Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • January 2025

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 Laboratory Customer Service 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
2	3-Methylglutaconic Acid						■		■	■			
14	Allergen, Chili Pepper IgE				■								
2	Alpha-Galactosidase Enzyme Activity, Serum					■	■						
3	Alprazolam					■	■			■	■		■
14	B Type Natriuretic Peptide				■								
14	Borrelia burgdorferi VlsE1/pepC10 Antibodies, CSF, Total by ELISA With Reflex to IgM and IgG by Immunoblot (Standard Two-Tier Testing, CSF)				■								
3	CA 27.29							■					
10–11	Carnitine Free & Total, Plasma			■									
3	Cholesterol Biosynthesis Intermediates									■			
3	Cortisol, Saliva									■			
3–4	Dermatomyositis Autoantibody Panel		■			■	■	■	■	■			■
4	Drug Detection Panel, Umbilical Cord Tissue, with Marijuana Metabolite									■			■
5	Glucagon					■	■						
14	HIV-1 RNA, Qualitative, TMA				■								
14	HIV-2 DNA/RNA PCR				■								
5	Hypercoagulation Diagnostic Interpretive Panel					■		■					
14	Immune Function Assay ATP				■								
5	Inhibin B									■			

Test Update Page #		Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT
5	Lp-PLA2 Activity					■	■		■	■	■	■	
11	Lyme Central Nervous System Infection IgG with Antibody Index Reflex, Serum and CSF			■									
11	Magnesium/Creatinine Ratio, Urine												■
12	Malaria Antigen, Screen and Microscopy Smear			■									
6	Marijuana Metabolite, Umbilical Cord Tissue, Qualitative					■			■	■			
12	Myelopathy, Autoimmune/Paraneoplastic Evaluation, Serum												■
6	Myeloperoxidase (MPO), for cardiac risk evaluation		■			■	■		■		■	■	
6	Oxidized Low-density Lipoprotein (OxLDL)					■	■	■		■	■	■	■
7	Polymyositis and Dermatomyositis Panel					■		■	■	■			■
8	Polymyositis Panel					■	■	■	■	■			■
14	Prostatic Secretions Culture				■								
8	Protein S Free Immunologic		■			■		■					■
14	Ristocetin Co-Factor				■								
8–9	Total Lipid Fatty Acid Profile, RBC						■						
13	Tubular Reabsorption of Phosphorus, Random Urine and Serum			■									
9	Tularemia Antibodies, IgG and IgM					■	■	■	■	■			
10	von Willebrand Diagnostic Interpretive Panel (Limited)							■					

Test Changes

Test Name	Order Code	Change	Effective Date
3-Methylglutaconic Acid	3MGA	**Includes:** **3-Methylglutaconate** **Interpretation** **Specimen Requirement:** 1 mL plasma from EDTA (Lavender) tube; Frozen; **Centrifuge, aliquot and freeze ASAP.** *OR* 1 mL plasma from sodium or lithium heparin (Green) tube; Frozen; **Centrifuge, aliquot and freeze ASAP.** **Methodology: Gas Chromatography Mass Spectrometry (GCMS)** **Reference Range:** 0 Years to **2** Years: **28–260 nmol/L** **2** Years to 12 Years: **26–298 nmol/L** 13 Years to 99 /Years: **25–289 nmol/L**	1/13/25
Alpha-Galactosidase Enzyme Activity, Serum	ALPGAL	**Special Information:** CRITICAL FROZEN. Thawed specimens are unacceptable. Separate specimens must be submitted when multiple tests are ordered. **Patient sex is required for interpretation of results.** Physician name and phone number are required. This test is New York DOH approved; **informed consent required.** **Specimen Requirement:** 2 mL serum from serum separator (Gold) tube; Minimum: **0.3** mL; CRITICAL FROZEN. Transfer 2 mL serum to a standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered. Physician name and phone number are required. *OR* 2 mL serum from no additive (Red) tube; Minimum: **0.3** mL; CRITICAL FROZEN. Transfer 2 mL serum to a standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered. Physician name and phone number are required.	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Alprazolam	ALPRA	**Special Information:** Timing of specimen collection: Pre-dose (trough) draw–At steady state concentration. **Do not use gel separator tubes. Hemolyzed specimens will be rejected. This test is New York DOH approved.** **Specimen Requirement:** 2 mL serum from no additive (Red) tube; Refrigerated; Do not use serum separator tubes. **Predose (trough) draw).** Separate serum from cells within 2 hours of collection **and transfer to standard aliquot tube.** *OR* 2 mL plasma from EDTA (Lavender) tube; Refrigerated; **Predose (trough) draw).** Separate plasma from cells within 2 hours of collection **and transfer to standard aliquot tube.** *OR* 2 mL plasma from sodium heparin (Green) tube; Refrigerated; **Predose (trough) draw).** Separate plasma from cells within 2 hours of collection **and transfer to standard aliquot tube.** *OR* 2 mL plasma from potassium oxalate/sodium fluoride (Gray) tube; Refrigerated; **Predose (trough) draw).** Separate plasma from cells within 2 hours of collection **and transfer to standard aliquot tube.** **Reference Range:** **0 Years to 99 Years: 10–100 ng/mL** **Dose-related range:** Anxiety: 10–40 ng/mL (Dose: 1–4 mg/d) **Dose-related range:** Phobia & panic: 50–100 ng/mL (Dose: 6–9 mg/d) **Dose-related range:** Toxic: Greater than 100 ng/mL **Reported:** 2–**8** days **CPT:** 80346/**G0480**	effective immediately
