Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • April 2020

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
4	Acetylcholine Receptor Antibodies with reflex						■		■		■	■		
4	Acetylcholine Receptor Binding Ab						■	■	■		■	■		
4	Acetylcholine Receptor Blocking Ab						■	■	■		■	■		
4	ACTH										■			
4	Allergen, Rice IgG						■	■		■				
5	Ammonia											■		
5	Aspergillus galactomannan CSF						■				■	■		
5	Bartonella henselae Abs						■	■		■	■			
5–6	Blastomyces Antigen						■	■			■	■		
6	B Type Natriuretic Peptide											■		
13	Canavan Disease Mutation, Whole Blood					■								
6	Chromosome Analysis, Bone Marrow												■	
6	Chromosome Analysis, Leukemic Blood												■	
13	Chromosome Analysis, Neoplastic Tissue			■										
6	Chromosome Analysis, Solid Tumor						■					■	■	
6	Cold Agglutinins						■	■			■	■		
7	Cross-Linked N-telopeptide, Urine										■			
7	DHEA-S											■		
7	Diphtheria Toxoid IgG Abs						■	■		■		■		
7	Endomysial Antibody, IgG						■	■			■	■		
7	Entamoeba histolytica Antigen						■					■		
13	Epi ProColon					■								
7	Fluoride										■	■		

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
8, 13	Fructosamine					■	■		■	■	■			■
13	Gaucher Disease Mutation, Whole Blood					■								
8	Glutamic Acid Decarboxylase Antibody					■	■	■		■				
8	Immunohistology					■								
9	Insulin Antibody					■		■		■				
9	Legionella Urinary Ag.											■		
9	Lipoprotein (a)					■	■					■		
9	LPT to Beryllium, BAL					■	■							
9	LPT to Beryllium, Blood					■	■							
13	Lung Cancer Hot Spot Panel v2 NGS 2 gene				■									
10	Lymphocyte Transformation Test to Candida Antigen		■			■		■		■		■		
10	Mitogen LTT		■									■		
13	Paroxetine				■									
13	PAX6 Gene Analysis				■									
10	Protein, Total											■		
10	Sex Hormone Binding Globulin									■				
13	Sialic Acid, CSF				■									
10	Specific Gravity, Body Fluid									■				
10	Supersaturation Profile, 24 Hour Urine					■		■						
11	Treponema Pallidum IgG					■					■			
11	TSH					■								
11	TSH Binding Inhibition					■		■		■		■		
11	Uric Acid											■		
11	Uric Acid, Urine 24 Hour						■				■	■		
11	Uric Acid, Urine Random						■				■	■		
12	Uric Acid, Urine Timed						■				■	■		
12	Urinalysis Only									■				
12	Urinalysis with Microscopic									■				
12	Urobilinogen Screen, Urine									■				
12	VDRL, CSF					■						■		

FISH TESTING UPDATE

The following test changes and new tests were previously announced in the June 2019 *Technical Update*. These changes are scheduled to occur on 4/7/20. We apologize for any inconvenience this delay may have caused.

TEST CHANGES

FISH for 5q Abnormalities Blood (5QFSH)

FISH for 7q Deletion Blood (FISH7Q)

FISH for 8;21 Translocation for AML Blood (AMLFSH)

FISH for 20q and CEP8 Blood (20Q8FH)

FISH for Acute Myeloid Leukemia Panel Blood (FAMLPN)

FISH for Aggressive B-Cell Lymphoma Blood (FABCFP)

FISH for BCL2 Blood (BCL2FH)

FISH for BCL6 Blood (BCL6FH)

FISH for B Lymphoblastic Leukemia Panel Blood (FSHBLL)

FISH for CBFB/MYH11 Blood (INV16F)

FISH for CCND1 Blood (CCND1F)

FISH for FGFR1 Blood (FGFR1F)

FISH for IgH/BCL2 Blood (FSHFCL)

FISH for IgH/CCND1 Blood (FSHMCL)

FISH for IGH/MYC Blood (814FSH)

FISH for MLL Blood (MLLFSH)

FISH for MYC (8q24) Blood (MYCFSH)

FISH for Myelodysplasia Blood (FSHMDS)

FISH for Myeloproliferative Neoplasms Panel Blood (MPNFSH)

