Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • March 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
15	Allergen, Cayenne Pepper													■
15	Allergen, Whey IgG													■
4	Androstenedione											■		
4	Anti-HMGCR Autoantibodies					■	■		■	■	■	■	■	
13	APOL1 Sequencing			■										
15	Bile Acids, Total													■
15	Bioavailable Testosterone/SHBG, Female & Child													■
16	Bordetella pertussis Culture				■									
16	Bordetella pertussis DFA				■									
4	Borrelia burgdorferi Antibodies, Total by ELISA, CSF		■											
15	Brucella Ab Total													■
4	CA 19-9					■								
15	Campylobacter jejuni Antibody, IgG													■
4	Cardiolipin Antibodies											■		
4	Cardiolipin IgA Antibodies											■		
4	Cardiolipin IgG Antibodies											■		
4	Cardiolipin IgM Antibodies											■		
4	Celiac Comprehensive Panel											■		
5	Chromosome Analysis, POC					■	■				■	■		
5	Cross-Linked N-telopeptide, Serum						■					■		
5	Cross-Linked N-telopeptide, Urine											■		
5	Cyclic Citrullinated Peptide Ab, IgG											■		

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	Cystinuria Profile, Quantitative 24 Hour Urine					■		■				■		
5	Direct Renin					■								
5	DNA Antibody											■		
5	DNA Antibody with Confirmation											■		
16	EBV by PCR Qualitative				■									
6	Epidermal Antibodies with Reflex to Titer					■					■			
15	Estriol, Serum													■
6	Ethanol						■							
6, 15	FISH Insight Analysis												■	■
6	FLT3 Mutation Detection by PCR						■							
6	Galectin-3					■	■		■	■	■	■		
7	Gastrin					■								
7	Gastrin Secretin Stimulation					■								
7	Gliadin (Deamidated) Antibodies											■		
7	Gliadin (Deamidated) IgA Ab											■		
7	Gliadin (Deamidated) IgG Ab											■		
7	Glomerular Basement Membrane IgG					■	■		■	■	■	■		
7	Helicobacter pylori Ab, IgA											■		
7	Helicobacter pylori Antibodies, IgG and IgA											■		
8	Heparin Anti Xa Assay						■			■		■		
8	Hepatitis E Antibody IgG					■	■		■		■	■		
8	Hepatitis E Antibody IgM					■	■		■	■	■	■		
14	Herpesvirus 6 IgG Ab													■
14	Histamine, Plasma													■
9	HIV-1 Genotype					■	■	■			■	■	■	
9	HSP-70 Antibody (Anti-68 kd Antigen)					■	■		■		■	■	■	
14	Ibuprofen													■
15	Influenza A Virus Antibody, IgM													■
15	Influenza B Virus Antibody, IgM													■
10	Kappa, Free, Serum											■		
10	Kappa/Lambda, Free, Serum											■		
10	Ketamine & Metabolite, Serum/Plasma					■						■	■	
10	Lambda, Free, Serum											■		
10	LPT to Beryllium, BAL							■						
10	LPT to Beryllium, Blood							■						
14	Mumps Virus RNA, Qualitative Real-Time PCR			■										
15	NAbFeron Ab													■
10	Neoencephalitis Paraneoplastic Profile with Recombx					■								
10	Neosensory Neuropathy Paraneoplastic Profile					■								
10	Niacin					■					■			
10,14	Norovirus Group 1 and 2 Detection by PCR					■	■				■		■	■
15	Phosphatidylserine IgG, IgM, & IgA Autoabs													■

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
15	Pneumococcal IgG Antibodies, 23 Serotypes													■
10	Polio Neutralization										■			
16	Poliovirus (Types 1,3) Antibodies, IFA				■									
14	Polychlorinated Biphenyls (PCB) Panel, Serum or Plasma													■
14	Potassium, Stool													■
15	Prolactin Macroadenoma													■
14	Propafenone													■
10	Prothrombin Gene Mutation										■			
11	PTT Incubated Mixing Study									■				
11	Pyruvate Kinase					■	■		■	■	■			
11	Rickettsia rickettsii IgG & IgM Abs							■						
15	Selenium, Plasma or Serum													■
14	Sodium, Stool													■
12	Synthetic Cannabinoid Metabolites-Expanded, Urine (Qualitative)		■			■	■		■		■	■	■	
15	Testosterone, Free, Adult Males by ED/LC-MS/MS													■
12	Thyroglobulin					■								
12	Thyroxine, Fr by Eq Dialysis/HPLC-TndmMS					■								
12	TPMT Phenotype/Enzyme Activity										■			
12	Tropheryma whipplei PCR		■			■	■		■		■	■		
15	Varicella Zoster by PCR													■
15	Vitamin K													■
15	West Nile Virus Antibody Panel CSF													■
15	West Nile Virus Antibody Panel Serum													■
15	West Nile Virus IgG, CSF													■
15	West Nile Virus IgG, Serum													■
15	West Nile Virus IgM, CSF													■
15	West Nile Virus IgM, Serum													■
15	Zinc, Whole Blood													■

Test Changes

Test Name	Order Code	Change	Effective Date
Androstenedione	ANDROS	**Stability:** Ambient: **24 hours** Refrigerated: **7** days Frozen: **2** months	4/24/18
