Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • August 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	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
30	Acetylcholinesterase, Amniotic Fluid					■								
17	Acetylcholinesterase and Fetal Hemoglobin, Amniotic Fluid				■									
17–20	Acylcarnitines, Plasma w/ Basic Interpretation				■									
4	Acylcarnitines, Plasma wo/ Interpretation		■					■						
4	Adalimumab Activity and Neutralizing Antibody												■	
4	Alkaline Phosphatase									■				
5	Alkaline Phosphatase Isoenzymes									■				
5	Allergen, Almond IgG						■							
5	Allergen, Ampicilloyl IgE						■	■	■		■	■	■	
6	Allergen, Barley IgG						■							
6	Allergen, Beef IgG						■							
6	Allergen, Cacao (Chocolate) IgG						■							
6	Allergen, Casein (Cow Milk) IgG						■							
6	Allergen, Chicken Meat IgG						■							
6	Allergen, Corn IgG						■							
6	Allergen, Egg White IgG						■							
6	Allergen, Lettuce IgG						■							
6	Allergen, Malt IgG						■							
6	Allergen, Oat IgG						■							
6	Allergen, Orange IgG						■							
6	Allergen, Peanut IgG						■							
6	Allergen, Pork IgG						■							

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
6	Allergen, Potato IgG					■	■					■		
6	Allergen, Rye IgG					■								
6	Allergen, Soybean IgG					■								
7	Allergen, Tomato IgG					■								
7	Allergen, Wheat IgG.					■								
7	Allergen, Whey IgG					■	■							
7	Allergen, Yeast (Bakers/Brewers) IgG					■								
7	Allergy Food Panel IgG					■								
7	Alpha Galactosidase, Serum					■	■							
7	Anti Mullerian Hormone					■	■			■	■	■		
30	ARX Sequence Analysis				■									
20	Bacterial PCR, Direct Specimen			■										
30	Barth Syndrome, Carrier				■									
30	Barth Syndrome, Initial Patient				■									
8	BCR/ABL1, Tyrosine Kinase Inhibitor Resistance, Kinase Domain Mutation Screen, Sanger Sequencing					■								
8	Bilirubin, Conjugated					■				■		■		
8	Bilirubin, Fractionated					■				■		■		
9	Bilirubin, Total					■				■				
9	Body Fluid Culture and Stain					■	■							
9	Borrelia burgdorferi Antibodies, IgG and IgM by Immunoblot (CSF)					■								
9	Borrelia burgdorferi Antibodies, Total by ELISA, CSF					■								
9	Calprotectin, Fecal					■								
21	Clonazepam			■										
30	Clonazepam & 7-Aminoclonazepam, Serum				■									
9	Comprehensive Metabolic Panel									■				
10, 30	Creatine Disorders Panel, Blood		■			■	■		■	■	■	■	■	■
11, 30	Creatine Disorders Panel, Urine		■			■	■	■	■	■	■	■	■	■
11	Des-Gamma-Carboxy Prothrombin, Serum											■		
11	G-6-PD Quantitative										■			
11	Hepatic Function Panel									■				
21	Hepatitis Delta Virus by Quantitative PCR			■										
30	Hepatitis D Virus RNA, PCR				■									
11	Homocysteine					■	■							
12, 30	Infliximab and Infliximab-dyyb Activity and Neutralizing Antibody												■	■
12, 30	Insulin Like Growth Factor II					■	■		■	■	■	■	■	■
12	Legionella Culture						■							
22	Leukemic Blood Cancer Chromosome Microarray + SNP			■										

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
12	Lyme Reflex Panel, CSF					■								
22	Methylphenidate and Metabolite Quantitative, Serum or Plasma			■										
30	M. tuberculosis Amplified, CSF				■									
30	Mycobacterium tuberculosis by QuantiFERON, Incubated				■									
30	Mycobacterium tuberculosis by QuantiFERON TB Gold				■									
22–23	Mycobacterium tuberculosis by QuantiFERON TB Gold Plus			■										
24	Mycobacterium tuberculosis by QuantiFERON TB Gold Plus, Incubated			■										
25–28	Organic Acids Ur, Quant w/ Basic Interpretation			■										
13	Organic Acids Ur, Quant wo/ Interpretation		■					■						
14	Orotic Acid, Urine					■	■	■		■	■	■		
14	Osmotic Fragility, Erythrocyte					■								
28	Oxidized Low-density Lipoprotein (LDL)			■										
29	Products of Conception Microarray + SNP			■										
14, 30	Ribosomal P Protein IgG Autoantibodies					■	■		■	■	■	■	■	■
14	Rickettsia rickettsii IgG & IgM Abs						■				■			
15	Rickettsia Typhi IgG & IgM Abs					■	■				■			
30	Ritalin				■									
15	Rotavirus Antigen Detection										■			
15	Strongyloides IgG Abs, Serum						■			■				
30	Tocainide				■									
15	Trichinella IgG Antibody					■	■		■		■	■		
16	Trypsinogen					■	■		■	■	■	■	■	
16	TSH									■				
16	U3RNP Fibrillarin Ab					■	■		■		■	■	■	
30	Universal Bacterial, Fungal, and AFB PCR				■									
16	Varicella Zoster IgM Ab, CSF					■								
16	Vitamin B12 w/reflex						■					■		

Test Changes

Test Name	Order Code	Change	Effective Date
Acylcarnitines, Plasma wo/ Interpretation	ACYLPL	**For Interfaced Clients Only: Test build may need to be modified** **Test Name:** Previously Acylcarnitines, Plasma **Includes:** 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 Glutarylcarnitine 3-OH-IsoValeryl/2-Methyl-3-OH-Butyrylcarnitine Malonylcarnitine (Note: *Interpretation and Review will be removed*)	9/25/18
Adalimumab Activity and Neutralizing Antibody	ADANEU	**CPT: 80299 x 1, 82397 x 1**	8/20/18
Alkaline Phosphatase	ALKP	**Reference Range:** Male **0–14 Days: 83–248 U/L** **15–364 Days: 122–469 U/L** **1–9 Years: 142–335 U/L** **10–12 Years: 129–417 U/L** **13–14 Years: 116–468 U/L** **15–16 Years: 82–331 U/L** **17–18 Years: 55–149 U/L** **19–99 Years: 38–113 U/L** Female **0–14 Days: 83–248 U/L** **15–364 Days: 122–469 U/L** **1–9 Years: 142–335 U/L** **10–12 Years: 129–417 U/L** **13–14 Years: 57–254 U/L** **15–16 Years: 50–117 U/L** **17–18 Years: 45–87 U/L** **19–99 Years: 34–123 U/L**	9/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Alkaline Phosphatase Isoenzymes	ALKISO	**Reference Range:** Bone %: 10.7–68.3% Bone Fraction: **12.9–52.6 U/L** Liver %: 26.0–86.2% Liver Fraction: **16.0–69.3 U/L** Intestinal %: 0.0–24.2% Intestine Fraction: **0.0–16.3 U/L** Alkaline Phosphatase Male **0–14 Days: 83–248 U/L** **15–364 Days: 122–469 U/L** **1–9 Years: 142–335 U/L** **10–12 Years: 129–417 U/L** **13–14 Years: 116–468 U/L** **15–16 Years: 82–331 U/L** **17–18 Years: 55–149 U/L** **19–99 Years: 38–113 U/L** Female **0–14 Days: 83–248 U/L** **15–364 Days: 122–469 U/L** **1–9 Years: 142–335 U/L** **10–12 Years: 129–417 U/L** **13–14 Years: 57–254 U/L** **15–16 Years: 50–117 U/L** **17–18 Years: 45–87 U/L** **19–99 Years: 34–123 U/L**	9/26/18
Allergen, Almond IgG	ALMIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	9/6/18
Allergen, Ampicilloyl IgE	AMPCIL	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Allergen, Ampicilloyl IgE (Note: *Allergen, Ampicilloyl class will be removed*) **Special Information: Multiple patient encounters should be avoided. Hemolyzed, icteric, or lipemic specimens are unacceptable. This test is New York DOH approved.** **Clinical Information: Allergen results of 0.10–0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen–specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. 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.** **Specimen Requirement: 0.25 mL** serum from a serum separator (gold) tube; Minimum: **0.25 mL (Minimum is 0.25 mL plus an extra 0.04 mL is required for each additional allergen ordered); Separate serum from cells ASAP or within 2 hours of collection; Transfer 0.25 mL serum plus an extra 0.1 mL for each additional allergen ordered to a standard aliquot tube; Multiple specimen tubes should be avoided;** Refrigerated **Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: **After separation from cells: 2 weeks** Frozen: **After separation from cells: 1 year** **Reference Range:** **< 0.10 kU/L: No significant level detected (Probability of IgE mediated clinical reaction); Class 0** **0.10–0.34 kU/L: Clinical relevance undetermined (Probability of IgE mediated clinical reaction); Class 0/1** **0.35–0.70 kU/L: Low (Probability of IgE mediated clinical reaction); Class 1** **0.71–3.50 kU/L: Moderate (Probability of IgE mediated clinical reaction); Class 2** **3.51–17.50 kU/L: High (Probability of IgE mediated clinical reaction); Class 3** **17.51–50.00 kU/L: Very high (Probability of IgE mediated clinical reaction); Class 4** **50.01–100.00 kU/L: Very high (Probability of IgE mediated clinical reaction); Class 5** **> 100.00 kU/L: Very high (Probability of IgE mediated clinical reaction); Class 6** **Days Performed:** Sunday–Saturday **Reported:** 2–**3** days	9/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Barley IgG	BARIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Allergen, Beef IgG	BEEFIG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Allergen, Cacao (Chocolate) IgG	CHOIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Allergen, Casein (Cow Milk) IgG	CSNIGG	**Clinical Information:** Values less than < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Allergen, Chicken Meat IgG	CHIIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Allergen, Corn IgG	CORIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Allergen, Egg White IgG	EGWIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Allergen, Lettuce IgG	LETIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Allergen, Malt IgG	MLTIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Allergen, Oat IgG	OATIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody.	8/20/18
