

Technical Update • April 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	Name Change Order Code	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
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3	AFP, Serum (Tumor Marker)												
11	Alcohol Confirmation, Urine												
3	Alpha-1 Antitrypsin Genotyping												
3	Alpha-1 Antitrypsin Phenotype and Genotype												
3	Alpha Subunit												
3	Alpha Thalassemia Gene Deletion												
11	Bone Marrow Chromosome Analysis with Reflex SNP Array												
13	Candida Profile with Immune Complex												
3	Clobazam												
4, 13	Complement Deficiency Assay												
4	Creatine, Blood												
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13	Drug Abuse Survey Urine with Confirmation												
5	Drug Detection Panel, TOF-MS, Umbilical Cord Tissue												
13	Fatty Acid Oxidation Probe Assay, Fibroblast Culture												
5	Fecal Lactoferrin												
5	Fecal Occult Blood Test												
5	HCG, Qualitative, Urine												
11	Hepatitis E Virus by Quantitative PCR												
5	Herpesvirus 6 IgM Antibody												

Summary of Changes
by Test Name

Order Code	Name Change	New Test	Special Information	Specimen Requirement	Component Change(s)	Methodology	Days Performed/Reported	Reference Range	Stability	CPT	Fee
6											
6	Hypercoagulation Diagnostic Interpretive Panel										
11	IgG CSF Index										
6	IgG Subclass 4										
7	IgG Subclasses										
8	IgG Subclasses 1, 2, 3, 4										
8	Iodide										
8	JAK2 Exon 12–16 Mutation Detection Bone Marrow										
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13	KIT Mutation Exons 8–11 and 17, Hematologic Neoplasms, Sequencing										
13	Lorazepam										
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9	NTRK Plus Gene Fusion NGS Panel										
10	OmegaCheck										
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12	Pan-Solid Tumor NGS Panel										
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13	Paroxetine										
12	Phosphatidylethanol (PEth)										
13	Plasminogen Activator Inhibitor Antigen										
10	Prealbumin										
10	Prenatal Quad Screen										
12	Products of Conception Chromosome Analysis with Reflex SNP Array										
13	Quetiapine										
12	Vitamin B1 (Thiamine), Whole Blood										
13	Vitamin B1, Whole Blood										
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10	Volatile Screen, Urine										
13	Ziprasidone										

Test Changes

Test Name	Order Code	Change	Effective Date
AFP–Maternal	AFPMAT	Reference Range: Screen Negative	5/28/19
AFP, Serum (Tumor Marker)	AFP	Stability: Ambient: 24 hours Refrigerated: 7 days Frozen: 28 days	4/2/19
Alpha-1 Antitrypsin Genotyping	HA1AT	For Interfaced Clients Only: Test build may need to be modified	6/18/19
Alpha 1 Antitrypsin Phenotype and Genotype	A1ATPG	For Interfaced Clients Only: Test build may need to be modified	6/18/19
Alpha Subunit	ALPSUB	Special Information: False positive elevations in serum free alpha-subunit levels may be seen in some women if blood specimens are drawn within 24 hours of ovulation. Patients with end-stage renal failure may have serum free alpha-subunit concentrations of up to 6 times the upper limit of reference range. Elevated alpha-subunit results on patients with elevated thyroid-stimulating hormone (TSH) should be interpreted with caution due to TSH cross-reactivity with the assay. Assisted reproduction involving ovarian hyperstimulation or in vitro fertilization may be associated with the elevation of serum free alpha-subunit levels. Pregnancy is associated with substantial physiological elevations in serum free alpha-subunit levels, paralleling chorionic gonadotropin (hCG) secretion. This test should not be ordered on pregnant patients. Grossly hemolyzed specimens will be rejected. Specimen Requirement: 1 mL serum from a plain no additive (red) tube; Minimum: 0.35 mL; Centrifuge and transfer into standard plastic aliquot tube; Frozen Days Performed: Wednesday Reported: 2–8 days CPT: 82397 x 1	Effective immediately
