Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • May 2024

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 Laboratory Customer Service 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
24	Adenovirus DFA				■								
3	Adiponectin					■	■		■	■	■	■	■
3	AFP, Serum (Tumor Marker)					■	■	■	■	■		■	
12	Allergen, Food, Anchovy IgE allergen			■									
12	Allergen, Food, Carob Gum/Locust Bean IgE			■									
13	Allergen, Food, Eggplant IgE			■									
13	Allergen, Food, Ginger IgE			■									
14	Allergen, Food, Lamb, IgE			■									
3	Allergen, Food, Pepper C. annum IgE		■										
14	Allergen, Food, Sardine IgE			■									
15	Allergen, Insect and Venum, Bumble Bee Venom IgE			■									
15	Allergen, Insects and Venom, Fire Ant (Solenopsis invicta), IgE			■									
24	Allergen, Jalapeno Pepper				■								
16–19	Allergen, Region 3 Respiratory Panel IgE, South Atlantic			■									
19	Allergen, Tree, Palm/Queen Tree IgE			■									
3–4	Allergic Bronchopulmonary Aspergillosis Panel		■			■	■	■	■	■	■	■	■
4	Aminolevulinic Acid (ALA) Urine					■	■						
19	Annatto Seed, IgE allergen			■									
4	B Cell CD20 Expression					■	■	■	■			■	

Test Update Page #		Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT
24	Bartonella PCR, tissue				■								
4	Bartonella Species by PCR		■										
20	Cauliflower IgE allergen			■									
4	Cell Count/Diff, Body Fluid						■						
24	Cocaine & Benzoylecgonine, Quant				■								
20	Cocaine Metabolite, Serum or Plasma, Quantitative			■									
5	Cryoglobulin, Qual w Reflex to IgG, IgA, IgM					■	■					■	
5	FLT3 ITD and TKD Mutation Detection by PCR					■	■		■			■	
5	Glutathione Total					■	■	■	■	■	■	■	
21	Goat Milk IgE allergen			■									
5–6	Hypersensitivity Pneumonitis Evaluation					■	■	■	■	■	■	■	■
24	IDH1/IDH2 Mutation, Blood/Bone marrow				■								
6	Lead, Blood						■						
21	Lima Bean/White Bean Allergen, IgE			■									
6	Lipoprotein Fractionation by NMR, Particle Count only		■			■	■	■		■	■	■	
7	Lipoprotein Fractionation by NMR with Lipids					■	■	■	■	■	■	■	
7	Malignancy Risk Assessment, Pelvic Mass, OVA1 Plus		■			■	■	■		■	■	■	
8	Mucopolysaccharides, Urine					■	■	■	■	■	■	■	■
8	Mumps Virus by PCR, Qualitative		■			■	■	■	■	■	■	■	
8–9	Myotonic Dystrophy Type 1 (DMPK) CTG Expansion		■			■	■	■	■	■	■	■	
22	Navy Bean, IgE allergen			■									
9	Neisseria meningitidis Tetravalent Antibodies, IgG (Vaccine Response)		■			■	■	■	■	■	■	■	■
22	Olives, IgE, allergen			■									
24	PAI-1 Genotype 5G/4G				■								
24	PD-L1 22C3 IHC with Tumor Proportion Score (TPS) Interpretation, pembrolizumab (KEYTRUDA)				■								
10	Pemphigoid Antibody Panel		■			■	■	■	■	■	■	■	
10	PM-Scl-100 Antibody, IgG by Immunoblot					■						■	
10–11	Porphobilinogen, Urine Quant					■	■	■	■	■	■	■	■
11	Protoporphyrins, Total, RBC		■										
24	Sezary Cell Staging				■								
24	Sezary Cells				■								
11	Thiocyanate						■						
11	U3RNP Fibrillarin Ab											■	
23	Ustekinumb Quantitation with Antibodies, Serum			■									
23–24	Vedolizumab Quantitation with Antibodies, Serum			■									
11	Y-Chromosome Microdeletion					■	■				■	■	

