Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • September 2026

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 Laboratory Customer Service 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	Applies to Regional Locations
2	Apolipoprotein, A-1					■								
2	Apolipoprotein A-1 & B					■								
2	Apolipoprotein, B					■								
8	B/Myeloid and T/Myeloid MRD by Flow Cytometry			■										
2	Beta Globin (HBB) Sequencing						■				■	■		
3	Colorectal cancer screening FIT		■			■								
3	Copper, Urine 24 Hour									■				
3	Enterovirus by PCR													
3	F2 Isoprostane/Creatinine Ratio											■		
12	Gastric Occult Blood				■									
3	Glutathione Total						■							
3	Heparin Anti Xa Assay									■				
3–4	Herpes Simplex Virus (HSV-1/2) PCR, Non-Lesion					■								
4	Herpes Simplex Virus (HSV-1 & HSV-2) and Varicella Zoster Virus (VZV), NAAT, Lesion Swab					■								
8–9	Human Papillomavirus (HPV) Type 16, Quantitative PCR, Plasma Cell Free DNA			■										
9–10	Human Papillomavirus (HPV) Type 18, Quantitative PCR, Plasma Cell Free DNA			■										

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	Applies to Regional Locations
10–11	Human Papillomavirus (HPV) Type 31/33/35/58, Quantitative PCR, Plasma Cell Free DNA			■										
11–12	Human Papillomavirus (HPV) Type 45/51/52, Quantitative PCR, Plasma Cell Free DNA			■										
4	Interleukin-2 Receptor, Soluble						■			■				
4	Itraconazole					■				■				
12	ORGANISM ID NOCARDIA				■									
4	Ova and Parasite Examination							■						
4	Pentobarbital					■								
4–5	Polychlorinated Biphenyls (PCB) Panel, Congeners, Serum or Plasma		■			■	■					■		
5	Porphyrins Evaluation, Whole Blood with reflex to fractionation		■			■	■	■	■	■	■	■	■	
6	Porphyrins, Total, Plasma with reflex to fractionation		■			■	■	■	■	■	■	■		
6	Thymidine Determination, Plasma		■		■	■	■	■	■	■	■	■	■	
7	Tumor Necrosis Factor						■							
7	Vitamin B3/Niacin					■	■					■		

Test Changes

Test Name	Order Code	Change	Effective Date
Apolipoprotein, A-1	APOA	**Special Information:** Patients should not be drawn for at least three months following surgery or myocardial infarction. Certain drugs, unstable weight or eccentric or imbalanced dietary habits may affect results. *Note: The following comment was removed from Special Information: Patient preparation: 12 hour fast prior to collection.*	effective immediately
Apolipoprotein A-1 & B	APOAB	**Special Information:** Patients should not be drawn for at least three months following surgery or myocardial infarction. Certain drugs, unstable weight or eccentric or imbalanced dietary habits may affect results. *Note: The following comment was removed from Special Information: Patient preparation: 12 hour fast prior to collection.*	effective immediately
Apolipoprotein, B	APOB	**Special Information:** Patients should not be drawn for at least three months following surgery or myocardial infarction. Certain drugs, unstable weight or eccentric or imbalanced dietary habits may affect results. *Note: The following comment was removed from Special Information: Patient preparation: 12 hour fast prior to collection.*	effective immediately
Beta Globin (HBB) Sequencing	BGHBB	**Specimen Requirement:** 3 mL Whole blood in an EDTA (Lavender) tube; Minimum: **2** mL; Container Sharing: No; Transport Temperature: Refrigerated *OR* 3 mL Whole blood in a ACD A or B (Yellow); Minimum: **2** mL; Container sharing: No; Transport Temperature: Refrigerated **Stability:** Ambient: 72 hours Refrigerated: **2 weeks** Frozen: Unacceptable **Days Performed: Varies** **Reported: 11-16 days**	9/24/26

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Colorectal cancer screening FIT	IFOBT	**Name:** Previously Fecal Occult Blood Test **Clinical Information: For asymptomatic colorectal cancer screening in average-risk patients. This test is designed to detect occult lower gastrointestinal bleeding associated with colorectal neoplasia. It is not intended for evaluation of overt gastrointestinal bleeding, melena, hematochezia, iron deficiency anemia, symptomatic patients, or suspected acute GI hemorrhage. Patients with symptoms or suspected GI bleeding should undergo appropriate clinical evaluation.**	effective immediately
Copper, Urine 24 Hour	UCOPD	**Reference Range:** **Copper, Urine 24 Hour: <40.0 ug/24 hrs**	effective immediately
Enterovirus by PCR	ENTNAS	**Aliases:** **Coxsackie Virus** **Echovirus** **EV Detection** **EV PCR** **EV RNA detection** **Poliovirus**	effective immediately
F2 Isoprostane/ Creatinine Ratio	F2	**Stability:** Ambient: 1 week Refrigerated: 1 week Frozen: 28 days	9/29/26
