Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • August 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.

IMPORTANT UPDATE:

- Effective immediately, all individual allergen and allergen panels are stable refrigerated for 30 days.
- Effective immediately, Tryptase is stable refrigerated for 30 days or frozen for 9 months.
- Effective immediately, Aureobasidium pullulans IgE is stable refrigerated for 30 days or frozen for 30 days.

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
2–3	(1,3) B-D Glucan					■	■	■	■	■	■	■		
3	Allergen, Food, Alpha-Gal IgE					■	■	■	■	■	■	■		
3	Alpha Subunit						■							
6	Anti-Neut Cyto Ab with Rfx to Titer and MPO/PR3 Ab				■									
3	Aspergillus Ab, CF										■			
3	Barbiturates							■	■					
3	Barbiturates Confirmation, Urine							■	■					
3	Coccidioides Ab, CF										■			
3	Coxsackie A Abs										■			
3	CMV, qualitative by PCR, non-blood (CSF, bone marrow, amniotic fluid, ocular fluid);		■											
6	Drgs of Abse, Oral Fluid				■									
6	Drug Analysis, Comprehensive				■									
3	Giardia lamblia IgG, IgA, IgM						■							
6	Gold				■									
3	Histoplasma Ab, CF										■			

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6	HIV 1 Drug Resistance by Next Generation Sequencing			■										
6	HIV-1 Genotype				■									
6	HIV-1 Qualitative Test by PCR				■									
4	IBD Serology Disease Panel					■		■		■				
4	Macroprolactin						■			■		■		
6	Methaqualone, GC/MS, Urine													■
4	Nicotine & Metabolites, Urine							■		■				
4	Oxalate									■				
6	Paraneoplastic Syndrome Ab Panel with Reflex				■									
4	PNH Panel by FCM							■						
5	Prolactin, Dilution Study					■	■			■		■		
6	Urinalysis with Reflex to Microscopic													■
5	Urine Free Cortisol by LC-MS/MS		■											
5	Urogenital Ureaplasma and Mycoplasma Species by PCR						■				■	■		
5	Vitamin D 25 Hydroxy										■			

