Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • November 2019

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	11-Deoxycorticosterone Qt, Serum/Plasma						■	■		■		■	■	
3	ALL NGS Panel Bone Marrow												■	
3	ALL NGS Panel Peripheral Blood												■	
3	Alpha Fetoprotein, CSF (Tumor Marker)						■					■		
3	Anaplasma phagocytophilum (HGA) Antibodies, IgG and IgM						■	■						
4	Anti Enterocyte Antibodies						■	■						
4	Babesia Microti IgG & IgM Abs						■	■			■			
4	BCR/ABL1 p190 Quantitative PCR Blood							■						
4	BCR/ABL1 p190 Quantitative PCR Bone Marrow							■						
4	BCR/ABL1 p210 Quantitative PCR Blood							■						
4	BCR/ABL1 p210 Quantitative PCR Bone Marrow							■						
4	BCR-ABL Qualitative Multiplex RT-PCR							■					■	
12	BCR-ABL Qualitative Multiplex RT-PCR Bone Marrow			■										
5, 13	Bioavailable Testosterone/SHBG, Female & Child						■						■	■
13	Bromide				■									
5	CALR (Calreticulin) Exon 9 Mutation Analysis Marrow												■	
5	CALR (Calreticulin) Exon 9 Mutation Blood												■	
5	Catecholamines Fractionated by LC-MS/MS, Urine Free									■		■		
6	CEBPA Mutation Analysis Blood												■	
6	CEBPA Mutation Analysis Marrow												■	

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
6	Chlamydia Antibody Panel, IgG					■	■					■		
6	Chromosome Analysis, Blood										■			
6, 13	Chronic Lymphoproliferative Disorder NGS Bone Marrow												■	■
6	Citrate, Serum					■								
7, 13	Copper, Free, Serum or Plasma		■			■	■			■	■	■		■
7	Cystine, Urine Quant					■				■	■			
7	FLT3 Tyrosine Kinase Domain Analysis Blood												■	
7	Galactose-1-Phosphate, Uridyl Trans.					■	■		■	■				
8	HDL Cholesterol Subclasses					■	■							
8, 13	Hematologic Neoplasm Next Generation Sequencing Panel Marrow												■	■
8, 13	Hematologic Neoplasm Next Generation Sequencing Panel Peripheral Blood												■	■
8	Hemoglobin, Plasma					■	■							
8	Hepatitis Delta Virus Antigen					■	■				■			
8	High Molecular Weight Kininogen					■	■				■	■		
13	Human Erythrocyte Ag				■									
9	JAK2 V617F Mutation Detection Bone Marrow												■	
13	Loxapine				■									
9	Lysozyme					■				■		■		
13	MELAS mtDNA Profile				■									
9	MPL Mutation Analysis Marrow												■	
13	Myelin Protein Zero DNA Sequencing Test				■									
9	Myeloid NGS Panel Bone Marrow												■	
9	Myeloproliferative Neoplasm Panel Marrow												■	
9	Myeloproliferative Neoplasm Panel Peripheral Blood												■	
12	Next Generation Sequencing Hotspot PIK3CA Gene Analysis			■										
9	NPM1 Mutation Detection Bone Marrow												■	
9	Nucleophosmin Gene (NPM1) Mutation Blood												■	
9	pH, Body Fluid						■							
9	P/Q-Type Voltage-Gated Calcium Channel (VGCC) Antibody		■			■								
13	Pregnanetriol				■									
10	Purine and Pyrimidine Panel							■		■	■			
13	RHCE Variant Antigen				■									
10	Routine, Prenatal Group B Strep PCR		■											
10	RPR					■						■		
11	RPR with Titer					■						■		
11, 13	Sulfonamides					■	■		■	■	■	■	■	■
11	Sulfonylurea Hypoglycemia Panel, Quantitative, Urine										■			
13	Thiocyanate, Urine Random				■									
11	Vitamin B7 (Biotin)									■				

Test Changes

Test Name	Order Code	Change	Effective Date