Glutathione Total	GLUTAT	**Specimen Requirements: 8.5** mL Whole blood in an ACD **A** (Yellow) tube; Minimum: **4.2** mL; Collection tube must be filled greater than 50% of total volume to maintain ratio of blood-to-liquid anticoagulant. Critical Refrigerated. Transport whole blood in original collection container. *OR* **3** mL; Collection tube must be filled greater than 50% of total volume to maintain ratio of blood-to-liquid anticoagulant. Critical Refrigerated. Transport whole blood in original collection container. *OR* **1 mL; Transfer at least 1 mL to standard aliquot tube with documentation of original collection tube.**; Container Sharing: No; Collection Temperature: Place specimen on ice after draw.; Transport Temperature: Refrigerated; ACD tube must be filled greater than 50% of total volume to maintain ratio of blood-to-liquid anticoagulant. Critical Refrigerated. Transport whole blood in original collection container. *OR* **6** mL Whole blood in an ACD **B** (Yellow) tube; Minimum: **4.2** mL; Collection tube must be filled greater than 50% of total volume to maintain ratio of blood-to-liquid anticoagulant. Critical Refrigerated. Transport whole blood in original collection container. *OR* **3** mL; Collection tube must be filled greater than 50% of total volume to maintain ratio of blood-to-liquid anticoagulant. Critical Refrigerated. Transport whole blood in original collection container. *OR* **1 mL; Transfer at least 1 mL to standard aliquot tube with documentation of original collection tube.**; Container Sharing: No; Collection Temperature: Place specimen on ice after draw.; Transport Temperature: Refrigerated; ACD tube must be filled greater than 50% of total volume to maintain ratio of blood-to-liquid anticoagulant. Critical Refrigerated. Transport whole blood in original collection container.	effective immediately
Heparin Anti Xa Assay	HEPASY	**Reference Range:** Heparin Anti Xa 0-99 Years: Therapeutic range: 0.3-0.7 (standard nomogram) IU/mL 0-99 Years: <0.1 IU/mL 0-99 Years: Stroke or Low dose protocol: 0.2-0.5 (see EPIC for detailed nomogram) IU/mL **0-99 Years: Urgent Range: =>1.00 to =<1.50 IU/mL** **0-99 Years: Critical Range: >1.50 IU/mL**	effective immediately
Herpes Simplex Virus (HSV-1/2) PCR, Non-Lesion	HSVPCR	**Clinical Information:** Herpes simplex viruses (HSV-1 and HSV-2) are enveloped DNA viruses that are members of the alpha-herpesviridae subfamily. HSV infections in humans can cause lesions at a variety of cutaneous and mucocutaneous sites. These lesions can be a result of the primary infection by the virus or they can result from a reactivation of the latent virus, causing recurrent episodes of the disease. While testing is typically performed on mucocutaneous swabs, more unusual presentations of disseminated disease, pneumonitis, central nervous system infection, or intraocular infection may require testing of alternative specimen types. Nucleic acid amplification tests are a sensitive method for detection of HSV in plasma, lower respiratory specimens, CSF, and ocular fluid. This lab-developed multiplex real-time PCR assay simultaneously qualitatively detects and differentiates HSV-1 and HSV-2 DNA targets. *(Continued on page 4)*	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Herpes Simplex Virus (HSV-1/2) PCR, Non-Lesion *(Continued from page 3)*		**Clinical Information (continued):** Viral nucleic acid is extracted from clinical samples using the EZ2 Connect (Qiagen). HSV-1 and HSV-2 DNA are amplified and detected using the RealStar alpha Herpesvirus PCR kit 1.0 (Altona) using species-specific primers and fluorescently labeled hydrolysis probes on a RotorGene Q (Qiagen) thermocycler. This specific procedure code (HSVPCR) can be used to order this test on plasma, bronchoalveolar lavage, bronchial wash, CSF, ocular fluid, and neonatal surface swab specimens. Utilize alternative orders for the following specimen types: HSVVZV for mucocutaneous lesion swabs.	
Herpes Simplex Virus (HSV-1 & HSV-2) and Varicella Zoster Virus (VZV), NAAT, Lesion Swab	HSVVZV	**Clinical Information:** Herpes simplex virus types 1 and 2 (HSV-1 and HSV-2), and varicella-zoster virus (VZV), are DNA viruses of the family Herpesviridae. HSV infections in humans can cause lesions at a variety of cutaneous and mucocutaneous sites. These lesions can be a result of the primary infection by the virus or they can result from a reactivation of the latent virus, causing recurrent episodes of the disease. Primary VZV infection results in chickenpox (varicella), which may rarely result in complications including encephalitis or pneumonia. Even when clinical symptoms of chickenpox have resolved, VZV remains dormant in the nervous system of the infected person (virus latency). In approximately 10 to 20% of cases, VZV reactivates later in life producing shingles. This lab-developed multiplex real-time PCR assay simultaneously qualitatively detects and differentiates HSV-1, HSV-2, and VZV DNA targets. Viral nucleic acid is extracted from clinical samples using the EZ2 Connect (Qiagen). Viral DNA is amplified and detected using the RealStar alpha Herpesvirus PCR kit 1.0 (Altona) using species-specific primers and fluorescently labeled hydrolysis probes on a RotorGene Q (Qiagen) thermocycler. This specific procedure code (SQHSVVZV) can be used to order this test on mucocutaneous lesion swabs. Utilize HSVPCR for HSV testing on all other non-lesional specimen types; and VZVPCR for VZV testing on all other non-lesional specimen types.	effective immediately
Interleukin-2 Receptor, Soluble	SIL2R	**Specimen Requirements:** 1 mL Serum from a SST (Gold) tube; Minimum: 0.4 mL; Container Sharing: No; Transport Temperature: Frozen, Critical; Critical Frozen. Separate serum from cells within 2 hours of collection, transfer into a standard aliquot tube and freeze **within 30 minuets.** Separate specimens must be submitted when multiple tests are ordered. *OR* 1 mL Serum from a No additive (Red) tube; Minimum: 0.4 mL; Container Sharing: No; Transport Temperature: Frozen, Critical; Critical Frozen. Separate serum from cells within 2 hours of collection, transfer into a standard aliquot tube and freeze **within 30 minuets.** Separate specimens must be submitted when multiple tests are ordered. **Reference Range:** Interleukin-2 Receptor, Soluble, Serum: **353.5–1019.8 pg/mL**	effective immediately
