/20/22
Glucose, Body Fluid	BFGLUC	**Stability:** Ambient: **7 days** Refrigerated: **7** days Frozen: Unacceptable	10/13/22

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis B Surface Ab, Immunity	AHBSI	**Special Information:** A non-reactive test result does not exclude the possibility of exposure to hepatitis B virus. Assay does not differentiate **Hepatitis B surface antibody from vaccination and or natural infection.** **Clinical Limitation: Test is not intended for use in screening blood, plasma, or tissue donors. Performance characteristics have not been established for immunocompromised patients. Performance has not been established for the use of cadaveric specimens.** Criteria for Rejection: Heat-inactivated, pooled, grossly hemolyzed, obvious microbial contamination. **Clinical Information:** To assess the presence of a recent or remote immune response to HBV infection or **Hepatitis B** vaccination. **Interpretations follow as: <8.00 mIU/mL: No evidence of antibodies to Hepatitis B surface antigen. 8.00–11.99 mIU/mL: Indeterminate result. In patients who were vaccinated 6-8 weeks prior to this draw or previously infected with HBV, repeat testing is suggested. Those who were vaccinated for Hepatitis B virus years ago, may fall into this category due to waning immunity over time. Clinical correlation is required. 12.00 mIU/mL or greater: These results are consistent with previous exposure and/or immunity to the hepatitis B virus antigen.**	9/20/22
Hepatitis B Surface Ab, Qual.	AHBSAG	**Special Information:** A non-reactive test result does not exclude the possibility of exposure to hepatitis B virus. Assay does not differentiate **Hepatitis B surface antibody from vaccination and or natural infection.** **Clinical Limitation: Test is not intended for use in screening blood, plasma, or tissue donors. Performance characteristics have not been established for immunocompromised patients. Performance has not been established for the use of cadaveric specimens.** Criteria for Rejection: Heat-inactivated, pooled, grossly hemolyzed, obvious microbial contamination. **Clinical Information:** To assess adequacy of recent or remote immune response to HBV infection or vaccination. **Negative values: No evidence of antibodies to Hepatitis B surface antigen. Equivocal values: Indeterminate result. In patients who were vaccinated 6-8 weeks prior to this draw or previously infected with HBV, repeat testing is suggested. Those who were vaccinated for Hepatitis B virus years ago, may fall into this category due to waning immunity over time. Clinical correlation is required. Positive values: These results are consistent with previous exposure and/or immunity to the hepatitis B virus antigen.**	9/20/22
Hepatitis B Surface Ab, Quant	AHBSQ	**Special Information:** A non-reactive test result does not exclude the possibility of exposure to hepatitis B virus. Assay does not differentiate **Hepatitis B surface antibody from vaccination and or natural infection.** **Clinical Limitation: Test is not intended for use in screening blood, plasma, or tissue donors. Performance characteristics have not been established for immunocompromised patients. Performance has not been established for the use of cadaveric specimens.** Criteria for Rejection: Heat-inactivated, pooled, grossly hemolyzed, obvious microbial contamination. **Clinical Information:** To assess the presence of a recent or remote immune response to HBV infection **or Hepatitis B** vaccination. **Interpretations follow as: <8.00 mIU/mL: No evidence of antibodies to Hepatitis B surface antigen. 8.00–11.99 mIU/mL: Indeterminate result. In patients who were vaccinated 6-8 weeks prior to this draw or previously infected with HBV, repeat testing is suggested. Those who were vaccinated for Hepatitis B virus years ago, may fall into this category due to waning immunity over time. Clinical correlation is required. 12.00 mIU/mL or greater: These results are consistent with previous exposure and/or immunity to the hepatitis B virus antigen.**	9/20/22

