Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • June 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	ADmark Alzheimer's Evaluation						■	■				■		
3	ADmark Phospho-Tau CSF						■	■			■			
16	Allergen, Pigeon Droppings IgE					■								
3	Aminolevulinic Acid (ALA) Urine						■	■			■			
3	Carboxyhemoglobin											■		
3–4	Chlamydia Amplification, Genital, Rectal and Oral Specimens		■				■							
12	Chlamydia trachomatis and Neisseria gonorrhoeae, NA Amplification, Ocular specimens			■										
16	Chlamydia trachomatis, Miscellaneous Sites, NA Amplification				■									
12	Chlamydia trachomatis, NA Amplification, Ocular specimens			■										
4–6	Complete Blood Count and Differential									■				
6	Cortisol									■		■		
6	Cytomegalovirus DNA Detection and Quantitation by PCR					■								
7	Dexamethasone		■			■	■				■	■		
7	Digoxin, Free					■				■				
16	DNA Fingerprinting				■									
16	G-6-PD Qualitative				■									
7	Gastrin											■		
7	Gastrin Secretin Stimulation											■		

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
7	GC Amplification, Genital, Rectal and Oral Specimens		■				■							
8	GC/Chlamydia Amplification, Genital, Rectal and Oral Specimens		■			■	■							
8, 15	Hemoglobin A2					■			■			■	■	■
8	Hemoglobin A2 and F					■								
13	Hemoglobin Electrophoresis			■										
13	Hemoglobin Evaluation Cascade			■										
8	Hemoglobin Fetal					■			■				■	
16	Hemoglobinopathy Eval				■									
14	Hemoglobin S and F monitoring			■										
14	Herpes Simplex Virus 1/2 Antibody (IgM), IFA with Reflex to Titer, Serum			■										
16	Herpes Simplex Virus 1/2 IgM Antibody with Reflex to IFA				■									
9	Hypersensitivity Pneumonitis II						■	■	■				■	
9	Insulin Like Growth Factor Bind, Prot 2					■	■				■			
9	Metanephrines, Urine 24 Hour					■	■							
9	Metanephrines, Urine Random					■	■							
16	Neisseria gonorrhoeae, Miscellaneous Sites, NA Amplification				■									
15	Neisseria gonorrhoeae, NA Amplification, Ocular specimens			■										
9	NF1/SPRED1 Comprehensive by NGS					■					■		■	
10	Paraneoplastic Autoantibody Evaluation, CSF					■					■			
10	Paraneoplastic Autoantibody Evaluation, Serum					■	■							
11	Platelet Antibody Detection					■	■				■	■		
11	Pregabalin					■					■			
11	PSA, Screening											■		
11	Testosterone, Free and Total					■			■					
16	Testosterone, Total and Free, Serum				■									
16	Torch Antibodies, IgG				■									
11	Vitamin B1, Whole Blood						■							
11	Vitamin B12											■		
11	Vitamin B12 & Folate											■		
12	von Willebrand Type 2N Sequence Analysis								■					

Test Changes

Test Name	Order Code	Change	Effective Date
ADmark Alzheimer's Evaluation	ADALZ	**Special Information: Do not order testing on individuals under the age of 18. Informed consent is required. Rejection criteria: Cerebrospinal fluid (CSF) samples that arrive in non-polypropylene tubes; CSF specimens with cell count > 500 erythrocytes/mm³** **Specimen Requirement:** 2 mL cerebrospinal fluid (CSF) collected in a polypropylene tube; Minimum: 0.5 mL; **CSF MUST be submitted in polypropylene tube; Tubes other than polypropylene are not acceptable;** Please send to Cleveland Clinic Laboratories ASAP after collection; Refrigerated *AND* 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Please send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quality and quantity; Refrigerated **Stability:** Ambient: Blood: 10 days, CSF: 3 days Refrigerated: Blood: 10 days, CSF: 21 days Frozen: Blood: **Unacceptable,** CSF: 4 months **Days Performed: Varies** **Reported:** 15–22 days	6/26/17
ADmark Phospho-Tau CSF	PHOTAU	**Special Information: Rejection criteria: Cerebrospinal fluid (CSF) samples that arrive in non-polypropylene tubes; CSF specimens with cell count > 500 erythrocytes/mm³** **Specimen Requirement:** 2 mL cerebrospinal fluid (CSF) **collected in a polypropylene tube;** Minimum: 0.5 mL; **CSF MUST be submitted in polypropylene tube; Tubes other than polypropylene are not acceptable;** Frozen **Days Performed: Varies** **Reported: 8–15** days	6/26/17
Aminolevulinic Acid (ALA) Urine	UAMINO	**Special Information:** Patient Prep: Refrain from alcohol consumption 24 hours prior to collection. Specimen preservation with acid or base is discouraged and may cause assay interference. Indicate total volume **and collection time interval on transport tube** and requisition. **Unacceptable conditions: Body fluids other than urine. This test is New York DOH approved.** **Specimen Requirement:** 4 mL 24-hour urine (well-mixed) in a clean container; Minimum: **1.2 mL;** Refrigerate during collection; **Transfer 4 mL aliquot to a standard transport tube;** Refrigerated *OR* 4 mL random urine in a clean container; Minimum: **1.2 mL; Transfer 4 mL aliquot to a standard transport tube;** Refrigerated **Days Performed:** Monday, Wednesday, **Friday** **Reported:** 2–5 days	Effective immediately
Carboxyhemoglobin	CO	**Stability:** Ambient: **28 days**	Effective immediately