Itraconazole	ITRAC	**Clinical Information:** Ranges are based on trough draw at steady-state concentration. Test performed by LC-MS/MS. Ranges are based off the Itraconazole trough levels alone, not combined with hydroxyitraconazole: Therapeutic: >1.0 μg/mL Prophylaxis: >0.**5** μg/mL Toxic: >**2.9** μg/mL (Toxic values will not be called.) The therapeutic, prophylactic, and toxic ranges were based on the 2016 Infectious Disease Society (IDSA) Clinical Practice Guidelines for the Management of Aspergillosis and consultation from Cleveland Clinic's Department of Infectious Disease. Reference ranges and high/low indicator flags are provided as general guidelines only. The treating physician must determine appropriate target levels/ dosing based on the specific clinical situation. **Reference Range:** Itraconazole: **0.6-2.9** ug/mL Hydroxyitraconazole: No Reference Range is Provided	effective immediately
Ova and Parasite Examination	OVAP	**Reflexed Test:** **Cryptosoridia** **Cyclospora** **Cystoisospora Examination**	effective immediately
Pentobarbital	PENTOB	**Clinical Limitation: This test does not differentiate between pentobarbital and amobarbital.**	effective immediately
Polychlorinated Biphenyls (PCB) Panel, Congeners, Serum or Plasma	PBPS	**Name:** Previously Polychlorinated Biphenyls (PCB) Panel, Serum or Plasma **Special Information: Polymer gel separation tubes (SST or PST)** are unacceptable. **Separate specimens must be submitted when multiple tests are ordered.** This test is New York DOH approved. *(Continued on page 5)*	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Polychlorinated Biphenyls (PCB) Panel, Congeners, Serum or Plasma *(Continued from page 4)*		**Clinical Information: Panel includes: 2,4,4'-Trichlorobiphenyl (PCB 28); 2,2',3,5'Tetrachlorobiphenyl (PCB 44);** 2,2',5,5'-Tetrachlorobiphenyl (PCB 52); 2,3',4,4'-Tetrachlorobiphenyl (PCB 66); 2,4,4',5Tetrachlorobiphenyl (PCB 74); 2,2',4,5,5'-Pentachlorobiphenyl (PCB 101); 2,3',4,4',5-Pentachlorobiphenyl (PCB 118); 2,2',3,4,4',5'-Hexachlorobiphenyl (PCB 138); **,2',4,4',5,5'Hexachlorobiphenyl (PCB 153); 2,3,3',4,4',5-Hexachlorobiphenyl (PCB 156); 2,2',3,4,4',5,5'-Hepta-chlorobiphenyl (PCB 180).** **Specimen Requirement:** 2 mL Serum from a No additive (Red); Minimum: 0.7 mL; Container Sharing: No; Transport Temperature: **Frozen**; Do not use serum separator tubes. Separate serum from cells within 2 hours of collection and transfer into standard aliquot tube. **Separate specimens must be submitted when multiple tests are ordered.** *OR* 2 mL Plasma from an EDTA (Lavender); Minimum: 0.7 mL; Container Sharing: No; Transport Temperature: Frozen; Do not use serum separator tubes. Separate plasma from cells within 2 hours of collection and transfer into standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered. **Stability:** Ambient: **2 days** Refrigerated: 2 weeks Frozen: 1 year	
Porphyrins Evaluation, Whole Blood with reflex to fractionation	PROPOR	**Name:** Previously Protoporphyrins, Total, RBC **Aliases:** **Erythrocyte Porphyrin** **Erythropoietic Protoporphyria (EPP)** **Free Erythrocyte Porphyrin (FEP)** **Protoporphyrin** **Protoporphyrins, Total, Erythrocytes** **RBC Porphyrins** **Red Blood Cell Porphyrins** **X-linked Dominant Protoporphyria (XLDPP, XLEPP, or XDP)** **Includes:** **Total Porphyrins, WB** **Protoporphyrins, Fractionation, WB if indicated** **Special Information:** Protect from light. **Patient MUST NOT consume any alcohol for 24 hours before specimen collection. A list of medications the patient is currently taking should be included. Hemolyzed specimens will be rejected. If the total erythrocyte porphyrin value is 80 mcg/dL or above, the protoporphyrin fractionation assay will automatically be performed at an additional charge. The fractionation test results include noncomplexed protoporphyrin and zinc-complexed protoporphyrin.** This test is New York State approved. **Clinical Information: This test is recommended for screening patients for possible erythropoietic protoporphyria and X-linked dominant protoporphyria. In addition, it can be used for evaluation of iron-deficiency anemia and chronic lead intoxication.** If testing for an acute porphyria, please consider ordering PBG, Screen (SQUPBG). If testing for a cutaneous porphyria, please consider ordering Porphyrins, Urine (UPORFR). If testing for erythropoietic porphyria, please consider ordering Total Erythrocyte Porphyrins (PROPOR). **Specimen Requirement: 4** mL Whole blood in a **Sodium heparin (Green) tube**; Minimum: **3** mL; Container Sharing: No; Transport Temperature: Refrigerated; Protect specimen from light**. Immediately place specimen on wet ice.** *OR* **4** mL Whole Blood in a EDTA (Lavender) tube; Minimum: **3** mL; Container Sharing: No; Transport Temperature: Refrigerated; Protect specimen from light. **Immediately place specimen on wet ice.** *OR* **4 mL Whole blood in a Lithium heparin (Green) tube; Minimum: 3 mL; Transport Temperature: Refrigerated; Protect specimen from light. Immediately place specimen on wet ice.** *OR* **4 mL Whole Blood in a EDTA (Royal blue) tube; Minimum: 3 mL; Container Sharing: No; Transport Temperature: Refrigerated; Protect specimen from light. Immediately place specimen on wet ice.** **Stability:** Ambient: Unacceptable Refrigerated: **7 days** Frozen: **Unacceptable** **Methodology: Spectrofluorometric** **Reference Range:** **Porphyrins Evaluation, WB: <80 mcg/dL** **Days Performed: Mon–Fri** **Reported: 4–6 days** **CPT: 84311x1**	9/24/26

