Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • July 2024

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
8	7AlphaC4			■									
2	Adenovirus by Qualitative PCR		■			■	■						
2	Anaerobe Culture						■						
2	Bilirubin, Direct	■	■					■					
2	Bilirubin, Fractionated							■					
2	Clonazepam as Metabolite, Urine		■			■	■	■					
3–4	COVID & Influenza A/B & RSV PCR, Routine		■			■	■	■		■		■	
9	COVID & Influenza A/B NAAT, Routine				■								
9	COVID NAAT, Lower Respiratory, Routine				■								
9	COVID NAAT, Upper Respiratory, Routine				■								
9	Cystinuria Profile, Quantitative 24 Hour Urine				■								
9	DNA Autoantibodies, Double Stranded				■								
4–5	Expanded Respiratory Pathogen Panel by PCR, Routine		■			■	■	■		■		■	
9	Expanded Respiratory Pathogen Panel by PCR, (with COVID) Expedited				■								
9	FLT3 ITD and TKD Mutation Detection by PCR				■								
6	Hepatic Function Panel							■					
6	HIV 1 Drug Resistance by Next Generation Sequencing					■							■
8	Hops, IgE allergen			■									
6	Lorazepam					■	■			■	■	■	■
6	Lupus Anticoagulant Diagnostic Interpretive Panel					■							

Test Update Page #		Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT
7	Pancreastatin					■	■		■	■	■	■	■
7	PNH Panel by FCM					■	■					■	
9	Prometheus Crohn's Prognostic				■								
9	Protein C Immunologic				■								
7	Quetiapine					■	■		■	■	■	■	
9	VW Multimer Panel				■								

Test Changes

Test Name	Order Code	Change	Effective Date
Adenovirus by Qualitative PCR	ADEPCR	**Name:** Previously Adenovirus PCR **Clinical Information:** Use to detect adenovirus groups A-F; **does not quantify viral load.** **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Frozen; Transfer to standard aliquot tube and freeze. *OR* 1 mL plasma from EDTA (Lavender) tube; Transfer to standard aliquot tube and freeze. *OR* 1 mL sputum in sterile container; Frozen; Specimen source required *OR* tissue in sterile container; Frozen; Transfer tissue to sterile container and freeze immediately. Specimen source required. Do not send tissues in optimal cutting temperature compound. *OR* 1 mL bronch (BAL) in sterile container; Frozen; Specimen source required *OR* 1 mL nasopharyngeal swab in viral transport media; Frozen; Specimen source required *OR* 1 mL cerebrospinal (CSF) in sterile container; Frozen; Specimen source required *OR* 1 mL whole blood in EDTA (Lavender) tube; Refrigerated; Do not freeze. *OR* **conjunctival swab in viral transport media; Frozen; Conjunctival swabs in viral transport media are acceptable for testing with a disclaimer.** *OR* **1 mL random urine in sterile container; Frozen; Transfer to standard aliquot tube and freeze.**	8/27/24
Anaerobe Culture	ANACUL	**Specimen Requirement:** 0.5 mL–10 mL body fluid in **sterile container;** Ambient; Acceptable alternate collection device: eSwab collection and transport system. Collection with eSwab is acceptable if fluid or tissue cannot be collected. *OR* biopsy in **sterile container**; Ambient *OR* surgical tissue in **sterile container**; Ambient	effective immediately
Bilirubin, Direct	DBIL	**For interface clients only–Test build may need to be modified** **Name:** Previously Bilirubin, Conjugated **Reference Range:** Bilirubin**, Direct:** < 0.2 mg/dL	8/27/24
Bilirubin, Fractionated	BILIFR	**For interface clients only–Test build may need to be modified** **Includes:** Total Bilirubin **Indirect Bilirubin** **Direct Bilirubin**	8/27/24
Clonazepam as Metabolite, Urine	UCLONO	**For interface clients only–Test build may need to be modified** **Name:** Previously Clonazepam & Metabolite, Urine **Includes:** 7-Amino Clonazepam *Clonazepam has been removed* **Clinical Information:** *clinical information has been removed* **Specimen Requirement: 1** mL random urine in clean container (No preservatives); Refrigerated	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