Chlamydia Amplification, Genital, Rectal and Oral Specimens	CT	**Test Name:** Previously Chlamydia Amplification, Genital **Specimen Requirement:** One vaginal swab using APTIMA Collection Vaginal Swab; Vaginal swab is optimal for screening asymptomatic women; May also be used for testing women with vaginal discharge or cervicitis; Ambient *OR* One urethral swab using APTIMA Collection Unisex Swab; Urethral swab is an alternative to first-catch urine for testing asymptomatic or symptomatic males; May also be used for testing women with symptoms of urethritis; Ambient *OR* One endocervical swab using APTIMA Collection Unisex Swab; Endocervical swab is an alternative to vaginal swab for screening asymptomatic women; May also be used for testing women with vaginal discharge or cervicitis; Ambient *OR* **One rectal swab using APTIMA Collection Unisex Swab; Note: The white swab provided in the collection kit is a cleaning swab and should not be used for collection; Please discard the white cleaning swab; Use the blue swab for specimen collection;** Ambient *(continued on page 4)*	7/27/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Chlamydia Amplification, Genital, Rectal and Oral Specimens *(continued from page 3)*		*OR* **One throat swab using APTIMA Collection Unisex Swab; Note: The white swab provided in the collection kit is a cleaning swab and should not be used for collection; Please discard the white cleaning swab; Use the blue swab for specimen collection;** Ambient *OR* Cervical specimen (unspecified) in Cytyc PreservCyt solution (ThinPrep); A vaginal swab is the optimal specimen for screening women; however, ThinPrep PreservCyt may also be used for cervical collections; The use of Cytyc PreservCyt Solution (ThinPrep) is not recommended unless performed in conjunction with a ThinPrep PAP test; Prior to cytology testing and within 30 days of collection, transfer a 1 mL aliquot into an APTIMA Specimen Transfer Tube; the specimen must have been stored at 2–30 °C; Ambient	
Complete Blood Count and Differential	CBCDIF	**Reference Range:** WBC 0–14 Days: 8.04–15.40 K/µL 15–30 Days: 7.80–15.91 K/µL 31–60 Days: 7.05–14.99 K/µL 61–179 Days: 6.00–13.32 K/µL 6–23 Months: 5.98–13.51 K/µL 2–5 Years: 4.86–13.38 K/µL 6–11 Years: 4.27–11.40 K/µL 12–14 Years: 3.84–9.84 K/µL 15–99 Years: 3.70–11.00 K/µL RBC 0–14 Days: 4.10–5.74 M/µL 15–30 Days: 3.16–4.80 M/µL 31–60 Days: 2.93–4.22 M/µL 61–179 Days: 3.43–4.80 M/µL 6–23 Months: 3.97–5.07 M/µL 2–5 Years: 3.84–4.97 M/µL 6–11 Years: 3.90–5.03 M/µL 12–14 Years: 3.93–5.29 M/µL 15–99 Years (Female): 3.90–5.20 M/µL 15–99 Years (Male): 4.20–6.00 M/µL Hemoglobin 0–14 Days: 13.4–20.0 g/dL 15–30 Days: 10.0–15.3 g/dL 31–60 Days: 8.9–12.7 g/dL 61–179 Days: 9.6–12.4 g/dL 6–23 Months: 10.1–12.7 g/dL 2–5 Years: 10.2–12.7 g/dL 6–11 Years: 10.6–13.4 g/dL 12–14 Years: 10.8–15.5 g/dL 15–99 Years (Male): 13.0–17.0 g/dL 15–99 Years (Female): 11.5–15.5 g/dL Hematocrit 0–14 Days: 39.6–57.2% 15–30 Days: 30.5–45.0% 31–60 Days: 26.8–37.5% 61–179 Days: 28.6–37.2% 6–23 Months: 30.8–37.9% 2–5 Years: 31.0–37.8% 6–11 Years: 32.2–39.8% 12–14 Years: 33.4–46.0% 15–99 Years (Male): 39.0–51.0% 15–99 Years (Female): 36.0–46.0% MCV 0–14 Days: 91.3–106.4 fL 15–30 Days: 89.4–103.0 fL 31–60 Days: 83.4–96.4 fL 61–179 Days: 74.1–88.3 fL 6–23 Months: 69.5–82.6 fL 2–5 Years: 71.3–85.0 fL 6–11 Years: 74.4–87.6 fL 12–14 Years: 76.7–90.6 fL 15–99 Years: 80.0–100.0 fL *(continued on page 5)*	7/26/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Complete Blood Count and Differential *(continued from page 4)*		MCH 0–14 Days: 31.1–35.9 pg 15–30 Days: 29.9–35.3 pg 31–60 Days: 27.8–32.5 pg 61–179 Days: 24.4–29.5 pg 6–23 Months: 22.7–27.5 pg 2–5 Years: 23.7–28.6 pg 6–11 Years: 24.8–29.5 pg 12–14 Years: 24.8–30.2 pg 15–99 Years: 26.0–34.0 pg MCHC 0–14 Days: 33.0–35.7 g/dL 15–30 Days: 32.7–35.1 g/dL 31–60 Days: 32.3–34.9 g/dL 61–179 Days: 31.9–34.4 g/dL 6–23 Months: 31.6–34.4 g/dL 2–5 Years: 31.8–34.7 g/dL 6–11 Years: 31.8–34.9 g/dL 12–14 Years: 31.5–34.8 g/dL 15–99 Years: 30.5–36.0 g/dL Red Cell Distribution Width 0–14 Days: 14.6–17.3% 15–30 Days: 14.3–16.8% 31–60 Days: 13.6–16.1% 61–179 Days: 12.2–15.3% 6–23 Months: 12.7–15.6% 2–5 Years: 12.4–14.9% 6–11 Years: 12.2–14.4% 12–14 Years: 12.3–14.6% 15–99 Years: 11.5–15.0% Platelet Count 0–23 Months: 150–450 K/µL 2–99 Years: 150–400 K/µL Mean Platelet Volume 0–14 Days: 10.2–12.0 fL 15–30 Days: 10.0–12.2 fL 31–60 Days: 9.2–11.1 fL 61–179 Days: 8.9–10.9 fL 6–23 Months: 8.7–10.6 fL 2–5 Years: 8.9–11.0 fL 6–11 Years: 9.2–11.4 fL 12–14 Years: 9.6–11.8 fL 15–99 Years: 9.0–12.7 fL Neutrophil % Refer to Absolute value Absolute Neutrophil 0–14 Days: 1.60–6.75 K/µL 15–30 Days: 1.18–5.45 K/µL 31–60 Days: 0.83–4.68 K/µL 61–179 Days: 0.97–7.20 K/µL 6–23 Months: 1.19–7.21 K/µL 2–5 Years: 1.54–8.29 K/µL 6–11 Years: 1.63–7.87 K/µL 12–14 Years: 1.54–7.47 K/µL 15–99 Years: 1.45–7.50 K/µL Lymphocyte % Refer to Absolute value *(continued on page 6)*	

