

Technical Update • March 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	Name Change Order Code	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
2	Aldolase												
2	Beta-2-Microglobulin, Serum												
2	Calcium, Total												
2, 6	Chromosome Analysis, Blood												
6	Chromosome Analysis with Reflex AML FISH panel												
6	Chromosome Analysis with Reflex MDS FISH												
2	Cysticercus IgG Ab, CSF												
6	Epi ProColon												
5	FISH for Renal Cell Carcinoma Panel												
5	FISH for Renal Cell Carcinoma TFE3												
5	FISH for Renal Cell Carcinoma TFEB												
3	HLA-B51												
3	IgG CSF Index												
3	Immune Function Assay ATP												
5	Lactate												
3	Legionella Urinary Ag.												
3	Mitotane												
6	Mucopolysaccharides (MPS), Quantitative, Urine												
6	Mucopolysaccharides (MPS) Screen, Urine												
3	Neuronal Ceroid Lipofuscinosis Enzyme CLN1												
4	Neuronal Ceroid Lipofuscinosis Enzyme CLN2												
6	Niemann-Pick Disease Type A Mutation, Fluid												
6	Polyols, Urine												

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
4	Protein Electrophoresis, Serum												
4	Protein Electrophoresis, Serum, with IFE												
4	STRATIFY JCV Antibody and Index with Reflex to Inhibition Assay												
6	Thyroid Cancer Mutation Panel												
6	Trifluoperazine												