11-Deoxycortico-sterone Qt, Serum/ Plasma	11DCOR	**Special Information: Grossly hemolyzed specimens will be rejected. This test is New York DOH approved.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Transfer into a standard aliquot tube; Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.3 mL; Transfer into a standard aliquot tube; Refrigerated *OR* 1 mL plasma from a sodium **or lithium heparin (green) tube;** Minimum: 0.3 mL; Transfer into a standard aliquot tube; Refrigerated *OR* 1 mL plasma from a **sodium heparin (light green) plasma separator tube (PST);** Minimum: 0.3 mL; Transfer into a standard aliquot tube; Refrigerated *OR* 1 mL plasma from a **lithium heparin (light green) plasma separator tube (PST);** Minimum: 0.3 mL; Transfer into a standard aliquot tube; Refrigerated **Stability:** Ambient: **After separation from cells:** Unacceptable Refrigerated: After separation from cells: 1 week Frozen: After separation from cells: 6 months **Methodology: High Performance** Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) **Days Performed:** Monday, Wednesday, Friday **Reported: 3–6** days	11/5/19
ALL NGS Panel Bone Marrow	ALLMRW	**CPT:** 81450 x 1	11/26/19
ALL NGS Panel Peripheral Blood	ALLPBL	**CPT:** 81450 x 1	11/26/19
Alpha Fetoprotein, CSF (Tumor Marker)	AFPCSF	**Special Information: Specimens other than CSF will be rejected. This test is New York DOH approved.** **Clinical Information:** The Beckman Coulter Access DXI AFP method is used. Results obtained with different assay methods or kits cannot be used interchangeably. Alpha Fetoprotein (AFP) is a valuable aid in the management of nonseminomatous testicular cancer patients when used in conjunction with information available from the clinical evaluation and other diagnostic procedures. Increased AFP concentrations have also been observed in ataxia telangiectasia, hereditary tyrosinemia, primary hepatocellular carcinoma, teratocarcinoma, gastrointestinal tract cancers with and without liver metastases, and in benign hepatic conditions such as acute viral hepatitis, chronic active hepatitis, and cirrhosis. The result cannot be interpreted as absolute evidence of the presence or absence of malignant disease. The result is not interpretable as a tumor marker in pregnant females. **Stability:** Ambient: **72** hours Refrigerated: **2 weeks** Frozen: 1 year	11/5/19
Anaplasma phagocytophilum (HGA) Antibodies, IgG and IgM	ANIGM	**Special Information: Bacterially contaminated, heat-inactivated, hemolyzed, icteric, turbid, or lipemic specimens will be rejected. This test is New York DOH approved.** **Clinical Information: Acceptable test for acute or convalescent phase of infection from Anaplasma phagocytophilum. May be useful when Polymerase Chain Reaction (PCR) testing is not an option (e.g., outside the 2 week window for acute phase). However, PCR testing is generally preferred.** **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: **0.2 mL; Transfer serum into a standard aliquot tube;** Refrigerated	11/18/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Anti Enterocyte Antibodies	ENTERO	**Special Information:** Medical history **form is required for testing and** must accompany specimen. Age of onset; age at Anti-Enterocyte Antibodies (AEA) testing; clinical manifestations, including diarrhea, hematochezia, vomiting, failure to thrive, peripheral edema, chronic cough/asthma, arthralgias/arthritis, fevers, recurrent infection (specify), skin rash (specify), other (specify); associated auto-Immune disorders, including glomerulonephritis, diabetes, other (specify); and any treatment in progress including but not limited to corticosteroids, Cyclosporine, Tacrolimus, or other (specify). **Thawed or thawing specimens (warm or cold) will be rejected.** **Specimen Requirement: 1 mL** serum from a plain no additive (red) tube; Minimum: 1 mL; Do not use serum separator tubes; Medical history **form** MUST accompany the specimen; Frozen	11/12/19