Alpha Thalassemia Gene Deletion	ATHALS	For Interfaced Clients Only: Test build may need to be modified	6/18/19
Clobazam	CLOBAZ	Special Information: Do not draw serum separator tubes. Draw specimen immediately before next scheduled dose. Trough specimens are recommended as therapeutic ranges are based on specimens drawn immediately before the next dose. This test is available for New York state. Clinical Information: Useful for monitoring clobazam therapy. The results of this test should be interpreted in conjunction with the patient's physical signs, symptoms, and other laboratory test results. Most individuals display optimal response to clobazam when serum levels of clobazam are between 30–300 ng/mL and n-desmethyloclobazam are between 300–3000 ng/mL. When clobazam levels are > 500 ng/mL or n-desmethyloclobazam levels are > 5000 ng/mL, risk of toxicity is increased. Some individuals may respond well outside of these ranges or may display toxicity within the therapeutic range. Therefore, interpretation should include clinical evaluation. Specimen Requirement: 0.5 mL serum from a plain no additive (red) tube; Minimum: 0.35 mL; Draw specimen immediately before next scheduled dose; Trough specimens recommended as therapeutic ranges are based on trough collections; Centrifuge within 2 hours of collection and transfer serum into standard plastic aliquot tube; Serum gel tube is not acceptable; Refrigerated Stability: Ambient: 28 days Refrigerated: 28 days Frozen: 28 days Days Performed: Tuesday, Thursday Reported: 2–6 days CPT: 80346 x 1 (G0480, if appropriate)	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Complement Deficiency Assay	COMPDP	<p>For Interfaced Clients Only: Test build may need to be modified</p> <p>Includes: Complement Deficiency Assay (Note: Complmnt Def, Qual will be removed)</p> <p>Note: <i>Total Complement Function Test will be added as an alias name, and the alias name Total Hemolytic Complement will be removed.</i></p> <p>Special Information: Samples must be collected in a red-top tube, without serum separator. If frozen, samples should be kept at minus 70 °C or colder.</p> <p>Clinical Limitation: Sera must be handled properly to prevent in vitro complement activation. Sample should not be frozen and thawed more than three times. This assay has not been evaluated for the pediatric population. Turbidimetric assays are not suitable for the measurement of highly lipemic or hemolyzed samples or samples containing high levels of circulating immune complexes due to the unpredictable degree of non-specific scatter these sample types may generate.</p> <p>Clinical Information: This assay is performed on the Binding Site Optilite turbidimetric analyzer. Assay results alone are not diagnostic, and results are to be interpreted in conjunction with other lab tests as well as the clinical presentation of the patient.</p> <p>Specimen Requirement: 1 mL serum from a plain no additive (red) tube; Minimum: 0.25 mL; Specimen must clot at room temperature for 60–65 minutes; Centrifuge, then remove serum and freeze at minus 70 °C or colder; Frozen</p> <p>Stability: Ambient: 4 hours Refrigerated: 24 hours Frozen: 30 days (at minus 70 °C or colder)</p> <p>Methodology: Turbidimetric Immunoassay (TUI)</p> <p>Reference Range: Complement Deficiency Assay: 41.7–95.1 U/mL</p>	5/29/19
