Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • July 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
3	Activated Partial Thromboplastin Time							■			■			
6	Beta-Glucosidase, Leukocytes			■										
3	Brucella abortus IgG, IgM					■	■					■		
3	BUN, Post Dialysis						■							
3	Coag Core Panel						■							
3	D-Dimer						■							
6	Edoxaban			■										
3	Fibrinogen						■							
7	HPRT				■									
4, 7	Hypercoagulation Diagnostic Interpretive Panel					■		■					■	■
7	Interleukin-6				■									
6	Interleukin-6 (IL-6)			■										
4, 7	Lupus Anticoagulant Diagnostic Interpretive Panel					■		■				■	■	■
7	MERRF mtDNA Evaluation				■									
7	N Glycan Analysis for CDG				■									
7	N Glycan and Transferrin for CDG				■									
7	Oligosaccharide and Glycan Screening				■									
5	Prothrombin Time						■				■			
5, 7	PTT Incubated Mixing Study					■		■					■	■
7	Retinal Dystrophy Panel, NGS				■									
7	Vascular Disease Panel				■									
5	Viscosity, Blood										■			
5	Viscosity, Serum						■				■			

Dear Valued Client,

Reference range changes previously announced in the June 2020 *Technical Update* for the following tests/panels will not go into effect until **August 4, 2020**. If you have any questions, please contact Client Services at 800.628.6816.

Hypercoagulation Diagnostic Interpretive Panel (HYPER)

Lupus Anticoagulant Diagnostic Interpretive Panel (LUPUSP)

Prothrombin Time and PTT Elevation Diagnostic Panel (PTPTTE)

Prothrombin Time Elevation Diagnostic Panel (PTEPNL)

Prothrombin Time Mixing Study (PTMIX)

PTT Elevation Diagnostic Panel (PTTEPL)

PTT Incubated Mixing Study (PTTIM)

Thrombin Time (TT)