COVID & Influenza A/B & RSV PCR, Routine	CVFLRS	**For interface clients only–Test build may need to be modified** **Name:** Previously COVID & Influenza A/B & RSV NAAT, Routine **For Cleveland Clinic providers, note that this test can only be ordered from an ambulatory setting, unless it is for a lower respiratory specimen. Inpatient/ED providers should order the expedited version of this test (SQEXCFR) on upper respiratory specimens.** **Clinical Limitation: For full limitations, refer to the assay instructions for use available on the manufacturer's website. The most important limitations are summarized as follows.** **In co-infections, there may be competitive interference causing loss of analytical sensitivity for one or more targets. Recent administration of intranasal vaccines (ie. FluMist) may lead to false positive results. As with any nucleic acid amplification test, positive results do not rule out coinfection with other organisms, detected organisms may not be the definite cause of disease, and negative results do not rule out infection.** **Clinical Information:** Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 (agent of COVID-19), influenza A (Flu A), influenza B (Flu B), and respiratory syncytial virus (RSV) can be similar. These viruses are responsible for significant morbidity and mortality, especially in young, immunocompromised, and elderly patients. Accurate and timely diagnosis and differentiation between these viruses can help guide appropriate antiviral therapy, decrease inappropriate use of antibiotics, and assist in infection prevention/control efforts. The FDA-cleared Panther Fusion SARS-CoV-2/Flu A/B/RSV assay is a fully automated multiplexed reverse-transcription real-time polymerase chain reaction (RT-PCR) test intended to aid in the differential diagnosis of SARS-CoV-2, Flu A, Flu B, and RSV infections in humans. It is not intended to detect influenza C virus infections. SARS-CoV-2, Flu A, Flu B, and RSV are generally detectable in nasopharyngeal (NP) swabs during the acute phase of infection. The assay has been modified and validated to additionally accept nasal swabs, lower respiratory specimens (bronchoalveolar lavage, tracheal aspirate, sputum), and swabs in alternative transport media such as liquid Amies (eSwab) and saline. Nasal swabs demonstrate modestly decreased analytical sensitivity compared to NP swabs in some studies, but can be useful in cases where a patient is unable or unwilling to have an NP swab collected. Some individuals can have disease isolated to the lower respiratory tract; consider submitting these specimen types in patients with evidence of lower respiratory disease. **Specimen Requirement: 3 mL** nasopharyngeal swab in universal transport media (UTM); Refrigerated; 1. Tilt patient's head back 70 degrees. 2. Gently and slowly insert a **mini-tipped flocked** swab with a flexible shaft through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. 3. Gently rub and roll the swab. 4. Leave swab in place for several seconds to absorb secretions. 5. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril. 6. Place swab, tip first, into the transport tube provided. Break the swab shaft at the score line, discard the top portion of the stem, and close the cap. *OR* **3 mL** swab(s) in saline; Refrigerated; Sterile saline may be used to collect swabs if UTM cannot be sourced. *OR* **1 mL** swab(s) in E-swab; Refrigerated; E-swabs **in liquid amies** may be used **to collect swabs** if UTM cannot be sourced. *OR* **3 mL** swab(s) in viral transport media; Refrigerated; Viral transport media (including VTM, M4RT, M5, or M6) may be used **to collect swabs** if UTM cannot be sourced. *OR* **3 mL** nasal in universal transport media (UTM); Refrigerated; 1. Insert the entire collection tip of the **regular-tip flocked** swab **with a rigid shaft (ie. Orcale 1063581)** 1/2-3/4 of an inch or 1-1.5 cm inside the nostril. 2. Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 4 times. 3. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab. 4. Repeat in the other nostril using the same swab. 5. Place swab, tip first, into the transport tube provided. Break the swab shaft at the score line, discard the top portion of the stem, and close the cap. *OR* 1 mL bronch (BAL) in sterile container; Refrigerated; Collect 2-3 mL into a sterile, leak-proof, screw-cap collection cup or sterile dry container. **If aliquotting is necessary, sterile aliquot tubes must be used. Do not dilute with transport media.** *(continued on page 4)*	8/27/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
