Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • October 2024

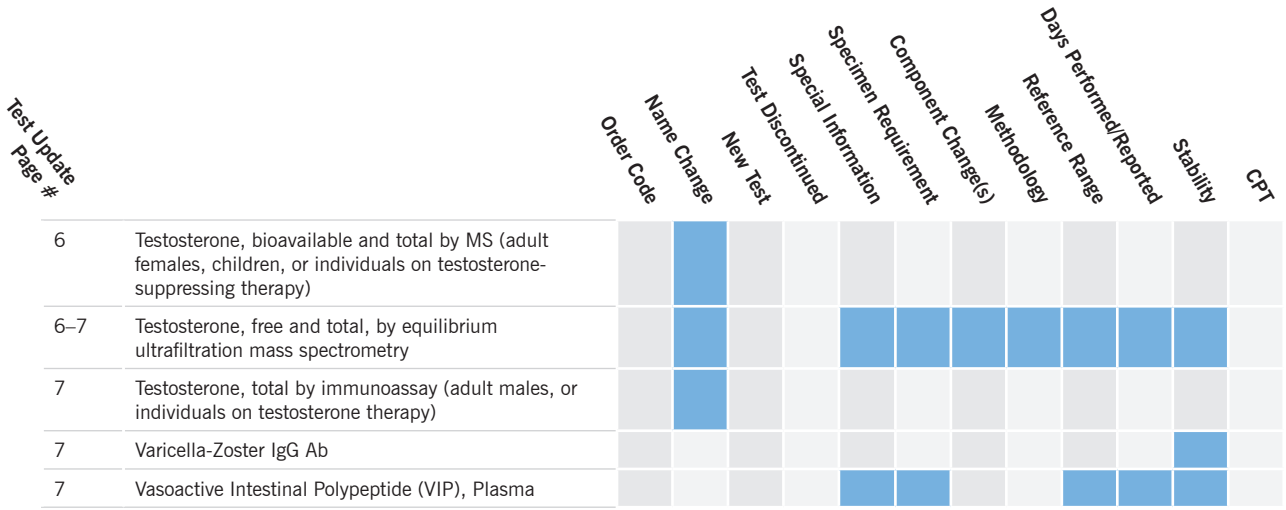
Cleveland Clinic Laboratories is dedicated to keeping you updated and informed about recent testing changes. This Technical Update is provided on a monthly basis to notify you of any changes to the tests in our catalog.

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	Acylglycines, Quantitative Analysis, Urine					■							
2	Adiponectin												■
2–3	Bile Acids, Total					■	■	■		■	■	■	
8	Brivaracetam			■									
8	Chitotriosidase Assay												■
3	Drug Detection Panel, Meconium, Qualitative												■
3	Drug Detection Panel, TOF-MS, Umbilical Cord Tissue												■
3	Enterovirus by PCR					■							
3	Ethosuximide					■	■	■	■	■	■	■	
4	Gabapentin					■	■	■	■	■	■	■	
4	Lacosamide												
4	Macroprolactin					■	■		■	■	■	■	
4	Oxalate, Plasma						■						
8	Perampanel			■									
5	Phenobarbital, Free					■	■		■		■	■	
5	Pregabalin					■	■	■	■	■	■	■	
5	Prolactin, Dilution Study					■	■		■	■	■	■	■
6	Rufinamide					■	■	■	■	■	■	■	
8	Telomere Biology Disorders Panel				■								
6	Testosterone, bioavailable and total by immunoassay (adult males, or individuals on testosterone therapy)		■										



Test Changes

Test Name	Order Code	Change	Effective Date
Acylglycines, Quantitative Analysis, Urine	UQACYL	**Special Information:** Submit Patient History for Biochemical Genetics form with specimen. Clinical information is necessary for appropriate interpretation. Additional required information includes age, gender, diet (e.g., TPN therapy), drug therapy, and family history.	effective immediately
Adiponectin	ADIP	CPT: 83520	effective immediately
Bile Acids, Total	BILETO	**For interface clients only–Test build may need to be modified** **Special Information: The reference intervals for adults >20 years old were obtained using fasting blood specimens. Reference intervals for children, adults <20 years old and pregnant women were obtained using random blood draw specimens.** **Clinical Limitation: Total bile acid concentration in serum is increased after meals; hence, samples should be collected under fasting conditions. This does not apply to women with intrahepatic cholestasis of pregnancy who will need peak bile acid testing and samples should be postprandial.** **This serum bile acid assay should not be used for patients receiving ursodeoxycholic acid, nor should it be used as the primary assay for the screening or diagnosis of genetic disorders of bile acid synthesis.** **Clinical Information: Use for the in vitro quantitative determination of total bile acids in serum or plasma.** **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Refrigerated; Allow specimen to clot completely at room temperature. **Centrifuge within 2 hours of collection and refrigerate. *OR* 1 mL serum from red plain tube; Refrigerated; Allow specimen to clot completely at room temperature. Centrifuge and transfer the serum to a plastic CCL tube within 2 hours of collection and refrigerate. *OR* 1 mL plasma from lithium heparin (Green) tube; Refrigerated; Centrifuge and transfer the plasma to a plastic CCL tube within 2 hours of collection and refrigerate. *OR* 1 mL plasma from lithium heparin plasma separator (Light Green) tube; Refrigerated; Centrifuge within 2 hours of collection and refrigerate. *OR* 1 mL plasma from EDTA (Lavender) tube; Refrigerated; Centrifuge and transfer the plasma to a plastic CCL tube within 2 hours of collection and refrigerate.