Allergen, Orange IgG	ORAIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Allergen, Peanut IgG	PNTIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody.	8/20/18
Allergen, Pork IgG	PORKIG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Allergen, Potato IgG	POTIGG	**Clinical Information: Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL** **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: **0.2 mL; Separate serum from cells ASAP or within 2 hours of collection and** transfer into standard aliquot tube; **Refrigerated** **Stability:** Ambient: **After separation from cells:** 1 week Refrigerated: **After separation from cells:** 1 month Frozen: **After separation from cells:** 1 year	8/20/18
Allergen, Rye IgG	RYEIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Allergen, Soybean IgG	SOYIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody.	8/20/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Tomato IgG	TOMIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Allergen, Wheat IgG.	WHTIGG	**Special Information: Hemolyzed, icteric, or lipemic specimens are unacceptable. Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.** **Clinical Information: Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody.**	8/20/18
Allergen, Whey IgG	WHEYG	**Special Information: Hemolyzed, icteric or lipemic specimens will be rejected. If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory.** **Clinical Information: Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL** **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.2 mL; Remove serum from cells ASAP or within 2 hours of collection **and transfer into standard aliquot tube; Refrigerated**	8/20/18
Allergen, Yeast (Bakers/Brewers) IgG	YEAIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Allergy Food Panel IgG	FPIGG	**Clinical Information:** Values < 2.00 mcg/mL represent absent or undetectable levels of allergen-specific IgG antibody. The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL	8/20/18
Alpha Galactosidase, Serum	ALPGAL	**Special Information: CRITICAL FROZEN.** Thawed specimens are unacceptable. **Separate specimens must be submitted when multiple tests are ordered. This test is New York DOH approved.** **Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: 0.2 mL; **Transfer 2 mL serum to a standard aliquot tube; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen** *OR* 2 mL serum from a plain no additive (red) tube; Minimum: 0.2 mL; **Transfer 2 mL serum to a standard aliquot tube; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen**	Effective immediately
Anti Mullerian Hormone	MULLER	**Special Information: Samples for Anti Mullerian Hormone (AMH) levels should be drawn on days 2–4 of the menstrual cycle. Patients taking a biotin dose of up to 5 mg/day should refrain from taking biotin for 4 hours prior to sample collection. Patients taking a biotin dose of 5 to 10 mg/day should refrain from taking biotin for 8 hours prior to sample collection. Patients taking a biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.** **Specimen Requirement:** 0.5 mL serum from a **serum separator (gold) tube;** Minimum: 0.2 mL; Separate serum from cells ASAP or within 2 hours of collection; Frozen **Stability:** Ambient: **3 days** Refrigerated: **5 days** Frozen: **6 months** **Reference Range:** Female **20–24 Years: 1.22–11.70 ng/mL** **25–29 Years: 0.89–9.85 ng/mL** **30–34 Years: 0.58–8.13 ng/mL** **35–39 Years: 0.15–7.49 ng/mL** **40–44 Years: 0.03–5.47 ng/mL** Male: **No reference range has been established for this population** **Days Performed: Monday, Wednesday, Friday** **Reported: 1–5** days	9/27/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
BCR/ABL1, Tyrosine Kinase Inhibitor Resistance, Kinase Domain Mutation Screen, Sanger Sequencing	KINASE	**Special Information:** The following information is required: 1. Patient's fusion type (p210, p190, p205 or p230) 2. Pertinent clinical history 3. Clinical or morphologic suspicion 4. Date of collection 5. Specimen source (blood or bone marrow) Form required: Hematopathology Patient Information Sheet. If BCR/ABL1 fusion type (p210, p190, p205 or p230) is not provided, BADX / BCR/ABL1, Qualitative, Diagnostic Assay will be performed at an additional charge. **In the event that no fusion form (p190, p205, p210 or p230) is identified by BADX testing, BCR/ABL1, Tyrosine Kinase Inhibitor Resistance, Kinase Domain Mutation Screen, Sanger Sequencing (KINASE) testing will be canceled.** Useful for evaluating patients with chronic myelogenous leukemia and Philadelphia chromosome positive B-cell acute lymphoblastic leukemia receiving tyrosine kinase inhibitor (TKI) therapy, who are apparently failing treatment. This is the preferred initial test to identify the presence of acquired BCR-ABL1 mutations associated with TKI-resistance. Testing is New York State approved.	Effective immediately
Bilirubin, Conjugated	CBIL	**Special Information: Protect from light.** **Note:** *Clinical Information will be removed for this test* **Stability:** Ambient: 2 days **if protected from light** Refrigerated: 7 days **if protected from light** Frozen: 6 months **if protected from light** **Reference Range:** **0–30 Days: < 0.2 mg/dL** **31–365 Days: < 0.2 mg/dL** **1–17 Years: < 0.2 mg/dL** **18–99 Years: < 0.2 mg/dL**	9/26/18
Bilirubin, Fractionated	BILIFR	**Special Information:** Protect from light. **Stability:** Ambient: 1 day **if protected from light** Refrigerated: 7 days **if protected from light** Frozen: 6 months **if protected from light** **Reference Range:** Bilirubin, Total 0–30 Days (mg/dL): Results are flagged as abnormal due to the age-related nature of reference intervals in this patient population. Clinician review of acceptable bilirubin levels and risk categories is recommended using age-related or other pertinent reference information (e.g., Bhutani nomograms). 31–365 Days: 0.2–1.3 mg/dL 1–**17** Years: 0.2–1.3 mg/dL **18**–99 Years: 0.2–1.3 mg/dL Bilirubin, Unconjugated 0–30 Days: **Results are flagged as abnormal due to the age-related nature of reference intervals in this patient population. Clinician review of acceptable bilirubin levels and risk categories is recommended using age-related or other pertinent reference information.** **31–365 Days: < 1.4 mg/dL** **1–17 Years: < 1.4 mg/dL** **18**–99 Years: **< 1.4 mg/dL** Bilirubin, Conjugated **0–30 Days: < 0.2 mg/dL** **31–365 Days: < 0.2 mg/dL** **1–17 Years: < 0.2 mg/dL** **18**–99 Years: **< 0.2 mg/dL**	9/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Bilirubin, Total	TBIL	**Special Information: Protect from light.** **Note:** *Clinical information will be removed for this test.* **Reference Range:** 0–30 Days (mg/dL): Results are flagged as abnormal due to the age-related nature of reference intervals in this patient population. Clinician review of acceptable bilirubin levels and risk categories is recommended using age-related or other pertinent reference information (e.g., Bhutani nomograms). 31–365 Days: 0.2–1.3 mg/dL 1–**17** Years: 0.2–1.3 mg/dL **18**–99 Years: 0.2–1.3 mg/dL	9/26/18
Body Fluid Culture and Stain	BFCUL	**Special Information:** Media and incubation conditions are employed for the recovery of aerobic bacteria from normally sterile body fluids (synovial, peritoneal, pericardial, pleural, amniotic). Disinfect overlying skin with iodine or chlorhexidine preparation and obtain specimen with needle and syringe. Push needle through septum of transport container and inject fluid into sterile container (or Port-A-Cul vial if anaerobic culture is also ordered). NEVER submit a swab specimen. Fluid may be inoculated into a blood culture bottle (up to 10 mL) provided a separate 1 mL aliquot is also submitted for preparation of Gram stain and inoculation of solid media. Broth cultures do not reflect bacterial burden, and a true pathogen may be obscured by overgrowth of more rapidly growing bacteria. Anaerobic cultures require a separate order. Abscess and drainage from tubes should be submitted with an order for wound culture rather than body fluid culture. **Specimens submitted in Red Top Vacutainer evacuated blood collection tubes are unacceptable. The internal walls of these tubes are coated with silica particles, which act as a clot activator and affects the recovery of microorganisms.** If culture is positive, identification will be performed at an additional charge for clinically significant organisms. Identification CPT codes that may apply include: 87077, 87106, 87107, 87153, 87158. Antimicrobial susceptibilities are performed when indicated, and the following CPT codes may apply: 87181, 87184, 87185, 87186 **Specimen Requirement:** 5 mL body fluid in a **sterile** container; Minimum: 2 mL; Transfer 5 mL aspirate to a sterile tube or container OR body fluid collected in blood culture bottles, accompanied by original specimen, if available; Ambient *OR* 5 mL amniotic fluid in a **sterile** container; Minimum: 2 mL; Ambient *OR* 5 mL pericardial fluid in a **sterile** container; Minimum: 2 mL; Ambient *OR* 5 mL peritoneal fluid in a **sterile** container; Minimum: 2 mL; Ambient *OR* 5 mL vesicle fluid in a **sterile** container; Minimum: 2 mL; Ambient *OR* 5 mL aspirate(s) in a **sterile** container; Aspirate of culdocentesis or thoracentesis are acceptable; Minimum: 2 mL; Ambient	8/9/18
