Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • October 2023

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
3	5-Methyltetrahydrofolate					■	■	■	■	■	■	■	
3	Aldosterone/Direct Renin Ratio					■							
12	Allergen, Honey Bee Components IgE			■									
12	Allergen, Honey Bee IgE with Reflex to Components			■									
13	Allergen, Paper Wasp Component IgE			■									
13	Allergen, Paper Wasp IgE with Reflex to Component			■									
13	Allergen, Sesame Seed rSes i 1 Component												■
13	Allergen, Sesame Seed with Component Reflex												■
14	Allergen, Total Venom Panel IgE with Reflex to Components			■									
14	Allergen, Wheat, rTri a 19 Omega-5-gliadin Component												■
14	Allergen, Wheat with Component Reflex												■
14	Allergen, Yellow Jacket (Common Wasp) Components IgE			■									
15	Allergen, Yellow Jacket (Common Wasp) IgE with Reflex to Components			■									
3	Alpha-Galactosidase Enzyme Activity, Leukocytes		■			■					■	■	
3	Alpha-Galactosidase Enzyme Activity, Serum		■								■		
4	Aminolevulinic Acid (ALA) Urine					■	■					■	
17	Aminolevulinic Acid Dehydratase (ALAD), Whole Blood				■								
15–16	COVID & Influenza A/B & RSV NAAT, Routine			■									

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
17	Cross-Linked N-telopeptide, Urine				■								
4	Cryptosporidium & Giardia Antigens by EIA					■							
4	Direct Renin					■							
4	DNA Antibody					■	■	■		■			
4	DNA Antibody with Confirmation					■	■	■		■			
4	Drug Detection Panel, Meconium, Qualitative												■
5	Expanded Respiratory Pathogen Panel by PCR (with COVID), Routine		■					■					
17	Infliximab or Biosimilar Activity and Neutralizing Antibody				■								
17	Infliximab, Serum			■									
17	Maternal Serum Screen, First Trimester, hCG, PAPP-A, NT				■								
17	Mycoplasma pneumoniae IgG				■								
5	Neopterin, CSF					■	■	■	■	■	■	■	
6	Neurotransmitter Metabolites/Amines					■	■	■	■	■	■	■	
6	Osmotic Fragility, Erythrocyte					■	■						
6	Oxalate, Plasma											■	
7	Plasma Thymidine Determination					■		■		■		■	
17	Porphobilinogen (PBG) Deaminase, Erythrocyte				■								
7	Porphobilinogen, Urine Quant					■	■						
17	Porphyrins, Fecal				■								
7	Porphyrins, Fractionation and Quantitation, Urine		■			■	■						
8	Porphyrins, Total, Plasma or Serum					■	■				■		
9	Prenatal Quad Screen					■	■	■	■	■	■	■	
9	Pyridoxal 5 phosphate, CSF					■	■	■	■	■	■	■	
17	Routine Flu A/B & RSV				■								
10	Succinyladenosine, CSF					■	■	■	■	■	■	■	
10–11	Tetrahydrobiopterin & Neopterin, CSF					■	■	■	■	■	■	■	
11	Total Erythrocyte Porphyrins					■	■						

Test Changes

Test Name	Order Code	Change	Effective Date
5-Methyltetrahydro-folate	5MTH	**Includes:** 5-MTHF Result **Special Information: Prior to collecting sample, contact Client Services to obtain sample collection containers consisting of 5 numbered tubes per set. CSF should be collected from the first drop into the containers in the order indicated. Fill each tube to the marked line (0.5 mL in tube 1; 1.0 mL in tubes 2, 3, 4, and 5). Tube #3 contains antioxidants to protect the sample from oxidation. One set of vials is required per patient.** **Clinical Information: Cerebral Folate deficiency** **Specimen Requirement: 4.5** mL cerebrospinal fluid (CSF) in **set of MNG Collection tubes**; Frozen; **CSF should be collected from the first drop into the containers in the order indicated. Fill each tube to the marked line (0.5 mL in tube 1; 1.0 mL in tubes 2, 3, 4, and 5).** Place specimens on ice after collection. **If specimen is blood contaminated, the tubes should immediately be centrifuged (prior to freezing) and the clear CSF transferred to new similarly labeled tubes then frozen ASAP at -80 C. Call Client Services at 800.628.6216 to obtain appropriate specimen collection containers.** *OR* **1 mL cerebrospinal fluid (CSF) in clean container; Frozen; This specimen to be used if 5-MTH is the only CSF Medical Neurogenetics test ordered.** **Stability:** Ambient: Unacceptable Refrigerated: **24 hours** Frozen: Indefinitely **Methodology: High Performance Liquid Chromatography with Electrochemical Detection** **Reference Range:** **0 Months to 6 Months: 40–240 nmol/L** **6 Months to 24 Months: 40–187 nmol/L** **2 Years to 5 Years: 40–150 nmol/L** **5 Years to 10 Years: 40–128 nmol/L** **10 Years to 99 Years: 40–120 nmol/L** **Days Performed: Tue–Fri** **Reported: 15–17** days	effective immediately
Aldosterone/Direct Renin Ratio	ALDREN	**Specimen Requirement:** 2 mL plasma from EDTA (Lavander) tube; Collection Ambient; Transport Ciritical Frozen; Centrifuge and remove plasma from cells within **4** hours of collection. Freeze plasma immediately after separation from cells.	10/10/23
