

Technical Update • December 2018

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
3	Acetazolamide												
3	Acetoacetate												
12	Acylcarnitines, Plasma w/ No Interpretation												
27	Acylcarnitines, Plasma wo/ Interpretation												
3	Adenovirus Culture												
13	Allergen, Cat Components IgE												
13-14	Allergen, Dog Components IgE												
14	Allergen, Dust Mite Components IgE												
15	Allergen, Hazelnut Components IgE												
15-16	Allergen, Peanut IgE with Reflex to Peanut Components, IgE												
16	Allergen, Soybean Components IgE												
16-17	Allergen, Walnut Components IgE												
27	Amino Acids, CSF												
17-18	Amino Acids, CSF w/ Basic Interpretation												
18	Amino Acids, CSF w/ No Interpretation												
27	Amino Acids, Plasma												
19	Amino Acids, Plasma w/ Basic Interpretation												
20	Amino Acids, Plasma w/ No Interpretation												
27	Amino Acids, Quantitative, Urine												
21	Amino Acids, Urine w/ Basic Interpretation												
22	Amino Acids, Urine w/ No Interpretation												
4	Arsenic, Fractionated Urine												

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	Days Performed/Reported	Reference Range	Stability	CPT	Fee
4	Arsenic, Hair													
27	Arsenic, Nails													
4-5	Arsenic, Urine 24 Hr													
5	BAL FCM Markers													
5	BAL FCM Markers Package													
5	Benzene Quantitation, Whole Blood													
5	Cadmium, Urine													
6	Calcium, Ionized													
6	Calculi (Stone) Analysis													
6	Calprotectin, Fecal													
6, 27	C. difficile Culture w/ reflex Cytotoxin Cell Assay													
23	C. difficile PCR with Reflex to EIA if Positive													
6	Circulating Tumor Cell Count													
23	Dermatomyositis Panel													
6	Digoxin													
7, 27	Enterovirus Culture													
27	ERBB2 (HER2/neu) Gene Amplification by FISH, Gastric Tissue													
7	Ethambutol													
7	FISH for CCND1 (Tissue)													
7	FISH for Chronic Lymphocytic Leukemia													
7	Flunitrazepam Screen, Urine													
7	Fluoxetine/Norfluoxetine													
7	Fluvoxamine, Serum and Plasma													
27	Hematologic Neoplasm Next Generation Sequencing Panel Marrow													
27	Hematologic Neoplasm Next Generation Sequencing Panel Peripheral Blood													
7	HIV 1 2 Combo (Ag/Ab) with reflex to differentiation													
7	Ibuprofen													
7	IgG Subclass 4													
8	IgG Subclasses													
9	IgG Subclasses 1,2,3,4													
27	Ketorolac													
10, 27	Melatonin													
10	Methylphenidate and Metabolite Quantitative, Serum or Plasma													
27	Myositis AssessR													
10	Narcolepsy Associated Ag, HLA-DQB1 Typing													
24	Organic Acids Ur, Quant w/ No Interpretation													
27	Organic Acids Ur, Quant wo/ Interpretation													
11	PNH Panel by FCM													
25	Polymyositis and Dermatomyositis Panel													

Test Update Page #	Summary of Changes by Test Name	Name Change	New Test	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
25	Polymyositis Panel											
26	Sarcoma Fusion NGS Panel											
11	Strychnine											
11, 27	Surface/Cytoplasmic IgM by FCM											
27	TGFBR1 and TGFBR2 for Loeyes-Dietz Syndrome											
11	Titanium, Serum or Plasma											

Test Changes

Test Name	Order Code	Change	Effective Date
Acetazolamide	ACETAZ	<p>Special Information: Separator tubes are unacceptable. This test is New York DOH approved.</p> <p>Specimen Requirement: 1 mL serum from a plain no additive (red) tube; Minimum: 0.4 mL; Do not use serum separator tube; Refrigerated</p> <p>*OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.4 mL; Refrigerated</p> <p>Stability: Ambient: 15 days Refrigerated: 1 month Frozen: 1 month</p> <p>Days Performed: Varies Reported: 5–8 days</p>	Effective immediately
Acetoacetate	ACETAC	<p>For Interfaced Clients Only: Test build may need to be modified</p> <p>Special Information: Serum gel tubes are unacceptable.</p> <p>Specimen Requirement: 3 mL serum from a plain no additive (red) tube; Minimum: 1.2 mL; Do not use serum separator tube; Centrifuge and aliquot serum into a plastic aliquot tube; Frozen</p> <p>Stability: Ambient: Unacceptable Refrigerated: 4 days Frozen: 29 days</p> <p>Days Performed: Monday–Sunday Reported: 8–12 days</p>	12/19/18
Adenovirus Culture	VADNO	CPT: 87254 x 1	12/18/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Arsenic, Fractionated Urine	UASFR	<p>Special Information: Patient demographics (Heavy Metals) form is required to meet State Health Department requirements. Indicate total volume and collection time interval. Urine collected within 48 hours after administration of a gadolinium (Gd) containing contrast media (may occur with MRI studies) or acid preserved urine specimens are not acceptable. Specimens contaminated with blood or fecal material or specimens transported in non-trace element-free transport tubes (with the exception of the original device) are not acceptable. This test is New York DOH approved.</p> <p>Clinical Information: The ACGIH Biological Exposure Index for the sum of inorganic and methylated species of arsenic is 35 µg/L. Inorganic species of arsenic are most toxic. Methylated species arise primarily from metabolism of inorganic species but may also come from dietary sources and are of moderate toxic potential. The organic species of arsenic are considered nontoxic and arise primarily from food. The sum of the inorganic, methylated, and organic species of arsenic may be lower than the total arsenic concentration due to the presence of unidentified organic species of arsenic. ARUP studies indicate that refrigeration of urine alone, during and after collection, preserves specimens adequately if tested within 14 days of collection.</p> <p>Specimen Requirement: 8 mL 24-hour urine (well-mixed) in a clean container; Minimum: 2 mL; Refrigerate during collection; HEAVY METALS FORM REQUIRED to meet State Health Department requirements; Collect in a plastic container; Specimen must not come into contact with glass or metal; Provide volume and collection time interval with specimen; Aliquot into a trace metal-free transport tube (ARUP supply #43116); Refrigerated</p> <p>*OR* 8 mL random urine in a clean container; Minimum: 2 mL; HEAVY METALS FORM REQUIRED to meet State Health Department requirements; Collect in a plastic container; Provide volume; Specimen must not come into contact with glass or metal; Aliquot into a trace metal-free transport tube (ARUP supply #43116); Refrigerated</p> <p>Days Performed: Sunday, Tuesday, Thursday, Saturday</p> <p>Reported: 2–6 days</p>	2/5/19
Arsenic, Hair	ARSHR	<p>Special Information: Patient demographics (Heavy Metals) form is required to meet State Health Department requirements. Specimen source is required.</p> <p>Clinical Information: Toxicity-arsenic poisoning. Hair arsenic levels above 1.00 mcg/g dry weight indicate excessive exposure. It is normal for some arsenic to be present in hair. Everyone is exposed to trace amounts of arsenic from a normal diet.</p> <p>Specimen Requirement: 0.5 g hair in a clean container; Minimum: 0.05 g; HEAVY METALS FORM REQUIRED to meet State Health Department requirements; Cut hair near scalp, at least 3 inches long and the width of a pencil; Do not apply tape to hair; Specimen source is required; Ambient</p> <p>Stability: Ambient: Preferred Refrigerated: Acceptable Frozen: Acceptable</p> <p>Days Performed: Tuesday</p> <p>Reported: 3–8 days</p>	2/5/19
Arsenic, Urine 24 Hr	UARSND	<p>Specimen Requirement: 8 mL 24-hour urine (well-mixed) in a clean container; Minimum: 2 mL; Refrigerate during collection; HEAVY METALS FORM REQUIRED to meet State Health Department requirements; Must collect in a plastic container; Specimen must not come into contact with glass or metal; Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances; Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, nonessential over-the-counter medications (upon the advice of their physician), and avoid shellfish and seafood for 48 to 72 hours; High concentrations of iodine may interfere with elemental testing; Abstinence from iodine-containing medications or contrast agents for at least 1 month prior to collecting specimens for elemental testing is recommended; Provide volume with specimen; Aliquot into a trace metal-free transport tube (ARUP supply #43116); Refrigerated</p>	2/5/19

