Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • April 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
5	11-Deoxycortisol						■	■		■		■		
5	AFP – Maternal											■		
5	Albumin, CSF											■		
5	Aldosterone											■		
5	Aldosterone, Urine											■		
5	Aldosterone, Urine 24 Hour											■		
5	ANA											■		
5	Aspergillus Ab, ID											■		
5	BAL FCM Markers					■		■						
6	BAL FCM Markers Package					■		■						
6	Blastomyces Ab, ID											■		
18	BRAF V600E Sequencing				■									
6	CA 19-9											■		
6	CEA											■		
6	Chromium, Urine						■							
6	CMV, IgG					■	■	■	■	■	■	■		
7	CMV, IgM					■			■		■	■		
7	Coccidioides Ab, ID											■		
7	Complete Blood Count					■								
7	Crithidia luciliae											■		
7	Cyanide, Blood						■							
7	Degradation Products						■					■		

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	Erythropoietin											■		
8-10	Fatty Acid Profile of Lipids					■	■			■	■	■		
16	FISH for 7q deletion			■										
16	FISH for 20q and CEP8			■										
10, 18	FISH for Cutaneous Melanoma												■	■
16	FISH for IGH/MYC Fixed Pellet			■										
10	Fondaparinux Assay						■					■		
10	Fragile X Syndrome DNA Analysis by PCR, Blood					■								
10	Fungal Antibodies, ID											■		
10-11	Fungitell Assay for (1,3)-B-D-Glucan					■	■							
18	Gene Analysis 21 Hydroxylase				■									
11	Growth Hormone											■		
11	Growth Hormone Stimulation											■		
11	Growth Hormone Suppression											■		
18	Hemoglobin A2 and F				■									
11	Hemoglobin, Urine						■					■		
11	Histone IgG Antibody											■		
18	H pylori Ab IgM				■									
16	Hydroxylase Gene(CYP21A2), Full Gene Analysis, Blood			■										
11	Ibuprofen					■		■						
17	Immature Platelet Fraction			■										
11	Insulin Like Growth Factor Bind, Prot 3					■								
11	Kappa, Free, Serum											■		
11	Kappa/Lambda, Free, Serum											■		
12	Lambda, Free, Serum											■		
18	Megaloblastic Anemia Panel				■									
18	MLH1 Hypermethylation and BRAF Mutation Analysis				■									
17	Mycoplasma hominis, Molecular Detection, PCR, Blood			■										
17-18	Mycoplasma hominis, Molecular Detection, PCR, Plasma			■										
12, 18	Polio Neutralization					■	■	■			■		■	■
12, 18	Procalcitonin						■		■	■		■		■
12	Sedimentation Rate, Westergren											■		
18	Serum Bactericidal Titer				■									
12	Thyroglobulin											■		
13	Toxoplasmosis, IgG Antibody					■		■	■	■	■	■		
13	Toxoplasmosis IgM					■	■	■	■	■	■	■		
14	Toxoplasmosis IgM and IgG, Ab					■	■	■	■	■	■	■		

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
14	Transglutaminase IgA Abs											■		
14	Transglutaminase IgG Abs											■		
14	Transglutaminase IgG and IgA											■		
14	Trofile Co-receptor Tropism Assay											■	■	
15	Urinalysis Only						■					■		
15	Vitamin B1, Plasma					■	■				■			

Dear valued client,

On August 1, 2016, Cleveland Clinic Laboratories launched a new online **Supply Storefront** that allows clients to order supplies needed for transporting specimens to our laboratories.

Starting on April 1, 2017, CCL's Logistics Department will only accept orders placed through the online Supply Storefront.

After April 1, any other ordering methods will no longer be accepted (such as the old supply order form on the CCL website, faxed orders, emails to Client Services, or contacting Logistics directly). Our objective is to remain compliant with laboratory operating standards and to streamline the ordering and fulfillment process.

Using our online **Supply Storefront** is easy:

1. On clevelandcliniclabs.com, click on **Order Supplies** on the right side of the homepage
   - On this page, you can watch a video that shows how to use the Storefront
2. Click on the **blue button** to access the Supply Storefront
3. Enter the password: **cclabs.123**
4. Find your supplies, select quantities needed, and add them to your cart
5. Click **Checkout** and enter the required contact information
6. Place the order, and an order confirmation will be sent by email

Please contact **Client Services** by calling 800.628.6816 or by emailing clientservices@ccf.org if you have any additional questions or require assistance.

Thank you for your cooperation.

Dear valued client,

Effective immediately, testing for Fragile X Syndrome (FRAX) no longer requires a completed informed consent form to accompany the specimen. It remains best practice for the ordering physician to obtain informed consent of the patient for genetic testing, but Cleveland Clinic Laboratories will no longer require the completed form. We encourage you to continue to follow American Congress of Obstetricians and Gynecologists (ACOG) guidelines* on informed consent for genetic testing, but again, you no longer need to involve the laboratory.

Please contact Jacqueline Riley, Genetic Counselor (rileyj2@ccf.org; 216.445.9747), with any questions.