Alpha-Galactosidase Enzyme Activity, Leukocytes	AGALAC	**Name:** Previously Alpha-Galactosidase (Leukocytes) **Special Information:** For optimal isolation of leukocytes, it is recommended that the specimen arrive refrigerated at the performing laboratory within 96 hours of collection to be stabilized. Specimens received after 96 hours could have falsely normal results. Do not collect the day before a major holiday. Specimen should be collected and packaged as close to shipping time as possible. **Grossly hemolyzed specimens will be rejected.** **Clinical Information:** Useful for diagnosing Fabry disease in male patients. Verifying abnormal serum alpha-galactosidase results in male patients with a clinical presentation suggestive of Fabry disease. Results from this assay do not reflect carrier status because of individual variation of alpha-galactosidase enzyme levels. Individuals with pseudodeficiency allelic variants can show reduced alpha-galactosidase A enzyme activity with this assay. Carrier detection using enzyme levels is unreliable in females, and mutation analysis using molecular methods is recommended. **Values below the reference range are consistent with a diagnosis Fabry Disease. When abnormal results are detected, a detailed interpretation is given.** **Stability:** Ambient: **6 days** Refrigerated: **6** days (preferred) Frozen: Unacceptable **Days Performed: Mon, Wed** **Reported:** 6–**10** days	11/9/23
Alpha-Galactosidase Enzyme Activity, Serum	ALPGAL	**Name:** Previously Alpha Galactosidase, Serum **Reported: 9–19** days	11/9/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Aminolevulinic Acid (ALA) Urine	UAMINO	**Special Information:** Patient Prep: Refrain from alcohol consumption 24 hours prior to collection. Specimen preservation with acid or base is discouraged and may cause assay interference. **Record** total volume and collection time interval on transport tube. Unacceptable conditions: Body fluids other than urine. This test is New York DOH approved. **Clinical Information:** Increased ALA concentration is associated with exposure to alcohol, lead and a variety of other agents. Massive elevation of ALA occurs in the acute prophyrias and hereditary tyrosinemia. **If testing for an acute porphyria, please consider ordering PBG, Screen (UPBG). 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 24-hour (well mixed) urine in clean container **(No preservatives)** Refrigerate during collection. Transport Refrigerated; **Patient should refrain from alcohol consumption 24 hours prior to collection.** Transfer 4mL aliquot to a standard transport tube. **Record total volume and collection time interval on specimen and requisition.** *OR* 4 mL random urine in clean container **(No preservatives); Transport Refrigerated; Patient should refrain from alcohol consumption 24 hours prior to collection.** Transfer 4mL aliquot to a standard transport tube. **Stability:** Ambient: Unacceptable Refrigerated: **2 weeks** Frozen: 1 month	11/9/23
Cryptosporidium & Giardia Antigens by EIA	OVAPSC	**Special Information:** Average TAT for this assay is 20 hrs. The Ova and Parasite Screen is a screening test for Giardia lamblia and Cryptosporidium species only. This test **offers rapid qualitative detection as compared to traditional microscopy based tests (OVAP or CRYSPO).** Ideally, fresh stool should be collected and immediately placed into 2 vial system: C&S/Cary-Blair and EcoFix vials. Preserved stool should be transported at ambient and/or refrigerated temperature. Unpreserved stool should not be submitted unless it can be delivered to the laboratory within 6 hours in a clean leakproof container. Unpreserved stool should be transported at either ambient or refrigerated temperature but never frozen. **Confirmatory microscopy based tests can not be performed on Cary-Blair, or C&S.** Interfering substances include barium, bismuth, metamucil, castor oil, mineral oil, or antiamoebic drugs.	11/9/23
Direct Renin	RENIND	**Specimen Requirement:** 1 mL plasma from EDTA (Lavander) tube;Collection Ambient; Transport Ciritical Frozen; Centrifuge and remove plasma from cells within **4** hours of collection. Freeze plasma immediately after separation from cells.	10/10/23
DNA Antibody	DNAAB	**For interface clients only–Test build may need to be modified** **Clinical Information: This test is used as an aid in diagnosis of systemic lupus erythematous in patients with positive anti-nuclear antibody (ANA) test result and for SLE treatment follow up. Clinical correlation is required.** **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Refrigerated *OR* **1 mL serum from no additive (Red) tube** **Reference Range: DNA Antibody (DNAAB): <= 200 IU/mL**	11/9/23
DNA Antibody with Confirmation	DNA	**For interface clients only–Test build may need to be modified** **Clinical Information: This test is used as an aid in diagnosis of systemic lupus erythematous in patients with positive anti-nuclear antibody (ANA) test result and for SLE treatment follow up. Clinical correlation is required.** **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Refrigerated *OR* **1 mL serum from no additive (Red) tube** **Reference Range: DNA Antibody (DNAAB): ≤ 200 IU/mL**	11/9/23
