Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • June 2018

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
5	5' Nucleotidase						■							
5	17-Hydroxyprogesterone						■							
5	ACADM PCR, Complete, Tier 2												■	
16	Adalimumab Activity and Neutralizing Antibody			■										
16	Allergen, Mouse Urine Proteins IgE			■										
16	Allergen, Phoma Betae IgE			■										
5	Alpha Thalassemia Gene Deletion					■								
5–6	Aminolevulinic Acid Dehydratase (ALAD), Whole Blood					■	■		■	■	■			
6	Babesia Microti IgG & IgM Abs					■	■							
17	Bacterial PCR, Direct Specimen			■										
23	BK Virus PCR Qual, Urine				■									
6	Bone marrow Cancer Chromosome Microarray + SNP						■				■	■		
7, 23	Calprotectin, Fecal					■	■				■	■		■
17	CEBPA Mutation Analysis Marrow			■										
23	Chlamydia trachomatis DFA				■									
7	Chromosomal Microarray SNP, Constitutional										■			
7	Cobalt, Serum or Plasma		■			■					■			
7	Complement C5					■	■		■	■	■	■		
8	Coxsackie A, 6 Antibodies					■	■				■	■		
23	Cytomegalovirus Antiviral Drug Resistance				■									
17	Cytomegalovirus Antiviral Drug Resistance by Sequencing			■										

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
18	FLT3 Tyrosine Kinase Domain Analysis Blood			■										
18	FLT3 Tyrosine Kinase Domain Mutation, Bone Marrow			■										
8	Helicobacter pylori Ab, IgG										■			
8	Hepatitis A Antibody, IgM					■								
8	Hepatitis B Core Antibody Total					■								
8	Hepatitis B Surface Ab, Immunity					■	■							
9	Hepatitis B Surface Ab, Qual.					■	■							
9	Hepatitis B Surface Ab, Quant					■	■					■		
9	Hepatitis E Antibody IgG										■			
9	Hepatitis E Antibody IgM										■			
18–19	High Sensitivity Total Testosterone			■										
9	HSV PCR, Miscellaneous Specimen Types											■		
10	Hypercoagulation Diagnostic Interpretive Panel						■			■				
10	Immunoglobulin D					■	■					■		
19	JAK2 Exon 12-15 Mutation Detection Bone Marrow			■										
19	JAK2 V617F Mutation Detection Bone Marrow			■										
23	Long Chain Fatty Acids				■									
10	Medium Chain Acyl-CoA Dehydrogenase, Tier 1, Targeted								■				■	
19	MPL Mutation Analysis Marrow			■										
10	MSI (PCR) X 2						■				■	■		
10	M. tuberculosis Amplified, CSF					■	■	■	■			■	■	
11	Mumps IgM Antibody					■	■				■	■		
11	MuSK Antibody Test					■	■			■	■	■		
11	Mycophenolic Acid and Metabolite					■				■				
23	Mycoplasma hominis PCR				■									
19	Myeloproliferative Neoplasm Panel Marrow			■										
19	Myeloproliferative Neoplasm Panel Peripheral Blood			■										
11	Neisseria meningitidis IgG Vaccine Response										■			
23	Norovirus Group 1 and 2 Detection by PCR													■
19	NPM1 Mutation Detection Bone Marrow			■										
23	Oil Red O LC				■									
23	Oncologic CytoScan HD SNP Array				■									
12	Ovarian Antibody Screen with Reflex to Titer, IFA		■			■	■	■	■	■	■	■	■	
12	Phospholipids, Serum or Plasma		■			■	■		■	■	■	■		
12	Porphobilinogen, Urine Quant					■	■							
12	Prenatal Quad Screen											■		
12	Prothrombin Gene Mutation										■			
12	Salicylate									■				
13	Sickle Cell Preparation					■								
13	Sotalol					■	■				■			

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
23	Toxicology Screen w/ confirmation, Urine				■									
20	Toxicology Screen with Confirmation, Urine			■										
13	Tropheryma whipplei PCR					■	■					■		
23	Universal Bacterial, Fungal, and AFB PCR				■									
13	Urobilinogen Screen, Urine											■		
20	Urogenital Ureaplasma and Mycoplasma Species by PCR			■										
13	Vancomycin						■							
14	Vascular Endothelial Growth Factor					■								
21–22	Very Long-Chain and Branched-Chain Fatty Acids Profile			■										
14	VIP					■								
14	Vitamin B5 (Pantothenic Acid) Bioassay					■	■				■	■		
14	Vitamin B7 (Biotin)					■					■			
14	Vitamin C					■					■	■		
23	Whipple's Disease DNA by PCR				■									
14–15	Y-Chromosome Microdeletion					■	■	■	■		■	■		

Dear Valued Client,

For several chemistry tests, additional information regarding sample collection has been added: “Patients taking a biotin dose of up to 5 mg/day should refrain from taking biotin for 4 hours prior to sample collection. Patients taking a biotin dose of 5 to 10 mg/day should refrain from taking biotin for 8 hours prior to sample collection. Patients taking a biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.” Please see the Special Information field of each affected test in the Test Directory for test-specific details. The following tests are affected:

- Beta HCG, Quantitative, Blood (HCGQT)
- Bioavailable Testosterone, SHBG, Adult Male (BTESTO)
- CA 125 (CA125)
- CA 15-3 (CA153)
- CKMB (MBE)
- CK, Total and CKMB (CKCKMB)
- DHEA-S (DHEAS)
- Estradiol-17 B (E2)
- Ferritin (FERR)
- Folate, Serum (SERFOL)
- FSH (FSH)
- LH (LH)
- LH, Pediatric (LHPED)
- LH with Tanner Stages (LHTAN)
- Luteinizing Hormone/Follicle Stimulating Hormone (XLHFSH)
- Myoglobin, Serum (MYOGLB)
- NT Pro BNP (NTBNP)
- Procalcitonin (PROCAL)
- Progesterone (PROG)
- Prolactin (PROL)
- PSA (PSA)
- PSA, Free (PSATF)
- PSA, Screening (PSAS1)
- PTH, Intact (PTHI)
- Sex Hormone Binding Globulin (SHBG2)
- T3, Free (FREET3)
- T4 (T4)
- T4, Free (FT4)
- T4/FTI (T4FTI)
- Testosterone (TESTO)
- Testosterone, Free and Total (FTESTO)
- Troponin T (TNT)
- TSH (TSH)
- Vitamin B12 (B12)
- Vitamin B12 & Folate (XB12F)
- Vitamin B12 w/reflex (B12RFX)

Test Changes

Test Name	Order Code	Change	Effective Date
5' Nucleotidase	NUC5P	**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; **Avoid hemolysis;** Refrigerated	7/31/18
17-Hydroxy-progesterone	HPROG	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL **(Serum, after separation from cells);** Transfer 1 mL serum to standard aliquot tube; Refrigerated *OR* 1 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 0.3 mL **(Plasma, after separation from cells);** Transfer 1 mL plasma to standard aliquot tube; Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.3 mL **(Serum, after separation from cells);** Transfer 1 mL serum to standard aliquot tube; Refrigerated *OR* 1 mL plasma from a sodium or lithium heparin (light green) plasma separator tube (PST); Minimum: 0.3 mL **(Plasma, after separation from cells);** Transfer 1 mL plasma to standard aliquot tube; Refrigerated	Effective immediately
ACADM PCR, Complete, Tier 2	ACADM	**CPT: 81406 x 1**	Effective immediately
Alpha Thalassemia Gene Deletion	ATHALS	**Note:** ***Alias names for this test include Alpha globin gene analysis, Alpha globin mutations,*** *Alpha Thal and Alpha Thalassemia*	Effective immediately