Test Changes

Test Name	Order Code	Change	Effective Date
(1,3) B-D Glucan	BDGLUC	**Includes (1,3) B-D Glucan (BDGCLN), (1,3) B-D Glucan, Qual (BDGQL)** **Special Information: Certain fungi, such as the genus Cryptococcus which produces very low levels of (1,3)-ß-D-glucan, may not result** **in serum (1,3)-ß-D-glucan sufficiently elevated so as to be detected by the assay. Infections with fungi of the order Mucorales such as Absidia, Mucor and Rhizopus which are not known to produce (1,3)-ß-D-glucan, are also observed to yield low serum (1,3)-ß-D-glucan titers.In addition, the yeast phase of Blastomyces dermatitidis produces little (1,3)-ß-D-glucan and may not be detected by the assay.** **Clinical Limitation: Samples obtained by heel or finger stick methods are unacceptable as the alcohol-soaked gauze used to prepare the site (and, potentially, the skin surface-pooling of blood) has been shown to contaminate the specimens.**The following sample conditions can interfere with an accurate result: hemolysis, turbidity caused by lipemia, visual bilirubin, turbid serum, and elevated levels of Immunoglobulin G.** **Clinical Information: Some individuals have elevated levels of (1,3)-ß-D-glucan that fall into the indeterminate zone. In such cases, additional surveillance testing is recommended**The frequency of patient testing will depend upon the relative risk of fungal infection.Sampling rate to no more than twice a week. The test is also limited to hospitalized patients.** **Specimen Requirement: 0.5 mL Serum from serum separator (Gold) tube; Minimum 0.25 mL; Refrigerated; Heel and fingerstick collections are unacceptable** *(continued on page 3)*	9/30/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
(1,3) B-D Glucan *(continued from page 2)*		**Stability:** Ambient: Unacceptable Refrigerated: **7 days** Frozen: **1 year** **Methodology: Colorimetric, Kinetic** **Reference Range:** **(1,3) B-D Glucan: <60 pg/mL** **(1,3) B-D Glucan, Qual: Negative** **Days Performed: Monday, Wednesday, Friday** **Reported: 1–5 days**	
Allergen, Food, Alpha-Gal IgE	GALIGE	**Special Information: Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York DOH approved.** **Clinical Information: Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. 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: 0.25 mL** serum from Serum Separator (Gold) tube; **Minimum 0.25 mL**; Refrigerated**; Separate serum from cells ASAP or within 2 hours of collection.** **Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: **After separation from cells: 2 weeks** Frozen: **After separation from cells: 1 year** **Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay** **Days Performed: Sunday through Saturday** **Reported: 2–3 days**	8/16/21
Alpha Subunit	ALPSUB	**Specimen Requirement: 1 mL serum from a Serum Separate (Gold) tube** OR 1 mL serum from No additive (Red) top tube; Minimum 0.35 mL**;** Frozen	effective immediately
Aspergillus Ab, CF	ASPRCF	**Reported: 3–6 days**	8/16/21
Barbiturates	BARBS	**Includes:** Butalbital, Pentobarbital, Phenobarbital**. Amobarbital and Secobarbital no longer reported** **Methodology: Quantitative Liquid Chromatography–Tandem Mass Spectrometry**	8/16/21
Barbiturates Confirmation, Urine	UBARBC	**Includes:** Butalbital, Pentobarbital, Phenobarbital**. Amobarbital and Secobarbital no longer reported** **Methodology: Quantitative Liquid Chromatography–Tandem Mass Spectrometry**	8/16/21
Coccidioides Ab, CF	COCICF	**Reported: 3–6 days**	8/16/21
Coxsackie A Abs	COXAAB	**Reported: 3–6 days**	8/16/21
CMV, qualitative by PCR, non-blood (CSF, bone marrow, amniotic fluid, ocular fluid);	CMVCSF	**Name: CMV, qualitative by PCR, non-blood (CSF, bone marrow, amniotic fluid, ocular fluid)** **Alias: CMV, qualitative by PCR, urine**	7/29/21
Giardia lamblia IgG, IgA, IgM	GIAGAM	**Specimen Requirement:** 2 mL serum from a Serum Separate tube or 2 mL serum from No additive (Red) top tube; **Minimum 0.75 mL;** Ambient **Note: Grossly hemolyzed, lipemic, or icteric samples will be rejected**	8/30/21
Histoplasma Ab, CF	HISTCF	**Reported: 3–6 days**	8/16/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
IBD Serology Disease Panel	IBDSER	**Includes:** Saccharomyces cerevisiae IgA (SACCA), Saccharomyces cerevisiae IgG (SACCG), Inflammatory Bowel Disease Interp, **ANCA IFA Titer, ANCA IFA Pattern**, EER Inflammatory Bowel Diseases. **Anti Neutro Cytopl Ab IgG (ANCAG) no longer reported.** **Note: Inflammatory Bowel Disease Panel and Inflammatory Bowel Disease Differentiation Panel aliases have been removed.** **Clinical Information: This test may be a useful tool for distinguishing ulcerative colitis (UC) from Crohn disease (CD) in patients with suspected inflammatory bowel disease. ANCA IFA is simultaneously tested on ethanol- and formalin-fixed slides to allow differentiation of C- and P-ANCA patterns.**	8/16/21
