Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • March 2021

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
2	ACTH Stimulation, 2 Time Points						■			■				
2	ACTH Stimulation, 3 Time Points									■				
3	Acylcarnitine C4, Ur					■	■		■			■		
3	Adenovirus PCR					■	■							
3, 11	Anti IgE												■	■
3	Bartonella PCR					■	■							
4	Bioavailable Testosterone/SHBG, Female & Child					■	■							
9	Carrier Testing Panel			■										
4	Chlamydia pneumoniae PCR					■								
4	CMV by PCR, non-blood specimens					■	■							
4	Cortisol									■				
4	C-Reactive Protein											■		
4	CSF Staff Review												■	
4	Cyanide, Blood					■	■					■		
11	Delta-Amino Levulinic Acid				■									
5, 11	Euglobulin Lysis Time					■	■			■	■	■		■
5	Hepatitis Acute Panel					■								
5	Herpesvirus 7 IgG and IgM Antibodies					■				■		■		
6	HIV Phenotype					■	■		■		■	■	■	
6	HSV PCR, Miscellaneous Specimen Types					■	■							
6	HTLV I/II DNA PCR					■								
11	Ketamine Confirmation, Urine				■									

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
6	Lyme Disease by PCR						■	■				■		
7	Phosphatidylserine IgG, IgM, & IgA Autoabs						■	■			■	■		
11	Purine Profile, Urinary				■									
9–10	Respiratory Panel and SARS-CoV-2 by Rapid PCR			■										
11	Respiratory Panel by Rapid PCR				■									
7	Rheumatoid Factor IgM Autoantibodies					■	■		■		■	■		
11	Silicon				■									
7	Somatostatin					■	■		■		■	■		
10	T-Cell Clonality Using Biomed-2 PCR Primers Bone Marrow			■										
7–8	Tetanus Toxoid IgG					■	■		■			■		
8	Toxoplasma PCR					■	■							
8	Tropheryma whipplei PCR					■	■							
8	Varicella Zoster by PCR					■	■							
11	Zinc, Urine 24 Hour				■									
10–11	Zinc, Urine Quantitative			■										
11	Zinc, Urine Random				■									

Test Changes

Test Name	Order Code	Change	Effective Date
ACTH Stimulation, 2 Time Points	ACTHS2	**Specimen Requirement:** 1 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.3 mL; Collect a baseline specimen, then collect a specimen **60 minutes** after intravenous/intramuscular administration of cortrosyn (cosyntropin); Refrigerated *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Collect a baseline specimen, then collect a specimen **60 minutes** after intravenous/intramuscular administration of cortrosyn (cosyntropin); Refrigerated *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.3 mL; Collect a baseline specimen, then collect a specimen **60 minutes** after intravenous/intramuscular administration of cortrosyn (cosyntropin); Centrifuge, aliquot and refrigerate; Refrigerated **Reference Range:** Cortisol, Basal Morning hours 6:00 to 10:00 am: 4.8–19.5 µg/dL Afternoon hours 4:00 to 8:00 pm: 2.5–11.9 µg/dL Interpretation: After cortrosyn stimulation, a peak cortisol response greater than 12.6 µg/dL may indicate appropriate cortisol secretion. This result should be interpreted within the clinical context and other test results. G.A. Kline, et al. Clinical Implications for Biochemical Diagnostic Thresholds of Adrenal Sufficiency Using a Highly Specific Cortisol Immunoassay. 2017 Clin. Biochem. 50:475-480	4/6/21
ACTH Stimulation, 3 Time Points	ACTHST	**Reference Range:** Cortisol, Basal Morning hours 6:00 to 10:00 am: 4.8–19.5 µg/dL Afternoon hours 4:00 to 8:00 pm: 2.5–11.9 µg/dL	4/6/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Acylcarnitine C4, Ur	UC4	**Note:** *Butyrylcarnitine, IBDH (Isobutyryl-CoA Dehydrogenase) Deficiency, Isobutyryl, Isobutyrylcarnitine, Isobutyryl-CoA Dehydrogenase (IBDH) Deficiency, and Short Chain Acyl-CoA Dehydrogenase (SCAD) Deficiency will be added as alias names.* **Special Information: If clinically feasible, discontinue L-carnitine supplementation at least 72 hours before specimen collection. This test is New York DOH approved.** **Clinical Information: Almost all patients with isobutyryl-CoA dehydrogenase deficiency excrete an abnormal amount of C4 in their urine. Some, but not all, affected individuals also excrete elevated levels of isobutyrylglycine. Conversely, patients with short-chain acyl-CoA dehydrogenase deficiency can have a normal excretion of C4.** **Specimen Requirement:** 5 mL random urine in a clean container; Minimum: 1 mL; Refrigerate ASAP; **Collect urine in clean plastic container;** Please include family history, clinical condition, diet and drug therapy, if any; Freeze immediately; Frozen **Stability:** Ambient: Unacceptable Refrigerated: **24 hours** Frozen: 1 week **Methodology:** Flow Injection Analysis-Tandem Mass Spectrometry **(FIA-**MS/MS)	4/13/21