Aminolevulinic Acid Dehydratase (ALAD), Whole Blood	ALADWB	**Special Information:** Patient Prep: Patient should abstain from alcohol for 24 hours prior to collection. Include a list of medications the patient is currently taking. After collection, immediately place specimen in an ice bath. Hemolyzed specimens **(mild to** grossly hemolyzed) are unacceptable. **Ambient or frozen whole blood will be rejected. Informed consent is required for New York clients. Note: Testing is not reported on Saturday or Sunday.** **Clinical Information: Preferred test** for the confirmation of a diagnosis of aminolevulinic acid dehydratase deficiency porphyria. **Aminolevulinic acid dehydratase (ALAD) activity can be inhibited in situations including hereditary tyrosinemia type 1, lead intoxication, and exposure to styrene, trichloroethylene, or bromobenzene. These causes should be ruled out when considering a diagnosis of ALAD deficiency porphyria (ADP). This method will not exhibit a decreased ALAD enzyme activity due to lead intoxication. Porphyrias are a group of inherited disorders resulting from enzyme defects in the heme biosynthetic pathway. A defect in the second enzyme of this pathway causes 5-aminolevulinic acid dehydratase deficiency porphyria. A marked deficiency of ALAD causes the accumulation and subsequent urinary excretion of large amounts of aminolevulinic acid. Urinary porphobilinogen (PBG) remains essentially normal, which rules out other forms of acute porphyria.** ADP is a rare **autosomal recessive acute hepatic** porphyria **that produces neurologic symptoms similar to those seen in acute intermittent porphyria. Symptoms include acute abdominal pain, peripheral neuropathy, nausea, vomiting, constipation, and diarrhea. Respiratory impairment, seizures, and psychosis are possible during an acute period. The workup of patients with a suspected porphyria is most effective when following a stepwise approach. Cautions: This assay is not useful in assessment of lead intoxication as it reactivates ALAD that has been inhibited by lead. Abstinence from alcohol is essential for at least 24 hours prior to specimen collection as ethanol suppresses ALAD activity. False-positive values may result from enzyme degradation due to improper specimen handling.** **Specimen Requirement:** 5 mL whole blood in a sodium heparin (green) tube; Minimum: 3 mL; Place specimen on ice after draw; **Fill tube completely;** Patient should abstain from alcohol for 24 hours; Include a list of medications the patient is currently taking; Send specimen to Cleveland Clinic Laboratories on the day of collection; Transport 5 mL whole blood in original tube; Refrigerated *OR* 5 mL whole blood in an EDTA (lavender) tube; Minimum: 3 mL; Place specimen on ice after draw; **Fill tube completely;** Patient should abstain from alcohol for 24 hours; Include a list of medications the patient is currently taking; Send specimen to Cleveland Clinic Laboratories on the day of collection; Transport 5 mL whole blood in original tube; Refrigerated *(continued on page 6)*	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Aminolevulinic Acid Dehydratase (ALAD), Whole Blood *(continued from page 5)*		*OR* 5 mL whole blood in a lithium heparin (green) tube; Minimum: 3 mL; Place specimen on ice after draw; **Fill tube completely;** Patient should abstain from alcohol for 24 hours; Include a list of medications the patient is currently taking; Send specimen to Cleveland Clinic Laboratories on the day of collection; Transport 5 mL whole blood in original tube; Refrigerated **Methodology:** Enzymatic **End Point** Spectrofluorometric **Reference Range (Not established for patients < 16 years old):** **≥ 4.0 nmol/L/sec** **3.5–3.9 nmol/L/sec (Indeterminate)** **< 3.5 nmol/L/sec (Diminished)** **Days Performed: Monday, Wednesday, Friday** **Reported:** 4–**5** days	
Babesia Microti IgG & IgM Abs	BMICGM	**Special Information: Bacterially contaminated, hemolyzed or lipemic specimens are unacceptable.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.1 mL; Remove serum from cells ASAP or within 2 hours of collection; **Parallel testing is preferred and convalescent specimens MUST be received within 30 days from receipt of the acute specimens; Please mark specimens plainly as ACUTE or CONVALESCENT;** Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.1 mL; Remove serum from cells ASAP or within 2 hours of collection; **Parallel testing is preferred and convalescent specimens MUST be received within 30 days from receipt of the acute specimens; Please mark specimens plainly as ACUTE or CONVALESCENT;** Refrigerated *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.1 mL; Remove plasma from cells ASAP or within 2 hours of collection; **Parallel testing is preferred and convalescent specimens MUST be received within 30 days from receipt of the acute specimens; Please mark specimens plainly as ACUTE or CONVALESCENT;** Refrigerated *OR* 1 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 0.1 mL; Remove plasma from cells ASAP or within 2 hours of collection; **Parallel testing is preferred and convalescent specimens MUST be received within 30 days from receipt of the acute specimens; Please mark specimens plainly as ACUTE or CONVALESCENT;** Refrigerated *OR* 1 mL plasma from an ACD A or B (yellow) tube; Minimum: 0.1 mL; Remove plasma from cells ASAP or within 2 hours of collection; **Parallel testing is preferred and convalescent specimens MUST be received within 30 days from receipt of the acute specimens; Please mark specimens plainly as ACUTE or CONVALESCENT;** Refrigerated	Effective immediately
Bone marrow Cancer Chromosome Microarray + SNP	BMHSNP	**Specimen Requirement:** 4 mL bone marrow in an EDTA (lavender) tube; Notes: Collect specimen Monday–Friday only; If aliquoting is necessary, sterile aliquot tubes must be used; Ambient *OR* **5–7 mL** bone marrow in a **sodium heparin (green) tube; EDTA is preferred container type;** Collect specimen Monday–Friday only; If aliquoting is necessary, sterile aliquot tubes must be used; Ambient **Stability:** Ambient: 48 hours Refrigerated: **Not preferred** Frozen: Unacceptable **Days Performed:** Monday–Friday **Reported:** 14 days	6/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Calprotectin, Fecal	CALPRO	**Note:** *Clinical Information will be removed for this test* **Specimen Requirement:** 5 g random stool in a sterile container; Minimum: 1 g; Collect stool in a preservative-free, sterile container; Refrigerated **Stability:** Ambient: **10** days Refrigerated: **10** days Frozen: 1 year **Days Performed: Monday, Wednesday, Friday** **Reported:** 2–4 days	7/31/18
Chromosomal Microarray SNP, Constitutional	CRMSNP	**Days Performed:** 3 days per week **Reported: 14** days	6/7/18
Cobalt, Serum or Plasma	COBALT	**Test Name:** Previously Cobalt, Serum **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). **Specimens that are not separated from the red cells, or clot, within 6 hours are unacceptable. Separator tubes will be rejected. This test is New York DOH approved.** **Clinical Information:** Occupational exposure or **toxic ingestion** monitoring. **Preferred test for evaluating metal ion release from metal-on-metal joint arthroplasty. Levels may be increased in asymptomatic patients with metal-on-metal prosthetics and should be considered in the context of the overall clinical scenario. Symptoms associated with cobalt toxicity vary based on route of exposure, and may include cardiomyopathy, allergic dermatitis, pulmonary fibrosis, cough and dyspnea.** Elevated results from noncertified trace element-free tubes may be due to contamination. Elevated concentrations of trace elements in serum should be confirmed with a second specimen collected in a navy blue top tube with no additive. **Days Performed: Sunday–Saturday** **Reported:** 2–6 days	Effective immediately