Babesia Microti IgG & IgM Abs	BMICGM	**Special Information:** Bacterially contaminated, hemolyzed or lipemic specimens are unacceptable. **This test is New York DOH approved.** **Clinical Information:** Useful if Giemsa stain is negative, but high suspicion of babesiosis exists. Will not detect B. duncani or strain MO-1. **Specimen Requirement:** 1 mL serum from a **serum separator (gold)** tube; Minimum: **0.2 mL;** Remove serum from cells ASAP or within 2 hours of collection; Parallel testing is preferred and convalescent specimens MUST be received within 30 days from receipt of the acute specimens; Please mark specimens plainly as ACUTE or CONVALESCENT; Refrigerated **Reference Range:** Babesia microti IgG Abs **< 1:16 Negative–No significant level of detectable Babesia IgG antibody** **1:16 Equivocal–Repeat testing in 10-14 days may be helpful** **> 1:16 Positive–IgG antibody to Babesia detected, which may indicate a current or past infection** Babesia microti IgM Abs **< 1:20 Negative–No significant level of detectable Babesia IgM antibody** **1:20 Equivocal–Repeat testing in 10-14 days may be helpful** **> 1:20 Positive–IgM antibody to Babesia detected, which may indicate a current or recent infection**	11/18/19
BCR/ABL1 p190 Quantitative PCR Blood	P190PB	**Specimen Requirement:** 10 mL whole blood in an EDTA (lavender) tube; Minimum: 4 mL; **If patient has low white blood cell count, please collect up to an additional 10 mL in EDTA (lavender) and forward all tubes to Cleveland Clinic Laboratories;** Ambient	11/26/19
BCR/ABL1 p190 Quantitative PCR Bone Marrow	P190BM	**Specimen Requirement:** 5 mL bone marrow in an EDTA (lavender) tube; Minimum: 2 mL; **If patient has low white blood cell count, please collect up to an additional 5 mL in EDTA (lavender) and forward all tubes to Cleveland Clinic Laboratories;** Ambient	11/26/19
BCR/ABL1 p210 Quantitative PCR Blood	P210PB	**Specimen Requirement:** 10 mL whole blood in an EDTA (lavender) tube; Minimum: 4 mL; **If patient has low white blood cell count, please collect up to an additional 10 mL in EDTA (lavender) and forward all tubes to Cleveland Clinic Laboratories;** Ambient	11/26/19
BCR/ABL1 p210 Quantitative PCR Bone Marrow	P210BM	**Specimen Requirement:** 4 mL bone marrow in an EDTA (lavender) tube; Minimum: 2 mL; **If patient has low white blood cell count, please collect up to an additional 4 mL in EDTA (lavender) and forward all tubes to Cleveland Clinic Laboratories;** Ambient	11/26/19
BCR-ABL Qualitative Multiplex RT-PCR	BCRQL	**Specimen Requirement:** 10 mL blood in an EDTA (lavender) tube; Minimum: 4 mL; **If patient has low white blood cell count, please collect up to an additional 10 mL in EDTA (lavender) and forward all tubes to Cleveland Clinic Laboratories;** Ambient *OR* 5 mL bone marrow in an EDTA (lavender) tube; Minimum: 2 mL**; If patient has low white blood cell count, please collect up to an additional 5 mL in EDTA (lavender) and forward all tubes to Cleveland Clinic Laboratories;** Ambient **CPT:** 81206 x 1, 81207 x 1, 81208 x 1, **G0452 x 1**	10/31/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Bioavailable Testosterone/SHBG, Female & Child	BTSTFC	**Special Information:** This test is suggested for women and children due to an improved sensitivity of testosterone by LC-MS/MS. **EDTA plasma is unacceptable. This test is New York DOH approved.** **CPT:** 84270 x 1, **84402 x 1,** 84403 x 1	11/18/19
CALR (Calreticulin) Exon 9 Mutation Analysis Marrow	CALRM	**CPT:** 81219 x 1	11/26/19
CALR (Calreticulin) Exon 9 Mutation Blood	CALR	**CPT:** 81219 x 1	11/26/19
