Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • December 2019

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	18 OH Corticosterone						■	■		■	■	■		
10	Acute Myeloid Leukemia (AML), MRD by FC			■										
3	Acylcarnitines, Plasma w/ Basic Consultation		■					■						
3	Acylcarnitines, Plasma w/ No Consultation		■											
3	AFB Culture & Stain						■					■		
10	Allergen, Brazil Nut Component IgE			■										
11	Alpha-Galactosidase (Leukocytes)			■										
12	Alpha Galactosidase, Leukocytes				■									
4	Aluminum						■	■						
4	Amino Acids, CSF w/ Basic Consultation		■					■						
4	Amino Acids, CSF w/ No Consultation		■											
4	Amino Acids, Plasma w/ Basic Consultation		■					■						
4	Amino Acids, Plasma w/ No Consultation		■											
4	Amino Acids, Urine w/ Basic Consultation		■					■						
4	Amino Acids, Urine w/ No Consultation		■											
4	Aminolevulinic Acid Dehydratase (ALAD), Whole Blood						■							
4	ANA Panel I						■					■		
5	C. difficile PCR with Reflex to EIA if Positive						■					■		
5	Celiac Gluten Free Panel						■							
5	Centromere Antibody						■					■		
5	Chromatin Antibody						■					■		
5	Chromium, Serum						■	■						

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	Cobalt, Serum or Plasma						■				■			
12	Duodenal Crystals					■								
6	ENA Antibody Panel											■		
6	Endomysial IgA Antibody											■		
6, 12	Flow Cytometric Immunophenotyping for Leukemia/Lymphoma						■						■	■
6	Hematologic Neoplasm Next Generation Sequencing Panel Marrow						■							
6	Hematologic Neoplasm Next Generation Sequencing Panel Peripheral Blood						■							
6	Jo 1 Antibody						■					■		
6	LSD, Urine						■	■			■	■		
6	Manganese, Serum						■	■				■		
7	Mitochondrial Antibody Panel											■		
7	Mitochondrial Antibody Screen											■		
12	Mitochondrial DNA/nuclear DNA ratio				■									
7	Myeloperoxidase Autoantibodies						■					■		
11	Next Generation Sequencing Hotspot PIK3CA Gene Analysis			■										
7	Nickel, Serum						■							
7	Organic Acids Ur, Quant w/ Basic Consultation		■						■					
7	Organic Acids Ur, Quant w/ No Consultation		■											
7	Pancreastatin						■	■		■	■	■	■	
7	Parietal Cell Antibody Panel											■		
7	Parietal Cell Antibody Screen											■		
8	Proteinase 3 Autoantibodies						■					■		
8	Ribosomal RNP Ab						■					■		
8	RNP Antibody						■					■		
8	Sarcoma Fusion NGS Panel						■						■	
8	Scleroderma IgG Ab						■					■		
8–9	Selenium, Plasma or Serum						■	■						
12	SHOX DNA Diagnostic				■									
9	Sjogren Antibodies											■		
9	Smith Abs, IgG						■					■		
9	Smooth Muscle Antibody Panel											■		
9	Smooth Muscle Antibody Screen											■		
9	SSA Antibody						■					■		
9	SS-B Antibody						■					■		
9	Titanium, Serum or Plasma							■			■			
12	Uveal Melanoma Prognostic				■									

Test Changes

Test Name	Order Code	Change	Effective Date
18 OH Corticosterone	18OHC	**Special Information: Separate specimens must be submitted when multiple tests are ordered.** **Specimen Requirement:** 3 mL serum from a serum separator (gold) tube; Minimum: **1 mL (Note: Submitting the minimum volume does not allow for repeat testing);** Centrifuge and **transfer serum into a standard plastic aliquot tube within 45 minutes** of collection; **Separate specimens must be submitted when multiple tests are ordered;** Frozen *OR* 3 mL **plasma from an EDTA (lavender) tube;** Minimum: **1 mL (Note: Submitting the minimum volume does not allow for repeat testing);** Centrifuge and **transfer plasma into a standard plastic aliquot tube within 45 minutes** of collection; **Separate specimens must be submitted when multiple tests are ordered;** Frozen *OR* 3 mL **plasma from a sodium or lithium heparin (green) tube;** Minimum: **1 mL (Note: Submitting the minimum volume does not allow for repeat testing);** Centrifuge and **transfer plasma into a standard plastic aliquot tube within 45 minutes** of collection; **Separate specimens must be submitted when multiple tests are ordered;** Frozen **Stability:** Ambient: 1 day Refrigerated: **1 day** Frozen: **90 days** **Methodology: High Performance** Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) **Reference Range:** Premature (26–28 Weeks): Day 4: 10–670 ng/dL Premature (31–35 Weeks): Day 4: 57–410 ng/dL **Full-Term** (31 Days–11 Months): 5–220 ng/dL 12–23 Months: 18–155 ng/dL **24 Months** to 9 Years: 6–85 ng/dL 10 to 14 Years: 10–72 ng/dL Adults: 9–58 ng/dL 8 a.m. Supine: 4–21 ng/dL 8 a.m. Upright: 5–46 ng/dL **Days Performed:** Monday **Reported: 8–13** days	2/4/20