Complement C5	COMPC5	**Special Information: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. Non-frozen specimens will be rejected. Specimens left to clot at refrigerated temperature and specimens exposed to repeated freeze/thaw cycles are unacceptable. This test is New York DOH approved.** **Clinical Information: Used as a follow-up test for complement activity screening when CH50 and AH50 are low or absent and high suspicion remains for complement deficiency.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL; Allow specimen to clot for one hour at room temperature; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Freeze immediately; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen** **Stability:** Ambient: **After separation from cells: 2 hours** Refrigerated: **After separation from cells: Unacceptable** Frozen: **After separation from cells: 2 weeks (Avoid repeated freeze/thaw cycles)** **Methodology: Radial Immunodiffusion (RID)** **Reference Range: 7–20 mg/dL** **Days Performed: Tuesday, Friday** **Reported:** 4–**9** days	8/7/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Coxsackie A, 6 Antibodies	COXSA6	**Special Information: This test is New York DOH approved.** **Specimen Requirement:** 2 mL serum from a plain no additive (red) tube; Minimum: 1 mL; **Centrifuge and transfer serum to a standard aliquot tube;** Ambient *OR* 2 mL serum from a **serum separator (gold) tube;** Minimum: 1 mL; **Centrifuge and transfer serum to a standard aliquot tube;** Ambient **Stability:** Ambient: **1 week** Refrigerated: **2 weeks** Frozen: **1 month** **Days Performed: Varies** **Reported: 4–9** days	8/9/18
Helicobacter pylori Ab, IgG	HPYLRI	**Days Performed:** Monday–Friday **Reported:** 1–3 days	Effective immediately
Hepatitis A Antibody, IgM	AHAVM	**Special Information: Not intended for use in screening blood, plasma, or tissue donors. Performance has not been established for the use of cadaveric specimens or the use of body fluids other than human serum. A reactive IgM anti-HAV result does not necessarily rule out other hepatitis infections. The results should be used and interpreted only in the context of the overall clinical picture. A negative test result does not exclude the possibility of exposure to hepatitis A virus. Specimens from individuals with Non-Hodgkin's Lymphoma may cross-react with this assay.** **Clinical Limitation: Criteria for rejection: Heat inactivated, pooled, grossly hemolyzed, obvious microbial contamination**	6/12/18
Hepatitis B Core Antibody Total	AHBCOT	**Special Information: Not intended for use in screening blood, plasma, or tissue donors. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients. Performance has not been established for the use of cadaveric specimens or the use of body fluids other than human serum. A nonreactive test result does not exclude the possibility of exposure to or infection with Hepatitis B Virus (HBV).** **Clinical Limitation: Criteria for rejection: Heat inactivated, pooled, grossly hemolyzed, obvious microbial contamination**	6/12/18
Hepatitis B Surface Ab, Immunity	AHBSI	**Special Information:** For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and chronic infection. Performance characteristics have not been established for therapeutic monitoring. **Test is not intended for use in screening blood, plasma, or tissue donors. Performance characteristics have not been established for immunocompromised or** immunosuppressed patients; results should be interpreted with caution. **Performance has not been established for the use of cadaveric specimens.** A non-reactive test result does not exclude the possibility of exposure to hepatitis B virus (HBV). Assay does not differentiate between vaccines and natural infections. A reactive anti-HBs result does not exclude co-infection by another hepatitis virus. Results obtained with the ARCHITECT AUSAB assay may not be used interchangeably with values obtained with different manufacturers' assay methods. **Clinical Information:** To assess the presence of a recent or remote immune response to HBV infection or vaccination. **Specimen Requirement: 0.5 mL** serum from a serum separator (gold) tube; Minimum: **0.25 mL;** Refrigerated *OR* **0.5 mL** plasma from an EDTA (lavender) tube; Minimum: **0.25 mL;** Refrigerated	6/4/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis B Surface Ab, Qual.	AHBSAG	**Special Information: For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and chronic infection. Performance characteristics have not been established for therapeutic monitoring. Test is not intended for use in screening blood, plasma, or tissue donors. Performance characteristics have not been established for immunocompromised or immunosuppressed patients; results should be interpreted with caution. Performance has not been established for the use of cadaveric specimens. A non-reactive test result does not exclude the possibility of exposure to hepatitis B virus (HBV). Assay does not differentiate between vaccines and natural infections. A reactive anti-HBs result does not exclude co-infection by another hepatitis virus. Results obtained with the ARCHITECT AUSAB assay may not be used interchangeably with values obtained with different manufacturers' assay methods.** **Clinical Limitation: Criteria for Rejection: Heat-inactivated, pooled, grossly hemolyzed, obvious microbial contamination** **Clinical Information:** To assess adequacy of recent or remote immune response to HBV infection or vaccination. **Specimen Requirement: 0.5 mL** serum from a serum separator (gold) tube; Minimum: **0.25 mL;** Refrigerated *OR* **0.5 mL** plasma from an EDTA (lavender) tube; Minimum: **0.25 mL;** Refrigerated	6/4/18
Hepatitis B Surface Ab, Quant	AHBSQ	**Special Information:** For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and chronic infection. Performance characteristics have not been established for therapeutic monitoring. **Test is not intended for use in screening blood, plasma, or tissue donors. Performance characteristics have not been established for immunocompromised or** immunosuppressed patients; results should be interpreted with caution. **Performance has not been established for the use of cadaveric specimens.** A non-reactive test result does not exclude the possibility of exposure to hepatitis B virus (HBV). Assay does not differentiate between vaccines and natural infections. A reactive anti-HBs result does not exclude co-infection by another hepatitis virus. Results obtained with the ARCHITECT AUSAB assay may not be used interchangeably with values obtained with different manufacturers' assay methods. **Clinical Information:** To assess the presence of a recent or remote immune response to HBV infection or vaccination. **Specimen Requirement: 0.5 mL** serum from a serum separator (gold) tube; Minimum: **0.25 mL;** Refrigerated *OR* **0.5 mL** plasma from an EDTA (lavender) tube; Minimum: **0.25 mL;** Refrigerated **Stability:** Ambient: **3 days** Refrigerated: **7** days Frozen: 14 days	6/4/18