Drug Detection Panel, Meconium, Qualitative	MECDRG	**CPT:** 80326; 80347; 80364; 80355; **80323**	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Expanded Respiratory Pathogen Panel by PCR (with COVID), Routine	RPPCR	**For interface clients only–Test build may need to be modified** **Name:** Previously Expanded Respiratory Pathogen Panel by PCR (without COVID), Routine **Specimen Requirement:** One nasopharyngeal swab; **UTM, VTM, or saline is acceptable.** Refrigerated *OR* 1 mL bronch (BAL) in sterile container; Refrigerated; If aliquotting is necessary, Sterile aliquot tubes must be used. Do not dilute with UTM or VTM *OR* one induced sputum in sterile container; Refrigerated; If aliquotting is necessary, Sterile aliquot tubes must be used. Do not dilute with UTM or VTM **Stability:** Ambient: **Nasopharyngeal Swab: Not acceptable.** Refrigerated: **Nasopharyngeal Swab: Stable for 3 days at 2-8°C Lower Respiratory Samples (BAL, induced sputum):** Stable for 7 days at 2-8°C Frozen: **Nasopharyngeal Swab:** Stable for 12 months at -70°C Lower Respiratory Samples **(BAL, induced sputum):** Stable for 30 days at -70°C **Reference Range:** Adenovirus (ADENO): Negative Coronavirus 229E (CV229E): Negative Coronavirus HKU1 (CVHKU1): Negative Coronavirus NL63 (CVNL63): Negative Coronavirus OC43 (CVOC43): Negative **COVID 19 Result NP (COVNP): Negative for COVID19 (SARS CoV2) by RT-PCR or equivalent method.** H Metapneumovirus (HMPV): Negative Rhino/Enterovirus (RHIENT): Negative Influenza A Virus (FLUARV): Negative Influenza A H1 Virus (FLUAH1): Negative Influenza A H3 Virus (FLUAH3): Negative **Influenza A H1N1 2009 (H1N109): Negative** Influenza B Virus (FLUBRV): Negative Parainfluenza 1 (PIV1): Negative Parainfluenza 2 (PIV2): Negative Parainfluenza 3 (PIV3): Negative Parainfluenza 4 (PIV4): Negative **RSV PCR (PCRRSV): Not Detected** **Bordetella parapertussis (BPARA): Not detected** **Bordetella pertussis (BORDET): Not detected** C. pneumoniae (CLPNEU): Negative M. pneumoniae (MYPNEU): Negative	effective immediately
Neopterin, CSF	NEOCSF	**Special Information: Place specimen on ice after draw. CSF should be collected from the first drop into the containers in the order indicated. Fill each tube to the marked line (0.5 mL in tube 1; 1.0 mL in tubes 2, 3, 4, and 5). Place specimens on ice after collection. Call Client Services at 444-5755 to obtain appropriate specimen collection containers.** **Clinical Information:** *no clinical information listed* **Specimen Requirement: 4.5** mL cerebrospinal fluid (CSF) in **Set of 5 MNG Collection Tubes;** Place specimen on ice after draw. Frozen; **CSF should be collected from the first drop into the containers in the order indicated. Fill each tube to the marked line (0.5 mL in tube 1; 1.0 mL in tubes 2, 3, 4, and 5). Place specimens on ice after collection. Call Client Services at 216.444.5755 or 800.628.6816 to obtain appropriate specimen collection containers.** *OR* **1 mL cerebrospinal fluid (CSF) in clean container; Place specimen on ice after draw. Frozen; This specimen is to be used if Neopterin is the only CSF Medical Neurogenetics test ordered. The minimum specimen is 0.5 mL** **Stability:** Ambient: Unacceptable Refrigerated: **Unacceptable** Frozen: Indefinitely **Methodology: HPLC with Fluorescent and Electrochemical Detection** **Reference Range:** **0 Years to 5 Years: 7–65 nmol/L** **5 Years to 10 Years: 7–40 nmol/L** **10 Years to 15 Years: 8–33 nmol/L** **16 Years to 99 Years: 8–28 nmol/L** **Days Performed: Tue–Fri** **Reported: 15–17** days	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Neurotransmitter Metabolites/Amines	NEUR	**Includes:** **5-Hydroxyindoleacetic acid** **Homovanillic acid** **3-o-methydopa** **Special Information: Call Client Services to obtain appropriate sample collection containers. Each set consists of 5 numbered centrifuge tubes in a small plastic bag. Tube #3 contains antioxidants necessary to protect the sample from oxidation. One set of tubes is required per patient.** **Clinical Information:** *no clinical information listed* **Specimen Requirement: 4.5** mL cerebrospinal fluid (CSF) in **Set of 5 MNG Collection Tubes;** Frozen; **CSF should be collected from the first drop into the containers in the order indicated. Fill each tube to the marked line (0.5 mL in tube 1; 1.0 mL in tubes 2, 3, 4, and 5).** Place specimens on ice after collection. **If specimen is blood contaminated, the tubes should be centrifuged immediately (prior to freezing) and the clear CSF transferred to new similarly labeled tubes then frozen ASAP at -80 C. Call Client Services at 216.444.5755 or 800.628.6816 to obtain sample collection tubes.** **Stability:** Ambient: Unacceptable Refrigerated: **Unacceptable** Frozen: Indefinitely **Methodology: High Performance Liquid Chromatography with Electrochemical Detection** **Reference Range:** **5-Hydroxyindoleacetic acid:** **Adults: 67–140 nmol/L** **0 Months to 2 Months: 208–1159 nmol/L** **2 Months to 6 Months: 179–711 nmol/L** **6 Months to 24 Months: 129–520 nmol/L** **2 Years to 5 Years: 74–345 nmol/L** **5 Years to 10 Years: 66–338 nmol/L** **10 Years to 15 Years: 67–189 nmol/L** **Homovanillic acid:** **Adults: 145–324 nmol/L** **0 Months to 2 Months: 337–1299 nmol/L** **2 Months to 6 Months: 450–1132 nmol/L** **6 Months to 24 Months: 294–1115 nmol/L** **2 Years to 5 Years: 233–928 nmol/L** **5 Years to 10 Years: 218–852 nmol/L** **10 Years to 15 Years: 167–563 nmol/L** **3-O-methyldopa:** **Adults: <100 nmol/L** **0 Years to 2 Years: <300 nmol/L** **2 Years to 5 Years: <150 nmol/L** **5 Years to 15 Years: <100 nmol/L** **Days Performed: Tue–Fri** **Reported: 15–17** days	effective immediately
Osmotic Fragility, Erythrocyte	OSMFER	**Special Information:** Grossly hemolyzed specimens are unacceptable. **This test is New York DOH approved.** **Specimen Requirement:** 5 mL whole blood in EDTA (Lavender) tube; Refrigerated; Specimens should be refrigerated within 30 minutes after collection. *OR* 5 mL whole blood in sodium or lithium heparin (Green) tube; Refrigerated; Specimens should be refrigerated within 30 minutes after collection. **Note:** *Unstained smears are no longer required.*	11/9/23