** **Stability:** Ambient: **48** hours Refrigerated: **30 days** Frozen: **30 days** *(continued on page 3)*	11/21/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Bile Acids, Total *(continued from page 2)*	BILETO	**Reference Range:** **0 Days to 5 Months: None established** **6 Months to 23 Months: < 25.8 umol/L** **2 Years to 4 Years: < 20.9 umol/L** **5 Years to 9 Years: < 12.4 umol/L** **10 Years to 19 Years: < 13.6 umol/L** **20 Years to 59 Years: < 7.5 umol/L** **60 Years to 999 Years: < 8.3 umol/L** **Pregnancy Reference Intervals (Non-fasting):** **First Trimester (up to 13 weeks gestation): < 15.3 umol/L** **Pregnancy Reference Interval (Non-fasting):** **Second Trimester (13–27 weeks gestation): < 11.4 umol/L** **Pregnancy Reference Interval (Non-fasting):** **Third Trimester (> 27 weeks gestation): < 10.4 umol/L** **Days Performed: Mon**–Sat **Reported: 1**–3 days	11/21/24
Drug Detection Panel, Meconium, Qualitative	MECDRG	**CPT:** 80323/**G0480; 80325/G0480; 80345/G0480; 80346/G0480; 80348/G0480; 80353/G0480; 80354/G0480;** 80355/**G0480; 80356/G0480; 80358/G0480; 80359/G0480; 80360/G0480; 80361/G0480; 80362/G0480; 80365/G0480; 80368/G0480; 80372/G0480; 80373/G0480; 83992/G0480**	effective immediately
Drug Detection Panel, TOF-MS, Umbilical Cord Tissue	DRGTOF	**CPT: 80325/G0480; 80345/G0480; 80346/G0480; 80348/G0480; 80353/G0480; 80354/G0480;** 80355/**G0480; 80356/G0480; 80358/G0480; 80359/G0480; 80361/G0480; 80363/G0480; 80365/G0480; 80368/G0480; 80372/G0480; 80373/G0480; 83992/G0480**	effective immediately
Enterovirus by PCR	ENTNAS	**Special Information:** Specimen source required. Heparinized specimens will be rejected. For cerebrospinal fluid (CSF) specimens, **the Meningitis Encephalitis Panel (MGEBF) is suggested as an alternate.** This test is New York DOH approved.	effective immediately
Ethosuximide	ETHO	**For interface clients only–Test build may need to be modified** **Special Information: Collect the specimen before the next dose (trough).** Unacceptable conditions: Whole blood, gel separator tubes. **Clinical Information: Monitoring concentrations in serum or plasma to assess drug therapy and patient compliance.** **Specimen Requirement:** 1 mL serum from no additive (Red) tube; Refrigerated; Timing of specimen collection: Pre-dose (trough). Do not **collect** in a gel separator tube. **Centrifuge and transfer the plasma/serum to a plastic CCL tube** within 2 hours of collection **and refrigerate. Transport and store at refrigerated temperature.** *OR* **1 mL plasma from green lithium heparin no-gel tube; Refrigerated; Timing of specimen collection: Pre-dose (trough). Do not collect in a gel separator tube. Centrifuge and transfer the plasma/serum to a plastic CCL tube within 2 hours of collection and refrigerate. Transport and store at refrigerated temperature.** **Stability:** Ambient: After separation from cells: **24 hours** Refrigerated: After separation from cells: **14 days** Frozen: After separation from cells: **30 days** **Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)** **Reference Range:** 40.0–100.0 ug/mL **Urgent: > 150.0 ug/mL** **Days Performed:** Mon–**Sat** **Reported: 1–3** days	11/19/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Gabapentin	GABA	**For interface clients only–Test build may need to be modified** **Special Information: Collect the specimen before the next dose (trough).** Unacceptable conditions: Whole blood, gel separator tubes. **Clinical Information: Monitoring concentrations in serum or plasma to assess drug therapy and patient compliance.** **Specimen Requirement:** 1 mL serum from no additive (Red) tube; Minimum: **0.5** mL; Refrigerated; **Timing of specimen collection: Pre-dose (trough).** Do not **collect in a gel** separator tube. **Centrifuge and transfer the plasma/serum to a plastic CCL tube** within 2 hours of collection **and refrigerate. Transport and store at refrigerated temperature.