Catecholamines Fractionated by LC-MS/MS, Urine Free	URCAT2	**Stability:** Ambient: Unacceptable Refrigerated: 1 week (unpreserved); NOTE: For longer stability, see special information; **1 month (preserved)** Frozen: **Unacceptable (unpreserved);** 6 months (preserved) **Reference Range:** Epinephrine, Urine per 24h 0–3 Years: Not Established 4–10 Years: 1–14 µg/d 11–17 Years: 1–18 µg/d 18–99 Years: 1–14 µg/d Norepinephrine, Urine 24h 0–3 Years: Not Established **4–10 Years: 7–65 µg/d** **11–17 Years: 12–96 µg/d** **18–99 Years: 14–120 µg/d** Dopamine, Urine 24 h 0–3 Years: Not Established **4–10 Years: 80–440 µg/d** **11–17 Years: 100–496 µg/d** **18–99 Years: 71–485 µg/d** Creatinine, Urine 24h Male 3–8 Years: 140–700 mg/d 9–12 Years: 300–1300 mg/d 13–17 Years: 500–2300 mg/d 18–50 Years: 1000–2500 mg/d 51–80 Years: 800–2100 mg/d 81–99 Years: 600–2000 mg/d Female 3–8 Years: 140–700 mg/d 9–12 Years: 300–1300 mg/d 13–17 Years: 400–1600 mg/d 18–50 Years: 700–1600 mg/d 51–80 Years: 500–1400 mg/d 81–99 Years: 400–1300 mg/d Epinephrine, Ur ratio to CRT 0–11 Months: 0–380 µg/g crt 1–3 Years: 0–82 µg/g crt 4–10 Years: 5–93 µg/g crt 11–17 Years: 3–58 µg/g crt 18–99 Years: 0–20 µg/g crt Norepinephrine, Ur ratio to CRT 0–11 Months: 25–310 µg/g crt 1–3 Years: 25–290 µg/g crt 4–10 Years: 27–110 µg/g crt 11–17 Years: 4–105 µg/g crt 18–99 Years: 0–45 µg/g crt Dopamine, Ur ratio to CRT 0–11 Months: 240–1290 µg/g crt 1–3 Years: 80–1220 µg/g crt 4–10 Years: 220–720 µg/g crt 11–17 Years: 120–450 µg/g crt 18–99 Years: 0–250 µg/g crt	11/18/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
CEBPA Mutation Analysis Blood	CEBPA	**CPT:** 81218 x 1	11/26/19
CEBPA Mutation Analysis Marrow	CEBPAM	**CPT:** 81218 x 1	11/26/19
Chlamydia Antibody Panel, IgG	CHLAMG	**Special Information: Contaminated, hemolyzed, or hyperlipemic sera will be rejected. Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Mark specimens plainly as acute or convalescent. This test is New York DOH approved.** **Clinical Information: Differentiate between Chlamydophila species (C. psittaci, C. pneumoniae). Because of cross-reactivity, a C. pneumoniae-specific reaction will exhibit titers two-fold or greater than C. trachomatis or C. psittaci serology. Limited value in the diagnosis of most oculogenital (e.g., eyes, genitalia) chlamydial infections. The Chlamydia antibody test contains both species- and genus-specific antigens, and serological cross-reactions may be seen in both acute and convalescent samples (less than 1:128). A C. pneumoniae-specific reaction will exhibit titers two-fold or greater than titers observed with C. trachomatis or C. psittaci serology. Any IgG titer may indicate past exposure to that particular species. IgG titers in recently infected individuals are typically greater than or equal to 1:512. The Chlamydia microimmunofluorescent assay slides utilize C. psittaci, C. pneumoniae, and nine serotypes of C. trachomatis. The LGV strains of C. trachomatis are not included in this assay.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.15 mL;** Separate serum from cells within 2 hours of collection **and transfer into a standard aliquot tube; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as acute or convalescent;** Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: **0.15 mL;** Separate serum from cells within 2 hours of collection **and transfer into a standard aliquot tube; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as acute or convalescent;** Refrigerated **Stability:** Ambient: After separation from cells: **48 hours** Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year **(Avoid repeated freeze/thaw cycles)**	11/12/19
Chromosome Analysis, Blood	CHRBLD	**Days Performed:** Sunday–Saturday **Reported: 14** days	Effective immediately
Chronic Lymphoproliferative Disorder NGS Bone Marrow	LPMNGS	**CPT:** 81450 x 1	11/26/19