FISH for PDGFRA Blood (PDGFRA)

FISH for PDGFRB Rearrangement Blood (PDGFRB)

FISH for PML/RARA Blood (APLFSH)

FISH for RARA Blood (RARFSH)

FISH for t(12;21)(p13;q22) Blood (1221FH)

FISH for Trisomy 4 and 10 Blood (FHT410)

NEW TESTS

FISH for 5q Abnormalities Bone Marrow (5QFSBM)

FISH for 7q Deletion Bone Marrow (FSH7QM)

FISH for 8;21 Translocation for AML Bone Marrow (AMLFBM)

FISH for 20q and CEP8 Bone Marrow (20Q8BM)

FISH for Acute Myeloid Leukemia Bone Marrow (FAMLPM)

FISH for Aggressive B-Cell Lymphoma Bone Marrow (FABCBM)

FISH for BCL2 Bone Marrow (BCL2FM)

FISH for BCL6 Bone Marrow (BCL6FM)

FISH for B Lymphoblastic Leukemia Panel Bone Marrow (FSBLLM)

FISH for CBFB/MYH11 Bone Marrow (INV16M)

FISH for CCND1 Bone Marrow (CCND1M)

FISH for FGFR1 Bone Marrow (FGFR1M)

FISH for IGH/BCL2 Bone Marrow (FSFCLM)

FISH for IGH/CCND1 Bone Marrow (FSMCLM)

FISH for IGH/MYC Bone Marrow (814FSM)

FISH for MLL Bone Marrow (MLLFBM)

FISH for MYC (8q24) Bone Marrow (MYCFSM)

FISH for Myelodysplasia Bone Marrow (FSMDSM)

FISH for Myeloproliferative Neoplasm Panel Bone Marrow (MPNFSM)

FISH for PDGFRA Bone Marrow (PGFRAM)

FISH for PDGFRB Rearrangement Bone Marrow (PDGFBM)

FISH for PML/RARA Bone Marrow (APLFBM)

FISH for RARA Bone Marrow (RARFSM)

FISH for t(12;21)(p13;q22) Bone Marrow (1221FM)

FISH for Trisomy 4 and 10 Bone Marrow (FT410M)