Oxalate, Plasma	OXLATE	**Stability:** Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: Unacceptable Frozen: After separation from cells: **3 days at < -14** degrees C and 4 weeks at < -60 degrees C.	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Plasma Thymidine Determination	PLTHY	**Clinical Information:** Plasma Thymidine/Deoxyuridine analyte is used for diagnosis of Mitochondrial neurogastrointestinal encephalomyopathy (MNGIE). **Thymidine phosphorylase Enzyme Analysis (ENZ06) may also be used for assessment of Variants of Uncertain Significance (VUS) identified during genetic testing (e.g. Next Generation Sequencing or Capillary Sequencing testing).** 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. Molecular genetic studies of MNGIE patients\tissues have revealed multiple deletions, depletion, and site-specific point mutations of mitochrondrial DNA. TP is a cytosolic enzyme required for nucleoside homeostatis. In MNGIE, TP activity is severely reduced and consequently levels of thymidine and deoxyuridine in plasma are dramatically elevated. MNGIE patients may benefit from hematopoietic stem cell transplantation. **Stability:** Ambient: Unacceptable Refrigerated: After separation from cells: 24 hours Frozen: After separation from cells: **7 days** **Reference Range: <700 nM**	effective immediately
Porphobilinogen, Urine Quant	UPBGQT	**Special Information: Protect from light. Record** total volume and collection time **interval on amber transport tube.** Body fluids other than urine are unacceptable. **This test is New York DOH approved.** **Clinical Information: This test is useful in determining metabolic response to IV hematin, and** to rule out acute intermittent porphyria (AIP) and other acute attack types of porphyrias associated with neurologic and/or psychiatric symptoms. **If testing for an acute porphyria, please consider ordering PBG, Screen (UPBG). 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:** 8 mL 24-hour (well mixed) urine in clean container; Refrigerate during collection. Transport Frozen; Protect from light. **Transfer aliquot to amber transport tube and record total volume and collection time interval on specimen and requisition.** *OR* 8 mL random urine in clean container; Transport Frozen; Protect from light. **Transfer aliquot to amber transport tube.**	11/9/23
Porphyrins, Fractionation and Quantitation, Urine	UPORFR	**Name:** Previously Porphyrins, Urine Fractionated **Special Information: Protect from light. Record** total volume and collection time **interval on amber transport tube.** Body fluids other than urine **are unacceptable.** This test is New York DOH approved. **Clinical Information: This test is useful to evaluate cutaneous photosensitivity to exclude or include porphyria cutanea tarda (PCT).** Results are normalized to creatinine concentration and reported as a ratio of amounts (micromoles of porphyrin/moles of creatinine). Evaluation of neurologic and/or psychiatric symptoms associated with acute attack forms of porphyrias such as acute intermittent porphyria (AIP) require urine porphobilinogen (PBG) testing. **If testing for an acute porphyria, please consider ordering PBG, Screen (UPBG). 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 24-hour (well mixed) urine in clean container; Refrigerate during collection. Transport Frozen; Protect from light. **Transfer aliquot to amber transport tube and record total volume and collection time interval on specimen and requisition.** *OR* 4 mL random urine in clean container; Transport Frozen; Protect from light. **Transfer aliquot to amber transport tube.**	11/9/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Porphyrins, Total, Plasma or Serum	SPORPH	**Name:** Previously Porphyrins, Serum Total **Special Information: Protect from light during collection, storage and shipment.** Hemolyzed samples and frozen whole blood are unacceptable. **This test is New York DOH approved.** **Clinical Information: This test is useful to monitor porphyria cutanea tarda (PCT) and to confirm diagnosis of suspected variegate porphyria (VP) and erythropoietic protoporphyria (EPP). If testing for an acute porphyria, please consider ordering PBG, Screen (UPBG). 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:** 2 mL serum from no additive (Red) tube; Frozen; Protect specimen from light **during collection, storage, and shipment.** Separate serum from cells **ASAP or** within 1 hour of collection. **Transfer serum to amber transport tube.** *OR* **2 mL plasma from sodium heparin (Green) tube; Frozen; Protect specimen from light during collection, storage, and shipment. Separate serum from cells ASAP or within 1 hour of collection. Transfer serum to amber transport tube.** *OR* **2 mL plasma from EDTA (Lavender) tube; Frozen; Protect specimen from light during collection, storage, and shipment. Separate serum from cells ASAP or within 1 hour of collection. Transfer serum to amber transport tube.