Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • July 2017

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

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

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

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

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
3	ACTH									■		■		
3	ACTH Stimulation, 2 Time Points											■		
3	ACTH Stimulation, 3 Time Points											■		
3	Alkaline Phosphatase Isoenzymes						■							
3, 11	Allergen, Animals Group							■					■	■
3	Allergen, Perch IgE						■							
12	Alpha-1-antitrypsin, SERPINA1 F and I Alleles				■									
12	Alpha-1-antitrypsin, SerpinA1 full sequencing				■									
12	Alpha 1 Anti-trypsin Serum Level and SERPINA1 Targeted Genotyping				■									
12	Alpha-1-antitrypsin targeted genotyping (Z,S)				■									
3	ANA by IFA with Reflex						■							
3	Androstenedione									■				
3	Blood Parasites					■	■							
4	Complement, Alternate Pathway (AH50), Functional					■	■				■			
4	Complement Component Level 3A					■	■			■		■		
4	Complement Component Level 4A					■	■							
4	Cross-Linked N-telopeptide, Serum						■							
4	Dexamethasone										■			
10	FISH for WWTR1/CAMTA1			■										
4	Fungitell Assay for (1,3)-B-D-Glucan					■								

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5	Hepatitis A Antibody, IgM											■		
5	Hepatitis B Core Antibody, IgM											■		
5	Hepatitis B Core Antibody Total											■		
5	Hepatitis Be Antibody					■	■				■			
5	Hepatitis B Surface Ab, Immunity											■		
5	Hepatitis B Surface Ab, Qual.											■		
5	Hepatitis B Surface Ab, Quant											■		
5	Hepatitis B Surface Antigen											■		
5	Hepatitis B Surface Antigen Conf											■		
5	Herpes Simplex IgM, Abs												■	
6	HIV 1 2 Combo (Antigen/Antibody)											■		
10	Human Alpha-1 Antitrypsin Genotyping			■										
6	Human Epididymis Protein 4											■		
6	Lactate, Precipitated									■		■		
6	Lactate/Pyruvate									■				
6–7	Levetiracetam						■			■		■		
7	Lp-PLA2 Activity					■	■				■	■		
7	Maternal Cell Contamination, Integrated Genetics					■	■		■		■			
8	Neopterin					■	■							
8	Neuron-Specific Enolase, Serum											■		
8	OmegaCheck					■	■				■	■		
8, 11	Organism Identification, Aerobic					■								■
8	Oxalate, Urine 24 Hour											■		
9	Primidone						■			■		■		
9	Rabies Antibody										■			
9	Staph aureus PCR					■						■		
10–11	Stool Gastrointestinal Panel by PCR			■										
9	Strongyloides IgG Abs, Serum					■	■			■	■			
9	Thyroglobulin									■				
9	Thyroid Cancer (Thyroglobulin) Monitoring									■				
9	Topiramate											■		
12	Toxic Shock Syndrome Abs				■									
9	TPMT Genotype Assay										■			
10	Trypsinogen					■			■		■			

Test Changes

Test Name	Order Code	Change	Effective Date
ACTH	ACTH	**Stability:** Ambient: **8 hours** Refrigerated: **8 hours** Frozen: 30 days **Reference Range: ≤ 46 pg/mL**	8/30/17
ACTH Stimulation, 2 Time Points	ACTHS2	**Stability:** Ambient: **24** hours Refrigerated: **7 days** Frozen: **14 days**	8/2/17
ACTH Stimulation, 3 Time Points	ACTHST	**Stability:** Ambient: **24** hours Refrigerated: **7 days** Frozen: **14 days**	8/2/17
Alkaline Phosphatase Isoenzymes	ALKISO	**Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: **2 mL;** Refrigerated	9/7/17
Allergen, Animals Group	ANIMLS	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Allergen, Chicken Feathers IgE Allergen, Chicken Feathers Class Allergen, Cow Epithelium (Dander) IgE Allergen, Cow Epithelium (Dander) Class Allergen, Goose Feathers IgE Allergen, Goose Feathers Class Allergen, Horse Dander IgE Allergen, Horse Dander Class **CPT:** 86003 **x 4**	8/31/17
Allergen, Perch IgE	PERCH	**Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: **0.4 mL;** Ambient *OR* 0.5 mL serum from a red top tube with no additive; Minimum: **0.4 mL;** Ambient	Effective immediately