COVID & Influenza A/B & RSV PCR, Routine *(continued from page 3)*	CVFLRS	**Specimen Requirement (continued):** *OR* 1 mL sputum in sterile container; Refrigerated; **Before collecting a sputum,** have the patient rinse **their** mouth with water **and discard the rinse fluid. Ask the patient to breathe deeply for three or four breaths, then hold their breath and** expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap collection cup or sterile dry container. **Induced sputum is also acceptable. If aliquotting is necessary, sterile aliquot tubes must be used. Do not dilute with transport media.** *OR* 1 mL tracheal aspirate in sterile container; Refrigerated; Collect 2-3 mL into a sterile, leak-proof, screw-cap collection cup or sterile dry container. **If aliquotting is necessary, sterile aliquot tubes must be used. Do not dilute with transport media.** **Stability:** Ambient: **24 hours** Refrigerated: 96 hours Frozen: 30 days **Methodology: Reverse Transcription/Polymerase Chain Reaction (RT/PCR)** **Reference Range:** **SARS-CoV-2 (Agent of** COVID-19**) RNA: Not detected** Influenza A **RNA: Not detected** Influenza B **RNA: Not detected** **Respiratory syncytial virus** (RSV) **RNA: Not detected**	8/27/24
Expanded Respiratory Pathogen Panel by PCR, Routine	RPPCR	**For interface clients only–Test build may need to be modified** **Name:** Previously Expanded Respiratory Pathogen Panel by PCR (with COVID), Routine **For Cleveland Clinic providers, note that this test can only be ordered from an ambulatory setting, unless it is for a lower respiratory specimen. Inpatient/ED providers should order the expedited version of this test (SQRPRACV) on upper respiratory specimens. Note that this test should rarely be ordered in the outpatient setting. Patients who may benefit include immunocompromised patients, those with severe underlying respiratory comorbidities, and those in whom testing may help avoid hospital admission. The test is very expensive, and if not covered by insurance, the patient will incur a substantial charge. Recommend discussing risks and benefits with the patient, and considering seeking insurance preauthorization.** **Clinical Limitation: For full limitations, refer to the assay instructions for use available on the manufacturer's website. The most important limitations are summarized as follows. This assay has lower sensitivity than others for detecting Bordetella pertussis. If pertussis infection is suspected, a dedicated B.pertussis molecular test should be ordered. Cross reactivity has been reported between B. bronchiseptica/parapertussis with B. pertussis, and between B. pertussis and Human rhinovirus/enterovirus. Recent administration of intranasal vaccines (ie. FluMist) may lead to false positive results. As with any nucleic acid amplification test, positive results do not rule out coinfection with other organisms, detected organisms may not be the definite cause of disease, and negative results do not rule out infection. Some patients may experience financial toxicity with this expanded multiplex panel, as it is variably reimbursed by insurance.