Anti-HMGCR Autoantibodies	HMGCR	**Special Information: Other body fluids are not acceptable. Contaminated, hemolyzed, grossly icteric, or severely lipemic specimens are unacceptable. This test is New York DOH approved.** **Clinical Information: Useful for differential diagnosis of myositis in patients with or without statin exposure. IgG antibodies to 3-hydroxy-3-methylglutaryl-coenzyme A reductase (HMGCR) are mainly associated with necrotizing autoimmune myopathy (NAM) in a subset of statin-treated patients. Although infrequent, these antibodies may also be observed in statin-naive patients with NAM. Strong clinical correlation is recommended in the absence of muscle fiber necrosis, elevated serum creatine kinase, perimysial pathology, and/or statin exposure.** **Specimen Requirement: 0.5 mL** serum from a serum separator (gold) tube; Minimum: **0.15 mL; Transfer 0.5 mL serum to 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)** **Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay** **Reference Range:** **Negative: 0–19 Units** **Days Performed:** Friday **Reported: 2–16** days **CPT: 83516 x 1**	5/8/18
Borrelia burgdorferi Antibodies, Total by ELISA, CSF	BBURGM	**Test Name:** Previously Lyme IgG & IgM Abs, CSF **Note:** *Lyme Antibodies, Total is a new alias name.*	Effective immediately
CA 19-9	CA199	**Special Information: Patients taking a Biotin dose of up to 5 mg/day should refrain from taking Biotin for 1 hour prior to sample collection. Patients taking a Biotin dose > 5 mg/day to 10 mg/day should refrain from taking Biotin for 2 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.**	Effective immediately
Cardiolipin Antibodies	CARDIO	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	4/24/18
Cardiolipin IgA Antibodies	CARDIA	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	4/24/18
Cardiolipin IgG Antibodies	CARDIG	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	4/24/18
Cardiolipin IgM Antibodies	CARDIM	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	4/24/18
Celiac Comprehensive Panel	CELCMP	**Stability:** Ambient: Serum: **1 day;** Whole Blood: 1 week Refrigerated: Serum: **7 days;** Whole blood: 1 week Frozen: Serum: **14 days** (Multiple freeze-thaw cycles for serum are not recommended); Whole blood: Unacceptable	4/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Chromosome Analysis, POC	CHRPOC	**Special Information: Long-standing fetal demise, delayed specimen transport and improper handling can increase the risk of tissue culture failure, which leads to no chromosome result.** **Specimen Requirement: 10 mm square** tissue in a sterile container; **Fresh tissue sample from the fetus, placenta, umbilical cord, amniotic membrane and chorionic membrane are accepted; Do not expose to formalin or other fixatives; Do not freeze; Place specimen in a sterile container containing RPMI, Hank's solution** or sterile saline; **Keep at room temperature; May refrigerate if specimen must be held overnight; Transport to Cleveland Clinic Laboratories as soon as possible to ensure cell viability; Ambient** **Stability:** Ambient: **Preferred** Refrigerated: **Acceptable** Frozen: Unacceptable **Days Performed: Monday–Friday** **Reported: 14–21** days	5/10/18
Cross-Linked N-telopeptide, Serum	NTX	**Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Remove serum from the gel as soon as possible, **no later than 2 hours from the time of collection;** Frozen **Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14 days** (Avoid repeated freeze/thaw cycles)	4/26/18
Cross-Linked N-telopeptide, Urine	UNTX2	**Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14 days** (Avoid repeated freeze/thaw cycles)	4/26/18
Cyclic Citrullinated Peptide Ab, IgG	CCP	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	4/26/18
Cystinuria Profile, Quantitative 24 Hour Urine	UCYS24	**For Interfaced Clients Only: Test build may need to be modified** **Special Information: Collect before intravenous pyelogram.** **Stability:** Refrigerated: **14 days** Frozen: **70** days	3/20/18
Direct Renin	RENIND	**Special Information:** Fasting specimens are recommended but not required. Record the time of day and patient's posture during blood collection (supine or upright). DO NOT pre-chill collection tubes, store tubes on ice or refrigerate; cryoactivation of prorenin occurs when samples are refrigerated. Process blood at room temperature. Centrifuge samples in a non-refrigerated centrifuge, immediately aliquot and freeze at minus 20 °C or colder. **Biotin levels of up to 100 mg/day have not shown interference with this assay. Patients taking > 100 mg/day to 300 mg/day should refrain from taking Biotin for 1 hour prior to sample collection. Patients taking a Biotin dose > 300 mg/day should consult with their physician or the laboratory prior to having a sample taken.**	Effective immediately