Test Changes

Test Name	Order Code	Change	Effective Date
Acetylcholine Receptor Antibodies with reflex	ACHABS	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Acetylcholine Receptor Binding Ab Acetylcholine Receptor Blocking Ab **Acetylcholine Receptor Binding Ab, Qualitative** **Acetylcholine Receptor Blocking Ab, Qualitative** **Clinical Information: Please refer to individual tests.** **Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14 days** **Reference Range:** Acetylcholine Receptor Binding Ab (0–99 Years): ≤ **0.20 nmol/L** Acetylcholine Receptor Blocking Ab: ≤ **20%** **Acetylcholine Receptor Binding Ab, Qualitative: Negative** **Acetylcholine Receptor Blocking Ab, Qualitative: Negative**	5/5/20
Acetylcholine Receptor Binding Ab	ACHRA	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Acetylcholine Receptor Binding Ab **Acetylcholine Receptor Binding Ab, Qualitative** **Clinical Information: Anti-acetylcholine receptor binding antibody test is used as an aid in diagnosis of myasthenia gravis. A negative result cannot exclude myasthenia gravis. Clinical correlation is required.** **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.1 mL; Refrigerated *OR* 0.5 mL serum from a plain no additive (red) tube; Minimum: 0.1 mL; Refrigerated **Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14 days** **Reference Range:** Acetylcholine Receptor Binding Ab (0–99 Years): ≤ **0.20 nmol/L** **Acetylcholine Receptor Binding Ab, Qualitative: Negative**	5/5/20
Acetylcholine Receptor Blocking Ab	ACEBLC	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Acetylcholine Receptor Blocking Ab **Acetylcholine Receptor Blocking Ab, Qualitative** **Clinical Information: Anti-acetylcholine receptor blocking antibody test is used as an aid in diagnosis of myasthenia gravis. A negative result cannot exclude myasthenia gravis. Clinical correlation is required.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Refrigerated **Stability:** Ambient: 1 day Refrigerated: 7 days Frozen: **2 years** **Reference Range:** Acetylcholine Receptor Blocking Ab: ≤ **20%** **Acetylcholine Receptor Blocking Ab, Qualitative: Negative**	5/5/20
ACTH	ACTH	**Days Performed: Monday–Friday** **Reported:** 1–4 days	Effective immediately
Allergen, Rice IgG	RICIGG	**Note:** *Rice (f9) IgG will be added as an alias name.* **Specimen Requirement:** 0.3 mL serum from a serum separator (gold) tube; Minimum: 0.2 mL; **Transfer serum to a standard plastic aliquot tube; Refrigerated** *OR* 0.3 mL serum from a plain no additive (red) tube; Minimum: 0.2 mL; **Transfer serum to a standard plastic aliquot tube; Refrigerated** **Methodology: Immunoassay (IA)**	5/19/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Ammonia	NH3	**Stability:** Ambient: Not Acceptable Refrigerated: After separation from cells: **2** hours Frozen: After separation from cells: **3** days	5/19/20
Aspergillus galactomannan CSF	ASGCSF	**Special Information: Specimens that are too viscous to pipette will be rejected.** **Stability:** Ambient: **48 hours** Refrigerated: 5 days Frozen: 5 months **Days Performed:** Monday–Friday **Reported: 2**–5 days	4/28/20
Bartonella henselae Abs	CATSC	**Special Information:** Acute and convalescent specimens must be labeled as such. Parallel testing is preferred, and convalescent specimens must be received within 30 days from the receipt of acute specimens. Please label specimens plainly as 'acute' or 'convalescent.' **Contaminated, hemolyzed, or severely lipemic specimens will be rejected. This test is New York DOH approved.** **Clinical Information: May be useful in diagnosing cat scratch disease in a patient with typical signs and symptoms and a compatible exposure history.** **Specimen Requirement:** 1 mL serum from a **serum separator (gold)** tube; Minimum: **0.15 mL; Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' or 'convalescent;'** Separate serum from cells ASAP or within 2 hours of collection **and transfer into a standard aliquot tube;** Refrigerated **Methodology: Semi-Quantitative Indirect Fluorescent Antibody** **Reference Range:** B. henselae IgM Ab Negative: < 1:16–**No significant level of Bartonella henselae IgM antibody detected** **Positive: ≥ 1:16–Presence of IgM antibody to Bartonella henselae detected, suggestive of current or recent infection** B. henselae IgG Ab Negative: < 1:64–**No significant level of Bartonella henselae IgG antibody detected** **Equivocal: 1:64–1:128–Questionable presence of Bartonella henselae IgG antibody detected; Repeat testing in 10–14 days may be helpful** **Positive: ≥ 1:256–Presence of IgG antibody to Bartonella henselae detected, suggestive of current or past infection**	4/28/20