** **Respiratory pathogens cause acute local and systemic disease, with the most severe cases occurring in children, the elderly, and immunocompromised individuals. Due to the similarity of diseases caused by many viruses and bacteria, diagnosis based on clinical symptoms alone is difficult. Identification of potential causative agents provides data to aid providers in determining appropriate patient treatment or triage, and public health response for disease containment. The BioFire Respiratory Panel 2.1 (RP2.1) is a multiplexed nucleic acid test that qualitatively detects and identifies nucleic acids from the following viral and bacterial targets from respiratory specimens: SARS-CoV-2 (Agent of COVID-19); Influenza A and subtypes H1, H1N1 2009, H3; Influenza B; Respiratory syncytial virus (RSV); Human metapneumovirus (hMPV); Human rhinovirus/enterovirus; Adenovirus; Parainfluenza 1-4; Coronaviruses 229E, OC43, NL63, HKU1; Chlamydia pneumoniae; Mycoplasma pneumoniae; and Bordetella pertussis and parapertussis. These respiratory pathogens are assayed in a single pouch through array-based localization and endpoint melting curve data analysis. The assay is FDA-cleared for nasopharyngeal swab testing, and has been modified and validated as a lab-developed test for lower respiratory specimens including bronchoalveolar lavage, sputum, and tracheal aspirate. B. pertussis and parapertussis targets are not reported for lower respiratory specimens.** *(continued on page 5)*	8/27/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Expanded Respiratory Pathogen Panel by PCR, Routine *(continued from page 4)*	RPPCR	**Specimen Requirement: 3 mL** nasopharyngeal swab in Universal Transport Media (UTM); Refrigerated; **1. Tilt patient's head back 70 degrees. 2. Gently and slowly insert a mini-tipped flocked swab with a flexible shaft through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. 3. Gently rub and roll the swab. 4. Leave swab in place for several seconds to absorb secretions. 5. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril. 6. Place swab, tip first, into the transport tube provided. Break the swab shaft at the score line, discard the top portion of the stem, and close the cap.** *OR* 1 mL bronch (BAL) in sterile container; Refrigerated; **Collect 2-3 mL into a sterile, leak-proof, screw-cap collection cup or sterile dry container.** If aliquotting is necessary, sterile aliquot tubes must be used. Do not dilute with **transport media.** *OR* **1 mL** induced sputum in sterile container; Refrigerated; **Before collecting a sputum, have the patient rinse their mouth with water and discard the rinse fluid. Ask the patient to breathe deeply for three or four breaths, then hold their breath and expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap collection cup or sterile dry container. Induced sputum is also acceptable.** If aliquotting is necessary, sterile aliquot tubes must be used. Do not dilute with **transport media.** *OR* **1 mL tracheal aspirate in sterile container; Refrigerated; Collect 2-3 mL into a sterile, leak-proof, screw-cap collection cup or sterile dry container. If aliquotting is necessary, sterile aliquot tubes must be used. Do not dilute with transport media.** *OR* **3 mL swab in viral transport media; Refrigerated; Viral transport media (including VTM, M4RT, M5, or M6) may be used to collect swabs if UTM cannot be sourced.** *OR* **Specimen Requirement (continued): 3 mL swab(s) in saline; Refrigerated; Sterile saline may be used to collect swabs if UTM cannot be sourced.** *OR* **1 mL swab(s) in E-swab; Refrigerated; E-swabs in liquid amies may be used to collect swabs if UTM cannot be sourced.** **Stability:** Ambient: 4 hours for nasopharyngeal swabs; **24 hours for lower respiratory specimens (BAL, sputum, tracheal aspirate)** Refrigerated: 3 days for nasopharyngeal swabs; 7 days for lower respiratory specimens (BAL, sputum, **tracheal aspirate**) Frozen: 30 days **Methodology: Reverse Transcription/Polymerase Chain Reaction (RT/PCR)** **Reference Range:** Adenovirus **DNA: Not detected** Coronavirus 229E **RNA: Not detected** Coronavirus HKU1 **RNA: Not detected** Coronavirus NL63 **RNA: Not detected** Coronavirus OC43 **RNA: Not detected** **SARS-CoV-2 (Agent of** COVID-19**) RNA: Not detected** **Human** metapneumovirus **(hMPV) RNA: Not detected** **Human** rhinovirus/enterovirus **RNA: Not detected** Influenza A **RNA: Not detected** Influenza A H1 **RNA: Not detected** Influenza A H3 **RNA: Not detected** Influenza A H1N1 2009 **RNA: Not detected** Influenza B **RNA: Not detected** Parainfluenza 1 **RNA: Not detected** Parainfluenza 2 **RNA: Not detected** Parainfluenza 3 **RNA: Not detected** Parainfluenza 4 **RNA: Not detected** **Respiratory syncytial virus** (RSV) **RNA: Not detected** **Bordetella parapertussis DNA: Not detected** **Bordetella pertussis DNA: Not detected** **Chlamydia** pneumoniae **DNA: Not detected** **Mycoplasma** pneumoniae **DNA: Not detected**	8/27/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatic Function Panel	HFP	**For interface clients only–Test build may need to be modified** **Includes:** Albumin Bilirubin, Total Bilirubin, **Direct** Alkaline Phosphatase AST ALT Protein, Total	8/27/24
HIV 1 Drug Resistance by Next Generation Sequencing	HIVNGS	**Special Information:** Please submit most recent viral load and test date, if available. Serum and heparinized specimens are unacceptable**. This test is New York State approved.** **CPT: 87900;** 87901; 87906	effective immediately
Lorazepam	LORAZE	**Special Information: Specimens collected in gel separator tubes and hemolyzed specimens will be rejected. This test is New York state approved.** **Clinical Information: This test is useful to optimize dosing and monitor patient adherence.** **Specimen Requirement: 2 mL plasma from potassium oxalate/sodium fluoride (Gray) tube; Minimum: 1 mL; Refrigerated; Do not use gel separator tubes. Separate plasma from cells within 2 hours of collection and transfer to standard aliquot tube.** *OR* 2 mL plasma from sodium heparin (Green) tube; Minimum: **1** mL; Refrigerated; Do not use **gel** separator tubes. **Separate plasma from cells within 2 hours of collection and transfer to standard aliquot tube.** *OR* **2 mL plasma from EDTA (Lavender) tube; Minimum: 1 mL; Refrigerated; Do not use gel separator tubes. Separate plasma from cells within 2 hours of collection and transfer to standard aliquot tube.** *OR* 2 mL serum from no additive (Red) tube; Minimum: **1** mL; Refrigerated; Do not use **gel** separator tubes. **Separate serum from cells within 2 hours of collection and transfer to standard aliquot tube.** **Stability:** Ambient: **After separation from cells: 1 week** Refrigerated: **After separation from cells: 2 weeks** Frozen: **After separation from cells: 3 years (Avoid repeated freeze/thaw cycles)** **Reference Range:** **Dose-Related Range:** 50-240 ng/mL**–Dose (Adult): 1–10 mg/d** **Toxic: Greater than 300 ng/mL** **Days Performed: Tue, Fri** **Reported: 2–8** days **CPT:** 80346/**G0480**	8/27/24
Lupus Anticoagulant Diagnostic Interpretive Panel	LUPUSP	**Special Information:** 3.2% sodium citrate is the preferred anticoagulant recommended by NCCLS. Patient preparation: Discontinue heparin therapy for 2 days prior to collection. If tests are abnormal, the following tests may be ordered and billed: PTT Mixing Study (85730), Factor II (85210), Factor V (85220), Factor VII (85230), Factor X (85260), Factor VIII (85247), Von Willebrand Factor Antigen (85246), Ristocetin Co-factor (85245), Factor IX Assay (85250), Factor XI Assay (85270), Factor XII Assay (85280), Reptilase Time (85635), D-Dimer (85379), Fibrinogen Ag (85385), Fibrinogen (85384), Bethesda Assay (85335), Factor VIII Chromogenic (85240), **Antithrombin Assay (85300), Protein C Functional (85303), Protein S Clottable (85306), and APC Resistance (85307).** Sample must be accompanied by the completed Clinical History Form for Hemostasis and Thrombosis Evaluation.	8/27/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Pancreastatin	PANCST	**Special Information:** Patient **must be fasting 10-12 hours and should avoid** any medications that may influence insulin levels for 48 hours, if possible. **Separate specimens must be submitted when multiple tests are ordered. CRITICAL FROZEN. Thawed specimens will be rejected.