Test Changes

Test Name	Order Code	Change	Effective Date
Activated Partial Thromboplastin Time	PTT	**Specimen Requirement:** 1 mL plasma from a 3.2% sodium citrate (light blue) tube; Minimum: 0.5 mL; **Collection tube must be filled to total fill volume; Inadequately filled tubes will be rejected;** Frozen *OR* **1.8 mL whole blood** in a 3.2% sodium citrate (light blue) tube; Minimum: 0.5 mL; **Collection tube must be filled to total fill volume; Inadequately filled tubes will be rejected; Ambient** **Reference Range:** 0–1 Days: 27.1–43.7 sec 2–5 Days: 22.0–48.0 sec 6–30 Days: 22.1–44.3 sec 1–3 Months: 20.8–40.2 sec 4–11 Months: 24.3–34.4 sec 1–99 Years: 23.0–32.4 sec **Urgent Range:** 0–99 Years: > 100.0 sec **Critical Range:** **0–99 Years: EXTREMELY ABNORMAL RESULT. No clot detected at 320 seconds. Refer to Heparin Nomogram for further actions.**	8/20/20
Brucella abortus IgG, IgM	BRUABS	**Special Information: If Brucella antibody screen IgM or IgG is reactive, then confirmation by Brucella total antibody agglutination testing will be performed at an additional cost, and this could delay turnaround time.** **Clinical Information:** To aid in diagnosis of brucellosis. Brucella canis, a rare cause of brucellosis, may not be detected by this method. **This test utilizes antigen derived from Brucella abortus strain W99. However, significant cross-reactivity exists for other Brucella species (except B. canis), therefore, the assays should not be used to differentiate infection at the species level. Detection of specific IgM or IgG-class antibody to B. melitensis and B. suis by this method has not been determined.** **Specimen Requirement: 1 mL** serum from a serum separator (gold) tube; Minimum: **0.4 mL; Centrifuge and transfer serum into a standard plastic aliquot tube;** Refrigerated *OR* **1 mL** serum from a plain no additive (red) tube; Minimum: **0.4 mL; Centrifuge and transfer serum into a standard plastic aliquot tube;** Refrigerated **Stability:** Ambient: **Unacceptable** Refrigerated: 14 days **(preferred)** Frozen: 14 days	7/14/20
BUN, Post Dialysis	BUNPO1	**Specimen Requirement:** 1 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.4 mL; Submit in original tube or aliquot specimen into CCL aliquot tube; **Post BUN must be collected within 8 hours of the Pre BUN;** Centrifuge and refrigerate *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.4 mL; **Post BUN must be collected within 8 hours of the Pre BUN;** Centrifuge and refrigerate	Effective immediately
Coag Core Panel	CORPNL	**Specimen Requirement: 1 mL** plasma from a 3.2% sodium citrate (light blue) tube; Collection tube must be filled to total fill volume; Inadequately filled tubes will be rejected; Frozen *OR* **1.8 mL whole blood** in a 3.2% sodium citrate (light blue) tube; Collection tube must be filled to total fill volume; Inadequately filled tubes will be rejected; **Ambient**	8/18/20
D-Dimer	DDMER	**Specimen Requirement: 1 mL** plasma from a 3.2% sodium citrate (light blue) tube; **Collection tube must be filled to total fill volume; Inadequately filled tubes will be rejected;** Frozen *OR* **1.8 mL whole blood** in a 3.2% sodium citrate (light blue) tube; **Collection tube must be filled to total fill volume; Inadequately filled tubes will be rejected; Ambient**	8/18/20
Fibrinogen	FIBCT	**Specimen Requirement:** 1 mL plasma from a 3.2% sodium citrate (light blue) tube; Collection tube must be filled to total fill volume; **Inadequately filled tubes will be rejected;** Frozen *OR* **1.8 mL whole blood** in a 3.2% sodium citrate (light blue) tube; Collection tube must be filled to total fill volume; **Inadequately filled tubes will be rejected; Ambient**	8/18/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hypercoagulation Diagnostic Interpretive Panel	HYPER	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Prothrombin Time (PT) APTT Fibrinogen Cardiolipin Antibodies PT Gene C-Reactive Protein Homocysteine **APTT Screen** **Thrombin Time** **Anti Xa Inhib Assay** Protein C Functional **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 the **Clinical and Laboratory Standards Institute (CLSI). Per pathologist review,** the following tests may be ordered and billed: **ATIII functional (85300); ATIII Antigen (85301); Protein S clottable (85306), APCR (85307);** PTT Incubated Mixing Add On (85730, 85732 x 2); Dilute Russell Viper Venom (85613); **Staclot (85730, 85732);** Platelet Neutralization (85597); Factor V Leiden (81241); MTHFR by PCR (81291); Reptilase (85635); Fibrinogen Antigen (85385); Prot C Immunologic (85302); Prot S Immunologic (85306); **Factor VIII clotting or chromogenic (85240).** Sample must be accompanied by the completed Clinical History Form for Hemostasis and Thrombosis Evaluation **and a medication list.** **CPT:** 81240 x 1, 83090 x 1, 85303 x 1, 85384 x 1, 85390 x 1, 85520 x 1, 85610 x 1, 85670 x 1, 85730 **x 2,** 86140 x 1, 86147 x 3	8/4/20
Lupus Anticoagulant Diagnostic Interpretive Panel	LUPUSP	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** APTT Anticardiolipin Ab IgG, IgM and IgA Beta 2 Glycoproteins IgG and IgM Prothrombin Time (PT) APTT Screen Thrombin Time Anti Xa Inhibitor Assay **Special Information:** 3.2% sodium citrate is the preferred anticoagulant recommended by the National Committee for Clinical Laboratory Standards (NCCLS). Patient preparation: Discontinue heparin therapy for 2 days prior to collection. If tests are abnormal, the following tests may be ordered and billed: **DRVVT (85613), Platelet Neutralization (85597), Staclot (85730, 85732), PTT Mixing Study (85730),** Factor II (85210), Factor V (85220), Factor X (85260), Factor VIII (85247), Von Willebrand Factor Antigen (85246), Ristocetin Co-factor (85245), Factor IX Assay (85250), Factor XI Assay (85270), Factor XII Assay (85280), Heparin FXa inhibition (85520), Fibrinogen, and Bethesda Assay. Sample must be accompanied by the completed Clinical History Form for Hemostasis and Thrombosis Evaluation. **Stability:** Ambient: **4 hours** Refrigerated: Unacceptable Frozen: 2 months **(plasma)** **CPT:** 85390 x 1, 85520 x 1, 85610 x 1, 85670 x 1, 85730 x 3, 86146 x 2, 86147 x 3	8/4/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Prothrombin Time	PT	**Specimen Requirement:** 1 mL plasma from a 3.2% sodium citrate (light blue) tube; Minimum: 0.5 mL; Collection tube must be filled to total fill volume; **Inadequately filled tubes will be rejected;** Frozen *OR* **1.8 mL whole blood** in a 3.2% sodium citrate (light blue) tube; Minimum: 0.5 mL; Collection tube must be filled to total fill volume; **Inadequately filled tubes will be rejected; Ambient** **Reference Range:** Prothrombin Time 0–1 Days: 9.7–14.8 sec 2–5 Days: 9.7–14.2 sec 6–30 Days: 9.7–13.3 sec 1–3 Months: 9.7–13.2 sec 4–11 Months: 9.7–12.9 sec 1–99 Years: 9.7–13.0 sec INR 0–1 Days: 0.9–1.5 2–5 Days: 0.9–1.4 6–30 Days: 0.9–1.3 1–3 Months: 0.9–1.3 4–11 Months: 0.9–1.3 1–99 Years: 0.9–1.3 **Urgent Range:** INR 0–99 Years: > 5.0 **0–99 Years: EXTREMELY ABNORMAL RESULT. No clot detected at 320 seconds. INR unable to be calculated. This could be due to an extreme hemostasis abnormality or a contaminated or clotted specimen. Suggest redraw.**	8/20/20
PTT Incubated Mixing Study	PTTIM	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** PT Screen APTT Screen Thrombin Time Heparin Anti Xa Assay **Special Information: If tests are abnormal in the panel, the following tests may be ordered and billed: PTT Immediate and 1 Hour Incubated Mix (85732 x 2), Factor II (85210), Factor V (85220), Factor VII (85230), Factor X (85260), Factor VIII (85247), Factor IX Assay (85250), Factor XI Assay (85270), Factor XII Assay** **CPT:** 85390 x 1, 85520 x 1, 85610 x 1, 85670 x 1, 85730 x 1	8/4/20
Viscosity, Blood	BLDVIS	**Days Performed:** Monday–Friday **Reported: 48–72 hours**	9/2/20
Viscosity, Serum	SERVIS	**Specimen Requirement:** 5 mL serum from a plain no additive (red) tube; Minimum: **15 mL (Collect 15 mL whole blood to ensure minimum serum volume of 5 mL);** Refrigerated *OR* 5 mL serum from a serum separator (gold) tube; Minimum: **15 mL (Collect 15 mL whole blood to ensure minimum serum volume of 5 mL);** Refrigerated **Days Performed:** Monday–Friday **Reported: 48–72 hours**	9/2/20