Borrelia burgdorferi Antibodies, IgG and IgM by Immunoblot (CSF)	LYIBCS	**Special Information:** Contaminated, heat-inactivated **or hemolyzed** specimens are unacceptable. If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory.	8/20/18
Borrelia burgdorferi Antibodies, Total by ELISA, CSF	BBURGM	**Special Information:** Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible. Heat-inactivated, contaminated **or hemolyzed** specimens are unacceptable.	8/20/18
Calprotectin, Fecal	CALPRO	**Note:** *Changes for this test were announced in the June Technical Update with a go-live date of 7/31/18. Due to unforeseen circumstances, the go-live date has been delayed (TBD). We apologize for any inconvenience this may have caused.*	TBD
Comprehensive Metabolic Panel	CMP	**Note:** *There will be reference range changes for this test. Please refer to Alkaline Phosphatase (ALKP) and Bilirubin, Total (TBIL).*	9/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Creatine Disorders Panel, Blood	GUANID	**Test Name:** Previously Guanidinoacetic Acid **Special Information: Clinical information is necessary for appropriate interpretation. Additional required information includes age, gender, diet (e.g., TPN therapy), drug therapy, and family history. Please submit Patient History for Creatine Deficiency Syndromes Testing form AND Biochemical Genetics Patient History form with specimen. Specimens exposed to more than one freeze/thaw cycle will be rejected. This test is New York DOH approved.** **Clinical Information: Initial test to diagnose or rule out creatine deficiency syndromes following clinical presentation. For proper result interpretation, order urine testing simultaneously.** **Specimen Requirement:** 1 mL plasma from an EDTA (lavender) tube; Minimum: **0.2 mL; Separate from cells ASAP or within 2 hours of collection, transfer into standard aliquot tube, and freeze immediately; Clinical information is necessary for appropriate interpretation; Additional required information includes age, gender, diet (e.g., TPN therapy), drug therapy, and family history; Please submit Patient History for Creatine Deficiency Syndromes Testing form AND Biochemical Genetics Patient History form with specimen;** Frozen *OR* 1 mL plasma from a sodium **or lithium heparin** (green) tube; Minimum: **0.2 mL; Separate from cells ASAP or within 2 hours of collection, transfer into standard aliquot tube, and freeze immediately; Clinical information is necessary for appropriate interpretation; Additional required information includes age, gender, diet (e.g., TPN therapy), drug therapy, and family history; Please submit Patient History for Creatine Deficiency Syndromes Testing form AND Biochemical Genetics Patient History form with specimen;** Frozen *OR* 1 mL **serum from a plain no additive (red) tube;** Minimum: **0.2 mL; Separate from cells ASAP or within 2 hours of collection, transfer into standard aliquot tube, and freeze immediately; Clinical information is necessary for appropriate interpretation; Additional required information includes age, gender, diet (e.g., TPN therapy), drug therapy, and family history; Please submit Patient History for Creatine Deficiency Syndromes Testing form AND Biochemical Genetics Patient History form with specimen;** Frozen *OR* 1 mL **serum from a serum separator (gold) tube;** Minimum: **0.2 mL; Separate from cells ASAP or within 2 hours of collection, transfer into standard aliquot tube, and freeze immediately; Clinical information is necessary for appropriate interpretation; Additional required information includes age, gender, diet (e.g., TPN therapy), drug therapy, and family history; Please submit Patient History for Creatine Deficiency Syndromes Testing form AND Biochemical Genetics Patient History form with specimen;** Frozen **Stability:** Ambient: Unacceptable Refrigerated: **1 week** Frozen: **2 weeks (Avoid repeated freeze/thaw cycles)** **Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)** **Reference Range:** Creatine: **Refer to report** Guanidinoacetic Acid: **Refer to report** **Days Performed: Monday** **Reported:** 3–**10 days** **CPT: 82540 x 1,** 82542 x 1	10/4/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Creatine Disorders Panel, Urine	UGUANI	**For Interfaced Clients Only: Test build may need to be modified** **Test Name:** Previously Guanidinoacetic Acid, Urine **Includes:** UGUANI Interpretation **Creatine, Urine** Guanidinoacetate, UR **Creatinine, Urine** **Special Information: Clinical information is necessary for appropriate interpretation. Additional required information includes age, gender, diet (e.g., TPN therapy), drug therapy, and family history. Please submit Patient History for Creatine Deficiency Syndromes Testing form AND Biochemical Genetics Patient History form with the specimen. Specimens exposed to more than one freeze/thaw cycle will be rejected. This test is New York DOH approved.** **Clinical Information: Initial test to diagnose or rule out creatine deficiency syndromes following clinical presentation. For proper result interpretation, order serum/plasma testing simultaneously.** **Specimen Requirement: 2 mL** random urine in a clean container; Minimum: **0.5 mL; Freeze immediately; Clinical information is necessary for appropriate interpretation; Additional required information includes age, gender, diet (e.g., TPN therapy), drug therapy, and family history; Please submit Patient History for Creatine Deficiency Syndromes Testing form AND Biochemical Genetics Patient History form with specimen;** Frozen *OR* **2 mL timed urine (well-mixed)** in a clean container; Minimum: **0.5 mL; Freeze immediately; Clinical information is necessary for appropriate interpretation; Additional required information includes age, gender, diet (e.g., TPN therapy), drug therapy, and family history; Please submit Patient History for Creatine Deficiency Syndromes Testing form AND Biochemical Genetics Patient History form with specimen;** Frozen **Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: **2 weeks (Avoid repeated freeze/thaw cycles)** **Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)** **Reference Range:** **Creatine, Urine: Refer to report** Guanidinoacetate, UR: **Refer to report** **Creatinine, Urine: Refer to report** **Days Performed:** Monday **Reported: 3–10** days **CPT: 82540 x 1,** 82542 x 1, **82570 x 1**	10/4/18
Des-Gamma-Carboxy Prothrombin, Serum	PIVKA	**Stability:** Ambient: **After separation from cells: 8 hours** Refrigerated: **After separation from cells: 1 week** Frozen: **After separation from cells: 3 weeks (Avoid repeated freeze/thaw cycles)**	9/11/18
G-6-PD Quantitative	G6PDQT	**Days Performed: Sunday–Saturday** **Reported:** 2–**4** days	8/28/18
Hepatic Function Panel	HFP	**Note:** *There will be reference range changes for this test. Please refer to Alkaline Phosphatase (ALKP), Bilirubin, Conjugated (CBIL), and Bilirubin, Total (TBIL).*	9/26/18
Homocysteine	HOMCYS	**Special Information: Homocysteine is not available for add–on test orders.** **Specimen Requirement:** 1 mL **plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: 0.5 mL; **Place specimen on ice after draw;** Centrifuge and separate plasma from cells **less than 1 hour after collection;** If collected in a non-gel separator tube, centrifuge and transfer plasma to a CCL tube and refrigerate; Refrigerated *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; **Place specimen on ice after draw;** Centrifuge and separate serum from cells **less than 1 hour after collection;** If collected in a non-gel separator tube, centrifuge and transfer serum to a CCL tube and refrigerate; Refrigerated	9/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Infliximab and Infliximab-dyyb Activity and Neutralizing Antibody	IFXNEU	**CPT: 80299 x 1, 82397 x 1**	8/20/18