CA 27.29	CA2729	**For interface clients only–Test build may need to be modified** **Special Information:** The CA27.29 test was performed using the Siemens Centaur XP chemiluminometric immunoassay method. Results obtained with different assay methods or kits cannot be used interchangeably. **CA 27.29 will be discontinued on May 20, 2025 and replaced with CA 15-3 performed using the Electrochemiluminescence Immunoassay by Roche Diagnostics. Prior to the discontinuation of CA 27.29 parallel testing of CA 27.29 and CA 15-3 will take place starting on February 18, 2025 until the discontinuation on May 20, 2025 to allow for the re-baselining of patients.**	2/18/25
Cholesterol Biosynthesis Intermediates	CBINTR	**Reference Range:** Desmosterol: **0.12–2.00** ug/mL 7-Dehydrocholesterol: 0.04–0.36 ug/mL Lathosterol: **0.17–2.85** ug/mL	1/13/25
Cortisol, Saliva	SCORT	**Reference Range:** 7 a.m. to 9 a.m.: 0.1-0.75 **ug/dL** 3 p.m. to 5 p.m.: <0.401 **ug/dL** 11 p.m. to midnight: <0.1 **ug/dL**	effective immediately
Dermatomyositis Autoantibody Panel	DERMYO	**For interface clients only–Test build may need to be modified** **Name:** Previously Dermatomyositis Panel **Includes:** Mi-2 (nuclear helicase protein) Antibody P155/140 Antibody TIF-1 gamma (155 kDa) Antibody SAE1 (SUMO activating enzyme) Antibody MDA5 (CADM-140) Antibody NXP-2 (Nuclear matrix protein-2) Ab **Dermatomyositis Interpretive Information** **Antinuclear Antibody (ANA), HEp-2, IgG** **ANA Interpretive Comment** **Special Information: REFLEX CRITERIA: Antibodies: Mi-2, P155/140, SAE1, MDA5, NXP2, TIF1-gamma, ANA** Hemolyzed, hyperlipemic, or icteric specimens will be rejected. Heat-treated or contaminated specimens are unacceptable. This test is New York DOH approved. **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Refrigerated; Separate **serum** from cells ASAP or within 2 hours of collection **and** transfer to standard aliquot tube. **Methodology:** Immunoblot (IB), Qualitative Immunoprecipitation **Semi-Quantitative Indirect Fluorescent Antibody** *(continued on page 4)*	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Dermatomyositis Autoantibody Panel *(continued from page 3)*		**Reference Range:** **Mi-2 Antibody: Negative** **P155/140 Antibody: Negative** **TIF-1 gamma Antibody: Negative** **SAE1 Antibody: Negative** **MDA5 Antibody: Negative** **NXP-2 Antibody: Negative** **Dermatomyositis Interpretation: Refer to report** **ANA HEp-2 IgG: < 1:80** **ANA Int Comment: Refer to report** **CPT:** 83516x2; 84182x4; **86039x1**	
Drug Detection Panel, Umbilical Cord Tissue, with Marijuana Metabolite	DTOFMP	**Includes:** Buprenorphine Codeine Dihydrocodeine Fentanyl Hydrocodone Hydromorphone Meperidine Methadone Methadone metabolite 6-Acetylmorphine Morphine Naloxone Oxycodone Oxymorphone Propoxyphene Tapentadol Tramadol N-desmethyltramadol O-desmethyltramadol Amphetamine Benzoylecgonine m-OH-Benzoylecgonine Cocaethylene Cocaine MDMA (Ecstasy) Methamphetamine Phentermine Alprazolam Alpha-OH-Alprazolam Butalbital Clonazepam 7-Aminoclonazepam Diazepam Lorazepam Midazolam Alpha-OH-Midazolam Nordiazepam Oxazepam Phenobarbital Temazepam Zolpidem Phencyclidine (PCP) Norbuprenorphine Norhydrocodone Noroxycodone Noroxymorphone **Carboxy-**THC Gabapentin **Reference Range: Refer to report** **CPT:** 80325/G0480; 80345/G0480; 80346/G0480; 80348/G0480; 80349/G0480; 80353/G0480; **80354/G0480;** 80355/G0480; 80356/G0480; 80358/G0480; 80359/G0480; 80361/G0480; 80362/G0480; 80365/G0480; 80367/G0480; 80368/G0480; 80372/G0480; 80373/G0480; 83992/G0480	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Glucagon	GLUCA	**Special Information: Fast 12 hours prior to collection.** Grossly hemolyzed specimens are unacceptable. Separate specimens must be submitted when multiple tests are ordered. This test is New York DOH approved. **Specimen Requirement:** 1 mL plasma from **protease inhibitor tube**; Frozen; **Fast 12 hours prior to collection.** Collect using Protease Inhibitor tube (PPACK; Phe-Pro-Arg-chloromethylketone) (ARUP supply #49662). A winged collection set must be used. Mix well. Separate from cells within 1 hour of collection and transfer plasma to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered.	effective immediately