** **Reported:** 2–**5** days **For interface clients only–Test build may need to be modified** **Includes:** **Patient's AFP** **Estimated Due Date** **MoM for DIA** **Patient's DIA** **MoM for AFP** **Maternal Screen Interpretation** **Specimen** **Dating** **Insulin Req Maternal Diabetes** **Family Hx Neural Tube Defect** **Maternal Race** **Number of Fetuses** **Maternal Age At Delivery** **Patient's uE3** **MoM for uE3** **Family History of Aneuploidy** **Smoking** **EER Maternal Serum, Quad** **Patient's hCG, 2nd Trimester** **hCG MoM, 2nd Trimester** **Gestational Age Calculated at Collection** **Maternal Weight**	11/9/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Prenatal Quad Screen	QUAD4	**Special Information: Hemolyzed specimens are unacceptable. This test is New York DOH approved.** **Clinical Information: Second-trimester screening test for trisomy 21 (Down syndrome), trisomy 18, and open neural tube defects.** **Specimen Requirement: 3** mL serum from serum separator (Gold) tube; Refrigerated; **Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.** Submit a **Maternal Serum Testing Patient History Form** with specimen. Complete clinical and demographic information is required for reporting. Specimen must be drawn between **14 weeks, 0 days** and **24 weeks, 6 days** gestation. **The recommended time for maternal serum screening is 16 to 18 weeks gestation.** *OR* **3 mL serum from no additive (Red) tube; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. Submit a Maternal Serum Testing Patient History Form with specimen. Complete clinical and demographic information is required for reporting. Specimen must be drawn between 14 weeks, 0 days and 24 weeks, 6 days gestation. The recommended time for maternal serum screening is 16 to 18 weeks gestation.** **Stability:** Ambient: **After separation from cells: 72 hours** Refrigerated: **After separation from cells: 2 weeks** Frozen: **After separation from cells: 1 year (avoid repeated freeze/thaw cycles)** **Methodology: Quantitative Chemiluminescent Immunoassay** **Reference Range:** AFP (maternal) (QNOTE): **Refer to report** **Days Performed: Sun–Sat** **Reported: 3–4** days	11/9/23
Pyridoxal 5 phosphate, CSF	P5PCSF	**Includes:** PLPCSF Results **Special Information: If the CSF is blood contaminated, the specimen should be immediately centrifuged (prior to freezing) and the clear CSF transferred to a new tube and frozen.** **Clinical Information:** *no clinical information listed* **Specimen Requirement:** 1 mL cerebrospinal fluid (CSF) in **clean container;** Frozen *OR* **3.5 mL cerebrospinal fluid (CSF) in other container; Frozen; CSF should be collected from the first drop into the containers in the order indicated. Fill each tube to the marked line (0.5 mL in tubes 1,2,and 5;1.0 mL in tubes 3 and 4). Place specimens on ice after collection. If specimen is blood contaminated, the tubes should be centrifuged immediately (prior to freezing) and the clear CSF transferred to new similarly labeled tubes then frozen ASAP at -80 C. Call Client Services at 216.444.5755 or 800.628.6816 to obtain sample collection vials.** **Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: Indefinitely **Methodology: High Performance Liquid Chromatography with Fluorescence Detection (HPLC-FL)** **Reference Range:** **0 Months to 3 Months: 30-80 nmol/L** **3 Months to 12 Months: 23-64 nmol/L** **1 Year to 4 Years: 18-50 nmol/L** **5 Years to 99 Years: 10-37 nmol/L** **Reported: 15–17** days	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Succinyladenosine, CSF	CSUCCN	**Includes:** **Succinyladenosine, CSF** **Special Information: Call Client Services to obtain appropriate sample collection containers. Each set consists of 5 numbered centrifuge tubes in a small plastic bag. Tube #3 contains antioxidants necessary to protect the sample from oxidation. One set of tubes is required per patient.** **Clinical Information:** *no clinical information listed* **Specimen Requirement: 4.5 mL** cerebrospinal fluid (CSF) in **Set of 5 MNG Collection Tubes;** Frozen; **CSF should be collected from the first drop into the containers in the order indicated. Fill each tube to the marked line (0.5 mL in tube 1; 1.0 mL in tubes 2, 3, 4, and 5).** Place specimens on ice after collection. **If the specimen is blood contaminated, the tubes should be centrifuged immediately (prior to freezing) and the clear CSF transferred to new similarly labeled tubes then frozen ASAP at -80 C. Call Client Services at 800.628.6816 or 216.444.5755 to obtain appropriate specimen collection containers.** *OR* **1 mL cerebrospinal fluid (CSF) in clean container; This specimen is to be used if Succinyladenosine is the only CSF Medical Neurogenetics test requested. Minimum volume is 0.5 mL.** **Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: Indefinitely **Methodology: High Performance Liquid Chromatography with Ultraviolet Detection (HPLC-UV)** **Reference Range: 0.74–4.92 umol/L** **Days Performed: Tue–Fri** **Reported: 15–17** days	effective immediately