*http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Ethics/Ethical-Issues-in-Genetic-Testing

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For several microbiology culture tests, additional information on isolate identification CPT codes and billing has been added to the Test Directory. Please see the Special Information field of each affected test in the Test Directory for test-specific details. The following tests are affected:

- Aeromonas/Plesiomonas Culture (AERPLE)
- Blood Parasites (BLDPAR)
- Body Fluid Culture and Stain (BFCUL)
- Bronchoscopy Culture and Gram Stain (BALCSM)
- Campylobacter Culture (CAMPY)
- Catheter Tip Culture (CTCUL)
- Cryptococcus Ag Detection (CAD)
- Cryptosporidia Examination (CRYSPO)
- CSF Culture & Stain (CSFCUL)
- Cystic Fibrosis Respiratory Culture (CFRCUL)
- Ear Culture (EARC)
- Ear Culture and Gram Stain (EARCSM)
- Eye Culture and Gram Stain (EYECSM)
- Fungal Blood Culture (HISTCL)
- Fungal Culture and Smear Hair, Skin, Nail (FHSNSM)
- Fungal Culture and Smear (Non Dermal) (FCULSM)
- Fungal Culture Hair, Skin, Nails (ACFSC)
- Fungal Culture (Non Dermal Sites) (FCUL)
- Fungus CSF Culture/CAD (FUNCSF)
- Fungus Screen (FUNGSC)
- Helicobacter pylori Culture (HPYCUL)
- Legionella Culture (LEGCUL)
- Microscopic Examination for Ehrlichia and Anaplasma (EHRLSM)
- Miscellaneous GC Screen (MISCGC)
- Nocardia Culture and Stain (NOCARD)
- Nocardia Culture Only (NOCARC)
- Respiratory Culture and Stain (RCULST)
- Sinus Culture and Gram Stain (SINUSC)
- Stool Culture/EIA (STCUL)
- Throat Culture, Routine (THRCUL)
- Tissue Culture & Stain (TISCUL)
- Urine Culture (URCUL)
- Vibrio Culture (VIBCUL)
- VRE Culture Screen (VRESC)
- Wound Culture and Gram Stain (WCUL)
- Yersinia Culture (YERCUL)