Hypercoagulation Diagnostic Interpretive Panel	HYPER	**For interface clients only–Test build may need to be modified** **Note:** *Total Protein S component has been removed* **Special Information:** Patient Preparation: Discontinue coumadin therapy for 7 days, heparin therapy for 2 days and thrombolytic therapy for 7 days prior to test, if possible. 3.2% sodium citrate is the preferred anticoagulant recommended by CLSI. Per Pathologist review, the following tests may be ordered and billed: Antithrombin III Antigen (**85300**), PTT Incubated Mixing Add On (85730, 85732 x2); Dilute Russell Viper Venom (85613); Platelet Neutralization (85597); Factor V Leiden (81241); Reptilase (85635); Fibrinogen Antigen (85385); D-Dimer (85379); Factor 8 chromogenic (85240); Sample must be accompanied by the completed Clinical History Form for Hemostasis and Thrombosis Evaluation and a medication list.	2/18/25
Inhibin B	INHIBB	**Reference Range:** **Female: <1 day: Reference range not established.** Female: 1 day–12 years: <=182 pg/mL Female: 13–41 years (regular cycle, follicular phase): 8–223 pg/mL Female: 42–50 years (regular cycle, follicular phase): <=107 pg/mL **Female:** 51–**99** years (postmenopausal): <=11 pg/mL **Female: >= 100 years: Reference range not established.** Male: < 15 days: 68–373 pg/mL Male: 15 days–6 months: 42–516 pg/mL Male: 7 months–7 years: 24–300 pg/mL Male: 8–30 years: 47–383 pg/mL Male: 31–**99** years: 10–357 pg/mL **Male: >= 100 years: Reference range not established.**	1/16/25
Lp-PLA2 Activity	PLAA2	**Special Information:** Fasting is not required. **Hemolyzed or lipemic** specimens will be rejected. **Clinical Information: This test is useful in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk of coronary heart disease (CHD) in patients with no prior history of cardiovascular events.** **Specimen Requirement: 0.5** mL serum from serum separator (Gold) tube; Minimum: **0.2** mL; Refrigerated; **Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube.** *OR* **0.5 mL serum from no additive (Red) tube; Minimum: 0.2 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube.** *OR* **0.5 mL plasma from EDTA (Lavender) tube; Minimum: 0.2 mL; Refrigerated; Separate plasma from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube.** **Stability:** Ambient: **24 hours** Refrigerated: **14** days Frozen: **18 months** **Methodology: Spectrophotometric, Enzymatic Assay** **Reference Range:** **Reduced Risk: <225** nmol/min/mL **Increased Risk: ≥225** nmol/min/mL **Days Performed: Varies** **Reported: 3**–5 days	3/18/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Marijuana Metabolite, Umbilical Cord Tissue, Qualitative	DRGTHC	**Clinical Information: Positive cutoff 0.2 ng/g.** This test is designed to detect and document exposure that occurred during approximately the last trimester of a full-term pregnancy, to a common metabolite **of THC (which may be present in cannabis products).** The pattern and frequency of drug(s) used by the mother cannot be determined by this test. A negative result does not exclude the possibility that a mother used drugs during pregnancy. Detection of drugs in umbilical cord tissue depends on the extent of maternal drug use, as well as drug stability, unique characteristics of drug deposition in umbilical cord tissue, and the performance of the analytical method. Drugs administered during labor and delivery**, or drugs administered directly to the infant after birth,** may be detected. Detection of drugs in umbilical cord tissue does not insinuate impairment and may not affect outcomes for the infant. **Methodology: Mass Spectrometry** **Reference Range:** **Carboxy-THC, Cord: Not detected**	effective immediately