ANA by IFA with Reflex	ANAIFR	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.7 mL;** Refrigerated *OR* 1 mL serum from a red top tube with no additive; Minimum: **0.7 mL;** Refrigerated	8/30/17
Androstenedione	ANDROS	**Reference Range:** Male**: 0.6–3.1 ng/mL** Female: **0.3–3.3 ng/mL**	8/30/17
Blood Parasites	BLDPAR	**Special Information:** Indicate travel history on the requisition. Peripheral blood should be drawn prior to the onset of chills, if possible. Rapid results can be critical to establishing appropriate therapy. Order will include a rapid screening immunochromatographic assay, microscopy (thick and thin smears), and pathologist review of all microscopic results. Preliminary results will be reported within 24–48 hours. For positive smears, the percentage of parasitemia is calculated with an additional charge of CPT code 85032. All positive blood smears are reviewed by a medical director with CPT code 87207 applied. **Specimen Requirement:** 4 mL whole blood in an EDTA lavender top tube; Minimum: 2 mL; **Transport to Cleveland Clinic Laboratories within 4 hours; Use STAT courier when necessary; Rapid results can be critical to establishing appropriate therapy;** Ambient	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Complement, Alternate Pathway (AH50), Functional	COMAP	**Special Information: Fasting is preferred.** This test uses a reagent or kit labeled by the manufacturer as Research Use Only. **This test is New York State approved.** **Clinical Information: Useful for investigation of suspected alternative pathway complement deficiency, atypical hemolytic uremic syndrome, C3 glomerulonephritis, and dense-deposit disease.** An absent AH50 should be confirmed with a repeat test on a different specimen. **Specimen Requirement:** 1 mL serum from a **red top tube with no additive;** Minimum: 0.2 mL; Place specimen on ice after draw; Fasting is preferred; Remove serum from cells ASAP, **transfer to plastic aliquot tube,** and freeze **within 30 minutes;** Frozen **Days Performed:** Varies **Reported: 2**–8 days	7/18/17
Complement Component Level 3A	COMP3A	**Special Information: CRITICAL FROZEN: Separate specimens must be submitted when multiple tests are ordered. Separate from cells within one hour of draw. Transfer 1 mL of plasma to a standard transport tube. Freeze at minus 70 °C or on dry ice immediately. This test is New York DOH approved.** **Clinical Information: 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 plasma from an EDTA lavender top tube; Minimum: **0.5 mL;** Separate specimens must be submitted when multiple tests are ordered; Separate from cells within 1 hour of draw; Transfer 1 mL of plasma to a standard transport tube; Freeze at minus 70 °C or on dry ice immediately; Critical Frozen **Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: Frozen at minus 70 °C for **1 month; NOTE: Frozen at minus 20 °C is unacceptable** **Reference Range: Refer to report**	8/30/17
Complement Component Level 4A	COMP4A	**Special Information:** CRITICAL FROZEN: Separate specimens must be submitted when multiple tests are ordered. Separate from cells within one hour of draw. Transfer 1 mL of plasma to a standard transport tube. Freeze at minus 70 °C or on dry ice immediately. **Alternately, the plasma may be frozen immediately at minus 20 °C and then transferred to minus 70 °C within 6 hours. This test is New York DOH approved.** **Clinical Information: Follow-up test for complement activity screening when CH50 is low or absent and AH50 is normal and high suspicion remains for complement deficiency.** **Specimen Requirement:** 1 mL plasma from an EDTA lavender top tube; Minimum: **0.5 mL;** Separate specimens must be submitted when multiple tests are ordered; Separate from cells within 1 hour of draw; Transfer 1 mL of plasma to a standard transport tube; Freeze at minus 70 °C or on dry ice immediately; **Alternately, the plasma may be frozen immediately at minus 20 °C and then transferred to minus 70 °C within 6 hours;** Critical Frozen	Effective immediately