Insulin Like Growth Factor II	IGFII	**Special Information: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. Hemolyzed, lipemic, or icteric specimens will be rejected. This test is New York DOH approved.** **Clinical Information: May be used as an adjunct to IGF-1 in the diagnosis of growth disorders.** **Specimen Requirement:** 0.5 mL serum from a plain no additive (red) tube; Minimum: **0.2 mL; Allow specimen to clot completely at room temperature;** Separate from cells **ASAP or within 2 hours** of collection, **transfer into standard aliquot tube, and freeze immediately; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen** *OR* 0.5 mL serum from a **serum separator (gold) tube;** Minimum: **0.2 mL; Allow specimen to clot completely at room temperature;** Separate from cells **ASAP or within 2 hours** of collection, **transfer into standard aliquot tube, and freeze immediately; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen** **Stability:** Ambient: **After separation from cells: 24 hours** Refrigerated: **After separation from cells: 2 days** Frozen: **After separation from cells: 2 months** **Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)** **Reference Range:** **Prepubertal (0–11 Years): 127–473 ng/mL** **Postpubertal (12 Years and older): 180–580 ng/mL** **Days Performed: Tuesday** **Reported: 2**–9 days **CPT: 83520 x 1**	10/2/18
Legionella Culture	LEGCUL	**Specimen Requirement:** 1 g surgical tissue in a sterile container; **Refrigerated** *OR* 1 mL transtracheal aspirate in a sterile container; **Refrigerated** *OR* 1 mL pleural fluid in a sterile container; **Refrigerated** *OR* 1 mL fluid from a lung biopsy; **Refrigerated** *OR* 1 mL sputum in a sterile container; **Refrigerated**	Effective immediately
Lyme Reflex Panel, CSF	LYMCSF	**Special Information:** If B. burgdorferi total antibodies by ELISA are 1.00 LIV or greater, then B. burgdorferi IgG antibody by immunoblot and IgM antibody by immunoblot will be added. Additional charges apply. **Contaminated, heat-inactivated, or hemolyzed specimens will be rejected.**	8/20/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Organic Acids Ur, Quant wo/ Interpretation	UORA	**For Interfaced Clients Only: Test build may need to be modified** **Test Name:** Previously Organic Acids Ur, Quant **Includes:** Lactate, Urine 2HydroxyButyrate, Ur Oxalic Acid, Urine 3HydroxyButyrate, Ur AcetoAcetate, Urine 3OH2MethButyrate, Ur Malonate, Urine 3-HydroxyIsoValerate MethylMalonate, Urine Benzoic Acid, Urine 3-Methylglutaconate 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,U 3HydroxyGlutaric Acid 2HydroxyGlutaricAcid a-KetoGlutarate, Ur HexanoylGlycine, Ur 4OHPhenylAcetate, Ur N-AcetylAsparticAcid 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 UOA Note (Note: *UOA Interpretation and Review will be removed)*	9/25/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Orotic Acid, Urine	UOROTC	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Orotic Acid, Urine Creatinine, Ur mg/mL Orotic Acid Interp (Note: *Orotidine, Urine has been removed*) **Special Information: CRITICAL FROZEN.** Urine specimens containing preservatives are unacceptable. **Separate specimens must be submitted when multiple tests are ordered.** **Specimen Requirement:** 2 mL **first-catch** urine in a clean container; Minimum: 1 mL; **Specimen must be stored refrigerated until frozen; Transfer 2 mL urine to a standard aliquot tube and freeze immediately; Separate specimens must be submitted when multiple tests are ordered;** Critical Frozen *OR* 2 mL random urine in a clean container; Minimum: 1 mL; **Specimen must be stored refrigerated until frozen; Transfer 2 mL urine to a standard aliquot tube and freeze immediately; Separate specimens must be submitted when multiple tests are ordered;** Critical Frozen **Stability:** Ambient: Unacceptable Refrigerated: 24 hours Frozen: 2 weeks **(Avoid repeated freeze/thaw cycles)** **Reference Range:** Orotic Acid, Urine 0–4 Years: 0.7–5.1 mmol/mol creatinine 5 Years and older: 0.2–1.5 mmol/mol creatinine **Days Performed: Thursday** **Reported:** 3–10 days	Effective immediately
Osmotic Fragility, Erythrocyte	OSMFER	**Special Information:** Grossly hemolyzed specimens are unacceptable.	Effective immediately
Ribosomal P Protein IgG Autoantibodies	RIBPRO	**Special Information: Plasma or other body fluids are unacceptable. Bacterially contaminated or severely lipemic specimens will be rejected. This test is New York DOH approved.** **Clinical Information: May be used in detecting central nervous system systemic lupus erythematosus (SLE), which is somewhat rare, or renal involvement in SLE. Autoantibodies reacting with cytoplasmic ribosomes are highly specific for SLE. Ribosomal-P antibodies are found in approximately 12% of patients with SLE and in 90% of patients with lupus psychosis; titers often increase more than fivefold during and before active phases of psychosis.** **Specimen Requirement: 1 mL** serum from a serum separator (gold) tube; Minimum: **0.2 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube;** Refrigerated **Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: **After separation from cells: 2 weeks** Frozen: **After separation from cells: 1 year (Avoid repeated freeze/thaw cycles)** **Methodology: Semi–Quantitative Multiplex Bead Assay** **Reference Range:** **Negative: ≤ 29 AU/mL** **Equivocal: 30–40 AU/mL** **Positive: ≥ 41 AU/mL** **Days Performed: Sunday**–Saturday **Reported:** 2–**3 days** **CPT: 83516 x 1**	10/9/18
Rickettsia rickettsii IgG & IgM Abs	ROCKY	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL;** Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube; Parallel testing is preferred and convalescent specimens MUST be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' or 'convalescent;' Refrigerated **Days Performed: Sunday–Saturday** **Reported:** 2–**4** days	8/20/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Rickettsia Typhi IgG & IgM Abs	TYPHUS	**Special Information: Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Contaminated, hemolyzed or severely lipemic specimens will be rejected. This test is New York DOH approved.** **Clinical Information: Antibody reactivity to Rickettsia typhi antigen should be considered group–reactive for the Typhus Fever group, which includes Rickettsia prowazekii. Seroconversion between acute and convalescent sera is considered strong evidence of recent infection. The best evidence for infection is a significant change (fourfold difference in titer) on two appropriately timed specimens, where both tests are done in the same laboratory at the same time. Acute–phase specimens are collected during the first week of illness, and convalescent–phase samples are generally obtained 2–4 weeks after resolution of illness. Ideally, these samples should be tested simultaneously at the same laboratory. If the sample submitted was collected during the acute phase of illness, submit a labeled convalescent sample within 25 days for paired testing.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL;** Separate serum from cells **ASAP** or within 2 hours of collection **and transfer into standard aliquot tube; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' or 'convalescent;'** Refrigerated **Days Performed: Sunday–Saturday** **Reported:** 2–**4** days	8/20/18
Rotavirus Antigen Detection	EROTA	**Days Performed:** Monday–**Friday** **Reported:** 1–**3 days**	Effective immediately
Strongyloides IgG Abs, Serum	STRSER	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL;** Transfer 1 mL serum into standard aliquot tube; Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: **0.3 mL;** Transfer 1 mL serum into standard aliquot tube; Refrigerated **Reference Range:** **≤ 0.9 IV: Negative–No significant level of Strongyloides IgG antibody detected** **1.0 IV: Equivocal–The Strongyloides IgG antibody result is borderline and therefore inconclusive. Recommend retesting in 2–4 weeks, if clinically indicated** **≥ 1.1 IV: Positive–IgG antibodies to Strongyloides detected, which may suggest current or past infection**	8/20/18
Trichinella IgG Antibody	TRICH	**Special Information: This test is New York DOH approved.** **Clinical Information: Used to screen for trichinella exposure. This test is not diagnostic and must be correlated with supporting patient history and pathologic findings.** **Specimen Requirement: 1 mL** serum from a **plain no additive (red) tube;** Minimum: **0.1 mL; Transfer 1 mL serum into standard aliquot tube; Refrigerated** *OR* **1 mL** serum from a serum separator (gold) tube; Minimum: **0.1 mL; Transfer 1 mL serum into standard aliquot tube; Refrigerated** **Stability:** Ambient: **1 week** Refrigerated: **2 weeks** Frozen: **1 month** **Methodology: Qualitative** Enzyme-linked Immunosorbent Assay **Days Performed: Varies** **Reported: 4–11** days	10/11/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Trypsinogen	TRYPSI	**Special Information:** Lipemic or **icteric** specimens will be rejected. **Specimen Requirement:** 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; **Frozen** *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; **Frozen** **Stability:** Ambient: **72 hours** Refrigerated: **5** days Frozen: **30** days **Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)** **Reference Range: 43 - 199 ng/mL** **Days Performed: Tuesday, Saturday** **Reported:** 3–**9** days **CPT: 83520 x 1**	7/30/2018