Adenovirus PCR	ADEPCR	**Special Information:** Specimen source required. Heparinized specimens **and tissues in optimal cutting temperature compound** are unacceptable. This test is New York DOH approved. **Specimen Requirement:** 1 mL whole blood from an EDTA (lavender) tube; Minimum: 0.5 mL; Transfer 1 mL whole blood to sterile aliquot tube; Do not freeze (Preferred transport temperature is refrigerated unless transport will be delayed outside of stated stability); Refrigerated *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Centrifuge, transfer 1 mL plasma to sterile aliquot tube and freeze; Frozen *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Centrifuge, transfer 1 mL serum to sterile aliquot tube and freeze; Frozen *OR* 1 mL sputum in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen *OR* Tissue in a sterile container; Transfer tissue to sterile container and freeze immediately; Specimen source required; **Do not send tissues in optimal cutting temperature compound;** Frozen *OR* 1 mL bronchoalveolar lavage (BAL) specimen in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen *OR* 1 mL nasopharyngeal swab in viral transport media (VTM); Minimum: 0.5 mL; Specimen source required; Frozen *OR* 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen	Effective immediately
Anti IgE	ANTIGE	**CPT: 83516 x 1**	3/11/21
Bartonella PCR	BARPCR	**Special Information:** Specimen source is required. **Tissues in optimal cutting temperature compound are unacceptable.** This test is New York DOH approved. **Specimen Requirement:** 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Separate plasma from cells and transfer to sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Separate serum from cells and transfer to sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL whole blood from an EDTA (lavender) tube; Minimum: 0.5 mL; Transfer 1 mL whole blood to a sterile aliquot tube; Specimen source required; Refrigerated *OR* 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Transfer 1 mL CSF to sterile aliquot tube; Specimen source required; Frozen *OR* Tissue in a sterile container; Transfer tissue to a sterile container and freeze immediately; Specimen source required; **Do not send tissues in optimal cutting temperature compound**; Frozen	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Bioavailable Testosterone/SHBG, Female & Child	BTSTFC	**Special Information: Collection between 6–10 a.m. is preferred but not required.** This test is suggested for women and children due to an improved sensitivity of testosterone by LC-MS/MS. EDTA plasma is unacceptable. This test is New York DOH approved. **Clinical Information:** The concentrations of free and bioavailable testosterone are derived from mathematical expressions based on constants for the binding of testosterone to albumin and/or sex hormone binding globulin. **6–10 a.m. collection is preferable since the reference ranges are determined based on collections during that time. Results for patients collected outside 6–10 a.m. will be reported but must be interpreted in the context of the alternate collection time. Samples collected after 10 a.m. could have falsely low testosterone, and results should be interpreted carefully.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.8 mL; Collection between 6–10 a.m. **preferred but not required;** Separate serum from cells ASAP or within 2 hours of collection; **See Clinical Information for additional details;** Refrigerated *OR* 1 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 0.8 mL; Collection between 6–10 a.m. **preferred but not required;** Separate plasma from cells ASAP or within 2 hours of collection; **See Clinical Information for additional details;** Refrigerated	Effective immediately
