Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • July 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
6	Aldosterone Suppression				■									
5	ALLOGEN AutoAntibody			■										
2	Androstenedione						■		■	■	■	■		
3	Antiglobulin Test, Indirect					■								
3	BCR/ABL1 Mutation Analysis for Tyrosine Kinase Inhibitor Resistance by NGS						■							
3	Blood Type & Screen, Prenatal Workup					■								
3	CD19 Count							■						
6	Complement Factor B				■									
3	Complete Blood Count and Differential							■		■				
6	C-Peptide Suppression				■									
3	Cryptosporidium & Giardia Antigens by EIA											■		
6	Flow Cytometry for Myeloma				■									
6	Flow Cytometry Hold Sample				■									
4	G-6-PD Quantitative					■	■		■	■	■	■		
4	Iron Stain						■							
4	Lyme Western Blot											■		
4	Methaqualone, GC/MS					■	■				■	■		
6	Myasthenia Gravis Evaluation with Muscle-Specific Kinase (MuSK) Reflex, Serum				■									
6	Myasthenia Gravis (MG)/Lambert-Eaton Syndrome (LES) Evaluation, Serum				■									
6	Norwalk-Like Virus Antigen				■									

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6	Nuclear TdT by FCM				■									
6	Peripheral Blood Low Grade Leuk Markers				■									
6	Rapid PCR Assay for Influenza/RSV				■									
4	Risperidone & Metabolite					■				■				
6	Surface/Cytoplasmic IgM by FCM				■									
4	T cell V-Beta by Flow Cytometry							■						
5	Type and Screen					■								
5	Urinalysis Only					■		■						
5	Urinalysis with Microscopic							■			■			
6	Urinalysis with Reflex to Microscopic			■										

Test Changes

Test Name	Order Code	Change	Effective Date
Androstenedione	ANDROS	**Specimen Requirement:** 1 mL Serum from Serum Separator (Gold) tube; Minimum 0.5 mL; Refrigerated *OR* 1 mL **plasma from Lithium Heparin Plasma Separator (Light Green) tube;** Minimum 0.5 mL**; Spin and remove from cells within 2 hours of collection; Refrigerated** *OR* 1 mL **plasma from EDTA (Lavender) tube;** Minimum 0.5 mL**; Spin and remove from cells within 2 hours of collection; Refrigerated** **Stability:** Ambient: **5 days** Refrigerated: **6 months** Frozen: **14 days (one freeze thaw allowed)** **Methodology: Electro Chemiluminescence Immunoassay (ECLIA)** **Reference Range:** Androstenedione **Male** **6-12 Months: <0.3 ng/mL** **1-7 Years: <0.3 ng/mL** **8-9 Years: <0.4 ng/mL** **10-11 Years: <0.5 ng/mL** **12-13 Years: <0.7 ng/mL** **14-15 Years: <1.0 ng/mL** **16-17 Years: 0.3-1.1 ng/mL** **18-99 Years: <1.6 ng/mL** **Female** **6-12 Months: <0.3 ng/mL** **1-7 Years: <0.3 ng/mL** **8-9 Years: <0.5 ng/mL** **10-11 Years: <1.3 ng/mL** **12-13 Years: <1.8 ng/mL** **14-15 Years: 0.4-2.0 ng/mL** **16-17 Years: 0.4-2.1 ng/mL** **18-99 Years: <1.6 ng/mL** Days Performed: Monday–Friday Reported: 1–3 days	8/3/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Antiglobulin Test, Indirect	IAGT	**Special Information: Does not include a crossmatch. Those specimens with a positive antibody screen will have antibody identification performed and will incur additional fees. All blood bank samples must be labeled with the patient's full name, date of birth, medical record number (or other unique number), date and time of sample collection, and the employee ID of the phlebotomist. Please see internal operating procedures for specimens collected outside of the Cleveland Clinic health system.** **Clinical Information:** Detect red cell antibody or antibodies in patient's serum. **The direct antiglobulin test detects in vivo sensitization of red cells with IgG or complement. Indications include transfusion reaction, hemolytic disease of the fetus and newborn, passenger lymphocyte syndrome following stem cell or solid organ transplantation, and immune hemolytic anemia. If IgG sensitization is detected, depending on the clinical situation, eluate testing for new red cell alloantibodies may be required.**	7/28/21
BCR/ABL1 Mutation Analysis for Tyrosine Kinase Inhibitor Resistance by NGS	KINASE	**Specimen Requirement:** 5 mL whole blood in EDTA (Lavender) tube; Minimum: 1 mL; **Critical refrigerated**; **Specimen must be delivered to Cleveland Clinic Laboratories by 3 pm EST; DO NOT collect the day before or the day of a major holiday; Separate specimens must be submitted when muliple tests are ordered;** Refrigerated ***OR*** 3 mL Bone Marrow; Minimum: 1 mL**; Critical refrigerated; Specimen must be delivered to Cleveland Clinic Laboratories by 3 pm EST; DO NOT collect the day before or the day of a major holiday; Separate specimens must be submitted when muliple tests are ordered;** Refrigerated	Effective immediately