** *OR* **1 mL plasma from green lithium heparin no-gel tube; Minimum: 0.5 mL; Refrigerated; Timing of specimen collection: Pre-dose (trough). Do not collect in a gel separator tube. Centrifuge and transfer the plasma/serum to a plastic CCL tube within 2 hours of collection and refrigerate. Transport and store at refrigerated temperature.** **Stability:** Ambient: After separation from cells: **24 hours** Refrigerated: After separation from cells: **14 days** Frozen: After separation from cells: **30 days** **Reference Range:** 2.0–20.0 ug/mL **Days Performed: Mon–Sat** **Reported: 1–3** days	10/22/24
Lacosamide	LACOS	**For interface clients only–Test build may need to be modified** **Includes:** Lacosamide **Note:** *Desmethyllacosamide has been removed* **Clinical Information:** Antiepileptic drug. Expected concentration of patients receiving 200-400 mg/day is 2.2-19.8 ug/mL for Lacosamide. Toxic range not established.	11/19/24
Macroprolactin	MACPRO	**Note:** *Special Information and Clinical Information have been removed* **Specimen Requirement: 2** mL serum from serum separator (Gold) tube; Minimum **1** mL; Frozen; **Patient must be awake for at least two hours before collection.** Separate serum from cells **ASAP or within 45 minutes of collection** and transfer into standard aliquot tube. **Separate specimens must be submitted when multiple tests are ordered.** *OR* **2 mL serum from no additive (Red) tube; Minimum 1 mL; Frozen; Patient must be awake for at least two hours before collection. Separate serum from cells ASAP or within 45 minutes of collection and transfer into standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered.** *OR* **2** mL plasma from **sodium or** lithium heparin (**Green**) tube; Minimum **1** mL; Frozen; **Patient must be awake for at least two hours before collection.** Separate plasma from cells **ASAP or within 45 minutes of collection** and transfer into standard aliquot tube. **Separate specimens must be submitted when multiple tests are ordered.** **Stability:** Ambient: After separation from cells: **14 days** Refrigerated: After separation from cells: **14** days Frozen: After separation from cells: **6** months **Methodology: Electro Chemiluminescence Immunoassay (ECLIA)** **Reference Range:** Prolactin: **Refer to report** Monomeric Prolactin: **Refer to report** Monomeric Prolactin Percent: **Refer to report** **Days Performed: Varies** **Reported: 6–11** days	11/21/24
Oxalate, Plasma	OXLATE	**Specimen Requirement: 3** mL plasma from lithium heparin (green) no-gel tube; Minimum: **2** mL; Place specimen on ice after draw. Critical frozen; Patient should avoid ingestion of vitamin C for 24 hours prior to sample collection. Fasting for 8 hours is recommended, but not required. Separate plasma from cells ASAP or within 1 hour of collection, transfer to standard aliquot tube, and freeze immediately.	11/19/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Phenobarbital, Free	PHENFR	**Special Information:** Gel barrier tubes **are not recommended.** **Clinical Information: This test is useful for therapeutic drug management. Trough levels are most reproducible.** **Specimen Requirement:** 3 mL plasma from sodium or lithium heparin (Green) tube; Minimum: **1.2** mL; Refrigerated; **Gel-barrier tubes are not recommended. Separate plasma from cells within 2 hours of collection and transfer to standard aliquot tube.** *OR* 3 mL serum from no additive (Red); Minimum: **1.2** mL; **Gel-barrier tubes are not recommended. Separate serum from cells within 2 hours of collection and transfer to standard aliquot tube.** **Stability:** Ambient: **After separation from cells: 72 hours** Refrigerated: **After separation from cells: Acceptable** Frozen: **After separation from cells: Acceptable** **Methodology:** **Immunoassay (IA)** **Ultrafiltration (ULT)** **Reported: 4–8** days	11/21/24