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Complete Blood Count and Differential *(continued from page 5)*		Absolute Lymphocyte 0–14 Days: 1.75–8.00 K/µL 15–30 Days: 2.11–8.38 K/µL 31–60 Days: 2.29–9.14 K/µL 61–179 Days: 2.14–8.99 K/µL 6–23 Months: 1.52–8.09 K/µL 2–5 Years: 1.13–5.77 K/µL 6–11 Years: 0.97–4.28 K/µL 12–14 Years: 0.97–3.33 K/µL 15–99 Years: 1.00–4.00 K/µL Monocyte % Refer to Absolute value Absolute Monocyte 0–14 Days: 0.52–1.77 K/µL 15–30 Days: 0.28–1.38 K/µL 31–60 Days: 0.28–1.21 K/µL 61–179 Days: 0.24–1.17 K/µL 6–23 Months: 0.25–1.15 K/µL 2–5 Years: 0.19–0.94 K/µL 6–11 Years: 0.19–0.85 K/µL 12–14 Years: 0.18–0.78 K/µL 15–99 Years: **< 0.87 K/µL** Eosinophil % Refer to Absolute value Absolute Eosinophil 0–14 Days: **< 0.67 K/µL** 15–30 Days: **< 0.81 K/µL** 31–60 Days: **< 0.64 K/µL** 61–179 Days: **< 0.75 K/µL** 6–23 Months: **< 0.83 K/µL** 2–5 Years: **< 0.54 K/µL** 6–11 Years: **< 0.53 K/µL** 12–14 Years: **< 0.39 K/µL** 15–99 Years: **< 0.46 K/µL** Basophil % Refer to Absolute value Absolute Basophil 0–14 Days: **< 0.12 K/µL** 15–30 Days: **< 0.08 K/µL** 31–60 Days: **< 0.08 K/µL** 61–179 Days: **< 0.08 K/µL** 6–23 Months: **< 0.07 K/µL** 2–5 Years: **< 0.07 K/µL** 6–11 Years: **< 0.07 K/µL** 12–14 Years: **< 0.06 K/µL** 15–99 Years: **< 0.11 K/µL**	
Cortisol	COR	**Stability:** Ambient: **24** hours Refrigerated: **7 days** Frozen: **14 days** **Reference Range:** AM: **5.3–22.5 µg/dL** PM: **3.4–16.8 µg/dL**	8/2/17
Cytomegalovirus DNA Detection and Quantitation by PCR	CMVQNT	**Special Information:** Store and transport whole blood at 2–8 °C for no longer than 36 hours. Plasma must be separated from whole blood within 36 hours of collection by centrifugation for samples stored at 2–8 °C or within 24 hours of collection for samples stored at temperatures up to 25 °C. Transfer plasma to a sterile, screw-capped polypropylene tube. **Bone Marrow is not accepted. Please order CMVCSF for CMV PCR on CSF/FLD/Tissue/Bone Marrow.**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Dexamethasone	DEXA	**Test Name:** Previously Dexamethasone, Serum **Special Information: Specimen should be collected between 8–10 a.m. This test is New York DOH approved.** **Clinical Information: Compliance assessment of dexamethasone suppression testing.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Collect between 8–10 a.m.; Separate serum from cells **ASAP** or within 2 hours of collection **and aliquot into standard transport tube;** Refrigerated *OR* 1 mL plasma from a sodium **or lithium heparin** green top tube; Minimum: 0.5 mL; Collect between 8–10 a.m.; Separate plasma from cells **ASAP** or within 2 hours of collection **and aliquot into standard transport tube;** Refrigerated *OR* 1 mL plasma from an EDTA lavender top tube; Minimum: 0.5 mL; Collect between 8–10 a.m.; Separate plasma from cells **ASAP** or within 2 hours of collection **and aliquot into standard transport tube;** Refrigerated **Stability:** Ambient: **After separation from cells:** Unacceptable Refrigerated: After separation from cells: 1 week Frozen: After separation from cells: 6 months **Days Performed: Wednesday, Saturday** **Reported: 3**–9 days	Effective immediately
Digoxin, Free	DIGFR	**Special Information: Grossly hemolyzed specimens will be rejected. This test is New York State approved.** **Clinical Information:** Useful for evaluating recrudescent (breakthrough) digoxin toxicity in renal-failure patients, assessing the need for more antidigoxin Fab to be administered, deciding when to reintroduce digoxin therapy, and monitoring patients with possible digoxin-like immunoreactive factors (DLIFs). The **suggested** therapeutic range is **0.4–0.9 ng/mL for patients ≥ 16 years of age.** Toxicity may be seen when free digoxin concentrations are ≥ 3.0 ng/mL. **Therapeutic ranges have not been established for patients < 16 years of age.** Pediatric patients may tolerate higher concentrations. Therapeutic concentrations for free digoxin are 25% lower than therapeutic values for total digoxin due to the separation of protein-bound digoxin in the assay. **Reference Range:** **< 16 Years: Therapeutic ranges have not been established** **≥ 16 Years: Therapeutic range: 0.4–0.9 ng/mL**	Effective immediately
Gastrin	GAST	**Stability:** Refrigerated: **6 days** Frozen: 30 days	Effective immediately
Gastrin Secretin Stimulation	GASTST	**Stability:** Refrigerated: **6 days** Frozen: 30 days	Effective immediately