Blastomyces Antigen	BLAS	**Special Information: Source must be indicated. List all antifungal agents patient is receiving.** Separate orders are required for each specimen. Rejection criteria: Specimen that is too viscous to pipette; Tissue, biopsy, sputum, bronchial brush, tracheal aspirate, fine-needle aspirate (FNA), bone marrow aspirate, stool or samples in transport media, fixative or Isolator tubes **Clinical Information:** Cautions: Sodium hydroxide and sputolysin. Cross-reactivity occurs between blastomycosis and histoplasmosis and in paracoccidioidomycosis, penicilliosis, coccidioidomycosis, aspergillosis, and sporotrichosis. **Specimen Requirement:** 2 mL **random urine in a sterile container;** Minimum: 0.5 mL; Use a sterile, **leak-proof** container; Indicate source; **List all antifungal agents patient is receiving; Ambient** *OR* 2 mL serum from a serum separator (gold) tube; Minimum: 1.2 mL; Centrifuge and transfer serum to standard plastic aliquot tube; **Indicate source; List all antifungal agents patient is receiving; Ambient** *OR* 2 mL serum from a plain no additive (red) tube; Minimum: 1.2 mL; Centrifuge and transfer serum to standard plastic aliquot tube; **Indicate source; List all antifungal agents patient is receiving; Ambient** *OR* 2 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.8 mL; Use a sterile, leak-proof container; Indicate source; **List all antifungal agents patient is receiving; Ambient** *(continued on page 6)*	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Blastomyces Antigen *(continued from page 5)*		*OR* 2 mL bronchoalveolar lavage (BAL) specimen in a sterile container; Minimum: 0.5 mL; Use a sterile, leak-proof container; Indicate source; **List all antifungal agents patient is receiving; Ambient** *OR* 2 mL plasma in an EDTA (lavender) tube; Minimum: 1.2 mL; **Indicate source; List all antifungal agents patient is receiving; Ambient** *OR* 2 mL plasma from a sodium heparin (green) tube; Minimum: 1.2 mL; Centrifuge and transfer plasma to standard plastic aliquot tube; **Indicate source; List all antifungal agents patient is receiving; Ambient** *OR* 2 mL plasma from a 3.2% sodium citrate (light blue) tube; Minimum: 1.2 mL; Centrifuge and transfer plasma to standard plastic aliquot tube; **Indicate source; List all antifungal agents patient is receiving; Ambient** *OR* 2 mL **body fluid in a sterile container;** Minimum: **0.5 mL; Use a sterile, leak-proof container; Indicate source; List all antifungal agents patient is receiving; Ambient** **Reference Range:** Blastomyces Ag Result: **Refer to report** Blastomyces Ag Interpretation: **Refer to report** **Days Performed:** Monday–Friday **Reported: 2–3** days	
B Type Natriuretic Peptide	BNP	**Stability:** Ambient: **8** hours Refrigerated: **24** hours Frozen: 9 months	4/28/20
Chromosome Analysis, Bone Marrow	CHRBMH	**CPT:** 88237 x 1**, 88264 x 1**	Effective immediately
Chromosome Analysis, Leukemic Blood	CHRBLL	**CPT:** 88237 x 1**, 88264 x 1**	Effective immediately
Chromosome Analysis, Solid Tumor	CHRSOL	**Special Information: Specimens collected and sent in formalin will be rejected.** **Stability:** Ambient: **Not preferred; Specimen will be cultured, but environmental conditions will be noted** Refrigerated: **Preferred** Frozen: **Not preferred; Specimen will be cultured, but environmental conditions will be noted** **CPT:** 88239 x 1, **88264 x 1**	5/28/20
Cold Agglutinins	COLD	**Special Information: Do not use serum separator tubes. Specimen must clot at room temperature. Refrigeration of specimens before separation of serum from cells will adversely affect results.** **Clinical Information: Elevated cold agglutinin titers may be seen during infections such as with Mycoplasma pneumoniae, influenza viruses, Epstein-Barr virus, and malaria parasites, among others, and also in certain hematological malignancies and autoimmune diseases such as autoimmune hemolytic anemia. Clinical correlation is required.** **Specimen Requirement:** 3 mL serum from a plain no additive (red) tube; Minimum: 2 mL; Do not use serum separator tubes; **Specimen must clot at room temperature; Refrigeration of specimens before separation of serum from cells will adversely affect results;** Ambient **Stability:** Ambient: 48 hours after serum is removed from the clot; Sample must clot at room temperature Refrigerated: **14 days after serum is removed from the clot; Sample must clot at room temperature** Frozen: **30 days after serum is removed from the clot; Sample must clot at room temperature** **Reference Range: Negative (Normal): < 1:32 at 4 °C**	5/5/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cross-Linked N-telopeptide, Urine	UNTX2	**Reference Range:** Male: **3.0 to 63.0 nM BCE/mM creatinine** Female: **5.0 to 65.0 nM BCE/mM creatinine**	6/2/20
DHEA-S	DHEAS	**Stability:** Ambient: **5 days** Refrigerated: **14** days Frozen: **12** months	4/2/20