Acylcarnitines, Plasma w/ Basic Consultation	ACYLBI	**For Interfaced Clients Only: Test build may need to be modified** **Test Name:** Previously Acylcarnitines, Plasma w/ Basic Interpretation	1/30/20
Acylcarnitines, Plasma w/ No Consultation	ACYLNI	**Test Name:** Previously Acylcarnitines, Plasma w/ No Interpretation	1/30/20
AFB Culture & Stain	AFC	**Clinical Information:** Culture is performed to identify an infection due to a mycobacterium. A single negative culture does not rule out the presence of a mycobacterial infection. Mycobacterial culture includes an acid fast stain and culture in liquid and on solid media. Stain results are reported within 24 hours of specimen receipt. Providers are notified of initial positive smear or culture results and any identification of M. tuberculosis. For AFB stain-positive sputum samples, polymerase chain reaction (PCR) for detection of M. tuberculosis and rifampin resistance (rpoB) will be performed automatically. Rifampin resistant and indeterminate results require confirmatory sequencing; additional charges may apply. PCR for M. tuberculosis vs. non-tuberculous mycobacteria may be performed if AFB stain is positive when indicated from bronchoalveolar lavage (BAL), fresh tissue and other sample types. Cultures for mycobacteria are incubated for 6 weeks and updated, if negative, on a weekly basis. **Extended incubation or other special requests must be approved in consultation with a medical director.** Specimens from all skin sites and wounds, fluid, and tissues of the extremities are cultured at both 35 °C and 30 °C to optimize recovery of M. marinum, M. chelonae, M. haemophilum and M. ulcerans. If these species are otherwise suspected, please notify the laboratory. Mycobacteria grown in culture are identified to species. Susceptibility testing is performed automatically for M. tuberculosis and by request for other species. **Multiple identification procedures may be required, with the following CPT codes billed as applicable: MALDI-TOF 87118, DNA Probe 87149, and Sequencing 87153.** **Days Performed:** Sunday–Saturday **Reported: 7 weeks**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Aluminum	ALUM	**Special Information:** Diet, medication, and nutritional supplements may introduce interfering substances. Patient should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). Unacceptable conditions: **Non-certified metals-free tubes.** Plasma. Separator tubes. Specimens that are not separated from the red cells or clot within 6 hours. This test is New York DOH approved. **Specimen Requirement:** 2 mL serum from a plain no additive (navy blue) tube; Minimum: 0.5 mL; Carefully clean skin with an alcohol swab prior to collection; Use powderless gloves; Do not use serum separator tubes; Remove serum from cells ASAP **or within 2 hours of collection** and aliquot into a trace metal-free transport tube (ARUP #43116); Ambient	12/2/19
Amino Acids, CSF w/ Basic Consultation	CAABI	**For Interfaced Clients Only: Test build may need to be modified** **Test Name:** Previously Amino Acids, CSF w/ Basic Interpretation	1/30/20
Amino Acids, CSF w/ No Consultation	CAANI	**Test Name:** Previously Amino Acids, CSF w/ No Interpretation	1/30/20
Amino Acids, Plasma w/ Basic Consultation	PAABI	**For Interfaced Clients Only: Test build may need to be modified** **Test Name:** Previously Amino Acids, Plasma w/ Basic Interpretation	1/30/20
Amino Acids, Plasma w/ No Consultation	PAANI	**Test Name:** Previously Amino Acids, Plasma w/ No Interpretation	1/30/20
Amino Acids, Urine w/ Basic Consultation	UAABI	**For Interfaced Clients Only: Test build may need to be modified** **Test Name:** Previously Amino Acids, Urine w/ Basic Interpretation	1/30/20
Amino Acids, Urine w/ No Consultation	UAANI	**Test Name:** Previously Amino Acids, Urine w/ No Interpretation	1/30/20