Macroprolactin	MACPRO	**Specimen Requirement:** 1 mL serum from serum separator tube; Frozen; Allow specimen to clot completely at room temperature. **Separate serum from cells and transfer into standard aliquot tube;** minimum 0.5 mL **OR** 1 mL plasma from Litherium Heparin PST (Lt. Green) tube OR 1 mL plasma from EDTA (Lavender) tube; Frozen**; Separate plasma from cells and transfer into standard aliquot tube** **Stability:** **Ambient: After separation from cells: 7 days** Refrigerated: After separation from cells: 7 days **Frozen: After separation from cells: 1 month** **Reference Range:** Prolactin (PLACTN)**:** Female age 10–99 years: **2.8–29.2 ng/mL**	8/16/19
Nicotine & Metabolites, Urine	UNICOT	**Includes:** Nicotine, Cotinine, Anabasine, 3-OH-Cotinine. **Nornicotine no longer reported** **Reference Range:** Nicotine**: <15 ng/mL** Cotinine**: <15 ng/mL** Anabasine**: <5 ng/mL** 3-OH-Cotinine: <50 ng/mL	8/16/21
Oxalate	OXLATE	**Reference Range: <2.1 umol/L**	8/16/21
PNH Panel by FCM	PNHPNL	**Includes:** Interpretation**, PNH RBC Clone-complete Ag loss (TYPE III), PNH RBC Clone-Partial Ag Loss (TYPE II), Sum of PNH RBC Clones (Type II + Type III) Ag loss,** PNH Granulocyte clone**,** Reviewed by **Special Information:** Do not draw on Fridays, weekends or holidays. Specimens greater than 48 hours old will be rejected. **Clinical Information:** The presence of paroxysmal nocturnal hemoglobinuria (PNH) clones in the erythrocyte and granulocyte populations is assessed in this procedure. For erythrocytes antibodies to Glycophorin A are used to specifically gate red cells and PNH clones are identified by lack of CD59 expression **for Type III, Type II and Sum of Type II and Type III cells.** For granulocytes, CD15 and CD 33 are used to specifically gate granulocytes. The PNH-type granulocytes are then identified by lack of expression of CD24 and lack of reactivity to Fluorescent Aerolysin (FLAER). The lower limit of detection for this assay is 0.01% PNH-type cells. The presence of a PNH clone occurs in classical hemolytic PNH, generally at levels above 1%. PNH clones may be seen in other disorders such as aplastic anemia and myelodysplastic syndrome. Thus, these results must be put in context of the clinical findings **Reference Range**: Interpretation: NEG **PNH RBC Clone-complete Ag loss (TYPE III): <0.01%** **PNH RBC Clone-Partial Ag loss (TYPE II): <0.01%** PNH Granulocyte clone: <0.01%	8/7/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Prolactin, Dilution Study	PROLM	**Special Information: Allow serum specimen to clot completely at room temperature. This test is New York DOH approved.** **Clinical Information:** This test is intended for patients with prolactin-secreting macroadenomas, where a high-dose hook effect is a consideration. **Pregnancy, lactation, and the administration of oral contraceptives can increase prolactin concentrations.** **Specimen Requirement:** 1 mL serum from serum separator tube; Frozen; Allow specimen to clot completely at room temperature. **Separate serum from cells and transfer into standard aliquot tube; minimum 1 mL** OR 1 mL plasma from Litherium Heparin PST (Lt. Green) tube OR 1 mL plasma from EDTA (Lavender) tube; Frozen; **Separate plasma from cells and transfer into standard aliquot tube** **Stability:** Ambient: After separation from cells: 7 days Refrigerated: **After separation from cells: 7 days** Frozen: **After separation from cells: 1 month** **Reference Range:** Prolact Macroadenoma (PROLMA)**:** Female age 10-99 years**: 2.8–29.2 ng/mL (Nonpregnant)**	8/16/19
Urine Free Cortisol by LC-MS/MS	UFRCRT	**Name: Urine Free Cortisol by LC-MS/MS**	10/21/21
Urogenital Ureaplasma and Mycoplasma Species by PCR	URMPCR	**Specimen Requirement:** Swab, GENITAL IN Viral Transport Media; Transfer genital swab to VTM. Specimen source required; Frozen OR 1 mL Urine, Random in Viral Transport Media; Transfer 1 mL urine to VTM. Specimen source required; Frozen OR Cervical Thin Prep; Collect Cervical specimen using ThinPrep Pap Test Collection kit. Vortex ThinPre PreservCyt solution and transfer 1 mL into a sterile container. Specimen source required; Frozen OR Vaginal Thin Prep; Collect vaginal specimen using ThinPrep Pap Test Collection kit. Vortex ThinPrep PreservCyt solution and transfer 1 mL into a sterile container. Specimen source required; Frozen **OR Swab, Rectal in Viral Transport Media; Transfer rectal swab to VTM. Specimen source required; Frozen** **OR Swab, Respiratory in Viral Transport Media; Transfer respiratory swab to VTM. Specimen source required; Frozen** **OR 1 mL Bronch (BAL) in Sterile container; Specimen source required; Minimum 0.5 mL; Frozen** **OR 1 mL Sputum in Sterile container; Specimen source required; Minimum 0.5 mL; Frozen** **OR 1 mL Aspirate, tracheal in Sterile Container; Specimen source required; Minimum 0.5 mL; Frozen** **Stability:** Ambient: **48 hours** Refrigerated: 10 days Frozen: **14 days** **Days Performed: Monday, Wednesday, Friday**	8/16/21
Vitamin D 25 Hydroxy	VITD	**Days Performed**: Monday through Saturday. **Testing is not performed on Sunday.**	8/3/21