Diphtheria Toxoid IgG Abs	DIPIGG	**Special Information:** 'Pre' and 'post' vaccination specimens should be submitted together for testing. 'Post' specimen should be drawn 30 days after immunization, and if shipped separately, must be received within 60 days of the 'pre' specimen. Clearly label specimens 'Pre-Vaccine' or 'Post-Vaccine.' **Plasma or other body fluids will be rejected. This test is New York DOH approved.** **Clinical Information:** (1) If the post-vaccination is < 1.0 IU/mL, the patient is considered a nonresponder. (2) If the post-vaccination concentration is greater than or equal to 1.0 IU/mL, a patient with a ratio of **< 1.5** is a nonresponder, a ratio of 1.5 to < 3.0, is a weak responder, and a ratio of 3.0 or greater, is a good responder. (3) If the pre-vaccination concentration is > 1.0 IU/mL, it may be difficult to assess the response based on a ratio alone. A post-vaccination concentration above 2.5 IU in this case is usually adequate. **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.15 mL; 'Pre' and 'post' vaccination specimens should be submitted together for testing; The 'post' specimen should be drawn 30 days after immunization; Label specimens clearly as 'Pre-Vaccine' or 'Post-Vaccine;'** Separate serum from cells ASAP **or within 2 hours of collection and transfer into a standard aliquot tube;** Refrigerated **Stability:** Ambient: After separation from cells: **48 hours** Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year **(Avoid repeated freeze/thaw cycles)** **Methodology: Quantitative Multiplex Bead Assay**	4/28/20
Endomysial Antibody, IgG	ENDIGG	**Special Information: Contaminated specimens will be rejected. This test is New York DOH approved.** **Clinical Information: The presence of endomysial antibodies IgG may be useful in identifying IgA-deficient patients at risk for celiac disease. To establish the diagnosis of celiac disease, a positive result must be confirmed through a biopsy of the small intestine. May aid in monitoring adherence to a gluten-free diet in patients with confirmed celiac disease.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.15 mL;** Separate serum from cells ASAP or within 2 hours of collection **and transfer into a standard aliquot tube;** Refrigerated **Stability:** Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year **(Avoid repeated freeze/thaw cycles)** **Days Performed:** Tuesday, **Friday** **Reported:** 2–9 days	4/28/20
Entamoeba histolytica Antigen	ENTEIA	**Special Information: Specimens in media or preservatives will be rejected. This test is New York DOH approved.** **Clinical Information: Test for persistent diarrhea (> 14 days) or known risk factors if E. histolytica is the suspected infectious agent.** **Stability:** Ambient: Unacceptable Refrigerated: **48 hours** Frozen: **2 weeks**	4/28/20
Fluoride	BFLUOR	**Stability:** Ambient: 30 days Refrigerated: 30 days Frozen: **28** months **Days Performed: Varies** **Reported:** 9–**10** days	6/1/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Fructosamine	FRUCTO	**Special Information: Fructosamine is affected by the presence of reducing molecules in the blood, such as bilirubin and ascorbic acid (vitamin C).** Patients are advised to abstain from ascorbic acid supplements 24 hours prior to sample collection. **Hypoproteinemic related conditions may affect fructosamine concentrations. Stability of EDTA whole blood before separation of cells was validated at 72 hours for ambient storage and 7 days of refrigerated storage.** **Clinical Limitation:** High levels of ascorbic acid interfere with the fructosamine assay. **Hemolyzed samples with hemolysis index > 100 mg/dL may be rejected. Icteric samples with icteric index > 5 mg/dL may be rejected.** **Clinical Information: Fructosamine is a useful alternative indicator of glycemic control in conditions in which HbA1c measurement is unreliable and for identifying impaired blood glucose control prior to noticeable changes in HbA1c. Fructosamine should not be used** as a substitute for HbA1c except in specific patient populations **(e.g., unreliable HbA1c due to interfering hemoglobin variants). Fructosamine concentrations may be affected by altered concentrations of protein in blood.** **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Allow specimen to clot completely at room temperature before centrifuging, then transfer to standard aliquot tube; Refrigerated *OR* 0.5 mL plasma from a lithium heparin (green) tube; Minimum: 0.3 mL; Refrigerated *OR* 0.5 mL plasma from an **EDTA (lavender)** tube; Minimum: 0.3 mL; Refrigerated **Methodology: Colorimetric, Kinetic** **Reference Range:** **0–99 Years: 202**–285 **µmol/L** **Days Performed: Monday–Friday** **Reported:** 2–3 days	5/19/20
Glutamic Acid Decarboxylase Antibody	GADCAB	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Glutamic Acid Decarboxylase Antibody **Glutamic Acid Decarboxylase Aby, Qualitative** **Note:** *Special Information will be removed.* **Clinical Information: Anti-glutamic acid decarboxylase antibody (GAD65) test, usually in conjunction with another test such as IA-2 antibody, is used as an aid in establishing the autoimmune nature of previously diagnosed type I diabetes mellitus or in predicting progression to type I diabetes mellitus in patients with certain autoimmune diseases, including autoimmune gastritis, among others. It is also used as an aid in diagnosis of stiff person syndrome and certain autoimmune nervous system diseases. Clinical correlation is required.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Frozen *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Frozen **Reference Range:** Glutamic Acid Decarboxylase Antibody: ≤ **5.0 IU/mL** **Glutamic Acid Decarboxylase Aby, Qualitative: Negative**	5/5/20