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Histoplasma galactomannan Antigen, Urine	UHISTO	**For interface clients only–Test build may need to be modified** **Test Name:** Previously Histoplasma Antigen, Urine **Clinical Information: Histoplasma galactomannan antigen, urine test is used as an aid in diagnosing histoplasmosis. A negative result cannot rule out infection. Low positive results may at times be due to cross-reactivity with Blastomyces, Talaromyces marneffei, Paracoccidioides, Aspergillus spp., and some Candida species. Clinical, radiological, and epidemiological correlation is required.** **Stability:** Ambient: **2 days** Refrigerated: 2 weeks Frozen: **60 days** **Reference Range:** **Urine Histoplasma Ag Quantitative (URHIST): < 0.20 ng/mL** Histoplasma Antigen (HISTAG): **Negative** **Days Performed: Tue–Fri** **Reported: 1–5** days	10/11/22
Human Epididymis Protein 4	HEP4	**Special Information: The Human Epididymis Protein 4 Antigen test was performed using the Abbott Architect chemiluminescent microparticle immunoassay method. Results obtained with different assay methods or kits cannot be used interchangeably.** **Clinical Limitation:** Criteria for rejection: Heat inactivated, pooled, grossly hemolyzed, obvious microbial contamination, cadaver samples or body fluids other than human serum. **Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Specimens containing HAMA may produce anomalous values when tested by this assay.** **Clinical Information: HE4 test is used as in aid in monitoring of progression or recurrence of disease in patients treated for ovarian carcinoma. The test should not be used for screening. Final interpretation requires correlation with clinical picture and other diagnostic modalities.**	9/20/22
JC Virus DNA, Ultrasensitive (LLOQ 10 copies/mL), Quantitative, Real-Time PCR, CSF	JCVPCR	**For interface clients only–Test build may need to be modified** **Includes:** **JC Virus DNA, Ultra, QN PCR (IU/mL)** **JC Virus DNA, Ultra, QN PCR (Log IU/mL)** **Specimen Requirement: 1.2** mL Cerebrospinal fluid (CSF) in sterile container; **Minimum: 0.6** mL; Frozen **Stability:** Ambient: 48 hours Refrigerated: **14** days Frozen: 30 days **Reference Range:** **JC Virus DNA, Ultra, QN PCR (IU/mL): Not Detected** **JC Virus DNA, Ultra, QN PCR (Log IU/mL): Not Detected**	effective immediately
Kappa, Free, Serum	FKAPPS	**Special Information: The Kappa Free Light Chain was performed using the Binding Site Optilite immunoturbidimetric method. Result obtained with different assay methods or kits cannot be used interchangeably.** **Clinical Limitation:** This assay has not been validated for the pediatric population. **Clinical Information:** Elevated serum levels of monoclonal free light chains are associated with malignant plasma cell proliferation (eg. multiple myeloma), **AL** amyloidosis, and light chain deposition disease. Raised serum levels of polyclonal free light chains may be associated with autoimmune **OR chronic infectious diseases.**	9/20/22

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Kappa/Lambda, Free, Serum	KLFRS	**Special Information: The Kappa Free Light Chain was performed using the Binding Site Optilite immunoturbidimetric method. Result obtained with different assay methods or kits cannot be used interchangeably. The Lambda Free Light Chain was performed using the Binding Site Optilite immunoturbidimetric method. Result obtained with different assay methods or kits cannot be used interchangeably.** **Clinical Limitation:** This assay has not been validated for the pediatric population. **Clinical Information:** Elevated serum levels of monoclonal free light chains are associated with malignant plasma cell proliferation (eg. multiple myeloma), **AL** amyloidosis, and light chain deposition disease. Raised serum levels of polyclonal free light chains may be associated with autoimmune diseases **or chronic infectious diseases.**	9/20/22
Kleihauer Betke Stain	HBFSTN	Reference Range: 0 mL of fetal blood present	10/11/22
Lactate Dehydrogenase, Body Fluid	BFLDH	**Special Information:** Indicate body fluid type/source. **Stability:** Ambient: **5** days Refrigerated: 2 days Frozen: Unacceptable	10/13/22
Lambda, Free, Serum	FLAMBS	**Special Information: The Lambda Free Light Chain was performed using the Binding Site Optilite immunoturbidimetric method. Result obtained with different assay methods or kits cannot be used interchangeably.** **Clinical Limitation:** This assay has not been validated for the pediatric population. **Clinical Information:** Elevated serum levels of monoclonal free light chains are associated with malignant plasma cell proliferation (eg. multiple myeloma), **AL** amyloidosis, and light chain deposition disease. Raised serum levels of polyclonal free light chains may be associated with autoimmune **OR chronic infectious diseases.**	9/20/22
Lipase, Fluid	FLIP	**Special Information: Indicate body fluid type/source.** **Stability:** Ambient: **5 days** Refrigerated: **7 days** Frozen: **Unacceptable**	10/13/22
Mitochondrial M2 IgG Serum	MITOS	**For interface clients only–Test build may need to be modified** **Test Name:** Previously Mitochondrial Antibody Screen **Clinical Information: Mitochondria M2 IgG test is used as an aid in diagnosing primary biliary cholangitis.** Clinical correlation is required. **Methodology: Semi Quantitative Enzyme Linked Immunosorbent Assay** **Reference Range:** **Mitochondria M2 IgG Qualitative (MITOQL): Negative** **Mitochondria M2 IgG Quantitative (MITOM2): ≤ 20 Units**	10/11/22
pH, Body Fluid	FLPH	**Special Information: This test is for pleural fluid only.** **Specimen Requirement:** 2–3 mL body fluid in clean container with no preservatives; Refrigerated; **Deliver to Lab or place in refrigerator immediately after collection. After 8 hours, the sample must be refrigerated and adding a small layer of mineral oil on top is recommended.** **Stability:** Ambient: **8** hours. **After 8 hours, the sample must be refrigerated and adding a small layer of mineral oil on top is recommended.** Refrigerated: **28** hours. **Adding a small layer of mineral oil on top is recommended.** Frozen: Unacceptable **Days Performed:** Sun–Sat; **24 hours**	10/11/22