Myeloperoxidase (MPO), for cardiac risk evaluation	MPO	**Name:** Previously Myeloperoxidase **Special Information: CRITICAL REFRIGERATED. Do not use gel separator tubes.** **Clinical Limitation: Erratic results can be observed if plasma is not centrifuged and separated from red cells immediately.** **Clinical Information: Elevated levels of plasma MPO are a sensitive indicator of inflammatory disorders.** **Specimen Requirement: 0.5** mL plasma from EDTA (Lavender) tube; Minimum: **0.2** mL; **Place specimen on ice after draw. CRITICAL REFRIGERATED. Place specimen on ice to chill. Within two hours of collection,** centrifuge **and** aliquot **approximately 2/3 of the upper plasma layer into a standard aliquot tube** and refrigerate**. Separate specimens must be submitted when multiple tests are ordered.** *OR* **0.5 mL plasma from sodium or lithium heparin (Green) tube; Minimum: 0.2 mL; Place specimen on ice after draw. CRITICAL REFRIGERATED. Do not use gel barrier tube. Place specimen on ice to chill. Within two hours of collection, centrifuge and aliquot approximately 2/3 of the upper plasma layer into a standard aliquot tube and refrigerate. Separate specimens must be submitted when multiple tests are ordered.** **Stability:** Ambient: Unacceptable Refrigerated: **5** days Frozen: 6 months **Methodology: Latex Enhanced Immunoturbidimetric Method** **Days Performed: Varies** **Reported: 3**–5 days	3/18/25
Oxidized Low-density Lipoprotein (OxLDL)	OXLDL	**For interface clients only–Test build may need to be modified** **Special Information: CRITICAL FROZEN. Lipemic or hemolyzed specimens will be rejected. Separate specimens must be submitted when multiple tests are ordered.** **Clinical Information: This test is useful in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases, especially as it pertains to the evaluation of oxidative stress. Oxidized LDL-particles are considered to be an important driving factor in the pathophysiology of atherosclerosis and oxLDL measurement has been used to test the efficacy of CVD drugs (eg, statins) to reduce oxidative stress.** **Specimen Requirement:** 0.5 mL plasma from EDTA (Lavender) tube; **CRITICAL FROZEN.** Gently invert **tube** 8 to 10 times **then** centrifuge **and aliquot** approximately 2/3 of the upper plasma layer **into a standard** aliquot tube **within 45 minutes of collection. Separate specimens must be submitted when multiple tests are ordered.** **Stability:** Ambient: Unacceptable Refrigerated: **Unacceptable** Frozen: **2 years (1 freeze/thaw cycle)** **Reference Range: 10–170 ng/mL** **Days Performed: Varies** **Reported: 4**–6 days **CPT: 83721**	3/18/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Polymyositis and Dermatomyositis Panel	MYOSPL	**For interface clients only–Test build may need to be modified** **Includes:** Jo-1 Antibody, IgG PL-12 (alanyl-tRNA synthetase) Antibody PL-7 (threonyl-tRNA synthetase) Antibody EJ (glycyl-tRNA synthetase) Antibody OJ (isoleucyl-tRNA synthetase) Antibody SRP (Signal Recognition Particle) Ab Mi-2 (nuclear helicase protein) Antibody P155/140 Antibody TIF-1 gamma (155 kDa) Antibody SAE1 (SUMO activating enzyme) Antibody MDA5 (CADM-140) Antibody NXP-2 (Nuclear matrix protein-2) Ab **Myositis Interpretive Information** **Antinuclear Antibody (ANA), HEp-2, IgG** **ANA Interpretive Comment** **Ha (tyrosyl-tRNA synthetase) Ab** **Ks (asparaginyl-tRNA synthetase) Ab** **Zo (phenylalanyl-tRNA synthetase) Ab** **Special Information: REFLEX CRITERIA: Antibodies: PL-7, PL12, EJ, OJ, SRP, Jo-1, Mi-2, P155/140, SAE1, MDA5, NXP2, TIF1-gamma, ANA, Ha, Ks, Zo.** Hemolyzed, hyperlipemic, or icteric specimens will be rejected. Heat-treated or contaminated specimens are unacceptable. This test is New York DOH approved. **Methodology:** Immunoblot (IB), Qualitative Immunoprecipitation **Semi-Quantitative Indirect Fluorescent Antibody** Semi-Quantitative Multiplex Bead Assay **Reference Range:** **Jo-1 Antibody, IgG: 0–40 AU/mL** **PL-12 Antibody: Negative** **PL-7 Antibody: Negative** **EJ Antibody: Negative** **OJ Antibody: Negative** **SRP Antibody: Negative** **Mi-2 Antibody: Negative** **P155/140 Antibody: Negative** **TIF-1 gamma Antibody: Negative** **SAE1 Antibody: Negative** **MDA5 Antibody: Negative** **NXP-2 Antibody: Negative** **Myositis Interpretation: Refer to report** **Antinuclear Antibody (ANA) HEp-2, IgG: < 1:80** **ANA Interp Comment: Refer to report** **Ha (tyrosyl-tRNA synthetase) Ab: Negative** **Ks (asparaginyl-tRNA synthetase) Ab: Negative** **Zo (phenylalanyl-tRNA synthetase) Ab: Negative** **CPT:** 83516x7; 86235x1; 84182x7; **86039x1** **For interface clients only–Test build may need to be modified** **Includes:** Jo-1 (Histidyl-tRNA Synthetase) Ab, IgG PL-12 (alanyl-tRNA synthetase) Antibody PL-7 (threonyl-tRNA synthetase) Antibody EJ (glycyl-tRNA synthetase) Antibody OJ (isoleucyl-tRNA synthetase) Antibody SRP (Signal Recognition Particle) Ab **Polymyositis Interpretive Information** **Antinuclear Antibody (ANA), Hep-2, IgG** **ANA Interpretive Comment** **Ha (tyrosyl-tRNA synthetase) Ab** **Ks (asparaginyl-tRNA synthetase) Ab** **Zo (phenylalanyl-tRNA synthetase) Ab** **Special Information: REFLEX CRITERIA: Antibodies: PL-7, PL12, EJ, OJ, SRP, Jo-1, ANA, Ha, Ks, Zo** Hemolyzed, hyperlipemic, or icteric specimens will be rejected. Heat-treated or contaminated specimens are unacceptable. This test is New York DOH approved. **Specimen Requirement:** 2 mL serum from serum separator (Gold) tube; Refrigerated; Separate from cells ASAP or within 2 hours of collection. Split serum into two 1 mL aliquots using standard aliquot tubes.	