Hepatitis E Antibody IgG	HEPIGG	**Days Performed:** Tuesday, **Thursday, Saturday** **Reported:** 2–**6** days	Effective immediately
Hepatitis E Antibody IgM	HEPIGM	**Days Performed:** Tuesday, **Thursday, Saturday** **Reported:** 2–**6** days	Effective immediately
HSV PCR, Miscellaneous Specimen Types	PCRHSV	**Stability:** Ambient: Tissue: Unacceptable; Plasma, serum, amniotic fluid, BAL: 8 hours Refrigerated: Tissue: Unacceptable; Plasma, serum, amniotic fluid, BAL: 72 hours Frozen: 3 months	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hypercoagulation Diagnostic Interpretive Panel	HYPER	**Specimen Requirement: 2 mL** serum from a serum separator (gold) tube; Minimum: **1 mL;** Indicate clearly which tube is plasma and which tube is serum; Submit Coagulation Consultation Patient History Form; Frozen *AND* 2 mL plasma from an EDTA (lavender) tube; Minimum: 1 mL; Refrigerated *AND* 4 mL whole blood in an EDTA (lavender) tube; Minimum: 2 mL; Refrigerated *AND* 6 mL plasma from a 3.2% sodium citrate (light blue) tube; Minimum: 3 mL; Frozen **Reference Range: Refer to individual components (See Homocysteine)**	6/7/18
Immunoglobulin D	IGDQNT	**Special Information: 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: 0.5 mL; Separate serum from cells ASAP or within 2 hours of collection **and transfer into standard aliquot tube; Frozen** **Stability:** Ambient: **After separation from cells:** 8 hours Refrigerated: **After separation from cells:** 48 hours Frozen: **After separation from cells:** 1 month	7/31/18
Medium Chain Acyl-CoA Dehydrogenase, Tier 1, Targeted	MCADD	**Methodology: Sanger Sequencing** **CPT: 81403 x 1**	Effective immediately
MSI (PCR) X 2	MSICCT	**Specimen Requirement:** Representative tumor: Formalin-fixed, paraffin-embedded (FFPE) tissue block, OR 10 unstained slides *AND* Representative patient normal: Formalin-fixed, paraffin-embedded (FFPE) tissue block, 5 unstained slides, preferably from separate block *OR* Representative tumor: Formalin-fixed, paraffin-embedded (FFPE) tissue block, OR 10 unstained slides *AND* 4 mL whole blood in an EDTA (lavender) tube; Representative patient normal: Whole blood if no FFPE tissue is available (e.g., small biopsies); **Ambient** **Stability:** Ambient: **Whole Blood–24 hours; Paraffin–embedded tissue–Indefinitely** Refrigerated: **Whole blood–7 days** Frozen: **Unacceptable** **Days Performed: 2 days per week** **Reported: 7** days	6/26/18
M. tuberculosis Amplified, CSF	MTBCSF	**For Interfaced Clients Only: Test build may need to be modified** **Special Information: Refer to specimen requirements for client-processed specimens. Blood, urine, swabs, stool, paraffin blocks and tissue are unacceptable. This test is New York DOH approved. Specimen source is required. In order to perform testing, it is essential to know whether or not the submitted specimen has been processed (digestion and decontamination procedure). If processed, smear results must be provided as a comment on the test order or requisition. Turnaround time will be delayed if the required information is not provided.** **Clinical Information: This panel uses PCR testing to detect M. tuberculosis complex isolates and determine possible resistance to rifampin treatment.** **Specimen Requirement: 5–10 mL** cerebrospinal fluid (CSF) in a sterile container; Minimum: 1 mL; **Label as 'Unprocessed CSF;' Specimen source required;** Refrigerated *OR* **2–5 mL digested/decontaminated** cerebrospinal fluid (CSF) in a sterile container; Minimum: 1 mL; **Indicate as "Processed CSF' and provide smear results and identify method of digestion; Each specimen should be placed in an individually sealed bag;** Refrigerated **Stability:** Ambient: **Unprocessed: 3 days; Processed: Unacceptable** Refrigerated: **Unprocessed: 1 week; Processed: 1 week** Frozen: **Unprocessed: 1 month; Processed: 1 month** **Methodology: Qualitative** Polymerase Chain Reaction **CPT:** 87556 x 1, **87798 x 1**	8/7/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Mumps IgM Antibody	MUMPSM	**Special Information:** Acute and convalescent specimens must be labeled as such; 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, hemolyzed, heat-inactivated, or severely lipemic specimens are unacceptable.** **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; Refrigerated **Stability:** Ambient: 2 days Refrigerated: 14 days Frozen: 1 year **(Avoid repeated freeze/thaw cycles)** **Days Performed:** Monday–Friday **Reported:** 2–**6** days	Effective immediately
MuSK Antibody Test	MUSK	**Special Information: This test is New York State approved.** **Clinical Information: Testing is useful for:** **1. Diagnosis of autoimmune muscle-specific kinase (MuSK) myasthenia gravis (MG)** **2. Second-line test aiding diagnosis of autoimmune MG in patients with new onset acquired MG evident clinically and electrophysiologically, but negative first-line serological tests** **3. Establishing a quantitative baseline value for MuSK antibodies that allows comparison with future levels if weakness is worsening.** **A positive result, in the appropriate clinical context, confirms the diagnosis of autoimmune muscle-specific kinase MG. Seropositivity justifies consideration of immunotherapy. Cautions: Immunosuppressant therapy is a common cause of false-seronegativity. It is, therefore, important to perform a comprehensive serological evaluation before initiating immunosuppressant therapy. Interpretation of a patient's serological and clinical status is further complicated when characteristic signs of MG are obscured by a superimposed steroid-induced myopathy.** **Specimen Requirement: 1.5 mL** serum from a plain no additive (red) tube; Minimum: **1 mL;** Refrigerated *OR* **1.5 mL** serum from a serum separator (gold) tube; Minimum: **1 mL;** Refrigerated **Stability:** Ambient: **72 hours** Refrigerated: **28** days Frozen: **28 days** **Reference Range: ≤ 0.02 nmol/L** **Days Performed:** Tuesday, Thursday **Reported:** 4–**11** days	8/2/18
Mycophenolic Acid and Metabolite	MYCMET	**Clinical Information:** Therapeutic monitoring for individuals taking mycophenolate. The therapeutic range is based on serum pre-dose (trough) draw at steady state concentration. A proposed therapeutic range is 1.0–3.5 μg/mL for a 2 g/day dose. A 3 g/day dose may have plasma concentrations up to 5.0 μg/mL. Trough concentrations between 2.0–4.0 μg/mL have been suggested to maximize efficacy and minimize adverse effects. Mycophenolic acid glucuronide is an inactive metabolite and a range of **35.0–100.0 μg/mL** indicates normal metabolism. During the first two weeks of transplantation, mycophenolic acid glucuronide concentrations are typically 100–250 μg/mL. Adverse effects of toxicity include abdominal pain, peripheral edema, cardiac abnormalities, hypertension and electrolyte disturbances. **Reference Range:** Mycophenolic Acid 0–99 Years: 1.0–3.5 μg/mL Myc. Acid Glucuronide 0–99 Years: **35.0–100.0 μg/mL**	Effective immediately