DNA Antibody	DNAAB	**Stability:** Ambient: **1 day** Refrigerated: **7** days Frozen: **14 days**	4/24/18
DNA Antibody with Confirmation	DNA	**Stability:** Ambient: **1 day** Refrigerated: **7** days Frozen: **14 days**	4/24/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Epidermal Antibodies with Reflex to Titer	EPIABS	**Special Information:** If the Intercellular Substance Antibody is positive, the titer will be performed at an additional cost. If the Basement Membrane Zone Antibody is positive, the titer will be performed at an additional charge. **Grossly hemolyzed, grossly lipemic and grossly icteric specimens will be rejected.** **Days Performed:** Wednesday, Friday **Reported:** 4–**9** days	3/19/18
Ethanol	ALCO	**Specimen Requirement:** 1 mL plasma from a lithium heparin (green) tube; Minimum: 0.5 mL; Do not collect in a gel separator tube; Prepare venipuncture site with aqueous Zephiran (benzalkonium chloride), aqueous Merthiolate (thimerosal), or povidone-iodine; Samples must be tightly closed; **Centrifuge and transfer plasma to a CCL tube;** Refrigerated *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Do not collect in a gel separator tube; Prepare venipuncture site with aqueous Zephiran (benzalkonium chloride), aqueous Merthiolate (thimerosal), or povidone-iodine; Samples must be tightly closed; **Centrifuge and transfer plasma to a CCL tube;** Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Do not collect in a gel separator tube; Prepare venipuncture site with aqueous Zephiran (benzalkonium chloride), aqueous Merthiolate (thimerosal), or povidone-iodine; Samples must be tightly closed; **Centrifuge and transfer serum to a CCL tube;** Refrigerated *OR* 1 mL plasma from a potassium oxalate/sodium fluoride (gray) tube; Minimum: 0.5 mL; Do not collect in a gel separator tube; Prepare venipuncture site with aqueous Zephiran (benzalkonium chloride), aqueous Merthiolate (thimerosal), or povidone-iodine; Samples must be tightly closed; **Centrifuge and transfer plasma to a CCL tube;** Refrigerated	Effective immediately
FISH Insight Analysis	ISIGHT	**CPT:** 88271 x 5, 88275 x 1	Effective immediately
FLT3 Mutation Detection by PCR	FLT3MD	**Specimen Requirement:** 5 mL whole blood in a **sodium heparin** (green) tube; Minimum: 5 mL; Separate specimens must be submitted when multiple tests are ordered; Specimen type required; Refrigerated *OR* 3 mL bone marrow in a **sodium heparin** (green) tube; Minimum: 3 mL; Separate specimens must be submitted when multiple tests are ordered; Specimen type required; Refrigerated	Effective immediately
Galectin-3	GAL3	**Special Information: Plasma or severely hemolyzed specimens are unacceptable. Specimens stored or transported at room temperature for more than 48 hours are not acceptable. This test is New York DOH approved.** **Clinical Information: Use for prognostication in heart failure. This test complements the prognostic value of N-terminal pro-brain natriuretic peptide (NT-proBNP). An elevated concentration of galectin-3 is associated with increased cardiovascular risk and adverse outcome in patients with heart failure. Medical management should rely on clinical findings. Low risk: ≤ 17.8 ng/mL; Intermediate risk: 17.9–25.9 ng/mL; Higher risk: > 25.9 ng/mL** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.2 mL;** Allow specimen to clot **completely at room temperature,** then separate serum from cells ASAP **or within 2 hours of collection and transfer to standard aliquot tube; Frozen** *OR* 1 mL serum from a plain no additive (red) tube; Minimum: **0.2 mL;** Allow specimen to clot **completely at room temperature,** then separate serum from cells ASAP **or within 2 hours of collection and transfer to standard aliquot tube; Frozen** **Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: **After separation from cells: 2 weeks** Frozen: **After separation from cells: 4 months (Avoid repeated freeze/thaw cycles)** **Methodology:** Enzyme **Immunoassay (EIA)** **Reference Range: ≤ 22.1 ng/mL** **Days Performed: Wednesday** **Reported:** 2–**9** days	5/10/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Gastrin	GAST	**Special Information:** Patient preparation: Preferably fasting for 12 hours or more. **Patients taking a Biotin dose of up to 5 mg/day should refrain from taking Biotin for 4 days prior to sample collection. Patients taking a Biotin dose > 5 mg/day to 10 mg/day should refrain from taking Biotin for 7 days 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.**	Effective immediately