Chlamydia pneumoniae PCR	CHLPCR	**Special Information: This test is New York DOH approved.**	Effective immediately
CMV by PCR, non-blood specimens	CMVCSF	**Special Information:** Specimen source is required. Heparinized specimens **and tissues in optimal cutting temperature compound** are unacceptable. This test is New York DOH approved. **Specimen Requirement:** 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Frozen *OR* 1 mL ocular fluid in a sterile container; Minimum: 0.5 mL; Frozen *OR* Tissue in a sterile container; **Transfer tissue to sterile container and freeze immediately; Specimen source required; Do not send tissues in optimal cutting temperature compound;** Frozen *OR* 1 mL bronchoalveolar lavage (BAL) in a sterile container; Minimum: 0.5 mL; Frozen *OR* 1 mL random urine in a sterile container; Minimum: 0.5 mL; Frozen *OR* 1 mL bone marrow in an EDTA (lavender) tube; Minimum: 0.5 mL; Send specimen in EDTA (lavender) tube or sterile container; Refrigerated *OR* 1 mL amniotic fluid in a sterile container; Minimum: 0.5 mL; Frozen	Effective immediately
Cortisol	COR	**Reference Range:** Morning hours 6:00 to 10:00 am: 4.8–19.5 µg/dL Afternoon hours 4:00 to 8:00 pm: 2.5–11.9 µg/dL	4/6/21
C-Reactive Protein	CRP	**Stability:** Ambient: **2 weeks** Refrigerated: **3 weeks** Frozen: **12 months**	Effective immediately
CSF Staff Review	CCCSFR	**CPT: 88108-26 x 1, 89051 x 1**	4/21/21
Cyanide, Blood	CYANID	**Special Information: Separate specimens must be submitted when multiple tests are ordered.** This test is New York DOH approved. **Specimen Requirement:** 1 mL whole blood in a potassium oxalate/sodium fluoride (gray) tube; Minimum: 0.4 mL; Separate specimens must be submitted when multiple tests are ordered; **Refrigerated** **Stability:** Ambient: Undetermined Refrigerated: **1 week** Frozen: 3 months	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Euglobulin Lysis Time	EUGLOB	**Special Information: Do not draw from an arm with a heparin lock or heparinized catheter. Citrated plasma samples should be collected by double centrifugation. Blood should be collected in a blue-top tube containing 3.2% buffered sodium citrate. Evacuated collection tubes must be filled to completion to ensure a proper blood to anticoagulant ratio. The sample should be mixed immediately by gentle inversion at least six times to ensure adequate mixing of the anticoagulant with the blood. A discard tube is not required prior to collection of coagulation samples, except when using a winged blood collection device (i.e., 'butterfly'), in which case a discard tube should be used. When noncitrate tubes are collected for other tests, collect sterile and nonadditive (red-top) tubes prior to citrate (blue-top) tubes. Any tube containing an alternate anticoagulant should be collected after the blue-top tube. Gel-barrier tubes and serum tubes with clot initiators should also be collected after the citrate tubes. Centrifuge for 10 minutes and carefully remove 2/3 of the plasma using a plastic transfer pipette, being careful not to disturb the cells. Deliver to a plastic transport tube, cap, and recentrifuge for 10 minutes. Use a second plastic pipette to remove the plasma, staying clear of the platelets at the bottom of the tube and deliver to a plastic transport tube with screw cap. Freeze immediately and maintain frozen until tested. Specimens that are hemolyzed, clotted, diluted with IV fluids or have thawed before arriving in the performing laboratory will be rejected.