Immunohistology		**Note:** *C3C (Immunofluorescence), CA 125, CD30 (1G12), CD95, Factor VIII Antigen, Glucagon, Insulin, Proliferating Cell Nuclear Antigen, and Ubiquitin will be removed as cross references/alias names, while ATRX and BAP1 will be added.*	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Insulin Antibody	INSAB	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Insulin Antibody **Insulin Antibody, Qualitative** **Clinical Information: Anti-insulin antibody test is used as an aid in diagnosis and prognosis of autoimmune diabetes mellitus in combination with other tests, such as anti-GAD65 and anti-IA-2 antibody. A single negative result cannot rule out autoimmune diabetes mellitus. The test is not reliable in patients who have previously received exogenous insulin. The test offers higher sensitivity in pediatric patients compared with adults. Clinical correlation is required.** **Reference Range:** Insulin Antibody (0–99 Years): < 0.4 U/mL **Insulin Antibody, Qualitative: Negative**	5/5/20
Legionella Urinary Ag.	LEGUAG	**Stability:** Ambient: 24 hours Refrigerated: 14 days Frozen: **30** days	4/2/20
Lipoprotein (a)	LPA	**Special Information: Freshly drawn serum from a fasting individual is preferred.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Allow specimen to clot completely at room temperature; **Recommended to** separate serum from cells within 2 hours of collection; Refrigerated **Stability:** Ambient: **24 hours** Refrigerated: **7 days** Frozen: **14 days**	5/5/20
LPT to Beryllium, BAL	BALBE	**Clinical Information: Lymphocyte proliferation test to beryllium is a cellular assay used as an aid in diagnosis of prior sensitization to beryllium in the environment. Beryllium-sensitized individuals may remain asymptomatic for extended periods and never develop chronic berylliosis. Clinical, epidemiological, and radiological correlation is required. Bronchoalveolar lavage (BAL) testing may offer higher sensitivity than whole blood testing.** **Specimen Requirement: 200 mL** bronchoalveolar lavage (BAL) specimen in a clean container; Minimum: 80 mL; Collect Monday–Thursday only; Deliver the specimen to Cleveland Clinic Laboratories **immediately, no later than** 24 hours post collection; **Do not aliquot; Specimen must remain at ambient temperature; Do not refrigerate; Do not freeze;** Ambient	6/2/20
LPT to Beryllium, Blood	BLDBE	**Clinical Information: Lymphocyte proliferation test to beryllium is a cellular assay used as an aid in diagnosis of prior sensitization to beryllium in the environment. Beryllium-sensitized individuals may remain asymptomatic for extended periods and never develop chronic berylliosis. Clinical, epidemiological, and radiological correlation is required. Bronchoalveolar lavage (BAL) testing may offer higher sensitivity than whole blood testing where pulmonary disease is suspected.** **Specimen Requirement:** 30 mL whole blood in a sodium heparin (green) tube; Minimum: 20 mL; Collect Monday–Thursday only; **Do not aliquot; Specimen must remain at ambient temperature; Do not refrigerate; Do not freeze;** Deliver the specimen to the performing lab at Cleveland Clinic Laboratories within **48 hours** of collection; Ambient	5/5/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Lymphocyte Transformation Test to Candida Antigen	LTT	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** **Ratio** **Phytohemagglutinin** **Comment** **Staff Review** **Test Name:** Previously Lymphocyte Transformation Test **Special Information:** Specimens should be sent only Monday through Thursday by 4:00 p.m. EST. Specimen must remain at ambient temperature. Do not refrigerate. Do not freeze. Specimens **will** be cancelled if they arrive in the lab greater than 24 hours post collection. Please call Cleveland Clinic Laboratories at 800.628.6816 to set up the order. If shipping specimen, make sure it is in an ambient mailer and marked as "critical specimen." **Clinical Information: The test is used to assess lymphocytes proliferative response to Candida antigen. This is especially useful in patients suspected of having chronic mucocutaneous candidiasis. Clinical correlation is required. The test is reviewed and signed out by staff.** **Stability:** Ambient: **24** hours Refrigerated: Unacceptable Frozen: Unacceptable **Reference Range:** **Ratio: ≥ 2.0 SI** **Phytohemagglutinin: ≥ 50.0 SI**	5/5/20
Mitogen LTT	LTTMS	**Test Name:** Previously LTT Mitogen Screen **Stability:** Ambient: **24** hours Refrigerated: Unacceptable Frozen: Unacceptable	5/5/20
Protein, Total	TP	**Stability:** Ambient: **6 days** Refrigerated: 4 weeks Frozen: **1 year**	4/2/20
Sex Hormone Binding Globulin	SHBG2	**Reference Range:** **Male** **0–17 Years: 14–82 nmol/L Reference ranges for this patient's age group have not been established. These reference ranges reflect verified or established ranges for the adult population. Interpret these ranges with caution using the clinical context and additional reference resources.** 18–99 Years: 14–82 nmol/L **Female** **0–20 Years: 25–122 nmol/L Reference ranges for this patient's age group have not been established. These reference ranges reflect verified or established ranges for the adult population. Interpret these ranges with caution using the clinical context and additional reference resources** 21–49 Years: 25–122 nmol/L 50–99 Years: 17–125 nmol/L	5/12/20