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Porphyrins, Total, Plasma with reflex to fractionation	SPORPH	**Name:** Previously Porphyrins, Total, Plasma or Serum **Aliases:** **Congenital Erythropoietic Porphyria (CEP)** **Coproporphyrin** **Erythropoietic Protoporphyria (EPP)** **Porphyria Cutanea Tarda (PCT)** **Protoporphyrin** **Uroporphyrin** **Variegate Porphyria** **X-linked Dominant Protoporphyria (XLDPP, XLEPP, or XDP)** **Includes:** **Porphyrins, Total, P** **Porphyrins, Fractionation, P if indicated** **Special Information: Patient MUST NOT consume any alcohol for 24 hours before specimen collection. A list of medications the patient is currently taking should be included. Protect specimen from light. Grossly hemolyzed, lipemic or icteric samples will be rejected. If total porphyrins are above 1.0 mcg/dL, then porphyrin fractionation will be performed at an additional charge.** This test is New York State approved. **Specimen Requirement: 3** mL **Plasma** from a **Sodium or Lithium heparin (Green) tube**; Minimum: 1 mL; Container Sharing: No; Transport Temperature: Frozen; Protect specimen from light. Separate **plasma** from cells **and** transfer to amber transport tube. *OR* **3** mL Plasma from an EDTA (Lavender) tube: Minimum: 1 mL; Container Sharing: No; Transport Temperature: Frozen; Protect specimen from light. Separate plasma from cells **and** transfer to amber transport tube. **Stability:** Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: **14** days Frozen: After separation from cells: **14 days** **Methodology: Spectrofluorometric** **Reference Range:** **Porphyrins, Total, P: < or = 1.0 mcg/dL** **Days Performed: Mon–Fri** **Reported: 3–5 days**	9/24/26
Thymidine Determination, Plasma	PLTHY	**Name:** Previously Thymidine and Deoxyuridine Analytes (Plasma) **Special Information: Test requisition is required to be sent with the sample. Separate plasma from cells ASAP and freeze.** **Clinical Information: This test provides quantitative analysis of thymidine in plasma. It is useful for evaluation of patients suspected of** Mitochondrial neurogastrointestinal encephalomyopathy (MNGIE). MNGIE is an autosomal recessive disorder caused by mutations in the gene encoding thymidine phosphorylase (TP). The disease is characterized clinically by impaired eye movements, gastrointestinal dysmotility, cachexia, peripheral neuropathy, myopathy and leukoencephalopathy. **Specimen Requirement: 2** mL Plasma from a Sodium heparin (Green) tube; Minimum: **1** mL; Container Sharing: No; Transport Temperature: Frozen, ASAP; Separate plasma from cells ASAP and transfer to standard aliquot tube and freeze. **Stability:** Ambient: **Unacceptable** Refrigerated: **Unacceptable** Frozen: **7 days** **Methodology: Tandem Mass Spectrometry** **Days Performed: Mon–Sat** **Reported: 4–16** days **CPT: 83789x1** *Note: Reference ranges and Included tests have been removed.*	9/24/26

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Tumor Necrosis Factor	TNFA2	**Specimen Requirements:** 1 mL Serum from a SST (Gold) tube; Minimum: 0.4 mL; Container Sharing: No; Transport Temperature: Frozen, Critical; Critical Frozen. Separate serum from cells within 2 hours of collection. Transfer into a standard aliquot tube and freeze **within 30 minuets.** Additional specimens must be submitted with multiple tests are ordered. *OR* 1 mL Serum from a No additive (Red) tube; Minimum: 0.4 mL; Container Sharing: No; Transport Temperature: Frozen, Critical; Critical Frozen. Separate serum from cells within 2 hours of collection. Transfer into a standard aliquot tube and freeze **within 30 minuets.** Additional specimens must be submitted with multiple tests are ordered. **Reference Range:** **Tumor Necrosis Factor–alpha, Serum:** <= **11.5** pg/mL	effective immediately
Vitamin B3/Niacin	B3VIT	**Special Information:** Patient should fast for 4 hours and avoid the use of vitamin supplements for 24 hours prior to collection. Hemolyzed samples or samples collected in EDTA tubes are unacceptable**. Separate specimens must be submitted when multiple tests are ordered.** **Specimen Requirement:** 1 mL Serum from a No additive (Red) tube; Minimum: 0.3 mL; Container Sharing: No; Transport Temperature: Frozen; Patient should fast for 4 hours prior to collection and avoid the use of vitamin supplements for 24 hours prior to collection. Protect specimen from light during storage and shipment. Separate serum from cells ASAP or within 2 hours of collection and freeze. Use amber transport tubes. **Separate specimens must be submitted when multiple tests are ordered.