Neisseria meningitidis IgG Vaccine Response	NMEN	**Days Performed: Tuesday** **Reported:** 2–**8** days	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Ovarian Antibody Screen with Reflex to Titer, IFA	OVARAN	**For Interfaced Clients Only: Test build may need to be modified** **Test Name:** Previously Ovarian Antibody **Special Information: If Ovarian Antibody Screen is positive, a titer will be performed at an additional cost. Grossly hemolyzed and grossly lipemic specimens will be rejected.** **Clinical Information: Ovarian Antibody is found in patients with premature ovarian failure, Addison's disease, and polyendocrinopathy syndromes.** **Specimen Requirement: 1 mL** serum from a plain no additive (red) tube; Minimum: **0.3 mL;** Do not use serum separator tubes; **Send using cold packs; Refrigerated** **Stability:** Ambient: **7 days** Refrigerated: **14 days** Frozen: **30 days** **Methodology:** Immunofluorescence **Reference Range:** Negative; **Ovarian antibody screen is at 1:5 dilution** **Days Performed: Wednesday** **Reported: 4–11 days** **CPT: 86255 x 1**	6/7/18
Phospholipids, Serum or Plasma	PHOLIP	**Test Name:** Previously Phospholipids, Serum **Special Information: Patient Prep: Patient should fast for 12 hours prior to specimen collection. This test is New York DOH approved.** **Clinical Information: This test is useful in the evaluation of liver disease, particularly obstructive jaundice.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Collect blood following a **12-hour fast; Allow specimen to clot completely at room temperature, then transfer serum into a standard aliquot tube; Refrigerated** *OR* 1 mL **plasma from an EDTA (lavender) tube;** Minimum: 0.5 mL; Collect blood following a **12-hour fast; Allow specimen to clot completely at room temperature, then transfer plasma into a standard aliquot tube; Refrigerated** *OR* 1 mL **plasma from a sodium or lithium heparin (green) tube;** Minimum: 0.5 mL; Collect blood following a **12-hour fast; Allow specimen to clot completely at room temperature, then transfer plasma into a standard aliquot tube; Refrigerated** **Stability:** Ambient: **After separation from cells: 8 hours** Refrigerated: **After separation from cells: 1 month** Frozen: **After separation from cells: 1 month** **Methodology: Spectrophotometry** **Reference Range: 160–300 mg/dL** **Days Performed:** Monday, **Wednesday,** Friday **Reported:** 2–**5** days	8/2/18
Porphobilinogen, Urine Quant	UPBGQT	**Special Information:** Indicate total volume and time of collection on requisition. **Body fluids other than urine are unacceptable.** **Specimen Requirement: 8 mL** 24-hour urine (well-mixed) in a clean container; Minimum: **3.5 mL;** Refrigerate during collection; Protect specimen from light; Frozen *OR* **8 mL** random urine in a clean container; Minimum: **3.5 mL;** Protect specimen from light; Frozen	Effective immediately
Prenatal Quad Screen	QUAD4	**Stability:** Ambient: **1 day** Refrigerated: **7** days Frozen: **14 days**	7/31/18
Prothrombin Gene Mutation	PTGEN	**Days Performed: 3** days per week **Reported:** 5 days	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Salicylate	SALI	**Reference Range:** 0–99 Years: **3.0–30.0 mg/dL** (See Clinical Information)	Effective immediately
Sickle Cell Preparation	SCKSOL	**Special Information:** If the Sickle Cell Preparation is positive, the **further evaluation by capillary electrophoresis** will be performed at an additional charge. The Sickle Cell Preparation test should not be performed on children less than 6 months old. For children less than 6 months of age, **the hemoglobin evaluation cascade (HBEVAL)** should be ordered. Further testing may be required which includes **high performance liquid chromatography, isoelectric focusing, and rarely** alkaline and acid electrophoresis. These tests will be performed at an additional charge.	Effective immediately
Sotalol	SOTAL	**Special Information:** Draw specimen prior to next dose–at steady state concentration. Please provide the following information if available: 1.) Dose–List drug amount and include the units of measure 2.) Route–List the route of administration (IV, oral, etc.) 3.) Dose Frequency–Indicate how often the dose is administered (per day, per week, as needed, etc.) 4.) Type of Draw–Indicate the type of blood draw (Peak, trough, random, etc.) **Whole blood is unacceptable. Gel separator tubes, light blue (sodium citrate), and yellow (SPS or ACD solution) tubes will be rejected.** **Specimen Requirement:** 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; **Pre-dose (trough) draw–At a steady state concentration;** Separate serum from cells within 2 hours of collection; Refrigerated *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; **Pre-dose (trough) draw–At a steady state concentration;** Separate plasma from cells within 2 hours of collection; Refrigerated **Days Performed:** Monday, Thursday **Reported: 2–6** days	Effective immediately
Tropheryma whipplei PCR	WHIPWB	**Special Information:** Must indicate specimen source. Heparinized specimens are not acceptable. **This test is New York DOH approved.** **Specimen Requirement:** 1 mL whole blood from an EDTA (lavender) tube; Minimum: 0.5 mL; Transfer 1 mL whole blood into sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Transfer 1 mL plasma into sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Transfer 1 mL serum into sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen *OR* **Tissue in a sterile container; Freeze immediately;** Specimen source required; Frozen *OR* **Formalin-fixed paraffin-embedded (FFPE) tissue in a sterile container;** Specimen source required; **Ambient** **Stability:** Ambient: **Whole blood, plasma, serum, CSF: 24 hours; Tissue: Unacceptable; FFPE: Indefinitely** Refrigerated: **Whole blood, plasma, serum, CSF: 2 weeks; Tissue: Unacceptable; FFPE: Indefinitely** Frozen: **Whole blood, plasma, serum, CSF: 1 month; Tissue: 1 month; FFPE: Unacceptable**	7/31/18
Urobilinogen Screen, Urine	UUROB	**Stability:** Ambient: **Clean container–2 hours / BD Urine Preservative tube–72 hours** Refrigerated: **24 hours**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Vancomycin	VANCRA	**Specimen Requirement:** 1 mL **serum from a plain no additive (red) tube;** Minimum: 0.5 mL; Do not collect in a gel separator tube; Centrifuge and transfer serum to a CCL tube and refrigerate; Refrigerated *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Do not collect in a gel separator tube; Centrifuge and transfer plasma to a CCL tube and refrigerate; Refrigerated *OR* 1 mL **plasma from a lithium heparin (green) tube;** Minimum: 0.5 mL; Do not collect in a gel separator tube; Centrifuge and transfer plasma to a CCL tube and refrigerate; Refrigerated	Effective immediately
Vascular Endothelial Growth Factor	VEGF	**Special Information:** This assay is performed using the QuantiGlo® Chemiluminescent EIA kit. Values obtained with different assay methods or kits cannot be used interchangeably. **Hemolyzed specimens are unacceptable.**	Effective immediately