Specific Gravity, Body Fluid	BFSPGV	**Reference Range: < 1.015**	5/24/20
Supersaturation Profile, 24 Hour Urine	SSAT24	**For Interfaced Clients Only: Test build may need to be modified** **Special Information: Specimens with pH > 8.0 will be rejected.**	4/9/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Treponema Pallidum IgG	TPAG	**Clinical Limitation: This test cannot distinguish venereal syphilis from endemic treponematoses. Final interpretation should be done in conjunction with treponemal confirmatory testing, RPR test result, and clinical correlation.** **Clinical Information: This confirmatory test is typically used as part of the syphilis reverse sequence testing algorithm where the screening test is reactive, but RPR is non-reactive. In general: A negative result cannot exclude recent Treponemal infection if specimen is collected within 7–10 days after appearance of suspect lesions or 2–3 weeks after an exposure. Clinical correlation is required. An equivocal result cannot exclude nonspecific reactivity or very recent Treponemal infection. Repeat testing is suggested 2–3 weeks after this draw if clinically warranted. A positive result suggests recent or past Treponemal infection. This test cannot distinguish venereal syphilis from endemic treponematoses. Final interpretation should be done in conjunction with treponemal confirmatory testing, RPR test result, and clinical correlation. Should further interpretation be needed, please contact Cleveland Clinic Laboratories at 800.628.6816.** **Days Performed:** Tuesday, **Thursday** **Reported:** 1–5 days	Effective immediately
TSH	TSH	**Note:** *Special Information will be removed.*	5/27/20
TSH Binding Inhibition	TBI	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** TSH Binding Inhibition **TSH Binding Inhibition, Qualitative** **Clinical Information: TSH receptor binding inhibition (TBI) test is based on a competitive Enzyme-Linked Immunosorbent Assay (ELISA) and detects all TSHR binding antibodies which may be used as an aid in diagnosis of autoimmune thyroid diseases. The results may be positive in both autoimmune hypo- and hyperthyroidism. Low positive results may occasionally be seen in non-autoimmune thyroid disorders, such as nodules, or in other autoimmune diseases. Clinical correlation is required.** **Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14 days** **Reference Range:** TSH Binding Inhibition (0–99 Years): ≤ **1.00 IU/L** **TSH Binding Inhibition, Qualitative: Negative**	5/5/20
Uric Acid	URIC	**Stability:** Ambient: **3 days** Refrigerated: **7** days Frozen: 6 months	Effective immediately
Uric Acid, Urine 24 Hour	UURICD	**Specimen Requirement:** 5 mL 24-hour urine (well-mixed) in a clean container; Minimum: 1 mL; **Mix well prior to decanting; Ambient** **Stability:** Ambient: **7 days with post collection NaOH treatment** Refrigerated: **7 days with post collection NaOH treatment** **Days Performed: 7 days per week** **Reported: 24** hours	Effective immediately
Uric Acid, Urine Random	UURICR	**Specimen Requirement:** 5 mL random urine in a clean container; Minimum: 1 mL; **Mix well prior to decanting; Ambient** **Stability:** Ambient: **7 days with post collection NaOH treatment** Refrigerated: **7 days with post collection NaOH treatment** **Days Performed: 7 days per week** **Reported: 24** hours	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Uric Acid, Urine Timed	UURICT	**Specimen Requirement:** 5 mL timed urine (well-mixed) in a clean container; Minimum: 1 mL; **Mix well prior to decanting; Ambient** **Stability:** Ambient: **7 days with post collection NaOH treatment** Refrigerated: **7 days with post collection NaOH treatment** **Days Performed: 7 days per week** **Reported: 24** hours	Effective immediately
Urinalysis Only	UA	**Reference Range:** Color: Yellow Clarity: Clear Glucose: Negative Ketones: Negative Bilirubin: Negative Specific Gravity: 1.005–1.030 Hemoglobin/Blood: Negative pH: **5.0**–8.0 Protein: Negative Urobilinogen: **Negative** (< 1.1) Ehrlich Units Nitrites: Negative Urine Leukocyte Esterase: Negative	Effective immediately
Urinalysis with Microscopic	UAWMIC	**Reference Range:** Color: Yellow Clarity: Clear Glucose: Negative Bilirubin: Negative Ketones: Negative Specific Gravity: 1.005–1.030 Hemoglobin/Blood: Negative pH: **5.0**–8.0 Protein: Negative Urobilinogen: **Negative** (< 1.1) Ehrlich Units Nitrites: Negative Urine Leukocyte Esterase: Negative Urine WBC: 0–5/HPF Urine RBC: 0–3/HPF Casts: 0/LPF	Effective immediately
Urobilinogen Screen, Urine	UUROB	**Reference Range: Negative** (< 1.1) Ehrlich Units	Effective immediately
VDRL, CSF	VDRLCF	**Clinical Information: Cerebrospinal fluid (CSF) VDRL test is used as an aid in diagnosis of neurosyphilis. CSF VDRL detects non-treponemal antibodies and has lower sensitivity than CSF treponemal tests such as FTA, therefore a negative CSF VDRL result cannot reliably rule out neurosyphilis (including ocular syphilis and otosyphilis). Clinical correlation is required.** **Stability:** Ambient: **24** hours Refrigerated: **7** days Frozen: **14 days**	5/5/20

