Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • February 2020

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

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

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

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

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
3	5' Nucleotidase						■	■				■		
3	Acetoacetate						■					■	■	
3	AFB Culture Only						■							
3	ALL NGS Panel Bone Marrow						■							
3	ALL NGS Panel Peripheral Blood						■							
3	Aluminum						■					■		
4	Amylase, Pancreatic						■	■		■	■	■		
4	Anti IgA Antibody											■		
4	Anti-Platelet Factor 4										■			
4–5	Arsenic, Urine 24 Hr						■	■						
5	Aspirin/Clopidogrel Resistance (Aggregation) Panel							■						
14	Bence Jones Protein, Qt Free Kappa/Lambda Light Chains					■								
5	Carnitine, Free and Total, Urine by Tandem Mass Spectrometry								■					
5	Chromium, Serum						■					■	■	
5	Chromosome Analysis with Reflex AML FISH panel												■	
6	Chromosome Analysis with Reflex MDS FISH												■	
6	Coxsackie B Abs						■	■				■	■	
6	Cryptosporidium & Giardia Antigens by EIA						■							
6	Diltiazem						■			■		■	■	
6	Duchenne/Becker Muscular Dystrophy (DMD) Deletion/Duplication with Reflex to Sequencing												■	
6	Echovirus Antibodies						■	■						

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
7	F2 Isoprostane/Creatinine Ratio						■	■				■		
14	Factor XIII V34L DNA					■								
13	Free Light Chains, Quantitative, Urine			■										
7	Gamma-Hydroxybutyric Acid, Serum						■				■			
7	Hemoglobin, Plasma										■			
7	Heparin Anti Xa Assay							■						
7	Herpes Simplex IgM, Abs						■					■		
7	Herpesvirus 6, Qual, Plasma, PCR						■			■		■		
7	HSV 1,2 Antibodies, IgG and IgM											■		
7–8	Hydroxylase-21 Antibody						■	■		■	■	■	■	
8	Iodine, Urine						■				■			
14	KIT Mutation Exons 8-11 and 17, Hematologic Neoplasms, Sequencing													■
8	Leptospira Antibody, IgM by Dot Blot						■	■			■		■	
9	Lipid Associated Sialic Acid						■				■	■		
9	Manganese, Serum						■					■	■	
9	Methylmalonic Acid Blood							■		■		■	■	
9	Myeloid NGS Panel Bone Marrow						■							
9	Myeloid NGS Panel Peripheral Blood						■							
10	Opiates Confirmation, Quantitation Serum/Plasma						■	■					■	
10	PML/RARA RTPCR						■							
10	Protein, Urine Qualitative						■							
10	Pseudocholinesterase, Total, Serum						■			■	■	■		
11	Selenium, Plasma or Serum						■	■			■		■	
11	Strongyloides IgG Abs, Serum						■	■		■	■	■	■	
12	Trypanosoma cruzi Antibody, IgM							■						
12	Urinalysis Only						■							
12	Urinalysis with Microscopic						■							
14	Urine Kappa/Lambda Free Light Chains (FLC) with Ratio					■								
12	Varicella Zoster IgG Ab, CSF										■			
14	Williams Syndrome, 7q11.23 Deletion, FISH					■								
14	X-Linked Intellectual Disability (XLID)					■								

Test Changes

Test Name	Order Code	Change	Effective Date
5' Nucleotidase	NUC5P	**Special Information: Avoid hemolysis. This test is New York DOH approved.** **Clinical Information: Determine whether enzyme elevation is due to hepatocellular or cholestatic pattern.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.2 mL; Separate serum from cells ASAP or within 2 hours of collection **and transfer into a standard aliquot tube;** Avoid hemolysis; Refrigerated **Days Performed:** Sunday–Saturday **Reported:** 2–**4** days	2/18/20
Acetoacetate	ACETAC	**Special Information:** Serum gel tubes, **plasma gel tubes, and specimens received at room temperature** are unacceptable. **Stability:** Ambient: Unacceptable Refrigerated: 4 days Frozen: **4 days (preferred)** **Days Performed:** Monday–Sunday **Reported: 9**–12 days	Effective immediately
AFB Culture Only	AFCO	**Special Information:** An acid-fast bacilli (AFB) stain will not be performed. **Blood cultures for AFB should ideally be drawn prior to administration of antimicrobials.** Patient Preparation: For blood cultures, select vein to use. Wipe off venipuncture site using a 70% alcohol pad. Apply Chloraprep to the skin over the selected venipuncture site and apply using up and down and back and forth strokes for a full 30 seconds. Allow the site to dry completely for 30–60 seconds. Swab septum of Isolator tube or Myco/F bottle using 70% alcohol. Draw 10 mL into adult Isolator tube, 1.5 mL into pediatric Isolator tube, or 5 mL if direct draw into the Myco/ F bottle. After inoculation, clean septum with 70% alcohol. Transport to Microbiology laboratory at Cleveland Clinic Laboratories within 4–6 hours is recommended. Do NOT transport glass Myco/F bottles using the pneumatic tube system.	Effective immediately
ALL NGS Panel Bone Marrow	ALLMRW	**Special Information:** The following genes are interrogated: ABL1, CBL, CDKN2A, EED, ETV6, EZH2, FBXW7, FLT3, IKZF1, JAK2, JAK3, KDM6A, KMT2A, KRAS, NOTCH1, NRAS, PAX5, PHF6, PTEN, RUNX1, **SH2B3,** STAT5B, SUZ12, TET2, TP53, and WT1	Effective immediately