Test Changes

Test Name	Order Code	Change	Effective Date
11-Deoxycortisol	DEOXY	**Special Information:** Indicate the patient's age on the requisition. **Unacceptable conditions: Grossly hemolyzed specimens. This test is New York DOH approved.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Separate serum from cells ASAP and refrigerate; Refrigerated *OR* **1 mL plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: 0.3 mL; **Separate plasma from cells ASAP and refrigerate;** Refrigerated *OR* 1 mL serum from a red top tube with no additive; Minimum: 0.3 mL; Separate serum from cells ASAP and refrigerate; Refrigerated *OR* 1 mL plasma from a sodium heparin **(light green) plasma separator tube (PST);** Minimum: 0.3 mL; Separate plasma from cells ASAP and refrigerate; Refrigerated **Methodology: High Performance** Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) **Days Performed: Monday, Wednesday, Friday** **Reported:** 3–**6 days**	Effective immediately
AFP–Maternal	AFPMAT	**Stability:** Ambient: **24** hours Refrigerated: **7** days Frozen: **14** days	4/4/17
Albumin, CSF	CSFALB	**Stability:** Ambient: **24** hours Refrigerated: **7** days Frozen: **14 days**	4/18/17
Aldosterone	ALDO	**Stability:** Ambient: 24 hours Refrigerated: **7** days Frozen: **4 weeks**	4/18/17
Aldosterone, Urine	UALDO1	**Stability:** Ambient: **24** hours Refrigerated: **7** days with boric acid preservative Frozen: 4 weeks with boric acid preservative	4/18/17
Aldosterone, Urine 24 Hour	UALDOS	**Stability:** Ambient: **24** hours Refrigerated: **7** days (with boric acid preservative) Frozen: 4 weeks (with boric acid preservative)	4/18/17
ANA	ANAS	**Stability:** Ambient: **24** hours Refrigerated: **7 days** Frozen: **14 days**	4/11/17
Aspergillus Ab, ID	ASPRID	**Stability:** Ambient: **24** hours Refrigerated: **7 days** Frozen: **14 days**	4/25/17
BAL FCM Markers	FCBAL	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** CD3 T Cell % CD4 T Cell % CD8 T Cell % CD4/CD8 Ratio **Clinical Information:** T cell subsets percentages will be reported along with a CD4/CD8 ratio. A BAL CD4/8 ratio of > 3.5 is associated with sarcoidosis in the appropriate clinical setting (Semin Respir Crit Care Med 2010;31:404-408).	5/31/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
BAL FCM Markers Package	BALFCM	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** CD3 T Cell % CD4 T Cell % CD8 T Cell % CD4/CD8 Ratio Cell Count and Differential **Clinical Information:** T cell subsets percentages will be reported along with a CD4/CD8 ratio. A BAL CD4/8 ratio of > 3.5 is associated with sarcoidosis in the appropriate clinical setting (Semin Respir Crit Care Med 2010;31:404-408).	5/31/17
Blastomyces Ab, ID	BLSTID	**Stability:** Ambient: **24** hours Refrigerated: **7 days** Frozen: **14 days**	4/25/17
CA 19-9	CA199	**Stability:** Ambient: **24** hours Refrigerated: 7 days Frozen: **14 days**	4/4/17
CEA	CEA	**Stability:** Ambient: **24** hours Refrigerated: 7 days Frozen: **14 days**	4/4/17
Chromium, Urine	UCHRO	**Specimen Requirement:** 8 mL 24-hour urine (well-mixed) in a clean container; Minimum: 1 mL; Refrigerate during collection; Submit specimen in two trace element-free **transport tubes, ARUP supply #43116;** Refrigerated *OR* 8 mL random urine in a clean container; Minimum: 1 mL; Refrigerated	Effective immediately
CMV, IgG	CMVG	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Cytomegalovirus IgG **CMV IgG Qual** **Special Information: Grossly hemolyzed, icteric or lipemic samples as well as samples containing particulate matter or exhibiting obvious microbial contamination will be rejected.** **Clinical Limitation: Results from immunosuppressed patients should be interpreted with caution. Screening of the general population should not be performed. The positive predictive value depends on the likelihood of the virus being present. Testing should only be performed on patients with clinical symptoms or when exposure is suspected.** **Clinical Information: The presence of CMV IgM should also be determined to assess the stage of CMV infection. Diagnosis of infectious diseases should not be established on the basis of a single test result, but should be determined in conjunction with clinical findings and other diagnostic procedures as well as in association with medical judgment. Diseases such as Epstein-Barr viral syndrome, toxoplasmosis and hepatitis may cause symptoms similar to CMV infection and must be excluded before confirmation of diagnosis.** **Specimen Requirement: 1 mL** serum from a serum separator (gold) tube; Minimum: 0.5 mL; Refrigerated **Stability:** Ambient: 24 hours Refrigerated: **7** days Frozen: **14 days** **Methodology: Chemiluminescence Immunoassay (CLIA)** **Reference Range:** Cytomegalovirus IgG: **Refer to report** **CMV IgG Qual: Negative** **Days Performed:** Monday, **Wednesday, Friday** **Reported:** 1–**4** days	5/31/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
CMV, IgM	CMVMAB	**Special Information: Grossly hemolyzed, icteric or lipemic samples as well as samples containing particulate matter or exhibiting obvious microbial contamination will be rejected.** **Clinical Limitation: Results from immunosuppressed patients should be interpreted with caution. Screening of the general population should not be performed. The positive predictive value depends on the likelihood of the virus being present. Testing should only be performed on patients with clinical symptoms or when exposure is suspected.** **Clinical Information: The presence of CMV IgG should also be determined as it may provide useful information for clinical interpretation of results. Diagnosis of infectious diseases should not be established on the basis of a single test result, but should be determined** in conjunction with clinical **findings and other diagnostic procedures as well as in association with medical judgment. Diseases such as Epstein-Barr viral syndrome, toxoplasmosis and hepatitis may cause symptoms similar to CMV infection and must be excluded before confirmation of diagnosis.** **Stability:** Ambient: 24 hours Refrigerated: 7 days Frozen: **14 days** **Methodology: Chemiluminescence Immunoassay (CLIA)** **Days Performed:** Monday, **Wednesday, Friday** **Reported:** 1–**4** days	5/31/17