VIP	VIP	**Special Information:** Grossly hemolyzed specimens are unacceptable. **Peripheral draws are preferred. Samples drawn (directly into the protease tube) from ports are acceptable, but not recommended, and run the risk of contamination.** Separate specimens must be submitted when multiple tests are ordered. This test is New York DOH approved.	Effective immediately
Vitamin B5 (Pantothenic Acid) Bioassay	VITB5	**Special Information: Grossly hemolyzed, warm greater than 24 hours, grossly lipemic, specimens containing particulate matter or microbial contamination, and specimens unprotected from light are unacceptable.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Aliquot serum into a plastic tube and protect from light; Frozen **Stability:** Ambient: Unacceptable Refrigerated: **7 days** Frozen: 21 days **Days Performed: Monday** **Reported: 3–13** days	7/31/18
Vitamin B7 (Biotin)	VITB7	**Special Information: Grossly hemolyzed, grossly lipemic, thawed (warm or cold), and** specimens not light protected are unacceptable. **Days Performed: Monday** **Reported: 2–18** days	Effective immediately
Vitamin C	VITC	**Special Information: Thawing and refreezing of the specimen and exposure to light will result in decreased Vitamin C concentration. EDTA plasma, whole blood, body fluids, and grossly** hemolyzed specimens are unacceptable. **Stability:** Ambient: **After separation from cells:** Unacceptable Refrigerated: **After separation from cells:** Unacceptable Frozen: After separation from cells: **1 year** **Days Performed:** 2–**7** days **Reported:** Sunday, **Tuesday–Thursday,** Saturday	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Y-Chromosome Microdeletion	YCMICR	**For Interfaced Clients Only: Test build may need to be modified** **Special Information: Counseling and informed consent are recommended for genetic testing. Do NOT freeze. Serum, frozen specimens, and severely hemolyzed specimens are unacceptable. This test is New York DOH approved.** **Clinical Limitation: Diagnostic errors can occur due to rare sequence variations. Mutations within individual genes included in the AZF regions will not be detected. Breakpoints of identified microdeletions will not be determined. Male infertility, due to causes other than Y chromosome microdeletions tested, has not been excluded.** **Clinical Information: Aids in determining the cause of azoospermia or oligospermia and helps predict effectiveness of assisted reproductive technologies in men with Y chromosome microdeletions. Background Information: Y Chromosome Microdeletion. Characteristics: Y chromosome microdeletions are typically characterized by azoospermia, severe to moderate oligospermia, or abnormal sperm morphology/motility in men with a normal physical evaluation. Assisted reproductive techniques are contraindicated for men carrying AZFa, AZFb, AZFbc or AZFabc microdeletions, which are classically associated with spermatogenic failure. Prevalence: 1 in 2,000 to 3,000 males carry Y chromosome deletions/microdeletions. Penetrance: Approaches 100% in males; variable expression may result in intra-familial variation of fertility in men with an identical microdeletion. Inheritance: Y-linked; microdeletions are typically de novo. Cause: Microdeletions of the Y chromosome azoospermia factor regions a, b or c (AZFa, AZFb or AZFc). Mutations Tested: Five common Y chromosome microdeletions: AZFa, AZFb, AZFc, AZFbc, and AZFabc.** *(continued on page 15)*	8/7/18
Y-Chromosome Microdeletion *(continued from page 14)*		**Clinical Sensitivity: Estimated at 5 to 10% for men with non-obstructive azoospermia or severe oligospermia. Methodology: Multiplex PCR followed by electrophoresis. Analytical Sensitivity and Specificity: Greater than 99%** **Specimen Requirement:** 3 mL whole blood in an **EDTA (lavender) tube;** Minimum: **1 mL; Do NOT freeze;** Send to Cleveland Clinic Laboratories on the day of collection; **Refrigerated** *OR* 3 mL whole blood in a **sodium or lithium heparin (green) tube;** Minimum: **1 mL; Do NOT freeze;** Send to Cleveland Clinic Laboratories on the day of collection; **Refrigerated** *OR* 3 mL whole blood in a **sodium citrate (light blue) tube;** Minimum: **1 mL; Do NOT freeze;** Send to Cleveland Clinic Laboratories on the day of collection; **Refrigerated** *OR* 3 mL whole blood in an ACD A or B (yellow) tube; Minimum: **1 mL; Do NOT freeze;** Send to Cleveland Clinic Laboratories on the day of collection; **Refrigerated** **Stability:** Ambient: **72 hours** Refrigerated: **1 week** Frozen: **Unacceptable** **Methodology:** Electrophoresis Polymerase Chain Reaction (PCR) **Days Performed: Tuesday,** Friday **Reported: 8–11** days	

New Tests

Test Name	Order Code	Change	Effective Date
Adalimumab Activity and Neutralizing Antibody	ADANEU	**Note:** *This test was previously announced in the May 2018 Technical Update.* **Price:** $389.00 (non-discountable)	Effective immediately
Allergen, Mouse Urine Proteins IgE	MOUUR	**Clinical Information:** Specific evaluation of allergic reactions. IgE (kU/L) Interpretation: < 0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; ≥ 100, Class 6–Very High **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.5 mL is preferred when possible); An extra 50 µL will be required for each additional allergen ordered; Refrigerated *OR* 0.5 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.3 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.5 mL is preferred when possible); An extra 50 µL will be required for each additional allergen ordered; Refrigerated *OR* 0.5 mL plasma from an EDTA (lavender) tube; Minimum: 0.3 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.5 mL is preferred when possible); An extra 50 µL will be required for each additional allergen ordered; Refrigerated **Stability:** Ambient: 1 day Refrigerated: 7 days Frozen: 14 days **Methodology:** Fluorescent Enzyme Immunoassay (FEIA) by ImmunoCAP **Reference Range:** Allergen, Mouse Urine Proteins IgE: < 0.35 kU/L Allergen, Mouse Urine Proteins Class: 0 **Days Performed:** Sunday–Saturday **Reported:** 1–2 days **CPT:** 86003 x 1	7/31/18
Allergen, Phoma Betae IgE	PHOMAB	**Clinical Information:** Specific evaluation of allergic reactions. IgE (kU/L) Interpretation: < 0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; ≥ 100, Class 6–Very High **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.5 mL is preferred when possible); An extra 50 µL will be required for each additional allergen ordered; Refrigerated *OR* 0.5 mL plasma from an EDTA (lavender) tube; Minimum: 0.3 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.5 mL is preferred when possible); An extra 50 µL will be required for each additional allergen ordered; Refrigerated *OR* 0.5 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.3 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.5 mL is preferred when possible); An extra 50 µL will be required for each additional allergen ordered; Refrigerated **Stability:** Ambient: 1 day Refrigerated: 7 days Frozen: 14 days **Methodology:** Fluorescent Enzyme Immunoassay (FEIA) by ImmunoCAP **Reference Range:** Allergen, Phoma Betae IgE: < 0.35 kU/L Allergen, Phoma Betae Class: 0 **Days Performed:** Sunday–Saturday **Reported:** 1–2 days **CPT:** 