TSH	TSH	**Reference Range:** **0–5 Days: 0.700–15.200 uU/mL** **6–90 Days: 0.720–11.000 uU/mL** **4–12 Months: 0.730–8.350 uU/mL** **1–6 Years: 0.700–5.970 uU/mL** **7–11 Years: 0.600–4.840 uU/mL** **12–20 Years: 0.510–4.300 uU/mL** **21–99 Years: 0.400–5.500 uU/mL** Pregnancy first trimester: 0.100–2.500 uU/mL Pregnancy second trimester: 0.200–3.000 uU/mL Pregnancy third trimester: 0.300–3.000 uU/mL	9/26/18
U3RNP Fibrillarin Ab	U3RNP	**Special Information: Grossly hemolyzed or severely lipemic specimens will be rejected. This test is New York DOH approved.** **Clinical Information: This test is recommended for the diagnosis of systemic sclerosis in patients negative for centromere, Scl-70, or RNA polymerase III antibodies. It may predict skeletal muscle involvement and pulmonary arterial hypertension. The presence of fibrillarin (U3-RNP) IgG antibodies in association with an ANA IFA nucleolar pattern is suggestive of systemic sclerosis (SSc). In SSc, these antibodies are associated with distinct clinical features, such as younger age at disease onset, frequent internal organ involvement (pulmonary hypertension, myositis and renal disease). Fibrillarin antibodies are detected more frequently in African American patients with SSc compared to other ethnic groups. Strong correlation with ANA IFA results is recommended. In a multi–ethnic cohort of SSc patients (n=98), U3-RNP antibodies detected by immunoblot had an agreement of 98.9% with the gold standard immunoprecipitation (IP) assay. Approximately 71% (5/7) of the borderline U3-RNP results with ANA nucleolar pattern in this cohort were IP negative.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; **Transfer 1 mL serum into standard aliquot tube;** Refrigerated **Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: **After separation from cells:** 2 weeks Frozen: **After separation from cells: 1 year** **Methodology: Immunoblot (IB), Qualitative** **Days Performed: Tuesday, Thursday, Saturday** **Reported:** 2–**5 days** **CPT: 86235 x 1**	10/9/18
Varicella Zoster IgM Ab, CSF	CVZVM	**Special Information: Specimen types other than CSF are unacceptable. Contaminated, heat-inactivated or hemolyzed specimens will be rejected.**	8/20/18
Vitamin B12 w/reflex	B12RFX	**Specimen Requirement:** 3 mL serum from a serum separator (gold) tube; Minimum: 2 mL; **Place specimen on ice after draw; Centrifuge** and separate serum from cells **less than 1 hour after collection; If collected in a non–gel separator tube, centrifuge and transfer serum to a CCL tube and refrigerate; Refrigerated** **Stability:** Ambient: **After separation from cells:** 24 hours Refrigerated: **After separation from cells:** 24 hours Frozen: **After separation from cells:** 7 days	9/26/18

New Tests

Test Name	Order Code	Change	Effective Date
Acetylcholinesterase and Fetal Hemoglobin, Amniotic Fluid	ACHEHB	**Special Information:** Patient History for Prenatal Cytogenetics form must be submitted with the specimen. Please include the amniotic fluid alpha fetoprotein (AFP) and MoM results, if available. This test is New York DOH approved. **Clinical Information:** Use following an abnormal amniotic fluid AFP result to evaluate the possibility of a fetal open neural tube defect. **Specimen Requirement:** 2 mL amniotic fluid in a clean container; Minimum: 1 mL; Must submit Patient History for Prenatal Cytogenetics form with the specimen; Include the Amniotic Fluid AFP and MoM results, if available; Ambient **Stability:** Ambient: 2 months Refrigerated: 4 months Frozen: 3 years **Methodology:** Gel Electrophoresis Radial Immunodiffusion (RID) **Reference Range:** Acetylcholinesterase: Negative Fetal Hemoglobin: Negative **Days Performed:** Monday, Wednesday **Reported:** 4–12 days **CPT:** 82013 x 1, 83033 x 1 **Price:** $188.00 (non-discountable)	10/2/18
Acylcarnitines, Plasma w/ Basic Interpretation	ACYLBI	**Includes:** 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 Glutarylcarnitine 3-OH-IsoValeryl/2-Methyl-3-OH-Butyrylcarnitine Malonylcarnitine Basic Interpretation *(continued on page 18)*	9/25/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Acylcarnitines, Plasma w/ Basic Interpretation *(continued from page 17)*		**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. **Specimen Requirement:** 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.2 mL; Remove plasma from cells ASAP; Refrigerated *OR* 1 mL plasma from a lithium heparin (green) tube; Minimum: 0.2 mL; Remove plasma from cells ASAP; Refrigerated *OR* 1 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.2 mL; Remove plasma from cells ASAP; Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.2 mL; Remove serum from cells ASAP; Refrigerated **Stability:** 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 **Methodology:** High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) **Reference Range:** Free L-carnitine 0–29 Days: 7–54 µmol/L 30–364 Days: 16–58 µmol/L 1–99 Years: 22–52 µmol/L Total L-carnitine 0–29 Days: 12–68 µmol/L 30–364 Days: 27–74 µmol/L 1–99 Years: 27–66 µmol/L Free/Total carnitine ratio 0–29 Days: 0.6–0.9 30–364 Days: 0.4–0.9 1–99 Years: 0.7–0.9 Acetylcarnitine 0–29 Days: 827–17279 nmol/L 30–364 Days: 589–24218 nmol/L 1–99 Years: 3571–17280 nmol/L Propionylcarnitine 0–29 Days: 58–894 nmol/L 30–364 Days: 81–811 nmol/L 1–99 Years: 155–703 nmol/L Iso/Butyrylcarnitine 0–29 Daysz: 19–239 nmol/L 30–364 Days: 14–266 nmol/L 1–99 Years: 50–364 nmol/L Isovaleryl/2-Methylbutyrylcarnitine 0–29 Days: 8–462 nmol/L 30–364 Days: 12–197 nmol/L 1–99 Years: 25–225 nmol/L Tiglylcarnitine 0–29 Days: 0–10 nmol/L 30–364 Days: 1–6 nmol/L 1–99 Years: 1–11 nmol/L Hexanoylcarnitine 0–29 Days: 1–85 nmol/L 30–364 Days: 6–101 nmol/L 1–99 Years: 7–69 nmol/L Octanoylcarnitine 0–29 Days: 14–176 nmol/L 30–364 Days: 20–223 nmol/L 1–99 Years: 22–282 nmol/L *(continued on page 19)*	

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Acylcarnitines, Plasma w/ Basic Interpretation *(continued from page 18)*		Decanoylcarnitine 0–29 Days: 14–178 nmol/L 30–364 Days: 17–202 nmol/L 1–99 Years: 12–251 nmol/L Decenoylcarnitine 0–29 Days: 12–190 nmol/L 30–364 Days: 28–211 nmol/L 1–99 Years: 23–323 nmol/L Dodecanoylcarnitine 0–29 Days: 12–132 nmol/L 30–364 Days: 9–196 nmol/L 1–99 Years: 9–114 nmol/L Dodecenoylcarnitine 0–29 Days: 3–47 nmol/L 30–364 Days: 2–55 nmol/L 1–99 Years: 2–42 nmol/L OH-Dodecenoylcarnitine 0–29 Days: 0–8 nmol/L 30–364 Days: 0–3 nmol/L 1–99 Years: 0–3 nmol/L 3-OH-Dodecanoylcarnitine 0–29 Days: 1–5 nmol/L 30–364 Days: 1–7 nmol/L 1–99 Years: 1–7 nmol/L Tetradecanoylcarnitine 0–29 Days: 6–40 nmol/L 30–364 Days: 5–57 nmol/L 1–99 Years: 7–46 nmol/L Tetradecenoylcarnitine 0–29 Days: 7–68 nmol/L 30–364 Days: 7–90 nmol/L 1–99 Years: 4–87 nmol/L 3-OH-Tetradecenoylcarnitine 0–29 Days: 0–9 nmol/L 30–364 Days: 1–11 nmol/L 1–99 Years: 1–12 nmol/L Tetradecadienoylcarnitine 0–29 Days: 4–46 nmol/L 30–364 Days: 4–44 nmol/L 1–99 Years: 4–42 nmol/L 3-OH-Tetradecanoylcarnitine 0–29 Days: 1–7 nmol/L 30–364 Days: 2–12 nmol/L 1–99 Years: 1–10 nmol/L Hexadecanoylcarnitine 0–29 Days: 22–244 nmol/L 30–364 Days: 40–225 nmol/L 1–99 Years: 47–174 nmol/L Hexadecenoylcarnitine 0–29 Days: 2–41 nmol/L 30–364 Days: 3–23 nmol/L 1–99 Years: 3–22 nmol/L 3-OH-Hexadecenoylcarnitine 0–29 Days: 0–2 nmol/L 30–364 Days: 0–2 nmol/L 1–99 Years: 0–2 nmol/L 3-OH-Hexadecanoylcarnitine 0–29 Days: 1–5 nmol/L 30–364 Days: 1–9 nmol/L 1–99 Years: 1–7 nmol/L Stearoylcarnitine 0–29 Days: 10–66 nmol/L 30–364 Days: 15–107 nmol/L 1–99 Years: 19–65 nmol/L *(continued on page 20)*	

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Acylcarnitines, Plasma w/ Basic Interpretation *(continued from page 19)*		Oleoylcarnitine 0–29 Days: 19–139 nmol/L 30–364 Days: 28–259 nmol/L 1–99 Years: 25–163 nmol/L 3-OH-Oleoylcarnitine 0–29 Days: 0–2 nmol/L 30–364 Days: 0–3 nmol/L 1–99 Years: 0–2 nmol/L Linoleoylcarnitine 0–29 Days: 5–67 nmol/L 30–364 Days: 10–136 nmol/L 1–99 Years: 11–95 nmol/L 3-OH-Linoleoylcarnitine 0–29 Days: 0–1 nmol/L 30–364 Days: 0–2 nmol/L 1–99 Years: 0–1 nmol/L Succinylcarnitine 0–29 Days: 10–128 nmol/L 30–364 Days: 8–108 nmol/L 1–99 Years: 15–59 nmol/L 3-OH-Butyryl/IsoButyrylcarnitine 0–29 Days: 2–84 nmol/L 30–364 Days: 6–114 nmol/L 1–99 Years: 3–40 nmol/L Glutarylcarnitine 0–29 Days: 6–78 nmol/L 30–364 Days: 7–58 nmol/L 1–99 Years: 16–126 nmol/L 3-OH-IsoValeryl/2-Methyl-3-OH-Butyrylcarnitine 0–29 Days: 6–109 nmol/L 30–364 Days: 7–53 nmol/L 1–99 Years: 7–42 nmol/L Malonylcarnitine 0–29 Days: 12–51 nmol/L 30–364 Days: 8–130 nmol/L 1–99 Years: 6–122 nmol/L **Days Performed:** 1 day per week **Reported:** 1–10 days **CPT:** 80500 x 1, 82017 x 1, 82379 x 1	