Creatine, Blood	CRTSER	<p>Test Name: Previously Creatine, Serum</p> <p>Special Information: Specimens exposed to more than one freeze/thaw cycle are unacceptable. This test is New York DOH approved.</p> <p>Clinical Information: Used to monitor patients receiving creatine supplementation.</p> <p>Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.2 mL; Separate serum from cells within 2 hours of collection, transfer into standard aliquot tube and freeze immediately; Frozen</p> <p>*OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.2 mL; Separate serum from cells within 2 hours of collection, transfer into standard aliquot tube and freeze immediately; Frozen</p> <p>*OR* 1 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 0.2 mL; Separate plasma from cells within 2 hours of collection, transfer into standard aliquot tube and freeze immediately; Frozen</p> <p>*OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.2 mL; Separate plasma from cells within 2 hours of collection, transfer into standard aliquot tube and freeze immediately; Frozen</p> <p>Stability: Ambient: Unacceptable Refrigerated: 1 week Frozen: 2 weeks (Avoid repeated freeze/thaw cycles)</p> <p>Reference Range: Creatine mg/dL: Refer to report Creatine, Ser/PI ≤ 10 Years: 37.0–117.0 μmol/L ≥ 11 Years: 9.0–90.0 μmol/L</p>	5/28/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Creatine Disorders Panel, Blood	GUANID	<p>For Interfaced Clients Only: Test build may need to be modified</p> <p>Includes: Creatine, Ser/PI Guanidinoacetic Acid GUANID Interpret</p> <p>Reference Range: Creatine, Ser/PI ≤ 10 Years: 37.0–117.0 $\mu\text{mol/L}$ ≥ 11 Years: 9.0–90.0 $\mu\text{mol/L}$ Guanidinoacetic Acid: Refer to report</p>	5/28/19
Drug Detection Panel, TOF-MS, Umbilical Cord Tissue	DRGTOF	<p>Specimen Requirement: At least 6 inches of umbilical cord (approximately the length of an adult hand) in a clean container; Minimum: 6 inches (Absolute minimum); Drain and discard any blood; Rinse the exterior of the cord segment with normal saline or sterile water; Pat the cord dry and transport at least 6 inches of umbilical cord in a routine urine collection cup or use the Security Kit for Meconium/Umbilical Drug Detection (ARUP supply #51548); Frozen</p>	Effective immediately
Fecal Lactoferrin	STLWBC	<p>Stability: Ambient: Unpreserved stool: 2 weeks; Preserved stool: Unacceptable Refrigerated: Unpreserved stool: 2 weeks; Preserved stool: Unacceptable Frozen: 1 month at minus 20 °C</p>	5/16/19
Fecal Occult Blood Test	IFOBT	<p>Specimen Requirement: Stool specimen; The only acceptable specimen is stool inoculated into a Polymedco sample collection vial; Bulk stool (stool not contained in a Polymedco collection vial) will be rejected; Record date and time of collection on the test vial; Patients should be instructed to place the inoculated test vial into the preaddressed mailer along with a copy of the order and mail to Cleveland Clinic Laboratories (Microbiology); Ambient</p> <p>Stability: Ambient: Inoculated collection vials are stable for up to 15 days Refrigerated: Inoculated collection vials are stable up to 30 days at 4 °C Frozen: Unacceptable</p>	5/15/19
HCG, Qualitative, Urine	UHCG	<p>Stability: Ambient: Assay immediately; Send on ice if delivery time exceeds 1 hour Refrigerated: 48 hours Frozen: 1 week</p>	4/2/19