ALL NGS Panel Peripheral Blood	ALLPBL	**Special Information:** Genes interrogated on the panel: ABL1, CBL, CDKN2A, EED, ETV6, EZH2, FBXW7, FLT3, IKZF1, JAK2, JAK3, KDM6A, KMT2A, KRAS, NOTCH1, NRAS, PAX5, PHF6, PTEN, RUNX1, **SH2B3,** STAT5B, SUZ12, TET2, TP53, and WT1	Effective immediately
Aluminum	ALUM	**Special Information:** Diet, medication, and nutritional supplements may introduce interfering substances. Patient should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). Unacceptable conditions: Plasma. Specimens that are not separated from the red cells or clot within **2 hours. Specimens collected and/or transported in containers other than specified.** This test is New York DOH approved. **Clinical Information:** Serum aluminum may be useful in the assessment of aluminum toxicity due to dialysis and is the preferred test for routine screening. Serum aluminum > 50.0 μg/L is consistent with overload and may correlate with toxicity. **Elevated levels of aluminum in serum should be confirmed with a second specimen due to a high susceptibility of the specimen to collection-related environmental contamination.** **Stability:** Ambient: **Indefinitely** Refrigerated: **Indefinitely** Frozen: **Indefinitely** (If the specimen is drawn and stored in the appropriate **container,** the trace element values do not change with time)	2/18/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Amylase, Pancreatic	AMYLPS	**Special Information: Grossly hemolyzed, grossly lipemic, or grossly icteric specimens will be rejected.** **Specimen Requirement:** 1 mL serum from a **serum separator (gold) tube;** Minimum: 0.5 mL; **Centrifuge and transfer 1 mL serum into a standard plastic aliquot tube;** Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; **Centrifuge and transfer 1 mL serum into a standard plastic aliquot tube;** Refrigerated **Methodology: Colorimetry** **Reference Range:** 0–23 Months: 0–20 U/L 2–17 Years: 9–35 U/L 18–99 Years: **13–53 U/L** **Days Performed:** Monday–**Saturday** **Reported: 2**–5 days	1/28/20
Anti IgA Antibody	ANTGA	**Stability:** Ambient: 1 week Refrigerated: 1 week Frozen: **2 weeks**	2/18/20
Anti-Platelet Factor 4	PLATF4	**Reference Range:** Anti-Platelet Factor 4 (0–99 Years): < 0.400 OD PF4 Interpretation: **Negative**	3/29/20
Arsenic, Urine 24 Hr	UARSND	**Special Information:** Patient demographics (Heavy Metals) form is required to meet State Health Department requirements. Indicate total volume. Patient preparation: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, nonessential over-the-counter medications (upon the advice of their physician), and avoid shellfish and seafood for 48–72 hours. High concentrations of iodine may interfere with elemental testing. **Collection of urine specimens from patients receiving iodinated or gadolinium-based contrast media should be avoided for a minimum of 72 hours post-exposure. Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post contrast media exposure.** Urine specimens collected within **72 hours** after administration **of iodinated or** gadolinium (Gd) contrast media and acid preserved samples are unacceptable. Specimens contaminated with blood or fecal material, or specimens transported in a non-trace element-free transport tube (with the exception of the original device) are unacceptable. ARUP studies indicate that refrigeration of urine alone, during and after collection, preserves specimens adequately if tested within 14 days of collection. This test is New York DOH approved. **Specimen Requirement:** 8 mL 24-hour urine (well-mixed) in a clean container; Minimum: 2 mL; Refrigerate during collection; HEAVY METALS FORM REQUIRED to meet State Health Department requirements; Must collect in a plastic container; Specimen must not come into contact with glass or metal; Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances; Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, nonessential over-the-counter medications (upon the advice of their physician), and avoid shellfish and seafood for 48–72 hours; High concentrations of iodine may interfere with elemental testing; **Collection of urine specimens from patients receiving iodinated or gadolinium-based contrast media should be avoided for a minimum of 72 hours post-exposure; Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post contrast media exposure;** Provide volume with specimen; Aliquot into a trace metal-free transport tube (ARUP #43116); Refrigerated *(continued on page 5)*	2/18/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Arsenic, Urine 24 Hr *(continued from page 4)*		*OR* 8 mL random urine in a clean container; Minimum: 2 mL; HEAVY METALS FORM REQUIRED to meet State Health