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
pH Urine by pH Meter	PHU	**Special Information:** Deliver to Lab or place in refrigerator immediately after collection. After 8 hours, the sample must be refrigerated and adding a small layer of mineral oil on top is recommended. **Specimen Requirement:** 10 mL random urine in clean container; **Collect and refrigerate ASAP; Transport Refrigerated; Deliver to Lab or place in refrigerator immediately after collection. After 8 hours, the sample must be refrigerated and adding a small layer of mineral oil on top is recommended.** **Stability:** Ambient: **8 hours. After 8 hours, the sample must be refrigerated and adding a small layer of mineral oil on top is recommended.** Refrigerated: **28 hours. Adding a small layer of mineral oil on top is recommended.** Frozen: **Unacceptable** **Reference Range: 4.6–8.0** pH units **Days Performed:** Sun–Sat; **24 hours**	10/11/22
Routine, Prenatal Group B Strep PCR	GBPCR	**Specimen Requirement:** One vaginal or rectal swab, culturette; **Copan Dual Swab and Transport Systems, 139C LQ Stuart or 138C LQ Amies**	10/11/22
Thyroglobulin	TG	**Special Information:** Serum is the only acceptable specimen type. Patients taking a Biotin dose of up to 5 mg/day should refrain from taking Biotin for 2 days prior to sample collection. Patients taking a Biotin dose > 5 mg/day to 10 mg/day should refrain from taking Biotin for 4 days prior to sample collection. Patients taking a Biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result. **The Thyroglobulin test was performed using the Siemens Immulite chemiluminescent immunometric method. Results obtained with different assay methods or kits cannot be used interchangeably. The Thyroglobulin Antibody test was performed using the Abbott Architect chemiluminescent microparticle immunoassay method. Results obtained with different assay methods or kits cannot be used interchangeably.**	9/20/22
Thyroglobulin Antibody	TGAB	Special Information: The Thyroglobulin Antibody test was performed using the Abbott Architect chemiluminescent microparticle immunoassay method. Results obtained with different assay methods or kits cannot be used interchangeably.	9/20/22
Thyroid Cancer (Thyroglobulin) Monitoring	THYMON	**Special Information:** If Thyroglobulin Antibody is positive, Thyroglobulin by LC/MS/MS will be performed at an additional charge. **The Thyroglobulin test was performed using the Siemens Immulite chemiluminescent immunometric method. Results obtained with different assay methods or kits cannot be used interchangeably. The Thyroglobulin Antibody test was performed using the Abbott Architect chemiluminescent microparticle immunoassay method. Results obtained with different assay methods or kits cannot be used interchangeably.**	9/20/22
Titanium, Serum or Plasma	TITAN	**Reported: 8–11** days	effective immediately
Triglyceride, Body Fluid	FTRIG	**Special Information:** Indicate body fluid type/**source.** **Stability:** Ambient: **5** days Refrigerated: **7** days Frozen: **Unacceptable** **Days Performed:** Sun–Sat; **24** hours	10/13/22
Urea Nitrogen, Fluid	FLUN	**Stability:** Ambient: **2** days Refrigerated: 7 days Frozen: **Unacceptable**	10/13/22