Cross-Linked N-telopeptide, Serum	NTX	**Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; **Remove from gel ASAP;** Frozen	Effective immediately
Dexamethasone	DEXA	**Days Performed:** Wednesday, Saturday **Reported:** 3–**6** days	Effective immediately
Fungitell Assay for (1,3)-B-D-Glucan	BDGLUC	**Special Information:** Do not aliquot; send specimen in original tube. Avoid exposure of specimen to atmosphere. Sample cannot be shared with multiple tests. Add on testing is not acceptable. Fungitell Titer is available upon request, on original sample tested at Viracor-IBT for Fungitell Assay with results > 500 pg/mL. **Samples are held for one week after initial testing date.** Ship on dry ice Monday through Friday. Friday shipments must be labeled for Saturday delivery. Unacceptable conditions: Lipemic, icteric, or hemolyzed specimens; Specimens that have been stored at ambient temperature; Specimens that have been stored at 2–8 °C for > 5 days	7/21/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis A Antibody, IgM	AHAVM	**Stability:** Ambient: 3 days Refrigerated: 7 days Frozen: **14 days**	7/18/17
Hepatitis B Core Antibody, IgM	AHBCM	**Stability:** Ambient: 3 days Refrigerated: 7 days Frozen: **14 days**	7/18/17
Hepatitis B Core Antibody Total	AHBCOT	**Stability:** Ambient: 3 days Refrigerated: 7 days Frozen: **14 days**	7/18/17
Hepatitis Be Antibody	AHBE	**Special Information: Patient Prep: For 24 hours prior to blood draw, patient should not take multivitamins or dietary supplements containing biotin (vitamin B7) that are commonly found in hair, skin, and nail supplements and multivitamins. Grossly hemolyzed, grossly lipemic and grossly icteric specimens will be rejected. Performance characteristics of this assay have not been established in patients under the age of 2 or in populations of immunocompromised or immunosuppressed patients. This assay is not licensed by FDA for testing cord blood samples or screening donors of blood, plasma, human cell, or tissue products. Date of draw is required. This test is New York State approved.** **Clinical Information: During recovery from acute hepatitis B, the hepatitis B envelope (Be) antigen level declines and becomes undetectable and hepatitis Be antibody (anti-HBe) appears in the serum. Anti-HBe usually remains detectable for several years after recovery from acute infection. In hepatitis B virus (HBV) carriers and in patients with chronic hepatitis B, positive anti-HBe results usually indicate inactivity of the virus and low infectivity of the patients. Positive anti-HBe results in the presence of detectable HBV DNA in serum indicate active viral replication.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Centrifuge and **remove serum from gel within 24 hours; Transfer to plastic aliquot tube** and freeze; Frozen **Days Performed:** Monday–Saturday **Reported:** 2–**3** days	Effective immediately
Hepatitis B Surface Ab, Immunity	AHBSI	**Stability:** Ambient: 3 days Refrigerated: 7 days Frozen: **14 days**	7/18/17
Hepatitis B Surface Ab, Qual.	AHBSAG	**Stability:** Ambient: 3 days Refrigerated: 7 days Frozen: **14 days**	7/18/17
Hepatitis B Surface Ab, Quant	AHBSQ	**Stability:** Ambient: **24 hours** Refrigerated: **6** days Frozen: **14 days**	7/18/17
Hepatitis B Surface Antigen	HBSAG	**Stability:** Ambient: 24 hours Refrigerated: 6 days Frozen: **14 days**	7/18/17
Hepatitis B Surface Antigen Conf	HBSAGC	**Stability:** Ambient: 24 hours Refrigerated: 6 days Frozen: **14 days**	7/18/17
Herpes Simplex IgM, Abs	HSVM	**CPT: 86694 x 1**	8/22/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
