

Technical Update • April 2022

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
2	(1,3) B-D Glucan													
2	21 Hydroxylase Antibody													
2	Aldosterone 24 hr, Urine													
2	Aldosterone/Direct Renin Ratio													
2, 6	Chromosome Analysis, Amniotic Fluid													
2, 6	Chromosome Analysis, Chorionic Villus													
3	Coronavirus 2019													
6	Creatinine-Cystatin C eGFR													
3	Cyclosporine													
6	Drug Detection Panel, Umbilical Cord Tissue, with Marijuana Metabolite													
3	Filariasis Abs IgG4													
3, 6	FISH Insight Analysis, Amniotic Fluid													
3	FK506													
3	Infectious Mononucleosis													
4	Lp-PLA2 Activity													
4	Mycoplasma genitalium													
4	Paraneoplastic Autoantibody Evaluation, Serum													
5	Phenobarbital, Free													
5	Polymyositis and Dermatomyositis Panel													
5	Polymyositis Panel													

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6	Schistosoma IgG Ab													
5	T cell V-Beta by Flow Cytometry													
5	Thyroglobulin													
5, 6	Thyroid Cancer (Thyroglobulin) Monitoring													
6	von Willebrand Disease (VWF) Sequencing													

Test Changes

Test Name	Order Code	Change	Effective Date
(1,3) B-D Glucan	BDGLUC	Stability: Ambient: Unacceptable Refrigerated: 7 days Frozen: 1 year	effective immediately
21 Hydroxylase Antibody	21OHAB	Special Information: Grossly hemolyzed or lipemic specimens are unacceptable. This test is New York DOH approved. Specimen Requirement: 1 mL serum from Serum Separator (Gold) tube; Minimum 0.3 mL; Refrigerated; Transfer 1 mL serum to standard aliquot tube. *OR* 1 mL serum from No additive (Red) tube; Minimum 0.3 mL; Refrigerated; Transfer 1 mL serum to standard aliquot	effective immediately
Aldosterone 24 hr, Urine	UALDO1	Reference Range: Aldosterone, Urine (UALDO): <28.1 ug/24 hrs	effective immediately
Aldosterone/Direct Renin Ratio	ALDREN	Reference Range: Aldosterone, Plasma (ALDO): 0 Days–30 Days: Not established 1 Month–12 Months: 5.8–110.0 ng/dL 1 Years–5 Years: <36.0 ng/dL 6 Years–9 Years: <24.0 ng/dL 10 Years–11 Years: <15.0 ng/dL 12 Years–14 Years: <22.0 ng/dL 15 Years–17 Years: 3.0–32.0 ng/dL 18 Years–99 Years: 3.1–35.4 ng/dL Direct Renin (RENDI): 0 Years–40 Years: Upright: 4.2–52.2 pg/mL 41 Years–99 Years: Upright: 3.6–81.6 pg/mL 0 Years–40 Years: Supine: 3.2–33.2 pg/mL 41 Years–99 Years: Supine: 2.5–45.1 pg/mL Aldos/Renin Ratio (ALREN): <3.8	effective immediately
Chromosome Analysis, Amniotic Fluid	FAMCYT	CPT: 88235; 88269 ; 88280; 88285 Price: \$867.00	effective immediately
Chromosome Analysis, Chorionic Villus	CVCYTO	CPT: 88235; 88267; 88280; 88285 Price: \$947.00	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Coronavirus 2019	COVID	<p>Specimen Requirement: 3 mL nasal swab in UTM, VTM, Sterile Saline, Phosphate Buffered Saline or eSwab *OR* 3 mL nasopharyngeal swab in UTM, VTM, Sterile Saline, Phosphate Buffered Saline or eSwab *OR* 3 mL throat swab in UTM, VTM, Sterile Saline, Phosphate Buffered Saline or eSwab *OR* one bronchial aspirate in sterile container *OR* one tracheal aspirate in sterile container *OR* one transtracheal aspirate in sterile container *OR* one bronch (BAL) in sterile container *OR* one nasopharyngeal lavage/wash in sterile container *OR* one sputum in sterile container *OR* one bronch washings in sterile container; Refrigerated</p> <p>Note: <i>saliva specimens are no longer acceptable</i></p>	4/19/22
Cyclosporine	CYCLO	<p>Stability: Ambient: 5 days Refrigerated: 7 days Frozen: 14 days</p>	effective immediately
Filariasis Abs IgG4	FILAR1	<p>Methodology: Immunoassay (IA) Reference Range: < 2.50</p>	effective immediately