Blood Type & Screen, Prenatal Workup	TSPN	**Special Information:** Those specimens with a positive antibody screen will have antibody identification performed and will incur additional fees. Antibody may be too weak to be detected and/or identified. Antibody Titer will be done if indicated. **All blood bank samples must be labeled with the patient's full name, date of birth, medical record number (or other unique number), date and time of sample collection, and the employee ID of the phlebotomist. Please see internal operating procedures for specimens collected outside of the Cleveland Clinic health system.** **Clinical Information:** Identification of risk of hemolytic disease of the newborn. If the antibody screen is positive and the antibody has been associated with hemolytic disease of the fetus and newborn, it will reflex to do the antibody titration**. The direct antiglobulin test detects in vivo sensitization of red cells with IgG or complement. Indications include transfusion reaction, hemolytic disease of the fetus and newborn, passenger lymphocyte syndrome following stem cell or solid organ transplantation, and immune hemolytic anemia. If IgG sensitization is detected, depending on the clinical situation, eluate testing for new red cell alloantibodies may be required.**	7/28/21
CD19 Count	ABS19	Component for WBC removed	8/7/21
Complete Blood Count and Differential	CBCDIF	**For interface clients only–Test build may need to be modified** **Note: Component added for Immature Gran percent and Immature Gran Absolute** **Reference Range:** **Immature Gran Abs** **0-1 Days: <0.29 K/uL** **2-13 Days: <0.28 K/uL** **14-30 Days: <0.23 K/uL** **31-90 Days: <0.10 K/uL** **91-179 Days: <0.07 K/uL** **0.5-1 Year: <0.15 K/uL** **2-5 Years: <0.07 K/uL** **6-11 Years: <0.05 K/uL** **12-17 Years: <0.04 K/uL** **18-999 Years: <0.10 K/uL** **Immature Gran %** **Refer to Absolute Value** **Note: No other reference ranges for CBC and Differential are changing**	Effective immediately
Cryptosporidium & Giardia Antigens by EIA	OVAPSC	**Stability:** Ambient: Preserved: 2 months; Unpreserved: **30 minutes** Refrigerated: Preserved: 2 months; Unpreserved: **30 minutes** Frozen: Preserved: 2 months; Unpreserved: Unacceptable	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
G-6-PD Quantitative	G6PDQT	**Special Information:** Do NOT freeze**. Grossly** hemolyzed, clotted or frozen specimens are unacceptable. **Note:** G6PD added as an alias **Specimen Requirement:** 3 mL whole blood in ACD A (Yellow) tube; Minimum 1.5 mL; Enzyme most stable in acid citrate dextrose (ACD). Do NOT freeze; Refrigerated OR 3 mL whole blood in EDTA (Lavendar) tube; Refrigerated (do not freeze) **Note: *3 mL whole blood in Sodium or Lithium Heparin (green) tube is no longer acceptable.*** **Stability:** Ambient: **24 hours** Refrigerated: **7 days** Frozen: Unacceptable **Methodology: Colorimetric, Kinetic,** Quantitative Enzymatic **Reference Range:** **G-6-PD Quantitative:** **0–99 years: 9.8-15.5 U/g Hb** **Days Performed: Monday–Friday** **Reported:** 2-4 days	8/30/21
Iron Stain	FESTMS	**Specimen Requirement: 1-2 mL Bronch (BAL) in clean container; Minimum 0.5 mL; Ambient; Send enough specimen to make 3 smears on glass slides. Label specimen with patient's name, patient number, time and date of collection.** **Note : blood is no longer an acceptable specimen**	8/7/21
Lyme Western Blot	LYMEWB	**Stability:** Ambient**: 3 days** Refrigerated**:** 14 days Frozen**: 30 days**	Effective immediately
Methaqualone, GC/MS, Urine	UMETHA	**Note:** *Clinical Information will be removed* **Specimen Requirement: 2 mL Urine, random clean container; Minimum 0.7 mL;** Refrigerated **Stability:** Ambient: **7 days** Refrigerated: **14 days** Frozen: 1 year **Days Performed: Varies** **Reported: 9-10 days**	7/19/21
Risperidone & Metabolite	RISPER	**Special Information:** Patient Prep: Pre-dose (trough) draw–At steady state concentration. Gel separator tubes are not acceptable. **Whole blood specimens will be rejected.** Light blue (citrate) or yellow (SPS or ACD solution) tubes are unacceptable. This test is New York DOH approved. **Note**: *Risperdal will be removed as an alias name.* **Clinical Information:** Optimize drug therapy and monitor patient adherence. This test detects risperidone (parent) and paliperidone (9-hydroxyrisperidone, metabolite). **The therapeutic range is based on serum pre-dose (trough) draw at steady-state concentration.** Adverse effects to risperidone therapy may include headache, nausea, dizziness, tachycardia, orthostatic hypotension and dyskinesia. **Reference Range:** **Therapeutic range (Risperidone) 20-60 ng/mL** **Therapeutic range (9-hydroxyrisperidone (Paliperidone)) 20-60 ng/mL** **Toxic range (Risperidone and Metabolite) Greater than 120 ng/mL**	Effective immediately