GC Amplification, Genital, Rectal and Oral Specimens	GC	**Test Name:** Previously GC Amplification, Genital **Specimen Requirement:** One endocervical swab using APTIMA Collection Unisex swab; Endocervical swab is an alternative to vaginal swab for screening asymptomatic women; May also be used for testing women with vaginal discharge or cervicitis; Ambient *OR* One urethral swab using APTIMA Collection Unisex Swab; Urethral swab is an alternative to first-catch urine for testing asymptomatic or symptomatic males; May also be used for testing women with symptoms of urethritis; Ambient *OR* One vaginal swab using APTIMA Collection Vaginal Swab; Vaginal swab is optimal for screening asymptomatic women; May also be used for testing women with vaginal discharge or cervicitis; Ambient *OR* **One rectal swab using APTIMA Collection Unisex Swab; Note: The white swab provided in the collection kit is a cleaning swab and should not be used for collection; Please discard the white cleaning swab; Use the blue swab for specimen collection;** Ambient *OR* **One throat swab using APTIMA Collection Unisex Swab; Note: The white swab provided in the collection kit is a cleaning swab and should not be used for collection; Please discard the white cleaning swab; Use the blue swab for specimen collection;** Ambient *OR* Cervical specimen (unspecified) in Cytyc PreservCyt solution (ThinPrep); Cytyc PreservCyt Solution (ThinPrep) is not recommended unless performed in conjunction with a ThinPrep PAP test; Prior to cytology testing and within 30 days of collection, transfer a 1 mL aliquot into an APTIMA Specimen Transfer Tube; the specimen must have been stored at 2–30 °C; Ambient	7/27/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
GC/Chlamydia Amplification, Genital, Rectal and Oral Specimens	GCCT	**Test Name:** Previously GC/Chlamydia Amplification, Genital **Special Information:** Because the predictive value of a test correlates with disease prevalence, positive results in low-prevalence populations should be interpreted carefully with the understanding that the likelihood of a false positive may be higher than a true positive. False positive results due to nonviable organism may occur if repeat NAAT is performed within three weeks after treatment. Patients treated for chlamydia should be retested three months after treatment. A test-of-cure is not recommended for patients with uncomplicated urogenital or rectal gonorrhea. Culture to recover N. gonorrhoeae for susceptibility testing is suggested if treatment failure is suspected. Specimens being submitted for culture need collection with a non-Aptima kit (culturette for N. gonorrhoeae; swab in M4 or universal transport media device for C. trachomatis). There is currently no FDA clearance for use of amplification assays on specimens outside of the genitourinary tract or urine from female patients. Culture is required for testing specimens from the **eye** if molecular testing validated for these sites is not available. Culture is preferred for testing extragenital sites from children and urethral or urine specimens from boys. Since NAAT is more sensitive, it may be run in conjunction with culture for purposes of treatment decision-making. NAAT is considered acceptable for testing vaginal secretions or urine from girls. **Specimen Requirement:** One endocervical swab using APTIMA Collection Unisex Swab; Endocervical swab is an alternative to vaginal swab for screening asymptomatic women; May also be used for testing women with vaginal discharge or cervicitis; Ambient *OR* One urethral swab using APTIMA Collection Unisex Swab; Urethral swab is an alternative to first-catch urine for testing asymptomatic or symptomatic males; May also be used for testing women with symptoms of urethritis; Ambient *OR* One vaginal swab using APTIMA Collection Vaginal Swab; Vaginal swab is optimal for screening asymptomatic women; May also be used for testing women with vaginal discharge or cervicitis; Ambient *OR* **One rectal swab using APTIMA Collection Unisex Swab; Note: The white swab provided in the collection kit is a cleaning swab and should not be used for collection; Please discard the white cleaning swab; Use the blue swab for specimen collection;** Ambient *OR* **One throat swab using APTIMA Collection Unisex Swab; Note: The white swab provided in the collection kit is a cleaning swab and should not be used for collection; Please discard the white cleaning swab; Use the blue swab for specimen collection;** Ambient *OR* Cervical specimen (unspecified) in Cytyc PreservCyt solution (ThinPrep); Cytyc PreservCyt Solution (ThinPrep) is not recommended unless performed in conjunction with a ThinPrep PAP test; Prior to cytology testing and within 30 days of collection, transfer a 1 mL aliquot into an APTIMA Specimen Transfer Tube; the specimen must have been stored at 2–30 °C; Ambient	7/27/17
Hemoglobin A2	HBA2	**Special Information:** Indicate ethnic or racial origin (when possible), date if transfused within previous month, and age of patient on requisition. **Clinical Limitation: Anemia due to iron deficiency may falsely lower hemoglobin A2 levels.** **Clinical Information: Quantification of hemoglobin A2 is useful in the evaluation of suspected beta thalassemia.** **Stability:** Ambient: **Unacceptable** Refrigerated: 7 days Frozen: **Unacceptable** **Methodology: Capillary Electrophoresis (CE)** **CPT: 83020 (Technical Component only) x 1**	7/26/17
Hemoglobin A2 and F	A2F	**Note:** *This test was previously announced in the April 2017 Technical Update as a discontinuation on 6/5/17. Instead, this test will continue to be offered. We apologize for any inconvenience this may have caused.*	See Note