Gastrin Secretin Stimulation	GASTST	**Special Information: Patients taking a Biotin dose of up to 5 mg/day should refrain from taking Biotin for 4 days prior to sample collection. Patients taking a Biotin dose > 5 mg/day to 10 mg/day should refrain from taking Biotin for 7 days 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.**	Effective immediately
Gliadin (Deamidated) Antibodies	GLIAD	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	4/26/18
Gliadin (Deamidated) IgA Ab	GLIIGA	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	4/26/18
Gliadin (Deamidated) IgG Ab	GLIIGG	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	4/26/18
Glomerular Basement Membrane IgG	GBMBG	**Special Information: This test is New York DOH approved.** **Clinical Information:** The presence of anti-glomerular basement membrane (GBM) antibodies **by multiplex bead assay** may aid in the diagnosis of Goodpasture syndrome. **False positive results may occur due to reactivity against other chains of type IV collagen. If multiplex bead assay is negative but there is strong suspicion for disease, renal biopsy may be indicated. A renal biopsy may also be essential in suspected Goodpasture disease with renal involvement, allowing diagnostic confirmation and assessment of renal prognosis.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.15 mL; Separate serum from cells ASAP or within 2 hours of collection** and transfer to 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)** **Methodology: Semi-Quantitative** Multiplex Bead Assay **Reference Range:** Negative: ≤ **19 AU/mL** **Equivocal: 20–25 AU/mL** Positive: ≥ **26 AU/mL** **Days Performed: Sunday**–Saturday **Reported:** 2–**3** days	5/8/18
Helicobacter pylori Ab, IgA	HPYLRA	**Stability:** Ambient: **1 day** Refrigerated: **7** days Frozen: **14 days** (Avoid multiple freeze/thaw cycles)	4/26/18
Helicobacter pylori Antibodies, IgG and IgA	HPYGA	**Stability:** Ambient: **1 day** Refrigerated: **7** days Frozen: **14 days** (Avoid multiple freeze/thaw cycles)	4/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
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; Frozen **Stability:** Ambient: **Centrifuge within one hour of phlebotomy and test or freeze platelet-poor plasma within 4 hours** Refrigerated: Unacceptable **Frozen: 2 weeks at ≤ minus 20 °C; 6 months at ≤ minus 70 °C** **Reference Range:** Heparin Anti Xa 0–99 Years: Therapeutic range: 0.3–0.7 **(standard nomogram)** IU/mL 0–99 Years: < 0.10 IU/mL **0–99 Years: Stroke or low dose protocol: 0.2–0.5 IU/mL**	Effective immediately
Hepatitis E Antibody IgG	HEPIGG	**Special Information: Specimens containing particulate material are unacceptable. This test is New York DOH approved.** **Clinical Information: Recommended for determining exposure to Hepatitis E Virus (HEV).** **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube;** Refrigerated *OR* 0.5 mL serum from a **clot activator** (red) tube; Minimum: **0.3 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube;** Refrigerated *OR* 0.5 mL **plasma from an EDTA (lavender) tube;** Minimum: **0.3 mL; Separate plasma from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube;** Refrigerated **Stability:** Ambient: **After separation from cells: Unacceptable** Refrigerated: **After separation from cells: 2 weeks** Frozen: **After separation from cells: Indefinitely (Avoid repeated freeze/thaw cycles)** **Methodology: Qualitative** Enzyme-linked Immunosorbent Assay **Days Performed: Tuesday, Friday** **Reported:** 2–**9** days	5/10/18
Hepatitis E Antibody IgM	HEPIGM	**Special Information: Specimens containing particulate material are not acceptable. This test is New York DOH approved.** **Clinical Information: Preferred test for diagnosing acute Hepatitis E Virus (HEV) infection.** **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube;** Refrigerated *OR* 0.5 mL serum from a **clot activator** (red) tube; Minimum: **0.3 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube;** Refrigerated *OR* 0.5 mL **plasma from an EDTA (lavender) tube;** Minimum: **0.3 mL; Separate plasma from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube;** Refrigerated **Stability:** Ambient: **After separation from cells: Unacceptable** Refrigerated: **After separation from cells: 2 weeks** Frozen: **After separation from cells: Indefinitely (Avoid repeated freeze/thaw cycles)** **Methodology: Qualitative** Enzyme-linked Immunosorbent Assay **Reference Range: Negative** **Days Performed: Tuesday, Friday** **Reported:** 2–**9** days	5/10/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