(continued on page 5)

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Arsenic, Urine 24 Hr <i>(continued from page 4)</i>		*OR* 8 mL random urine in a clean container; Minimum: 2 mL; HEAVY METALS FORM REQUIRED to meet State Health Department requirements; Must collect in a plastic container; Specimen must not come into contact with glass or metal; Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances; Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, nonessential over-the-counter medications (upon the advice of their physician), and avoid shellfish and seafood for 48 to 72 hours; High concentrations of iodine may interfere with elemental testing; Abstinence from iodine-containing medications or contrast agents for at least 1 month prior to collecting specimens for elemental testing is recommended; Provide volume with specimen; Aliquot into a trace metal-free transport tube (ARUP supply #43116); Refrigerated	
BAL FCM Markers	FCBAL	CPT: 86356 x 3	1/24/19
BAL FCM Markers Package	BALFCM	CPT: 86356 x 3, 89051 x 1	1/24/19
Benzene Quantitation, Whole Blood	BENZE	Days Performed: Varies Reported: 5–8 days	Effective immediately
Cadmium, Urine	URCAD	Special Information: Patient demographics (Heavy Metals) form is required to meet State Health Department requirements. Collection volume and interval MUST be indicated. Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and nonessential over-the-counter medications (upon the advice of their physician). High concentrations of iodine may interfere with elemental testing. Abstinence from iodine-containing medications or contrast agents for at least 1 month prior to collecting specimens is recommended. ARUP studies indicate that refrigeration of urine alone, during and after collection, preserves specimens adequately, if tested within 14 days of collection. Urine collected within 48 hours after administration of a gadolinium (Gd) containing contrast media (may occur with MRI studies) and acid preserved specimens are unacceptable. Specimens contaminated with blood or fecal material, and specimens transported in non-trace element free transport tubes (with the exception of the original device) are unacceptable. This test is New York DOH approved. Specimen Requirement: 8 mL 24-hour urine (well-mixed) in a clean container; Minimum: 1 mL; Refrigerate during collection; HEAVY METALS FORM REQUIRED to meet State Health Department requirements; Must collect in a plastic container; Specimen must not come into contact with glass, rubber or metal; Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances; Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician); High concentrations of iodine may interfere with elemental testing; Abstinence from iodine-containing medications or contrast agents for at least 1 month prior to collecting specimens for elemental testing is recommended; Aliquot into trace metal-free transport tube (ARUP supply #43116); Refrigerated *OR* 8 mL random urine in a clean container; Minimum: 1 mL; Refrigerate during collection; HEAVY METALS FORM REQUIRED to meet State Health Department requirements; Must collect in a plastic container; Specimen must not come into contact with glass, rubber or metal; Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances; Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician); High concentrations of iodine may interfere with elemental testing; Abstinence from iodine-containing medications or contrast agents for at least 1 month prior to collecting specimens for elemental testing is recommended; Aliquot into trace metal-free transport tube (ARUP supply #43116); Refrigerated	2/5/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Calcium, Ionized	ICA	<p>Special Information: Specimens must be received in an unopened primary tube. Do not aliquot. Test not available for add-on testing.</p> <p>Specimen Requirement: 3.5 mL serum from a serum separator (gold) tube; Fill tube completely and allow to clot; Do not expose to air (anaerobic handling); Centrifuge within 2 hours of collection; Refrigerated</p> <p>*OR* 5 mL serum from a serum separator (gold) tube; Fill tube completely and allow to clot; Do not expose to air (anaerobic handling); Centrifuge within 2 hours of collection; Refrigerated</p> <p>Stability: Ambient: 4 hours (after separation from cells) Refrigerated: 7 days (after separation from cells) Frozen: Unacceptable</p>	1/30/19
Calculi (Stone) Analysis	CSA	<p>Note: Changes to this test were previously announced in the October Technical Update with a go-live date of 12/6/18. The new go-live date for these changes will be 1/17/19. We apologize for any inconvenience this may have caused.</p>	1/17/19
Calprotectin, Fecal	CALPRO	<p>For Interfaced Clients Only: Test build may need to be modified</p> <p>Includes: Calprotectin, Fecal Calprotectin Interp</p> <p>Special Information: The assay has a reporting range of 27.1 to 3000 mg/kg with interpretations of normal (< 50 mg/kg), borderline (50–120 mg/kg) and abnormal (> 120 mg/kg). Calprotectin results generated by the FDA-approved QUANTA Lite extended range assay cannot be directly compared to those determined by other methods. For assistance with interpretation of serial testing results in patients with samples submitted prior to 10/16/18, please contact Cleveland Clinic Laboratories at 800.628.6816 or 216.444.5755 to discuss options.</p> <p>Clinical Information: The quantitative detection of calprotectin is an in vitro diagnostic test to aid in the diagnosis of inflammatory bowel disease (IBD) in conjunction with other clinical and laboratory findings. Fecal calprotectin is an indicator of neutrophils in the stool and is not specific for IBD. Elevations in fecal calprotectin may be caused by proton pump inhibitors, non-steroid anti-inflammatory drugs, and intestinal impairments other than IBD (e.g., diverticulitis, celiac disease, infections, cancer).</p> <p>Reference Range: Calprotectin, Fecal (0–99 Years) Normal: < 50.0 mg/kg Borderline : 50.0–120.0 mg/kg Test should be re-evaluated in 4–6 weeks Abnormal: > 120.0 mg/kg</p>	2/5/19
C. difficile Culture w/ reflex Cytotoxin Cell Assay	CDCULT	CPT: 87075 x 1	Effective immediately
Circulating Tumor Cell Count	CTCBPC	<p>Special Information: Patient Prep: If the patient is on doxorubicin therapy, allow at least 1 week following administration of a dose of doxorubicin before drawing blood. MUST indicate source of metastatic cancer with order. Specimens not collected in the CellSave™ tube or collected in expired CellSave™ tubes are unacceptable. Short draws will also be rejected. This assay is FDA approved only for breast, prostate, or colorectal metastatic cancers; other types will not be tested. This test is New York DOH approved.</p> <p>Specimen Requirement: 20 mL whole blood in CellSave™ Preservative tubes; Minimum: 16 mL (Note: Minimum volume is 8 mL per tube); Patient Prep: If patient is on doxorubicin therapy, allow at least 1 week following administration of a dose of doxorubicin before blood draw; Draw two tubes (CellSave™ Preservative Tube, ARUP supply #44867) and fill completely; Do NOT refrigerate or freeze; Send specimen to Cleveland Clinic Laboratories on the day of collection; Source of metastatic cancer is REQUIRED with the order; Ambient</p>	Effective immediately