Aminolevulinic Acid Dehydratase (ALAD), Whole Blood	ALADWB	**Specimen Requirement:** 5 mL whole blood in a sodium heparin (green) tube; Minimum: 3 mL; Place specimen on ice after draw; Fill tube completely; Patient should abstain from alcohol for 24 hours; Include a list of medications the patient is currently taking; Send specimen to Cleveland Clinic Laboratories on the day of collection; **Sending in the original tube is preferred, but not required;** Refrigerated *OR* 5 mL whole blood in an EDTA (lavender) tube; Minimum: 3 mL; Place specimen on ice after draw; Fill tube completely; Patient should abstain from alcohol for 24 hours; Include a list of medications the patient is currently taking; Send specimen to Cleveland Clinic Laboratories on the day of collection; **Sending in the original tube is preferred, but not required;** Refrigerated *OR* 5 mL whole blood in a lithium heparin (green) tube; Minimum: 3 mL; Place specimen on ice after draw; Fill tube completely; Patient should abstain from alcohol for 24 hours; Include a list of medications the patient is currently taking; Send specimen to Cleveland Clinic Laboratories on the day of collection; **Sending in the original tube is preferred, but not required;** Refrigerated	Effective immediately
ANA Panel I	ANA1	**Clinical Information: The test is used to screen for and aid in diagnosis of systemic autoimmune diseases, especially for systemic lupus erythematosus. Clinical correlation is required.** **Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14 days**	1/14/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
C. difficile PCR with Reflex to EIA if Positive	CDREFL	**Special Information:** Unformed stools are tested for the presence of C. difficile toxin B gene by polymerase chain reaction (PCR). Stool specimens positive for C. difficile toxin by PCR will be followed by toxin enzyme immunoassay (EIA) testing within 8 hours. A negative toxin EIA result is reported with the following comment: "Toxin EIA is less sensitive than cell cytotoxin and PCR assays. Clinical correlation of PCR positive/toxin EIA negative results is required to distinguish C. difficile colonization from disease." **Whenever possible, this test should be performed on specimens that are less than 24 hours old.** **Stability:** Ambient: 24 hours Refrigerated: **72 hours** Frozen: Unacceptable	1/28/20
Celiac Gluten Free Panel	CELGLU	**Clinical Information:** The Celiac Gluten Free panel is ordered in patients already on a gluten-free diet. In such patients, the antibody levels and the morphologic findings on biopsy may be diminished, and only the HLA testing may be useful. HLA-DQ genotyping HLA-DQA1: ------ HLA-DQB1: ------ Interpretation: The HLA-DQ genotype of the patient is/is NOT associated with increased risk of celiac disease. The strongest reported HLA associations with celiac disease include DQ2 (DQ2.5 or DQA1*05-DQB1*0201 & DQ2.2 or DQA1*02:01-DQB1*02:02) and DQ8 (DQA1*0301/DQB1*0302)1-3. This test is useful for family members of celiac patients and patients with negative serology results. This testing can rule out celiac disease with a high negative predictive value (NPV) of 95–100% depending on the ethnic background. **HLA typing should only be attempted in patients who are already on a gluten-free diet prior to serological diagnosis and/or those with equivocal biopsy results.**	Effective immediately
Centromere Antibody	CENTRO	**Clinical Information: Anti-centromere antibody is used as an aid in diagnosis of systemic sclerosis. Clinical correlation is required.** **Stability:** Ambient: 1 day Refrigerated: **7 days** Frozen: **14 days**	1/14/20
Chromatin Antibody	CHRMTN	**Clinical Information: Anti-chromatin antibody is used as an aid in diagnosis of systemic lupus erythematosus. Clinical correlation is required.** **Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	1/14/20
Chromium, Serum	CHRSER	**Special Information:** Patient Prep: 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). Unacceptable conditions: **Non-certified metals-free tubes.** Separator tubes. Specimens that are not separated from the red cells or clot within 6 hours. This test is New York DOH approved. **Specimen Requirement:** 2 mL serum from a plain no additive (navy blue) tube; Minimum: 0.5 mL; **Do not draw separator tubes;** Remove serum from cells ASAP or within **2 hours** of collection and aliquot into a trace metal-free transport tube (ARUP #43116); Ambient	12/2/19