Coccidioides Ab, ID	COCIID	**Stability:** Ambient: **24** hours Refrigerated: **7 days** Frozen: **14 days**	4/25/17
Complete Blood Count	CBC	**Note:** *This test was previously announced in the March 2017 Technical Update. Reference range and component changes will go live on 4/26/17. We apologize for any inconvenience this may have caused.*	4/26/17
Crithidia luciliae	CRITH	**Stability:** Ambient: **24** hours Refrigerated: **7** days Frozen: **14 days**	4/18/17
Cyanide, Blood	CYANID	**Specimen Requirement:** 1 mL whole blood in a potassium oxalate/sodium fluoride (gray) tube; Minimum: 0.5 mL; Refrigerated *OR* **1 mL whole blood in an EDTA lavender top tube;** Minimum: 0.5 mL; Refrigerated *OR* **1 mL whole blood in a sodium or lithium heparin green top tube;** Minimum: 0.5 mL; Refrigerated	Effective immediately
Degradation Products	FDP	**Specimen Requirement:** 2 mL whole blood in a Thrombo Wellco (blue) tube; Do not use (sodium citrate) light blue top tube; **Centrifuge and separate the serum; Centrifuge, aliquot and freeze** **Stability:** Ambient: **Unacceptable; Once the specimen is drawn, let the tube sit at room temperature for 30–60 minutes to clot; Centrifuge the sample and separate the serum and refrigerate** Refrigerated: **The separated serum is stable for up to 1 week if stored at 2–8 °C** Frozen: **The separated serum can be frozen at minus 15 °C to minus 25 °C for up to 1 month**	Effective immediately
Erythropoietin	EPO	**Stability:** Ambient: **24** hours Refrigerated: 7 days Frozen: **14 days**	4/4/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Fatty Acid Profile of Lipids	CFA	**Special Information: Do not draw children under the age of 2. This test is not available for children under the age of 2. Pediatric samples for patients under 2 years old will be rejected.** Additionally, this test is not available for patients residing in New York state. **Patient preparation: Must be fasting** for 8–12 hours. **Serum is accepted with a disclaimer.** **Specimen Requirement: 3 mL** plasma from an EDTA lavender top tube; Minimum: **2.5 mL;** Patient **must** be fasting for 8–12 hours prior to collection; **NOTE: Do not draw children under the age of 2; Draw 2 tubes to ensure adequate specimen volume; Centrifuge, aliquot and freeze immediately;** Frozen *OR* **3 mL serum from a red top tube with no additive;** Minimum: **2.5 mL; Serum is accepted with a disclaimer;** Patient **must** be fasting for 8–12 hours prior to collection; **NOTE: Do not draw children under the age of 2; Draw 2 tubes to ensure adequate specimen volume; Centrifuge, aliquot and freeze immediately;** Frozen *OR* **3 mL serum from a serum separator (gold) tube;** Minimum: **2.5 mL; Serum is accepted with a disclaimer;** Patient **must** be fasting for 8–12 hours prior to collection; **NOTE: Do not draw children under the age of 2; Draw 2 tubes to ensure adequate specimen volume; Centrifuge, aliquot and freeze immediately;** Frozen **Stability:** Ambient: **Unacceptable** Refrigerated: **Unacceptable** Frozen: **6 weeks** **Reference Range:** a-Linolenic, C18:3w3 **2**–12 Years: **7–50 µmol/L** 13–99 Years: 13–80 µmol/L EPA, C20:5w3 **2**–12 Years: **5–63 µmol/L** 13–99 Years: 5–**210 µmol/L** DPA, C22:5w3 **2**–12 Years: **7–37 µmol/L** 13–99 Years: 11–50 µmol/L DHA, C22:6w3 **2**–12 Years: **22–172 µmol/L** 13–99 Years: 31–213 µmol/L Linoleic Ac, C18:2w6 **2**–12 Years: **523–1532 µmol/L** 13–99 Years: 821–2032 µmol/L g-Linolenic, C18:3w6 **2**–12 Years: 4–**25 µmol/L** 13–99 Years: 5–46 µmol/L Eicosadienoic, 20:2w6 **2**–12 Years: **4.3–12.2 µmol/L** 13–99 Years: 5.2–22.5 µmol/L Dihomogamma Linolenic, 20:3w6 **2**–12 Years: **20–114 µmol/L** 13–99 Years: 27–140 µmol/L Arachidonic, C20:4w6 **2**–12 Years: **130–434 µmol/L** 13–99 Years: 158–521 µmol/L Docosadienoic, 22:2w6 **2**–12 Years: ≤ **0.8 µmol/L** 13–99 Years: ≤ **2.0 µmol/L** DTA, C22:4w6 **2**–12 Years: **2.6–14.1 µmol/L** 13–99 Years: 2.6–18.1 µmol/L Mead Acid, C20:3w9 **2**–12 Years: ≤ **4.4 µmol/L** 13–99 Years: ≤ **8.3 µmol/L** Myristoleic, C14:1w5 **2**–12 Years: 0.8–**5.8 µmol/L** 13–99 Years: 0.8–9.7 µmol/L *(continued on page 9)*	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Fatty Acid Profile of Lipids *(continued from page 8)*		Palmitoleic, C16:1w7 **2**–12 Years: **21–120 µmol/L** 13–99 Years: 30–256 µmol/L Vaccenic Ac, C18:1w7 **2**–12 Years: **29–83 µmol/L** 13–99 Years: 40–122 µmol/L Oleic Acid, C18:1w9 **2**–12 Years: **476–1318 µmol/L** 13–99 Years: 466–1470 µmol/L 11 Eicosenoic, 20:1w9 **2**–12 Years: **3.8–11.3 µmol/L** 13–99 Years: 3.7–18.1 µmol/L Nervonic Ac, C24:1w9 **2**–12 Years: ≤ **2.0 µmol/L** 13–99 Years: 1.1–2.7 µmol/L Capric, C10:0 **2**–12 Years: **1.7–6.0 µmol/L** 13–99 Years: **0.8**–6.2 µmol/L Lauric Acid, C12:0 **2**–12 Years: **1.8–27.0 µmol/L** 13–99 Years: 2.2–27.3 µmol/L Myristic Acid, C14:0 **2**–12 Years: **11–92 µmol/L** 13–99 Years: 15–139 µmol/L Palmitic Acid, C16:0 **2**–12 Years: **576–1595 µmol/L** 13–99 Years: 667–2526 µmol/L Stearic Acid, C18:0 **2**–12 Years: **309–640 µmol/L** 13–99 Years: 250–629 µmol/L Arachidic Ac, C20:0 **2**–12 Years: **1.6–3.3 µmol/L** 13–99 Years: 1.3–4.7 µmol/L Behenic, C22:0 **2**–12 Years: **0.7–1.9 µmol/L** 13–99 Years: 0.6–2.9 µmol/L Lignoceric, C24:0 **2**–12 Years: **0.78–1.64 µmol/L** 13–99 Years: 0.63–2.45 µmol/L Hexacosanoic, C26:0 **2**–12 Years: ≤ **0.36 µmol/L** 13–99 Years: ≤ **0.43 µmol/L** Pentadecanoic, C15:0 **2**–12 Years: ≤ **13.5 µmol/L** 13–99 Years: ≤ **20.6 µmol/L** Heptadecanoic, C17:0 **2**–12 Years: ≤ **18.5 µmol/L** 13–99 Years: ≤ **24.4 µmol/L** Nonadecanoic, C19:0 **2**–12 Years: ≤ **1.66 µmol/L** 13–99 Years: ≤ **1.89 µmol/L** Heneicosanoic, C21:0 **2**–12 Years: ≤ **0.48 µmol/L** 13–99 Years: ≤ **0.74 µmol/L** Tricosanoic, C23:0 **2**–12 Years: ≤ **0.49 µmol/L** 13–99 Years: ≤ **0.78 µmol/L** Palmitelaidic, C16:1w7t **2**–12 Years: ≤ **0.4 µmol/L** 13–99 Years: ≤ **1.8 µmol/L** Total C18-trans **2**–12 Years: ≤ **29 µmol/L** 13–99 Years: ≤ **59 µmol/L** *(continued on page 10)*	