Herpesvirus 6 IgM Antibody	HHV6M	<p>Specimen Requirement: 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.1 mL; Transfer 0.5 mL serum to standard aliquot tube; Ambient *OR* 0.5 mL serum from a plain no additive (red) tube; Minimum: 0.1 mL; Transfer 0.5 mL serum to standard aliquot tube; Ambient</p> <p>Stability: Ambient: 7 days Refrigerated: 14 days Frozen: 30 days</p> <p>Methodology: Immunofluorescence Days Performed: Monday–Friday Reported: 3–5 days</p>	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hypercoagulation Diagnostic Interpretive Panel	HYPER	<p>For Interfaced Clients Only: Test build may need to be modified</p> <p>Includes: Hypercoagulation Diagnostic Interpretive Panel Thrombin Time Anti Xa Inhib Assay aPTT Screen</p> <p>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. Submit a Coagulation Consultation Patient History Sheet. 3.2% sodium citrate is the preferred anticoagulant recommended by the National Committee for Clinical Laboratory Standards (NCCLS). If tests are abnormal in the panel, the following tests may be ordered and billed: PTT Incubated Mixing Add On (85730, 85732 x 2); Dilute Russell Viper Venom (85613); Platelet Neutralization (85597); Factor V Leiden (81241); MTHFR by PCR (81291); Reptilase (85635); Fibrinogen Antigen (85385); Prot C Immunologic (85302); Prot S Immunologic (85306). Sample must be accompanied by the completed Clinical History Form for Hemostasis and Thrombosis Evaluation.</p> <p>Reference Range: Hypercoagulation Diagnostic Interpretive Panel: Refer to individual components Thrombin Time 0–1 Days: < 17.4 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 Anti Xa Inhib Assay: Refer to report aPTT Screen 0–1 Days: 28.7–45.1 sec 2–5 Days: 23.3–49.4 sec 6–30 Days: 23.5–45.6 sec 1–3 Months: 22.1–41.4 sec 4–11 Months: 25.8–35.5 sec 1–99 Years: 24.4–33.4 sec</p> <p>CPT: 81240 x 1, 83090 x 1, 85240 x 1, 85300 x 1, 85303 x 1, 85306 x 1, 85307 x 1, 85384 x 1, 85390 x 1, 85520 x 1, 85610 x 1, 85670 x 1, 85730 x 3, 85732 x 1, 86140 x 1, 86147 x 3</p>	5/28/19
IgG Subclass 4	IGG4	<p>Reference Range: IgG Subclass 4 0–2 Years: 0.5–78.4 mg/dL 2–4 Years: 1.0–53.7 mg/dL 4–6 Years: 1.8–112.5 mg/dL 6–8 Years: 0.4–99.2 mg/dL 8–10 Years: 1.9–93.2 mg/dL 10–12 Years: 1.6–115.0 mg/dL 12–14 Years: 3.7–136.0 mg/dL 14–18 Years: 11.0–157.0 mg/dL 18–99 Years: 3.9–86.4 mg/dL</p>	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
IgG Subclasses	IGGSUB	<p>Reference Range:</p> <p>IgG Subclass 1</p> <p>0-2 Years: 194.0-842.0 mg/dL</p> <p>2-4 Years: 315.0-945.0 mg/dL</p> <p>4-6 Years: 306.0-945.0 mg/dL</p> <p>6-8 Years: 288.0-918.0 mg/dL</p> <p>8-10 Years: 432.0-1020.0 mg/dL</p> <p>10-12 Years: 423.0-1060.0 mg/dL</p> <p>12-14 Years: 342.0-1150.0 mg/dL</p> <p>14-18 Years: 315.0-855.0 mg/dL</p> <p>18-99 Years: 382.4-928.6 mg/dL</p> <p>IgG Subclass 2</p> <p>0-2 Years: 22.5-300.0 mg/dL</p> <p>2-4 Years: 36.0-225.0 mg/dL</p> <p>4-6 Years: 60.5-345.0 mg/dL</p> <p>6-8 Years: 44.0-375.0 mg/dL</p> <p>8-10 Years: 72.0-430.0 mg/dL</p> <p>10-12 Years: 76.0-355.0 mg/dL</p> <p>12-14 Years: 100.0-455.0 mg/dL</p> <p>14-18 Years: 64.0-495.0 mg/dL</p> <p>18-99 Years: 241.8-700.3 mg/dL</p> <p>IgG Subclass 3</p> <p>0-2 Years: 18.6-85.3 mg/dL</p> <p>2-4 Years: 17.3-67.6 mg/dL</p> <p>4-6 Years: 9.9-122.1 mg/dL</p> <p>6-8 Years: 15.5-85.3 mg/dL</p> <p>8-10 Years: 12.7-85.3 mg/dL</p> <p>10-12 Years: 17.3-173.0 mg/dL</p> <p>12-14 Years: 28.3-125.0 mg/dL</p> <p>14-18 Years: 23.0-196.0 mg/dL</p> <p>18-99 Years: 21.8-176.1 mg/dL</p> <p>IgG Subclass 4</p> <p>0-2 Years: 0.5-78.4 mg/dL</p> <p>2-4 Years: 1.0-53.7 mg/dL</p> <p>4-6 Years: 1.8-112.5 mg/dL</p> <p>6-8 Years: 0.4-99.2 mg/dL</p> <p>8-10 Years: 1.9-93.2 mg/dL</p> <p>10-12 Years: 1.6-115.0 mg/dL</p> <p>12-14 Years: 3.7-136.0 mg/dL</p> <p>14-18 Years: 11.0-157.0 mg/dL</p> <p>18-99 Years: 3.9-86.4 mg/dL</p> <p>IgG</p> <p>0-6 Months: 206-676 mg/dL</p> <p>6-9 Months: 208-868 mg/dL</p> <p>9-12 Months: 282-1026 mg/dL</p> <p>1-2 Years: 331-1164 mg/dL</p> <p>2-3 Years: 407-1009 mg/dL</p> <p>3-4 Years: 423-1090 mg/dL</p> <p>4-5 Years: 444-1187 mg/dL</p> <p>5-8 Years: 608-1229 mg/dL</p> <p>8-10 Years: 584-1509 mg/dL</p> <p>10-99 Years: 717-1411 mg/dL</p>	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
