Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • June 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	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
10	Adulterants Survey, Urine					■								
7	Apixaban Assay				■									
7	ATIII Antigen				■									
2	Dilute Russell Viper Venom Time										■			
10	Early Onset Obesity Evaluation					■								
7	Edoxaban				■									
8	Factor VIII Chromogenic				■									
8	Factor XIII Antigen				■									
2	Factor XII Assay										■			
2, 10	FLT3 Tyrosine Kinase Domain Mutation, Bone Marrow												■	■
3	Hepatitis C Genotyping						■	■			■	■	■	
3	Hypercoagulation Diagnostic Interpretive Panel										■			
3	LMW Anti Xa Assay							■						
3	Lupus Anticoagulant Diagnostic Interpretive Panel										■			
3	Platelet Function Screen							■						
10	Porphobilinogen Deaminase					■								
9	Porphobilinogen (PBG) Deaminase, Erythrocyte				■									
10	Porphobilinogen, Serum					■								
9	Porphyrins, Fecal				■									
10	Porphyrins, Plasma					■								
10	Porphyrins, Stool					■								
3	Porphyrins, Urine Fractionated						■							

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
10	Porphyrins, Urine Total					■								
4	Protein S Immunologic									■				
4	Prothrombin Time and PTT Elevation Diagnostic Panel									■				
4	Prothrombin Time Elevation Diagnostic Panel									■				
4	Prothrombin Time Mixing Study									■				
5	PTT Elevation Diagnostic Panel									■				
5	PTT Incubated Mixing Study									■				
5	Quinidine						■	■			■	■	■		
5	Rivaroxaban Assay							■							
6	Spinal Muscular Atrophy Carrier Screening and Diagnostic									■					
10	Thioridazine					■									
6	Thrombin Time										■				
6	Total Erythrocyte Porphyrins						■	■	■	■	■	■			
6	Triglyceride, Body Fluid												■		
6	Triglycerides												■		

Test Changes

Test Name	Order Code	Change	Effective Date
Dilute Russell Viper Venom Time	DRVVT	**Note:** *Due to unforeseen circumstances, the changes to reference ranges that were announced in the May Technical Update are now effective immediately. We apologize for any inconvenience this may have caused.*	Effective immediately
Factor XII Assay	FXIIC	**Reference Range:** 0–1 Days: **15–124%** 2–5 Days: **12–110%** 6–30 Days: **19–108%** 1–3 Months: **28–145%** 4–11 Months: **44–153%** **1–5 Years: 71–172%** **6–10 Years: 67–186%** **11–16 Years: 38–182%** **17–999 Years: 58–218%** **Urgent Range:** 0–**999** Years: After Pathologist Review: < 5%	7/14/20
FLT3 Tyrosine Kinase Domain Mutation, Bone Marrow	F3TKDM	**CPT:** 81246 x 1	6/2/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis C Genotyping	HEPGEN	**Special Information: Unspun PPT tubes will be rejected. The HCV LiPA genotype assay usually requires a minimum viral load of 300 IU/mL to obtain a genotype.** **Note:** *Hepatitis C Viral RNA, Genotype, LiPA will be added as an alias name.* **Clinical Information:** This assay is designed for the genotyping of Hepatitis C virus (HCV) in human serum and plasma. **The HCV LiPA genotype assay can detect all 6 major HCV genotypes (1–6)** and HCV subtypes 1a and 1b. **If the banding pattern does not sufficiently differentiate between subtypes within genotype 1, only the genotype may be reported. Determination of hepatitis C genotype is often required to select the most appropriate direct acting agent(s) (DAA) for the treatment of hepatitis C. Some DAA's are only effective for the treatment of hepatitis C genotype 1, whereas others may be used for additional genotypes.