** *OR* 1 mL Serum from a SST (Gold) tube; Minimum: 0.3 mL; Container Sharing: No; Transport Temperature: Frozen; Patient should fast for 4 hours prior to collection and avoid the use of vitamin supplements for 24 hours prior to collection. Protect specimen from light during storage and shipment. Separate serum from cells ASAP or within 2 hours of collection and freeze. Use amber transport tubes. **Separate specimens must be submitted when multiple tests are ordered.** *OR* 1 mL Plasma from a Sodium or Lithium heparin (Green) tube; Minimum: 0.3 mL; Container Sharing: No; Transport Temperature: Frozen; Patient should fast for 4 hours prior to collection and avoid the use of vitamin supplements for 24 hours prior to collection. Protect specimen from light during storage and shipment. Separate plasma from cells ASAP or within 2 hours of collection and freeze. Use amber transport tubes. **Separate specimens must be submitted when multiple tests are ordered.** *OR* 1 mL Plasma from a Lithium heparin PST (Lt. Green) tube; Minimum: 0.3 mL; Container Sharing: No; Transport Temperature: Frozen; Patient should fast for 4 hours prior to collection and avoid the use of vitamin supplements for 24 hours prior to collection. Protect specimen from light during storage and shipment. Separate plasma from cells ASAP or within 2 hours of collection and freeze. Use amber transport tubes. **Separate specimens must be submitted when multiple tests are ordered.** **Stability:** Ambient: After separation from cells: 6 hours Refrigerated: **3 days** Frozen: After separation from cells: 1 month	effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
B/Myeloid and T/ Myeloid MRD by Flow Cytometry	BTMRD	**Specimen Requirement:** 6 mL Whole blood in a Sodium heparin (Green) tube; Minimum: 1 mL; Container Sharing: No; Transport Temperature: Ambient *OR* 2 mL Bone marrow in a Sodium heparin (Green) tube; Minimum 1 mL; Container Sharing: No; Transport Temperature: Ambient *OR* 4 mL Whole blood in a EDTA (Lavender) tube; Minimum: 1 mL; Container Sharing: No; Transport Temperature: Ambient **Stability:** Ambient: 5 days Refrigerated: 5 days Frozen: Unacceptable **Methodology:** Flow Cytometry (FC) **Days Performed:** Mon–Fri **Reported:** 2–4 days **CPT:** Varies	9/29/26
Human Papillomavirus (HPV) Type 16, Quantitative PCR, Plasma Cell Free DNA	HPVQ16	**Clinical Limitation:** Detection of hrHPV cfDNA is not diagnostic of cancer or cancer recurrence, and can be observed rarely in immunocompromised individuals. Absence of hrHPV cfDNA detection does not rule out an HPV-associated malignancy, precursor lesion, or HPV infection. Mutations in primer/probe binding sites may affect assay sensitivity and quantitation, though this is unlikely given inclusion of multiple gene targets. False positive results may be seen in instances of cross-reactivity with rare HPV genotypes. Quantitative values should be interpreted with caution, as biological, pre-analytical, and analytical variability can all contribute to assay imprecision; in general, changes should not be interpreted as significant unless greater than a three-fold difference. The clinical performance characteristics of this assay have not been evaluated for cancer screening, minimal residual disease testing, or for patients with malignancies other than oropharyngeal squamous cell carcinoma. Results should be evaluated in the context of clinical history, imaging, exam, and other laboratory findings. If results are incongruent with history, recommend submitting a new specimen for re-testing by this or another method. **Clinical Information:** While cervical carcinoma incidence in the United States has been declining since the 1990s, rates of oropharyngeal squamous cell carcinoma (OPSCC) continue to increase. High-risk human papillomavirus (hrHPV) status in OPSCC significantly influences prognosis and treatment. Recent studies have identified plasma cell-free hrHPV DNA (cfDNA) as an important biomarker for OPSCC disease recurrence. HPV-16 is overwhelmingly the most prevalent HPV type involved in OPSCC, accounting for >85% of cases, followed by HPV-35, HPV-33, HPV-18, HPV-45, and others. This assay is a lab-developed quantitative real-time PCR that simultaneously targets 12 different amplicons specific to HPV-16, performed on plasma. CfDNA is extracted from 4 mL of EDTA plasma using the Qiagen EZ2 Connect MDx ccfDNA kit. HPV-16 DNA is subsequently amplified on a Biorad CFX Opus Dx Real Time PCR system. Human DNA is also amplified as an internal control, and distinguished from HPV signal using different fluorophore-tagged hydrolysis probes. The assay is calibrated against NIBSC WHO international standard for HPV-16, and reported in international units (IU)/mL of plasma. **Specimen Requirement:** 20 mL of Blood from a Lavender EDTA tube; Minimum: 0.8 mL; Specimen sharing is permitted among HBVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is requested, regardless of whether 1, 2, 3, or all 4 tests are ordered. The absolute minimum volume on which testing can be performed is 4 mL of plasma (approximately 8 mL of whole blood).; Container Sharing: Yes; Transport Temperature: Centrifuge, aliquot and refrigerate.; Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for lavender-top EDTA tubes, or 1,300 RCF for white-top PPT tubes, for a minimum of 10 minutes) within 6 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Specimen sharing is permitted among HPVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is sufficient, regardless of whether 1, 2, 3, or all 4 tests are ordered. *OR* 20 mL of Blood from a White PPT EDTA tube; Minimum: 0.8 mL; Specimen sharing is permitted among HBVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is requested, regardless of whether 1, 2, 3, or all 4 tests are ordered. *(continued on page 9)*	11/17/26