Cobalt, Serum or Plasma	COBALT	**Special Information:** Patient Prep: 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). **Unacceptable conditions: Non-certified metals-free tubes.** Specimens collected and/or transported in containers other than specified will be rejected. This test is New York DOH approved. **Clinical Information:** Occupational exposure or toxic ingestion monitoring. Whole blood is the preferred test for evaluating metal ion release from metal-on-metal joint arthroplasty. Serum levels may be increased in asymptomatic patients with metal-on-metal prosthetics and should be considered in the context of the overall clinical scenario. Symptoms associated with cobalt toxicity vary based on route of exposure, and may include cardiomyopathy, allergic dermatitis, pulmonary fibrosis, cough and dyspnea. **Days Performed:** Sunday–Saturday **Reported:** 2–**4** days	12/2/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
ENA Antibody Panel	ENAID	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	1/14/20
Endomysial IgA Antibody	ENDOMY	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	1/14/20
Flow Cytometric Immunophenotyping for Leukemia/ Lymphoma	RLLLIP	**Special Information:** Flow Cytometry will be performed using the following antibodies: CD3, CD4, CD5, **CD7,** CD8, CD13, CD16/56, CD19, CD34, CD45, KAPPA, LAMBDA. Based on review of the flow cytometry results, the following tests may be ordered and billed: Additional flow cytometry markers, molecular and FISH assays. Note: If 16 or more markers are interpreted, then CPT 88188 will change to 88189. **CPT:** 88184 x 1, 88185 **x 11,** 88188 x 1	12/16/19
Hematologic Neoplasm Next Generation Sequencing Panel Marrow	HNMNGS	**Note:** *Changes to this test were announced in the October and November Technical Updates. The go-live date for changes is TBD. We apologize for any inconvenience this may have caused.*	TBD
Hematologic Neoplasm Next Generation Sequencing Panel Peripheral Blood	HNPNGS	**Note:** *Changes to this test were announced in the October and November Technical Updates. The go-live date for changes is TBD. We apologize for any inconvenience this may have caused.*	TBD
Jo 1 Antibody	JO1	**Clinical Information: Anti-Jo-1 antibody is used as an aid in diagnosis of** polymyositis and dermatomyositis, **especially with pulmonary involvement. A negative result cannot rule out polymyositis or dermatomyositis. Clinical correlation is required.** **Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	1/14/20
LSD, Urine	ULSD	**Special Information:** Do not collect in glass containers. **Specimens in glass containers are unacceptable. Specimens received at room temperature will be rejected. If positive, turnaround time may be extended.** **Specimen Requirement:** 2 mL random urine in a clean container **(No preservatives);** Minimum: **0.9 mL; Do not use glass container;** Refrigerated **Stability:** Ambient: **1 day** Refrigerated: 30 days Frozen: **30 days at minus 20 °C** **Days Performed:** Monday–Sunday **Reported:** 9–**10** days	1/13/20
Manganese, Serum	SMANG	**Special Information:** Patient Prep: 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). **Unacceptable conditions: Non-certified metals-free tubes. Hemolyzed specimens. Separator tubes. Specimens that are not separated from the red cells, or clot, within 6 hours. This test is New York DOH approved.** **Clinical Information:** Less than 5% of manganese present in circulation resides in the serum. **Specimen Requirement:** 2 mL serum from a plain no additive (navy blue) tube; Minimum: 0.5 mL; **Do not draw separator tubes; Remove serum from cells ASAP or within 2 hours of collection** and aliquot into a trace metal-free transport tube (ARUP #43116); Ambient **Stability:** Ambient: If the specimen is drawn and stored in the appropriate container, the trace element values do not change with time.	12/2/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Mitochondrial Antibody Panel	MITO	**Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14** days	1/14/20
Mitochondrial Antibody Screen	MITOS	**Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14** days	1/14/20
Myeloperoxidase Autoantibodies	ANCAP	**Clinical Information: This test is used as an aid in diagnosis of patients with autoimmune vasculitidies. The final interpretation should be done in conjunction with Anti-Neutrophil Cytoplasmic Antibody (ANCA) IFA test results and clinical correlation.** **Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	1/14/20