** **Specimen Requirement: 2 mL** plasma from an EDTA (white) plasma preparation tube (PPT); Minimum: **0.6 mL; Separate plasma from whole blood within 24 hours of collection by centrifugation at 800-1600 x g for 20 minutes at room temperature; Transfer plasma to a sterile polypropylene screw-cap vial; Transport using cold packs;** Refrigerated *OR* **2 mL** plasma from an EDTA (lavender) tube; Minimum: **0.6 mL;** Separate plasma from whole blood within **24 hours** of collection by centrifugation **at 800-1600 x g for 20 minutes at room temperature;** Transfer plasma to a sterile polypropylene screw-cap vial; **Transport using cold packs;** Refrigerated *OR* **2 mL** serum from a serum separator (gold) tube; Minimum: **0.6 mL; Separate serum from whole blood within 24 hours of collection by centrifugation at 800-1600 x g for 20 minutes at room temperature; Transfer serum to a sterile polypropylene screw-cap vial; Transport using cold packs;** Refrigerated *OR* **2 mL** serum from a **plain no additive (red)** tube; Minimum: **0.6 mL; Separate serum from whole blood within 24 hours of collection by centrifugation at 800-1600 x g for 20 minutes at room temperature; Transfer serum to a sterile polypropylene screw-cap vial; Transport using cold packs;** Refrigerated **Stability:** Ambient: **72 hours** Refrigerated: **14 days** Frozen: **42** days **Reference Range: Refer to report** **Days Performed: 7 days per week** **Reported: 3–6** days	6/16/20
Hypercoagulation Diagnostic Interpretive Panel	HYPER	**Reference Range:** **Note:** *Refer to reference range changes for Prothrombin Time and PTT Elevation Diagnostic Panel (PTPTTE), PTT Elevation Diagnostic Panel (PTTEPL), and Thrombin Time (TT).*	7/14/20
LMW Anti Xa Assay	LMWHEP	**Specimen Requirement:** 1 mL platelet-poor plasma from a 3.2% sodium citrate (light blue) tube; Minimum: 0.5 mL; **A minimum of 0.5 mL platelet-poor plasma is needed; Therefore, draw no less than 1.5 mL whole blood in a 1.8 mL 3.2% sodium citrate tube;** Frozen	Effective immediately
Lupus Anticoagulant Diagnostic Interpretive Panel	LUPUSP	**Reference Range:** **Note:** *Refer to reference range changes for Prothrombin Time and PTT Elevation Diagnostic Panel (PTPTTE), PTT Elevation Diagnostic Panel (PTTEPL), and Thrombin Time (TT). Due to unforeseen circumstances, the changes to reference ranges that were announced in the May Technical Update are now effective immediately. We apologize for any inconvenience this may have caused.*	See note
Platelet Function Screen	PLTSCP	**Specimen Requirement:** 7 mL whole blood in a 3.2% sodium citrate (light blue) tube; Minimum: 4.5 mL; **Test must be completed within 4 hours of collection;** Ambient	Effective immediately
Porphyrins, Urine Fractionated	UPORFR	**Special Information:** Indicate total volume and collection time with specimen. **Protect specimen from light. Body fluids other than urine will be rejected. This test is New York DOH approved.**	7/9/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Protein S Immunologic	PROTSI	**Reference Range:** Total Protein S 0–1 Days: **15**–76% 2–5 Days: 27–**98%** 6–30 Days: **41**–117% 1–3 Months: **67**–149% 4–11 Months: **68**–150% 1–5 Years: **67**–163% 6–10 Years: **51–157%** 11–16 Years: 64–127% 17–**999** Years: 74–156% Free Protein S 0–1 Days: **14–90%** 2–5 Days: **14–90%** 6–30 Days: **14–90%** 1–3 Months: 49–**114%** 4–11 Months: 50–**116%** 1–5 Years: **43 -167%** 6–10 Years: **45–150%** 11–16 Years: 53–**133%** 17–**999** Years: 55–148%	7/14/20