New Tests

Test Name	Order Code	Change	Effective Date
Beta Globin (HBB) Sequencing	BGLSEQ	**Note: New test was announced in the May update, but financial information was not available at that time** **CPT:** 81364 **Price:** $955.00	effective immediately
BRAF V600E Mutation Detection Blood	BRAFPB	**Clinical Limitation:** This test is designed to detect only the V600E variant in the BRAF gene. Other variants in BRAF will not be identified by this test. The lower limit of detection of this assay is approximately 0.1% variant allele fraction (vaf) for the BRAF V600E variant. The result cannot be used as a standalone basis for diagnosis of malignancy, and needs to be considered in the context of clinical and morphologic presentation. **Clinical Information:** This assay uses Droplet Digital PCR to detect the BRAF V600E mutation, which may be useful in hairy cell leukemia and in multiple other neoplasms including melanoma, colorectal carcinoma, papillary thyroid carcinoma, and Langerhans cell histiocytosis. **Specimen Requirement:** 4 mL whole blood in EDTA (Lavender) tube; Minimum 1 mL; Collection Ambient; Transport Refrigerated **Stability:** Ambient: 48 hours Refrigerated: up to 7 days Frozen: Unacceptable **Methodology:** Droplet Digital Polymerase Chain Reaction (PCR) **Reference Range:** Refer to report **Days Performed:** 3 days per week **Reported:** 5 days	9/15/22
BRAF V600E Mutation Detection Bone Marrow	BRAFBM	**Clinical Limitation:** This test is designed to detect only the V600E variant in the BRAF gene. Other variants in BRAF will not be identified by this test. The lower limit of detection of this assay is approximately 0.1% variant allele fraction (vaf) for the BRAF V600E variant. The result cannot be used as a standalone basis for diagnosis of malignancy, and needs to be considered in the context of clinical and morphologic presentation. **Clinical Information:** This assay uses Droplet Digital PCR to detect the BRAF V600E mutation, which may be useful in hairy cell leukemia and in multiple other neoplasms including melanoma, colorectal carcinoma, papillary thyroid carcinoma, and Langerhans cell histiocytosis. **Specimen Requirement:** 2 mL bone marrow in EDTA (Lavender) tube; Minimum 0.5 mL; Collection and Transport Ambient **Stability:** Ambient: Bone marrow-up to 48 hours Refrigerated: Bone marrow-up to 7 days Frozen:Bone marrow-unacceptable **Methodology:** Droplet Digital Polymerase Chain Reaction (PCR) **Days Performed:** 3 days per week **Reported:** 5 days	9/15/22

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
BRAF V600E Mutation Detection Other	BRAFO	**Special Information:** May be reported with reduced sensitivity in cases of suboptimal amplification due to specimen type (with comment) **Clinical Limitation:** This test is designed to detect only the V600E variant in the BRAF gene. Other variants in BRAF will not be identified by this test. The lower limit of detection of this assay is approximately 0.1% variant allele fraction (vaf) for the BRAF V600E variant. The result cannot be used as a standalone basis for diagnosis of malignancy, and needs to be considered in the context of clinical and morphologic presentation. **Clinical Information:** This assay uses Droplet Digital PCR to detect the BRAF V600E mutation, which may be useful in hairy cell leukemia and in multiple other neoplasms including melanoma, colorectal carcinoma, papillary thyroid carcinoma, and Langerhans cell histiocytosis. **Specimen Requirement:** One clot in formalin-fixed, paraffin-embedded block; Collection and Transport Ambient; Paraffin-embedded clot should be delivered to Anatomic Pathology for accessioning and cutting. *OR* 10 mm square formalin fixed paraffin block in clean container; Collection and Transport Ambient; Paraffin-embedded tissue should be delivered to Anatomic Pathology for accessioning and cutting. **Stability:** Ambient: Paraffin-embedded tissue-indefinitely; Paraffin-embedded clot-indefinitely Refrigerated: Paraffin-embedded tissue-unacceptable; Paraffin-embedded clot-unacceptable Frozen: Paraffin-embedded tissue-unacceptable; Paraffin-embedded clot-unacceptable **Methodology:** Droplet Digital Polymerase Chain Reaction (PCR) **Reference Range:** Refer to report **Days Performed:** 3 days per week **Reported:** 5 days	9/15/22
FISH for CRLF2 and CRLF2/IGH Panel Blood	CRIGBP	**Clinical Information:** This panel uses a CRLF2 break apart probe and a CRLF2/IGH dual fusion probe to detect rearrangements involving the CRLF2 gene and translocations of the CRLF2 and IGH genes. **Specimen Requirement:** 2–3 mL blood in sodium heparin (Green) tube; Ambient *OR* 2–3 mL blood in EDTA (Lavender) tube; Ambient **Stability:** Ambient: Preferred Refrigerated: Acceptable Frozen: Not acceptable **Methodology:** Fluorescent In-Situ Hybridization (FISH) **Days Performed:** 5 days per week; 8:00 am–4:30 pm **Reported:** 7 days	9/15/22
FISH for CRLF2 and CRLF2/IGH Panel Bone Marrow	CRIGMP	**Clinical Information:** This panel uses a CRLF2 break apart probe and a CRLF2/IGH dual fusion probe to detect rearrangements involving the CRLF2 gene and translocations of the CRLF2 and IGH genes. **Specimen Requirement:** 2–3 mL bone marrow in sodium heparin (Green) tube; Ambient *OR* 2–3 mL bone marrow in EDTA (Lavender) tube; Ambient **Stability:** Ambient: Preferred Refrigerated: Acceptable Frozen: Not acceptable **Methodology:** Fluorescent In-Situ Hybridization (FISH) **Days Performed:** 5 days per week; 8:00 am–4:30 pm **Reported:** 7 days	9/15/22