HIV 1 2 Combo (Antigen/Antibody)	HIV12C	**Stability:** Ambient: 3 days Refrigerated: 1 week Frozen: **14** days	7/18/17
Human Epididymis Protein 4	HEP4	**Stability:** Ambient: 24 hours Refrigerated: **7** days Frozen: **14** days	7/18/17
Lactate, Precipitated	LACPRE	**Stability:** Ambient: **48** hours; Stability information is for TCA treated sample Refrigerated: 1 month; Stability information is for TCA treated sample Frozen: 3 months; Stability information is for TCA treated sample **Reference Range:** **0–90 Days: 1.0–3.5 mmol/L** **3–24 Months: 1.0–3.3 mmol/L** **2–17 Years: 1.0–2.4 mmol/L** **18–99 Years: 0.5–2.2 mmol/L**	9/13/17
Lactate/Pyruvate	LACPYR	**Reference Range:** Lactate **0–90 Days: 1.0–3.5 mmol/L** **3–24 Months: 1.0–3.3 mmol/L** **2–17 Years: 1.0–2.4 mmol/L** **18–99 Years: 0.5–2.2 mmol/L** Pyruvate 0–99 Years: 0.03–0.08 mmol/L	9/13/17
Levetiracetam	LEVET	**Specimen Requirement:** 1 mL serum from a red top tube with no additive; Minimum: 0.5 mL; Do not use tubes containing cell separator gel; Centrifuge; Transfer serum to a clean, tightly sealed tube and refrigerate; Levetiracetam samples that are not separated from red cells within 48 hours of collection or hemolyzed samples not analyzed within 48 hours are rejected and credited; Refrigerated *OR* 1 mL plasma from an EDTA navy blue top tube; Minimum: 0.5 mL; **Do not use tubes containing cell separator gel; Centrifuge; Transfer plasma to a clean, tightly sealed tube and refrigerate; Levetiracetam samples that are not separated from red cells within 48 hours of collection or hemolyzed samples not analyzed within 48 hours are rejected and credited;** Refrigerated *OR* 1 mL plasma from a navy blue top tube with no additive; Minimum: 0.5 mL; **Do not use tubes containing cell separator gel; Centrifuge; Transfer plasma to a clean, tightly sealed tube and refrigerate; Levetiracetam samples that are not separated from red cells within 48 hours of collection or hemolyzed samples not analyzed within 48 hours are rejected and credited;** Refrigerated *OR* 1 mL plasma from an EDTA pink top tube; Minimum: 0.5 mL; **Do not use tubes containing cell separator gel; Centrifuge; Transfer plasma to a clean, tightly sealed tube and refrigerate; Levetiracetam samples that are not separated from red cells within 48 hours of collection or hemolyzed samples not analyzed within 48 hours are rejected and credited;** Refrigerated *OR* 1 mL plasma from a sodium heparin navy top tube; Minimum: 0.5 mL; **Do not use tubes containing cell separator gel; Centrifuge; Transfer plasma to a clean, tightly sealed tube and refrigerate; Levetiracetam samples that are not separated from red cells within 48 hours of collection or hemolyzed samples not analyzed within 48 hours are rejected and credited;** Refrigerated *OR* 1 mL plasma from an EDTA royal blue top tube; Minimum: 0.5 mL; **Do not use tubes containing cell separator gel; Centrifuge; Transfer plasma to a clean, tightly sealed tube and refrigerate; Levetiracetam samples that are not separated from red cells within 48 hours of collection or hemolyzed samples not analyzed within 48 hours are rejected and credited;** Refrigerated *OR* 1 mL plasma from a sodium or lithium heparin green top tube; Minimum: 0.5 mL; Do not use tubes containing cell separator gel; Centrifuge; Transfer plasma to a clean, tightly sealed tube and refrigerate; **Levetiracetam samples that are not separated from red cells within 48 hours of collection or hemolyzed samples not analyzed within 48 hours are rejected and credited;** Refrigerated	9/13/17

(continued on page 7)