86003 x 1	7/31/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Bacterial PCR, Direct Specimen	BCTPCR	**Special Information:** Rejection Criteria: Swabs will be rejected. Test will not be performed on blood or blood components. Specimens from non-sterile sites will be rejected. Specimens received in formalin or other transport media will be rejected. **Clinical Limitation:** This test will not be able to identify organisms in a polymicrobial population. This test is not validated for sterile fluids or fresh-frozen plasma-embedded (FFPE) samples. These samples will be sent to a reference laboratory for testing. **Clinical Information:** Routine culture results for orders will be reviewed to determine if testing is indicated. **Specimen Requirement:** One fresh frozen tissue specimen in a sterile container; Frozen **Stability:** Ambient: Unacceptable Refrigerated: Stable up to 24 hours at 2–8 °C Frozen: Stable for 2 weeks at minus 20 °C **Methodology:** Polymerase Chain Reaction (PCR) Sequencing **Days Performed:** Once per week **Reported:** 1–2 weeks **CPT:** 87801 x 1 **Price:** $245.00 (non-discountable)	7/31/18
CEBPA Mutation Analysis Marrow	CEBPAM	**Note:** *This test was previously announced in the May 2018 Technical Update.* **Price:** $689.00 (non-discountable)	6/26/18
Cytomegalovirus Antiviral Drug Resistance by Sequencing	CYTSEQ	**Special Information:** Please submit most recent viral load and test date, if available. Heparinized specimens are unacceptable. This test is New York DOH approved. **Clinical Limitation:** This test may be unsuccessful if the plasma CMV DNA viral load is < 1,500 CMV DNA copies/mL of plasma. **Clinical Information:** Used to determine antiviral drug resistance to cidofovir, foscarnet sodium, and ganciclovir. Codons 457–630 of the UL97 gene and codons 393–1000 of the UL54 gene are sequenced. Mutations associated with resistance to ganciclovir, cidofovir, and foscarnet are reported. Mutations in viral sub-populations below 20% of total may not be detected. **Specimen Requirement:** 4 mL plasma from an EDTA (lavender) tube; Minimum: 1.5 mL; Draw 2 tubes to ensure adequate volume; Separate plasma from cells within 8 hours of collection; Transfer 4 mL plasma into a standard aliquot tube; Submit most recent viral load and test date, if available; Frozen *OR* 4 mL plasma from an EDTA (white) plasma preparation tube (PPT); Minimum: 1.5 mL; Draw 2 tubes to ensure adequate volume; Separate plasma from cells within 8 hours of collection; Transfer 4 mL plasma into a standard aliquot tube; Submit most recent viral load and test date, if available; Frozen **Stability:** Ambient: 8 hours Refrigerated: 72 hours Frozen: 1 month **Methodology:** Polymerase Chain Reaction/Sequencing **Days Performed:** Sunday–Saturday **Reported:** 3–4 days **CPT:** 87910 x 1 **Price:** $639.00 (non-discountable)	8/7/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
FLT3 Tyrosine Kinase Domain Analysis Blood	F3TKD	**Specimen Requirement:** 4 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Next Gen Sequencing **Days Performed:** 2 days per week **Reported:** 7 days **CPT:** 81246 x 1, G0452 x 1 **Price:** $704.00 (non-discountable)	6/26/18
FLT3 Tyrosine Kinase Domain Mutation, Bone Marrow	F3TKDM	**Note:** *This test was previously announced in the May 2018 Technical Update. Please note that the order code FLT3TM has been changed to F3TKDM.* **Price:** $704.00 (non-discountable)	6/26/18
High Sensitivity Total Testosterone	HSTSTO	**Clinical Information:** Reference Intervals verified from Kushnir MM, Blamires T, Rockwood AL, Roberts WL, Yue B, Erdogan E, et al. Liquid chromatography–tandem mass spectrometry assay for androstenedione, dehydroepiandrosterone, and testosterone with pediatric and adult reference intervals. Clin Chem 2010;56:1138-47 **Specimen Requirement:** 2 mL serum from a plain no additive (red) tube; Minimum: 1 mL; Separate serum from cells within 2 hours of collection; Keep refrigerated for transport; Refrigerated *OR* 2 mL plasma from a sodium heparin (green) tube; Minimum: 1 mL; Separate plasma from cells within 2 hours of collection; Keep refrigerated for transport; Refrigerated **Stability:** Ambient: 4 days Refrigerated: 14 days Frozen: 6 months **Methodology:** Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** Female Premature (26–28 Weeks): 5–16 ng/dL Premature (31–35 Weeks): 5–22 ng/dL Newborn: 20–64 ng/dL 1–5 Months: < 20 ng/dL 6–24 Months: < 9 ng/dL 2–3 Years: < 20 ng/dL 4–5 Years: < 30 ng/dL 6–7 Years: < 7 ng/dL 8–9 Years: 1–11 ng/dL 10–11 Years: 3–32 ng/dL 12–13 Years: 6–50 ng/dL 14–15 Years: 6–52 ng/dL 16–17 Years: 9–58 ng/dL 18–59 Years: 9–55 ng/dL 60 Years or older: 5–32 ng/dL Premenopausal (18 Years and older): 9–55 ng/dL Postmenopausal: 5–32 ng/dL Tanner Stage I: 2–17 ng/dL Tanner Stage II: 5–40 ng/dL Tanner Stage III: 10–63 ng/dL Tanner Stage IV–V: 11–62 ng/dL *(continued on page 19)*	7/31/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
High Sensitivity Total Testosterone *(continued from page 18)*		Male Premature (26–28 Weeks): 59–125 ng/dL Premature (31–35 Weeks): 37–198 ng/dL Newborn: 75–400 ng/dL 1–5 Months: 14–363 ng/dL 6–24 Months: < 37 ng/dL 2–3 Years: < 15 ng/dL 4–5 Years: < 19 ng/dL 6–7 Years: < 13 ng/dL 8–9 Years: 2–8 ng/dL 10–11 Years: 2–165 ng/dL 12–13 Years: 3–619 ng/dL 14–15 Years: 31–733 ng/dL 16–17 Years: 158–826 ng/dL 18–39 Years: 300–1080 ng/dL 40–59 Years: 300–890 ng/dL 60 Years and older: 300–720 ng/dL Tanner Stage I: 2–15 ng/dL Tanner Stage II: 3–303 ng/dL Tanner Stage III: 10–851 ng/dL Tanner Stage IV–V: 162–847 ng/dL **Days Performed:** Monday–Friday **Reported:** 1–5 days **CPT:** 84403 x 1	
JAK2 Exon 12-15 Mutation Detection Bone Marrow	JAK2NM	**Note:** *This test was previously announced in the May 2018 Technical Update.* **Price:** $561.00 (non-discountable)	6/26/18
JAK2 V617F Mutation Detection Bone Marrow	JAK2M	**Note:** *This test was previously announced in the May 2018 Technical Update.* **Price:** $561.00 (non-discountable)	6/26/18
MPL Mutation Analysis Marrow	MPLM	**Note:** *This test was previously announced in the May 2018 Technical Update.* **Price:** $942.00 (non-discountable)	6/26/18
Myeloproliferative Neoplasm Panel Marrow	MPNM	**Note:** *This test was previously announced in the May 2018 Technical Update.* **Price:** $719.00 (non-discountable)	6/26/18
Myeloproliferative Neoplasm Panel Peripheral Blood	MPNP	**Note:** *This test was previously announced in the May 2018 Technical Update.* **Price:** $719.00 (non-discountable)	6/26/18
NPM1 Mutation Detection Bone Marrow	NPM1M	**Note:** *This test was previously announced in the May 2018 Technical Update.* **Price:** $691.00 (non-discountable)	6/26/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Toxicology Screen with Confirmation, Urine	UTOXRF	**Includes:** Ethanol, Urine Phencyclidine, Urine Benzodiazepines, Ur Cocaine, Urine Amphetamines, Urine Cannabinoids, Urine Opiates, Urine Barbiturates, Urine Oxycodone, Urine **Special Information:** Urine sent for confirmation for all components not reported as negative. **Specimen Requirement:** 5 mL random urine in a clean container; Minimum: 3 mL; Refrigerated **Stability:** Ambient: Unacceptable Refrigerated: 5 days Frozen: Unacceptable **Methodology:** Enzymatic Kinetic Interaction of Microparticles in a Solution **Days Performed:** Sunday–Saturday **Reported:** 8 hours **CPT:** 80307 x 1 **Price:** $195.00	7/31/18