Prothrombin Time and PTT Elevation Diagnostic Panel	PTPTTE	**Reference Range:** Prothrombin Time and PTT Elevation Diagnostic Panel: Refer to individual components Anti Xa Inhib Assay: Refer to report PT Screen: 0–1 Days: **< 14.9 sec** 2–5 Days: **< 14.3 sec** 6–30 Days: **< 13.4 sec** 1–3 Months: **< 13.3 sec** 4–11 Months: **< 13.0 sec** **1–5 Years: < 10.7 sec** **6–10 Years: < 11.3 sec** **11–16 Years: < 11.2 sec** **17**–99 Years: < 13.1 sec Incubated PTT 1:1 Mix (0–99 Years): < 35.0 sec APTT Screen: 0–1 Days: **28.2–47.4 sec** 2–5 Days: **22.9–52.0 sec** 6–30 Days: **23.1–48.0 sec** 1–3 Months: **21.7–43.5 sec** 4–11 Months: **25.3–37.3 sec** **1–5 Years: 21.3–31.6 sec** **6–10 Years: 23.1–31.6 sec** **11–16 Years: 23.1–32.5 sec** **17**–99 Years: **24.0–35.1 sec** Immediate PTT 1:1 Mix: 0–99 Years: < 33.2 sec Thrombin Time: 0–1 Days: **< 17.3 sec** 2–5 Days: < 17.9 sec 6–30 Days: < 17.9 sec 1–3 Months: < 18.2 sec 4–11 Months: < 19.1 sec 1–99 Years: < 18.6 sec PT 1:1 Mix (0–99 Years): < 13.1 sec *(Note: There will be no other reference range changes for PTPTTE)*	7/14/20
Prothrombin Time Elevation Diagnostic Panel	PTEPNL	**Reference Range:** **Note:** *Refer to reference range changes for Prothrombin Time and PTT Elevation Diagnostic Panel (PTPTTE), PTT Elevation Diagnostic Panel (PTTEPL), and Thrombin Time (TT).*	7/14/20
Prothrombin Time Mixing Study	PTMIX	**Reference Range:** **Note:** *Refer to reference range changes for Prothrombin Time and PTT Elevation Diagnostic Panel (PTPTTE) and PTT Elevation Diagnostic Panel (PTTEPL).*	7/14/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
PTT Elevation Diagnostic Panel	PTTEPL	**Reference Range:** PTT Elevation Diagnostic Panel: Refer to individual components Anti Xa Inhib Assay: Refer to report PT Screen: 0–1 Days: **< 14.9 sec** 2–5 Days: **< 14.3 sec** 6–30 Days: **< 13.4 sec** 1–3 Months: **< 13.3 sec** 4–11 Months: **< 13.0 sec** **1–5 Years: < 10.7 sec** **6–10 Years: < 11.3 sec** **11–16 Years: < 11.2 sec** **17**–99 Years: **< 13.1 sec** APTT Screen: 0–1 Days: **28.2–47.4 sec** 2–5 Days: **22.9–52.0 sec** 6–30 Days: **23.1–48.0 sec** 1–3 Months: **21.7–43.5 sec** 4–11 Months: **25.3–37.3 sec** **1–5 Years: 21.3–31.6 sec** **6–10 Years: 23.1–31.6 sec** **11–16 Years: 23.1-32.5 sec** **17**–99 Years: **24.0–35.1 sec** Immediate PTT 1:1 Mix: 0–99 Years: < 33.2 sec Incubated PTT 1:1 Mix (0–99 Years): < 35.0 sec Thrombin Time: 0–1 Days: **< 17.3 sec** 2–5 Days: < 17.9 sec 6–30 Days: < 17.9 sec 1–3 Months: < 18.2 sec 4–11 Months: < 19.1 sec 1–99 Years: < 18.6 sec	7/14/20
PTT Incubated Mixing Study	PTTIM	**Reference Range:** **Note:** *Refer to reference range changes for Prothrombin Time and PTT Elevation Diagnostic Panel (PTPTTE), PTT Elevation Diagnostic Panel (PTTEPL), and Thrombin Time (TT).*	7/14/20