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Polymyositis Panel	POLMYO	**Methodology:** **Immunoblot (IB), Qualitative** Immunoprecipitation **Semi-Quantitative Indirect Fluorescent Antibody** Semi-Quantitative Multiplex Bead Assay **Reference Range:** **Jo-1 Antibody, IgG: 0–40 AU/mL** **PL-12 Antibody: Negative** **PL-7 Antibody: Negative** **OJ Antibody: Negative** **EJ Antibody: Negative** **SRP Antibody: Negative** **Polymyositis Interpretation: Refer to report** **Antinuclear Antibody (ANA) HEp-2, IgG: < 1:80** **ANA Interp Comment: Refer to report** **Ha (tyrosyl-tRNA synthetase) Ab: Negative** **Ks (asparaginyl-tRNA synthetase) Ab: Negative** **Zo (phenylalanyl-tRNA synthetase) Ab: Negative** **CPT:** 83516x5; 86235x1; **84182x3; 86039x1**	effective immediately
Protein S Free Immunologic	PROTSI	**For interface clients only–Test build may need to be modified** **Name:** Previously Protein S Immunologic **Includes:** Free Protein S **Note:** *Total Protein S has been removed* **Clinical Information:** For use in the evaluation of the hypercoagulable state due to congenital or acquired protein S deficiency. This is an immunologic assay which detects the **free protein S** in plasma. Only the free protein is functional as a cofactor to protein C. **CPT:** 85306	2/18/25
Total Lipid Fatty Acid Profile, RBC	LFARBC	**Includes:** C10:0 Capric C12:0 Lauric C14:0 Myristic C15:0 Pentadecanoic C16:0 Palmitic C17:0 Heptadecanoic C18:0 Stearic C20:0 Arachidic C22:0 **Behenic** C23:0 Tricosanoic C24:0 **Lignoceric** C25:0 Pentacosanoic C26:0 Hexacosanoic C28:0 Octacosanoic C30:0 C10:1 **(n-9)** Caproleic C12:1 **(n-9)** Dodecaenoic C16:1 (n-9) C17:1 Heptadecaenoic C18:1 (n-9) Oleic C20:1 (n-9) Eicosenoic C20:3 (n-9) Mead C22:1 (n-9) **Erucic** C24:1 (n-9) Nervonic C26:1 **Hexacosaenoic** C14:1 (n-5) Myristoleic C16:1 (n-7) Palmitoleic C18:1 (n-7) Vaccenic C18:1 (n-5) C20:3 (n-7) C14:2 Myristolenic C16:2 **(n-6)** Palmitolenic C18:2 (n-6) Linoleic C18:2 (n-6) Conj–Rumenic *(continued on page 9)*	1/13/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Total Lipid Fatty Acid Profile, RBC *(continued from page 8)*	LFARBC	**Includes (continued):** C18:3 (n-6) Gamma Linolenic C20:2 (n-6) Eicosadienoic C20:3 (n-6) Dihomo-g-linolenic C20:4 (n-6) Arachidonic C22:2 (n-6) Docosadienoic C22:4 (n-6) Adrenic C22:5 (n-6) Docosapentaenoic C24:2 (n-6) C26:2 Hexacosadienoic C18:3 (n-3) Alpha Linolenic C20:5 (n-3) Eicosapentaenoic C22:5 (n-3) C22:6 (n-3) Docosahexaenoic Pristanic Phytanic C16:1 Trans **SUM** C18:1 Trans **SUM** C18:2 Trans **SUM** **C**16:0 DMA **plasmalogen** **C**18:0 DMA **plasmalogen** Total **C**18:1 DMA **plasmalogen** Total Saturates Total W9 Total W7&5 Total W6 Total W3 Total Branched Total Trans Total DMA **dimethylacetal** Total Fatty Acids Arachidonic/DHA Ratio C16**:0** DMA/**C**16:0 **Ratio** C18**:0** DMA/**C**18:0 **Ratio** **Interpretation** **Specimen Requirement:** 3 mL whole blood in EDTA (Lavender) tube; **Minimum: 1.5 mL**; Ambient; Patient should be fasting or specimen collected before a meal. Collect Monday–Wednesday only. Specimen MUST be sent to Cleveland Clinic Laboratories on the day of collection.	1/13/25
Tularemia Antibodies, IgG and IgM	TULGMA	**For interface clients only–Test build may need to be modified** **Includes:** F. tularensis, IgG F. tularensis, IgM **F. tularensis Antibody Interpretation** **Special Information:** Contaminated, heat-inactivated, or turbid specimens will be rejected. This test is New York DOH approved. **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. *OR* 1 mL serum from no additive (Red) tube; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. **Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)** **Reference Range:** F. tularensis IgG: **Negative** F. tularensis IgM: **Negative** **F. tularensis Antibody Interpretation: Refer to report**	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