FISH Insight Analysis, Amniotic Fluid	ISIGHT	<p>CPT: 88271x5; 88274x2 Price: \$511.00</p>	effective immediately
FK506	FK506	<p>Stability: Ambient: 5 days Refrigerated: 7 days Frozen: 14 days</p>	effective immediately
Infectious Mononucleosis	MONOLX	<p>Test Name: Previously Infectious Mono Slide Test</p> <p>Clinical Information: Infectious Mononucleosis rapid test is used as an aid in diagnosis of acute infection with Epstein-Barr virus (EBV). The antibody levels may occasionally remain elevated up to several months after a primary EBV infection. Final interpretation should be done in conjunction with EBV-specific serology and clinical correlation. False positive results may occasionally be seen with other infectious agents such as Cytomegalovirus, Toxoplasma, and HIV among others as well as non-infectious conditions such as lymphoma. Clinical correlation is required.</p> <p>Specimen Requirement: 0.5 mL serum from Serum Separator (Gold) tube; Minimum 0.25 mL; Centrifuge, aliquot and freeze. *OR* 0.5 mL plasma from EDTA (Lavender) tube; Minimum 0.25 mL *OR* 0.5 mL plasma from Lithium heparin Plasma Separator (Light Green) tube; Minimum 0.25 mL</p> <p>Stability: Ambient: 24 hours Refrigerated: 48 hours Frozen: 3 months</p> <p>Methodology: Immunochromatography</p> <p>Days Performed: 7 days a week 24 hours</p> <p>Reported: 8 hours</p>	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Lp-PLA2 Activity	PLAA2	<p>Special Information: Fasting is preferred, but not required. Grossly hemolyzed specimens will be rejected.</p> <p>Clinical Information: Lipoprotein-associated phospholipase A2 (Lp-PLA2), also known as platelet activating factor acetylhydrolase, is an inflammatory enzyme that circulates bound mainly to low-density lipoproteins and has been found to be localized and enriched in atherosclerotic plaques. In multiple clinical trials, LpPLA2 activity has been shown to be an independent predictor of coronary heart disease and stroke in the general population. Measurement of Lp-PLA2 may be used along with traditional cardiovascular risk factor measures for identifying individuals at higher risk of cardiovascular disease events. Clinical management may include beginning or intensifying risk reduction strategies.</p> <p>Specimen Requirement: 1 mL serum from Serum Separator (Speckled or Tiger Top) tube; Minimum: 0.5 mL; Refrigerated; Fasting is preferred, but not required. Gently invert tube 5 times immediately after draw. DO NOT SHAKE. Allow blood to clot 30 minutes. Centrifuge at 1300 rcf for 10 minutes. *OR* 1 mL serum from Serum Separator (Gold) tube; Refrigerated; Minimum: 0.5 mL; Fasting is preferred, but not required. Gently invert tube 5 times immediately after draw. DO NOT SHAKE. Allow blood to clot 30 minutes. Centrifuge at 1300 rcf for 10 minutes.</p> <p>Note: <i>plasma specimens are no longer acceptable</i></p> <p>Stability: Ambient: 7 days Refrigerated: 28 days Frozen: 28 days</p> <p>Methodology: Enzymatic</p> <p>Reported: 4–5 days</p>	effective immediately
Mycoplasma genitalium	MYGPCR	<p>Test Name: Previously Mycoplasma genitalium by PCR</p> <p>Special Information: Specimen source is required. This test is New York DOH approved.</p> <p>Specimen Requirement: One endocervical APTIMA Collection Unisex swab; Refrigerated *OR* One urethral APTIMA Collection Unisex swab; Refrigerated *OR* One random urine APTIMA Urine specimen collection kit; Refrigerated *OR* One genital Aptima Multitest Collection Kit; Refrigerated</p> <p>Stability: Ambient: Aptima: 30 days Refrigerated: Aptima: 30 days Frozen: Aptima: 90 days</p> <p>Methodology: Transcription-Mediated Amplification</p> <p>Reference Range: Mycoplasma genitalium PCR (MYGPC): Negative</p> <p>Days Performed: Mon–Sat</p> <p>Reported: 2–5 days</p>	effective immediately