** **Clinical Information: Increased fibrinolytic activity is suggested by fibrin clot lysis that occurs in less than 3 hours. A shortened Euglobulin Lysis Time (ELT) result implies excessive fibrinolytic activity that may be secondary to pregnancy, obstetric complications (hydatidiform mole, amniotic fluid embolus), hypofibrinogenemia, malignancy, severe liver disease or thrombolytic therapy. Excessive fibrinolysis may also occur with dysfibrinogenemia, factor XIII deficiency, decreased PAI-1 levels or decreased alpha -2- antiplasmin activity. Clinical bleeding is a possible result of excessive fibrinolysis.** **Specimen Requirement:** 2 mL plasma from a 3.2% sodium citrate (light blue) tube; Minimum: **1 mL; Centrifuge, aliquot and freeze ASAP; Critical frozen** **Stability:** Ambient: **Unacceptable** Refrigerated: Unacceptable Frozen: **30 days** **Reference Range: Normal, 3 hours or longer** **Days Performed: Thursday** **Reported: 5–9** days	Effective immediately
Hepatitis Acute Panel	HACUTP	**Special Information:** If the Hepatitis C Antibody (IA) is positive, **Hepatitis C Virus (HCV) RNA** test is suggested. Hepatitis B Surface Antigen Confirmation will be performed and billed on all initially reactive Hepatitis B Surface Antigen tests. **Clinical Limitation: Methodology not approved for donor testing.** **Clinical Information:** Sero-diagnosis of acute **viral** hepatitis **due to Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), or Hepatitis C Virus (HCV). HCV antibodies appear 4–6 weeks after infection using this third generation antibody assay. Should very recent HCV infection be suspected, HCV RNA testing may be attempted.**	Effective immediately
Herpesvirus 7 IgG and IgM Antibodies	HHV7	**Special Information: Grossly hemolyzed, lipemic, or icteric samples will be rejected.** **Note:** *Clinical information will be removed.* **Stability:** Ambient: 1 week Refrigerated: 2 weeks Frozen: **30 days** **Reference Range:** Herpesvirus 7 IgG Abs: **Refer to report** Herpesvirus 7 IgM Abs: **Refer to report**	4/22/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
HIV Phenotype	HIVPHE	**Note:** *HIV Phenotypic Resistance Testing will be added as an alias name.* **Special Information: Assay is intended for use ONLY for patients with viral loads greater than or equal to 500 copies/mL.** **Clinical Information: Direct quantitative measurement** of **how well a patient's virus responds to antiretrovirals. Report includes drug resistance information for all approved nucleoside reverse transcriptase inhibitors (NRTIs), nonnucleoside reverse transcriptase inhibitors (NNRTIs), and protease inhibitors (PIs), as well as a measure of replication capacity which can provide treatment insight.** **Specimen Requirement:** 3 mL plasma from an EDTA (white) plasma preparation tube (PPT); Minimum: 1 mL; **Collect two EDTA PPT white tubes** and centrifuge within **6 hours** of collection; **Transfer plasma to one or more screw-cap tubes and** freeze immediately; Frozen *OR* 3 mL plasma from an EDTA (lavender) tube; Minimum: 1 mL; **Collect two EDTA (lavender) tubes and centrifuge within 6 hours of collection;** Transfer plasma to **one or more** screw-cap tubes **and freeze immediately;** Clearly indicate 'EDTA Plasma' on the specimen label; Frozen **Stabilty:** Ambient: **6 hours** Refrigerated: 24 hours Frozen: 2 weeks **(Avoid freeze/thaw cycles)** **Methodology:** **Reverse Transcription/Polymerase Chain Reaction (RT/PCR)** Transfection, Luciferase Activity **Days Performed:** Sunday–Saturday **Reported: 23–30** days **CPT:** 87903 x 1, 87904 **x 11**	4/27/21
HSV PCR, Miscellaneous Specimen Types	PCRHSV	**Special Information: Specimen source is required. Heparinized specimens and tissues in optimal cutting temperature compound are unacceptable. This test is New York DOH approved.** **Specimen Requirement:** 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Separate plasma from cells and transfer into sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Separate serum from cells and transfer into sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL amniotic fluid in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen *OR* 1 mL bronchoalveolar lavage (BAL) in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen *OR* Tissue in a sterile container; Freeze immediately; Specimen source required; **Do not send tissues in optimal cutting temperature compound;** Frozen *OR* 1 mL ocular fluid in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen	Effective immediately