Department requirements; Must collect in a plastic container; Specimen must not come into contact with glass or metal; Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances; Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, nonessential over-the-counter medications (upon the advice of their physician), and avoid shellfish and seafood for 48–72 hours; High concentrations of iodine may interfere with elemental testing; **Collection of urine specimens from patients receiving iodinated or gadolinium-based contrast media should be avoided for a minimum of 72 hours post-exposure; Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post contrast media exposure;** Provide volume with specimen; Aliquot into a trace metal-free transport tube (ARUP #43116); Refrigerated	
Aspirin/Clopidogrel Resistance (Aggregation) Panel	ASPCLP	**Specimen Requirement:** 7 mL whole blood in a 3.2% sodium citrate (light blue) tube; Minimum: 3.5 mL; **Please indicate the precise antiplatelet therapy that the patient is receiving at the time of testing [i.e. aspirin dose, clopidogrel (PLAVIX) dose];** Sample must arrive in the Manual Hematology-Coagulation laboratory at Cleveland Clinic Laboratories within 3 hours of collection, **after 7:00 a.m. EST on Mondays** and before 11:00 p.m. EST Monday through Friday; **Test not performed on major holidays; DO NOT SPIN;** Ambient	2/4/20
Carnitine, Free and Total, Urine by Tandem Mass Spectrometry	UCARFT	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** **Creatinine, Urine** Carnitine, Free, Urine Carnitine, Total, Urine Carnitine, Esterified, Urine Carnitine, E/F Ratio, Urine	2/18/20
Chromium, Serum	CHRSER	**Special Information:** Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). Unacceptable conditions: **Plasma. EDTA (royal blue) or** separator tubes. Specimens that are not separated from the red cells or clot within **2 hours. Specimens transported in tubes other than specified.** This test is New York DOH approved. **Clinical Information:** Preferred test for evaluating metal ion release from metal-on-metal joint arthroplasty. May be useful in the assessment of deficiency or overload. For the assessment of hexavalent chromium exposure, chromium in blood or red blood cells (RBCs) is preferred. **Elevated results may be due to skin or collection-related contamination, including the use of a noncertified metal-free collection/transport tube. If contamination concerns exist due to elevated levels of serum chromium, confirmation with a second specimen collected in a certified metal-free tube is recommended. Whole blood is the preferred specimen type for evaluating chromium metal ion release from metal-on-metal joint arthroplasty. Whole blood chromium levels may be increased in asymptomatic patients with metal-on-metal prosthetics and should be considered in the context of the overall clinical scenario. The form of chromium greatly influences distribution. Trivalent chromium resides in the plasma and is usually not of clinical importance. Hexavalent chromium is considered highly toxic; however, chromium serum levels should not be used to assess toxic exposures to hexavalent chromium as it is predominately taken up and retained by red blood cells. Symptoms associated with chromium toxicity vary based on route of exposure and dose and may include dermatitis, impairment of pulmonary function, gastroenteritis, hepatic necrosis, bleeding, and acute tubular necrosis.** **Stability:** Ambient: **Indefinitely** Refrigerated: **Indefinitely** Frozen: **Indefinitely** **Days Performed:** Monday–**Sunday** **Reported:** 2–5 days	2/18/20
Chromosome Analysis with Reflex AML FISH panel	CHRAML	**CPT:** 88262 x 1	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Chromosome Analysis with Reflex MDS FISH	CHRMDS	**CPT:** 88237 x 1, 88262 x 1	Effective immediately
Coxsackie B Abs	COXBAB	**Special Information: Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of acute specimens.** Label specimens plainly as 'acute' or 'convalescent.' **Cerebrospinal fluid (CSF) or plasma will be rejected. Contaminated, hemolyzed, or severely lipemic specimens are unacceptable. This test is New York DOH approved.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; **Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of acute specimens; Label specimens plainly as 'acute' or 'convalescent';** Separate serum from cells ASAP or within 2 hours of collection **and transfer into a standard aliquot tube;** Refrigerated *OR* 1 mL **serum from a plain no additive (red)** tube; Minimum: 0.3 mL; **Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of acute specimens; Label specimens plainly as 'acute' or 'convalescent';** Separate serum from cells ASAP or within 2 hours of collection **and transfer into a standard aliquot tube;** Refrigerated **Stability:** Ambient: **48 hours** Refrigerated: 2 weeks Frozen: 1 year **(Avoid repeated freeze/thaw cycles)** **Days Performed:** Monday–**Friday** **Reported:** 7–10 days	2/18/20