von Willebrand Diagnostic Interpretive Panel (Limited)	VWFPR	**For interface clients only–Test build may need to be modified** **Includes:** Prothrombin Time (PT) APTT Collagen Binding Assay(CBA) Factor VIII assay (FVIII) von Willebrand Factor Antigen (VWF) CBA/VWF Ratio FVIII/VWF Ratio von Willebrand Multimer VWF:GpIbM Activity **GpIbM/VWF Ratio**	2/18/25

New Tests

Test Name	Order Code	Change	Effective Date
Carnitine Free & Total, Plasma	CARNPL	**Special Information:** Decant plasma/serum from cells within 2 hours from collection. Fasting is not required, but the information is helpful for test interpretation; indicate patient fasting hours when possible. Carnitine, fish oil, and omega-3 supplements affect test results; indicate supplement use on the requisition. **Clinical Limitation:** The free plasma carnitine levels can respectively increase or decrease substantially after recent carnitine supplementation or renal dialysis. **Clinical Information:** Useful in the evaluation of individuals at risk for a deficiency of free carnitine, which may occur during treatment with valproate, in persons receiving chronic renal dialysis, and in some forms of malnourishment. When combined with the profile of plasma acylcarnitine species, useful in the diagnostic evaluation of individuals suspected of having a disorder of mitochondrial fatty acid beta-oxidation and many genetic disorders of organic acid metabolism. **Specimen Requirement:** 1 mL plasma from green sodium heparin no gel tube; Minimum: 0.2 mL; Frozen; Centrifuge and transfer the plasma/serum to a plastic CCL tube within 2 hours of collection and freeze. *OR* 1mL serum from red plain tube; Minimum: 0.2 mL; Frozen; Centrifuge and transfer the plasma/serum to a plastic CCL tube within 2 hours of collection and freeze. *OR* 1 mL plasma from mint lithium heparin plasma separator tube; Minimum: 0.2 mL; Frozen; Centrifuge and transfer the plasma/serum to a plastic CCL tube within 2 hours of collection and freeze. *OR* 1 mL plasma from lavender EDTA tube; Minimum: 0.2 mL; Frozen; Centrifuge and transfer the plasma/serum to a plastic CCL tube within 2 hours of collection and freeze. **Stability:** Ambient: After separation from cells: 24 hours Refrigerated: After separation from cells: 30 days Frozen: After separation from cells: 90 days **Methodology:** Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** Free L-carnitine: 0 Days to 30 Days: 6.9–35.6 umol/L 31 Days to 364 Days: 21.3–75.1 umol/L 1 Year to 6 Years: 20.0–54.8 umol/L 7 Years to 17 Years: 18.7–55.3 umol/L 18 Years and above: 20.0–53.0 umol/L Total L-carnitine: 0 Days to 30 Days: 20.0–51.1 umol/L 31 Days to 364 Days: 33.0–93.9 umol/L 1 Year to 6 Years: 26.4–69.3 umol/L 7 Years to 17 Years: 25.8–65.6 umol/L 18 Years and above: 26.4–66.0 umol/L *(continued on page 11)*	3/18/25

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Carnitine Free & Total, Plasma *(continued from page 10)*	CARNPL	**Reference Range (continued):** Esterified L-Carnitine: 0 Days to 30 Days: 6.5–23.2 umol/L 31 Days to 364 Days: 4.6–24.9 umol/L 1 Year to 6 Years: 2.7–17.4 umol/L 7 Years to 17 Years: 2.8–13.4 umol/L 18 Years and above: 3.0–15.6 umol/L Esterified Carnitine / Free Carnitine Ratio: 0 Days to 30 Days: 0.2–1.8 31 Days to 364 Days: 0.1–0.7 1 Year to 6 Years: 0.1–0.6 7 Years to 17 Years: 0.1–0.5 18 Years and above: 0.1–0.7 **Days Performed:** 2 days per week **Reported:** 1–4 days **CPT:** 82379	3/18/25
Lyme Central Nervous System Infection IgG with Antibody Index Reflex, Serum and CSF	LYMCNS	**Special Information:** Both CSF and serum are required for this test. CSF and serum must be collected within 24 hours (maximum) of each other and be rubber banded together prior to being sent to the performing laboratory. This test begins with IgG screening of the CSF specimen. If the screen is negative, no additional testing will be performed. If the screen is positive, the paired CSF and serum specimens will be used to establish the antibody index at additional cost. The additional quantitative assays determine levels for anti-Borrelia species IgG levels in CSF and serum, total IgG in CSF and serum, and albumin in CSF and serum. Grossly hemolyzed or lipemic specimens will be rejected. CSF contaminated with blood will be rejected. This test is New York state approved. **Clinical Limitation:** A single negative result should not be used to exclude the diagnosis of neuroinvasive Lyme disease in a patient with appropriate exposure history and symptoms suggestive of infection. **Clinical Information:** This test is useful for aiding in the diagnosis of neuroinvasive Lyme disease