New Tests

Test Name	Order Code	Change	Effective Date
Chromosome Analysis, Neoplastic Tissue	CHRNPT	**Specimen Requirement:** 2 cubic cm tissue in a sterile container; Tissue should be cut with sterile instruments and placed in sterile container which holds sterile saline; If delay in transport is anticipated, sterile transport media (such as RPMI 1640) should be obtained from Cleveland Clinic Laboratories at 800.628.6816; Refrigerated **Stability:** Ambient: Not preferred; Specimen will be cultured, but environmental conditions will be noted Refrigerated: Preferred Frozen: Not preferred; Specimen will be cultured, but environmental conditions will be noted **Days Performed:** Sunday–Saturday **Reported:** 21 days **CPT:** 88239 x 1, 88264 x 1	5/26/20

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Fructosamine	FRUCTO	$41.00 (non-discountable)	82985	5/19/20

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Canavan Disease Mutation, Whole Blood	CANVAN	This test will no longer be available.	5/26/20
Epi ProColon	EPCOL	**Note:** *This test was previously announced in the March Technical Update as being scheduled for discontinuation on 4/7/20. Please note that this test is no longer scheduled for discontinuation and will remain in our directory. We apologize for any inconvenience this may have caused.*	Effective immediately
Gaucher Disease Mutation, Whole Blood	GAUCHR	This test will no longer be available.	5/26/20
Lung Cancer Hot Spot Panel v2 NGS 2 gene	LNG2GN	This test will no longer be available. Suggest ordering alternative test Lung Cancer Hotspot Gene Panel (LNG550)	5/28/20
Paroxetine	PAROX	This test will no longer be available.	5/7/20
PAX6 Gene Analysis	PAX6	This test will no longer be available.	5/7/20
Sialic Acid, CSF	SIACSF	This test will no longer be available.	5/7/20