Pregabalin	PBALIN	**For interface clients only–Test build may need to be modified** **Special Information: Collect the specimen before the next dose (trough).** **Unacceptable conditions: Whole blood, gel separator tubes.** **Clinical Information: Monitoring concentrations in serum or plasma to assess drug therapy and patient compliance.** **Specimen Requirement:** 1 mL serum from no additive (Red) tube; Minimum **0.5** mL; Refrigerated; **Timing of specimen collection:** Pre-dose (trough). **Do not collect in a gel separator tube. Centrifuge and transfer the plasma/serum to a plastic CCL tube** within 2 hours of collection **and refrigerate. Transport and store at refrigerated temperature.** *OR* **1 mL plasma from green lithium heparin no-gel tube; Minimum: 0.5 mL; Refrigerated; Timing of specimen collection: Pre-dose (trough). Do not collect in a gel separator tube. Centrifuge and transfer the plasma/serum to a plastic CCL tube within 2 hours of collection and refrigerate. Transport and store at refrigerated temperature.** **Stability:** Ambient: **After separation from cells: 24 hours** Refrigerated: **After separation from cells: 14 days** Frozen: **After separation from cells: 30 days** **Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)** **Reference Range: 2.0–8.0 ug/mL** **Days Performed: Mon**–Sat **Reported: 1–3** days	11/19/24
Prolactin, Dilution Study	PROLM	**Special Information:** *removed* **Clinical Information:** This test is **useful for quantifying prolactin in serum specimens** where the high-dose hook effect is **suspected (e.g., presence of pituitary tumor with symptoms of prolactinoma and lower than expected serum prolactin concentration).** **Specimen Requirement: 1.5** mL serum from serum separator (Gold) tube; **Refrigerated;** Separate serum from cells and transfer into standard aliquot tube. *OR* **1.5** mL plasma from lithium heparin plasma separator (Light Green) tube; **Refrigerated;** Separate plasma from cells and transfer into standard aliquot tube. *OR* **1.5 mL serum from no additive (Red) tube; Refrigerated; Separate serum from cells and transfer into standard aliquot tube.** **Stability:** Ambient: After separation from cells: **7 days** Refrigerated: After separation from cells: **14** days Frozen: After separation from cells: **14 days (3 freeze/thaw cycles)** **Methodology: Electro Chemiluminescence Immunoassay (ECLIA)** **Reference Range:** Male: **4.0–15.2** ng/mL Female: **4.8–23.3** ng/mL **Days Performed: Varies** **Reported: 4–5** days **CPT:** 84146x**2**	11/21/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Rufinamide	RUFIN	**For interface clients only–Test build may need to be modified** **Special Information: Collect the specimen before the next dose (trough).** Unacceptable conditions: Whole blood, gel separator tubes. **Clinical Information: Monitoring concentrations in serum or plasma to assess drug therapy and patient compliance.** **Specimen Requirement:** 1 mL serum from no additive (Red) tube; Refrigerated; **Do not collect in a gel separator tube. Centrifuge and transfer the plasma/serum to a plastic CCL tube** within 2 hours **of collection and refrigerate. Transport and store at refrigerated temperature.** *OR* **1 mL plasma from green lithium heparin no-gel tube; Refrigerated; Do not collect in a gel separator tube. Centrifuge and transfer the plasma/serum to a plastic CCL tube within 2 hours of collection and refrigerate. Transport and store at refrigerated temperature.** **Stability:** Ambient: After separation from cells: **24** hours Refrigerated: After separation from cells: **14 days** Frozen: After separation from cells: **30 days** **Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)** **Reference Range: 3.0**–30.0 ug/mL **Days Performed:** Mon–**Sat** **Reported:** 1–3 **days**	11/19/24