New Tests

Test Name	Order Code	Change	Effective Date
Urinalysis with Reflex to Microscopic	LAB1237	**CPT: 81003** **Price: $25.00**	8/7/21
HIV 1 Drug Resistance by Next Generation Sequencing	HIVNGS	**Special Information:** Please submit most recent viral load and test date, if available. Serum and heparinized specimens are unacceptable. **Clinical Limitation:** This test detects populations down to 10 percent of the total population which may account for resistance interpretation differences between methods. Some insertions or deletions may be difficult to detect using this software. This test may be unsuccessful if the plasma HIV-1 RNA viral load is less than 500 copies per mL of plasma. **Clinical Information:** This assay predicts HIV-1 resistance to protease inhibitors, nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and integrase inhibitors. The protease gene, integrase gene and the reverse transcriptase gene of the viral genome are sequenced using Next Generation Sequencing. Drug resistance is assigned using the Stanford hivdb database. This test should be used in conjunction with clinical presentation and other laboratory markers. A patient's response to therapy depends on multiple factors, including patient adherence, percentage of resistant virus population, dosing, and drug pharmacology issues. **Specimen Requirement:** 2.5 mL plasma from EDTA (Lavender) tube; Minimum 1.5 mL; Frozen; Separate plasma from cells within 24 hours and transfer plasma to a standard aliquot tube. Please submit most recent viral load and test date, if available. **Stability:** Ambient: After separation from cells: 24 hours Refrigerated: After separation from cells: 72 hours Frozen: After separation from cells: 3 months **Methodology:** Massive Parallel Sequencing **Days Performed: S**unday through Saturday **Reported:** 5–11 days	8/16/21

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Methaqualone, GC/MS, Urine	UMETHA	$166.00; Nondiscountable	CPT: 80368	effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Anti-Neut Cyto Ab with Rfx to Titer and MPO/PR3 Ab	NCYTO	This test will no longer be available – suggested replacement: Neutrophil Cytoplasmic Antibody (ANCA)	8/16/21
Drgs of Abse, Oral Fluid	ORLDOA	This test will no longer be available	7/29/21
Drug Analysis, Comprehensive	DRANCO	This test will no longer be available	7/29/21
Gold	GOLD	This test will no longer be available	7/29/21
HIV-1 Genotype	HIVGEN	This test will no longer be available – replaced by (new) test HIV 1 Drug Resistance by Next Generation Sequencing (HIVNGS)	8/16/21
HIV-1 Qualitative Test by PCR	HIV1QL	This test will no longer be available – order HIV Quant RNA by PCR	9/7/21
Paraneoplastic Syndrome Ab Panel with Reflex	PARSYN	This test will no longer be available – suggested replacement: Paraneoplastic Autoantibody Evaluation, Serum (PARNEO)	8/3/21