Tetrahydrobiopterin & Neopterin, CSF	TBIOPT	**Includes:** Tetrahydrobiopterin Neopterin **Special Information:** Call **Client Services** to obtain appropriate sample collection **containers.** Each **set** consists of 5 numbered centrifuge tubes in a small plastic bag. Tube #3 contains antioxidants necessary to protect the sample from oxidation. One set of tubes is required per patient. **Clinical Information:** *no clinical information listed* **Specimen Requirement: 4.5** mL cerebrospinal fluid (CSF) from set of 5 MNG Collection Tubes; Frozen; **CSF should be collected from the first drop into the containers in the order indicated. Fill each tube to the marked line (0.5 mL in tube 1; 1.0 mL in tubes 2, 3, 4, and 5). Place specimens on ice after collection. If specimen is blood contaminated, the tubes should be centrifuged immediately (prior to freezing) and the clear CSF transferred to new similarly labeled tubes then frozen ASAP at -80 C. Call Client Services at 216.444.5755 or 800.628.6816 to obtain sample collection tubes.** **Stability:** Ambient: Unacceptable Refrigerated: **Unacceptable** Frozen: Indefinitely **Methodology:** **High Performance Liquid Chromatography with Electrochemical Detection** **High Performance Liquid Chromatography with Fluorescence Detection (HPLC-FL)** *(continued on page 11)*	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Tetrahydrobiopterin & Neopterin, CSF *(continued from page 10)*		**Reference Range:** Tetrahydobiopterin (TBIOPT02): **Adults: 10–30 nmol/L** **0 Months to 2 Months: 40–105 nmol/L** **2 Months to 6 Months: 23–98 nmol/L** **6 Months to 24 Months: 18–58 nmol/L** **2 Years to 5 Years: 18–50 nmol/L** **5 Years to 10 Years: 9–40 nmol/L** **10 Years to 15 Years: 9–32 nmol/L** Neopterin (TBIOPT01): **Adults: 8–28 nmol/L** **0 Years to 5 Years: 7–65 nmol/L** **5 Years to 10 Years: 7–40 nmol/L** **10 Years to 15 Years: 8–33 nmol/L** **Days Performed: Tue–Fri** **Reported: 15–17** days	
Total Erythrocyte Porphyrins	PROPOR	**Clinical Information:** Useful as a screen for erythropoietic protoporphyria (EPP) in patients with cutaneous photosensitivity. Elevated EP results are seen in early and late iron deficiency, in the anemia of chronic disease, and in chronic lead poisoning (typically when blood lead is > 25 µg/dL). Elevated protoporphyrin (as in erythropoietic protoporphyria) and zinc coproporphyrin (usually associated with childbirth) can increase the apparent EP signal. A more specific test for free protoporphyrin is Porphyrins, Serum Total (SPORPH). Hemolyzed, clotted, or improperly aliquoted specimens may show false elevations. **If testing for an acute porphyria, please consider ordering PBG, Screen (UPBG). 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:** 1 mL whole blood in EDTA (Royal blue) tube; Refrigerated; Protect specimen from light during collection, storage, and shipment. Transfer 1 mL whole blood to an amber transport tube. Specimens not protected from light will be run with a disclaimer. *OR* 1 mL whole blood in EDTA (Lavender) tube; Refrigerated; Protect specimen from light during collection, storage, and shipment. Transfer 1 mL whole blood to an amber transport tube. Specimens not protected from light will be run with a disclaimer.	11/9/23

New Tests

Test Name	Order Code	Change	Effective Date
Allergen, Honey Bee Components IgE	HBEECP	**Clinical Information:** As an aid in diagnosis allergy to honey bee. **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 1 mL plasma from lithium heparin plasma separator (Light Green) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 1 mL plasma from EDTA (Lavender) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 1 mL serum from no additive (Red) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. **Minimum** 0.5 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 1 mL is preferred when possible. **Stability:** Ambient: 1 Day Refrigerated: 30 Days Frozen: 30 Days **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Apis mellifera phospholipase A2 native 1 (APIM1): <0.10 kU/L Apis mellifera hyaluronidase native 2 (APIM2): <0.10 kU/L Apis mellifera acid phosphatase native 3 (APIM3): <0.10 kU/L Apis mellifera dipeptidyl peptidase native 5 (APIM5): <0.10 kU/L Apis mellifera icarapin native 10 (APIM10): <0.10 kU/L **Days Performed:** Sun–Sat 7:00 am–11:00 pm **Reported:** 1–2 days	11/9/23
Allergen, Honey Bee IgE with Reflex to Components	HBEERF	**Clinical Information:** As an aid in diagnosis allergy to honey bee. **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 1 mL plasma from lithium heparin plasma separator (Light Green) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 1 mL plasma from EDTA (Lavender) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 1 mL serum from no additive (Red) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. **Minimum** 0.5 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 1 mL is preferred when possible. **Stability:** Ambient: 1 Day Refrigerated: 30 Days Frozen: 30 Days **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Allergen, Honey Bee IgE (BEE): < 0.35 kU/L Allergen, Honey Bee Class (BEECL): 0 **Days Performed:** Sun–Sat 7:00 am–11:00 pm **Reported:** 1–2 days	11/9/23