Nickel, Serum	NICKEL	**Special Information:** 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). **Unacceptable conditions: Non-certified metals-free tubes.** Specimens collected and/or transported in containers **other than specified.** Heparin anticoagulant. Specimens not separated from the red cells or clot within 2 hours. **Clinical Information:** Serum nickel testing is intended to detect potentially toxic exposure.	12/2/19
Organic Acids Ur, Quant w/ Basic Consultation	UORABI	**For Interfaced Clients Only: Test build may need to be modified** **Test Name:** Previously Organic Acids Ur, Quant w/ Basic Interpretation	1/30/20
Organic Acids Ur, Quant w/ No Consultation	UORANI	**Test Name:** Previously Organic Acids Ur, Quant w/ No Interpretation	1/30/20
Pancreastatin	PANCST	**Special Information:** Patient **must** be fasting 10–12 hours prior to collection. Patient should not be on any medications that may influence insulin levels, if possible, for at least 48 hours prior to collection. **Specimen Requirement: 2 mL serum from a serum separator (gold) tube;** Minimum: **1 mL; Centrifuge, aliquot serum into a plastic vial,** and freeze; Frozen **Methodology: Enzyme Immunoassay (EIA)** **Reference Range: 100–288.7 pg/mL** **Days Performed:** Monday, **Tuesday, Wednesday** **Reported: 8–12** days **CPT: 86316 x 1**	12/2/19
Parietal Cell Antibody Panel	PARIET	**Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14** days	1/14/20
Parietal Cell Antibody Screen	PARIES	**Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14** days	1/14/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Proteinase 3 Autoantibodies	ANCAC	**Clinical Information: This test is used as an aid in diagnosis of patients with autoimmune vasculitidies. The final interpretation should be done in conjunction with Anti-Neutrophil Cytoplasmic Antibody (ANCA) IFA test results and clinical correlation.** **Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	1/14/20
Ribosomal RNP Ab	RRNP	**Clinical Information: Anti-ribosomal RNA (ribosomal P) antibody is used as an aid in diagnosis of systemic lupus erythematosus, especially lupus psychosis. Clinical correlation is required.** **Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	1/14/20
RNP Antibody	ARNP	**Clinical Information: Anti-RNP antibody is used as an aid in diagnosis of systemic autoimmune diseases, especially systemic lupus erythematosus and mixed connective tissue disease. Cross-reactivity with Anti-Smith antibody is not uncommon. Clinical correlation is required.** **Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	1/14/20
Sarcoma Fusion NGS Panel	SRCNGS	**Special Information: Interrogated genes: ALK, BCOR, CAMTA1, CCNB3, CIC, CSF1, EPC1, EWSR1, FOS, FOSB, FOXO1, FUS, GLI1, HMGA2, JAZF1, MEAF6, MKL2, NCOA2, NTRK1, NTRK2, NTRK3, NUT, PAX3, PDGFB, PLAG1, ROS1, SS18, STAT6, TAF15, TCF12, TFE3, TFG, USP6, YWHAE** **CPT:** 81445 x 1	12/2/19
Scleroderma IgG Ab	SCL70	**Clinical Information: Scl-70/Scleroderma antibody test is used as an aid in diagnosis of systemic sclerosis, especially the diffuse cutaneous form. A negative result cannot rule out systemic sclerosis. The final interpretation should consider clinical picture and other test results such as anti-centromere antibody.** **Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	1/14/20
Selenium, Plasma or Serum	PSELEN	**Special Information:** Patient Prep: 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). **Unacceptable conditions: Non-certified metals-free tubes.** Separator tubes. Specimens that are not separated from the red cells or clot within 6 hours are unacceptable. **This test is New York DOH approved.** **Clinical Information: Serum selenium levels can be used in the determination of deficiency or toxicity. Plasma and serum contain 75% of the selenium measured in whole blood and reflects recent dietary intake. Selenium deficiency can occur endemically or as a result of sustained TPN or restricted diets and has been associated with cardiomyopathy and may exacerbate hypothyroidism. Selenium toxicity is relatively rare. Excess intake of selenium can result in symptoms consistent with selenosis, including mild nerve damage, gastrointestinal upset, white blotchy nails, and hair loss.** **Specimen Requirement:** 2 mL plasma from an EDTA (royal blue) tube; Minimum: 0.5 mL; Do not use plasma separator tubes; 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); Separate plasma from cells ASAP or within **2 hours** of collection and aliquot into a trace metal-free transport tube (ARUP #43116); Ambient	12/2/19