Digoxin	DIG	<p>Stability: Ambient: After separation from cells: 24 hours Refrigerated: After separation from cells: 4 days Frozen: After separation from cells: 1–2 weeks</p>	12/20/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Enterovirus Culture	VENT	CPT: 87254 x 1	12/18/18
Ethambutol	ETHAMB	Special Information: Separator tubes are unacceptable. This test is New York DOH approved. Days Performed: Varies Reported: 8–11 days	Effective immediately
FISH for CCND1 (Tissue)	CCND1T	For Interfaced Clients Only: Test build may need to be modified Test Name: Previously FISH for CCND1 (Paraffin) Note: <i>There will be a new order code for this test.</i>	1/2/19
FISH for Chronic Lymphocytic Leukemia	CLLFSH	Special Information: This test includes FISH testing for the TP53 gene at 17p13.1, the ATM gene at 11q22.3, the centromere of chromosome 12, the D13S319 loci at 13q14, the LAMP1 gene at 13q34, and IGH/CCND1 rearrangements. CPT: 88271 x 7, 88275 x 3, 88291 x 1	1/23/19
Flunitrazepam Screen, Urine	FLUNU	Days Performed: Varies Reported: 5–12 days	Effective immediately
Fluoxetine/ Norfluoxetine	FLUOX	Days Performed: Varies Reported: 5–8 days	Effective immediately
Fluvoxamine, Serum and Plasma	FLUVOX	Days Performed: Varies Reported: 5–8 days	Effective immediately
HIV 1 2 Combo (Ag/Ab) with reflex to differentiation	HIV12C	For Interfaced Clients Only: Test build may need to be modified Includes: HIV 1 2 Ag/Ab HIV-1/2 Ab HIV Interpretation Test Name: Previously HIV 1 2 Combo (Antigen/Antibody) Reference Range: HIV 1 2 Ag/Ab: Non-reactive HIV-1/2 Ab: Negative	1/31/19
Ibuprofen	IBUPRO	Days Performed: Varies Reported: 8–11 days	Effective immediately
IgG Subclass 4	IGG4	Stability: Ambient: 24 hours Refrigerated: 8 days Frozen: 30 days 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: 4.0–99.2 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	2/5/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
IgG Subclasses	IGGSUB	<p>Stability: Ambient: 24 hours Refrigerated: 8 days Frozen: 30 days</p> <p>Reference Range: 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: 423.3–1060.0 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> 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 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 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: 4.0–99.2 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 IgG 0–6 Months: 206–676 mg/dL 6–9 Months: 208–868 mg/dL 9–12 Months: 282–1026 mg/dL 1–2 Years: 331–1164 mg/dL 2–3 Years: 407–1009 mg/dL 3–4 Years: 423–1090 mg/dL 4–5 Years: 444–1187 mg/dL 5–8 Years: 608–1229 mg/dL 8–10 Years: 584–1509 mg/dL 10–99 Years: 717–1411 mg/dL	2/5/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
IgG Subclasses 1,2,3,4	IG1234	<p>Stability: Ambient: 24 hours Refrigerated: 8 days Frozen: 30 days</p> <p>Reference Range: 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: 423.3-1060.0 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> 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 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 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: 4.0-99.2 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	2/5/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Melatonin	MELAT	<p>Note: <i>The following alias names have been added: N-acetyl-5-methoxy-tryptamine, Sleep hormone</i></p> <p>Special Information: Patient Prep: Fasting specimen is preferred. Melatonin concentration varies with light and dark cycle. The concentration is lower during the day and higher at night. Patients treated with pituitary or steroid hormones influence the concentration; should be discontinued for 2 days prior to collection.</p> <p>Clinical Information: The pineal gland is considered a neuroendocrine transducer because of its importance in photoperiodism. The major hormone of the pineal gland is melatonin (N-acetyl-5-methoxy-tryptamine). It is the major indole compound synthesized by the pineal gland. It is converted from serotonin by hydroxy indole-O-methyl transferase. It is excreted into the urine as 6-sulfatoxymelatonin, N-acetyl serotonin, other glucuronide and sulfate forms, and also a small amount as unconjugated "free" melatonin. Melatonin has potent melanocyte contracting properties. Melatonin is primarily secreted during the dark (night) cycle. Levels drop dramatically after exposure to bright light. Melatonin binds to various proteins including albumin. Patients with cancer frequently have decreased levels of melatonin as do patients with impaired central nervous system (CNS) function. Elevated levels can be found in sympathetic orthostatic hypotension. Melatonin has a stimulatory and suppressive feedback on gonadotropin release depending on melatonin levels. Altered levels of melatonin have been reported with sleep disorders, jet lag, depression, stress, schizophrenia, hypothalamic amenorrhea, pregnancy, anorexia nervosa, immunological disorders, as well as sexual maturation during puberty.</p> <p>Specimen Requirement: 3 mL plasma from an EDTA (lavender) tube; Minimum: 1 mL; Draw 2 tubes to ensure adequate volume; Patient Prep: Fasting specimen preferred; Melatonin concentration varies with light and dark cycle; The concentration is lower during the day and higher at night; Patients treated with pituitary or steroid hormones influence the concentration: Should be discontinued for 2 days prior to collection; Centrifuge, aliquot plasma into standard aliquot tube and freeze; Frozen</p> <p>*OR* 3 mL serum from a serum separator (gold) tube; Minimum: 1 mL; Draw 2 tubes to ensure adequate volume; Patient Prep: Fasting specimen preferred; Melatonin concentration varies with light and dark cycle; The concentration is lower during the day and higher at night; Patients treated with pituitary or steroid hormones influence the concentration: Should be discontinued for 2 days prior to collection; Centrifuge, aliquot serum into standard aliquot tube and freeze; Frozen</p> <p>*OR* 3 mL serum from a plain no additive (red) tube; Minimum: 1 mL; Draw 2 tubes to ensure adequate volume; Patient Prep: Fasting specimen preferred; Melatonin concentration varies with light and dark cycle; The concentration is lower during the day and higher at night; Patients treated with pituitary or steroid hormones influence the concentration: Should be discontinued for 2 days prior to collection; Centrifuge, aliquot serum into standard aliquot tube and freeze; Frozen</p> <p>Stability: Ambient: Unstable Refrigerated: 24 hours Frozen: 90 days</p> <p>Methodology: Enzyme-Linked Immunosorbent Assay (ELISA) Extraction (EXT)</p> <p>Reference Range: Day time: 2.0–80.0 pg/mL Night time: 18.5–180.0 pg/mL</p> <p>Days Performed: Wednesday Reported: 3–8 days CPT: 83520 x 1</p>	Effective immediately
Methylphenidate and Metabolite Quantitative, Serum or Plasma	RITALN	<p>Days Performed: Varies Reported: 8–11 days</p>	Effective immediately
Narcolepsy Associated Ag, HLA-DQB1 Typing	NARCAB	<p>Note: <i>Changes to this test were previously announced in the September Technical Update with a go-live date of 11/13/18. The new go-live date for these changes will be 12/13/18. We apologize for any inconvenience this may have caused.</i></p>	12/13/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