IgG Subclasses 1,2,3,4	IG1234	<p>Reference Range:</p> <p>IgG Subclass 1 0–2 Years: 194.0–842.0 mg/dL 2–4 Years: 315.0–945.0 mg/dL 4–6 Years: 306.0–945.0 mg/dL 6–8 Years: 288.0–918.0 mg/dL 8–10 Years: 432.0–1020.0 mg/dL 10–12 Years: 423.0–1060.0 mg/dL 12–14 Years: 342.0–1150.0 mg/dL 14–18 Years: 315.0–855.0 mg/dL 18–99 Years: 382.4–928.6 mg/dL</p> <p>IgG Subclass 2 0–2 Years: 22.5–300.0 mg/dL 2–4 Years: 36.0–225.0 mg/dL 4–6 Years: 60.5–345.0 mg/dL 6–8 Years: 44.0–375.0 mg/dL 8–10 Years: 72.0–430.0 mg/dL 10–12 Years: 76.0–355.0 mg/dL 12–14 Years: 100.0–455.0 mg/dL 14–18 Years: 64.0–495.0 mg/dL 18–99 Years: 241.8–700.3 mg/dL</p> <p>IgG Subclass 3 0–2 Years: 18.6–85.3 mg/dL 2–4 Years: 17.3–67.6 mg/dL 4–6 Years: 9.9–122.1 mg/dL 6–8 Years: 15.5–85.3 mg/dL 8–10 Years: 12.7–85.3 mg/dL 10–12 Years: 17.3–173.0 mg/dL 12–14 Years: 28.3–125.0 mg/dL 14–18 Years: 23.0–196.0 mg/dL 18–99 Years: 21.8–176.1 mg/dL</p> <p>IgG Subclass 4 0–2 Years: 0.5–78.4 mg/dL 2–4 Years: 1.0–53.7 mg/dL 4–6 Years: 1.8–112.5 mg/dL 6–8 Years: 0.4–99.2 mg/dL 8–10 Years: 1.9–93.2 mg/dL 10–12 Years: 1.6–115.0 mg/dL 12–14 Years: 3.7–136.0 mg/dL 14–18 Years: 11.0–157.0 mg/dL 18–99 Years: 3.9–86.4 mg/dL</p>	Effective immediately
Iodide	BIODIN	<p>Special Information: Allow specimen to clot for 30 minutes prior to centrifugation. High concentrations of gadolinium and iodine are known to interfere with most metals tests. If gadolinium-containing or iodine-containing contrast media have been administered, a specimen cannot be collected for 96 hours.</p> <p>Days Performed: Monday, Wednesday, Friday</p> <p>Reported: 2–4 days</p> <p>CPT: 83789 x 1</p>	Effective immediately
JAK2 Exon 12–16 Mutation Detection Bone Marrow	JAK2NM	<p>Test Name: Previously JAK2 Exon 12-15 Mutation Detection Bone Marrow</p> <p>Clinical Information: This test uses next generation sequencing to detect mutations in JAK2 exons 12 through 16. This test is intended to detect variant mutations in myeloproliferative neoplasms, especially polycythemia vera, lacking a JAK2 V617F mutation.</p>	5/28/19
JAK2 Exon 12–16 Sequencing Blood	JAKNON	<p>Test Name: Previously JAK2 Exon 12–15 Sequencing Blood</p> <p>Clinical Information: This assay uses next generation sequencing to detect mutations in JAK2 exons 12 through 16. This assay is intended for detection of variant JAK2 mutations in myeloproliferative neoplasms, especially polycythemia vera, lacking the JAK2 V617F mutation.</p> <p>CPT: 81403 x 1, G0452 x 1</p>	5/28/19
JAK2 V617F Mutation Detection Blood	JAK2	<p>Clinical Information: This assay uses next generation sequencing to detect a JAK2 V617F mutation in suspected non-CML myeloproliferative disorders or overlap myelodysplastic/myeloproliferative disease.</p> <p>CPT: 81270 x 1, G0452 x 1</p>	5/28/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
LPT to Beryllium, BAL	BALBE	<p>For Interfaced Clients Only: Test build may need to be modified</p> <p>Includes: PHA Simulation Index Beryllium 1.0 uM D3 Beryllium 10 uM D3 Beryllium 10 uM D5 Beryllium 100 uM D3 Beryllium 100 uM D5 Beryllium 1.0 uM D5 (Note: <i>Candida albicans</i> will be removed)</p> <p>Reference Range: PHA Simulation Index: ≥ 10.0 SI Beryllium 1.0 uM D3: ≤ 3.0 SI Beryllium 10 uM D3: ≤ 3.0 SI Beryllium 10 uM D5: ≤ 3.0 SI Beryllium 100 uM D3: ≤ 3.0 SI Beryllium 100 uM D5: ≤ 3.0 SI Beryllium 1.0 uM D5: ≤ 3.0 SI</p>	5/28/19