Citrate, Serum	CITRAT	**Special Information: Specimens received at room temperature will be rejected.**	12/9/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Copper, Free, Serum or Plasma	FRCOP	**Test Name:** Previously Copper, Serum Free (Direct) **Special Information: Separator tubes are unacceptable.** **Note:** *Clinical Information will be removed.* **Specimen Requirement: 3 mL** serum from a plain no additive (navy blue) tube; Minimum: **1.2 mL;** Do not use serum separator tubes; Remove serum from cells ASAP **or within 2 hours of collection** and aliquot into a trace metal-free transport tube (ARUP #43116) **or acid-washed transfer vial (ARUP #54350); Refrigerated** *OR* **3 mL plasma from an EDTA (royal blue) tube;** Minimum: **1.2 mL; Do not use plasma separator tubes; Remove plasma from cells ASAP or within 2 hours of collection and aliquot into a trace metal-free transport tube (ARUP #43116) or acid-washed transfer vial (ARUP #54350); Refrigerated** **Stability:** Ambient: **1 month** Refrigerated: **1 month** Frozen: 1 month **Reference Range:** Copper, **Ser/Pl** Free (Direct): **Refer to report** **Days Performed: Varies** **Reported: 9–12** days	11/18/19
Cystine, Urine Quant	UCYSTD	**Special Information: Critical Frozen. Refrigerated or ambient specimens will be rejected. Separate specimens must be submitted when multiple tests are ordered.** Provide clinical information along with age, gender, diet, drug therapy and family history. **This test is New York DOH approved.** **Clinical Information:** This test is indicated only to monitor cystinuria patients on therapy. **Reference Range:** 0–2 Months: **≤ 870 µmol/g crt** **3–11 Months: ≤ 300 µmol/g crt** **1–2 Years: ≤ 150 µmol/g crt** **3–5 Years: ≤ 125 µmol/g crt** **6–11 Years: ≤ 100 µmol/g crt** **12 Years and older: ≤ 150 µmol/g crt** **Days Performed: Monday–Friday** **Reported:** 4–8 days	11/18/19
FLT3 Tyrosine Kinase Domain Analysis Blood	F3TKD	**CPT:** 81246 x 1	11/26/19
Galactose-1-Phosphate, Uridyl Trans.	G1PHOS	**Note:** *Galactose-1-Phosphate Uridyltransferase (GALT Enzyme), RBC will be added as an alias name.* **Special Information: Do NOT freeze.** Hemolyzed specimens are unacceptable. **This test is New York DOH approved.** **Clinical Information:** Enzyme activity may not differentiate variant form of galactosemia or carriers. To monitor therapy in patients with galactosemia, order Galactose-1-Phosphate in red blood cells. One U/g Hb is equivalent to one µmol/hour/gram of hemoglobin (µmol/hr/g hb). **Genotype/Galactose-1-Phosphate Uridyltransferase activity (µmol h-1 gHb-1): Classic galactosemia (G/G), ≤ 0.7; Duarte galactosemia (D/G), 3.1–7.8; Classic galactosemia carrier (G/N), 6.5–16.2; Duarte homozygous (D/D), 6.4–16.5; Duarte carrier (D/N), 12.0–24.0; Normal (N/N), ≥ 19.4** **Specimen Requirement:** 7 mL whole blood in a sodium heparin (green) tube; Minimum: 3 mL; Place specimen on ice after draw; **Do NOT freeze;** Refrigerated *OR* 7 mL whole blood in a lithium heparin (green) tube; Minimum: 3 mL; Place specimen on ice after draw; **Do NOT freeze;** Refrigerated *OR* 7 mL whole blood in an EDTA (lavender) tube; Minimum: 3 mL; Place specimen on ice after draw; **Do NOT freeze;** Refrigerated **Methodology:** Enzymatic **Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)** **Reference Range: ≥ 19.4 U/g Hb**	11/18/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
HDL Cholesterol Subclasses	HDLSUB	**Special Information: Patient Prep: If a cholesterol measurement is to be performed along with other lipid tests,** the patient should fast **9**–12 hours prior to collection. **Specimen Requirement:** 3 mL serum from a plain no additive (red) tube; Minimum: 1.5 mL; **If a cholesterol measurement is to be performed along with other lipid tests,** the patient should fast **9**–12 hours prior to collection; Refrigerated *OR* 3 mL plasma from a sodium heparin (green) tube; Minimum: 1.5 mL; **If a cholesterol measurement is to be performed along with other lipid tests,** the patient should fast **9**–12 hours prior to collection; Refrigerated *OR* 3 mL serum from a serum separator (gold) tube; Minimum: 1.5 mL; **If a cholesterol measurement is to be performed along with other lipid tests,** the patient should fast **9**–12 hours prior to collection; Refrigerated	12/16/19