HIV-1 Genotype	HIVGEN	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** HIV Genotyping **EER HIV-1 Genotype by Sequencing** **Special Information: Please submit most recent viral load and test date (if available).** Serum or **heparinized specimens are unacceptable. This test is New York DOH approved.** **Clinical Limitation: Some insertions or deletions may be difficult to detect using this software. This test may not detect minor HIV-1 populations less than 20% of the total population. This test may be unsuccessful if the plasma HIV-1 RNA viral load is < 1000 HIV-1 RNA copies/mL of plasma.** **Clinical Information: HIV-1 genotyping provides antiretroviral susceptibility information for protease inhibitors (PI) and reverse transcriptase inhibitors (NRTI, NNRTI). Intended for patients with viral load > 1000 copies/mL. This test predicts HIV-1 resistance to protease and reverse transcriptase inhibitor antiretroviral drugs. The protease gene and codons 1-335 of the reverse transcriptase gene of the viral genome are sequenced using the ViroSeq HIV-1 Genotyping System kit. Drug resistance is assigned using ViroSeq software. The most current resistance algorithm and drug list is available by selecting the Drug Resistance Report. This test should be used in conjunction with clinical presentation and other laboratory markers. A patient's response to therapy depends on multiple factors including patient compliance, percentage of resistant virus population, dosing, and drug pharmacology issues. Resistance interpretations may vary with test methodology.** **Specimen Requirement: 4 mL** plasma from an EDTA (lavender) tube; Minimum: **1.5 mL;** Separate plasma from cells within **6 hours and transfer to standard aliquot tube; Submit most recent viral load and test date with specimen (if available); Draw 2 EDTA tubes to ensure adequate volume;** Frozen *OR* **4 mL** plasma from an EDTA (white) plasma preparation tube (PPT); Minimum: **1.5 mL;** Separate plasma from cells within **6 hours and transfer to standard aliquot tube; Submit most recent viral load and test date with specimen (if available); Draw 2 EDTA tubes to ensure adequate volume;** Frozen **Stability:** Ambient: **On cells: 6 hours; After separation from cells:** 24 hours Refrigerated: **After separation from cells: 5** days Frozen: **After separation from cells: 4 months** **Days Performed:** Sunday–Saturday **Reported: 4–8** days **CPT:** 87901 x 1	5/17/18
HSP-70 Antibody (Anti-68 kd Antigen)	AB68KD	**Special Information: Unacceptable conditions include plasma, urine, heat inactivated and contaminated specimens. This test is New York DOH approved.** **Clinical Information: This test is not recommended for evaluation of general hearing loss. The presence of HSP70 IgG antibodies may be useful in predicting corticosteroid responsiveness in a subset of patients with autoimmune inner ear disease (AIED) characterized by idiopathic rapidly progressive sensorineural hearing loss (SNHL). HSP70 IgG antibodies are also associated with a number of autoimmune diseases and have also been reported in apparently healthy individuals. A negative result does not rule out response to treatment or a diagnosis of AIED.** **Specimen Requirement: 0.5 mL** serum from a plain no additive (red) tube; Minimum: **0.1 mL; Transfer 0.5 mL serum into standard aliquot tube;** Refrigerated *OR* **0.5 mL** serum from a **serum separator (gold) tube;** Minimum: **0.1 mL; Transfer 0.5 mL serum into standard aliquot tube;** Refrigerated **Stability:** Ambient: **48 hours** Refrigerated: **2 weeks** Frozen: **1 year** **Methodology: Immunoblot (IB), Qualitative** **Days Performed: Sunday, Tuesday, Thursday** **Reported: 2**–5 days **CPT: 83516 x 1**	5/3/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Kappa, Free, Serum	FKAPPS	**Stability:** Ambient: 24 hours Refrigerated: 21 days Frozen: **14 days**	3/6/18
Kappa/Lambda, Free, Serum	KLFRS	**Stability:** Ambient: 24 hours Refrigerated: 21 days Frozen: **14 days**	3/6/18
Ketamine & Metabolite, Serum/ Plasma	KETMIN	**Note:** *For component Norketamine, Serum/Plasma: The intravenous administration of 2 mg/kg of Ketamine followed by continuous infusion of 41 mcg/kg/minute produced an average steady-state plasma concentration of 2200 ng Ketamine/mL and an average peak Norketamine level of 1050 ng/mL which occurred near the end of the **3 hour** infusion.* **Stability:** Ambient: **14** days Refrigerated: **14** days Frozen: **9** months **CPT: 80357 x 1,** (G0480, if appropriate)	5/7/18
Lambda, Free, Serum	FLAMBS	**Stability:** Ambient: 24 hours Refrigerated: 21 days Frozen: **14 days**	3/6/18
LPT to Beryllium, BAL	BALBE	**For Interfaced Clients Only: Test build may need to be modified**	5/1/18
LPT to Beryllium, Blood	BLDBE	**For Interfaced Clients Only: Test build may need to be modified**	5/1/18