Mercaptopurine	MERCAP	<p>Special Information: Gel tubes are unacceptable. Category: Antineoplastic</p> <p>Specimen Requirement: 2 mL serum from a plain no additive (red) tube; Minimum: 0.3 mL; Do not use serum separator tubes; Centrifuge and transfer to standard plastic aliquot tube; Refrigerated</p> <p>*OR* 2 mL plasma from a sodium heparin (green) tube; Minimum: 0.3 mL; Do not use plasma separator tubes; Centrifuge and transfer to standard plastic aliquot tube; Refrigerated</p> <p>Stability: Ambient: 72 hours Refrigerated: 7 days Frozen: 180 days</p> <p>Days Performed: Monday–Sunday</p> <p>Reported: 6–10 days</p>	Effective immediately
MPL Mutation Analysis Blood	MPL	<p>Clinical Information: This test uses next generation sequencing to detect MPL exon 10 mutations, as seen in myeloproliferative neoplasms.</p> <p>CPT: 81403 x 1, G0452 x 1</p>	5/28/19
NTRK Plus Gene Fusion NGS Panel		<p>For Interfaced Clients Only: Test build may need to be modified</p> <p>Note: Order code <i>NTRKGN</i> has been removed. <i>NTRKGN</i> has been added as an alias name.</p> <p>Test Name: Previously NTRK Gene Analysis</p> <p>Special Information: Genes involved in fusions that are interrogated in this test: ALK, BCOR, CAMTA1, CCNB3, CIC, CSF1, EPC1, EWSR1, FOS, FOSB, FOXO1, FUS, GLI1, HMGA2, JAZF1, MEAF6, MKL2, NCOA2, NTRK1, NTRK2, NTRK3, NUTM1, PAX3, PDGFB, PLAG1, ROS1, SS18, STAT6, TAF15, TCF12, TFE3, TFG, USP6, YWHAE</p> <p>Clinical Limitation: This test does not detect single nucleotide variants; some data show acquired kinase domain resistance mutations that are not interrogated by this test.</p> <p>Clinical Information: NTRK Plus Gene Fusion NGS Panel may be used for detection of NTRK fusions that may make patients with solid tumors candidates for Larotrectinib (VITRAKVI) in rare circumstances. The NTRK Plus Gene Fusion NGS Panel is used to interrogate 34 genes for fusions, including NTRK1, NTRK2, and NTRK3. Given their potential clinical relevance, results for all tested genes are reported.</p> <p>Specimen Requirement: 10 mm square formalin-fixed paraffin-embedded (FFPE) tissue block; Include copy of original pathology report with submitted specimen; FFPE tissue slides; Transport and store slides at ambient temperature; 10 unstained sections formalin-fixed paraffin-embedded tissue (FFPET) on charged, unbaked slides plus one H&E stained slide with best tumor area circled by pathologist; Ambient</p> <p>Days Performed: 2 days per week</p> <p>Reported: 14 days</p>	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
OmegaCheck	OMEGAC	<p>Clinical Information: OmegaCheck™ may be performed on individuals with hypercholesterolemia, hypertriglyceridemia, hypertension, and/or those at high metabolic or cardiovascular risk. Relative Risk: Low Risk OmegaCheck™ (% by weight): ≥ 5.5; Moderate Risk OmegaCheck™ (% by weight): 3.8–5.4; High Risk OmegaCheck™ (% by weight): ≤ 3.7</p> <p>Reference Range: OmegaCheck: > 5.4 % by wt Arachidonic acid/EPA ratio: 3.7–40.7 Omega-6/3 Ratio: 3.7–14.4 EPA: 0.2–2.3 % by wt DPA: 0.8–1.8 % by wt DHA: 1.4–5.1 % by wt Arachidonic Acid: 8.6–15.6 % by wt Linoleic Acid: 18.6–29.5 % by wt</p>	4/22/19
Prealbumin	PREALB	<p>Stability: Ambient: 3 days Refrigerated: 6 months Frozen: 1 year</p>	4/2/19
Prenatal Quad Screen	QUAD4	<p>Reference Range: AFP (maternal): Screen Negative</p>	5/28/19