Hematologic Neoplasm Next Generation Sequencing Panel Marrow	HNMNGS	**CPT:** 81455 x 1	11/26/19
Hematologic Neoplasm Next Generation Sequencing Panel Peripheral Blood	HNPNGS	**CPT:** 81455 x 1	11/26/19
Hemoglobin, Plasma	HGBP	**Special Information:** Separate plasma from cells ASAP. Delayed separation from cells will elevate plasma hemoglobin. Unacceptable: EDTA and citrated plasma. **This test is New York DOH approved.** **Clinical Information: Identify increased concentration, which is indicative of acute intravascular destruction of erythrocytes. Not of clinical value in the diagnosis of chronic hemolytic disorders.** **Specimen Requirement:** 2 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 0.7 mL; Separate plasma from cells ASAP or within 2 hours of collection **and transfer into a standard aliquot tube;** Refrigerated	11/12/19
Hepatitis Delta Virus Antigen	HDVAG	**Special Information: Grossly hemolyzed or lipemic specimens will be rejected. This test is New York DOH approved.** **Clinical Information: Diagnose Hepatitis Delta Virus (HDV) infection in patient with documented acute or chronic Hepatitis B Virus (HBV) and at risk for HDV infection. Consider ordering HBV core IgM antibody to determine whether HDV infection is a coinfection or a superinfection with HBV.** **Specimen Requirement:** 1 mL serum from a plain no additive (red) tube; Minimum: **0.5 mL; Transfer serum to a standard aliquot tube;** Frozen *OR* 1 mL serum from a **serum separator (gold) tube;** Minimum: **0.5 mL; Transfer serum to a standard aliquot tube;** Frozen **Days Performed:** Varies **Reported: 8–11** days	11/18/19
High Molecular Weight Kininogen	HMWK	**Special Information: Do not draw from an arm with a heparin lock or heparinized catheter. Collect blood in a blue-top tube containing 3.2% buffered sodium citrate. When using a winged collection device (e.g., butterfly), a discard tube is required prior to collection of coagulation samples. Separate specimens must be submitted when multiple tests are ordered.** **Specimen Requirement:** 2 mL plasma from a sodium citrate (light blue) tube; Minimum: 1 mL; **Fill collection tubes completely; Mix by gentle inversion at least 6 times;** Centrifuge, aliquot and freeze **immediately; Separate specimens must be submitted when multiple tests are ordered;** Frozen **Stability:** Ambient: **4 hours** Refrigerated: Unacceptable Frozen: **2 years (Four freeze/thaw cycles are acceptable)** **Days Performed: Monday** **Reported: 5**–9 days	12/3/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
JAK2 V617F Mutation Detection Bone Marrow	JAK2M	**CPT:** 81270 x 1	11/26/19
Lysozyme	LYSO2	**Special Information: Hemolyzed, icteric, lipemic, or contaminated specimens will be rejected. This test is New York DOH approved.** **Clinical Information:** Serum lysozyme levels may be elevated in acute myelomonocytic leukemia (FAB-M4), chronic myelomonocytic leukemia (CMML), and chronic myelocytic leukemia (CML). Increased serum lysozyme activity is present in tuberculosis, sarcoidosis, megaloblastic anemias, acute bacterial infections, ulcerative colitis, regional enteritis, and Crohn's disease. Elevated levels of serum lysozyme occur during severe renal insufficiency, renal transplant rejection, urinary tract infections, pyelonephritis, glomerulonephritis, and nephrosis. **Stability:** Ambient: After separation from cells: **Unacceptable** Refrigerated: After separation from cells: **5 days** Frozen: After separation from cells: **1 month** **Reference Range: ≤ 2.75 µg/mL**	11/18/19