Hemoglobin Fetal	HBF	**Clinical Information: Increased hemoglobin F may be seen in beta thalassemia, hereditary persistence of fetal hemoglobin, and sickle cell anemia.** **Methodology: Capillary Electrophoresis (CE)** **CPT: 83020 (Technical Component only) x 1**	7/26/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hypersensitivity Pneumonitis II	HYPNE2	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Saccharopolyspora rectivirgula (formerly Micropolyspora faeni) Saccharomonospora viridis Thermoactinomyces candidus Thermoactinomyces sacchari Thermoactinomyces vulgaris Aspergillus fumigatus Aureobasidium pullulans IgG Alternaria tenuis IgG Cladosporium herbarum IgG Penicillium notatum IgG Phoma spp IgG Trichoderma viride IgG **Specimen Requirement:** 3 mL serum from a serum separator (gold) tube; Minimum: 2 mL; **Use cold packs;** Refrigerated *OR* **3 mL serum from a red top tube with no additive;** Minimum: 2 mL; **Use cold packs;** Refrigerated **Methodology: Immunoassay (IA)** **CPT:** 86001 **x 6,** 86606 x 1, 86609 x 5	6/30/17
Insulin Like Growth Factor Bind, Prot 2	IGFBP2	**Special Information: Rejection criteria: Gross hemolysis, gross lipemia, specimens received at room temperature** **Clinical Information: The concentration of IGFBP-2 is inversely correlated with changes in growth hormone (GH) secretion. IGFBP-2 may also be used as a marker of metastatic prostatic carcinoma.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.2 mL; Fasting is preferred; **Transport using cold packs; Refrigerated** *OR* 1 mL serum from a red top tube with no additive; Minimum: 0.2 mL; Fasting is preferred; **Transport using cold packs; Refrigerated** **Days Performed: Tuesday** **Reported: 5–13** days	Effective immediately
Metanephrines, Urine 24 Hour	UMETAN	**Special Information:** Indicate total volume on requisition. Adjust urine pH to **3 or less** by adding 6M HCl in 1 mL increments if storage/transport will be greater than 24 hours from end of collection. Random urine metanephrines are orderable using test code UMETRA. **Stability requirements are based on samples that have a pH of 3 or less.** **Specimen Requirement:** 10 mL 24-hour urine (well-mixed) in a clean container; Minimum: 3 mL; Refrigerate during collection; **Indicate total volume on requisition; Adjust urine pH to 3 or less by adding 6M HCl in 1 mL increments if storage/transport will be greater than 24 hours from end of collection;** Refrigerated	Effective immediately
Metanephrines, Urine Random	UMETRA	**Special Information:** Adjust urine pH to **3 or less** by adding 6M HCl in 1 mL increments if storage/transport will be greater than 24 hours from end of collection. **Specimen stability is currently based on samples with a pH of 3 or less.** **Specimen Requirement:** 10 mL random urine in a clean container; Minimum: 3 mL; **Adjust urine pH to 3 or less by adding 6M HCl in 1 mL increments if storage/transport will be greater than 24 hours from end of collection;** Refrigerated	Effective immediately
NF1/SPRED1 Comprehensive by NGS	NFIB1	**Special Information: Do not ship on ice.** **Days Performed:** Monday–Friday **Reported: 27–**35 days **CPT:** 81408 x 1**, 81479 x 2**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Paraneoplastic Autoantibody Evaluation, CSF	PARCSF	**Special Information:** Include name, phone number, mailing address, and email address (if applicable) of ordering physician. Reflex algorithm: If indirect immunofluorescence assay (IFA) (ANN1C, ANN2C, ANN3C, PCA1C, PCA2C, PCTRC, AMPHC, CRMC, AGN1C) is indeterminate, then paraneoplastic autoantibody Western blot is performed at an additional charge. If IFA patterns suggest NMO/AQP4-IgG, then NMO/AQP4-IgG FACS is performed at an additional charge. If NMO/AQP4-IgG FACS screen assay is positive, then NMO/AQP4-IgG FACS titration assay is performed at an additional charge. If IFA patterns suggest CRMP-5-IgG, then CRMP-5-IgG Western blot is performed at an additional charge. If IFA patterns suggest GAD65 antibody, then GAD65 antibody radioimmunoassay is performed at an additional charge. If IFA patterns suggest neuronal voltage-gated potassium channel-complex autoantibody, then VGKC-complex antibody IPA is performed at an additional charge. **If VGKCC > 0.00, LGI1-IgG CBA, CSF (Leucine-Rich Glioma Inactivated Protein-1 IgG, CSF) and CASPR2-IgG CBA, CSF (Contactin-Associated Protein-Like-2-IgG, CSF) are performed at an additional charge.** If IFA patterns suggest amphiphysin antibody, then amphiphysin Western blot is performed at an additional charge. If IFA patterns suggest NMDA-R, then NMDA-R antibody CBA and/or NMDA-R titer is performed at an additional charge. If IFA patterns suggest AMPA-R, then AMPA-R antibody CBA and/or AMPA-R titer is performed at an additional charge. If IFA patterns suggest GABA-B-R, then GABA-B-R antibody CBA and/or GABA-B-R titer is performed at an additional charge. In patients with a history of tobacco use or other lung cancer risk, or if thymoma is suspected, PAVAL / Paraneoplastic Autoantibody Evaluation, Serum is also recommended. **Causes for rejection: Grossly hemolyzed, grossly lipemic, grossly icteric** **Days Performed:** Monday–Sunday **Reported: 4–9** days	Effective immediately