(continued on page 9)

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Selenium, Plasma or Serum *(continued from page 8)*		*OR* 2 mL serum from a plain no additive (navy blue) tube; Minimum: 0.5 mL; Do not use serum separator tubes; 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); Separate serum from cells ASAP or within **2 hours** of collection and aliquot into a trace metal-free transport tube (ARUP #43116); Ambient	
Sjogren Antibodies	XSSAB	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	1/14/20
Smith Abs, IgG	SMAB	**Clinical Information: Anti-Sm (Smith) antibody is used as an aid in diagnosis of** systemic lupus erythematosus, **and its presence is associated with renal disease. A negative result cannot rule out systemic lupus erythematosus. Clinical correlation is required.** **Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	1/14/20
Smooth Muscle Antibody Panel	SMOOTH	**Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14 days**	1/14/20
Smooth Muscle Antibody Screen	SMTHS	**Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14 days**	1/14/20
SSA Antibody	ANTSSA	**Clinical Information: Anti-SSA (anti-Ro) antibody is used as an aid in** diagnosis of **a variety of systemic autoimmune diseases,** Sjogren's syndrome, **among others. Clinical correlation is required.** **Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	1/14/20
SS-B Antibody	SSB	**Clinical Information: Anti-SSB (anti-La) antibody is used as an aid in** diagnosis of **a variety of systemic autoimmune diseases, especially for** Sjogren's syndrome **and systemic** lupus **erythematosus. Clinical correlation is required.** **Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	1/14/20
Titanium, Serum or Plasma	TITAN	**Specimen Requirement:** 2 mL plasma from an EDTA **(royal** blue**)** tube; Minimum: 0.6 mL; Separate plasma from cells **ASAP or** within 2 hours of collection; Transfer plasma into a trace metal-free transport tube (ARUP #43116) **or acid-washed transfer vial (ARUP #54350);** Refrigerated *OR* 2 mL serum from a plain no additive (navy blue) tube; Minimum: 0.6 mL; Separate serum from cells **ASAP or** within 2 hours of collection; Transfer serum into a trace metal-free transport tube (ARUP #43116) **or acid-washed transfer vial (ARUP #54350);** Refrigerated **Days Performed:** Varies **Reported: 6–9** days	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Acute Myeloid Leukemia (AML), MRD by FC	AMLMRD	**Special Information:** For optimal results, bone marrow specimens should be received in the performing lab within 24 hours of collection, and peripheral blood specimens should be received within 48 hours of collection. Specimens submitted outside of this range will be evaluated for quality using appropriate internal controls, and the results will be qualified appropriately. If sending samples outside of indicated stability, please transport refrigerated. **Specimen Requirement:** 2 mL bone marrow in a sodium heparin (green) tube; Specimen must be received by Cleveland Clinic Laboratories on the day of collection by noon EST; DO NOT collect the day before or after a major holiday; Ambient *OR* 2 mL bone marrow in an EDTA (lavender) tube; Specimen must be received by Cleveland Clinic Laboratories on the day of collection by noon EST; DO NOT collect the day before or after a major holiday; Ambient *OR* 3 mL peripheral blood in an EDTA (lavender) tube; Specimen must be received by Cleveland Clinic Laboratories on the day of collection by noon EST; DO NOT collect the day before or after a major holiday; Ambient *OR* 3 mL peripheral blood in a sodium heparin (green) tube; Specimen must be received by Cleveland Clinic Laboratories on the day of collection by noon EST; DO NOT collect the day before or after a major holiday; Ambient **Stability:** Ambient: Bone marrow: 24 hours; Peripheral blood: 48 hours Refrigerated: Acceptable Frozen: Unacceptable **Methodology:** Flow Cytometry (FC) **Days Performed:** Monday–Sunday **Reported:** 2–3 days **CPT:** Varies	12/10/19