PNH Panel by FCM	PNHPNL	CPT: 88184 x 1, 88185 x 2, 88187 x 1	1/24/19
Strychnine	STRYCH	Special Information: Separator tubes are unacceptable. This test is New York DOH approved. Note: <i>Clinical Information has been removed.</i> Days Performed: Varies Reported: 5–11 days	Effective immediately
Surface/Cytoplasmic IgM by FCM	IGMICYT	CPT: 88184 x 1, 88185 x 1	1/24/19
Titanium, Serum or Plasma	TITAN	Special Information: Separator tubes are unacceptable. This test is New York DOH approved. Days Performed: Varies Reported: 5–8 days	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Acylcarnitines, Plasma w/ No Interpretation	ACYLNI	<p>Includes:</p> <ul style="list-style-type: none"> Free L-carnitine Total L-carnitine Free/Total carnitine ratio Acetylcarnitine Propionylcarnitine Iso/Butyrylcarnitine Isovaleryl/2-Methylbutyrylcarnitine Tiglylcarnitine Hexanoylcarnitine Octanoylcarnitine Decanoylcarnitine Decenoylcarnitine Dodecanoylcarnitine Dodecenoylcarnitine OH-Dodecenoylcarnitine 3-OH-Dodecanoylcarnitine Tetradecanoylcarnitine Tetradecenoylcarnitine 3-OH-Tetradecenoylcarnitine Tetradecadienoylcarnitine 3-OH-Tetradecanoylcarnitine Hexadecanoylcarnitine Hexadecenoylcarnitine 3-OH-Hexadecenoylcarnitine 3-OH-Hexadecanoylcarnitine Stearoylcarnitine Oleoylcarnitine 3-OH-Oleoylcarnitine Linoleoylcarnitine 3-OH-Linoleoylcarnitine Succinylcarnitine 3-OH-Butyryl/IsoButyrylcarnitine Glutaryl carnitine 3-OH-IsoValeryl/2-Methyl-3-OH-Butyrylcarnitine Malonylcarnitine <p>Special Information: Decant plasma/serum from cells within 2 hours of collection. Indicate patient fasting hours when the specimen was collected. Fasting is not required, but the information is helpful for test interpretation. Carnitine, fish oil and omega-3 supplements affect test results; indicate supplement use on the requisition. Specimens on patients < 1 month old are sent to an outside reference laboratory (currently Mayo).</p> <p>Specimen Requirement: 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.2 mL; Remove plasma from cells ASAP; Refrigerated</p> <p>*OR* 1 mL plasma from a lithium heparin (green) tube; Minimum: 0.2 mL; Remove plasma from cells ASAP; Refrigerated</p> <p>*OR* 1 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.2 mL; Remove plasma from cells ASAP; Refrigerated</p> <p>*OR* 1 mL plasma from a sodium heparin (green) tube; Minimum: 0.2 mL; Remove plasma from cells ASAP; Refrigerated</p> <p>*OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.2 mL; Remove serum from cells ASAP; Refrigerated</p> <p>Stability:</p> <ul style="list-style-type: none"> Ambient: Plasma on the cells: Up to 2 hours Refrigerated: Plasma on the cells: 3 days; Plasma removed from the cells: 18 days Frozen: Plasma removed from the cells: 60 days <p>Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)</p> <p>Days Performed: 1 day per week</p> <p>Reported: 1-10 days</p> <p>CPT: 82017 x 1, 82379 x 1</p>	1/29/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Cat Components IgE	CATCP	<p>Includes: nFel d1 nFel d2 nFel d4 Allergen class guide</p> <p>Clinical Limitation: Allergen results of 0.10–0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p> <p>Specimen Requirement: 0.8 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>*OR* 0.8 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>*OR* 0.8 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>Stability: Ambient: 1 day Refrigerated: 7 days Frozen: 14 days</p> <p>Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p>Reference Range: nFel d1: < 0.35 kU/L nFel d2: < 0.35 kU/L nFel d4: < 0.35 kU/L</p> <p>Days Performed: Sunday–Saturday</p> <p>Reported: 1–2 days</p> <p>CPT: 86008 x 3</p> <p>Price: \$98.00 (non-discountable)</p>	12/18/18
Allergen, Dog Components IgE	DOGCP	<p>Includes: rCan f1 rCan f2 rCan f5 rCan f3 Allergen class guide</p> <p>Clinical Information: Allergen results of 0.10–0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p> <p>Specimen Requirement: 0.8 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>*OR* 0.8 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>*OR* 0.8 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p><i>(continued on page 14)</i></p>	12/18/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Dog Components IgE <i>(continued from page 13)</i>		<p>Stability: Ambient: 1 day Refrigerated: 7 days Frozen: 14 days</p> <p>Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p>Reference Range: rCan f1: < 0.35 kU/L rCan f2: < 0.35 kU/L rCan f5: < 0.35 kU/L rCan f3: < 0.35 kU/L</p> <p>Days Performed: Sunday–Saturday</p> <p>Reported: 1–2 days</p> <p>CPT: 86008 x 4</p> <p>Price: \$132.00 (non-discountable)</p>	
Allergen, Dust Mite Components IgE	DUSTCP	<p>Includes: rDer p2 rDer p10 rDer p1 Allergen class guide</p> <p>Clinical Information: Allergen results of 0.10–0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p> <p>Specimen Requirement: 0.8 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>*OR* 0.8 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>*OR* 0.8 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>Stability: Ambient: 1 day Refrigerated: 7 days Frozen: 14 days</p> <p>Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p>Reference Range: rDer p2: < 0.35 kU/L rDer p10: < 0.35 kU/L rDer p1: < 0.35 kU/L</p> <p>Days Performed: Sunday–Saturday</p> <p>Reported: 1–2 days</p> <p>CPT: 86008 x 3</p> <p>Price: \$98.00 (non-discountable)</p>	12/18/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Hazelnut Components IgE	HZNTCP	<p>Includes: Cor a1 Cor a8 Cor a9 Cor a14 Allergen class guide</p> <p>Clinical Information: Allergen results of 0.10–0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p> <p>Specimen Requirement: 0.8 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>*OR* 0.8 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>*OR* 0.8 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>Stability: Ambient: 1 day Refrigerated: 7 days Frozen: 14 days</p> <p>Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p>Reference Range: Cor a1: < 0.35 kU/L Cor a8: < 0.35 kU/L Cor a9: < 0.35 kU/L Cor a14: < 0.35 kU/L</p> <p>Days Performed: Sunday–Saturday</p> <p>Reported: 1–2 days</p> <p>CPT: 86008 x 4</p> <p>Price: \$132.00 (non-discountable)</p>	12/18/18
Allergen, Peanut IgE with Reflex to Peanut Components, IgE	PNTRFX	<p>Includes: Allergen, Peanut IgE Allergen, Peanut Class</p> <p>Clinical Information: Values ≥ 0.35 kU/L will reflex to the Allergen Peanut Component IgE panel and will be billed accordingly. Specific evaluation of allergic reactions. IgE (kU/L) Interpretation: < 0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50–99.99, Class 5–Very High; ≥ 100, Class 6–Very High</p> <p>Specimen Requirement: 1.3 mL serum from a serum separator (gold) tube; Minimum: 0.8 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 1.3 mL is preferred when possible); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>*OR* 1.3 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.8 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 1.3 mL is preferred when possible); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>*OR* 1.3 mL plasma from an EDTA (lavender) tube; Minimum: 0.8 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 1.3 mL is preferred when possible); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p>	12/18/18