Cryptosporidium & Giardia Antigens by EIA	OVAPSC	**Includes:** Confirmation of cryptosporidium using modified acid fast stain. Additional charges may apply. (Note: *Test directory update to remove references to confirmation with fluorescent method that is no longer performed)*	2/2/20
Diltiazem	DILTIA	**Special Information: Do not collect in plasma or serum gel tubes.** **Stability:** Ambient: 72 hours Refrigerated: **14 days (preferred)** Frozen: **180 days** **Methodology:** High Performance Liquid Chromatography **with Ultraviolet Detection (HPLC-UV)** **CPT: 80299 x 1**	Effective immediately
Duchenne/Becker Muscular Dystrophy (DMD) Deletion/ Duplication with Reflex to Sequencing	DBMDYS	**CPT:** 81161 x 1; **If reflexed, add 81408 x 1**	2/4/20
Echovirus Antibodies	ECHOV	**Special Information:** Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of acute specimens. **Label specimens plainly as 'acute' or 'convalescent.'** Plasma **or cerebrospinal fluid (CSF)** are unacceptable. **Contaminated, hemolyzed, or severely lipemic specimens will be rejected.** This test is New York DOH approved. **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of acute specimens; Label samples plainly as 'acute' or 'convalescent;' Separate serum from cells **ASAP or** within 2 hours of collection and transfer into a **standard** aliquot tube; Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.3 mL; Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of acute specimens; Label samples plainly as 'acute' or 'convalescent;' Separate serum from cells **ASAP or** within 2 hours of collection and transfer into a **standard** aliquot tube; Refrigerated	2/18/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
F2 Isoprostane/ Creatinine Ratio	F2	**Special Information: Ship specimen on the day of collection. Testing is not performed on major holidays. Specimens other than preservative-free urine will be rejected. Samples received outside of stability limits are unacceptable. Specimens that are improperly labeled or stored will be rejected.** **Clinical Limitation: Conditions that result in excessive generation of free radicals (e.g., atherosclerosis, smoking, and alcoholism) can result in increased levels of urinary isoprostanes.** **Specimen Requirement:** 2 mL random urine in a clean container **(No preservatives);** Minimum: 1.5 mL; **Transfer 2 mL aliquot into a yellow top tube without preservative;** Refrigerated **Days Performed:** Monday–Friday **Reported:** 6–**7** days	3/31/20
Gamma-Hydroxybutyric Acid, Serum	GHBSER	**Special Information: Do not use gel tubes.** **Days Performed:** Sunday–Saturday **Reported: 6**–10 days	Effective immediately
Hemoglobin, Plasma	HGBP	**Days Performed:** Sunday–Saturday **Reported:** 2–**4** days	2/18/20
Heparin Anti Xa Assay	HEPASY	**Specimen Requirement:** 1 mL platelet-poor plasma from a 3.2% sodium citrate (light blue) tube; Minimum: 0.5 mL; **A minimum of 0.5 mL platelet-poor plasma is needed; therefore, draw no less than 1.5 mL whole blood in a 1.8 mL sodium citrate tube;** Frozen	Effective immediately
Herpes Simplex IgM, Abs	HSVM	**Clinical Information: Herpes Simplex Virus (HSV) IgM antibody test is used as an aid in diagnosis of primary HSV infection. The test may become positive during HSV reactivation. Cannot exclude recent primary HSV infection if the specimen is collected within 7–10 days after onset of signs and symptoms. Non-specific reactivity is not uncommon with HSV IgM serology. Clinical correlation is required.** **Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14 days**	3/31/20
Herpesvirus 6, Qual, Plasma, PCR	HV6PCR	**Special Information:** EDTA plasma is the only acceptable specimen type for this assay. **Grossly hemolyzed specimens will be rejected.** **Methodology:** DNA Probe Hybridization **Real-Time** Polymerase Chain Reaction **(RT-PCR)** **Days Performed:** Monday–**Friday** **Reported:** 3–6 days	2/4/20
HSV 1,2 Antibodies, IgG and IgM	HSVGM	**Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14 days**	3/31/20