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
FISH for CRLF2 Blood	CRLF2B	**Clinical Information:** This assay uses a break apart FISH probe to detect rearrangements involving the CRLF2 gene at Xp22.33. **Specimen Requirement:** 2–3 mL blood in sodium heparin (Green) tube; Ambient *OR* 2–3 mL blood in EDTA (Lavender) tube; Ambient **Stability:** Ambient: Preferred Refrigerated: Acceptable but not preferred Frozen: Not acceptable **Methodology:** Fluorescent In-Situ Hybridization (FISH) **Days Performed:** 5 days per week; 8:00 am–4:30 pm **Reported:** 7 days	9/15/22
FISH for CRLF2 Bone Marrow	CRLF2M	**Clinical Information:** This assay uses a break FISH apart probe to detect rearrangements involving the CRLF2 gene at Xp22.33. **Specimen Requirement:** 2–3 mL bone marrow in sodium heparin (Green) tube; Ambient *OR* 2–3 mL bone marrow in EDTA (Lavender) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: Acceptable but not preferred Frozen: Not acceptable **Methodology:** Fluorescent In-Situ Hybridization (FISH) **Days Performed:** 5 days per week; 8:00 am–4:30 pm **Reported:** 7 days	9/15/22
FISH for CRLF2/IGH Blood	CRIGHB	**Clinical Information:** This assay uses a dual fusion probe to detect translocations involving the CRLF2/IGH genes. **Specimen Requirement:** 2–3 mL blood in sodium heparin (Green) tube; Ambient *OR* 2–3 mL blood in EDTA (Lavender) tube; Ambient **Stability:** Ambient: Preferred Refrigerated: Acceptable but not preferred Frozen: Not acceptable **Methodology:** Fluorescent In-Situ Hybridization (FISH) **Days Performed:** 5 days per week; 8:00 am–4:30 pm **Reported:** 7 days	9/15/22
FISH for CRLF2/IGH Bone Marrow	CRIGHM	**Clinical Information:** This assay uses a dual fusion probe to detect translocations involving the CRLF2/IGH genes. **Specimen Requirement:** 2–3 mL bone marrow in sodium heparin (Green) tube; Ambient *OR* 2–3 mL bone marrow in EDTA (Lavender) tube; Ambient **Stability:** Ambient: Preferred Refrigerated: Acceptable but not preferred Frozen: Not acceptable **Methodology:** Fluorescent In-Situ Hybridization (FISH) **Days Performed:** 5 days per week; 8:00 am–4:30 pm **Reported:** 7 days	9/15/22