Testosterone, bioavailable and total by immunoassay (adult males, or individuals on testosterone therapy)	BTESTO	**Name:** Previously Bioavailable Testosterone,SHBG, Adult Male	11/19/24
Testosterone, bioavailable and total by MS (adult females, children, or individuals on testosterone-suppressing therapy)	BTSTFC	**Name:** Previously Bioavailable Testosterone/SHBG, Female & Child	11/19/24
Testosterone, free and total, by equilibrium ultrafiltration mass spectrometry	TFTEST	**For interface clients only–Test build may need to be modified** **Name:** Previously Testosterone, Total and Free, Serum **Special Information:** NOTE: Patient's age and sex are required. Hemolyzed, icteric or grossly lipemic specimens will be rejected. **Specimens from patients with recently administered isotopes will be rejected.** This test is New York DOH approved. **Clinical Information: This test is useful to evaluate hirsutism and masculinization in women, or to evaluate testicular function in clinical states in which the testosterone-binding proteins may be altered (obesity, cirrhosis, thyroid disorders). The concentration of free testosterone is very low, typically <2% of the total testosterone concentration. In most men and women, >50% of total circulating testosterone is bound to sex hormone-binding globulin (SHBG) and most of the rest is bound to albumin. Routinely available assay methods used to measure total testosterone are not sensitive enough to quantitate accurately the free testosterone fraction directly. Free testosterone is estimated in this profile by an indirect method, equilibrium ultrafiltration.** **Specimen Requirement: 2.2** mL serum from no additive (Red) tube; Minimum: **1.8** mL **Note: Minimum volume does not allow for repeat testing; Ambient;** Separate serum from cells **within 1 hour** and transfer to standard aliquot tube. **Stability:** Ambient: **7 days** Refrigerated: **7 days** Frozen: **5.58 years (9 freeze/thaw cycles)** **Methodology:** **Equilibrium Ultrafiltration** High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) *(continued on page 7)*	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Testosterone, free and total, by equilibrium ultrafiltration mass spectrometry *(continued from page 6)*		**Reference Range:** Testosterone, Free: **Refer to report** Testosterone, Total: **Refer to report** **% Free Testosterone: Refer to report** **Days Performed: Varies** **Reported: 5–7** days	
Testosterone, total by immunoassay (adult males, or individuals on testosterone therapy)	TESTO	**Name:** Previously Testosterone	11/19/24
Varicella-Zoster IgG Ab	VZVG2	**Clinical Limitation:** Results from immunosuppressed patients should be interpreted with caution. **Clinical Information:** A negative result does not rule out acute infection. If exposure to Varicella-Zoster virus is suspected, despite a negative finding, a second sample should be collected and tested no less than one-two weeks later. A positive result generally indicates exposure to the pathogen or administration of specific immunoglobulins, but is no indication of active infection or stage of disease. The results are not by themselves diagnostic and should be considered in association with other clinical data and patient symptoms. Screening of the general population leads to no appreciable diagnostic advantage. The performance characteristics with individuals vaccinated with VZV (ROD strain) have not been established. **Stability:** Ambient: **3 days** Refrigerated: 7 days Frozen: **30** days	10/10/24