Quinidine	QUINID	**Special Information: Patient Prep: Collect immediately prior to next dose. Serum separator tubes will be rejected.** **Clinical Information: Quinidine is useful in the treatment of acute and chronic supraventricular arrhythmias and ectopic rhythm disturbances. Quinidine clearance can be altered by changes in plasma proteins and in renal and/or hepatic dysfunction. Both quinidine and the related isomer quinine possess antimalarial schizonticide activity. Quinidine levels are monitored to ensure that adequate therapeutic levels are achieved and to avoid toxicity.** **Specimen Requirement:** 1 mL serum from a plain no additive (red) tube; Minimum: **0.2 mL;** Do not use serum separator tubes; Collect immediately prior to next dose; **Ambient** *OR* 1 mL plasma from a sodium or **lithium heparin (green)** tube; Minimum: **0.2 mL; Do not use plasma separator tubes;** Collect immediately prior to next dose; **Ambient** *OR* 1 mL plasma from an **EDTA (lavender)** tube; Minimum: **0.2 mL;** Collect immediately prior to next dose; **Ambient** **Stability:** Ambient: **4 days** Refrigerated: **7 days** Frozen: **Not established** **Reference Range: 2.0–5.0 mg/L** **Days Performed: Monday**–Saturday **Reported:** 2–3 days	Effective immediately
Rivaroxaban Assay	RVXBAN	**Specimen Requirement: 0.7 mL** plasma from a 3.2% sodium citrate (light blue) tube; Minimum: **0.5 mL;** Frozen	7/14/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Spinal Muscular Atrophy Carrier Screening and Diagnostic	SMAGEN	**Methodology: Polymerase Chain Reaction (PCR)**	6/2/20
Thrombin Time	TT	**Reference Range:** 0–1 Days: **< 17.3 sec** 2–5 Days: < 17.9 sec 6–30 Days: < 17.9 sec 1–3 Months: < 18.2 sec 4–11 Months: < 19.1 sec 1–99 Years: < 18.6 sec	7/14/20
Total Erythrocyte Porphyrins	PROPOR	**For Interfaced Clients Only: Test build may need to be modified** **Special Information: Lead testing should be performed FIRST to avoid potential contamination issues. Protect from light. Specimens not protected from light will be acceptable with a disclaimer. Specimens not collected in EDTA will be rejected. Clotted specimens are unacceptable. This test is New York DOH approved.** **Clinical Information: Useful as a screen for erythropoietic protoporphyria (EPP) in patients with cutaneous photosensitivity. Elevated EP results are seen in early and late iron deficiency, in the anemia of chronic disease, and in chronic lead poisoning (typically when blood lead is > 25 µg/dL). Elevated protoporphyrin (as in erythropoietic protoporphyria) and zinc coproporphyrin (usually associated with childbirth) can increase the apparent EP signal. A more specific test for free protoporphyrin is Porphyrins, Serum Total (SPORPH). Hemolyzed, clotted, or improperly aliquoted specimens may show false elevations.** **Specimen Requirement:** 1 mL whole blood in an **EDTA (royal blue)** tube; Minimum: 0.5 mL; Protect specimen from light **during collection, storage, and shipment; Transfer 1 mL whole blood to an amber transport tube;** Specimens not protected from light will be run with a disclaimer; Refrigerated *OR* 1 mL whole blood in an **EDTA (lavender)** tube; Minimum: 0.5 mL; Protect specimen from light **during collection, storage, and shipment; Transfer 1 mL whole blood to an amber transport tube;** Specimens not protected from light will be run with a disclaimer; Refrigerated **Methodology: Fluorometry (FLM)** **Reference Range: 0–35 µg/dL** **Days Performed: Monday, Wednesday, Saturday** **Reported: 2–5 days**	7/9/20
Triglyceride, Body Fluid	FTRIG	**Stability:** Ambient: **2 days** Refrigerated: 10 days Frozen: 3 months	Effective immediately