** This test is New York DOH approved. **Clinical Information: This test can be useful to diagnose and predict disease recurrence, potential outcome, and efficacy of therapy in neuroendocrine tumors (NETs). Pancreastatin plays a role in human intermediary metabolism and disease and qualitative hereditary alterations in the primary structure may give rise to individual differences in glucose disposition.** **Specimen Requirement: 2 mL serum from serum separator (Gold) tube; Critical Frozen; Patient must be fasting 10-12 hours and should avoid any medications that may influence insulin levels for 48 hours, if possible. Allow specimen to clot for 2 hours at room temperature. Separate serum from cells and transfer to standard aliquot tube and freeze. Separate specimens must be submitted when multiple tests are ordered.** **Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: **6 months** **Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)** **Reference Range: Refer to report** **Days Performed: Varies** **Reported:** 8–**11** days **CPT: 86316**	8/27/24
PNH Panel by FCM	PNHPNL	**Special Information:** Do not draw on Fridays, weekends or holidays. Specimens greater than 48 hours old will be rejected. **Specimen Requirement:** 4 mL whole blood in EDTA (Lavender) tube; Ambient; Peripheral blood **samples to be** delivered to the flow cytometry lab within 24 hours of draw time. Samples greater than 48 hours old will be rejected. Do not draw on Fridays, weekends or holidays. *OR* **4 mL whole blood in EDTA (Lavender) tube; Refrigerated collection and transport; Peripheral blood samples to be delivered to the flow cytometry lab within 24 hours of draw time. Samples greater than 48 hours old will be rejected. Do not draw on Fridays, weekends or holidays.** **Stability:** Ambient: 48 hours Refrigerated: **48 hours** Frozen: Unacceptable	7/16/24
Quetiapine	QUETIA	**Special Information: Unspun specimens and gel separator tubes will be rejected. This test is New York state approved.** **Clinical Information: This test is useful to optimize drug therapy and monitor patient adherence. Quetiapine is an antipsychotic drug indicated for the treatment of schizophrenia and bipolar disorder. The pharmacokinetics of quetiapine are influenced by drug-drug interactions that may inhibit or induce CYP3A4 metabolism. Adverse effects may include somnolence, hypotension, dizziness, fatigue, constipation, weight gain.** **Specimen Requirement: 1** mL serum from no additive (Red) top; Minimum: **0.5** mL; Refrigerated; Do not use serum separator tubes. **Separate serum from cells within 2 hours and transfer to standard aliquot tube.** *OR* **1 mL plasma from EDTA (Lavender) tube; Minimum: 0.5 mL; Refrigerated; Do not use plasma separator tubes. Separate plasma from cells within 2 hours and transfer to standard aliquot tube.** **Stability:** Ambient: **24 hours** Refrigerated: **2 weeks** Frozen: **4 months** **Methodology:** Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** **Therapeutic Range: 100-1000 ng/mL** **Toxic: Greater than 1000 ng/mL** **Days Performed: Wed** **Reported: 2–9** days **CPT:** 80342/**G0480**	8/27/24

New Tests

Test Name	Order Code	Change	Effective Date
7AlphaC4	7ALPC4	**Special Information:** Collection prior to 9am after overnight fast. **Clinical Information:** This test is useful as a surrogate measure of stool bile acids (BA) and elevated levels may be diagnostic for bile acid malabsorption (BAM), also known as bile acid diarrhea (BAD). Overall, the data indicates that fasting serum C4 has excellent negative predictive value when normal in ruling out bile acid diarrhea. Key limitations of the assay include the need to use first morning fasting samples (before 9AM) because of diurnal variation of serum C4 levels. Confounding of the fasting serum C4 data interpretation can arise because of hypertriglyceridemia, alcohol intake and liver disease. **Specimen Requirement:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.4 mL; Frozen; Collect prior to 9am after overnight fast. Separate serum from cells within 2 hours of collection and transfer to standard aliquot tube. *OR* 0.5 mL serum from