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Paper Wasp Component IgE	PWSPCP	**Clinical Information:** As an aid in diagnosis allergy to paper wasp. **Specimen Requirement:** 0.5 mL serum from serum separator (Gold) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 0.5 mL plasma from lithium heparin plasma separator (Light Green) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 0.5 mL plasma from EDTA (Lavender) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 0.5 mL serum from no additive (Red) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. **Minimum** 0.3 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. **Stability:** Ambient: 1 Day Refrigerated: 30 Days Frozen: 30 Days **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Polistes dominula native Antigen 5 (POLD5): <0.10 kU/L **Days Performed:** Sun–Sat 7:00 am–11:00 pm **Reported:** 1–2 days	11/9/23
Allergen, Paper Wasp IgE with Reflex to Component	PWSPRF	**Clinical Information:** As an aid in diagnosis of allergy to paper wasp. **Specimen Requirement:** 0.5 mL serum from serum separator (Gold) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 0.5 mL plasma from lithium heparin plasma separator (Light Green) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 0.5 mL plasma from EDTA (Lavender) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 0.5 mL serum from no additive (Red) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. **Minimum** 0.4 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. **Stability:** Ambient: 1 Day Refrigerated: 30 Days Frozen: 30 Days **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Allergen, Paper Wasp IgE (PWASP): < 0.35 kU/L Allergen, Paper Wasp Class (PWACL): 0 **Days Performed:** Sun–Sat 7:00 am–11:00 pm **Reported:** 1–2 days	11/9/23
Allergen, Sesame Seed rSes i 1 Component	SESMCP	**Note: New test was announced in the August update, but financial information was not available at that time** **CPT:** 86008	effective immediately
Allergen, Sesame Seed with Component Reflex	SESMRX	**Note: New test was announced in the August update, but financial information was not available at that time** **CPT:** 86003	effective immediately

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Total Venom Panel IgE with Reflex to Components	VENOMS	**Clinical Information:** As an aid in diagnosis of allergy to bee/wasp venoms. **Specimen Requirement:** 1.4 mL serum from serum separator (Gold) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 1.4 mL plasma from lithium heparin plasma separator (Light Green) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 1.4 mL plasma from EDTA (Lavender) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 1.4 mL serum from no additive (Red) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. **Minimum** 0.7 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 1.4 mL is preferred when possible. **Stability:** Ambient: 1 Day Refrigerated: 30 Days Frozen: 30 Days **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Allergen, Honey Bee IgE (BEE): < 0.35 kU/L Allergen, Honey Bee Class (BEECL): 0 Allergen, Common Wasp (Yellow Jacket) IgE (YJAK): < 0.35 kU/L Allergen, Common Wasp (Yellow Jacket) Class (YHACL): 0 Allergen, Paper Wasp IgE (PWASP): < 0.35 kU/L Allergen, Paper Wasp Class (PWACL): 0 **Days Performed:** Sun–Sat 7:00 am–11:00 pm **Reported:** 1–2 days	11/9/23
Allergen, Wheat, rTri a 19 Omega-5-gliadin Component	OMEGA5	**Note: New test was announced in the August update, but financial information was not available at that time** **CPT:** 86008	effective immediately
Allergen, Wheat with Component Reflex	WHTRFX	**Note: New test was announced in the August update, but financial information was not available at that time** **CPT:** 86003	effective immediately
Allergen, Yellow Jacket (Common Wasp) Components IgE	YJAKCP	**Clinical Information:** As an aid in diagnosis allergy to yellow jacket. **Specimen Requirement:** 0.5 mL serum from serum separator (Gold) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 0.5 mL plasma from lithium heparin plasma separator (Light Green) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 0.5 mL plasma from EDTA (Lavender) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 0.5 mL serum from no additive (Red) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. **Minimum** 0.3 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. **Stability:** Ambient: 1 Day Refrigerated: 30 Days Frozen: 30 Days **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Vespinae Vespula phospholipase native A1 (VESV1): <0.10 kU/L Vespinae Vespula native A5 (VESV5): <0.10 kU/L **Days Performed:** Sun–Sat 7:00 am–11:00 pm **Reported:** 1–2 days	11/9/23

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Yellow Jacket (Common Wasp) IgE with Reflex to Components	YJAKRF	**Clinical Information:** As an aid in diagnosis of allergy to yellow jacket (common wasp). **Specimen Requirement:** 0.6 mL serum from serum separator (Gold) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 0.6 mL plasma from lithium heparin plasma separator (Light Green) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 0.6 mL plasma from EDTA (Lavender) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. *OR* 0.6 mL serum from no additive (Red) tube; Refrigerated; An extra 50uL will be required for each additional allergen ordered. **Minimum** 0.4 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.6 mL is preferred when possible. **Stability:** Ambient: 1 Day Refrigerated: 30 Days Frozen: 30 Days **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Allergen, Common Wasp (Yellow Jacket) IgE (YJAK): < 0.35 kU/L Allergen, Common Wasp (Yellow Jacket) Class (YHACL): 0 **Days Performed:** Sun–Sat 7:00 am–11:00 pm **Reported:** 1–2 days	11/9/23