Vasoactive Intestinal Polypeptide (VIP), Plasma	VIP	**Special Information:** Critical Frozen. **Collect in prechilled tube.** Separate specimens must be submitted when multiple tests are ordered. **Grossly hemolyzed, lipemic, icteric, or clotted specimens will be rejected.** **Specimen Requirement: 2** mL plasma from EDTA (Lavender) tube; **Place specimen on ice after draw.** CRITICAL FROZEN. **Collect in prechilled tube.** Separate plasma from cells immediately and transfer to standard aliquot tube and freeze. Separate specimens must be submitted when multiple tests are ordered. **Stability:** Ambient: After separation from cells: **4 hours** Refrigerated: After separation from cells: **24 hours** Frozen: After separation from cells: **3 months** **Reference Range: 0–89.1** pg/mL **Days Performed:** Mon**, Thu** **Reported: 4–8** days	10/8/24

New Tests

Test Name	Order Code	Change	Effective Date
Brivaracetam	BRIV	**Special Information:** Collect the specimen before the next dose (trough). Unacceptable conditions: Whole blood, gel separator tubes. **Clinical Information:** Monitoring concentrations in serum or plasma to assess drug therapy and patient compliance. **Specimen Requirement:** 1 mL serum from no additive (Red) tube; Minimum: 0.5 mL; Refrigerated; Timing of specimen collection: Pre-dose (trough). Do not collect in a gel separator tube. Centrifuge and transfer the plasma/serum to a plastic CCL tube within 2 hours of collection and refrigerate. Transport and store at refrigerated temperature. *OR* 1 mL plasma from green lithium heparin no-gel tube; Minimum: 0.5 mL; Refrigerated; Timing of specimen collection: Pre-dose (trough). Do not collect in a gel separator tube. Centrifuge and transfer the plasma/serum to a plastic CCL tube within 2 hours of collection and refrigerate. Transport and store at refrigerated temperature. **Stability:** Ambient: After separation from cells: 24 hours Refrigerated: After separation from cells: 14 days Frozen: After separation from cells: 30 days **Methodology:** Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** 0.2–2.0 ug/mL **Days Performed:** Mon–Sat **Reported:** 1–3 days	11/19/24
Chitotriosidase Assay	CHITO	**Note: New test was announced in the September update. Financial information was not available at that time.** **CPT:** 84999	10/29/24
Perampanel	PRMP	**Special Information:** Collect the specimen before the next dose (trough). Unacceptable conditions: Whole blood, gel separator tubes. **Clinical Information:** Monitoring concentrations in serum or plasma to assess drug therapy and patient compliance. **Specimen Requirement:** 1 mL serum from no additive (Red) tube; Minimum: 0.5 mL; Refrigerated; Timing of specimen collection: Pre-dose (trough). Do not collect in a gel separator tube. Centrifuge and transfer the plasma/serum to a plastic CCL tube within 2 hours of collection and refrigerate. Transport and store at refrigerated temperature. *OR* 1 mL plasma from green lithium heparin no-gel tube; Minimum: 0.5 mL; Refrigerated; Timing of specimen collection: Pre-dose (trough). Do not collect in a gel separator tube. Centrifuge and transfer the plasma/serum to a plastic CCL tube within 2 hours of collection and refrigerate. Transport and store at refrigerated temperature. **Stability:** Ambient: After separation from cells: 24 hours Refrigerated: After separation from cells: 14 days Frozen: After separation from cells: 30 days **Methodology:** Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** 0.18–0.98 ug/mL **Days Performed:** Mon–Sat **Reported:** 1–3 days	11/19/24

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Telomere Biology Disorders Panel	TELPAN	Test will no longer be orderable.	11/19/24