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Fatty Acid Profile of Lipids *(continued from page 9)*		LA/DGLA **2**–12 Years: **7–41** 13–99 Years: 11–46 EPA/DGLA **2**–12 Years: **0.11–0.94** 13–99 Years: 0.07–5.98 AA/EPA **2**–12 Years: **2–43** 13–99 Years: 1–57 Triene Tetraene Ratio **2**–12 Years: ≤ **0.018** 13–99 Years: ≤ **0.023** **Days Performed: Varies** **Reported: 16–24** days	
FISH for Cutaneous Melanoma	CMFISH	**CPT:** 88377 **x 2**	4/6/17
Fondaparinux Assay	FONDXA	**Specimen Requirement: 1 mL** plasma from a sodium citrate (light blue) tube; Minimum: **1 mL; 2 mL plasma is recommended if repeat testing is required; Centrifuge, aliquot and freeze ASAP** **Stability:** Ambient: **Centrifuge and separate the plasma; Plasma stable for 4 hours at room temperature** Refrigerated: **Unacceptable** Frozen: **Centrifuge, aliquot and freeze plasma; Plasma frozen at minus 20 °C stable for 1 month and frozen at minus 70 °C stable for up to 6 months**	Effective immediately
Fragile X Syndrome DNA Analysis by PCR, Blood	FRAX	**Note: Methylation analysis will no longer be performed.**	Effective immediately
Fungal Antibodies, ID	FUNID	**Stability:** Ambient: **24** hours Refrigerated: **7 days** Frozen: **14 days**	4/25/17
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. **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 to 8 °C for > 5 days.** **Clinical Information: There are reports in the peer reviewed literature of lowered assay specificity in patients with gram positive bacteremia. Patients with renal failure on hemodialysis utilizing cellulose membranes may have false positive results. Patients treated with fractionated blood products such as albumin and immunoglobulin and in specimens and subjects exposed to glucan-containing gauze. Patients require 3 to 4 days for the restoration of baseline levels of serum (1,3)- ß-D-glucan after surgical exposure to (1,3)- ß-D-glucan-containing sponges and gauze. Accordingly, the timing of sampling of surgical patients should take this into account. Samples obtained by heel or finger stick methods are unacceptable as the alcohol-soaked gauze used to prepare the site (and potentially, the skin surface-pooling of blood) has been shown to contaminate the specimens. A negative test result cannot rule out the diagnosis of invasive fungal disease. Patients at risk for invasive fungal disease should be tested twice per week. The performance of the Fungitell ß-D Glucan assay has not been evaluated with specimens from neonates and infants < 6 months of age. Patients whose GI tract is colonized with Candida and have mucositis may have a positive Fungitell ß-D Glucan assay result without invasive fungal disease.** *(continued on page 11)*	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Fungitell Assay for (1,3)-B-D-Glucan *(continued from page 10)*		The Fungitell ß-D Glucan assay is indicated for presumptive diagnosis of fungal **infection. It should be used in conjunction with other diagnostic procedures.** The Fungitell ß-D Glucan assay does not detect certain fungal species such as the genus Cryptococcus, which produces very low levels of (1,3)- ß-D-glucan. This assay also does not detect the Zygomycetes, such as Absidia, Mucor and Rhizopus, which are not known to produce (1,3)- ß-D-glucan. **Specimen Requirement: 2 mL** serum from a serum separator (gold) tube; Minimum: **0.5 mL for adults,** 0.2 mL **for infants/pediatric samples;** Collect 3–5 mL blood in a serum separator gel tube (SST); Centrifuge specimen within 2 hours; Ship serum gel tube frozen; NOTE: DO NOT ALIQUOT SPECIMEN; **Send specimen in original tube; Avoid exposure of specimen to atmosphere; Sample cannot be shared with multiple tests; Add on testing not acceptable;** Frozen	
Growth Hormone	GH	**Stability:** Ambient: **24** hours Refrigerated: 7 days Frozen: **14 days**	4/4/17
Growth Hormone Stimulation	GHSTM	**Stability:** Ambient: **24** hours Refrigerated: 7 days Frozen: **14 days**	4/4/17
Growth Hormone Suppression	GHSUP	**Stability:** Ambient: **Serum separator (gold) tube (SST) and Potassium oxalate/sodium fluoride (gray): 24 hours; Lithium heparin (light green) plasma separator tube (PST):** 8 hours Refrigerated: **SST (gold):** 7 days; **Potassium oxalate/sodium fluoride (gray): 24 hours; Lithium heparin (light green) PST: 3 days** Frozen: **SST (gold): 14 days; Potassium oxalate/sodium fluoride (gray) and Lithium heparin (light green) PST: Unacceptable**	4/4/17
Hemoglobin, Urine	UHGB	**Specimen Requirement:** 5 mL random urine in a clean container; Minimum: 3 mL; Refrigerated *OR* **7 mL random urine in a BD Urine Preservative tube (yellow);** Minimum: **7 mL; Ambient** **Stability:** Ambient: **Clean container:** 2 hours; **BD Urine Preservative tube: 72 hours** Refrigerated: 24 hours	Effective immediately
Histone IgG Antibody	HISTON	**Stability:** Ambient: **24** hours Refrigerated: 7 days Frozen: **14 days**	4/11/17
Ibuprofen	IBUPRO	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Ibuprofen **Time Since Dose** **Special Information: For timed specimens, the time since last dose should be selected from the available options (0 minutes, 60 minutes, 120 minutes, or 180 minutes). For untimed (random) samples, the "untimed sample" option should be selected.** Unacceptable conditions: Separator tubes. This test is New York DOH approved.	4/27/17
Insulin Like Growth Factor Bind, Prot 3	IGFBP3	**Note:** *This test was previously announced in the March 2017 Technical Update. Reference range, special information, days, and stability changes will go live on 4/26/17. We apologize for any inconvenience this may have caused.*	4/26/17
Kappa, Free, Serum	FKAPPS	**Stability:** Ambient: **24** hours Refrigerated: **21 days**	4/20/17
Kappa/Lambda, Free, Serum	KLFRS	**Stability:** Ambient: **24** hours Refrigerated: **21 days**	4/20/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Lambda, Free, Serum	FLAMBS	**Stability:** Ambient: **24** hours Refrigerated: **21 days**	4/20/17
Polio Neutralization	PNEUT	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Poliovirus Type 1 Poliovirus Type 3 **Special Information: Unacceptable conditions: Plasma. Contaminated, hemolyzed, or severely lipemic specimens. This test is New York DOH approved.** **Clinical Information: The presence of neutralizing antibodies against poliovirus implies immunity. The serum neutralization test is serotype specific.** Antibodies against one type does not indicate immunity against the other type. Results ≥ 1:10 titer indicates an antibody to Poliovirus is detected, which may represent prior immunization or current or past infection. **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.2 mL;** Separate from cells ASAP or within 2 hours of collection; Refrigerated *OR* 1 mL serum from a red top tube with no additive; Minimum: **0.2 mL;** Separate from cells ASAP or within 2 hours of collection; Refrigerated **Days Performed:** Monday–**Friday** **Reported:** 7–**12** days **CPT:** 86658 **x 2**	Effective immediately
Procalcitonin	PROCAL	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; **Aliquot specimen into CCL aliquot tube;** Frozen *OR* 1 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.5 mL; Refrigerated *OR* 1 mL serum from a red top tube with no additive; Minimum: 0.5 mL; Refrigerated *OR* 1 mL plasma from a lithium heparin green top tube; Minimum: 0.5 mL; Refrigerated *OR* **1 mL plasma from an EDTA lavender top tube;** Minimum: 0.5 mL; Refrigerated **Stability:** Ambient: **24** hours Refrigerated: **48 hours** Frozen: **3** months **Methodology: Electro Chemiluminescence Immunoassay (ECLIA)** **Reference Range: < 0.09 ng/mL**	5/30/17
Sedimentation Rate, Westergren	WSR	**Stability:** Ambient: **4 hours** Refrigerated: 24 hours	Effective immediately
Thyroglobulin	TG	**Stability:** Ambient: **24 hours** Refrigerated: **7** days Frozen: 2 months	4/18/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Toxoplasmosis, IgG Antibody	TOXG	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Toxoplasma IgG **Toxo IgG Qual** **Special Information: Grossly hemolyzed or lipemic samples as well as samples containing particulate matter or exhibiting obvious microbial contamination will be rejected. Bacterial contamination or heat inactivation of the specimen may affect the test result. The concentrations of anti-Toxoplasma gondii IgG in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity.** **Clinical Limitation: Do not rely on any single test result as the sole determinant in diagnosing recently acquired infection. If acute infection is suspected, a patient sample should be tested for the presence of Toxoplasma–specific IgG and IgM Antibodies.** **Clinical Information: The magnitude of the measured result is not indicative of the amount of antibody present. Equivocal results should have a new sample collected and tested no less than one or two weeks later.** **Stability:** Ambient: **24** hours Refrigerated: **7 days** Frozen: **14 days** **Methodology: Chemiluminescence Immunoassay (CLIA)** **Reference Range:** Toxoplasma IgG: **Refer to report** **Toxo IgG Qual: Negative** **Days Performed:** Monday, **Wednesday, Friday** **Reported:** 1–**4** days	5/31/17