Test Changes

Test Name	Order Code	Change	Effective Date
Aldolase	ALD	Stability: Ambient: 3 days Refrigerated: 30 days Frozen: 6 months	3/3/20
Beta-2-Microglobulin, Serum	B2M	Stability: Ambient: 3 days Refrigerated: 3 days Frozen: 6 months Reference Range: 0–59 Years: 0.8–2.4 mg/L 60–99 Years: < 3.1 mg/L	Effective immediately
Calcium, Total	CA	Methodology: NM-BAPTA	Effective immediately
Chromosome Analysis, Blood	CHRBLD	CPT: 88230 x 1, 88262 x 1, 88289 x 1	Effective immediately
Cysticercus IgG Ab, CSF	CYSGCS	Special Information: Serum will be rejected. Contaminated, heat-inactivated, hemolyzed, lipemic, or icteric specimens are unacceptable. Clinical Information: Diagnosis of central nervous system infections can be accomplished by demonstrating the presence of intrathecally-produced specific antibody. Interpretation of results may be complicated by low antibody levels found in cerebrospinal fluid (CSF), passive transfer of antibody from blood, and contamination via bloody taps. A negative result does not rule out infection. If clinical suspicion is high, repeat testing after 4 weeks. Cross-reaction with antibodies against Echinococcus ssp. have been reported. Specimen Requirement: 1 mL cerebrospinal fluid (CSF) in a clean container; Minimum: 0.3 mL; Transfer 1 mL CSF to a standard aliquot tube; Refrigerated Stability: Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year (Avoid repeated freeze/thaw cycles) Reference Range: ≤ 0.8 IV: Negative—No significant level of cysticercosis IgG antibody detected 0.9–1.1 IV: Equivocal—Questionable presence of cysticercosis IgG antibody detected; Repeat testing in 10–14 days may be helpful ≥ 1.2 IV: Positive—IgG antibodies to cysticercosis detected, which may suggest current or past infection Days Performed: Saturday Reported: 2–9 days	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
HLA-B51	HLAB	<p>Test Name: Previously HLA-B</p> <p>Specimen Requirement: 4 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; Ambient</p> <p>Methodology: Sequence Specific Oligonucleotide Probe (SSOP)</p> <p>CPT: 81373 x 1</p>	Effective immediately
IgG CSF Index	TOURT	<p>Clinical Information: Determination of intrathecal IgG synthesis as an aid in the evaluation of central nervous system (CNS) autoimmune diseases, especially multiple sclerosis, and CNS infections such as neurosyphilis and neuroborreliosis, among others.</p> <p>Specimen Requirement: 1 mL cerebrospinal fluid (CSF) in a clean container; Refrigerated</p> <p>*AND* 1 mL serum from a serum separator (gold) tube; Collect cerebrospinal fluid (CSF) and blood within same 24-hour period; Refrigerated</p> <p>(Note: <i>This is a directory update to indicate that both specimen types are required.</i>)</p>	4/28/20
Immune Function Assay ATP	IMMFUN	<p>Special Information: Specimens must be collected Monday–Friday AFTER 6 a.m. EST only and received in testing lab by 12:00 noon EST on the day of collection. Samples must NOT be drawn in green top lithium heparin tubes. Specimen types other than heparinized whole blood collected in sodium heparin tubes are unacceptable. Whole blood that is frozen, refrigerated, clotted, or received in a transfer tube will be rejected. Specimens > 30 hours old will be rejected.</p> <p>Clinical Information: This is an immune cell function assay that detects cell-mediated immunity in an immunosuppressed population. The assay detects cell-mediated immunity by measuring the concentration of adenosine triphosphate (ATP) from CD4 cells following stimulation.</p> <p>Specimen Requirement: 2–3 mL whole blood in a sodium heparin (green) tube; Minimum: 0.5 mL; Specimen must be collected AFTER 6 a.m. EST and received at Cleveland Clinic Laboratories on the day of collection by 12:00 noon EST Monday–Friday; DO NOT collect the day before or after a major holiday; Critical ambient temperature; Ambient</p> <p>Days Performed: Monday–Saturday</p> <p>Reported: 3–4 days</p>	4/14/20
Legionella Urinary Ag.	LEGUAG	<p>Days Performed: Sunday–Friday</p> <p>Reported: 1–3 days</p>	Effective immediately
Mitotane	MTANE	<p>Special Information: Gel-barrier tubes are not recommended.</p> <p>Days Performed: Monday, Wednesday, Friday</p> <p>Reported: 6–10 days</p>	2/27/20
Neuronal Ceroid Lipofuscinosis Enzyme CLN1	CLN1	<p>Clinical Information: Neuronal ceroid lipofuscinoses (NCL) comprise a group of recessively inherited neurodegenerative disorders involved in lysosomal protein catabolism. Clinically, they are characterized by vision loss, seizures, mental regression, behavioral changes, and movement disorders. All patients with classic infantile onset NCL, 8% of patients with late infantile NCL, and 21% of patients with juvenile NCL have a deficiency of palmitoyl protein thioesterase I (PPT).</p> <p>Specimen Requirement: Dried blood spots on filter paper (newborn screening card); 2 full circles; Ambient</p> <p>*OR* 10 mL whole blood in an ACD A or B (yellow) tube; Minimum: 6 mL; Collect Monday–Thursday only; Specimen MUST arrive at Cleveland Clinic Laboratories before 3:00 p.m. EST on the day of collection; Do not spin; Ambient</p> <p>*OR* Two cultured fibroblasts in two T-25 cultured fibroblast flasks; Ambient</p> <p>*OR* 10 mL whole blood in a sodium heparin (green) tube; Minimum: 6 mL; Collect Monday–Thursday only; Specimen MUST arrive at Cleveland Clinic Laboratories before 3:00 p.m. EST on the day of collection; Do not spin; Ambient</p> <p>Stability: Ambient: 24 hours Refrigerated: 48 hours Frozen: Unacceptable</p> <p>Days Performed: Varies (one day per week)</p> <p>Reported: 8–11 days</p>	3/5/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Neuronal Ceroid Lipofuscinosis Enzyme CLN2	CLN2	<p>Clinical Information: Approximately 80% of patients with late infantile Neuronal Ceroid Lipofuscinosis (NCL) and 7% of patients with juvenile onset NCL have a deficiency of the lysosomal enzyme tripeptidyl peptidase 1 (TPP1). The disease is characterized by seizures, ataxia, myoclonus, psychomotor retardation, speech impairment, and vision loss.</p> <p>Specimen Requirement: Dried blood spots on filter paper (newborn screening card); 2 full circles; Ambient</p> <p>*OR* 10 mL whole blood in an ACD A or B (yellow) tube; Minimum: 6 mL; Collect Monday–Thursday only; Specimen MUST arrive at Cleveland Clinic Laboratories before 3:00 p.m. EST on the day of collection; Do not spin; Ambient</p> <p>*OR* Two cultured fibroblasts in two T-25 cultured fibroblast flasks; Ambient</p> <p>*OR* 10 mL whole blood in a sodium heparin (green) tube; Minimum: 6 mL; Collect Monday–Thursday only; Specimen MUST arrive at Cleveland Clinic Laboratories before 3:00 p.m. EST on the day of collection; Do not spin; Ambient</p> <p>Stability: Ambient: 24 hours Refrigerated: 24 hours Frozen: Unacceptable</p> <p>Days Performed: Varies (one day per week)</p> <p>Reported: 8–11 days</p>	3/5/20
Protein Electrophoresis, Serum	SEPG	<p>Reference Range: Total protein (18–99 Years): 6.3–8.0 g/dL Albumin: 3.37–4.23 g/dL Alpha-1 globulin: 0.18–0.31 g/dL Alpha-2 globulin: 0.52–0.97 g/dL Beta globulin: 0.84–1.36 g/dL Gamma globulin: 0.70–1.44 g/dL M Spike Concentration: 0.00 g/dL</p>	4/28/20
Protein Electrophoresis, Serum, with IFE	SEPGRX	<p>Reference Range: Total protein (18–99 Years): 6.3–8.0 g/dL Albumin: 3.37–4.23 g/dL Alpha-1 globulin: 0.18–0.31 g/dL Alpha-2 globulin: 0.52–0.97 g/dL Beta globulin: 0.84–1.36 g/dL Gamma globulin: 0.70–1.44 g/dL M Spike Concentration: 0.00 g/dL</p>	4/28/20
STRATIFY JCV Antibody and Index with Reflex to Inhibition Assay	JCVIDX	<p>Special Information: The STRATIFY JCV Antibody and Index with Reflex to Inhibition will be performed at no charge. Interpretive criteria: Negative: < 0.20; Indeterminate: 0.20–0.40; Positive: > 0.40. Hemolyzed specimens will be rejected. If reflexed, turnaround time may be extended.</p> <p>Clinical Information: JC Virus (JCV) is associated with progressive multifocal leukoencephalopathy (PML). Detection of antibodies to JCV in serum or plasma is a reliable indicator of exposure to JCV. The analytical performance characteristics were determined for multiple sclerosis patients.</p> <p>Days Performed: Monday–Saturday</p> <p>Reported: 2–5 days</p>	2/27/20