COVID & Influenza A/B & RSV NAAT, Routine	CVFLRS	**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-approved 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. 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 Reference:** 1. U.S. Centers for Disease Control (CDC). Testing Guidance for Clinicians When SARS-CoV-2 and Influenza Viruses are Co-circulating. Accessed September 1, 2023. https://www.cdc.gov/flu/professionals/diagnosis/testing-guidance-for-clinicians.htm. 2. U.S. Centers for Disease Control (CDC). Respiratory Syncytial Virus Infection (RSV): For Healthcare Providers. Accessed September 1, 2023. https://www.cdc.gov/rsv/clinical/index.html. 3. U.S. Food and Drug Administration (FDA). 510(k) Substantial Equivalence Determination Decision Summary K222736. Accessed September 1, 2023. https://www.accessdata.fda.gov/cdrh_docs/reviews/K222736.pdf. *(continued on page 16)*	11/9/23

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
COVID & Influenza A/B & RSV NAAT, Routine *(continued from page 15)*	CVFLRS	**Specimen Requirement:** Nasopharyngeal swab in universal transport media (UTM); Refrigerated; 1 .Tilt patient's head back 70 degrees. 2. Gently and slowly insert a 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* nasal swab in universal transport media (UTM); Refrigerated; 1. Insert the entire collection tip of the swab provided (usually ½ to ¾ of an inch, or 1 to 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 tracheal aspirate in sterile container; Refrigerated; Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. *OR* 1 mL bronch (BAL) in sterile container; Refrigerated; Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. *OR* 1 mL sputum in sterile container; Refrigerated; Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap collection cup or sterile dry container. *OR* swab in saline; Refrigerated; Sterile saline may be used if UTM cannot be sourced. *OR* E-swab; Refrigerated; E-swab may be used if UTM cannot be sourced. *OR* swab in viral transport media; Refrigerated; Viral transport media (including VTM, M4RT, M5, or M6) may be used if UTM cannot be sourced. **Stability:** Refrigerated: 96 hours Frozen: 30 days **Methodology:** Nucleic Acid Amplification (NAA) **Reference Range:** COVID 19 Result NP (COVNP): Negative for COVID19 (SARS CoV2) by RT-PCR or equivalent method. Influenza A PCR (PCRFLA): Not Detected Influenza B PCR (PCRFLB): Not Detected RSV PCR (PCRRSV): Not Detected **Days Performed:** Sun–Sat 24 hours **Reported:** 1 day	11/9/23

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Infliximab, Serum	INFLIX	**Special Information:** Patients taking a biotin dose greater than 5 mg/day should refrain from taking biotin for at least 24 hours. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result. **Clinical Limitation:** Infliximab drug levels greater than 25 ug/mL may result in falsely-decreased infliximab anti-drug antibody levels. **Clinical Information:** Trough total (free and bound) infliximab level and total (free and bound) anti-drug antibody levels for patients undergoing therapy with infliximab, -abda, -dyyb, and -axxq. Draw just prior to scheduled dose. In adults with active IBD treated with anti-TNF agents, the AGA suggests reactive therapeutic drug monitoring to guide treatment changes. 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. **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Minimum** 0.5 mL; Refrigerated *OR* 1 mL serum from no additive (Red) tube; **Minimum** 0.5 mL; Refrigerated **Stability:** Ambient: 7 days Refrigerated: 14 days Frozen: 60 days **Methodology:** Enzyme-Linked Immunosorbent Assay (ELISA) Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** Infliximab Free Drug Level (IFXTDM): >=3 ug/mL Infliximab Antibody Total Drug Level (IFXADA): <10 AU/mL **Days Performed:** Mon, Thu 7:30 am–4:00 pm **Reported:** 1–4 days	11/9/23

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Aminolevulinic Acid Dehydratase (ALAD), Whole Blood	ALADWB	Test will no longer be orderable. Refer to ordering instructions for remaining porphyria tests for recommended replacement testing.	11/9/23
Cross-Linked N-telopeptide, Urine	UNTX2	Test will no longer be orderable. Recommended replacement test is C Telopeptide, Beta Cross Linked (CTELO).	1/16/24
Infliximab or Biosimilar Activity and Neutralizing Antibody	IFXNEU	Test will no longer be orderable. Recommended replacement test is Infliximab, Serum (INFLIX).	11/9/23
Maternal Serum Screen, First Trimester, hCG, PAPP-A, NT	MATFIR	Test will no longer be orderable. There is no recommended replacement.	11/9/23
Mycoplasma pneumoniae IgG	MYCOG	Test will no longer be orderable. Recommended replacement test is Mycoplasma pneumoniae PCR (MYCPCR).	11/9/23
Porphobilinogen (PBG) Deaminase, Erythrocyte	PBGDEP	Test will no longer be orderable. Refer to ordering instructions for remaining porphyria tests for recommended replacement testing.	11/9/23
Porphyrins, Fecal	STPRPH	Test will no longer be orderable. Refer to ordering instructions for remaining porphyria tests for recommended replacement testing.	11/9/23
Routine Flu A/B & RSV	RTFRSV	Test will no longer be orderable. Recommended replacement test is COVID & Influenza A/B & RSV NAAT, Routine (CVFLRS).	11/9/23