HTLV I/II DNA PCR	HTLV12	**Special Information: Hemolyzed specimens will be rejected.**	4/27/21
Lyme Disease by PCR	LYPCR	**Special Information:** Specimen source is required. Heparinized specimens **and tissues in optimal cutting temperature compound are unacceptable.** This test is New York DOH approved. **Specimen Requirement:** 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Centrifuge, transfer plasma to a sterile container and freeze; Frozen *OR* 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Frozen *OR* 1 mL synovial fluid in a sterile container; Minimum: 0.5 mL; Frozen *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Centrifuge, transfer serum to a sterile container and freeze; Frozen *OR* Tissue in a sterile container; Transfer tissue to sterile container and freeze immediately; Specimen source required; **Do not send tissues in optimal cutting temperature compound**; Frozen **Stability:** Ambient: 8 hours **(serum, plasma, CSF); Unacceptable (tissue)** Refrigerated: 3 days **(serum, plasma, CSF); Unacceptable (tissue)** Frozen: 1 year	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Phosphatidylserine IgG, IgM, & IgA Autoabs	PHOGMA	**Special Information: Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens will be rejected. This test is New York DOH approved.** **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tub**e;** Minimum: **0.25 mL;** Refrigerated *OR* 0.5 mL serum from a plain no additive (red) tube; Minimum: **0.25 mL;** Refrigerated **Stability:** Ambient: After separation from cells: **48 hours** Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 month (Avoid repeated freeze/thaw cycles) **Reference Range:** Phosphatidylserine IgG: **< 16 GPS (IgG antiphosphatidylserine units)** Phosphatidylserine IgM: **< 22 MPS (IgM antiphosphatidylserine units)** Phosphatidylserine IgA: **< 20 APS (IgA antiphosphatidylserine units)**	Effective immediately
Rheumatoid Factor IgM Autoantibodies	RFMAB	**Clinical Information: Elevated Rheumatoid Factor is found in collagen vascular diseases such as systemic lupus erythematosus (SLE), rheumatoid arthritis, scleroderma, Sjogren's syndrome, and in other conditions such as leprosy, tuberculosis, syphilis, malignancy, thyroid disease and in a significant percentage of otherwise normal elderly patients.** **Specimen Requirement:** 1 mL **serum** from a serum separator (gold) tube; Minimum: 0.5 mL; **Ambient** *OR* 1 mL **serum from a plain no additive (red)** tube; Minimum: 0.5 mL**; Ambient** **Stability:** Ambient: **5** days Refrigerated: **7 days** Frozen: **90 days** **Methodology: Immunoturbidimetric Assay** **Days Performed: Tuesday**–Saturday **Reported:** 2–4 days	4/22/21
Somatostatin	SOMATO	**Special Information:** CRITICAL FROZEN. Additional specimens must be submitted when multiple tests are ordered. **Specimens that are grossly hemolyzed, icteric, lipemic or thawed will be rejected.** **Clinical Information:** Useful in diagnosis of somatostatin-producing tumors. **Elevated levels of somatostatin are observed with somatostatinoma, medullary thyroid carcinoma and pheochromocytoma.** **Specimen Requirement:** 2 mL plasma from an EDTA (lavender) tube; Minimum: 0.6 mL; Draw in **two** pre-chilled EDTA lavender top tubes; **Immediately** separate plasma from cells, **transfer into standard aliquot tube** and freeze; **Additional specimens must be submitted when multiple tests are ordered; Critical Frozen** **Stability:** Ambient: 8 hours Refrigerated: 8 hours Frozen: 28 days **(Do not thaw)** **Methodology:** Extraction (EXT) **Immunoassay (IA)** **Days Performed: Tuesday** **Reported: 8–9** days	4/29/21