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Levetiracetam *(continued from page 6)*		*OR* 1 mL plasma from an EDTA lavender top tube; Minimum: 0.5 mL; **Do not use tubes containing cell separator gel; Centrifuge; Transfer plasma to a clean, tightly sealed tube and refrigerate; Levetiracetam samples that are not separated from red cells within 48 hours of collection or hemolyzed samples not analyzed within 48 hours are rejected and credited;** Refrigerated **Stability:** Refrigerated: 1 week Frozen: **1** month **Reference Range: 12.0–46.0 µg/mL**	
Lp-PLA2 Activity	PLAA2	**Special Information:** The Lp-PLA2 Activity assay may be useful for individuals at intermediate or high risk for developing coronary heart disease. **Causes for rejection: Specimens other than serum or EDTA plasma; samples not processed properly; samples older than stability limits** **Clinical Information:** Lp-PLA2 Activity levels should be interpreted in conjunction with clinical findings and other diagnostic tests. This test does not replace blood cholesterol tests or other traditional risk factors identified for coronary heart disease or ischemic stroke. **Based on the documented clinical utility of Lp-PLA2 Activity to assess risk of CHD (1), the following cut-off has been defined for Lp-PLA2 Activity: A cut-off of ≥ 75 nmol/min/mL defines a population with increased relative risk of developing CHD (Reference: 1-The Lp-PLA2 Studies Collaboration. Lancet. 2010; 375: 1536-1544).** **Specimen Requirement:** 1 mL serum from a **speckled or tiger top serum separator tube;** Minimum: 0.5 mL; Gently invert tube 5 times immediately after draw; DO NOT SHAKE; Allow blood to clot 30 minutes; Centrifuge at 1300 RCF for 10 minutes; Refrigerated *OR* 1 mL plasma from an EDTA lavender top tube; Minimum: 0.5 mL; Gently invert tube 8 to 10 times after draw; Centrifuge immediately for 10 minutes at 1300 RCF at room temperature; Pre-squeeze transfer pipet bulb and draw off approximately 2/3 of the upper plasma layer; Note: This ensures that the buffy coat and red cells remain undisturbed; **Aliquot plasma into transport tube labeled as "EDTA plasma;" Store refrigerated at 2–8 °C until ready to ship;** Refrigerated *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Gently invert tube 5 times immediately after draw; DO NOT SHAKE; Allow blood to clot 30 minutes; Centrifuge at 1300 RCF for 10 minutes; Refrigerated **Stability:** Ambient: 7 days Refrigerated: **28** days Frozen: **28** days at minus 20 °C; **28** days **at minus 70 °C** **Days Performed: Monday**–Saturday **Reported: 4**–6 days	Effective immediately
Maternal Cell Contamination, Integrated Genetics	MATRNL	**Special Information:** This test is only available in combination with **Integrated** Genetics prenatal genetic testing. A maternal sample is required for maternal cell contamination testing in conjunction with all **Integrated** Genetics prenatal molecular testing. **Causes for rejection: Frozen specimen, hemolysis, quantity not sufficient for analysis, improper container, unlabeled or mislabeled specimen** **Clinical Limitation: False positive or false negative results may occur for reasons that include genetic variants, technical handling, blood transfusions, bone marrow transplantation, mislabeling of samples, or erroneous representation of family relationships.** **Specimen Requirement:** 10 mL whole blood in an ACD A (yellow) tube; Minimum: **10 mL;** Ambient *OR* 10 mL whole blood in an EDTA lavender top tube; Minimum: **10 mL;** Ambient **Methodology:** **Capillary Electrophoresis (CE)** Polymerase Chain Reaction (PCR) **Days Performed: Monday**–Saturday **Reported: 11–16** days	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Neopterin	NEOPT	**Special Information: CRITICAL: MUST** protect from light. **Specimens not protected from light will be rejected. If tube other than a gel-barrier tube is used, transfer separated serum or plasma to a plastic transport tube.