Paraneoplastic Autoantibody Evaluation, Serum	PARNEO	**Special Information:** Reflex Algorithm: If IFA (ANN1S, ANN2S, ANN3S, PCABP, PCAB2, PCATR, AMPHS, CRMS, AGN1S) patterns are indeterminate, paraneoplastic autoantibody Western blot is performed at an additional charge. If client requests or if IFA patterns suggest CRMP-5-IgG, CRMP-5-IgG Western blot is performed at an additional charge. If IFA patterns suggest NMO/AQP4-IgG, NMO/AQP4-IgG FACS is performed at an additional charge. If the results of NMO/AQP4-IgG FACS assay require further evaluation, then NMO/AQP4-IgG FACS titration assay will be performed at an additional charge. If IFA patterns suggest amphiphysin antibody, amphiphysin Western blot is performed at an additional charge. If IFA patterns suggest GAD65 antibody, GAD65 antibody radioimmunoassay is performed at an additional charge. If IFA patterns suggest NMDA-R, NMDA-R Ab CBA and/or NMDA-R Ab IF Titer Assay is performed at an additional charge. If IFA patterns suggest AMPA-R, AMPA-R Ab CBA and/or AMPA-R Ab IF Titer Assay is performed at an additional charge. If IFA patterns suggest GABA-B-R, GABA-B-R Ab CBA and/or GABA-B-R Ab IF Titer Assay is performed at an additional charge. If ACh receptor binding antibody is > 0.02, ACh receptor modulating antibodies and CRMP-5-IgG Western blot are performed at an additional charge. CRMP-5-IgG Western blot is also performed by specific request for more sensitive detection of CRMP-5-IgG. Testing should be requested in cases of subacute basal ganglionic disorders (chorea, Parkinsonism), cranial neuropathies (especially loss of vision, taste, or smell) and myelopathies. **If VGKC > 0.00, LGI1-IgG CBA, S (Leucine-Rich Glioma Inactivated Protein-1 IgG, Serum) and CASPR2-IgG CBA, S (Contactin-Associated Protein-Like-2-IgG, Serum) are performed at an additional charge. Causes for specimen rejection: Grossly hemolyzed, grossly lipemic, grossly icteric** **Specimen Requirement:** 4 mL serum from a **red top tube with no additive;** Minimum: 2 mL; Collect 2 specimen tubes to ensure adequate specimen volume; Refrigerated *OR* 4 mL serum from a **serum separator (gold) tube;** Minimum: 2 mL; Collect 2 specimen tubes to ensure adequate specimen volume; Refrigerated	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Platelet Antibody Detection	PLTDET	**Special Information:** Unacceptable Conditions: Microbial contamination, hemolyzed, lipemic, or heat inactivated samples. Testing for neonatal **alloimmune** thrombocytopenia should be performed using a maternal **serum, since platelet antibody may not be detected in a neonatal serum. False negative results are common in infant samples. 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, aliquot and freeze;** For newborns < 30 days old, collect specimen from the mother; Frozen **Stability:** Ambient: Unacceptable Refrigerated: **48 hours** Frozen: 1 month **Days Performed:** Monday–Saturday **Reported: 2**–4 days	Effective immediately
Pregabalin	PBALIN	**Clinical Information: Monitoring serum pregabalin (Lyrica) concentrations, assessing compliance, and adjusting dosage in patients. Pregabalin is an anticonvulsant drug used to treat partial seizures in patients and is a more potent successor to gabapentin. Pregabalin is commonly used for neuropathic pain and fibromyalgia. This test can be used by physicians to assess compliance and may be clinically useful in patients with renal failure who generally require lower dosages. Therapeutic and toxic ranges are not well defined. Therapeutic concentrations are reported to be from 2 to 5 mcg/mL, while toxicity may occur at concentrations above 10 mcg/mL. Clinical Reference: 1. Baselt R: Disposition of Toxic Drugs and Chemicals in Man. 10th edition. Biomedical Publications. Seal Beach, CA, 2014; 2. Hiemke, C, Baumann P, Bergemann N, et al: AGNP Consensus Guidelines for Therapeutic Drug Monitoring in Psychiatry: Update 2011. Pharmacopsychiatry 2011;44:195-235** **Days Performed: Tuesday** **Reported:** 2–**12** days	Effective immediately
PSA, Screening	PSAS1	**Stability:** Ambient: **24** hours Refrigerated: **3** days Frozen: **24 weeks**	Effective immediately
Testosterone, Free and Total	FTESTO	**Special Information: Samples can only be frozen once; do not refreeze.** **Clinical Limitation:** Patients who have been administered certain radioactive isotopes may have levels of radioactivity that interfere with the assay. Patients who have been administered radioactive isotopes within the last 48 hours cannot be tested. **Methodology:** **Electro** Chemiluminescence Immunoassay **(ECLIA)** Tracer Ultrafiltration	7/26/17