Toxoplasmosis IgM	TOXMAB	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** **Toxo IgM Qual** Toxoplasmosis, IgM Antibody **Special Information: Grossly hemolyzed or lipemic samples as well as samples containing particulate matter or exhibiting obvious microbial contamination will be rejected. Bacterial contamination or heat inactivation of the specimen may affect the test results.** **Clinical Limitation: The assay is not, in and of itself, diagnostic and should be considered in conjunction with the patient's clinical presentation/history and other laboratory test results. Infections such as Epstein-Barr virus, Cytomegalovirus and different hepatitis viruses may cause symptoms similar to toxoplasmosis and must be excluded before confirmation of diagnosis. Samples collected early in the course of the infection may not have detectable levels of specific IgM. A nonreactive IgM result may be due to delayed seroconversion and does not rule out current infection. If clinical exposure to Toxoplasma gondii is suspected despite a negative finding, a second sample should be collected and tested. Specific IgM Antibodies are usually detected in patients with recent primary infection, but they may be found in patients with reactivated infections, and they are sometimes found in patients with no other detectable evidence of recent infection.** **Clinical Information: The magnitude of the measured result is not indicative of the amount of antibody present. Equivocal results should have a new sample collected and tested three weeks later.** **Specimen Requirement: 1 mL** serum from a serum separator (gold) tube; Minimum: 0.5 mL; Refrigerated **Stability:** Ambient: **24** hours Refrigerated: **7** days Frozen: **14 days** **Methodology: Chemiluminescence Immunoassay (CLIA)** **Reference Range:** **Toxo IgM Qual: Negative** Toxoplasmosis, IgM Antibody: **Refer to report** **Days Performed:** Monday, **Wednesday, Friday** **Reported:** 1–**4** days	5/31/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Toxoplasmosis IgM and IgG, Ab	TOXMG	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** **Toxo IgM Qual** Toxoplasmosis, IgM Antibody **Toxo IgG Qual** Toxoplasma IgG **Special Information: Grossly hemolyzed or lipemic samples as well as samples containing particulate matter or exhibiting obvious microbial contamination will be rejected.** **Clinical Limitation: The assay is not, in and of itself, diagnostic and should be considered in conjunction with the patient's clinical presentation/history and other laboratory test results. Infections such as Epstein-Barr virus, Cytomegalovirus and different hepatitis viruses may cause symptoms similar to toxoplasmosis and must be excluded before confirmation of diagnosis. Samples collected early in the course of the infection may not have detectable levels of specific IgM. A nonreactive IgM result may be due to delayed seroconversion and does not rule out current infection. If clinical exposure to Toxoplasma gondii is suspected despite a negative finding, a second sample should be collected and tested. Specific IgM Antibodies are usually detected in patients with recent primary infection, but they may be found in patients with reactivated infections, and they are sometimes found in patients with no other detectable evidence of recent infection.** **Clinical Information: The magnitude of the measured result is not indicative of the amount of antibody present.** Equivocal results should have a new sample **collected and tested three weeks later.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.5 mL;** Refrigerated **Stability:** Ambient: 24 hours Refrigerated: **7 days** Frozen: 14 days **Methodology: Chemiluminescence Immunoassay (CLIA)** **Reference Range:** **Toxo IgM Qual: Negative** Toxoplasmosis, IgM Antibody: **Refer to report** **Toxo IgG Qual: Negative** Toxoplasma IgG: **Refer to report** **Days Performed:** Monday, **Wednesday, Friday** **Reported:** 1–**4** days	5/31/17
Transglutaminase IgA Abs	TGIGA	**Stability:** Ambient: **24** hours Refrigerated: 7 days Frozen: **14 days**	4/11/17
Transglutaminase IgG Abs	TGIGG	**Stability:** Ambient: **24** hours Refrigerated: 7 days Frozen: **14 days**	4/11/17
Transglutaminase IgG and IgA	TGLGMA	**Stability:** Ambient: **24** hours Refrigerated: 7 days Frozen: **14 days**	4/11/17
Trofile Co-receptor Tropism Assay	TROFLE	**Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: **14 days** **CPT: 87999 x 1**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Urinalysis Only	UA	**Specimen Requirement:** 10 mL random urine in a clean container; Minimum: 5 mL; Refrigerated *OR* **7 mL random urine in a BD Urine Preservative tube (yellow);** Minimum: **7 mL; Ambient** **Stability:** Ambient: **Clean container:** 2 hours; **BD Urine Preservative tube: 72 hours** Refrigerated: 24 hours	4/4/17
Vitamin B1, Plasma	PVITB1	**Special Information:** Do not use **for evaluation of** thiamine deficiency. **Separate specimens must be submitted when multiple tests are ordered. Unacceptable conditions: Hemolyzed specimens or specimens other than heparin or EDTA plasma. This test is New York DOH approved.** **Clinical Information:** Thiamine (vitamin B1) is reported. However, thiamine diphosphate (TDP), the biologically active form of thiamine, is not found in measurable concentration in plasma, and is best determined in whole blood specimens. Plasma thiamine concentration reflects recent intake rather than body stores. Whole blood is the preferred specimen for thiamine assessment. Approximately 80% of thiamine present in whole blood is found in red blood cells. **Specimen Requirement: 1 mL** plasma from a sodium or lithium heparin green top tube; Minimum: 0.2 mL; **Separate plasma from cells** within 1 hour of collection; **Transfer 1 mL plasma to an ARUP Standard Transport Tube; Separate specimens must be submitted when multiple tests are ordered;** Frozen *OR* **1 mL** plasma from an EDTA lavender top tube; Minimum: 0.2 mL; **Separate plasma from cells** within 1 hour of collection; **Transfer 1 mL plasma to an ARUP Standard Transport Tube; Separate specimens must be submitted when multiple tests are ordered;** Frozen **Days Performed:** Sunday–Saturday **Reported:** 3–**5** days	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
FISH for 7q deletion	FISH7Q	**Note:** *This test was previously announced in the March 2017 Technical Update.* **Price:** $725.00 (non-discountable)	4/11/17
FISH for 20q and CEP8	20Q8FH	**Note:** *This test was previously announced in the March 2017 Technical Update.* **Price:** $745.00 (non-discountable)	4/11/17
FISH for IGH/MYC Fixed Pellet	814FSH	**Specimen Requirement:** 2–3 mL bone marrow in a sodium heparin green top tube; If aliquoting is necessary, sterile aliquot tubes must be used; Ambient *OR* 2–3 mL bone marrow in an EDTA lavender top tube; If aliquoting is necessary, sterile aliquot tubes must be used; Ambient *OR* 5–7 mL blood in a sodium heparin green top tube; If aliquoting is necessary, sterile aliquot tubes must be used; Ambient *OR* 5–7 mL blood in an EDTA lavender top tube; If aliquoting is necessary, sterile aliquot tubes must be used; Ambient **Stability:** Ambient: 48 hours Refrigerated: Not preferred Frozen: Unacceptable **Methodology:** Fluorescent In-Situ Hybridization (FISH) **Days Performed:** 3 days per week **CPT:** 88271 x 2, 88275 x 1, 88291 x 1 **Price:** $765.00 (non-discountable)	5/11/17
Hydroxylase Gene(CYP21A2), Full Gene Analysis, Blood	21GENA	**Special Information:** A patient information form is required for all patients and a signed informed consent form for NY residents only are required. These forms can be obtained by contacting Client Services at 800-628-6816 or 216-444-5755. It can also be found at: http://www.mayomedicallaboratories.com/it-mmfiles/InformedConsent.pdf. Whole blood specimens received frozen will be rejected. **Clinical Information:** Because of the complexity of the genetic structure of the CYP21A2 locus, and the possibility that a patient's congenital adrenal hyperplasia (CAH) may be due to other gene defects, genetic testing results should be correlated carefully with clinical and biochemical data. This testing strategy is superior to approaches previously used, but may still miss some complex and large-scale genetic rearrangements or deletions, as well as genetic changes in far upstream or downstream gene-regulatory elements that impair CYP21A2 gene expression. This can lead to false negative test results. Rare polymorphism in primer binding sites can lead to selective allelic drop-out, which can lead to false negative or false positive diagnosis. Patients without genetic evidence of disease causing CYP21A2 genetic changes may still suffer from CAH, but due to a different enzyme defect. Additional and expanded biochemical steroid profiling is, therefore, recommended if the clinical picture is strongly suggestive of CAH. **Specimen Requirement:** 3 mL whole blood in an EDTA lavender top tube; Minimum: 1 mL; Invert several times to mix blood; Send specimen in original tube; Collect only on Monday, Tuesday or Wednesday and deliver to Cleveland Clinic Laboratories by 12:00 noon EST on Wednesday; Specimen preferred to arrive at performing lab within 96 hours of collection; A signed "Informed Consent for Genetic Testing" form for New York state residents and a completed "CYP21A2 Gene Testing Patient Information" form are required; These forms are available through Client Services at 800.628.6816 or 216.444.5755; Ambient **Stability:** Ambient: Preferred receipt within 96 hours Refrigerated: Preferred receipt within 96 hours Frozen: Do not send frozen whole blood specimens **Methodology:** DNA Sequencing Multiplex-Ligation Probe Amplification (MLPA) Polymerase Chain Reaction (PCR) **Reference Range:** Refer to report **Days Performed:** Varies **Reported:** 15–23 days **CPT:** 81402 x 1, 81405 x 1 **Price:** $1400.00 (non-discountable)	4/10/17