Volatile Screen, Urine	UVLTSR	<p>Days Performed: Monday–Sunday Reported: 2–3 days CPT: 80320 x 1, (G0480, if appropriate)</p>	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Alcohol Confirmation, Urine	UETOHC	<p>Special Information: Limited utility in the assessment of acute ethanol exposure. To assess ethanol exposure up to several days post-exposure, Ethyl Glucuronide, Urine reflex to Confirm/Quant (UEGLUC) is preferred. This test is New York DOH approved.</p> <p>Clinical Information: For medical purposes only; not valid for forensic use. The absence of expected drug(s) and/or drug metabolite(s) may indicate inappropriate timing of specimen collection relative to drug administration, poor drug absorption, diluted/adulterated urine, or limitations of testing. The concentration value must be greater than or equal to the cutoff to be reported as positive. Interpretive questions should be directed to the laboratory. Positive cutoff = 5 mg/dL</p> <p>Specimen Requirement: 4 mL random urine in a clean container (No preservatives); Minimum: 1 mL; Ambient</p> <p>Stability: Ambient: 1 week Refrigerated: 1 month Frozen: 3 years (Avoid repeated freeze/thaw cycles)</p> <p>Methodology: Gas Chromatography/Flame Ionization Detection (GC-FID)</p> <p>Days Performed: Sunday–Saturday</p> <p>Reported: 2–5 days</p> <p>CPT: 80320 x 1, (G0480, if appropriate)</p> <p>Price: \$45.00 (non-discountable)</p>	4/9/19
Bone Marrow Chromosome Analysis with Reflex SNP Array	BMCHF	<p>Special Information: If the results are normal, suboptimal, or no growth, SNP array testing will be added at an additional charge.</p> <p>Specimen Requirement: 2–3 mL bone marrow in a sodium heparin (green) tube; Minimum: 1 mL; If aliquoting is necessary, sterile aliquot tubes must be used; Ambient</p> <p>Stability: Ambient: 48 hours Refrigerated: Not preferred Frozen: Not preferred</p> <p>Methodology: Culture Karyotyping Microscopy Comparative genomic hybridization-oligo based</p> <p>Days Performed: 7 days per week</p> <p>Reported: 28–30 days</p>	5/19/19
Hepatitis E Virus by Quantitative PCR	HPEPCR	<p>Special Information: The limit of quantification for this RNA test is 3.3 log IU/mL (1800 IU/mL). If the test DID NOT DETECT the virus, the test result will be reported as "< 3.3 log IU/mL (< 1800 IU/mL)." If the test DETECTED the presence of the virus but was not able to accurately quantify the number of international units, the test result will be reported as "Not Quantified." Heparinized specimens are unacceptable.</p> <p>Clinical Information: Confirm and quantify the presence of hepatitis E virus.</p> <p>Specimen Requirement: 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Specimen source must be indicated; Frozen</p> <p>*OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Specimen source must be indicated; Frozen</p> <p>Stability: Ambient: 24 hours Refrigerated: 1 week Frozen: 1 week</p> <p>Methodology: Polymerase Chain Reaction (PCR), Quant</p> <p>Reference Range: Not detected</p> <p>Days Performed: Monday, Thursday</p> <p>Reported: 3–6 days</p> <p>CPT: 87799 x 1</p> <p>Price: \$204.00 (non-discountable)</p>	5/14/19
IgG CSF Index	TOURT	<p>Note: This test was previously announced in the March Technical Update.</p> <p>Price: \$65.00 (non-discountable)</p>	4/30/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Pan-Solid Tumor NGS Panel	PSTNGS	Note: This test was previously announced in the February Technical Update. The new order code will be PSTNGS. We apologize for any inconvenience this may have caused.	3/29/19
Phosphatidylethanol (PEth)	PETH	Note: This test was previously announced in the March Technical Update. Price: \$156.00 (non-discountable)	Effective immediately