Vitamin B1, Whole Blood	B1VIT	**Specimen Requirement:** 3 mL whole blood in a sodium or lithium heparin green top tube; Minimum: 0.6 mL; Transfer 3 mL whole blood to a standard false-bottom aliquot tube and freeze immediately; Note: Orange-capped tubes are not acceptable; Separate specimens must be submitted when multiple tests are ordered; **Do NOT use plasma separator tubes;** Critical Frozen *OR* 3 mL whole blood in an EDTA lavender top tube; Minimum: 0.6 mL; Transfer 3 mL whole blood to a standard false-bottom aliquot tube and freeze immediately; Note: Orange-capped tubes are not acceptable; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen	Effective immediately
Vitamin B12	B12	**Stability:** Ambient: Unacceptable Refrigerated: 24 hours Frozen: **2 months, freeze once, protect from light**	Effective immediately
Vitamin B12 & Folate	XB12F	**Stability:** Ambient: Unacceptable Refrigerated: 24 hours Frozen: **2 months, freeze once, protect from light**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
von Willebrand Type 2N Sequence Analysis	TYPE2N	**Methodology:** **Next Gen Sequencing** **Bi-directional Sequence Analysis** Polymerase Chain Reaction (PCR)	6/23/17

New Tests

Test Name	Order Code	Change	Effective Date
Chlamydia trachomatis and Neisseria gonorrhoeae, NA Amplification, Ocular specimens	CTNGAO	**Special Information:** This assay does not detect Chlamydia pneumoniae. This test is used for specimens that are not FDA approved for this assay. Acceptable non-FDA-approved specimen types are ocular swabs. Specimens must be collected using an APTIMA swab collection kit. Specimen source is required. This test is New York State approved. **Clinical Information:** This report is intended for use in clinical monitoring or management of patients; it is not intended for use in medico-legal applications. In general, this assay should not be used to assess therapeutic success or failure, since nucleic acids from these organisms may persist for three weeks or more following antimicrobial therapy. The presence of blood is not expected to interfere with this assay. **Specimen Requirement:** One APTIMA Collection Unisex Swab from ocular (corneal/conjunctiva) only sites; Indicate specimen source; Refrigerated **Stability:** Ambient: 60 days Refrigerated: 60 days Frozen: 1 year **Methodology:** Transcription-Mediated Amplification **Reference Range:** Negative **Days Performed:** Monday–Saturday **Reported:** 2–4 days **CPT:** 87491 x 1, 87591 x 1 **Price:** $170.00 (non-discountable)	7/27/17
Chlamydia trachomatis, NA Amplification, Ocular specimens	CTNAAO	**Special Information:** This assay does not detect Chlamydia pneumoniae. This test is used for specimens that are not FDA approved for this assay. Acceptable non-FDA-approved specimen types are ocular swabs. Specimens must be collected using an APTIMA swab collection kit. Specimen source is required. This test is New York State approved. **Clinical Information:** This report is intended for use in clinical monitoring or management of patients; it is not intended for use in medico-legal applications. In general, this assay should not be used to assess therapeutic success or failure, since nucleic acids from these organisms may persist for three weeks or more following antimicrobial therapy. The presence of blood is not expected to interfere with this assay. **Specimen Requirement:** One APTIMA Collection Unisex Swab from ocular (corneal/conjunctiva) only sites; Indicate specimen source; Refrigerated **Stability:** Ambient: 60 days Refrigerated: 60 days Frozen: 1 year **Methodology:** Transcription-Mediated Amplification **Reference Range:** Negative **Days Performed:** Monday–Saturday **Reported:** 2–4 days **CPT:** 87491 x 1 **Price:** $145.00 (non-discountable)	7/27/17

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Hemoglobin Electrophoresis	HBELEC	**Includes:** Hb A Percent Hb F Percent Hb A2 Percent Abnormal Hemoglobin Interpretation Reviewed by **Special Information:** If a variant hemoglobin is present, additional testing will be performed to identify the variant. Additional testing may include: Hemoglobin HPLC, acetate agar electrophoresis, cellulose acetate electrophoresis, sickle solubility, or isoelectric focusing. **Clinical Information:** This test is designed for evaluation of suspected hemoglobin variants or beta thalassemia. If there is clinical suspicion for alpha thalassemia, suggest ordering "Hemoglobin Evaluation Cascade." **Specimen Requirement:** 4 mL peripheral blood in an EDTA lavender top tube; Minimum: 0.5 mL; Refrigerated **Stability:** Ambient: Unacceptable Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Capillary Electrophoresis (CE) **Days Performed:** 5 days per week **Reported:** 1–5 days **CPT:** 83020 x 1 **Price:** $149.00	7/26/17