Hydroxylase-21 Antibody	21OHAB	**Special Information: Grossly** hemolyzed **or lipemic** specimens are unacceptable. **Note:** *21-Hydroxylase Autoantibodies, Serum will be added as an alias name.* **Clinical Information: This assay is intended for the qualitative determination of antibodies to steroid 21-hydroxylase in human serum. A positive result** is indicative of primary adrenal insufficiency (Addison's disease). Results should be interpreted within the context of clinical symptoms, including functional adrenal testing. **In males with adrenal insufficiency and negative results for 21-hydroxylase antibodies, X-Linked Adrenoleukodystrophy (X-ALD) should be excluded by using Very Long-Chain and Branched-Chain Fatty Acids Profile (FATLON) in plasma for screening.** *(continued on page 8)*	2/18/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hydroxylase-21 Antibody *(continued from page 7)*		**Specimen Requirement:** 1 mL serum from a plain no additive (red) tube; Minimum: **0.3 mL;** Transfer 1 mL serum to a standard aliquot tube; Refrigerated *OR* 1 mL serum from a **serum separator (gold)** tube; Minimum: **0.3 mL;** Transfer 1 mL serum to a standard aliquot tube; Refrigerated **Stability:** Ambient: After separation from cells: **24 hours** Refrigerated: After separation from cells: 1 week Frozen: After separation from cells: **1 month** **Methodology: Qualitative Enzyme-linked Immunosorbent Assay** **Reference Range: Negative** **Days Performed:** Tuesday, **Friday** **Reported:** 3–**8** days **CPT: 83516 x 1**	
Iodine, Urine	UIODNE	**Special Information:** Must collect in plastic container. Indicate total volume and collection time interval. Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and nonessential over-the-counter medications for 48 hours (upon the advice of their physician). Additionally, the administration of iodine-based contrast media and drugs containing iodine may yield elevated results. Unacceptable conditions: Urine collected within **72 hours** after administration of a gadolinium (Gd) or iodine (I) containing contrast media (may occur with MRI studies), acid preserved urine, specimens contaminated with blood or fecal material, specimens transported in non-trace element-free transport tube (with the exception of the original device). This test is New York DOH approved. **Reference Range:** Creatinine Urine per volume: Not established Creatinine, per 24 hour: Refer to report Iodine, Urine per Volume 0–15 Years: Not established 16–99 Years: 26.0–705.0 µg/L Iodine, per gram of CRT: **35.0–540.0 µg/g crt** Iodine, Urine per 24h 0–15 Years: Not established 16–99 Years: 93.0–1125.0 µg/d	2/18/20
Leptospira Antibody, IgM by Dot Blot	LEPTDB	**Special Information:** Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of the acute specimens. Please mark specimen plainly as 'acute' or 'convalescent.' **Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens will be rejected. Any other body fluids are unacceptable. This test is New York DOH approved.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.2 mL; Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of the acute specimens; Please label specimen plainly as 'acute' or 'convalescent;'** Separate serum from cells ASAP or within 2 hours of collection **and transfer into a standard aliquot tube;** Refrigerated *OR* 1 mL plasma from a sodium or lithium heparin (green) tube; Minimum: **0.2 mL; Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of the acute specimens; Please label specimen plainly as 'acute' or 'convalescent;'** Separate plasma from cells ASAP or within 2 hours of collection **and transfer into a standard aliquot tube;** Refrigerated **Stability:** Ambient: **After separation from cells:** 48 hours Refrigerated: **After separation from cells:** 2 weeks Frozen: **After separation from cells:** 1 year (Avoid repeated freeze/thaw cycles) **Reference Range:** **Negative: No significant level of Leptospira IgM antibody detected** **Equivocal: Questionable presence of Leptospira IgM antibody detected; Repeat testing in 10–14 days may be helpful** **Positive: Presence of IgM antibody to Leptospira detected, suggestive of a current or recent infection**	2/18/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Lipid Associated Sialic Acid	LIPSIA	**Clinical Information:** Lipid Associated Sialic Acid is a useful adjunct in the management of a variety of malignancies. It is generally used in conjunction with other tumor markers. Values obtained with different assay methods should not be used interchangeably in serial testing. It is recommended that only one assay method be used consistently to monitor each patient's course of therapy. This procedure does not provide serial monitoring; it is intended for one-time use only. **Reference Range: 8–23 mg/dL** **Days Performed:** Tuesday, Thursday **Reported: 5–8** days	Effective immediately
Manganese, Serum	SMANG	**Special Information:** Patient Prep: Diet, medication and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals and non-essential over-the-counter medications (upon the advice of their physician). Unacceptable conditions: **Plasma.** Hemolyzed specimens. Separator tubes **or EDTA (royal blue) tubes.** Specimens that are not separated from the red cells, or clot, within **2 hours. Specimens transported in tubes other than specified.** This test is New York DOH approved. **Clinical Information:** Less than 5% of manganese present in circulation resides in the serum. **Elevated results may be due to skin or collection-related contamination, including the use of a noncertified metal-free collection/transport tube. If contamination concerns exist due to elevated levels of serum manganese, confirmation with a second specimen collected in a certified metal-free tube is recommended.** **Stability:** Ambient: **Indefinitely** Refrigerated: **Indefinitely** Frozen: **Indefinitely** **Days Performed:** Monday–**Sunday** **Reported:** 2–6 days	2/18/20