** **Specimen Requirement:** 0.8 mL serum in a serum separator (gold) tube; Minimum: 0.3 mL, **Note: This volume does NOT allow for repeat testing; CRITICAL: MUST** protect from light; **Specimens that are not protected from light will be rejected;** Refrigerated *OR* 0.8 mL plasma from an EDTA lavender top tube; Minimum: 0.3 mL, **Note: This volume does NOT allow for repeat testing; Transfer separated plasma to a plastic transport tube; CRITICAL: MUST** protect from light; **Specimens that are not protected from light will be rejected;** Refrigerated *OR* 0.8 mL serum from a red top tube with no additive; Minimum: 0.3 mL, **Note: This volume does NOT allow for repeat testing; Transfer separated serum to a plastic transport tube; CRITICAL: MUST** protect from light; **Specimens that are not protected from light will be rejected;** Refrigerated	Effective immediately
Neuron-Specific Enolase, Serum	NSE	**Stability:** Ambient: 1 week Refrigerated: 1 week Frozen: **Unacceptable**	Effective immediately
OmegaCheck	OMEGAC	**Clinical Information:** OmegaCheck™ may be performed on individuals with hypercholesterolemia, hypertriglyceridemia, hypertension, and/or those at high metabolic or cardiovascular risk. Relative Risk: Low Risk OmegaCheck™ (% by weight): ≥ 5.5; Moderate Risk OmegaCheck™ (% by weight): 3.8–5.4; High Risk OmegaCheck™ (% by weight): ≤ 3.7. **Increasing blood levels of long-chain n–3 fatty acids are associated with a lower risk of sudden cardiac death (1). Based on the top (75th percentile) and bottom (25th percentile) quartiles of the Cleveland HeartLab (CHL) reference population, the following risk categories were established for OmegaCheck: A cut-off of ≥ 5.5% by weight defines a population at low relative risk, 3.8-5.4% by weight defines a population at moderate relative risk, and ≤ 3.7% by weight defines a population at high relative risk of sudden cardiac death. The totality of the scientific evidence demonstrates that when consumption of fish oils is limited to 3 g per day or less of EPA and DHA, there is no significant risk for increased bleeding time beyond the normal range. A daily dosage of 1 g of EPA and DHA lowers the circulating triglycerides by about 7–10% within two to three weeks (Reference: 1-Albert et al. NEJM. 2002; 346: 1113-1118).** **Specimen Requirement:** 0.5 mL whole blood in an EDTA lavender top tube; Minimum: 0.1 mL; Gently invert tube 8–10 times immediately after draw; DO NOT SHAKE; **Do not centrifuge;** Store EDTA whole blood at 2–8 °C after collection and ship the same day; Refrigerated **Stability:** Ambient: 10 weeks Refrigerated: 10 weeks Frozen: Unacceptable at minus 20 °C; **Stable 10 weeks at minus 70 °C** **Days Performed:** Monday–**Friday** **Reported:** 5–8 days	Effective immediately
Organism Identification, Aerobic	OIDAER	**Clinical Information:** To identify aerobic bacterial organism. **Multiple identification procedures may be required with the CPT codes 87077, 87153 and 87158 applied, based on the number of tests performed. Antimicrobial susceptibilities are performed upon request. A separate order must be placed for this utilizing the test code Organism MIC (OMIC).**	7/31/17
Oxalate, Urine 24 Hour	UOXALD	**Stability:** Refrigerated: **7 days** Frozen: **7 days**	7/20/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Primidone	PRIM	**Specimen Requirement:** 1 mL plasma from a sodium or lithium heparin green top tube; Minimum: 0.5 mL; **Collect immediately prior to next dose;** Refrigerated *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; **Collect immediately prior to next dose; Refrigerated** **Stability:** Ambient: **After separation from cells: 48** hours Refrigerated: After separation from cells: **14 days** Frozen: After separation from cells: **14 days** **Reference Range:** Primidone 0–99 Years: **5.0–10.0 µg/mL** Phenobarbital 0–99 Years: 15.0–40.0 µg/mL	9/13/17