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
KIT D816V Mutation Detection Blood	K816PB	**Clinical Limitation:** This test is designed to detect only the D816V variant in the KIT gene. Other variants in KIT will not be identified by this test. The lower limit of detection of this assay is approximately 0.1% variant allele fraction (vaf) for the KIT D816V variant. The result cannot be used as a standalone basis for diagnosis of malignancy, and needs to be considered in the context of clinical and morphologic presentation. **Clinical Information:** This assay uses Droplet Digital PCR to detect the KIT D816V mutation to aid in clinical diagnosis of systemic mastocytosis. **Specimen Requirement:** 4 mL whole blood in EDTA (Lavender) tube; Minimum 1 mL; Collection Ambient; Transport Refrigerated **Stability:** Ambient: Up to 48 hours Refrigerated: Up to 7 days Frozen: Unacceptable **Methodology:** Droplet Digital Polymerase Chain Reaction (PCR) **Days Performed:** 3 days per week **Reported:** 5 days **CPT:** 81273 **Price:** $335.00	9/15/22
KIT D816V Mutation Detection Bone Marrow	K816BM	**Clinical Limitation:** This test is designed to detect only the D816V variant in the KIT gene. Other variants in KIT will not be identified by this test. The lower limit of detection of this assay is approximately 0.1% variant allele fraction (vaf) for the KIT D816V variant. The result cannot be used as a standalone basis for diagnosis of malignancy, and needs to be considered in the context of clinical and morphologic presentation. **Clinical Information:** This assay uses Droplet Digital PCR to detect the KIT D816V mutation to aid in clinical diagnosis of systemic mastocytosis. **Specimen Requirement:** 2 mL bone marrow in EDTA (Lavender) tube; Minimum 0.5 mL; Collection and Transport Ambient **Stability:** Ambient: Bone marrow-up to 48 hours Refrigerated: Bone marrow-up to 7 days Frozen: Unacceptable **Methodology:** Droplet Digital Polymerase Chain Reaction (PCR) **Days Performed:** 3 days per week **Reported:** 5 days **CPT:** 81273 **Price:** $335.00	9/15/22
Kit D816V Mutation Detection Other	K816O	**Special Information:** May be reported with reduced sensitivity in cases of suboptimal amplification due to specimen type (with comment) **Clinical Limitation:** This test is designed to detect only the D816V variant in the KIT gene. Other variants in KIT will not be identified by this test. The lower limit of detection of this assay is approximately 0.1% variant allele fraction (vaf) for the KIT D816V variant. The result cannot be used as a standalone basis for diagnosis of malignancy, and needs to be considered in the context of clinical and morphologic presentation. **Clinical Information:** This assay uses Droplet Digital PCR to detect the KIT D816V mutation to aid in clinical diagnosis of systemic mastocytosis. **Specimen Requirement:** One clot in formalin-fixed, paraffin-embedded block; Collection and Transport Ambient; Paraffin-embedded clots should be delivered to Anatomic Pathology for accessioning and cutting.*OR* 10 mm square formalin fixed paraffin block in formalin-fixed, paraffin-embedded block; Collection and Transport Ambient; Paraffin-embedded tissue should be delivered to Anatomic Pathology for accessioning and cutting. *(continued on page 13)*	9/15/22

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Kit D816V Mutation Detection Other *(continued from page 12)*		**Stability:** Ambient: Paraffin-embedded tissue- indefinitely; Paraffin-embedded clot- indefinitely Refrigerated: Paraffin-embedded tissue- unacceptable; Paraffin-embedded clot- unacceptable Frozen: Paraffin-embedded tissue- unacceptable; Paraffin-embedded clot- unacceptable **Methodology:** Droplet Digital Polymerase Chain Reaction (PCR) **Days Performed:** 3 days per week **Reported:** 5 days **CPT:** 81273	
Meningitis Encephalitis Panel	MGEBF	**Specimen Requirement:** 0.5 mL CSF collected by lumbar puncture in CSF Tube; Minimum 0.2 mL; Collection Temperature Ambient; Transport Temperature Refrigerated **Stability:** Ambient: Room temp for up to one day Refrigerated: Up to 7 days **Methodology:** Reverse Transcription/Polymerase Chain Reaction (RT/PCR) **Days Performed:** 7 days a week; 24 hours **Reported:** 1–2 days	9/13/22

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
BK Virus Quantitation, Urine	UBKQT	$155.00	87799	effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Mitochondrial Antibody Panel	MITO	Test will no longer be orderable. Recommended replacement test is Mitochondrial M2 IgG Serum (MITOS)	10/11/22
Myeloma Prognostic Risk Signature (MyPRS)	MYPRST	Test will no longer be orderable.	effective immediately
Parietal Cell Antibody Panel	PARIET	Test will no longer be orderable. Recommended replacement test is Gastric Parietal Cell IgG Serum (PARIES)	10/11/22
Smooth Muscle Antibody Panel	SMOOTH	Test will no longer be orderable. Recommended replacement test is F-Actin (Smooth Muscle) Antibody, IgG ELISA (SMTHS)	10/11/22