Bacterial PCR, Direct Specimen	BCTPCR	**Note:** *This test was announced in the June Technical Update with a go-live date of 7/31/18. Due to unforeseen circumstances, the go-live date has been rescheduled for 9/25/18. We apologize for any inconvenience this may have caused.*	9/25/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Clonazepam	CLONAS	**Special Information:** Patient Prep: Timing of specimen collection: Pre-dose (trough) draw–At steady state concentration. Gel separator tubes are unacceptable. Plasma or whole blood collected in light blue (sodium citrate) tubes will be rejected. Hemolyzed specimens will be rejected. This test is New York DOH approved. **Clinical Information:** Used to optimize drug therapy and monitor patient adherence. Adverse effects may include drowsiness, headache, fatigue and ataxia. **Specimen Requirement:** 2 mL plasma from a potassium oxalate/sodium fluoride (gray) tube; Minimum: 1 mL; Do not draw gel separator tube; Timing of specimen collection: Pre-dose (trough) draw–At steady state concentration; Separate plasma from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated *OR* 2 mL serum from a plain no additive (red) tube; Minimum: 1 mL; Do not draw gel separator tube; Timing of specimen collection: Pre-dose (trough) draw–At steady state concentration; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated *OR* 2 mL plasma from a sodium heparin (green) tube; Minimum: 1 mL; Do not draw gel separator tube; Timing of specimen collection: Pre-dose (trough) draw–At steady state concentration; Separate plasma from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated *OR* 2 mL plasma from an EDTA (lavender) tube; Minimum: 1 mL; Do not draw gel separator tube; Timing of specimen collection: Pre-dose (trough) draw–At steady state concentration; Separate plasma from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated **Stability:** Ambient: After separation from cells: 1 week Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 3 years (Avoid repeated freeze/thaw cycles) **Methodology:** Quantitative Liquid Chromatography–Tandem Mass Spectrometry **Reference Range:** (Dose-related) 20–70 ng/mL–Dose (Adult) 1–8 mg/d **Days Performed:** Tuesday, Friday **Reported:** 2–6 days **CPT:** 80346 x 1, (G0480, if appropriate) **Price:** $91.00	9/27/18
Hepatitis Delta Virus by Quantitative PCR	HDVPCR	**Special Information:** Specimen source is required. If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory. **Clinical Information:** Used to confirm and quantify the presence of hepatitis D virus. The quantitative range of this assay is 2.1–6.8 log IU/mL (120–5,800,000 IU/mL). A negative result (< 2.1 log IU/mL or < 120 IU/mL) does not rule out the presence of PCR inhibitors in the patient specimen or HDV RNA concentrations below the level of detection of the test. Inhibition may also lead to underestimation of viral quantitation. The limit of quantification for this test is 2.1 log IU/mL (120 IU/mL). If the test did NOT detect the virus, the result will be reported as "< 2.1 log IU/mL (< 120 IU/mL)." If the test DETECTED the presence of the virus but was not able to accurately quantify the number of copies, the result will be reported as "Not Quantified." **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Specimen source required; Separate serum from cells and transfer into sterile aliquot tube; Frozen **Stability:** Ambient: 24 hours Refrigerated: 1 week Frozen: 4 months **Methodology:** Polymerase Chain Reaction (PCR), Quant **Reference Range:** Not detected **Days Performed:** Monday, Thursday **Reported:** 3–6 days **CPT:** 87799 x 1 **Price:** $235.00 (non-discountable)	10/11/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Leukemic Blood Cancer Chromosome Microarray + SNP	BLLSNP	**Recommended Usage:** To detect copy number changes and loss of heterozygosity (LOH)/copy neutral LOH in hematological malignancies at diagnosis, prognostication or disease progression for clinically relevant chromosomal abnormalities. **Specimen Requirement:** 5–7 mL peripheral blood in an EDTA (lavender) tube; Collect specimen Monday–Friday only; Ambient **Stability:** Ambient: Stable for 48 hours Refrigerated: Not preferred Frozen: Unacceptable **Methodology:** Microarray **Days Performed:** Monday–Friday **Reported:** 14 days **CPT:** 81406 x 1, G0452 x 1	8/30/18
Methylphenidate and Metabolite Quantitative, Serum or Plasma	RITALN	**Special Information:** CRITICAL FROZEN. Patient Prep: Collect specimen 1–6 hours post dose. Separate specimens must be submitted when multiple tests are ordered. Separator tubes are unacceptable. This test is New York DOH approved. **Clinical Information:** Used for monitoring patient adherence. **Specimen Requirement:** 2 mL serum from a plain no additive (red) tube; Minimum: 0.7 mL; Collect specimen 1–6 hours post dose; Do NOT use separator tubes; Separate from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen *OR* 2 mL plasma from an EDTA (lavender) tube; Minimum: 0.7 mL; Collect specimen 1–6 hours post dose; Do NOT use separator tubes; Separate from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen **Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: 5 months **Methodology:** High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) **Reference Range:** Refer to report **Days Performed:** Varies **Reported:** 4–11 days **CPT:** 80360 x 1, (G0480, if appropriate) **Price:** $113.00 (non-discountable)	10/16/18
Mycobacterium tuberculosis by QuantiFERON TB Gold Plus	INFTBP	**Includes:** TB Result Nil Result TB1 Antigen minus Nil Result TB2 Antigen minus Nil Result Mitogen minus Nil Result TB Interpretation **Special Information:** External clients must be pre-approved to collect and submit specimens. Please refer any requests from outside laboratories to Client Services at 800.628.6816 or 216.444.5755. Specialized blood collection tubes are required. Clients with questions concerning how to order the QuantiFERON–TB Gold PLUS tubes can call Client Services at 800.628.6816 or 216.444.5755. Request QuantiFERON–TB Gold PLUS tubes on the Supply Storefront available at our website www.clevelandcliniclabs.com. Blood collection tubes should be at room temperature 17–25 °C (62.6–77 °F) at the time of blood collection. For each patient, collect 1 mL of blood by venipuncture directly into each of the QFT–Plus Blood Collection Tubes. This procedure should be performed by a trained phlebotomist. As 1 mL tubes draw blood relatively slowly, keep the tube on the needle for 2–3 seconds once the tube appears to have completed filling. This will ensure that the correct volume is drawn. *(continued on page 23)*	9/12/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Mycobacterium tuberculosis by QuantiFERON TB Gold Plus *(continued from page 22)*		The black mark on the side of the tubes indicates the validated range of 0.8–1.2 mL. If the level of blood in any tube is outside of the indicator mark, a new blood sample should be obtained. Under or over–filling of the tubes outside of the 0.8–1.2 mL range may lead to erroneous results. If a "butterfly needle" is being used to collect blood, a "purge" tube should be used to ensure that the tubing is filled with blood prior to the QFT–Plus Blood Collection Tubes being used. DO NOT COLLECT USING A LINE DRAW. QFT–Plus Blood Collection Tubes can be used up to an altitude of 2650 feet (810 meters) above sea level. HA QFT–Plus Blood Collection Tubes should be used at altitudes between 3350 and 6150 feet (1020 and 1875 meters). If using QFT–Plus Blood Collection Tubes outside these altitude ranges between 2650 and 3350 feet (810 and 1020 meters) or above 6150 feet (1875 meters), or if low blood draw volume occurs, users can collect blood with a syringe and immediately transfer 1 mL to each of the 4 tubes. For safety reasons, this is best performed by removing the syringe needle, ensuring appropriate safety procedures, removing the caps from the 4 QFT–Plus Blood Collection Tubes and adding 1 mL of blood to each (to the black mark on the side of the tube label which indicates the validated range of 0.8–1.2 mL). Replace the caps securely and mix as described below. Ensure each tube (Nil, TB1, TB2 and Mitogen) is identifiable by its label or other means once the cap is removed by the performing laboratory. Immediately after filling the tubes, shake them 10 times just firmly enough to make sure the entire inner surface of the tube is coated with blood. This will dissolve antigens on the tube walls. Over vigorous shaking may cause gel disruption and could lead to aberrant results. The tubes must be kept at room temperature and sent ASAP. DO NOT CENTRIFUGE. Tubes must reach Cleveland Clinic Laboratories at the Main Campus within 12 hours of collection. **Clinical Information:** Screening test for Tuberculosis (TB) **Specimen Requirement:** Four special tubes (QuantiFERON Gold PLUS tubes only) must be drawn: Grey cap with white ring (Nil control), Green cap with white ring (TB1 Ag), Yellow cap with white ring (TB2 Ag), Purple cap with white ring (Mitogen Control); Tubes must be kept at ambient temperature until received in the testing laboratory; DO NOT CENTRIFUGE; See Special Information section; Samples collected on Saturday or Sunday must be received at Cleveland Clinic Laboratories by 11:00 p.m. EST; Ambient **Stability:** Ambient: Refer To Special Information Refrigerated: Unacceptable Frozen: Unacceptable **Methodology:** Enzyme-Linked Immunosorbent Assay (ELISA) **Reference Range:** TB Result: Negative TB1 Antigen minus Nil Result: < 0.35 IU/mL TB2 Antigen minus Nil Result: < 0.35 IU/mL TB Interpretation: No evidence of current or previous infection with Mycobacterium tuberculosis **Days Performed:** Monday–Saturday **Reported:** 2–3 days **CPT:** 86480 x 1 **Price:** $113.00 (non-discountable)	