Rabies Antibody	RABIES	**Days Performed:** Monday, Wednesday, Thursday **Reported:** 4–**5** weeks	Effective immediately
Staph aureus PCR	SAPCR	**Special Information:** This test will be performed on nasal swabs collected in Amies or Stuart's transport media. Unacceptable specimens include: Wooden swabs, wire swabs, gel swabs, dry swabs, charcoal swabs, calcium alginate swabs, and swabs collected in transport media other than Amies or Stuart's. Unacceptable specimens will be rejected for the assay. **This assay is not validated for testing on patients ≤ 21 years of age; an alternate method of culture (SANSAL–MRSA/Staph aureus Culture Screen) will be performed on these specimens.** **Stability:** Ambient: 24 hours–**Acceptable specimens should be kept at room temperature (15–28 °C) if they will be processed within 24 hours; otherwise store at 2–8 °C** Refrigerated: 5 days Frozen: Unacceptable; Will be rejected	7/6/17
Strongyloides IgG Abs, Serum	STRSER	**Special Information: Bacterially contaminated, heat-inactivated, hemolyzed, icteric, or lipemic specimens are unacceptable. This test is New York DOH approved.** **Clinical Information: Aid in the diagnosis of Strongyloides. Positive results in patients from endemic areas may not represent active infection.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.05 mL; Aliquot 1 mL serum into standard transport tube;** Refrigerated *OR* 1 mL serum from a red top tube with no additive; Minimum: **0.05 mL; Aliquot 1 mL serum into standard transport tube;** Refrigerated **Reference Range:** **0.99 IV or less: Negative–No significant level of Strongyloides IgG antibody detected** **1.00 IV or greater: Positive–IgG antibodies to Strongyloides detected, which may suggest current or past infection** **Days Performed: Tuesday–Saturday** **Reported:** 2–**5 days**	Effective immediately
Thyroglobulin	TG	**Reference Range: 1.6–59.9 ng/mL**	8/30/17
Thyroid Cancer (Thyroglobulin) Monitoring	THYMON	**Reference Range:** Thyroglobulin **1.6–59.9 ng/mL** Thyroglobulin Antibody Screen < 14.4 IU/mL	8/30/17
Topiramate	TOPIR	**Stability:** Refrigerated: After separation from cells: **1** week Frozen: After separation from cells: **4** weeks	7/20/17
TPMT Genotype Assay	TPMTGN	**Days Performed: 2 days per week** **Reported: 5 days**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Trypsinogen	TRYPSI	**Special Information:** Grossly lipemic specimens will be rejected. This test is not available for New York patient testing. **Methodology: Radioimmunoassay (RIA)** **Days Performed:** Sunday, Wednesday **Reported:** 3–**7** days	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
FISH for WWTR1/ CAMTA1		**Clinical Information:** This FISH assay detects the t(1;3)(p36;q25) WWTR1-CAMTA1 translocation associated with epithelioid hemangioendothelioma. **Specimen Requirement:** Four slides formalin-fixed paraffin-embedded (FFPE) tissue block; Minimum: 4 slides; Pre and post H&E with 4 unstained slides; Ambient **Stability:** Ambient: FFPE slides room temperature **Methodology:** Fluorescent In-Situ Hybridization (FISH) **Days Performed:** 3 days per week **CPT:** 88377 x 1	8/29/17
Human Alpha-1 Antitrypsin Genotyping	HA1AT	**Specimen Requirement:** 5 mL whole blood in an EDTA lavender top tube; Minimum: 1 mL; Ambient **Stability:** Ambient: Whole blood–24 hours Refrigerated: Whole Blood–5 days Frozen: Whole Blood–Unacceptable **Methodology:** High Resolution Melt Analysis **Days Performed:** 1 day per week **CPT:** 81332 x 1, 81479 x 1, G0452 x 1 **Price:** $302.00	7/26/17
Stool Gastrointestinal Panel by PCR	STGIPR	**Includes:** Campy jejun/coli/ups C. diff (Toxin A/B) P. shigelloides Salmonella species Vibrio par/vul/chol Vibrio cholerae Yersinia enterocolitica E. coli (EAEC) E. coli (EPEC) E. coli (ETEC) E. coli (STEC) E. coli O157 Shig/E. coli (EIEC) Cryptosporidium Cyclospora E. histolytica Giardia lamblia Adenovirus F 40/41 Astrovirus Norovirus GI/GII Rotavirus A Sapovirus I, II, IV, V *(continued on page 11)*	8/22/17