(continued on page 16)

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Peanut IgE with Reflex to Peanut Components, IgE <i>(continued from page 15)</i>		<p>Stability: Ambient: 1 day Refrigerated: 7 days Frozen: 14 days</p> <p>Methodology: Fluorescent Enzyme Immunoassay (FEIA) by ImmunoCAP</p> <p>Reference Range: Allergen, Peanut IgE: < 0.35 kU/L Allergen, Peanut Class: 0</p> <p>Days Performed: Sunday–Saturday</p> <p>Reported: 1–2 days</p> <p>CPT: 86003 x 1</p> <p>Price: \$33.00</p>	
Allergen, Soybean Components IgE	SYBNCP	<p>Includes: nGly m5 nGly m6 nGly m4 Allergen class guide</p> <p>Clinical Information: Allergen results of 0.10–0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p> <p>Specimen Requirement: 0.8 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>*OR* 0.8 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>*OR* 0.8 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.8 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>Stability: Ambient: 1 day Refrigerated: 7 days Frozen: 14 days</p> <p>Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p>Reference Range: nGly m5: < 0.35 kU/L nGly m6: < 0.35 kU/L nGly m4: < 0.35 kU/L</p> <p>Days Performed: Sunday–Saturday</p> <p>Reported: 1–2 days</p> <p>CPT: 86008 x 3</p> <p>Price: \$98.00 (non-discountable)</p>	12/18/18
Allergen, Walnut Components IgE	WLNTCP	<p>Includes: Jug r1 Jug r3 Allergen class guide</p> <p>Clinical Information: Allergen results of 0.10–0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p>	12/18/18

(continued on page 17)