New Tests

Test Name	Order Code	Change	Effective Date
FISH for Renal Cell Carcinoma Panel	TRFCCP	<p>Specimen Requirement: 4 μm formalin-fixed paraffin-embedded (FFPE) block slides; Minimum: 4 μm; Pre and post H&E with four unstained slides with defined marked areas for analysis; Ambient</p> <p>Stability: Ambient: FFPE slides at room temperature</p> <p>Methodology: Fluorescent In-Situ Hybridization (FISH)</p> <p>Days Performed: 5 days per week</p> <p>Reported: 5 days</p> <p>CPT: 88377 x 2</p> <p>Price: \$808.00 (non-discountable)</p>	Effective immediately
FISH for Renal Cell Carcinoma TFE3	TFE3RC	<p>Specimen Requirement: 4 μm formalin-fixed paraffin-embedded (FFPE) block slides; Minimum: 4 μm; Pre and post H&E with four unstained slides with defined marked areas for analysis; Ambient</p> <p>Stability: Ambient: FFPE slides at room temperature</p> <p>Methodology: Fluorescent In-Situ Hybridization (FISH)</p> <p>Days Performed: Monday–Friday</p> <p>Reported: 5 days</p> <p>CPT: 88377 x 1</p> <p>Price: \$615.00 (non-discountable)</p>	Effective immediately
FISH for Renal Cell Carcinoma TFEB	TFEBRC	<p>Specimen Requirement: 4 μm formalin-fixed paraffin-embedded (FFPE) block slides; Minimum: 4 μm; Pre and post H&E with four unstained slides with defined marked areas for analysis; Ambient</p> <p>Stability: Ambient: FFPE slides at room temperature</p> <p>Methodology: Fluorescent In-Situ Hybridization (FISH)</p> <p>Days Performed: 5 days per week</p> <p>Reported: 5 days</p> <p>CPT: 88377 x 1</p> <p>Price: \$588.00 (non-discountable)</p>	Effective immediately
Lactate	LACT	<p>Special Information: PEDIATRIC METABOLIC STUDIES-order Lactate, Precipitated (LACPRE, 81323)</p> <p>Clinical Information: Avoid hemostasis (e.g., tourniquet use). Specimen on ice immediately. Separate from cells within 60 minutes of collection. Evaluation of lactic acidosis</p> <p>Specimen Requirement: 1 mL plasma from a potassium oxalate/sodium fluoride (gray) tube; Minimum: 0.4 mL; Avoid hemostasis (e.g., tourniquet use); Place specimen immediately on ice; Separate from cells within 60 minutes of collection and aliquot into CCL aliquot tube; Centrifuge, aliquot and refrigerate</p> <p>Stability: Ambient: After separation from cells: 8 hours Refrigerated: After separation from cells: 14 days Frozen: Unacceptable</p> <p>Methodology: Colorimetric Enzyme Assay</p> <p>Reference Range: 0–90 Days: 1.0–3.5 mmol/L 3–24 Months: 1.0–3.3 mmol/L 2–17 Years: 1.0–2.4 mmol/L 18–99 Years: 0.5–2.2 mmol/L</p> <p>Days Performed: 7 days per week</p> <p>Reported: 8 hours</p> <p>CPT: 83605 x 1</p> <p>Price: \$48.00</p>	3/5/20

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Chromosome Analysis, Blood	CHRBLD	\$755.00 (non-discountable)	88230, 88262, 88289	Effective immediately

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Chromosome Analysis with Reflex AML FISH panel	CHRAML	\$452.00 (non-discountable)	88262	Effective immediately
Chromosome Analysis with Reflex MDS FISH	CHRMDS	\$749.00 (non-discountable)	88237, 88262	Effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Epi ProColon	EPCOL	This test will no longer be available.	4/7/20
Mucopolysaccharides (MPS), Quantitative, Urine	UMPSR	This test will no longer be available.	3/3/20
Mucopolysaccharides (MPS) Screen, Urine	UMPSSC	This test will no longer be available.	3/3/20
Niemann-Pick Disease Type A Mutation, Fluid	NIEM2	This test will no longer be available.	4/7/20
Polyols, Urine	UPOLY	This test will no longer be available.	4/30/20
Thyroid Cancer Mutation Panel	TYMUT	This test will no longer be available.	4/30/20
Trifluoperazine	TRIFLU	This test will no longer be available.	4/30/20