Triglycerides	TRIG	**Stability:** Ambient: **2 days** Refrigerated: **10** days Frozen: **3 months**	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Apixaban Assay	APIXBN	**Specimen Requirement:** 0.7 mL plasma from a 3.2% sodium citrate (light blue) tube; Minimum: 0.5 mL; Frozen **Stability:** Ambient: 4 hours Refrigerated: Unacceptable Frozen: 4 weeks **Methodology:** Chromogenic **Days Performed:** Sunday–Saturday **Reported:** 4 hours **CPT:** 80299 x 1 **Price:** $95.00 (non-discountable)	7/14/20
ATIII Antigen	AT3AG	**Specimen Requirement:** 2 mL plasma from a 3.2% sodium citrate (light blue) tube; Minimum: 1 mL; Frozen **Stability:** Ambient: 4 hours Refrigerated: Unacceptable Frozen: 4 weeks **Methodology:** Latex Immunoassay (LIA) **Reference Range:** 0–1 Days: 40–80% 2–5 Days: 42–85% 6–30 Days: 49–99% 1–3 Months: 74–111% 4–11 Months: 85–114% 1–5 Years: 89–132% 6–10 Years: 97–125% 11–16 Years: 83–126% 17–999 Years: 80–120% **Days Performed:** Monday–Friday **Reported:** 1 week **CPT:** 85300 x 1 **Price:** $85.00 (non-discountable)	7/14/20
Edoxaban	EDOXBN	**Specimen Requirement:** 0.7 mL plasma from a 3.2% sodium citrate (light blue) tube; Minimum: 0.5 mL; Frozen **Stability:** Ambient: 4 hours Refrigerated: Unacceptable Frozen: 4 weeks **Methodology:** Chromogenic **Days Performed:** Monday–Friday **CPT:** 80299 x 1	7/14/20

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Factor VIII Chromogenic	F8CH	**Specimen Requirement:** 1 mL platelet-poor plasma from a 3.2% sodium citrate (light blue) tube; Centrifuge, aliquot and freeze ASAP; Frozen **Stability:** Ambient: 4 hours Refrigerated: Unacceptable Frozen: 4 weeks **Methodology:** Chromogenic **Reference Range:** 0–1 Days: 22–179% 2–5 Days: 22–155% 6–30 Days: 26–158% 1–3 Months: 34–126% 4–11 Months: 38–110% 1–5 Years: 59–143% 6–10 Years: 58–133% 11–16 Years: 53–132% 17–999 Years: 50–150% **Days Performed:** Monday–Friday **Reported:** 1–2 days **CPT:** 85240 x 1 **Price:** $85.00 (non-discountable)	7/14/20
Factor XIII Antigen	F13AG	**Specimen Requirement:** 1 mL plasma from a 3.2% sodium citrate (light blue) tube; Frozen **Stability:** Ambient: 4 hours Refrigerated: Unacceptable Frozen: 14 days at minus 20 °C; 6 months at or below minus 70 °C **Methodology:** Latex Agglutination **Reference Range:** 0–1 Days: 43–152% 2–5 Days: 70–167% 6–30 Days: 62–171% 1–3 Months: 57–200% 4–11 Months: 73–188% 1–5 Years: 114–166% 6–10 Years: 103–175% 11–16 Years: 90–163% 17–999 Years: 87–180% **Days Performed:** Monday–Friday **CPT:** 85290 x 1 **Price:** $88.00 (non-discountable)	7/14/20

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Porphobilinogen (PBG) Deaminase, Erythrocyte	PBGDEP	**Includes:** Porphobilinogen deaminase RBC Hemoglobin **Special Information:** Hemoglobin (collected within past 48 hours) must be performed and submitted with the order. Clotted specimens will be rejected. Body fluids other than EDTA preserved whole blood are unacceptable. This test is New York DOH approved. **Clinical Information:** Useful to confirm a diagnosis of acute intermittent porphyria (AIP) following a positive urine porphobilinogen (PBG) test. Useful for evaluating disease risk in family members of an individual with a confirmed diagnosis of AIP. PBG deaminase (hydroxymethylbilane synthase or uroporphyrinogen I synthase) is expressed in units of mU per gram hemoglobin at 37 °C. In persons genetically susceptible to AIP, PBG deaminase concentrations are approximately half of reference values. Normal concentrations of erythrocyte PBG deaminase may include abnormal