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Mycobacterium tuberculosis by QuantiFERON TB Gold Plus, Incubated	INTPGP	**Includes:** TB Result Nil Result TB1 Antigen minus Nil Result TB2 Antigen minus Nil Result Mitogen minus Nil Result TB Interpretation **Special Information:** External clients must be pre-approved to collect and submit specimens. Please refer any requests from outside laboratories to Client Services at 800.628.6816 or 216.444.5755. Specialized blood collection tubes are required. Clients with questions concerning how to order the QuantiFERON–TB Gold PLUS tubes can call Client Services at 800.628.6816 or 216.444.5755. Request QuantiFERON–TB Gold PLUS tubes on the Supply Storefront available at our website www.clevelandcliniclabs.com. Blood collection tubes should be at room temperature 17–25 °C (62.6–77 °F) at the time of blood collection. For each patient, collect 1 mL of blood by venipuncture directly into each of the QFT–Plus Blood Collection Tubes. This procedure should be performed by a trained phlebotomist. As 1 mL tubes draw blood relatively slowly, keep the tube on the needle for 2–3 seconds once the tube appears to have completed filling. The black mark on the side of the tubes indicates the validated range of 0.8–1.2 mL. If the level of blood in any tube is outside of the indicator mark, a new blood sample should be obtained. Under or over–filling of the tubes outside of the 0.8–1.2 mL range may lead to erroneous results. If a "butterfly needle" is being used to collect blood, a "purge" tube should be used to ensure that the tubing is filled with blood prior to the QFT–Plus Blood Collection Tubes being used. DO NOT COLLECT USING A LINE DRAW. QFT–Plus Blood Collection Tubes can be used up to an altitude of 2650 feet (810 meters) above sea level. Refer to the manufacturer's instructions for use if outside this altitude. Immediately after filling the tubes, shake them 10 times just firmly enough to make sure the entire inner surface of the tube is coated with blood. This will dissolve antigens on the tube walls. Over vigorous shaking may cause gel disruption and could lead to aberrant results. Following labeling, filling and shaking, the tubes must be transferred to a 37 °C ± 1 °C incubator as soon as possible, and within 16 hours of collection. Prior to incubation, maintain tubes at room temperature (22 °C ± 5 °C [71.6 °F ± 9 °F]). If QFT–Plus Blood Collection Tubes are not incubated at 37 °C directly after blood collection and shaking, invert the tubes to mix 10 times prior to incubation at 37 °C. Incubate the QFT–Plus Blood Collection Tubes UPRIGHT at 37 °C ± 1 °C for 16 to 24 hours. The incubator does not require CO2 or humidification. After incubation of the blood collection tubes at 37 °C ± 1 °C, tubes may be held between 4–27 °C for up to 3 days prior to centrifugation. After incubation of the tubes at 37 °C ± 1 °C, harvesting of the plasma is facilitated by centrifuging tubes for 15 minutes at 2000 to 3000 RCF (g). The gel plug will separate the cells from the plasma. If this does not occur, the tubes should be re-centrifuged. Samples can be stored in centrifuged QFT–Plus Blood Collection Tubes for up to 28 days at 2–8 °C. **Clinical Information:** Screening test for Tuberculosis (TB) **Specimen Requirement:** External clients must be pre-approved by testing laboratory manager to collect and submit specimens (800.628.6816 or 216.444.5755); Four special Qiagen collection tubes must be drawn; Do not collect using a line draw; Tubes must be incubated and processed per the protocol in Special Information section **Stability:** Ambient: Refer to Special Information Refrigerated: 28 days Frozen: Unacceptable **Methodology:** Enzyme-Linked Immunosorbent Assay (ELISA) **Reference Range:** TB Result: Negative TB1 Antigen minus Nil Result: < 0.35 IU/mL TB2 Antigen minus Nil Result: < 0.35 IU/mL TB Interpretation: No evidence of current or previous infection with Mycobacterium tuberculosis **Days Performed:** Monday–Saturday **Reported:** 2–3 days **CPT:** 86480 x 1 **Price:** $113.00 (non-discountable)	9/12/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Organic Acids Ur, Quant w/ Basic Interpretation	UORABI	**Includes:** Lactate, Urine 2HydroxyButyrate, Ur Oxalic Acid, Urine 3HydroxyButyrate, Ur 2OH-IsoValerate, 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 2MEButyrylGlycine,Ur Malate, Urine Adipic Acid, Urine 5-Oxo-Proline, Urine 3MECrotonylGlycine,U 3HydroxyGlutaricAcid 2HydroxyGlutaricAcid a-KetoGlutarate, Ur HexanoylGlycine, Ur 4OHPhenylAcetate, Ur N-AcetylAsparticAcid 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 Glutarate, Urine 3MethylGlutarate, Ur ButyrylGlycine, Ur 3-Methylglutaconate Basic Interpretation **Specimen Requirement:** 10 mL random urine in a clean container (No preservatives); Minimum: 5 mL; Place specimen on ice after collection; Frozen **Stability:** Ambient: 3 hours Refrigerated: 24 hours Frozen: 3 months **Methodology:** Gas Chromatography Mass Spectrometry (GCMS) **Reference Range:** Lactate, Urine 0–29 Days: 35.5–282.4 µmol/mmolCr 30–364 Days: 15.4–198.6 µmol/mmolCr 1–99 Years: 2.9–47.2 µmol/mmolCr 2HydroxyButyrate, Ur 0–29 Days: 0.2–9.6 µmol/mmolCr 30–364 Days: 0.0–15.0 µmol/mmolCr 1–99 Years: 0.0–2.7 µmol/mmolCr *(continued on page 26)*	9/25/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Organic Acids Ur, Quant w/ Basic Interpretation *(continued from page 25)*		Oxalic Acid, Urine 0–29 Days: 2.2–73.4 µmol/mmolCr 30–364 Days: 6.9–76.4 µmol/mmolCr 1–99 Years: 0.7–12.4 µmol/mmolCr 3HydroxyButyrate, Ur 0–29 Days: 0.1–4.4 µmol/mmolCr 30–364 Days: 0.4–9.9 µmol/mmolCr 1–99 Years: 0.1–2.6 µmol/mmolCr 2OH-IsoValerate, Ur 0–29 Days: 0.0–0.2 µmol/mmolCr 30–364 Days: 0.0–0.1 µmol/mmolCr 1–99 Years: 0.0–0.1 µmol/mmolCr AcetoAcetate, Urine 0–29 Days: 0.0–0.1 µmol/mmolCr 30–364 Days: 0.0–2.3 µmol/mmolCr 1–99 Years: 0.0–0.5 µmol/mmolCr 3OH2MethButyrate, Ur 0–29 Days: 0.0–0.8 µmol/mmolCr 30–364 Days: 0.0–5.6 µmol/mmolCr 1–99 Years: 0.0–1.3 µmol/mmolCr Malonate, Urine 0–29 Days: 0.0–0.4 µmol/mmolCr 30–364 Days: 0.0–0.4 µmol/mmolCr 1–99 Years: 0.0–0.1 µmol/mmolCr 3-HydroxyIsoValerate 0–29 Days: 0.0–72.4 µmol/mmolCr 30–364 Days: 1.7–119.3 µmol/mmolCr 1–99 Years: 2.1–27.3 µmol/mmolCr MethylMalonate, Urine 0–29 Days: 0.0–2.0 µmol/mmolCr 30–364 Days: 0.0–2.2 µmol/mmolCr 1–99 Years: 0.0–0.6 µmol/mmolCr Benzoic Acid, Urine 0–29 Days: 0.0–9.6 µmol/mmolCr 30–364 Days: 0.0–16.3 µmol/mmolCr 1–99 Years: 0.0–14.6 µmol/mmolCr EthylMalonate, Urine 0–29 Days: 0.6–34.5 µmol/mmolCr 30–364 Days: 0.7–82.7 µmol/mmolCr 1–99 Years: 0.5–6.2 µmol/mmolCr Succinate, Urine 0–29 Days: 1.1–219.5 µmol/mmolCr 30–364 Days: 7.7–189.6 µmol/mmolCr 1–99 Years: 0.3–27.4 µmol/mmolCr MethylSuccinate, Ur 0–29 Days: 0.0–5.6 µmol/mmolCr 30–364 Days: 0.1–6.8 µmol/mmolCr 1–99 Years: 0.0–1.4 µmol/mmolCr Uracil, Urine 0–29 Days: 0.0–1.6 µmol/mmolCr 30–364 Days: 0.0–7.7 µmol/mmolCr 1–99 Years: 0.0–5.1 µmol/mmolCr Fumarate, Urine 0–29 Days: 1.0–26.4 µmol/mmolCr 30–364 Days: 2.2–19.8 µmol/mmolCr 1–99 Years: 0.3–2.6 µmol/mmolCr IsoButyrylGlycine,U 0–29 Days: 0.0–1.1 µmol/mmolCr 30–364 Days: 0.0–1.1 µmol/mmolCr 1–99 Years: 0.0–1.2 µmol/mmolCr 2MEButyrylGlycine,Ur 0–29 Days: 0.0–1.0 µmol/mmolCr 30–364 Days: 0.0–0.9 µmol/mmolCr 1–99 Years: 0.0–0.4 µmol/mmolCr *(continued on page 27)*	