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Human Papillomavirus (HPV) Type 16, Quantitative PCR, Plasma Cell Free DNA *(Continued from page 8)*		**Specimen Requirement (continued):** The absolute minimum volume on which testing can be performed is 4 mL of plasma (approximately 8 mL of whole blood).; Container Sharing: Yes; Transport Temperature: Centrifuge, aliquot and refrigerate.; Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for lavender-top EDTA tubes, or 1,300 RCF for white-top PPT tubes, for a minimum of 10 minutes) within 6 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Specimen sharing is permitted among HPVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is sufficient, regardless of whether 1, 2, 3, or all 4 tests are ordered. **Stability:** Ambient: 24 hours Refrigerated: 7 days Frozen: 30 days **Methodology:** Polymerase Chain Reaction (PCR), Quant **Reference Range:** HPV Type 16 DNA, Plasma HPV Type 16 DNA, Plasma, IU/mL **Days Performed:** 1 day per week; 7:00 am–3:30 pm **Reported:** 7–10 days **CPT:** 87799x1	11/17/26
Human Papillomavirus (HPV) Type 18, Quantitative PCR, Plasma Cell Free DNA	HPVQ18	**Clinical Limitation:** Detection of hrHPV cfDNA is not diagnostic of cancer or cancer recurrence, and can be observed rarely in immunocompromised individuals. Absence of hrHPV cfDNA detection does not rule out an HPV-associated malignancy, precursor lesion, or HPV infection. Mutations in primer/probe binding sites may affect assay sensitivity and quantitation, though this is unlikely given inclusion of multiple gene targets. False positive results may be seen in instances of cross-reactivity with rare HPV genotypes. Quantitative values should be interpreted with caution, as biological, pre-analytical, and analytical variability can all contribute to assay imprecision; in general, changes should not be interpreted as significant unless greater than a three-fold difference. The clinical performance characteristics of this assay have not been evaluated for cancer screening, minimal residual disease testing, or for patients with malignancies other than oropharyngeal squamous cell carcinoma. Results should be evaluated in the context of clinical history, imaging, exam, and other laboratory findings. If results are incongruent with history, recommend submitting a new specimen for re-testing by this or another method. **Clinical Information:** While cervical carcinoma incidence in the United States has been declining since the 1990s, rates of oropharyngeal squamous cell carcinoma (OPSCC) continue to increase. High-risk human papillomavirus (hrHPV) status in OPSCC significantly influences prognosis and treatment. Recent studies have identified plasma cell-free hrHPV DNA (cfDNA) as an important biomarker for OPSCC disease recurrence. HPV-16 is overwhelmingly the most prevalent HPV type involved in OPSCC, accounting for >85% of cases, followed by HPV-35, HPV-33, HPV-18, HPV-45, and others. This assay is a lab-developed quantitative real-time PCR that simultaneously targets 11 different amplicons specific to HPV-18, performed on plasma. CfDNA is extracted from 4 mL of EDTA plasma using the Qiagen EZ2 Connect MDx ccfDNA kit. HPV-18 DNA is subsequently amplified on a Biorad CFX Opus Dx Real Time PCR system. Human DNA is also amplified as an internal control, and distinguished from HPV signal using different fluorophore-tagged hydrolysis probes. The assay is calibrated against NIBSC WHO international standard for HPV-18, and reported in international units (IU)/mL of plasma. **Specimen Requirement:** 20 mL of Blood from a White PPT EDTA tube; Minimum: 0.8 mL; Specimen sharing is permitted among HBVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is requested, regardless of whether 1, 2, 3, or all 4 tests are ordered. The absolute minimum volume on which testing can be performed is 4 mL of plasma (approximately 8 mL of whole blood).; Container Sharing: Yes; Transport Temperature: Centrifuge, aliquot and refrigerate.; Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for lavender-top EDTA tubes, or 1,300 RCF for white-top PPT tubes, for a minimum of 10 minutes) within 6 hours of collection. *(continued on page 10)*	11/17/26

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Human Papillomavirus (HPV) Type 18, Quantitative PCR, Plasma Cell Free DNA *(Continued from page 9)*		**Specimen Requirement (continued):** Plasma must be aliquoted first if sample is to be frozen. Specimen sharing is permitted among HPVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is sufficient, regardless of whether 1, 2, 3, or all 4 tests are ordered. *OR* 20 mL of Blood from a Lavender EDTA tube; Minimum: 0.8 mL; Specimen sharing is permitted among HBVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is requested, regardless of whether 1, 2, 3, or all 4 tests are ordered. The absolute minimum volume on which testing can be performed is 4 mL of plasma (approximately 8 mL of whole blood).; Container Sharing: Yes; Transport Temperature: Centrifuge, aliquot and refrigerate.; Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for lavender-top EDTA tubes, or 1,300 RCF for white-top PPT tubes, for a minimum of 10 minutes) within 6 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Specimen sharing is permitted among HPVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is sufficient, regardless of whether 1, 2, 3, or all 4 tests are ordered. **Stability:** Ambient: 24 hours Refrigerated: 7 days Frozen: 30 days **Methodology:** Polymerase Chain Reaction (PCR), Quant **Reference Range:** HPV Type 18 DNA, Plasma HPV Type 18 DNA, Plasma, IU/mL **Days Performed:** 1 day per week; 7:00 am–3:30 pm **Reported:** 7–10 days **CPT:** 87799x1	11/17/26