Methylmalonic Acid Blood	MMA	**Specimen Requirement:** 2 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.7 mL; Centrifuge and **transfer plasma to a clean, tightly sealed tube within 2 hours of collection;** Refrigerate within 24 hours; Refrigerated *OR* 2 mL plasma from a sodium heparin (green) tube; Minimum: 0.7 mL; Centrifuge and transfer plasma to a clean, tightly sealed tube **within 2 hours of collection;** Refrigerate within 24 hours; Refrigerated *OR* 2 mL serum from a plain no additive (red) tube; Minimum: 0.7 mL; Centrifuge and **transfer serum to a clean, tightly sealed tube within 2 hours of collection;** Refrigerate within 24 hours; Refrigerated *OR* 2 mL serum from a serum separator (gold) tube; Minimum: 0.7 mL; Centrifuge and **transfer serum to a clean, tightly sealed tube within 2 hours of collection**; Refrigerate within 24 hours; Refrigerated **Stability:** Ambient: **48 hours** Refrigerated: **14 days** Frozen: **6 months** **Methodology:** High Performance Liquid Chromatography/**Tandem** Mass Spectrometry **(LC/MS/MS)** **Days Performed:** Monday–**Friday** **Reported:** 1–6 days	3/3/20
Myeloid NGS Panel Bone Marrow	MYMNGS	**Special Information: The following genes are interrogated: ABL, ASXL1, BCOR, BCORL1, CALR, CBL, CEBPA, CSFR3, CUX1, DDX41, DNMT3A, EED, ETNK1, ETV6, EZH2, FLT3, GATA1, GATA2, IDH1, IDH2, JAK2, KIT, KMT2A, KRAS, MPL, NF1, NPM1, NRAS, PHF6, PIGA, PPMID, PTEN, PTPN11, RAD2, RUNX1, SETBP1, SF3B1, SH2B3, SMC1A, SMC3, SRSF2, STAG2, STAT3, STAT5B, SUZ12, TET2, TP53, U2AF1, WT1, and ZRSR2**	Effective immediately
Myeloid NGS Panel Peripheral Blood	MYPNGS	**Special Information: The following genes are interrogated: ABL1, ASXL1, BCOR, BCORL1, CALR, CBL, CEBPA, CSF3R, CUX1, DDX41, DNMT3A, EED, ETNK1, ETV6, EZH2, FLT3, GATA1, GATA2, IDH1, IDH2, JAK2, KIT, KMT2A, KRAS, MPL, NF1, NPM1, NRAS, PHF6, PIGA, PPMID, PTEN, PTPN11, RAD2, RUNX1, SETBP1, SF3B1, SH2B3, SMC1A, SMC3, SRSF2, STAG2, STAT3, STAT5B, SUZ12, TET2, TP53, U2AF1, WT1, and ZRSR2**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Opiates Confirmation, Quantitation Serum/ Plasma	OPISEC	**Special Information: Separator tubes or hemolyzed specimens will be rejected. Specimens exposed to repeated freeze/thaw cycles are unacceptable. Plasma or whole blood collected in sodium citrate (light blue) tubes will be rejected. This test is New York DOH approved.** **Specimen Requirement:** 1 mL plasma from a **potassium oxalate/sodium fluoride (gray) tube;** Minimum: 0.5 mL; Do not use plasma separator tubes; Separate plasma from cells ASAP or within 2 hours of collection **and transfer into a standard aliquot tube;** Refrigerated *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Do not use plasma separator tubes; Separate plasma from cells ASAP or within 2 hours of collection **and transfer into a standard aliquot tube;** Refrigerated *OR* 1 mL plasma from a sodium heparin (green) tube; Minimum: 0.5 mL; Do not use plasma separator tubes; Separate plasma from cells ASAP or within 2 hours of collection **and transfer into a standard aliquot tube;** Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Do not use serum separator tubes; Separate serum from cells ASAP or within 2 hours of collection **and transfer into a standard aliquot tube;** Refrigerated **CPT: 80361 x 1, 80365 x 1** (G0480, if appropriate)	2/6/20
PML/RARA RTPCR	APLPCR	**Note:** *There is a clinically significant charting name change associated with this test. Change the charting name for component PML-RARA Translocation t(15;17) to PML-RARA Translocation. PML-RARA Detection by RT-PCR, Quantitative will be added as an alias name.*	2/18/20
Protein, Urine Qualitative	UPROT	**Special Information:** Turbidity, X-ray contrast media, and certain drugs may affect results. **Protein measurements on visibly bloody urine samples will be reported as: "Visible blood causes falsely elevated results for analyte protein. Due to this limitation, protein will not be reported for patients whose urine contains visible blood."**	2/24/20