Urogenital Ureaplasma and Mycoplasma Species by PCR	URMPCR	**Special Information:** Specimen source required. This test is New York DOH approved. **Clinical Information:** This test detects and speciates Ureaplasma parvum, Ureaplasma urealyticum, Mycoplasma hominis, and Mycoplasma genitalium; consider ordering for cases of non-gonococcal urethritis. A negative result does not rule out the presence of PCR inhibitors in the patient specimen or test-specific nucleic acid in concentrations below the level of detection by this test. **Specimen Requirement:** Genital swab in Viral Transport Media (VTM); Minimum: 0.5 mL; Transfer genital swab to VTM; Specimen source required; Frozen *OR* 1 mL random urine in Viral Transport Media (VTM); Minimum: 0.5 mL; Transfer 1 mL urine to VTM; Specimen source required; Frozen *OR* Cervical specimen collected using ThinPrep Pap Test Collection kit; Minimum: 0.5 mL; Vortex ThinPrep PreservCyt solution and transfer 1 mL into a sterile container; Specimen source required; Frozen *OR* Vaginal specimen collected using ThinPrep Pap Test Collection kit; Minimum: 0.5 mL; Vortex ThinPrep PreservCyt solution and transfer 1 mL into a sterile container; Specimen source required; Frozen **Stability:** Ambient: 24 hours Refrigerated: 10 days Frozen: 3 months **Methodology:** Qualitative Polymerase Chain Reaction **Days Performed:** Monday, Thursday **Reported:** 3–6 days **CPT:** 87798 x 1 **Price:** $206.00 (non-discountable)	8/9/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Very Long-Chain and Branched-Chain Fatty Acids Profile	FATLON	**Includes:** Pristanic Acid Phytanic Acid Ratio Pristanic Acid to Phytanic Acid C22:0 Behenic Acid C24:0 Tetracosanoic Acid C26:0 Hexacosanoic Acid Ratio C24:0 to C22:0 Ratio C26:0 to C22:0 **Special Information:** CRITICAL FROZEN. Clinical information is needed for appropriate interpretation. Age, gender, diet (e.g., TPN therapy), drug therapy, and family history are also required. Patient Prep: Fasting specimen is preferred for adults. For infants and children, draw specimen prior to feeding or 2–3 hours after a meal. Must submit Biochemical Genetics Patient History Form with the specimen. Separate specimens must be submitted when multiple tests are ordered. Room temperature specimens greater than 24 hours and refrigerated specimens greater than 48 hours are unacceptable. Specimens exposed to more than one freeze/thaw cycle are not acceptable. This test is New York DOH approved. **Clinical Information:** This is an initial test to screen for disorders of peroxisomal biogenesis and/or function, including X-linked adrenoleukodystrophy and Zellweger syndrome. **Specimen Requirement:** 0.5 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 0.2 mL; Patient Prep: Fasting specimen is preferred for adults; For infants and children, draw specimen prior to feeding or 2–3 hours after a meal; Separate plasma from cells and transfer into a standard aliquot tube; Freeze immediately; Must submit Biochemical Genetics Patient History Form with the specimen; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen *OR* 0.5 mL plasma from an EDTA (lavender) tube; Minimum: 0.2 mL; Patient Prep: Fasting specimen is preferred for adults; For infants and children, draw specimen prior to feeding or 2–3 hours after a meal; Separate plasma from cells and transfer into a standard aliquot tube; Freeze immediately; Must submit Biochemical Genetics Patient History Form with the specimen; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen **Stability:** Ambient: After separation from cells: 24 hours Refrigerated: After separation from cells: 72 hours Frozen: After separation from cells: 1 month **Methodology:** Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** Pristanic Acid 0–11 Months: < 0.31 µmol/L 1–2 Years: < 0.55 µmol/L 3–6 Years: < 0.46 µmol/L 7 Years and older: < 0.26 µmol/L Phytanic Acid 0–11 Months: 0.03–2.13 µmol/L 1–2 Years: 0.23–5.03 µmol/L 3–6 Years: 0.33–2.53 µmol/L 7 Years and older: 0.25–2.07 µmol/L Ratio Pristanic Acid to Phytanic Acid 0–11 Months: < 0.91 1–2 Years: < 0.28 3–6 Years: < 0.28 7 Years and older: < 0.28 *(continued on page 22)*	8/2/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Very Long-Chain and Branched-Chain Fatty Acids Profile *(continued from page 21)*		C22:0 Behenic Acid 0–11 Months: 28.94–93.50 µmol/L 1–2 Years: 28.94–93.50 µmol/L 3–6 Years: 28.94–93.50 µmol/L 7 Years and older: 28.94–93.50 µmol/L C24:0 Tetracosanoic Acid 0–11 Months: 24.25–77.75 µmol/L 1–2 Years: 24.25–77.75 µmol/L 3–6 Years: 24.25–77.75 µmol/L 7 Years and older: 24.25–77.75 µmol/L C26:0 Hexacosanoic Acid 0–11 Months: 0.17–0.73 µmol/L 1–2 Years: 0.17–0.73 µmol/L 3–6 Years: 0.17–0.73 µmol/L 7 Years and older: 0.17–0.73 µmol/L Ratio C24:0 to C22:0 0–11 Months: 0.64–1.02 1–2 Years: 0.64–1.02 3–6 Years: 0.64–1.02 7 Years and older: 0.64–1.02 Ratio C26:0 to C22:0 0–11 Months: 0.003–0.015 1–2 Years: 0.003–0.015 3–6 Years: 0.003–0.015 7 Years and older: 0.003–0.015 **Days Performed:** Tuesday **Reported:** 3–10 days **CPT:** 82726 x 1 **Price:** $148.00 (non-discountable)	

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Calprotectin, Fecal	CALPRO	$115.00	83993	7/31/18
Norovirus Group 1 and 2 Detection by PCR	NORPCR	$176.00 (non-discountable)	87798	Effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
BK Virus PCR Qual, Urine	UBKQAL	This test will no longer be available. Suggest ordering BK Virus Quantitation, Urine (UBKQT).	8/2/18
Chlamydia trachomatis DFA	CHLDFA	This test will no longer be available. Suggest ordering Chlamydia Amplification, Genital, Rectal and Oral Specimens (CT) or Chlamydia trachomatis, NA Amplification, Ocular Specimens (CTNAAO).	6/25/18
Cytomegalovirus Antiviral Drug Resistance	CYTOSQ	This test will no longer be available. Suggest ordering Cytomegalovirus Antiviral Drug Resistance by Sequencing (CYTSEQ).	8/7/18
Long Chain Fatty Acids	LONFAT	This test will no longer be available. Suggest ordering Very Long-Chain and Branched-Chain Fatty Acids Profile (FATLON).	8/2/18
Mycoplasma hominis PCR	MYPCR	This test will no longer be available. Suggest ordering Urogenital Ureaplasma and Mycoplasma Species by PCR (URMPCR).	8/9/18
Oil Red O LC	OILRED	This test will no longer be available.	7/31/18
Oncologic CytoScan HD SNP Array	HDSNP	This test will no longer be available.	8/2/18
Toxicology Screen w/ confirmation, Urine	UTOXWC	This test will no longer be available. Suggest ordering Toxicology Screen with Confirmation, Urine (UTOXRF).	7/31/18
Universal Bacterial, Fungal, and AFB PCR	FABPCR	This test will no longer be available. Suggest ordering Bacterial PCR, Direct Specimen (BCTPCR), Universal PCR, Fungal (FUNPCR) and Universal PCR, Acid Fast Bacilli (AFBPCR).	7/31/18
Whipple's Disease DNA by PCR	WHIPDN	This test will no longer be available. Suggest ordering Tropheryma whipplei PCR (WHIPWB).	7/31/18