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Walnut Components IgE <i>(continued from page 16)</i>		<p>Specimen Requirement: 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.5 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>*OR* 0.5 mL plasma from an EDTA (lavender) tube; Minimum: 0.3 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.5 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>*OR* 0.5 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.3 mL (Submitting the minimum volume will not allow for repeat testing or add-ons. Required volume of 0.5 mL is preferred); An extra 50 µL will be required for each additional allergen ordered; Refrigerated</p> <p>Stability: Ambient: 1 day Refrigerated: 7 days Frozen: 14 days</p> <p>Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p>Reference Range: Jug r1: < 0.35 kU/L Jug r3: < 0.35 kU/L</p> <p>Days Performed: Sunday–Saturday</p> <p>Reported: 1–2 days</p> <p>CPT: 86008 x 2</p> <p>Price: \$65.00 (non-discountable)</p>	
Amino Acids, CSF w/ Basic Interpretation	CAABI	<p>Includes: Taurine Aspartic Acid Hydroxyproline Threonine Serine Asparagine Glutamine Proline Glycine Alanine Citrulline Valine Cystine Methionine Isoleucine Leucine Tyrosine Phenylalanine Ornithine Lysine Histidine Arginine Glutamic Acid Alpha Amino adipic Acid Sarcosine Hydroxylysine Amino Acid, CSF Review Basic Interpretation</p> <p>Special Information: 1. ≥ 1 mL cerebrospinal fluid (CSF) from vial # 2 preferred 2. Indicate family history, clinical condition, diet/or drug therapy information 3. Analysis of a simultaneous plasma is strongly recommended; Age of patient or date of birth needed</p> <p><i>(continued on page 18)</i></p>	1/29/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Amino Acids, CSF w/ Basic Interpretation <i>(continued from page 17)</i>		<p>Clinical Information: Evaluation of unexplained mental retardation, neurologic deterioration, movement disorders, microcephaly, evaluation of disorders of amino acids, mitochondrial energy disorders</p> <p>Specimen Requirement: 1 mL cerebrospinal fluid (CSF) in a clean container; Minimum: 0.5 mL; Frozen</p> <p>Stability: Ambient: Unacceptable Refrigerated: 24 hours Frozen: 2 weeks</p> <p>Methodology: Ion Exchange Chromatography</p> <p>Reference Range: Refer to report</p> <p>Days Performed: Varies</p> <p>Reported: 3–15 days</p> <p>CPT: 80500 x 1, 82139 x 1</p>	
Amino Acids, CSF w/ No Interpretation	CAANI	<p>Includes: Taurine Aspartic Acid Hydroxyproline Threonine Serine Asparagine Glutamine Proline Glycine Alanine Citrulline Valine Cystine Methionine Isoleucine Leucine Tyrosine Phenylalanine Ornithine Lysine Histidine Arginine Glutamic Acid Alpha Amino adipic Acid Sarcosine Hydroxylysine Amino Acid, CSF Review Amino Acids, CSF Note</p> <p>Special Information: 1. ≥ 1 mL cerebrospinal fluid (CSF) from vial # 2 preferred 2. Indicate family history, clinical condition, diet/or drug therapy information 3. Analysis of a simultaneous plasma is strongly recommended; Age of patient or date of birth needed</p> <p>Clinical Information: Evaluation of unexplained mental retardation, neurologic deterioration, movement disorders, microcephaly, evaluation of disorders of amino acids, mitochondrial energy disorders</p> <p>Specimen Requirement: 1 mL cerebrospinal fluid (CSF) in a clean container; Minimum: 0.5 mL; Frozen</p> <p>Stability: Ambient: Unacceptable Refrigerated: 24 hours Frozen: 2 weeks</p> <p>Methodology: Ion Exchange Chromatography</p> <p>Reference Range: Refer to report</p> <p>Days Performed: Varies</p> <p>Reported: 3–15 days</p> <p>CPT: 82139 x 1</p>	1/29/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Amino Acids, Plasma w/ Basic Interpretation	PAABI	<p>Special Information: Indicate clinical condition, diet and/or drug therapy information (if applicable), and family history information (if relevant). Age of patient or date of birth is needed.</p> <p>Clinical Information: Evaluation for disorders of amino acid metabolism or mitochondrial disorders; evaluation of unexplained mental retardation, neurological deterioration, failure to thrive, recurrent vomiting, acidosis or hyperammonemia</p> <p>Specimen Requirement: 1 mL plasma from a sodium heparin (green) tube; Minimum: 0.5 mL; Remove plasma from cells within 45 minutes of collection; Freeze plasma; Frozen</p> <p>*OR* 1 mL plasma from a lithium heparin (green) tube; Minimum: 0.5 mL; Remove plasma from cells within 45 minutes of collection; Freeze plasma; Frozen</p> <p>Stability: Ambient: Unacceptable Refrigerated: 24 hours Frozen: 2 weeks</p> <p>Methodology: High Performance Liquid Chromatography with Ultraviolet Detection (HPLC-UV)</p> <p>Reference Range: Phenylalanine 0–30 Days: 38–137 µm/L 1–23 Months: 31–75 µm/L 2–18 Years: 26–91 µm/L 19–99 Years: 35–85 µm/L Tyrosine 0–1 Month: 55–147 µm/L 1–24 Months: 22–108 µm/L 2–18 Years: 24–115 µm/L 18–99 Years: 34–112 µm/L Taurine: Refer to report Aspartic Acid: Refer to report Hydroxyproline: Refer to report Threonine: Refer to report Serine: Refer to report Asparagine: Refer to report Glutamine: Refer to report Proline: Refer to report Glycine: Refer to report Alanine: Refer to report Citrulline: Refer to report Valine: Refer to report Methionine: Refer to report Allo Isoleucine (0–99 Years): 0–2 µm/L Cystine: Refer to report Isoleucine: Refer to report Leucine: Refer to report Ornithine: Refer to report Lysine: Refer to report Arginine: Refer to report Glutamic Acid: Refer to report Alpha Amino adipic Acid: Refer to report Sarcosine: Refer to report Histidine: Refer to report Hydroxylysine: Refer to report</p> <p>Days Performed: Monday–Friday</p> <p>Reported: 1–5 days</p> <p>CPT: 80500 x 1, 82139 x 1</p>	1/29/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Amino Acids, Plasma w/ No Interpretation	PAANI	<p>Special Information: Indicate clinical condition, diet and/or drug therapy information (if applicable), and family history information (if relevant). Age of patient or date of birth is needed.</p> <p>Clinical Information: Evaluation for disorders of amino acid metabolism or mitochondrial disorders; evaluation of unexplained mental retardation, neurological deterioration, failure to thrive, recurrent vomiting, acidosis or hyperammonemia</p> <p>Specimen Requirement: 1 mL plasma from a sodium heparin (green) tube; Minimum: 0.5 mL; Remove plasma from cells within 45 minutes of collection; Freeze plasma; Centrifuge, aliquot and freeze</p> <p>*OR* 1 mL plasma from a lithium heparin (green) tube; Minimum: 0.5 mL; Centrifuge, aliquot and freeze</p> <p>Stability: Ambient: Unacceptable Refrigerated: 24 hours Frozen: 2 weeks</p> <p>Methodology: High Performance Liquid Chromatography with Ultraviolet Detection (HPLC-UV)</p> <p>Reference Range: Phenylalanine 0–30 Days: 38–137 $\mu\text{m/L}$ 1–23 Months: 31–75 $\mu\text{m/L}$ 2–18 Years: 26–91 $\mu\text{m/L}$ 19–99 Years: 35–85 $\mu\text{m/L}$ Tyrosine 0–1 Month: 55–147 $\mu\text{m/L}$ 1–24 Months: 22–108 $\mu\text{m/L}$ 2–18 Years: 24–115 $\mu\text{m/L}$ 18–99 Years: 34–112 $\mu\text{m/L}$ Taurine: Refer to report Aspartic Acid: Refer to report Hydroxyproline: Refer to report Threonine: Refer to report Serine: Refer to report Asparagine: Refer to report Glutamine: Refer to report Proline: Refer to report Glycine: Refer to report Alanine: Refer to report Citrulline: Refer to report Valine: Refer to report Methionine: Refer to report Allo Isoleucine (0–99 Years): 0–2 $\mu\text{m/L}$ Cystine: Refer to report Isoleucine: Refer to report Leucine: Refer to report Ornithine: Refer to report Lysine: Refer to report Arginine: Refer to report Glutamic Acid: Refer to report Alpha Amino adipic Acid: Refer to report Sarcosine: Refer to report Histidine: Refer to report Hydroxylysine: Refer to report</p> <p>Days Performed: 5 days per week</p> <p>Reported: 1–5 days</p> <p>CPT: 82139 x 1</p>	1/29/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Amino Acids, Urine w/ Basic Interpretation	UAABI	<p>Includes:</p> <ul style="list-style-type: none"> Leucine Taurine Aspartic Acid Hydroxyproline Threonine Serine Proline Citrulline Valine Cystine Methionine Isoleucine Tyrosine Ornithine Lysine Histidine Arginine Glutamic Acid Alpha Amino adipic Acid Sarcosine Asparagine Glutamine Glycine Alanine Phenylalanine Hydroxylysine Basic Interpretation <p>Special Information: Submission of simultaneous plasma specimen is recommended. Indicate clinical condition, diet and /or drug therapy information (if applicable), and family history information (if relevant). Age of patient or date of birth is needed.</p> <p>Clinical Information: Evaluations of unexplained mental retardation, neurological deterioration, recurrent vomiting, growth retardation, acidosis, hyperammonemia; evaluation for amino acid or mitochondrial disorders</p> <p>Specimen Requirement: 10 mL random urine in a clean container; Minimum: 2 mL; Frozen</p> <p>Stability:</p> <ul style="list-style-type: none"> Ambient: Unacceptable Refrigerated: 24 hours Frozen: 2 weeks <p>Methodology: Ion Exchange Chromatography</p> <p>Reference Range: Refer to report</p> <p>Days Performed: Monday–Friday</p> <p>Reported: 1–5 days</p> <p>CPT: 80500 x 1, 82139 x 1</p>	1/29/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Amino Acids, Urine w/ No Interpretation	UAANI	<p>Includes:</p> <ul style="list-style-type: none"> Leucine Taurine Aspartic Acid Hydroxyproline Threonine Serine Proline Citrulline Valine Cystine Methionine Isoleucine Tyrosine Ornithine Lysine Histidine Arginine Glutamic Acid Alpha Amino adipic Acid Sarcosine Asparagine Glutamine Glycine Alanine Phenylalanine Hydroxylysine Amino Acid, Urine Note <p>Special Information: Submission of simultaneous plasma specimen is recommended. Indicate clinical condition, diet and /or drug therapy information (if applicable), and family history information (if relevant). Age of patient or date of birth is needed.</p> <p>Clinical Information: Evaluations of unexplained mental retardation, neurological deterioration, recurrent vomiting, growth retardation, acidosis, hyperammonemia; evaluation for amino acid or mitochondrial disorders</p> <p>Specimen Requirement: 10 mL random urine in a clean container; Minimum: 2 mL; Frozen</p> <p>Stability:</p> <ul style="list-style-type: none"> Ambient: Unacceptable Refrigerated: 24 hours Frozen: 2 weeks <p>Methodology: High Performance Liquid Chromatography with Ultraviolet Detection (HPLC-UV)</p> <p>Reference Range: Refer to report</p> <p>Days Performed: Monday–Friday</p> <p>Reported: 1–5 days</p> <p>CPT: 82139 x 1</p>	1/29/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