Tetanus Toxoid IgG	TETAN	**Note:** *Anti-tetanus toxoid IgG, C. tetani, Clostridium tetani, Tetanus Immune Response, and Tetanus toxoid antibodies will be added as alias names.* **Special Information:** 'Pre' and 'post' vaccine specimens can be submitted **separately or** together for testing; if shipped separately, post specimen must be received within 60 days of pre specimen. Mark specimens plainly as 'pre-vaccine' or 'post-vaccine'. **This test is New York DOH approved.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.2 mL; Separate serum from cells ASAP or within 2 hours of collection; **'Pre' and 'post' vaccine specimens may be submitted separately or together, and post specimens must be received within 60 days from receipt of the pre specimens; Label specimens plainly as 'pre-vaccine' and 'post-vaccine;'** Refrigerated *(continued on page 8)*	4/20/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Tetanus Toxoid IgG *(continued from page 7)*		**Stability:** Ambient: After separation from cells: **48 hour**s Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year (**Avoid repeated freeze/thaw cycles** **Methodology: Quantitative Multiplex Bead Assay**	
Toxoplasma PCR	TXPCR	**Special Information: Heparinized specimens and tissues in optimal cutting temperature compound are unacceptable. This test is New York DOH approved.** **Specimen Requirement:** 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Frozen *OR 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Refrigerated *OR* 1 mL amniotic fluid in a sterile container; Minimum: 0.5 mL; Refrigerated *OR* 1 mL vitreous fluid in a sterile container; Minimum: 0.5 mL; Refrigerated *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Refrigerated *OR* 25 mg Tissue (frozen) in a sterile container; **Transfer tissue to sterile container and freeze immediately; Specimen source required; Do not send tissues in optimal cutting temperature compound;** Frozen	Effective immediately
Tropheryma whipplei PCR	WHIPWB	**Special Information:** Must indicate specimen source. Heparinized specimens **and tissues in optimal cutting temperature compound** are unacceptable. This test is New York DOH approved. **Specimen Requirement:** 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Transfer 1 mL plasma into sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Transfer 1 mL serum into sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL whole blood from an EDTA (lavender) tube; Minimum: 0.5 mL; Transfer 1 mL whole blood into sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen *OR* Tissue in a sterile container; **Transfer tissue to sterile container** and freeze immediately; Specimen source required; **Do not send tissues in optimal cutting temperature compound;** Frozen *OR* Formalin-fixed paraffin-embedded (FFPE) tissue in a sterile container; Specimen source required; Ambient	Effective immediately
Varicella Zoster by PCR	VZPCR	**Special Information:** Specimen source required. Heparinized specimens **and tissues in optimal cutting temperature compound** are unacceptable. This test is New York DOH approved. **Specimen Requirement:** 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Specimen source is required; Frozen *OR* 1 mL ocular fluid in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen *OR* 1 mL vesicle fluid swab in M4 or Universal Transport Media (UTM); Minimum: 0.5 mL; Specimen source is required; May also use viral transport media (VTM) (ARUP supply #12884); Frozen *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Specimen source is required; Frozen *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Specimen source is required; Frozen *OR* Tissue in a sterile container; **Transfer tissue to sterile container and freeze immediately;** Specimen source required; **Do not send tissues in optimal cutting temperature compound;** Frozen	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Carrier Testing Panel	CSPANL	**Special Information:** This test may not be appropriate as a stand-alone finding for diagnosis of suspected disease or for follow-up testing of the partners of known carriers. Genetic consultation may be of benefit in determining the appropriate