Human Papillomavirus (HPV) Type 31/33/35/58, Quantitative PCR, Plasma Cell Free DNA	HPVQOA	**Clinical Limitation:** Detection of hrHPV cfDNA is not diagnostic of cancer or cancer recurrence, and can be observed rarely in immunocompromised individuals. Absence of hrHPV cfDNA detection does not rule out an HPV-associated malignancy, precursor lesion, or HPV infection. Mutations in primer/probe binding sites may affect assay sensitivity and quantitation, though this is unlikely given inclusion of multiple gene targets. False positive results may be seen in instances of cross-reactivity with rare HPV genotypes. Quantitative values should be interpreted with caution, as biological, pre-analytical, and analytical variability can all contribute to assay imprecision; in general, changes should not be interpreted as significant unless greater than a three-fold difference. The clinical performance characteristics of this assay have not been evaluated for cancer screening, minimal residual disease testing, or for patients with malignancies other than oropharyngeal squamous cell carcinoma. Results should be evaluated in the context of clinical history, imaging, exam, and other laboratory findings. If results are incongruent with history, recommend submitting a new specimen for re-testing by this or another method **Clinical Information:** While cervical carcinoma incidence in the United States has been declining since the 1990s, rates of oropharyngeal squamous cell carcinoma (OPSCC) continue to increase. High-risk human papillomavirus (hrHPV) status in OPSCC significantly influences prognosis and treatment. Recent studies have identified plasma cell-free hrHPV DNA (cfDNA) as an important biomarker for OPSCC disease recurrence. HPV-16 is overwhelmingly the most prevalent HPV type involved in OPSCC, accounting for >85% of cases, followed by HPV-35, HPV-33, HPV-18, HPV-45, and others. This assay is a lab-developed quantitative real-time PCR that simultaneously targets 5 different amplicons specific to HPV-31, 5 amplicons specific to HPV-33, 5 amplicons specific to HPV-35, and 4 amplicons specific to HPV-58, performed on plasma. The four HPV types included in this assay are not distinguished from each other. CfDNA is extracted from 4 mL of EDTA plasma using the Qiagen EZ2 Connect MDx ccfDNA kit. HPV-31/33/35/58 DNA is subsequently amplified on a Biorad CFX Opus Dx Real Time PCR system. Human DNA is also amplified as an internal control, and distinguished from HPV signal using different fluorophore-tagged hydrolysis probes. The assay is calibrated against NIBSC WHO international standard for HPV-33, and reported in international units (IU)/mL of plasma. *(continued on page 11)*	11/17/26

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Human Papillomavirus (HPV) Type 31/33/35/58, Quantitative PCR, Plasma Cell Free DNA *(Continued from page 10)*		**Specimen Requirement:** 20 mL of Blood from a White PPT EDTA tube; Minimum: 0.8 mL; Specimen sharing is permitted among HBVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is requested, regardless of whether 1, 2, 3, or all 4 tests are ordered. The absolute minimum volume on which testing can be performed is 4 mL of plasma (approximately 8 mL of whole blood).; Container Sharing: Yes; Transport Temperature: Centrifuge, aliquot and refrigerate.; Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for lavender-top EDTA tubes, or 1,300 RCF for white-top PPT tubes, for a minimum of 10 minutes) within 6 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Specimen sharing is permitted among HPVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is sufficient, regardless of whether 1, 2, 3, or all 4 tests are ordered. *OR* 20 mL of Blood from a Lavender EDTA tube; Minimum: 0.8 mL; Specimen sharing is permitted among HBVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is requested, regardless of whether 1, 2, 3, or all 4 tests are ordered. The absolute minimum volume on which testing can be performed is 4 mL of plasma (approximately 8 mL of whole blood).; Container Sharing: Yes; Transport Temperature: Centrifuge, aliquot and refrigerate.; Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for lavender-top EDTA tubes, or 1,300 RCF for white-top PPT tubes, for a minimum of 10 minutes) within 6 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Specimen sharing is permitted among HPVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is sufficient, regardless of whether 1, 2, 3, or all 4 tests are ordered. **Stability:** Ambient: 24 hours Refrigerated: 7 days Frozen: 30 days **Methodology:** Polymerase Chain Reaction (PCR), Quant **Reference Range:** HPV Type 31/33/35/58 DNA, Plasma HPV Type 31/33/35/58 DNA, Plasma, IU/mL **Days Performed:** 1 day per week; 7:00 am–3:30 pm **Reported:** 7–10 days **CPT:** 87799x1	11/17/26