Pseudocholi-nesterase, Total, Serum	PCHE	**Special Information: Patient Prep: For cases of prolonged apnea following surgery, wait at least 24 hours before obtaining specimen.** **Clinical Information: Useful for monitoring exposure to organophosphorus insecticides. Monitoring patients with liver disease, particularly those undergoing liver transplantation. Identifying patients who are homozygous or heterozygous for an atypical gene and have low levels of pseudocholinesterase (PCHE). This test is not useful for the differential diagnosis of jaundice. Cautions: Certain drugs and anesthetic agents may produce in-vitro inhibition of the PCHE activity. Therefore, it is recommended that blood** specimens be drawn 24 **to 48 hours** post-operatively on those patients who have experienced prolonged apnea after surgery. **There are some homozygous and heterozygous individuals who are sensitive to succinylcholine although their total pseudocholinesterase values are normal. A dibucaine inhibition test is necessary to confirm the presence of the abnormal allele in these individuals. Chemotherapy may interfere with test results, depending on the impact it has on the liver. PCHE levels may be lower due to this, and if so, testing should be repeated at a later date.** **Stability:** Ambient: **24 hours** Refrigerated: **14** days **(preferred)** Frozen: **365** days **Methodology: Colorimetry** **Reference Range:** Male: **5320–12920 U/L** Female **0–15 Years: 5320–12920 U/L** **16–39 Years: 4260–11250 U/L** **40–41 Years: 5320–12920 U/L** **42 Years and older: 5320–12920 U/L** **Note: Females age 18–41 years who are pregnant or taking hormonal contraceptives: 3650–9120 U/L** **Days Performed: Monday–Friday** **Reported:** 2–3 days	1/28/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Selenium, Plasma or Serum	PSELEN	**Special Information:** Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). Unacceptable conditions: Specimens that are not separated from the red cells or clot within **2 hours. Specimens collected and/or transported in containers other than specified.** This test is New York DOH approved. **Clinical Information:** Serum selenium levels can be used in the determination of deficiency or toxicity. Plasma and serum contains 75% of the selenium measured in whole blood and reflects recent dietary intake. Selenium deficiency can occur endemically or as a result of sustained total parenteral nutrition (TPN) or restricted diets and has been associated with cardiomyopathy and may exacerbate hypothyroidism. Selenium toxicity is relatively rare. Excess intake of selenium can result in symptoms consistent with selenosis, including mild nerve damage, gastrointestinal upset, white blotchy nails, and hair loss. **Elevated results may be due to contamination from skin or other collection-related issues, including the use of a noncertified metal-free collection/transport tube. If contamination concerns exist due to elevated levels of serum/plasma selenium, confirmation with a second specimen collected in a certified metal-free tube is recommended.** **Specimen Requirement:** 2 mL plasma from an EDTA (royal blue) tube; Minimum: 0.5 mL; Diet, medication, and nutritional supplements may introduce interfering substances; Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician); Separate plasma from cells ASAP or within 2 hours of collection and aliquot into a trace metal-free transport tube (ARUP #43116); Ambient *OR* 2 mL serum from a plain no additive (navy blue) tube; Minimum: 0.5 mL; Diet, medication, and nutritional supplements may introduce interfering substances; Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician); Separate serum from cells ASAP or within 2 hours of collection and aliquot into a trace metal-free transport tube (ARUP #43116); Ambient **Stability:** Ambient: **Indefinitely** Refrigerated: **Indefinitely** Frozen: **Indefinitely** **Reference Range: 23.0–190.0 µg/L**	2/18/20
Strongyloides IgG Abs, Serum	STRSER	**Special Information: Heat inactivation of samples is not recommended. Avoid repeat freezing and thawing of the specimen. Bacterial contamination may affect results and should be avoided. Patients with equivocal results should have the test repeated with a fresh sample in 2–4 weeks.** **Clinical Limitation: Cross reactions with antibodies against other worms and parasites cannot be excluded.** **Clinical Information: This test detects IgG produced against two recombinant and specific Strongyloides stercoralis antigens. It cannot determine the time of infection; however, it can be negative during the first few weeks after an acute infection. IgG levels may remain elevated for life but may also decline with adequate treatment. Equivocal results may be seen during early infection, years after spontaneous clearance, post treatment, in immunosuppressed patients, or due to cross-reactivity with certain nematodes, Filariae, among others. Clinical and epidemiological correlation is required.** **Specimen Requirement: 0.5 mL** serum from a serum separator (gold) tube; Minimum: 0.3 mL; Refrigerated *OR* **0.5 mL** serum from a plain no additive (red) tube; Minimum: 0.3 mL; Refrigerated **Stability:** Ambient: **48 hours** Refrigerated: **7 days** Frozen: **14 days** **Methodology: Qualitative** Enzyme-linked Immunosorbent Assay **Reference Range: Negative** **Days Performed: Monday, Thursday** **Reported: 1–6** days	3/31/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Trypanosoma cruzi Antibody, IgM	TCAIGM	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.2 mL;** Separate serum from cells ASAP or within 2 hours of collection and transfer into a **standard aliquot tube;** Parallel testing is preferred, and convalescent specimens must be received within 30 days of the acute specimens; Label specimens plainly as 'acute' or 'convalescent;' Refrigerated	2/18/20