forms of hepatic PBG deaminase. This test is most useful for family studies to determine which family members are at risk for AIP and is best performed in association with a specimen from the proband. Because of ambiguous results, this test is not generally recommended for diagnosis. **Specimen Requirement:** 3 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; This test requires two specimen tubes; Separate specimens must be submitted when multiple tests are ordered; Frozen *AND* 2.5 mL whole blood in an EDTA (lavender) tube; Minimum: 0.5 mL; Fill tube to at least half of fill volume; Refrigerated **Stability:** Ambient: PBG deaminase: 4 hours; Hemoglobin: 24 hours Refrigerated: PBG deaminase: 1 week; Hemoglobin: 48 hours Frozen: PBG deaminase: 1 month; Hemoglobin: Unacceptable **Methodology:** Automated Cell Counter Fluorometric Quantitative Enzymatic **Days Performed:** Refer to individual components **Reported:** 2–7 days **CPT:** 82657 x 1, 85018 x 1 **Price:** $82.00 (non-discountable)	7/9/20
Porphyrins, Fecal	STPRPH	**Special Information:** Critical frozen. Protect from light. Must submit separate specimens when multiple tests are ordered. Complete timed collections (24-72 hour) are unacceptable. Liquid stool is unacceptable. Specimens stored in one gallon cans or other large containers will be rejected. This test is New York DOH approved. **Clinical Information:** Useful for distinguishing among acute intermittent porphyria (AIP), variegate porphyria (VP), and hereditary coproporphyria (HCP). Bacterial modification of fecal porphyrins is extensive. The recommended specimen for uroporphyrin and coproporphyrin is urine (random or 24-hour). The recommended specimen for protoporphyrin is serum. **Specimen Requirement:** 5 g random stool in a clean container; Minimum: 1 g; Protect from light during collection, storage, and shipment; Separate specimens must be submitted when multiple tests are ordered; Wrap in foil and freeze specimen immediately after collection; Critical Frozen **Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: 3 weeks **Methodology:** High Performance Liquid Chromatography (HPLC) **Days Performed:** Monday, Thursday **Reported:** 3–8 days **CPT:** 84126 x 1 **Price:** $160.00 (non-discountable)	7/9/20

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
FLT3 Tyrosine Kinase Domain Mutation, Bone Marrow	F3TKDM	$641.00 (non-discountable)	81246	6/2/20

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Adulterants Survey, Urine	UADULT	This test will no longer be available.	7/14/20
Early Onset Obesity Evaluation	OBESTY	This test will no longer be available.	7/14/20
Porphobilinogen Deaminase	PBGDEA	This test will no longer be available. Suggest ordering Porphobilinogen (PBG) Deaminase, Erythrocyte (PBGDEP)	7/9/20
Porphobilinogen, Serum	PBG	This test will no longer be available. Suggest ordering alternative tests Porphobilinogen Screen (UPBG) or Porphobilinogen, Urine Quant (UPBGQT)	7/9/20
Porphyrins, Plasma	PLPORP	This test will no longer be available. Suggest ordering Porphyrins, Serum Total (SPORPH)	7/9/20
Porphyrins, Stool	STPORP	This test will no longer be available. Suggest ordering Porphyrins, Fecal (STPRPH)	7/9/20
Porphyrins, Urine Total	UPORP	This test will no longer be available. Suggest ordering alternative test Porphyrins, Urine Fractionated (UPORFR)	7/9/20
Thioridazine	THIORI	This test will no longer be available.	7/14/20