MPL Mutation Analysis Marrow	MPLM	**CPT:** 81403 x 1	11/26/19
Myeloid NGS Panel Bone Marrow	MYMNGS	**CPT:** 81450 x 1	11/26/19
Myeloproliferative Neoplasm Panel Marrow	MPNM	**CPT:** 81479 x 1	11/26/19
Myeloproliferative Neoplasm Panel Peripheral Blood	MPNP	**CPT:** 81479 x 1	11/26/19
NPM1 Mutation Detection Bone Marrow	NPM1M	**CPT:** 81310 x 1	11/26/19
Nucleophosmin Gene (NPM1) Mutation Blood	NPM1	**CPT:** 81310 x 1	11/26/19
pH, Body Fluid	FLPH	**Specimen Requirement: 2–3 mL** body fluid in a clean container **(No preservatives);** Minimum: **2–3 mL;** Place on ice immediately after collection; Refrigerated	12/24/19
P/Q-Type Voltage-Gated Calcium Channel (VGCC) Antibody	VOLTCA	**Test Name:** Previously Voltage-Gated Calcium Channel IgG Autoantibodies **Note:** *There is a clinically significant charting name change associated with this test. Component name = P/Q-Type Calcium Channel Antibody*	11/18/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Purine and Pyrimidine Panel	UPURPY	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Uracil Thymine Adenine Hypoxanthine Xanthine Orotic Acid Dihydroorotic Uric Acid Deoxythymidine Deoxyuridine Thymidine Uridine Deoxyadenosine Deoxyinosine Deoxyguanosine Adenosine Inosine Guanosine 5-Aminoimidazole-4-carboxamide 1-beta-D-ribofuranoside (AICAR) Succinyladenosine **S-Sulfocysteine** Dihydrouracil Dihydrothymine N-carbamoyl-beta-alanine N-carbamoyl-beta-aminoisobutyric Acid Interpretation Reviewed by **Reference Range:** **S-Sulfocysteine** **0–3 Years: ≤ 11 mmol/mol Cr** **4–6 Years: ≤ 5 mmol/mol Cr** **7–12 Years: ≤ 5 mmol/mol Cr** **13–18 Years: ≤ 5 mmol/mol Cr** **18 Years and older: ≤ 5 mmol/mol Cr** *(Note: There will be no other changes to reference ranges for Purine and Pyrimidine Panel.)* **Days Performed: Tuesday** **Reported: 8–17** days	11/14/19
Routine, Prenatal Group B Strep PCR	GBPCR	**Test Name:** Previously Group B Strep PCR	Effective immediately
RPR	RPR	**Clinical Information: Rapid Plasma Reagin (RPR) is a semi-quantitative non-treponemal test that is only used when syphilis screen (i.e., treponemal) test is positive/reactive. RPR is also used for treatment followup of treponemal infections, mainly venereal syphilis. RPR may be reactive due to a range of other causes, certain infections (HIV, tuberculosis, malaria, etc.), anti-phospholipid syndrome, endocarditis, and malignancies, among others. Clinical correlation is required.** **Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14 days**	1/2/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
RPR with Titer	RPRT	**Special Information:** If reactive, then RPR Quant Titer will be ordered and charged. When a reactive specimen is found, Ohio state law requires completion of an Ohio Department of Health confidential report form. **Clinical Information: Rapid Plasma Reagin (RPR) is a semi-quantitative non-treponemal test that is only used when syphilis screen (i.e., treponemal) test is positive/reactive. RPR is also used for treatment followup of treponemal infections, mainly venereal syphilis. RPR may be reactive due to a range of other causes, certain infections (HIV, tuberculosis, malaria, etc.), anti-phospholipid syndrome, endocarditis, and malignancies, among others. Clinical correlation is required.** **Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14 days**	1/2/20