T cell V-Beta by Flow Cytometry	TVBETA	Flow Slide (FLOSLD) added	8/7/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Type and Screen	TSCR	**Special Information:** Does not include a crossmatch. Those specimens with a positive antibody screen will have antibody identification performed and will incur additional fees. **All blood bank samples must be labeled with the patient's full name, date of birth, medical record number (or other unique number), date and time of sample collection, and the employee ID of the phlebotomist. Please see internal operating procedures for specimens collected outside of the Cleveland Clinic health system.** **Clinical Information:** Identify blood group and type; screen the serum for the presence of red cell antibodies prior to transfusion. **The direct antiglobulin test detects in vivo sensitization of red cells with IgG or complement. Indications include transfusion reaction, hemolytic disease of the fetus and newborn, passenger lymphocyte syndrome following stem cell or solid organ transplantation, and immune hemolytic anemia. If IgG sensitization is detected, depending on the clinical situation, eluate testing for new red cell alloantibodies may be required.**	7/28/21
Urinalysis Only	UA	**For interface clients only–Test build may need to be modified** **Special Information:** Protein measurements from UA on visibly bloody samples will be reported as: "Visible blood causes falsely elevated results for analyte Protein. Due to this limitation, Protein will not be reported for patients whose urine contains visible blood**".**	Effective immediately
Urinalysis with Microscopic	UAWMIC	**For interface clients only: Test build may need to be modified** **Note: Component added for Bacteria** **Reference range:** Color: Yellow Clarity: Clear Glucose: Negative mg/dL Bilirubin: Negative Ketones: Negative Specific Gravity: 1.005–1.030 Hemoglobin/Blood: Negative pH: 5.0–8.0 Protein: Negative mg/dL Urobilinogen: Negative (<1.1) Ehrlich Units Nitrogen: Negative Urine Leukocyte Esterase: Negative Urine WBC: 0–5 /HPF Urine RBC: 0–3 /HPF Casts: 0 /LPF **Bacteria: None Seen /HPF**	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
ALLOGEN AutoAntibody	LAB1507	**Specimen Requirement:** 18 mL whole blood in a plain no additive (red) tube; Three 6 mL red top tubes; DO NOT CENTRIFUGE OR SEPARATE; Ambient **Stability:** Ambient: 7 days **Methodology:** Multiplex Bead Assay **Days Performed:** Monday–Friday **Reported:** 15 days **CPT:** 83516	7/15/21

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Urinalysis with Reflex to Microscopic	LAB1237	**Special Information:** If Hemoglobin/Blood, Leukocyte Esterase and/or Protein is/are positive, then Microscopic Analysis will be performed and billed. Protein measurements from UA on visibly bloody samples will be reported as: "Visible blood causes falsely elevated results for analyte Protein. Due to this limitation, Protein will not be reported for patients whose urine contains visible blood". **Clinical Information:** Detection of abnormal urinary chemical or cellular elements **Specimen Requirement:** 10 mL urine random in clean container; Minimum 5 mL; Refrigerated *OR* 7 mL urine random in BD Urine Preservative tube (Yellow); Minimum 7 mL; Ambient **Stability:** Ambient: 2 hours clean container; 72 hours BD Urine Preservative tube Refrigerated: 24 hours clean container; 72 hours BD Urine Preservative tube **Methodology:** Chemical **Days Performed:** Sunday through Saturday **Reported:** 8 hours **CPT:** 81003	Effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Aldosterone Suppression	ALDOSU	this test will no longer be available	effective immediately
Complement Factor B	C3PA	this test will no longer be available	effective immediately
C-Peptide Suppression	CPEPSP	this test will no longer be available	effective immediately
Flow Cytometry for Myeloma	FCMYEL	this test will no longer be available	8/7/21
Flow Cytometry Hold Sample	FLOHLD	this test will no longer be available	8/7/21
Myasthenia Gravis Evaluation with Muscle-Specific Kinase (MuSK) Reflex, Serum	MYSGRV	this test will no longer be available	effective immediately
Myasthenia Gravis (MG)/Lambert-Eaton Syndrome (LES) Evaluation, Serum	MGLESE	this test will no longer be available	8/3/21
Norwalk-Like Virus Antigen	NORWLK	this test will no longer be available; recommended replacement: Norovirus Group 1 and 2 Detection by PCR (NORPCR).	effective immediately
Nuclear TdT by FCM	TDTNUC	this test will no longer be available	8/7/21
Peripheral Blood Low Grade Leuk Markers	PBLGLY	this test will no longer be available	8/7/21
Rapid PCR Assay for Influenza/RSV	FLRSV	this test will no longer be available	effective immediately
Surface/Cytoplasmic IgM by FCM	IGMCYT	this test will no longer be available	effective immediately