C. difficile PCR with Reflex to EIA if Positive	CDREFL	<p>Special Information: Unformed stools are tested for the presence of C. difficile toxin B gene by PCR. Stool specimens positive for C. difficile toxin by PCR will be followed by toxin enzyme immunoassay (EIA) testing within 8 hours. A negative toxin EIA result is reported with the following comment: "Toxin EIA is less sensitive than cell cytotoxin and PCR assays. Clinical correlation of PCR positive/toxin EIA negative results is required to distinguish C. difficile colonization from disease."</p> <p>Clinical Information: A positive PCR result for C. difficile may represent infection or colonization. This multistep algorithm was implemented in response to 2017 IDSA guidelines recommending PCR testing as a stand-alone test for C. difficile infection (CDI) only if clinicians agree at the institutional level to NOT submit stool specimens on patients receiving laxatives and to submit stool specimens only from patients with unexplained and new onset of 3 or more unformed stools in 24 hours for testing for CDI. Observational studies have reported higher CDI-related complications among patients with EIA toxin positive specimens in comparison to patients with EIA toxin negative/PCR positive results.</p> <p>Specimen Requirement: 5 mL stool in a sterile container; Formed stools, samples from patients < 2 years old, and specimens received in preservative, frozen, on swabs or wooden applicator sticks will be rejected; Refrigerated</p> <p>Stability: Ambient: 24 hours Refrigerated: 5 days Frozen: Unacceptable</p> <p>Methodology: Polymerase Chain Reaction (PCR)</p> <p>Reference Range: No Clostridium difficile toxin detected</p> <p>Days Performed: Sunday–Saturday</p> <p>Reported: 1–3 days</p> <p>CPT: 87493 x 1</p> <p>Price: \$196.00</p>	1/22/19
Dermatomyositis Panel	DERMYO	<p>Includes: Mi-2 (nuclear helicase protein) Antibody P155/140 Antibody SAE1 (SUMO activating enzyme) Antibody MDA5 (CADM-140) Antibody NXP-2 (Nuclear matrix protein-2) Ab TIF-1 gamma (155 kDa) Antibody</p> <p>Special Information: Hemolyzed, hyperlipemic, or icteric specimens will be rejected. Heat-treated or contaminated specimens are unacceptable. This test is New York DOH approved.</p> <p>Clinical Information: This test may be useful for the evaluation of patients with characteristic cutaneous manifestations of dermatomyositis with or without muscle weakness.</p> <p>Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Separate from cells ASAP or within 2 hours of collection, then transfer serum to standard aliquot tube; Refrigerated</p> <p>Stability: Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year</p> <p>Methodology: Immunoblot (IB), Qualitative Immunoprecipitation</p> <p>Days Performed: Monday, Tuesday, Thursday, Friday</p> <p>Reported: 8–19 days</p> <p>CPT: 83516 x 6</p> <p>Price: \$234.00 (non-discountable)</p>	1/29/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Organic Acids Ur, Quant w/ No Interpretation	UORANI	<p>Includes:</p> <ul style="list-style-type: none"> Lactate, Urine 2HydroxyButyrate, Ur Oxalic Acid, Urine 3HydroxyButyrate, Ur AcetoAcetate, Urine 3OH2MethButyrate, Ur Malonate, Urine 3-HydroxyIsoValerate MethylMalonate, Urine Benzoic Acid, Urine EthylMalonate, Urine Succinate, Urine MethylSuccinate, Ur Uracil, Urine Fumarate, Urine IsoButyrylGlycine, U Glutarate, Urine 3MethylGlutarate, Ur ButyrylGlycine, Ur 2MEButyrylGlycine,Ur Malate, Urine Adipic Acid, Urine 5-Oxo-Proline, Urine 3MECrotonylGlycine,Ur 3HydroxyGlutaric Acid,U 2HydroxyGlutaricAcid,U a-KetoGlutarate, Ur HexanoylGlycine, Ur 4OHPhenylAcetate, Ur N-AcetylAsparticAcid, Ur Suberic Acid, Urine SuccinylAcetone, Ur 2-OxoAdipic Acid, Ur Aconitate, Urine IsoCitric Acid, Urine MethylCitrate, Urine Sebacic Acid, Urine 4OHPhenylLactate, Ur N-AcetylTyrosine, Ur SuberylGlycine, Ur Pyruvate, Urine 2OH-Isovalerate, Ur 3-Methylglutaconate <p>Special Information: Order code UORANI is for urine organic acid analysis on patients of any age.</p> <p>Specimen Requirement: 10 mL random urine in a clean container (No preservatives); Minimum: 5 mL; Place specimen on ice after collection; Frozen</p> <p>Stability:</p> <ul style="list-style-type: none"> Ambient: 3 hours Refrigerated: 24 hours Frozen: 3 months <p>Methodology: Gas Chromatography Mass Spectrometry (GCMS)</p> <p>Days Performed: 2 days per week</p> <p>Reported: 4–7 days</p> <p>CPT: 83918 x 1</p>	1/29/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Polymyositis and Dermatomyositis Panel	MYOSPL	<p>Includes: Jo-1 Antibody, IgG PL-7 (threonyl-tRNA synthetase) Antibody PL-12 (alanyl-tRNA synthetase) Antibody EJ (glycyl-tRNA synthetase) Antibody SRP (Signal Recognition Particle) Ab OJ (isoleucyl-tRNA synthetase) Antibody Mi-2 (nuclear helicase protein) Antibody P155/140 Antibody SAE1 (SUMO activating enzyme) Antibody MDA5 (CADM-140) Antibody NXP-2 (Nuclear matrix protein-2) Ab TIF-1 gamma (155 kDa) Antibody</p> <p>Special Information: Hemolyzed, hyperlipemic, or icteric specimens will be rejected. Heat-treated or contaminated specimens are unacceptable. This test is New York DOH approved.</p> <p>Clinical Information: This test may be useful for the evaluation of patients with progressive proximal muscle weakness and/or cutaneous manifestations suggestive of dermatomyositis and/or associated connective tissue disease.</p> <p>Specimen Requirement: 2 mL serum from a serum separator (gold) tube; Minimum: 1 mL (Note: Total minimum is 1 mL. Requires 0.5 mL per aliquot tube); Separate from cells ASAP or within 2 hours of collection; Split serum into two 1 mL aliquots using standard aliquot tubes; Refrigerated</p> <p>Stability: Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year</p> <p>Methodology: Immunoblot (IB), Qualitative Immunoprecipitation Semi-Quantitative Multiplex Bead Assay</p> <p>Days Performed: Monday, Tuesday, Thursday, Friday</p> <p>Reported: 8–19 days</p> <p>CPT: 83516 x 11, 86235 x 1</p> <p>Price: \$528.00 (non-discountable)</p>	1/29/19
Polymyositis Panel	POLMYO	<p>Includes: Jo-1 (Histidyl-tRNA Synthetase) Ab, IgG PL-7 (threonyl-tRNA synthetase) Antibody PL-12 (alanyl-tRNA synthetase) Antibody EJ (glycyl-tRNA synthetase) Antibody SRP (Signal Recognition Particle) Ab OJ (isoleucyl-tRNA synthetase) Antibody</p> <p>Special Information: Hemolyzed, hyperlipemic, or icteric specimens will be rejected. Heat-treated or contaminated specimens are unacceptable. This test is New York DOH approved.</p> <p>Clinical Information: This test may be useful for the evaluation of patients with progressive proximal muscle weakness and antisynthetase syndrome.</p> <p>Specimen Requirement: 2 mL serum from a serum separator (gold) tube; Minimum: 1 mL (Note: Total minimum volume is 1 mL. Requires 0.5 mL per aliquot tube); Separate from cells ASAP or within 2 hours of collection; Split the serum into two 1 mL aliquots using standard aliquot tubes; Refrigerated</p> <p>Stability: Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year</p> <p>Methodology: Immunoprecipitation Semi-Quantitative Multiplex Bead Assay</p> <p>Days Performed: Monday, Tuesday, Thursday, Friday</p> <p>Reported: 8–19 days</p> <p>CPT: 83516 x 5, 86235 x 1</p> <p>Price: \$276.00 (non-discountable)</p>	1/29/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Sarcoma Fusion NGS Panel	SRCNGS	<p>Specimen Requirement: 10 mm square formalin-fixed paraffin-embedded (FFPE) block; FFPE slides; Transport and store slides at ambient temperature; 10 unstained sections FFPE on charged, unbaked slides plus one H & E stained slide with best tumor area circled by a pathologist; Ambient</p> <p>Stability: Ambient: Formalin-fixed paraffin-embedded slides; Transport and store slides at ambient temperature Refrigerated: Unacceptable Frozen: Unacceptable</p> <p>Methodology: Next Gen Sequencing</p> <p>Days Performed: 1 day per week</p> <p>Reported: 14 days</p> <p>CPT: 81445 x 1, 88381 x 1</p> <p>Price: \$1942.00 (non-discountable)</p>	1/22/19