Hemoglobin Evaluation Cascade	HBEVAL	**Includes:** RBC Hemoglobin Hematocrit MCV MCH MCHC RDW-CV Hb A Percent Hb F Percent Hb A2 Percent Abnormal Hemoglobin Interpretation Reviewed by **Special Information:** Indicate age of patient, and/or ethnic background and date of most recent blood transfusion. If an abnormal hemoglobin or abnormal distribution of hemoglobins is found, additional hemoglobin studies will be charged separately. These tests may include alkaline and acid electrophoresis, isoelectric focusing, sickle solubility, and/or ferritin. **Clinical Information:** To detect or rule out abnormal hemoglobin and thalassemias. **Specimen Requirement:** 8 mL whole blood in an EDTA lavender top tube; Minimum: 0.5 mL; Draw two 4 mL tubes; Refrigerated *OR* 0.5 mL whole blood in an EDTA microtainer tube; Minimum: 0.5 mL; Refrigerated **Stability:** Ambient: Unacceptable Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Capillary Electrophoresis (CE) **Days Performed:** 5 days per week **Reported:** 1–5 days **CPT:** 83020 x 1, 85041 x 1 **Price:** $159.00	7/26/17

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Hemoglobin S and F monitoring	HBSFMO	**Includes:** Hb S Percent Hb F Percent Interpretation Reviewed by **Clinical Information:** This test is intended for monitoring the levels of Hemoglobin S and Hemoglobin F in patients with a previously confirmed diagnosis of sickle cell anemia. For initial workup of patients with a suspected hemoglobinopathy, please order "Hemoglobin Evaluation Cascade." **Specimen Requirement:** 4 mL peripheral blood in an EDTA lavender top tube; Minimum: 0.5 mL; Refrigerated **Stability:** Ambient: Unacceptable Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Capillary Electrophoresis (CE) **Days Performed:** 5 days per week **Reported:** 1–5 days **CPT:** 83020 x 1 **Price:** $149.00	7/26/17
Herpes Simplex Virus 1/2 Antibody (IgM), IFA with Reflex to Titer, Serum	HSVIFA	**Special Information:** If HSV 1 IgM Screen is positive, HSV 1 IgM Titer will be performed at an additional charge. If HSV 2 IgM Screen is positive, HSV 2 IgM Titer will be performed at an additional charge. Grossly hemolyzed, grossly lipemic, and cord blood specimens will be rejected. **Clinical Information:** HSV IgM is detectable in serum from > 90% of patients with primary HSV infection; however, HSV IgM is also found in 30% of patients with reactivated HSV. **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Ambient *OR* 1 mL serum from a red top tube with no additive; Minimum: 0.3 mL; Ambient **Stability:** Ambient: 7 days Refrigerated: 14 days Frozen: 30 days **Methodology:** Immunofluorescence **Reference Range:** HSV 1 IgM Screen: Negative HSV 2 IgM Screen: Negative **Days Performed:** Monday–Saturday **Reported:** 2–3 days **CPT:** 86695 x 1, 86696 x 1 **Price:** $117.00 (non-discountable)	6/5/17

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Neisseria gonorrhoeae, NA Amplification, Ocular specimens	NGNAAO	**Special Information:** This test is used for specimens that are not FDA approved for this assay. Acceptable non-FDA-approved specimen types are ocular swabs. Specimens must be collected using an APTIMA swab collection kit. Specimen source is required. This test is New York State approved. **Clinical Information:** This report is intended for use in clinical monitoring or management of patients; it is not intended for use in medico-legal applications. The presence of blood is not expected to interfere with this assay. **Specimen Requirement:** One APTIMA Collection Unisex Swab from ocular (corneal/conjunctiva) only sites; Indicate specimen source; Refrigerated **Stability:** Ambient: 60 days Refrigerated: 60 days Frozen: 1 year **Methodology:** Transcription-Mediated Amplification **Reference Range:** Negative **Days Performed:** Monday–Saturday **Reported:** 2–4 days **CPT:** 87591 x 1 **Price:** $145.00 (non-discountable)	7/27/17

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Hemoglobin A2	HBA2	$61.00	83020 (Technical Component only)	7/26/17

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Allergen, Pigeon Droppings IgE	PIGEON	This test will no longer be available.	8/31/17
Chlamydia trachomatis, Miscellaneous Sites, NA Amplification	NAACT	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).	7/27/17
DNA Fingerprinting		This test will no longer be available.	7/26/17
G-6-PD Qualitative	G6PD	This test will no longer be available. Suggest ordering G-6-PD Quantitative (G6PDQT).	7/26/17
Hemoglobinopathy Eval	HBHPLC	This test will no longer be available. Suggest ordering Hemoglobin Evaluation Cascade (HBEVAL).	7/26/17
Herpes Simplex Virus 1/2 IgM Antibody with Reflex to IFA	12HSV	This test will no longer be available. Suggest ordering Herpes Simplex Virus 1/2 Antibody (IgM), IFA with Reflex to Titer, Serum (HSVIFA).	6/5/17
Neisseria gonorrhoeae, Miscellaneous Sites, NA Amplification	NAAGC	This test will no longer be available. Suggest ordering GC Amplification, Genital, Rectal and Oral Specimens (GC) or Neisseria gonorrhoeae, NA Amplification, Ocular specimens (NGNAAO).	7/27/17
Testosterone, Total and Free, Serum	TFTEST	This test will no longer be available. Suggest ordering Testosterone, Free and Total (FTESTO).	7/26/17
Torch Antibodies, IgG	TRCHG	This test will no longer be available. Suggest ordering CMV, IgG (CMVG), Herpes Simplex Type 1 and 2 IgG Antibodies (HSVG12), Rubella IgG Antibody (RUBIGG), and Toxoplasmosis, IgG Antibody (TOXG).	7/27/17