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Organic Acids Ur, Quant w/ Basic Interpretation *(continued from page 26)*		Malate, Urine 0–29 Days: 0.4–12.8 µmol/mmolCr 30–364 Days: 0.9–11.1 µmol/mmolCr 1–99 Years: 0.0–1.1 µmol/mmolCr Adipic Acid, Urine 0–29 Days: 0.5–52.5 µmol/mmolCr 30–364 Days: 5.0–53.8 µmol/mmolCr 1–99 Years: 0.3–9.2 µmol/mmolCr 5-Oxo-Proline, Urine 0–29 Days: 0.0–7.3 µmol/mmolCr 30–364 Days: 0.0–7.8 µmol/mmolCr 1–99 Years: 0.4–3.1 µmol/mmolCr 3MECrotonylGlycine,U 0–29 Days: < 0.3 µmol/mmolCr 30–364 Days: < 0.3 µmol/mmolCr 1–99 Years: < 0.3 µmol/mmolCr 3HydroxyGlutaricAcid 0–29 Days: 0.0–0.7 µmol/mmolCr 30–364 Days: 0.0–2.5 µmol/mmolCr 1–99 Years: 0.0–0.7 µmol/mmolCr 2HydroxyGlutaricAcid 0–29 Days: 3.0–49.1 µmol/mmolCr 30–364 Days: 4.4–66.9 µmol/mmolCr 1–99 Years: 0.6–17.7 µmol/mmolCr a-KetoGlutarate, Ur 0–29 Days: 0.0–403.2 µmol/mmolCr 30–364 Days: 0.2–355.8 µmol/mmolCr 1–99 Years: 0.2–42.7 µmol/mmolCr HexanoylGlycine, Ur 0–29 Days: 0.0–0.5 µmol/mmolCr 30–364 Days: 0.0–0.3 µmol/mmolCr 1–99 Years: 0.0–0.1 µmol/mmolCr 4OHPhenylAcetate, Ur 0–29 Days: 3.1–146.6 µmol/mmolCr 30–364 Days: 14.3–569.5 µmol/mmolCr 1–99 Years: 5.7–147.5 µmol/mmolCr N-AcetylAsparticAcid 0–29 Days: 0.2–40.0 µmol/mmolCr 30–364 Days: 0.0–69.0 µmol/mmolCr 1–99 Years: 0.1–8.9 µmol/mmolCr Suberic Acid, Urine 0–29 Days: 0.0–23.1 µmol/mmolCr 30–364 Days: 2.4–30.7 µmol/mmolCr 1–99 Years: 0.0–7.4 µmol/mmolCr SuccinylAcetone, Ur 0–29 Days: < 0.4 µmol/mmolCr 30–364 Days: < 0.4 µmol/mmolCr 1–99 Years: < 0.4 µmol/mmolCr 2-OxoAdipic Acid, Ur 0–29 Days: 0.0–0.0 µmol/mmolCr 30–364 Days: 0.0–2.8 µmol/mmolCr 1–99 Years: 0.0–3.3 µmol/mmolCr Aconitate, Urine 0–29 Days: 5.9–161.3 µmol/mmolCr 30–364 Days: 26.3–330.8 µmol/mmolCr 1–99 Years: 8.5–109.6 µmol/mmolCr IsoCitric Acid, Urine 0–29 Days: 2.4–297.4 µmol/mmolCr 30–364 Days: 43.9–537.3 µmol/mmolCr 1–99 Years: 9.1–271.9 µmol/mmolCr MethylCitrate, Urine 0–29 Days: 0.0–16.8 µmol/mmolCr 30–364 Days: 1.7–25.4 µmol/mmolCr 1–99 Years: 1.0–13.9 µmol/mmolCr *(continued on page 28)*	

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Organic Acids Ur, Quant w/ Basic Interpretation *(continued from page 27)*		Sebacic Acid, Urine 0–29 Days: 0.0–4.6 µmol/mmolCr 30–364 Days: 0.0–12.4 µmol/mmolCr 1–99 Years: 0.0–0.3 µmol/mmolCr 4OHPhenylLactate, Ur 0–29 Days: 0.4–112.6 µmol/mmolCr 30–364 Days: 1.1–88.2 µmol/mmolCr 1–99 Years: 1.3–23.0 µmol/mmolCr N-AcetylTyrosine, Ur 0–29 Days: 0.0–3.7 µmol/mmolCr 30–364 Days: 0.0–4.9 µmol/mmolCr 1–99 Years: 0.0–1.2 µmol/mmolCr SuberylGlycine, Ur 0–29 Days: 0.0 µmol/mmolCr 30–364 Days: 0.0 µmol/mmolCr 1–99 Years: 0.0 µmol/mmolCr Pyruvate, Urine 0–29 Days: 0.4–5.7 µmol/mmolCr 30–364 Days: 0.2–13.2 µmol/mmolCr 1–99 Years: 0.1–2.6 µmol/mmolCr Glutarate, Urine 0–29 Days: 0.0–6.2 µmol/mmolCr 30–364 Days: 0.4–6.6 µmol/mmolCr 1–99 Years: 0.0–1.4 µmol/mmolCr 3MethylGlutarate, Ur 0–29 Days: 0.0–0.9 µmol/mmolCr 30–364 Days: 0.1–1.4 µmol/mmolCr 1–99 Years: 0.0–0.6 µmol/mmolCr ButyrylGlycine, Ur 0–29 Days: 0.0–2.7 µmol/mmolCr 30–364 Days: 0.0–2.7 µmol/mmolCr 1–99 Years: 0.0–0.7 µmol/mmolCr 3-Methylglutaconate 0–29 Days: 0.0–5.2 µmol/mmolCr 30–364 Days: 0.0–7.9 µmol/mmolCr 1–99 Years: 0.0–2.0 µmol/mmolCr **Days Performed:** 2 days per week **CPT:** 80500 x 1, 83918 x 1	
Oxidized Low-density Lipoprotein (LDL)	OXLDL	**Special Information:** Store plasma or serum at 2–8 °C after collection and ship the same day. Unacceptable conditions: Specimens other than EDTA plasma or serum, improper labeling, samples not stored properly, samples older than stability limits **Clinical Information:** The oxidized LDL test may be ordered for individuals at low or intermediate risk of metabolic syndrome or cardiovascular disease. Additionally, this test is useful in individuals who have cardiovascular disease and are at risk for an adverse cardiac event. All ages: < 60 U/L low risk, 60–69 U/L moderate risk, ≥ 70 U/L high risk **Specimen Requirement:** 0.5 mL plasma from an EDTA (lavender) tube; Minimum: 0.2 mL; Draw and gently invert 8 to 10 times; Centrifuge for 10 minutes; Pre-squeeze transfer pipet bulb and draw off approximately 2/3 of the upper plasma layer; Note: This ensures that the buffy coat and red cells remain undisturbed; Transfer plasma into aliquot tube labeled as 'EDTA plasma' and cap tightly; Discard original tube and store aliquot tube refrigerated at 2–8 °C until ready to ship (ship same day); Refrigerated *OR* 0.5 mL serum from a serum separator (speckled or tiger top) tube; Minimum: 0.2 mL; Gently invert tube 5 times immediately after draw; Do NOT shake; Allow blood to clot 30 minutes; Centrifuge for 10 minutes; Send specimen in original collection tube; Store refrigerated at 2–8 °C until ready to ship (ship same day); Refrigerated **Stability:** Ambient: Unacceptable Refrigerated: 7 days Frozen: 28 days at minus 20 °C; 6 months at minus 70 °C to minus 80 °C **Methodology:** Enzyme-Linked Immunosorbent Assay (ELISA) **Days Performed:** Monday–Friday **Reported:** 2–6 days **CPT:** 83520 x 1 **Price:** $39.00 (non-discountable)	8/7/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Products of Conception Microarray + SNP	POCSNP	**Special Information:** While chromosomal microarray is widely used in postnatal situations, this same technology can be applied to investigate chromosomal aberrations in prenatal cases as well. A few examples include cases of recurrent pregnancy loss, spontaneous abortions and intrauterine fetal demise. Chromosomal microarray can also aid in further delineation of abnormalities found by conventional cytogenetics in prenatal cases, or can be used to find results in cases of poor or no growth, where sufficient metaphases were not obtained to complete a full cytogenetic analysis. Specimens collected and sent in formalin will be rejected. **Clinical Information:** Reflex tests: Chromosomes and FISH. These tests may incur additional charges. **Recommended Usage:** Diagnosing chromosomal causes for fetal death, determining recurrence risk of future pregnancy losses. Specimen types accepted are chorionic villi, fetal tissue, placenta and umbilical cord. **Specimen Requirement:** 30 mg chorionic villus in a sterile container; Sterile saline, RPMI 1640 or Hanks should be added to specimen in sterile container; Specimen should be transported refrigerated and remain refrigerated upon receipt; Fetal tissue, placenta and umbilical cord specimens are also accepted; Refrigerated **Stability:** Ambient: Not recommended Refrigerated: Preferred Frozen: Frozen tissue (or snap frozen) is acceptable for Microarray testing. Frozen is not acceptable for chromosome analysis. **Methodology:** Microarray **Days Performed:** Monday–Friday **Reported:** 14 days **CPT:** 81229 x 1	8/30/18

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Creatine Disorders Panel, Blood	GUANID	$145.00 (non-discountable)	82540, 82542	10/4/18
Creatine Disorders Panel, Urine	UGUANI	$160.00 (non-discountable)	82540, 82542, 82570	10/4/18
Infliximab and Infliximab-dyyb Activity and Neutralizing Antibody	IFXNEU	$400.00 (non-discountable)	80299, 82397	8/20/18
Insulin Like Growth Factor II	IGFII	$98.00 (non-discountable)	83520	10/2/18
Ribosomal P Protein IgG Autoantibodies	RIBPRO	$39.00 (non-discountable)	83516	10/9/18

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Acetylcholinesterase, Amniotic Fluid	ACHE	This test will no longer be available. Suggest ordering Acetylcholinesterase and Fetal Hemoglobin, Amniotic Fluid (ACHEHB).	10/2/18
ARX Sequence Analysis	ARXSEQ	This test will no longer be available.	9/27/18
Barth Syndrome, Carrier	BARCAR	This test will no longer be available.	9/27/18
Barth Syndrome, Initial Patient	BARINI	This test will no longer be available.	9/27/18
Clonazepam & 7-Aminoclonazepam, Serum	CLONOS	This test will no longer be available. Suggest ordering Clonazepam (CLONAS).	9/27/18
Hepatitis D Virus RNA, PCR	HDPCR	This test will no longer be available. Suggest ordering Hepatitis Delta Virus by Quantitative PCR (HDVPCR).	10/11/18
M. tuberculosis Amplified, CSF	MTBCSF	Note: *Changes for this test were previously announced in the June/July Technical Updates; however, this test will no longer be available. We apologize for any inconvenience this may have caused, and we suggest ordering Mycobacterium tuberculosis Complex and Rifampin Resistance by PCR (MTBAM1).*	8/7/18
Mycobacterium tuberculosis by QuantiFERON, Incubated	INFINC	This test will no longer be available. Suggest ordering Mycobacterium tuberculosis by QuantiFERON TB Gold Plus, Incubated (INTPGP).	9/12/18
Mycobacterium tuberculosis by QuantiFERON TB Gold	INFTBG	This test will no longer be available. Suggest ordering Mycobacterium tuberculosis by QuantiFERON TB Gold Plus (INFTBP).	9/12/18
Ritalin	RITAL	This test will no longer be available. Suggest ordering Methylphenidate and Metabolite Quantitative, Serum or Plasma (RITALN).	10/16/18
Tocainide	TOCAIN	This test will no longer be available.	8/20/18
Universal Bacterial, Fungal, and AFB PCR	FABPCR	Note: *This test was announced in the June Technical Update with a discontinuation date of 7/31/18. Due to unforeseen circumstances, the date for discontinuation has been rescheduled for 9/25/18. We apologize for any inconvenience this may have caused, and we suggest ordering Bacterial PCR, Direct Specimen (BCTPCR), Universal PCR, Fungal (FUNPCR) and Universal PCR, Acid Fast Bacilli (AFBPCR).*	9/25/18