New Tests

Test Name	Order Code	Change	Effective Date
Beta-Glucosidase, Leukocytes	GAUCHD	**Special Information:** It is recommended that the specimen arrive refrigerated within 96 hours of collection in order to be stabilized for optimal isolation of leukocytes. Collect specimen Monday through Thursday only and not the day before a holiday. Specimen should be collected and packaged as close to shipping time as possible. Please include Biochemical Genetics Patient Information form with the specimen. Grossly hemolyzed specimens will be rejected. **Clinical Information:** This test provides diagnostic testing for patients with clinical signs and symptoms suspicious for Gaucher disease. It is not intended for carrier detection. Individuals affected with Gaucher disease will have enzyme levels less than 3.53 nmol/h/mg protein. It has been shown that some carriers will also have less than 3.53 nmol/h/mg protein activity. Cautions: Enzyme levels may be normal in individuals receiving enzyme replacement therapy. **Specimen Requirement:** 6 mL whole blood in an EDTA (lavender) tube; Minimum: 2 mL; Draw 2 tubes; Deliver to Cleveland Clinic Laboratories ASAP on the day of collection; Draw Monday–Thursday only, and do not draw the day before a holiday; Specimen must be received at Cleveland Clinic Laboratories by 12:00 noon EST on Thursday; Send specimen in the original tube; Do not transfer blood to other containers; Specimen should be collected and packaged as close to shipping time as possible; Please submit the Biochemical Genetics Patient Information form with the specimen; Refrigerated **Stability:** Ambient: 72 hours Refrigerated: 4 days (preferred) Frozen: Unacceptable **Methodology:** Flow Injection Analysis-Tandem Mass Spectrometry (FIA-MS/MS) **Reference Range:** Refer to report **Days Performed:** Varies **Reported:** 6–11 days **CPT:** 82963 x 1 **Price:** $450.00 (non-discountable)	6/30/20
Edoxaban	EDOXBN	**Note:** *This test was previously announced in the June Technical Update.* **Stability:** Ambient: 4 hours Refrigerated: Unacceptable Frozen: 4 weeks (plasma only) **Price:** $111.00 (non-discountable)	7/14/20
Interleukin-6 (IL-6)	INLKN6	**Special Information:** Frozen samples can be thawed once. Separate serum from cells as soon as possible. Lipemic and hemolyzed samples should be avoided. **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Refrigerated **Stability:** Ambient: 24 hours Refrigerated: 7 days Frozen: 14 days (Frozen samples can be thawed once) **Methodology:** Immunoenzymatic Assay **Reference Range:** < 6.0 pg/mL **Days Performed:** 7 days per week **Reported:** 1 day **CPT:** 83520 x 1 **Price:** $138.00	8/4/20

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Hypercoagulation Diagnostic Interpretive Panel	HYPER	$1017.00	81240, 83090, 85303, 85384, 85390, 85520, 85610, 85670, 85730 x 2, 86140, 86147 x 3	8/4/20
Lupus Anticoagulant Diagnostic Interpretive Panel	LUPUSP	$759.00	85390, 85520, 85610, 85670, 85730 x 3, 86146 x 2, 86147 x 3	8/4/20
PTT Incubated Mixing Study	PTTIM	$276.00	85390, 85520, 85610, 85670, 85730	8/4/20

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
HPRT	HPRT	This test will no longer be available.	8/6/20
Interleukin-6	INT6	This test will no longer be available. Suggest ordering Interleukin-6 (IL-6) (INLKN6)	8/4/20
MERRF mtDNA Evaluation	MERRF	This test will no longer be available.	8/6/20
N Glycan Analysis for CDG	CDG	This test will no longer be available.	Effective immediately
N Glycan and Transferrin for CDG	NCDG	This test will no longer be available.	Effective immediately
Oligosaccharide and Glycan Screening	OLIGLY	This test will no longer be available.	Effective immediately
Retinal Dystrophy Panel, NGS	RETDYS	This test will no longer be available.	8/6/20
Vascular Disease Panel	VASDPL	This test will no longer be available.	8/4/20