Human Papillomavirus (HPV) Type 45/51/52, Quantitative PCR, Plasma Cell Free DNA	HPVQOB	**Clinical Limitation:** Detection of hrHPV cfDNA is not diagnostic of cancer or cancer recurrence, and can be observed rarely in immunocompromised individuals. Absence of hrHPV cfDNA detection does not rule out an HPV-associated malignancy, precursor lesion, or HPV infection. Mutations in primer/probe binding sites may affect assay sensitivity and quantitation, though this is unlikely given inclusion of multiple gene targets. False positive results may be seen in instances of cross-reactivity with rare HPV genotypes. Quantitative values should be interpreted with caution, as biological, pre-analytical, and analytical variability can all contribute to assay imprecision; in general, changes should not be interpreted as significant unless greater than a three-fold difference. The clinical performance characteristics of this assay have not been evaluated for cancer screening, minimal residual disease testing, or for patients with malignancies other than oropharyngeal squamous cell carcinoma. Results should be evaluated in the context of clinical history, imaging, exam, and other laboratory findings. If results are incongruent with history, recommend submitting a new specimen for re-testing by this or another method. **Clinical Information:** While cervical carcinoma incidence in the United States has been declining since the 1990s, rates of oropharyngeal squamous cell carcinoma (OPSCC) continue to increase. High-risk human papillomavirus (hrHPV) status in OPSCC significantly influences prognosis and treatment. Recent studies have identified plasma cell-free hrHPV DNA (cfDNA) as an important biomarker for OPSCC disease recurrence. HPV-16 is overwhelmingly the most prevalent HPV type involved in OPSCC, accounting for >85% of cases, followed by HPV-35, HPV-33, HPV-18, HPV-45, and others. *(continued on page 12)*	11/17/26

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Human Papillomavirus (HPV) Type 45/51/52, Quantitative PCR, Plasma Cell Free DNA *(Continued from page 11)*		**Clinical Information (Continued):** This assay is a lab-developed quantitative real-time PCR that simultaneously targets 5 different amplicons specific to HPV-45, 4 amplicons specific to HPV-51, and 6 amplicons specific to HPV-52, performed on plasma. The three HPV types included in this assay are not distinguished from each other. CfDNA is extracted from 4 mL of EDTA plasma using the Qiagen EZ2 Connect MDx ccfDNA kit. HPV-45/51/52 DNA is subsequently amplified on a Biorad CFX Opus Dx Real Time PCR system. Human DNA is also amplified as an internal control, and distinguished from HPV signal using different fluorophore-tagged hydrolysis probes. The assay is calibrated against NIBSC WHO international standard for HPV-45, and reported in international units (IU)/mL of plasma. **Specimen Requirement:** 20 mL of Blood from a White PPT EDTA tube; Minimum: 0.8 mL; Specimen sharing is permitted among HBVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is requested, regardless of whether 1, 2, 3, or all 4 tests are ordered. The absolute minimum volume on which testing can be performed is 4 mL of plasma (approximately 8 mL of whole blood).; Container Sharing: Yes; Transport Temperature: Centrifuge, aliquot and refrigerate.; Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for lavender-top EDTA tubes, or 1,300 RCF for white-top PPT tubes, for a minimum of 10 minutes) within 6 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Specimen sharing is permitted among HPVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is sufficient, regardless of whether 1, 2, 3, or all 4 tests are ordered. *OR* 20 mL of Blood from a Lavender EDTA tube; Minimum: 0.8 mL; Specimen sharing is permitted among HBVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is requested, regardless of whether 1, 2, 3, or all 4 tests are ordered. The absolute minimum volume on which testing can be performed is 4 mL of plasma (approximately 8 mL of whole blood).; Container Sharing: Yes; Transport Temperature: Centrifuge, aliquot and refrigerate.; Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for lavender-top EDTA tubes, or 1,300 RCF for white-top PPT tubes, for a minimum of 10 minutes) within 6 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Specimen sharing is permitted among HPVQ16, HPVQ18, HPVQOA, and HPVQOB. A single collection of 20 mL whole blood (yielding approximately 10 mL plasma) is sufficient, regardless of whether 1, 2, 3, or all 4 tests are ordered. **Stability:** Ambient: 24 hours Refrigerated: 7 days Frozen: 30 days **Methodology:** Polymerase Chain Reaction (PCR), Quant **Reference Range:** HPV Type 45/51/52 DNA, Plasma HPV Type 45/51/52 DNA, Plasma, IU/mL **Days Performed: 1** day per week; 7:00 am–3:30 pm **Reported:** 7–10 days **CPT:** 87799x1	11/17/26

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Gastric Occult Blood	FGSTRO	This test will no longer be performable.	10/20/26
ORGANISM ID NOCARDIA	LAB1141	Test will no longer be performable. Recommend replacement is Organism Identification, Aerobic (OIDAER)	9/15/26