Neoencephalitis Paraneoplastic Profile with Recombx	CEPHAL	**Special Information:** Whole blood is not an acceptable specimen. Serum must be separated from cells within 48 hours of collection. **The following tests are included: CASPR2 Antibody, GAD65 Neurological Syndrome Antibody, LGI1 Autoantibody, NMDA Receptor (NR1-subunit) Autoantibody, Recombx® Amphiphysin Autoantibody, Recombx® CV2 Autoantibody, Recombx® Hu Autoantibody, Recombx® MaTa Autoantibody, VGKC Antibody**	Effective immediately
Neosensory Neuropathy Paraneoplastic Profile	NEOSEN	**Special Information:** Serum must be separated from cells within 48 hours of collection. Whole blood is not an acceptable specimen. **The following tests are included: Recombx® Amphiphysin Autoantibody, Recombx® CV2 Autoantibody, Recombx® Hu Autoantibody**	Effective immediately
Niacin	B3VIT	**Special Information: Grossly hemolyzed and grossly lipemic specimens are unacceptable. Specimens warm from thawing or not protected from light will be rejected. This test is New York State approved.** **Days Performed:** 1 day per week **Reported:** 3–**15** days	Effective immediately
Norovirus Group 1 and 2 Detection by PCR	NORPCR	**Special Information: This test is New York DOH approved.** **Clinical Information: 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:** 1 mL stool in a clean container **(No preservatives);** Minimum: 0.5 mL; Frozen **Days Performed: Monday, Wednesday,** Friday **Reported: 2–**6 days **CPT: 87798 x 1**	5/3/18
Polio Neutralization	PNEUT	**Days Performed:** Monday–Friday **Reported:** 7–**10** days	3/12/18
Prothrombin Gene Mutation	PTGEN	**Days Performed: 2 days per week** **Reported:** 7–10 days	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
PTT Incubated Mixing Study	PTTIM	**Reference Range:** PT Screen 0–1 Days: 7.9–14.8 sec 2–5 Days: 7.4–14.2 sec 6–30 Days: 7.2–13.3 sec 1–3 Months: 7.2–13.2 sec 4–11 Months: 8.3–12.9 sec 1–99 Years: 8.4–13.0 sec APTT Screen 0–1 Days: 28.7–45.1 sec 2–5 Days: 23.3–49.4 sec 6–30 Days: 23.5–45.6 sec 1–3 Months: 22.1–41.4 sec 4–11 Months: 25.8–35.5 sec 1–99 Years: 24.4–33.4 sec Immediate PTT 1:1 Mix 0–99 Years: **< 30.9 sec** Incubated PTT 1:1 Mix 0–99 Years: **< 33.6 sec** Thrombin Time 0–1 Days: < 17.4 sec 2–5 Days: < 17.9 sec 6–30 Days: < 17.9 sec 1–3 Months: < 18.2 sec 4–11 Months: < 19.1 sec 1–99 Years: < 18.6 sec Heparin Anti Xa 0–99 Years: Therapeutic range: 0.3–0.7 **(standard nomogram)** IU/mL 0–99 Years: < 0.10 IU/mL **0–99 Years: Stroke or low dose protocol: 0.2–0.5 IU/mL**	Effective immediately
Pyruvate Kinase	PYRKIN	**Special Information: Do NOT freeze. This test is New York DOH approved.** **Clinical Information: Preferred initial test to screen for pyruvate kinase (PK) deficiency. Patients who have been recently transfused have normal donor cells that may mask PK deficient erythrocytes.** **Specimen Requirement: 1 mL** whole blood from an EDTA (lavender) tube; Minimum: **0.5 mL; Do NOT freeze; Transfer 1 mL whole blood to standard aliquot tube;** Refrigerated *OR* **1 mL** whole blood from an ACD **A or** B (yellow) tube; Minimum: **0.5 mL; Do NOT freeze; Transfer 1 mL whole blood to standard aliquot tube;** Refrigerated *OR* **1 mL** whole blood from a **sodium or lithium heparin (green) tube;** Minimum: **0.5 mL; Do NOT freeze; Transfer 1 mL whole blood to standard aliquot tube;** Refrigerated **Methodology: Quantitative Enzymatic** **Reference Range: 4.6–11.2 U/g Hb** **Days Performed: Sunday**–Saturday **Reported:** 2–**3** days	5/8/18
Rickettsia rickettsii IgG & IgM Abs	ROCKY	**For Interfaced Clients Only: Test build may need to be modified**	3/6/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Synthetic Cannabinoid Metabolites-Expanded, Urine (Qualitative)	K2	**Test Name:** Previously Synthetic Cannabinoid Metabolite, Screen with confirmation **Note:** *Testing includes* ***5-Fluoro-PB-22 3-Carboxyindole; 5F-ADB 3,3-dimethyl-butanoic acid; 5F-AMB 3-methyl-butanoic acid;*** *AB-CHMINACA 3-methyl-butanoic acid;* ***AB-FUBINACA oxobutanoic acid;*** *AB-PINACA N-pentanoic acid;* ***ADB-CHMINACA 3,3-dimethyl-butanoic acid;*** *ADB-PINACA N-pentanoic acid; ADBICA N-pentanoic acid;* ***AKB48 N-pentanoic acid; BB-22 3-Carboxyindole; FUB-AMB 3-methyl-butanoic acid; JWH-018 N-pentanoic acid; MDMB-FUBINACA 3,3-dimethyl-butanoic acid; PB-22 3-Carboxyindole;*** *UR-144 N-pentanoic acid* **Special Information: This test is New York State approved.** **Clinical Information: Drug of abuse monitoring. Category: Synthetic cannabinoid** **Specimen Requirement: 3 mL** random urine in a clean container **(No preservatives);** Minimum: **1.2 mL; Collect in a plastic container;** Refrigerated **Stability:** Ambient: **30 days** Refrigerated: **30 days** Frozen: **30 days** **Methodology:** High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) **Days Performed: Tuesday, Thursday** **Reported:** 4–8 days **CPT: 80352 x 1, (G0480, if appropriate)**	5/7/18