Sulfonamides	SULFA	**Special Information:** Separator tubes are unacceptable. This test is New York DOH approved. **Clinical Information: Note the following interfering substances: Acetaminophen; Benzocaine; Furosemide; Lidocaine; para-aminobenzoic acid; Thiazide diuretics** **Specimen Requirement:** 1 mL serum from a plain no additive (red) tube; Minimum: **0.4 mL;** Separate serum from cells within 2 hours of collection **and transfer to a standard aliquot tube; Do NOT draw serum separator tubes;** Refrigerated *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: **0.4 mL;** Separate plasma from cells within 2 hours of collection **and transfer to a standard aliquot tube; Do NOT draw plasma separator tubes;** Refrigerated **Stability:** Ambient: After separation from cells: **24 hours** Refrigerated: After separation from cells: **3 months** Frozen: After separation from cells: **3 months** **Methodology: Spectrophotometry (S)** **Reference Range: Refer to report** **Days Performed: Varies** **Reported:** 9–**12** days **CPT: 80375 x 1 (G0480, if appropriate)**	11/18/19
Sulfonylurea Hypoglycemia Panel, Quantitative, Urine	USULFO	**Days Performed:** Varies **Reported:** 6–**13** days	11/18/19
Vitamin B7 (Biotin)	VITB7	**Reference Range:** **< 12 Years: 100.0–2460.2 pg/mL (Pediatric)** **≥ 12 Years:** 221.0–3004.0 pg/mL **(Adult)**	11/25/19

New Tests

Test Name	Order Code	Change	Effective Date
BCR-ABL Qualitative Multiplex RT-PCR Bone Marrow	BCRQLM	**Note:** *This test was previously announced in the June and July Technical Updates. It was determined that this new order code will not be needed. Please refer to changes for BCR-ABL Qualitative Multiplex RT-PCR (BCRQL). We apologize for any inconvenience this may have caused.*	Effective immediately
Next Generation Sequencing Hotspot PIK3CA Gene Analysis	PIK3GN	**Specimen Requirement:** 3–5 mL fine needle aspirate (FNA) in CytoLyt solution; FNA specimens are preserved in CytoLyt solution and should be stored at 4 °C until DNA extraction can be performed; Transport to Cleveland Clinic Laboratories at ambient temperature is acceptable; Ambient *OR* 10 mm square formalin-fixed paraffin block; Formalin-fixed paraffin-embedded (FFPE) tissue slides; Transport and store slides at ambient temperature; 10 unstained section FFPE tissue on charged, unbaked slides plus one H&E stained section with best tumor area circled by a pathologist; Ambient **Stability:** Ambient: Indefinitely for formalin-fixed paraffin-embedded tissue (FFPET) slides; FFPET slides and FNA specimens can be transported at ambient temperature Refrigerated: 2 weeks for FNA specimens Frozen: Unacceptable **Methodology:** Next Gen Sequencing **Days Performed:** Bi-weekly **Reported:** 8 days **CPT:** 81404 x 1	11/26/19

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Bioavailable Testosterone/SHBG, Female & Child	BTSTFC	$94.00 (non-discountable)	84270, 84402, 84403	11/18/19
Chronic Lymphoproliferative Disorder NGS Bone Marrow	LPMNGS	$1250.00 (non-discountable)	81450	11/26/19
Copper, Free, Serum or Plasma	FRCOP	$148.00 (non-discountable)	82525	11/18/19
Sulfonamides	SULFA	$132.00 (non-discountable)	80375	11/18/19

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Hematologic Neoplasm Next Generation Sequencing Panel Marrow	HNMNGS	$1512.00 (non-discountable)	81455	11/26/19
Hematologic Neoplasm Next Generation Sequencing Panel Peripheral Blood	HNPNGS	$1512.00 (non-discountable)	81455	11/26/19

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Bromide	BROM	This test will no longer be available.	11/18/19
Human Erythrocyte Ag	HEA	This test will no longer be available.	1/2/20
Loxapine	LOXAP	This test will no longer be available.	1/7/20
MELAS mtDNA Profile	MELAS	This test will no longer be available.	1/7/20
Myelin Protein Zero DNA Sequencing Test	MPZERO	This test will no longer be available.	1/7/20
Pregnanetriol	PREGNA	This test will no longer be available.	1/7/20
RHCE Variant Antigen	RHCE	This test will no longer be available.	1/2/20
Thiocyanate, Urine Random	UTHIOC	This test will no longer be available.	11/18/19