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Immature Platelet Fraction	IPFR	**Specimen Requirement:** 2 mL whole blood in an EDTA lavender top tube; Refrigerated **Stability:** Ambient: 24 hours Refrigerated: 48 hours **Methodology:** Automated Cell Counter Fluorescent Flow Cytometry **Reference Range:** Male 0–179 Days: 2.0–6.8% 6–23 Months: 1.4–3.8% 2–5 Years: 1.1–3.6% 6–11 Years: 1.0–4.9% 12–14 Years: 1.6–6.1% 15–99 Years: 0.9–7.2% Female 0–179 Days: 1.3–6.8% 6–23 Months: 1.4–4.5% 2–5 Years: 1.0–3.6% 6–11 Years: 1.0–4.7% 12–14 Years: 1.4–6.4% 15–99 Years: 0.9–7.2% **Days Performed:** Sunday–Saturday **Reported:** 8 hours **CPT:** 85055 x 1 **Price:** $38.00	4/3/17
Mycoplasma hominis, Molecular Detection, PCR, Blood	MYPCRB	**Clinical Information:** Useful for rapid, sensitive, and specific identification of Mycoplasma hominis from whole blood. This test does not detect other mycoplasmas or ureaplasmas (including Mycoplasma pneumoniae, a common cause of community acquired pneumonia). **Specimen Requirement:** 1 mL whole blood in an EDTA lavender top tube; Minimum: 0.5 mL; Send specimen in original tube; Refrigerated *OR* 1 mL whole blood in an EDTA royal blue top tube; Minimum: 0.5 mL; Send specimen in original tube; Refrigerated **Stability:** Ambient: Unacceptable Refrigerated: 7 days Frozen: 7 days **Methodology:** Fluorescence Resonance Energy Transfer (FRET) Real-Time Polymerase Chain Reaction (RT-PCR) **Days Performed:** Monday–Friday **Reported:** 4–7 days **CPT:** 87798 x 1 **Price:** $432.00 (non-discountable)	4/3/17
Mycoplasma hominis, Molecular Detection, PCR, Plasma	MYPCRP	**Clinical Information:** Useful for rapid, sensitive, and specific identification of Mycoplasma hominis from plasma. This test does not detect other mycoplasmas or ureaplasmas (including Mycoplasma pneumoniae, a common cause of community acquired pneumonia). **Specimen Requirement:** 1 mL plasma from an EDTA lavender top tube; Minimum: 0.5 mL; Spin down promptly and transfer to sterile screw-capped vial; Refrigerated *OR* 1 mL plasma from an EDTA royal blue top tube; Minimum: 0.5 mL; Spin down promptly and transfer to sterile screw-capped vial; Refrigerated *(continued on page 18)*	4/3/17