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
C. difficile Culture w/ reflex Cytotoxin Cell Assay	CDCULT	\$135.00 (non-discountable)	87075	Effective immediately
Hematologic Neoplasm Next Generation Sequencing Panel Marrow	HNMNGS	\$1575.00 (non-discountable)	81455, G0452	12/1/18
Hematologic Neoplasm Next Generation Sequencing Panel Peripheral Blood	HNPNGS	\$1575.00 (non-discountable)	81455, G0452	12/1/18
Melatonin	MELAT	\$215.00 (non-discountable)	83520	Effective immediately

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Enterovirus Culture	VENT	\$124.00 (non-discountable)	87254	12/18/18
Surface/Cytoplasmic IgM by FCM	IGMCT	\$292.00 (non-discountable)	88184, 88185	1/24/19

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Acylcarnitines, Plasma w/ Interpretation	ACYLPL	This test will no longer be available. Suggest ordering Acylcarnitines, Plasma w/ Basic Interpretation (ACYLBI) or Acylcarnitines, Plasma w/ No Interpretation (ACYLNI).	1/29/19
Amino Acids, CSF	AAQTCF	This test will no longer be available. Suggest ordering Amino Acids, CSF w/ Basic Interpretation (CAABI) or Amino Acids, CSF w/ No Interpretation (CAANI).	1/29/19
Amino Acids, Plasma	AAQTPL	This test will no longer be available. Suggest ordering Amino Acids, Plasma w/ No Interpretation (PAANI) or Amino Acids, Plasma w/ Basic Interpretation (PAABI).	1/29/19
Amino Acids, Quantitative, Urine	AAQTUR	This test will no longer be available. Suggest ordering Amino Acids, Urine w/ Basic Interpretation (UAABI) or Amino Acids, Urine w/ No Interpretation (UAANI).	1/29/19
Arsenic, Nails	ARSNL	This test will no longer be available.	2/5/19
ERBB2 (HER2/neu) Gene Amplification by FISH, Gastric Tissue	HER2GT	This test will no longer be available.	Effective immediately
Ketorolac	KETOR	This test will no longer be available.	2/4/19
Myositis AssessR	MYOSIT	This test will no longer be available. Suggest ordering Polymyositis Panel (POLMYO), Dermatomyositis Panel (DERMYO), or Polymyositis and Dermatomyositis Panel (MYOSPL).	1/29/19
Organic Acids Ur, Quant w/ Interpretation	UORA	This test will no longer be available. Suggest ordering Organic Acids Ur, Quant w/ Basic Interpretation (UORABI) or Organic Acids Ur, Quant w/ No Interpretation (UORANI).	1/29/19
TGFBR1 and TGFBR2 for Loey-Dietz Syndrome	TGFB	This test will no longer be available.	1/29/19