Paraneoplastic Autoantibody Evaluation, Serum	PARNEO	<p>For interface clients only: Test build may need to be modified</p> <p>Includes: Interpretive Comments Amphiphysin Ab Anti-Glial Nuclear Ab, Type 1 Anti-Neuronal Nuclear Ab, Type 1 Anti-Neuronal Nuclear Ab, Type 2 Anti-Neuronal Nuclear Ab, Type 3 CRMP-5-IgG Neuronal (V-G) K+ Channel Ab Calcium Channel Bind Ab, P/Q Type and N-Type Purkinje Cell Cytoplasmic Ab Type 1 Purkinje Cell Cytoplasmic Ab Type 2 Purkinje Cell Cytoplasmic Ab Type Tr</p> <p>Note: <i>AChR Ganglionic Neuronal Ab has been removed</i></p> <p>CPT: 86255x9; 83519x2; 86596x1</p>	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Phenobarbital, Free	PHENFR	<p>Includes: Phenobarbital–Unbound</p> <p>Special Information: Gel barrier tubes will be rejected. This test is New York DOH approved.</p> <p>Clinical Limitation: Reporting Limit: 0.5 mcg/mL.</p> <p>Clinical Information: Approximately 54% of phenobarbital is unbound to serum proteins (free) at therapeutic concentrations.</p> <p>Specimen Requirement: 2 mL serum from No additive (Red) tube; Minimum 0.7 mL; Refrigerated; Do not use gel barrier tubes. Separate serum from cells ASAP or within 2 hours of collection and transfer into a standard aliquot tube. *OR* 2 mL plasma from EDTA (Lavender) tube; Minimum 0.7 mL; Refrigerated; Do not use gel barrier tubes. Separate plasma from cells ASAP or within 2 hours of collection and transfer into a standard aliquot tube.</p> <p>Stability: Ambient: 3 months Refrigerated: 3 months Frozen: 18 months</p> <p>Methodology: High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)</p> <p>Reference Range: Phenobarbital–Unbound: Refer to report mcg/mL</p> <p>Days Performed: Varies</p> <p>Reported: 8–9 days</p>	effective immediately
Polymyositis and Dermatomyositis Panel	MYOSPL	<p>Methodology: Immunoblot (IB), Qualitative Immunoprecipitation Semi-Quantitative Multiplex Bead Assay</p>	effective immediately
Polymyositis Panel	POLMYO	<p>Methodology: Immunoprecipitation Semi-Quantitative Multiplex Bead Assay</p>	effective immediately
T cell V-Beta by Flow Cytometry	TVBETA	<p>Stability: Ambient: Specimen must be less than 48 hours old. Specimens greater than 48 hours old will be rejected. Refrigerated: Unacceptable</p>	effective immediately
Thyroglobulin	TG	<p>CPT: 84432; 86800</p>	effective immediately
Thyroid Cancer (Thyroglobulin) Monitoring	THYMON	<p>CPT: 84432; 86800 Price: \$110.00</p>	effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Creatinine-Cystatin C eGFR	CRECYS	Note: New test was announced in the January update, but financial information was not available at that time CPT: 82565, 82610 Price: \$103.00	effective immediately
von Willebrand Disease (VWF) Sequencing	VWFSEQ	Note: New test was announced in the January update, but financial information was not available at that time CPT: 81408 Price: \$2650.00	effective immediately

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Chromosome Analysis, Amniotic Fluid	FAMCYT	\$867.00	88235; 88269; 88280; 88285	effective immediately
Chromosome Analysis, Chorionic Villus	CVCYTO	\$947.00	88235; 88267; 88280; 88285	effective immediately
FISH Insight Analysis, Amniotic Fluid	ISIGHT	\$511.00	88271x5; 88274x2	effective immediately
Schistosoma IgG Ab	SCHIST	\$135.00	86682	effective immediately
Thyroid Cancer (Thyroglobulin) Monitoring	THYMON	\$110.00	88432; 86800	effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Drug Detection Panel, Umbilical Cord Tissue, with Marijuana Metabolite	DTOFMP	Test will no longer be orderable. Recommended replacement tests are Drug Detection Panel, TOF-MS, Umbilical Cord Tissue (DRGTOF) and Marijuana Metabolite, Umbilical Cord Tissue, Qualitative (DRGTHC)	5/10/22