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Mycoplasma hominis, Molecular Detection, PCR, Plasma *(continued from page 17)*		**Stability:** Ambient: Unacceptable Refrigerated: 7 days Frozen: 7 days **Methodology:** Fluorescence Resonance Energy Transfer (FRET) Real-Time Polymerase Chain Reaction (RT-PCR) **Days Performed:** Monday–Friday **Reported:** 4–7 days **CPT:** 87798 x 1 **Price:** $432.00 (non-discountable)	

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
FISH for Cutaneous Melanoma	CMFISH	$1410.00 (non-discountable)	88377 x 2	4/6/17

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Polio Neutralization	PNEUT	$91.00 (non-discountable)	86658 x 2	Effective immediately
Procalcitonin	PROCAL	$148.00	84145	5/30/17

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
BRAF V600E Sequencing	BRAF	This test will no longer be available. Suggest ordering BRAF Gene Analysis.	6/1/17
Gene Analysis 21 Hydroxylase	21GENE	This test will no longer be available. Suggest ordering Hydroxylase Gene(CYP21A2), Full Gene Analysis, Blood (21GENA).	4/10/17
Hemoglobin A2 and F	A2F	This test will no longer be available.	6/5/17
H pylori Ab IgM	HPYLM	This test will no longer be available. Suggest ordering Helicobacter pylori Breath Test, Adult (HPYLBR), Helicobacter pylori Breath Test, Pediatric (HPYBRP), Helicobacter pylori Antigen by EIA, Stool (HPYLAG), Helicobacter pylori Ab, IgG (HPYLRI) or Helicobacter pylori Ab, IgA (HPYLRA).	4/11/17
Megaloblastic Anemia Panel	ANEMIA	This test will no longer be available. Other testing options include Vitamin B12 (B12), Methylmalonic Acid Blood (MMA), Intrinsic Factor Blocking Antibody (INTFCT), or Gastrin (GAST).	Effective immediately
MLH1 Hypermethylation and BRAF Mutation Analysis	MLBRF	This test will no longer be available. Suggest ordering BRAF Gene Analysis and MLH1 Promoter Hypermethylation.	6/1/17
Serum Bactericidal Titer	SBACT	This test will no longer be available.	Effective immediately