or neuroborreliosis due to Borrelia species associated with Lyme disease. It compares the level of IgG antibodies to Lyme disease-causing Borrelia species in spinal fluid (CSF) and serum. The level of anti-Borrelia species IgG is normalized to total IgG and albumin in CSF and serum. This test can help identify whether the presence of IgG to Borrelia species in the CSF is due to true intrathecal antibody synthesis, suggesting neuroinvasive Lyme disease, versus antibody presence due to passive diffusion through the blood-brain barrier or, possibly, due to blood contamination of the CSF as a result of a traumatic lumbar puncture. **Specimen Requirement:** 1.2 mL cerebrospinal fluid (CSF) in sterile container; Refrigerated; Both CSF and serum are required for this test and must be collected within the same 24-hour period. Aliquot CSF from tube 2, 3, or 4. Rubber band together with serum if collected at the same time. *AND* 1.2 serum from serum separator (Gold) tube; Refrigerated; Both CSF and serum are required for this test and must be collected within the same 24-hour period. Rubber band together with CSF if collected at the same time. **Stability:** Ambient: Unacceptable Refrigerated: 11 days Frozen: 35 days **Methodology:** Enzyme-Linked Immunosorbent Assay (ELISA) **Reference Range:** Lyme CNS Infection IgG, CSF: Negative Lyme CNS Infection IgG Interp: Refer to report Lyme CNS Infection IgG, Serum: Refer to report **Days Performed:** 1–5 days **Reported:** Mon, Wed, Fri **CPT:** 86618	1/9/25
Magnesium/Creatinine Ratio, Urine	UMGCRR	**Note:** *New test was announced in the November update. Financial information was not available at that time.* **CPT:** 82570; 83735	1/14/25

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Malaria Antigen, Screen and Microscopy Smear	MALAGS	**Name:** Previously announced in November as Malaria Binax Antigen, screen **Includes:** Blood Parasite Microscopy smear, including % parasitemia (BPMSM) **Special Information:** The malaria antigen test should be treated as a STAT test and processed immediately upon receipt in the lab. It is crucial to use this test for patients who have an appropriate travel history and a strong suspicion of malaria. Blood samples must also be delivered to the lab promptly after collection to ensure the accuracy, reliability and appropriate utilization of the test results. All malaria antigen screen tests will be reflexed to Blood parasite microscopy smear, regardless of a positive or negative result. **Clinical Limitation:** A negative test result does not exclude infection with malaria, particularly at low levels of parasitemia. Test performance depends on antigen load in the specimen and may not directly correlate with microscopy performed on the same specimen. Binax antigen test can cross react with rheumatoid factor, chronic viral infections such as hepatitis C and other parasitic infections. The Binax malaria test can be affected by the prozone effect, and both antigens may test positive due to dual infection or high levels of parasitemia. The antigen test may also remain positive for days after clearance of malarial parasitic infection. False negatives are also possible for HRP-2 negative Plasmodium falciparum species. **Clinical Information:** Malaria is a major parasitic disease, which is endemic in many countries in various areas of the world. Each year it causes up to 3 million deaths and close to 5 billion cases of clinical illness worldwide. The rapid malaria antigen screen has better sensitivity of detection for Plasmodium falciparum as compared to the other Plasmodium species. It provides rapid results and is designed to be used as a screening tests but all test results are paired with a blood parasite microscopy smear. The antigen test is not designed to be used for assessment of treatment efficacy or as a test-of-cure as residual plasmodium antigen may be detected several days following clearance as determined by microscopy. **Specimen Requirement:** 2-3 mL whole blood in EDTA (Lavender) tube; Minimum: 0.5 mL; Collect Ambient; Transport Refrigerated; Prompt delivery of specimens to the laboratory is crucial for accurate and reliable results. Laboratories that are unable to deliver specimens within a few hours of collection should conduct an initial screening for malaria, such as a Malaria Binax antigen test, before sending the specimen. This preliminary testing helps ensure timely diagnosis and effective patient management. Refer to Blood Parasite Microscopy smear, including % parasitemia for additional specimens (slides) needed to complete reflex testing. **Stability:** Ambient: 24 hours Refrigerated: 24 hours Frozen: Unacceptable **Methodology:** Immunochromatography **Days Performed:** 7 days a week 24 hours **Reported:** 1–8 hours **CPT:** 87899x2	1/7/25