Thyroglobulin	TG	**Special Information:** Serum is the only acceptable specimen type. **Patients taking a Biotin dose of up to 5 mg/day should refrain from taking Biotin for 2 days prior to sample collection. Patients taking a Biotin dose > 5 mg/day to 10 mg/day should refrain from taking Biotin for 4 days 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.**	Effective immediately
Thyroxine, Fr by Eq Dialysis/HPLC-TndmMS	T4HPLC	**Special Information: Free T4 by LCMSMS** is not recommended for routine **screening** of thyroid disorders. **Free T4 measurement by immunoassay (test code FT4) is the preferred method. FT4 by LCMSMS is primarily useful in patients who may have abnormalities in binding proteins which may interfere with routine measurements of free T4 by immunoassay.** Unacceptable conditions: Plasma. This test is New York DOH approved.	Effective immediately
TPMT Phenotype/ Enzyme Activity	TPMT	**Days Performed:** Monday, Wednesday, Friday **Reported:** 4–**6** days	Effective immediately
Tropheryma whipplei PCR	WHIPWB	**Test Name:** Previously Whipple's Disease PCR, whole blood **Special Information: Must indicate specimen source. Heparinized specimens are not acceptable. If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory.** **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** **Stability:** Ambient: **8 hours** Refrigerated: **5** days Frozen: **2 weeks** **Methodology: Qualitative** Polymerase Chain Reaction **Days Performed: Tuesday,** Friday **Reported:** 3–**6** days	5/1/18

New Tests

Test Name	Order Code	Change	Effective Date
APOL1 Sequencing	APOL1S	**Special Information:** Prior to any genetic testing we recommend genetic counseling. MUST submit Molecular Genetics test requisition form with specimen. Ethnicity MUST be included. Include detailed information including ethnicity, clinical history and family history. Package and ship specimen to remain cold, but not frozen. Ship via overnight express (FedEx). **Clinical Information:** Compared to individuals without recent African ancestry, African Americans have high rates of kidney disease. Two independent polymorphisms in the APOL1 gene have been shown to be likely associated with the following forms of kidney disease: focal segmental glomerulosclerosis (FSGS) and hypertension-attributed end-stage kidney disease (H-ESKD). The first polymorphism, termed G1, is a two-locus APOL1 polymorphic allele consisting of c.1024A>G; p.Ser342Gly (rs73885319) and c.1152T>G; p.Ile384Met (rs60910145); the second polymorphism, termed G2, is a 6-base pair deletion c.1164_1169delTTATAA (rs71785313). Individuals carrying two risk alleles (G1/G2) have an odds ratio of 7.3 of developing renal disease as compared to individuals carrying neither G1 or G2, while individuals carrying only one risk allele (G1 or G2) have an odds ratio of just 1.26 as compared to individuals carrying neither G1 or G2. A recessive model of inheritance best explains this finding. These APOL1 risk polymorphisms for kidney disease occur in more than 30% of African-American chromosomes while they are virtually absent in non-African chromosomes. Natural selection provides a plausible explanation as either of the resulting variant proteins provides heightened Trypanosoma lytic activity for heterozygotes with little increased risk for kidney disease. Reasons for Referral: Determination of c.1024A>G, c.1152T>G, and c.1164_1169delTTATAA status: Prior to donation of a kidney, as a limited diagnostic tool, for determination of carrier status. Methodology: Targeted gene sequencing of APOL1 exon 6 in which c.1024A>G, c.1152T>G, and c.1164_1169delTTATAA are embedded. References: 1. S.B. Satko, et al. *Kidney Int*. suppl 67, (s94), S46 (2005). 2. G. Genovese, et al. *Science* 329: 841-845 (2010). 