testing strategy in these circumstances. Two of three EDTA tubes used for Hemoglobin Evaluation Cascade **Clinical Limitation:** The test does not include all known pathogenic variants and mechanisms of disease for the diseases tested. A negative result reduces but does not eliminate the risk of carrier status or disease. Residual risk of carrier status after a negative test varies with ethnicity, which influences both the carrier rate and the test's detection rate. **Clinical Information:** The test is intended for carrier screening in adults of reproductive age. Testing includes the most common pathogenic variants for cystic fibrosis, Bloom syndrome, Canavan disease, familial dysautonomia, familial hyperinsulinism, Fanconi anemia type C, Fragile X syndrome, Gaucher disease, glycogen storage disease type 1a, Joubert syndrome, maple syrup urine disease 1b, mucolipidosis IV, Niemann-Pick syndrome types A and B, spinal muscular atrophy, Usher syndrome type 1F and Usher syndrome type III. Thalassemias and hemoglobinopathies are also evaluated. **Specimen Requirement:** 12 mL whole blood in an EDTA (lavender) tube; Draw three 4 mL tubes; Blood specimens are transported and stored at room temperature no longer than 48 hours; Refrigerated **Stability:** Ambient: Blood may be transported ambient temperature within 48 hours Refrigerated: Blood may be transported ambient temperature within 48 hours; After 48 hours blood must be stored at 2–8 °C for up to 7 days Frozen: Frozen samples will be rejected **Methodology:** Capillary Electrophoresis (CE) Fragment Analysis by Capillary Electrophoresis Matrix-assisted Laser Desorption/ionization Time of Flight Mass Spectrometry (MALDI-TOF) Multiplex-Ligation Probe Amplification (MLPA) Polymerase Chain Reaction (PCR) Single Nucleotide Extension (SNE) **Days Performed:** 1 day per week **Reported:** 10 days **CPT:** 81200 x 1, 81205 x 1, 81209 x 1, 81220 x 1, 81242 x 1, 81243 x 1, 81250 x 1, 81251 x 1, 81255 x 1, 81260 x 1, 81290 x 1, 81329 x 1, 81330 x 1, 81400 x 2, 81401 x 1, 81479 x 1, 83020 x 1, 85041 x 1 **Price:** $1838.00	6/19/21
Respiratory Panel and SARS-CoV-2 by Rapid PCR	RPRACV	**Special Information:** Nasopharyngeal swabs only. Dry swabs (swabs not received in viral transport media) will be rejected. Sputum and bronchoalveolar (BAL) specimens should be sent for Respiratory Panel by PCR (RPPCR) testing. **Clinical Information:** This test is primarily to be used for patients who have met Cleveland Clinic criteria to rule-out the novel coronavirus (COVID-19) and are going to be admitted to a Cleveland Clinic Hospital. This test may also be used in situations wherein a rapid respiratory virus panel could improve access to beds. The test is very expensive. If rapid results are not required, the Respiratory Panel by PCR assay with next day results should be ordered. **Specimen Requirement:** One nasopharyngeal swab in Universal Transport Media (UTM), Viral Transport Media (VTM), or saline is accepted; Frozen **Stability:** Ambient: Stable for 4 hours at room temperature (15–25 °C) Refrigerated: Stable for up to 3 days refrigerated (2–8 °C) Frozen: Stable for up to 30 days (minus 15 °C to minus 70 °C) **Methodology:** Qualitative Polymerase Chain Reaction *(continued on page 10)*	Effective immediately

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Respiratory Panel and SARS-CoV-2 by Rapid PCR *(continued from page 9)*		**Reference Range:** Adenovirus: Negative Coronavirus 229E: Negative Coronavirus HKU1: Negative Coronavirus NL63: Negative Coronavirus OC43: Negative COVID 19 Result NP: Negative for COVID19 (SARS CoV2) by PCR H. Metapneumovirus: Negative Rhino/Enterovirus: Negative Influenza A Virus: Negative Influenza A H1 Virus: Negative Influenza A H3 Virus: Negative Influenza A H1N1 2009: Negative Influenza B Virus: Negative Parainfluenza 1: Negative Parainfluenza 2: Negative Parainfluenza 3: Negative Parainfluenza 4: Negative RSV PCR: Negative Bordetella parapertussis: Negative Bordetella Pertussis: Negative C. pneumoniae: Negative M. pneumoniae: Negative **Days Performed:** 7 days per week **Reported:** 4 hours	