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Stool Gastrointestinal Panel by PCR *(continued from page 10)*		**Special Information:** The stool must be passed into a clean, dry, wide-mouthed container and not contaminated by urine or water. Select bloody, slimy, or watery portions of the stool using the collection spoon provided in the cap of the container. Place enough stool in the Cary-Blair Transport vial to bring the liquid level up to the "fill to here" line. Tighten the cap and shake the vial until the mixture appears homogeneous. Specimens received > 96 hours after collection, in transport media other than Cary Blair (e.g., formalin, PVA, swabs, unpreserved stool), or frozen will be rejected. Stool contaminated with urine or water will be rejected. **Clinical Limitation:** A positive result may indicate viable or nonviable organism. Not all infectious etiologies of diarrhea are detected by the assay. False negatives may occur due to genetic variability in the region targeted by the primers. **Clinical Information:** Targets detected by this multiplex PCR assay include the following bacteria or associated toxins: Campylobacter spp. [C. jejuni, C. coli, C. upsaliensis], Clostridium difficile toxin A/B, Plesiomonas shigelloides, Salmonella spp., Vibrio spp. [V. parahaemolyticus, V. vulnificus, V. cholerae], Yersinia spp., Enteroaggregative Escherichia coli [EAEC], Enteropathogenic E. coli [EPEC], Enterotoxigenic E. coli [ETEC], and Shiga-like toxin-producing E. coli [STEC] stx1/stx2 with specific identification of E. coli O157 serogroup, Shigella/ Enteroinvasive E. coli [EIEC]. Viruses and parasites detected include: Adenovirus F 40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, Sapovirus [Genogroups I, II, IV, V], Cryptosporidium spp., Cyclospora cayetanensis, Entamoeba histolytica, and Giardia intestinalis (formerly G. lamblia). The primary indication for testing is > 7 days of moderate to severe diarrheal disease. When clinical symptoms or epidemiologic factors suggest a specific etiology, testing for that agent is recommended before ordering this type of comprehensive panel. For example, testing for Clostridium difficile toxin should be requested for patients with recent exposure to antimicrobial agents. Data supporting the FDA approval is available in *J Clin Microbiol*, 2015; 53:915-25 http://jcm.asm.org/content/53/3/915.long. **Specimen Requirement:** One stool specimen in a Cary-Blair kit; Ambient **Stability:** Ambient: 4 days Refrigerated: 4 days Frozen: Frozen specimens are unacceptable and will be rejected **Methodology:** Qualitative Polymerase Chain Reaction **Days Performed:** 7 days per week **Reported:** 1–2 days **CPT:** 87507 x 1 **Price:** $705.00 (non-discountable)	

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Allergen, Animals Group	ANIMLS	$132.00	86003 x 4	8/31/17
Organism Identification, Aerobic	OIDAER	$63.00	87077	7/31/17

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Alpha-1-antitrypsin, SERPINA1 F and I Alleles	SERPFI	This test will no longer be available. Suggest ordering Human Alpha-1 Antitrypsin Genotyping (HA1AT).	8/31/17
Alpha-1-antitrypsin, SerpinA1 full sequencing	A1ASEQ	This test will no longer be available. Suggest ordering Human Alpha-1 Antitrypsin Genotyping (HA1AT).	8/31/17
Alpha 1 Anti-trypsin Serum Level and SERPINA1 Targeted Genotyping	A1APG	This test will no longer be available. Suggest ordering Human Alpha-1 Antitrypsin Genotyping (HA1AT).	8/31/17
Alpha-1-antitrypsin targeted genotyping (Z,S)	A1ADNA	This test will no longer be available. Suggest ordering Human Alpha-1 Antitrypsin Genotyping (HA1AT).	8/31/17
Toxic Shock Syndrome Abs	TSS	This test will no longer be available.	Effective immediately