3. D. Cohen, et al. *Transplantation* 92:722-725 (2011). **Specimen Requirement:** 5 mL whole blood in an EDTA (lavender) tube; Minimum: 0.2 mL (Absolute minimum with a normal WBC count; Preferred volumes are 5 mL for adult and child, 2–3 mL for infant); Must submit the Molecular Genetics test requisition form with the specimen; Please include detailed clinical information including ethnicity, clinical history, and family history; Send specimen with cold pack; Refrigerated *OR* 5 mL whole blood in an ACD A or B (yellow) tube; Minimum: 0.2 mL (Absolute minimum with a normal WBC count; Preferred volumes are 5 mL for adult and child, 2–3 mL for infant); Must submit the Molecular Genetics test requisition form with the specimen; Please include detailed clinical information including ethnicity, clinical history, and family history; Send specimen with cold pack; Refrigerated *OR* 10 μg extracted DNA (from whole blood ONLY) at a minimum of 100 ng/μL in an EDTA (lavender) tube; Must submit the Molecular Genetics test requisition form with the specimen; Please include detailed clinical information including ethnicity, clinical history, and family history; Refrigerated *OR* 10 μg extracted DNA (from whole blood ONLY) at a minimum of 100 ng/μL in an ACD A or B (yellow) tube; Must submit the Molecular Genetics test requisition form with the specimen; Please include detailed clinical information including ethnicity, clinical history, and family history; Refrigerated **Stability:** Refrigerated: 7 days **Methodology:** Sequencing **Days Performed:** Varies **Reported:** 8–16 days **CPT:** 81479 x 1 **Price:** $355.00 (non-discountable)	3/20/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Mumps Virus RNA, Qualitative Real-Time PCR	MUMPCR	**Specimen Requirement:** Oral/buccal swab in sterile, leak-proof container in 3 mL M4 media, viral culture medium (green-cap) tube or equivalent Universal Transport Media (UTM); Minimum: 0.35 mL; Send specimen using cold pack; Refrigerated **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: 30 days **Methodology:** Real-Time Polymerase Chain Reaction (RT-PCR) **Reference Range:** Not detected **Days Performed:** Monday–Saturday **Reported:** 2–3 days **CPT:** 87798 x 1 **Price:** $335.00 (non-discountable)	3/21/18

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Herpesvirus 6 IgG Ab	HHV6	$129.00 (non-discountable)	86790	3/7/18
Histamine, Plasma	PHISTA	$146.00	83088	3/7/18
Ibuprofen	IBUPRO	$162.00	80329	3/7/18
Norovirus Group 1 and 2 Detection by PCR	NORPCR	$320.00 (non-discountable)	87798	5/3/18
Polychlorinated Biphenyls (PCB) Panel, Serum or Plasma	PBPS	$146.00 (non-discountable)	82441	3/7/18
Potassium, Stool	SK	$38.00	84999	3/7/18
Propafenone	PROPA	$126.00 (non-discountable)	80299	3/7/18
Sodium, Stool	SNA	$38.00	84302	3/7/18

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Allergen, Cayenne Pepper	CAYENN	$33.00	86003	3/7/18
Allergen, Whey IgG	WHEYG	$65.00	86001	3/7/18
Bile Acids, Total	BILETO	$63.00 (non-discountable)	82239	3/7/18
Bioavailable Testosterone/SHBG, Female & Child	BTSTFC	$59.00 (non-discountable)	84270, 84403	3/7/18
Brucella Ab Total	BRUAGG	$58.00 (non-discountable)	86622	3/7/18
Campylobacter jejuni Antibody, IgG	CAMIGG	$191.00 (non-discountable)	86625	3/7/18
Estriol, Serum	ESTRIO	$65.00 (non-discountable)	82677	3/7/18
FISH Insight Analysis	ISIGHT	$510.00 (non-discountable)	88271 x 5, 88275	Effective immediately
Influenza A Virus Antibody, IgM	INFLAM	$72.00	86710	3/7/18
Influenza B Virus Antibody, IgM	INFLBM	$72.00	86710	3/7/18
NAbFeron Ab	NABFAB	$430.00 (non-discountable)	86352	3/7/18
Phosphatidylserine IgG, IgM, & IgA Autoabs	PHOGMA	$72.00 (non-discountable)	86148 x 3	3/7/18
Pneumococcal IgG Antibodies, 23 Serotypes	PNE23	$382.00 (non-discountable)	86317 x 23	3/7/18
Prolactin Macroadenoma	PROLM	$48.00 (non-discountable)	84146	3/7/18
Selenium, Plasma or Serum	PSELEN	$109.00	84255	3/7/18
Testosterone, Free, Adult Males by ED/LC-MS/MS	FTESAM	$195.00	84402	3/7/18
Varicella Zoster by PCR	VZPCR	$308.00	87798	3/7/18
Vitamin K	VITK	$65.00 (non-discountable)	84597	3/7/18
West Nile Virus Antibody Panel CSF	CNILE	125.00 (non-discountable)	86788, 86789	3/7/18
West Nile Virus Antibody Panel Serum	NILE	$125.00 (non-discountable)	86788, 86789	3/7/18
West Nile Virus IgG, CSF	CWESTG	$87.00	86789	3/7/18
West Nile Virus IgG, Serum	WESTG	$64.00 (non-discountable)	86789	3/7/18
West Nile Virus IgM, CSF	CWESTM	$87.00	86788	3/7/18
West Nile Virus IgM, Serum	WESTM	$61.00 (non-discountable)	86788	3/7/18
Zinc, Whole Blood	ZINCWB	$90.00	84630	3/7/18

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Bordetella pertussis Culture	BORCUL	This test will no longer be available. Suggest ordering BORDETELLA PERTUSSIS DETECTION BY NAAT (BORAMP).	5/1/18
Bordetella pertussis DFA	BORDFA	This test will no longer be available. Suggest ordering BORDETELLA PERTUSSIS DETECTION BY NAAT (BORAMP).	5/1/18
EBV by PCR Qualitative	EBPCR	This test will no longer be available. Suggest ordering EBV by PCR Quantitative (EBVQNT).	5/15/18
Poliovirus (Types 1,3) Antibodies, IFA	POLIO	Note: *This test was previously announced in the February 2018 Technical Update with a discontinuation date of 4/19/18. Testing will be discontinued on 3/12/18, and we suggest ordering Polio Neutralization (PNEUT). We apologize for any inconvenience this may have caused.*	3/12/18