Allergen, Brazil Nut Component IgE	BRAZCP	**Clinical Information:** The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis. **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL (Submitting the minimum volume will not allow for repeat or add-on testing. Required volume of 0.5 mL is preferred when possible); An extra 50 µL will be required for each additional allergen ordered; Refrigerated *OR* 0.5 mL plasma from a sodium heparin (light green) plasma separator tube (PST); Minimum: 0.3 mL (Submitting the minimum volume will not allow for repeat or add-on testing. Required volume of 0.5 mL is preferred when possible); An extra 50 µL will be required for each additional allergen ordered; Refrigerated *OR* 0.5 mL plasma from an EDTA (lavender) tube; Minimum: 0.3 mL (Submitting the minimum volume will not allow for repeat or add-on testing. Required volume of 0.5 mL is preferred when possible); An extra 50 µL will be required for each additional allergen ordered; Refrigerated **Stability:** Ambient: 1 day Refrigerated: 7 days Frozen: 14 days **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Ber e 1 IgE: < 0.35 kU/L **Days Performed:** Sunday–Saturday **Reported:** 1–2 days **CPT:** 86008 x 1 **Price:** $39.00 (non-discountable)	2/11/20

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Alpha-Galactosidase (Leukocytes)	AGALAC	**Special Information:** For optimal isolation of leukocytes, it is recommended that the specimen arrive refrigerated at the performing laboratory within 96 hours of collection to be stabilized. Specimens received after 96 hours could have falsely normal results. Do not collect the day before a major holiday. Specimen should be collected and packaged as close to shipping time as possible. **Clinical Information:** Useful for diagnosing Fabry disease in male patients. Verifying abnormal serum alpha-galactosidase results in male patients with a clinical presentation suggestive of Fabry disease. Results from this assay do not reflect carrier status because of individual variation of alpha-galactosidase enzyme levels. Individuals with pseudodeficiency allelic variants can show reduced alpha-galactosidase A enzyme activity with this assay. Carrier detection using enzyme levels is unreliable in females, and mutation analysis using molecular methods is recommended. **Specimen Requirement:** 6 mL whole blood in an ACD B (yellow) tube; Minimum: 2 mL; Collect Monday–Wednesday only; Do not collect specimen on the day before a major holiday; Specimen must be sent to Cleveland Clinic Laboratories on the same day as collection; Send specimen in original tube; Do not transfer to other containers; Refrigerated *OR* 6 mL whole blood in an ACD A (yellow) tube; Minimum: 2 mL; Collect Monday–Wednesday only; Do not collect specimen on the day before a major holiday; Specimen must be sent to Cleveland Clinic Laboratories on the same day as collection; Send specimen in original tube; Do not transfer to other containers; Refrigerated *OR* 6 mL whole blood in an EDTA (lavender) tube; Minimum: 2 mL; Collect Monday–Wednesday only; Do not collect specimen on the day before a major holiday; Specimen must be sent to Cleveland Clinic Laboratories on the same day as collection; Send specimen in original tube; Do not transfer to other containers; Refrigerated **Stability:** Ambient: 72 hours Refrigerated: 4 days (preferred) Frozen: Unacceptable **Methodology:** Flow Injection Analysis-Tandem Mass Spectrometry (FIA-MS/MS) **Reference Range:** ≥ 10.32 nmol/hr/mg protein **Days Performed:** Varies **Reported:** 6–11 days **CPT:** 82657 x 1 **Price:** $408.00 (non-discountable)	12/5/19
Next Generation Sequencing Hotspot PIK3CA Gene Analysis	PIK3GN	**Note:** *This test was previously announced in the November Technical Update.* **Price:** $856.00 (non-discountable)	11/26/19

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Flow Cytometric Immunophenotyping for Leukemia/Lymphoma	RLLLIP	$1145.00 (non-discountable)	88184, 88185 x 11, 88188	12/16/19

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Alpha Galactosidase, Leukocytes	AGAL	This test will no longer be available. Suggest ordering Alpha-Galactosidase (Leukocytes) (AGALAC).	12/5/19
Duodenal Crystals	DUOCRY	This test will no longer be available.	1/21/20
Mitochondrial DNA/ nuclear DNA ratio	MTRAT	This test will no longer be available.	2/4/20
SHOX DNA Diagnostic	SHOX	This test will no longer be available.	2/4/20
Uveal Melanoma Prognostic	UVEAL	This test will no longer be available.	1/30/20