no additive (Red) tube; Minimum: 0.4 mL; Frozen; Collect prior to 9am after overnight fast. Separate serum from cells within 2 hours of collection and transfer to standard aliquot tube. *OR* 0.5 mL plasma from EDTA (Lavender) tube; Minimum: 0.4 mL; Frozen; Collect prior to 9am after overnight fast. Separate plasma from cells within 2 hours of collection and transfer to standard aliquot tube. *OR* 0.5 mL plasma from sodium or lithium heparin (Green) tube; Minimum: 0.4 mL; Frozen; Collect prior to 9am after overnight fast. Separate plasma from cells within 2 hours of collection and transfer to standard aliquot tube. **Stability:** Ambient: After separation from cells: 24 hours Refrigerated: After separation from cells: 9 days Frozen: After separation from cells: 9 days **Methodology:** Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Days Performed:** Varies **Reported:** 11–12 days **CPT:** 82542	7/30/24
Hops, IgE allergen	HPSIGE	**Special Information:** Lipemic samples may be rejected. This test is New York State approved. **Specimen Requirement:** 0.5 mL serum from no additive (Red) tube; Minimum 0.34 mL; Frozen **Stability:** Ambient: 4 weeks Refrigerated: 4 weeks Frozen: 6 months **Methodology:** Fluorescent Enzyme Immunoassay (FEIA) by ImmunoCAP **Reference Range:** Hop/Fuit cone IgE: < 0.35 kU/L Hop/Fuit Cone IgE Class: Class Interpretation: 0 = < 0.10 kU/L, Negative Class Interpretation: 0/1 = 0.10–0.34 kU/L, Equivocal/Borderline Class Interpretation: 1 = 0.35–0.69 kU/L, Low Positive Class Interpretation: 2 = 0.70–3.49 kU/L, Moderate Positive Class Interpretation: 3 = 3.50–17.49 kU/L, High Positive Class Interpretation: 4 = 17.50–49.99 kU/L, Very High Positive Class Interpretation: 5 = 50.00–99.99 kU/L, Very High Positive Class Interpretation: 6 = > 99.99 kU/L, Very High Positive **Days Performed:** Mon–Fri **Reported:** 2–6 days **CPT:** 86003	effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
COVID & Influenza A/B NAAT, Routine	COVFLU	Test will no longer be orderable. Recommended replacement test is COVID & Influenza A/B & RSV NAAT, Routine (CVFLRS).	8/27/24
COVID NAAT, Lower Respiratory, Routine	ITCOVD	Test will no longer be orderable. Recommended replacement test is COVID & Influenza A/B & RSV NAAT, Routine (CVFLRS).	8/27/24
COVID NAAT, Upper Respiratory, Routine	COVID	Test will no longer be orderable. Recommended replacement test is COVID & Influenza A/B & RSV NAAT, Routine (CVFLRS).	8/27/24
Cystinuria Profile, Quantitative 24 Hour Urine	UCYS24	Test will no longer be orderable. Recommended replacement test is Cystine, Urine Quant (UCYSTD) if only measurement of Cystine is needed. If other analytes included in the current panel are required (Arginine, Lysine, and Ornithine), urine amino acid analysis (UAABI) may be ordered instead.	effective immediately
DNA Autoantibodies, Double Stranded	DSDNA	Test will no longer be orderable. Recommended replacement tests are DNA Antibody with Confirmation (DNA) or DNA Antibody (DNAAB) or Crithidia luciliae (CRITH).	8/27/24
Expanded Respiratory Pathogen Panel by PCR, (with COVID) Expedited	RPRACV	Test will no longer be orderable. Recommended replacement test is Expanded Respiratory Pathogen Panel by PCR, Routine (RPPCR).	8/27/24
FLT3 ITD and TKD Mutation Detection by PCR	FLT3IT	Test will no longer be orderable. Recommended replacement tests are FLT3 ITD Mutation Analysis Blood (F3ITD) or FLT3 ITD Mutation Analysis Bone Marrow (F3ITDM), FLT3 Tyrosine Kinase Domain Analysis Blood (F3TKD) or FLT3 Tyrosine Kinase Domain Mutation, Bone Marrow (F3TKDM), FLT3 Mutation Blood (FLT3PB) or FLT3 Mutation Bone Marrow (F3MRW).	8/27/24
Prometheus Crohn's Prognostic	CROHN	Test will no longer be orderable. There is no recommended replacement.	effective immediately
Protein C Immunologic	PRCAG	Test will no longer be orderable. There is no recommended replacement.	8/27/24
VW Multimer Panel	VWMULP	Test will no longer be orderable. Recommended replacement test is von Willebrand Diagnostic Interpretive Panel (Limited) [VWFPR].	8/27/24