Myelopathy, Autoimmune/ Paraneoplastic Evaluation, Serum	MLPTHY	**Note:** *New test was announced in the November update. Financial information was not available at that time.* **CPT:** 84182x1; 86053x1; 86255x16; 86341x1; 86363x1	effective immediately

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Tubular Reabsorption of Phosphorus, Random Urine and Serum	TRPHOS	**Special Information:** Fasting is required. Both serum and urine are required. Grossly hemolyzed specimens will be rejected. This test is New York state approved. **Clinical Information:** This test is useful for assessing renal reabsorption of phosphorus in a variety of pathological conditions associated with hypophosphatemia including hypophosphatemic rickets, tumor-induced osteomalacia, and tumoral calcinosis. It is also useful for adjusting phosphate replacement therapy in severe deficiency states monitoring the renal tubular recovery from acquired Fanconi syndrome. **Specimen Requirement:** 0.5 serum from no additive (Red) tube; Minimum: 0.5 mL; Frozen; Fasting required. Both serum and urine are required. Separate serum from cells ASAP and transfer to standard aliquot tube. Label specimen as serum. AND 4 mL random urine in clean container; Minimum: 1 mL; Refrigerated; Both serum and urine are required. Label specimen as urine. **Stability:** Ambient: Serum: Unacceptable; Urine: 7 days Refrigerated: Serum: 7 days; Urine: 30 days Frozen: Serum: 7 days; Urine: 14 days **Methodology:** Calculation Colorimetric Enzyme Assay Photometric **Reference Range:** Phosphorus (Inorganic), S: Reference values have not been established for patients <12 months of age. Male: 1 Year to 4 Years: 4.3–5.4 mg/dL 5 Years to 13 Years: 3.7–5.4 mg/dL 14 Years to 15 Years: 3.5–5.3 mg/dL 16 Years to 17 Years: 3.1–4.7 mg/dL 18 Years to 99 Years: 2.5–4.5 mg/dL Female: 1 Year to 7 Years: 4.3–5.4 mg/dL 8 Years to 13 Years: 4.0–5.2 mg/dL 14 Years to 15 Years: 3.5–4.9 mg/dL 16 Years to 17 Years: 3.1–4.7 mg/dL 18 Years to 99 Years: 2.5–4.5 mg/dL TRP (Tubular Reabsorption of Phosphorus): >80% see Note Note: tubular reabsorption of phosphorus levels must be interpreted in light of the prevailing plasma phosphorus and glomerular filtration rate Random TmP/GFR (Tubular Maximum Phosphorus Reabsorption/GFR): 2.6–4.4 mg/dL 0.80–1.35 mmol/L Creatinine, S: Male: 0 Months to 11 Months: 0.17–0.42 mg/dL 1 Year to 5 Years: 0.19–0.49 mg/dL 6 Years to 10 Years: 0.26–0.61 mg/dL 11 Years to 14 Years: 0.35–0.86 mg/dL 15 Years to 99 Years: 0.74–1.35 mg/dL Female: 0 Months to 11 Months: 0.17–0.42 mg/dL 1 Year to 5 Years: 0.19–0.49 mg/dL 6 Years to 10 Years: 0.26–0.61 mg/dL 11 Years to 15 Years: 0.35–0.86 mg/dL 16 Years to 99 Years: 0.59–1.04 mg/dL Creatinine, Random, U: Reference values have not been established for patients who are less than 18 years of age 18 Years to 99 Years: 16–326 mg/dL **Days Performed:** Sun–Sat **Reported:** 1–2 days **CPT:** 82565; 82570; 84100; 84105	effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Allergen, Chili Pepper IgE	CHILI	Test will no longer be orderable.	effective immediately
B Type Natriuretic Peptide	BNP	Test will no longer be orderable. Recommended replacement test is NT Pro BNP (NTBNP).	2/18/25
Borrelia burgdorferi VlsE1/pepC10 Antibodies, CSF, Total by ELISA With Reflex to IgM and IgG by Immunoblot (Standard Two-Tier Testing, CSF)	BBURGM	Test will no longer be orderable. Recommended replacement test is Lyme Central Nervous System Infection IgG with Antibody Index Reflex, Serum and CSF (LYMCNS).	3/18/25
HIV-1 RNA, Qualitative, TMA	HIVTMA	Test will no longer be orderable. Recommended replacement test is Human Immunodeficiency Virus 1 (HIV-1) RNA, Quantitative PCR, Plasma (HIVRNA) for the clinical management of HIV-1 infected patients.	effective immediately
HIV-2 DNA/RNA PCR	HIV2PC	Test will no longer be orderable. Recommended replacement test is Miscellaneous Send Out Test (MISC1)	2/18/25
Immune Function Assay ATP	IMMFUN	Test will no longer be orderable.	3/18/25
Prostatic Secretions Culture	PSCUL	Test will no longer be orderable. Recommended replacement test is Urine Culture (URCUL).	2/18/25
Ristocetin Co-Factor	RISCOF	Test will no longer be orderable. Recommended replacement test is VWF GPIbM Activity (VGPIBM).	2/18/25