Products of Conception Chromosome Analysis with Reflex SNP Array	POCHF	Special Information: Long-standing fetal demise, delayed specimen transport and improper handling can increase the risk of tissue culture failure, which leads to no chromosome result. Rejection criteria: Specimen collected and sent in formalin. Clinical Information: Evaluate the cause of miscarriage. Specimen Requirement: 10 mm square products of conception (POC) specimen in a sterile container; Fresh tissue sample from the fetus, placenta, umbilical cord, amniotic membrane and chorionic membrane are accepted; Do not expose to formalin or other fixatives; Do not freeze; Place specimen in a sterile container containing RPMI, Hank's solution or sterile saline; Keep at room temperature; May refrigerate if specimen must be held overnight; Transport to the laboratory as soon as possible to ensure cell viability; Ambient Stability: Ambient: Preferred Refrigerated: Acceptable Frozen: Unacceptable Methodology: Culture Karyotyping Microscopy Comparative genomic hybridization-oligo based Days Performed: 7 days per week Reported: 28–30 days	5/20/19
Vitamin B1 (Thiamine), Whole Blood	B1WB	Clinical Information: Use for nutritional assessment of vitamin B1 (thiamine). Whole blood is the preferred specimen since approximately 80% of thiamine in whole blood is found in red blood cells. Specimen Requirement: 2 mL whole blood in an EDTA (lavender) tube; Minimum: 0.6 mL; Refrigerated Stability: Ambient: 8 hours Refrigerated: 7 days Frozen: 6 months at minus 70 °C Methodology: High Performance Liquid Chromatography (HPLC) Reference Range: Vitamin B1 (TDP), Whole Blood 0–17 Years: 84–213 nmol/L; Comment: Reference ranges for this patient's age group have not been established. These reference ranges reflect verified or established ranges for the adult population. Interpret these ranges with caution using the clinical context and additional reference resources. 18–99 Years: 84–213 nmol/L Days Performed: 5 days per week Reported: 1–4 days CPT: 84425 x 1 Price: \$78.00 (non-discountable)	5/28/19

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
JAK2 Exon 12–16 Sequencing Blood	JAKNON	\$605.00 (non-discountable)	81403, G0452	5/28/19
JAK2 V617F Mutation Detection Blood	JAK2	\$624.00 (non-discountable)	81270, G0452	5/28/19
KIT Mutation Exons 8–11 and 17, Hematologic Neoplasms, Sequencing	KITEML	\$548.00 (non-discountable)	81272	Effective immediately
Plasminogen Activator Inhibitor Antigen	PA11M	\$395.00 (non-discountable)	83520	Effective immediately
Vitamin B5 (Pantothenic Acid) Bioassay	VITB5	\$131.00 (non-discountable)	84591	Effective immediately
Ziprasidone	ZIPRA	\$129.00 (non-discountable)	80342, (G0480, if appropriate)	Effective immediately

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Complement Deficiency Assay	COMPD	\$149.00	86162	5/29/19
Lorazepam	LORAZE	\$114.00 (non-discountable)	80346, (G0480, if appropriate)	Effective immediately
Parainfluenza 1,2,3 Abs	PAR123	\$135.00 (non-discountable)	86790 x 3	Effective immediately
Paroxetine	PAROX	\$85.00 (non-discountable)	80299	Effective immediately
Quetiapine	QUETIA	\$118.00 (non-discountable)	80342, (G0480, if appropriate)	Effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Candida Profile with Immune Complex	CNDIMM	This test will no longer be available.	5/28/19
Drug Abuse Survey Urine with Confirmation	UCDASR	This test will no longer be available. Suggest ordering Toxicology Screen with Confirmation, Urine (UTOXRF).	5/30/19
Fatty Acid Oxidation Probe Assay, Fibroblast Culture	FAO	This test will no longer be available.	4/30/19
Osmolality, Body Fluid	FLOSM	This test will no longer be available.	Effective immediately
Vitamin B1, Whole Blood	B1VIT	This test will no longer be available. Suggest ordering Vitamin B1 (Thiamine), Whole Blood (B1WB).	5/28/19