Urinalysis Only	UA	**Special Information:** If hemoglobin/blood, leukocyte esterase and/or protein is/are positive, then microscopic analysis will be performed and billed. **Protein measurements from Urinalysis Only (UA) on visibly bloody samples will be reported as: "Visible blood causes falsely elevated results for analyte protein. Due to this limitation, protein will not be reported for patients whose urine contains visible blood."**	2/25/20
Urinalysis with Microscopic	UAWMIC	**Special Information: Protein measurements from Urinalysis with Microscopic (UAWMIC) on visibly bloody samples will be reported as: "Visible blood causes falsely elevated results for analyte protein. Due to this limitation, protein will not be reported for patients whose urine contains visible blood."**	2/25/20
Varicella Zoster IgG Ab, CSF	CVZVG	**Reference Range:** **134.9 IV or less: Negative–No significant level of IgG antibody to varicella-zoster virus detected** **135.0–164.9 IV: Equivocal–Repeat testing in 10–14 days may be helpful** **165.0 IV or greater: Positive–IgG antibody to varicella-zoster virus detected, which may indicate a current or past varicella-zoster infection**	2/18/20

New Tests

Test Name	Order Code	Change	Effective Date
Free Light Chains, Quantitative, Urine	UFLCKL	**Special Information:** Include total volume and collection time interval on transport tube and with order. This test is New York DOH approved. **Clinical Information:** Results of urine free light chain testing can be used to monitor disease progression or response to therapy in patients for whom urine electrophoresis is unable to provide reliable Bence Jones Protein quantification. Results of urine kappa and lambda free light chains must be interpreted in conjunction with urine immunofixation. The free light chain quantitative values may be misleading in specimens with high levels of urinary polyclonal free light chains, and absent Bence Jones protein by immunofixation; therefore correlation with urine immunofixation is required to identify inconsistent results. Total urine protein is determined turbidimetrically by adding the albumin and kappa and/or lambda light chains. This value may not agree with the total protein as determined by chemical methods, which characteristically underestimate urinary light chains. **Specimen Requirement:** 1 mL 24-hour urine (well-mixed) in a clean container; Minimum: 0.5 mL; Refrigerate during collection; Transfer 1 mL aliquot from a well-mixed 24-hour collection into a standard aliquot tube; Record total volume and collection time interval on tube; Refrigerated *OR* 1 mL random urine in a clean container; Minimum: 0.5 mL; Urine supernatant is also acceptable; Refrigerated **Stability:** Ambient: Unacceptable Refrigerated: 3 weeks Frozen: 6 months **Methodology:** Quantitative Immunoturbidimetric **Reference Range:** Free Urinary Kappa Light Chains: 0.00–32.90 mg/L Free Urinary Kappa Excretion/Day: Refer to report Free Urinary Lambda Light Chains: 0.00–3.79 mg/L Free Urinary Lambda Excretion/Day: Refer to report Total Protein: < 150 mg/d **Days Performed:** Sunday–Saturday **Reported:** 2–4 days **CPT:** 83520 x 2, 84156 x 1 **Price:** $124.00 (non-discountable)	2/18/20

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
KIT Mutation Exons 8-11 and 17, Hematologic Neoplasms, Sequencing	KITEML	$1035.00 (non-discountable)	81272	Effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Bence Jones Protein, Qt Free Kappa/ Lambda Light Chains	UBJP	This test will no longer be available. Suggest ordering Free Light Chains, Quantitative, Urine (UFLCKL) and Monoclonal Protein, Urine (URMPA).	2/18/20
Factor XIII V34L DNA	XIIIVL	This test will no longer be available.	4/2/20
Urine Kappa/Lambda Free Light Chains (FLC) with Ratio	UKLFRE	This test will no longer be available. Suggest ordering Free Light Chains, Quantitative, Urine (UFLCKL) and Monoclonal Protein, Urine (URMPA).	2/18/20
Williams Syndrome, 7q11.23 Deletion, FISH	WMS	This test will no longer be available.	4/2/20
X-Linked Intellectual Disability (XLID)	XLID	This test will no longer be available.	4/2/20