T-Cell Clonality Using Biomed-2 PCR Primers Bone Marrow	TCBMDM	**Note:** *This test was previously announced in the January Technical Update.* **CPT:** 81340 x 1, 81342 x 1, G0452 x 1 **Price:** $1472.00	3/1/21
Zinc, Urine Quantitative	UZINCQ	**Special Information:** Collect in clean plastic container. Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). Collection from patients receiving iodinated or gadolinium-based contrast media must be avoided for a minimum of 72 hours post-exposure as high concentrations of iodine or gadolinium may interfere with elemental testing. Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post contrast media exposure. Acid preserved urine, urine collected within 72 hours after administration of iodinated or gadolinium-based contrast media, and urine contaminated with blood or fecal material will be rejected. This test is New York DOH approved. **Clinical Information:** Can indicate acute toxicity or deficiency. Zinc is predominantly eliminated in the feces. Elevated urine zinc may suggest excessive zinc supplementation but should be interpreted with a corresponding serum or plasma zinc concentration. **Specimen Requirement:** 8 mL 24-hour urine (well-mixed) in a plastic container; Minimum: 1 mL; Refrigerate during collection; Collect in clean plastic container and refrigerate during collection; Mix specimen well and transfer 8 mL to ARUP Trace Element-Free Transport Tube (ARUP supply #43116) labeled with total volume and collection time interval; Diet, medication, and nutritional supplements may introduce interfering substances; Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician); Collection from patients receiving iodinated or gadolinium-based contrast media must be avoided for a minimum of 72 hours post-exposure; Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post contrast media exposure; Refrigerated *(continued on page 11)*	4/15/21

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Zinc, Urine Quantitative *(continued from page 10)*		*OR* 8 mL random urine in a plastic container; Minimum: 1 mL; Collect in clean plastic container; Mix specimen well and transfer 8 mL to ARUP Trace Element-Free Transport Tube (ARUP supply #43116) labeled with total volume and collection time interval; Diet, medication, and nutritional supplements may introduce interfering substances; Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician); Collection from patients receiving iodinated or gadolinium-based contrast media must be avoided for a minimum of 72 hours post-exposure; Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post contrast media exposure; Refrigerated **Stability:** Ambient: 1 week Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Inductively Coupled Plasma / Mass Spectrometry (ICP-MS) **Days Performed:** Sunday–Saturday **Reported:** 2–6 days **CPT:** 84630 x 1 **Price:** $36.00 (non-discountable)	

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Anti IgE	ANTIGE	$129.00 (non-discountable)	83516	3/11/21
Euglobulin Lysis Time	EUGLOB	$88.00 (non-discountable)	85360	Effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Delta-Amino Levulinic Acid	UDALVA	This test will no longer be available. Suggest ordering alternative test Aminolevulinic Acid (ALA) Urine (UAMINO)	Effective immediately
Ketamine Confirmation, Urine	UKETA	This test will no longer be available.	4/8/21
Purine Profile, Urinary	UPURIN	This test will no longer be available.	4/8/21
Respiratory Panel by Rapid PCR	RPRAPD	This test will no longer be available. Suggest ordering Respiratory Panel and SARS-CoV-2 by Rapid PCR (RPRACV)	Effective immediately
Silicon	SILIC	This test will no longer be available.	Effective immediately
Zinc, Urine 24 Hour	UZINCD	This test will no longer be available. Suggest ordering Zinc, Urine Quantitative (UZINCQ)	4/15/21
Zinc, Urine Random	UZINCR	This test will no longer be available. Suggest ordering Zinc, Urine Quantitative (UZINCQ)	4/15/21