Test Changes

Test Name	Order Code	Change	Effective Date
Adiponectin	ADIP	**Specimen Requirement: 0.5** mL serum from serum separator (Gold) tube; **Minimum: 0.2 mL; Frozen; Allow specimen to clot for 15-20 minutes. Separate serum from cells within 2 hours of collection and transfer to standard aliquot tube.** *OR* **0.5** mL serum from no additive (Red) tube; **Minimum 0.2 mL; Frozen; Allow specimen to clot for 15-20 minutes. Separate serum from cells within 2 hours of collection and transfer to standard aliquot tube.** *OR* **0.5 mL plasma from lithium heparin plasma separator (Light Green) tube; Minimum 0.2 mL; Frozen; Separate plasma from cells within 2 hours of collection and transfer to standard aliquot tube.** **Stability:** Ambient: After separation from cells: **48 hours** Refrigerated: After separation from cells: **1** week Frozen: After separation from cells: **1 month** **Methodology: Radioimmunoassay (RIA)** **Reference Range:** **0 Years to 7 Years: 2.33–26.5 ug/mL** **8 Years to 9 Years: 3.96–14.9 ug/mL** **10 Years to 11 Years: 3.36–13.8 ug/mL** **12 Years to 13 Years: 4.50–13.2 ug/mL** **14 Years to 15 Years: 3.67–13.7 ug/mL** **16 Years to 19 Years: 2.74–13.3 ug/mL** **Male 19 Years to 99 Years: 2.00–13.9 ug/mL** **Female 19 Years to 99 Years: 4.00–19.4 ug/mL** **Days Performed: Wed** **Reported: 2–9** days **CPT: 83519**	5/20/24
AFP, Serum (Tumor Marker)	AFP	**For interface clients only–Test build may need to be modified** **Special Information:** The Alpha-Fetoprotein test was performed using the Siemens Centaur XP chemiluminometric immunoassay method **and the Beckman Unicel DxI immunoenzymatic assay.** Results obtained with different assay methods or kits cannot be used interchangeably. **For the sake of consistency in patient management purposes, parallel testing will occur for a period of 12 weeks to generate a new baseline for individual patients.** **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Refrigerated *OR* **1 mL serum from plain red tube; Refrigerated** **Stability:** Ambient: **7 days** Refrigerated: **14** days Frozen: **30** days **Methodology:** Chemiluminescence Immunoassay (CLIA) **Immunoenzymatic Assay** **Reference Range:** AFP, Serum (Tumor Marker) Centaur XP: < 11.00 ng/mL **AFP, Serum (Tumor Marker) DxI: <9.0 ng/mL**	6/20/24
Allergen, Food, Pepper C. annum IgE	CAYENN	**Name:** Previously Allergen, Cayenne Pepper **Includes:** ImmunoCAP Score IgE **Allergen, Food, Pepper C. annuum IgE**	7/2/24
Allergic Bronchopulmonary Aspergillosis Panel	ABPA	**For interface clients only–Test build may need to be modified** **Name:** Prevously Bronchopulmonary Aspergillosis **Special Information: Hemolyzed, icteric or** lipemic specimens **will be** rejected. **This test is New York state approved.** **Specimen Requirement: 2.3** mL serum from serum separator (Gold) tube; Refrigerated; **Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.** *OR* **2.3 mL serum from no additive (Red) tube; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.** *(continued on page 4)*	7/2/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Allergic Bronchopulmonary Aspergillosis Panel *(continued from page 3)*		**Stability:** Ambient: **48 hours** Refrigerated: **2** weeks Frozen: **1 year** **Methodology:** **Immunodiffusion (ID)** **Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay** **Reference Range:** **ABPA Immunoglobulin E: </= 214 kU/L** **ABPA Allergen, Fungi/Mold, A. fumigatus IgE: </= 0.34 kU/L** **ABPA A. fumigatus #1 Ab, Precipitin: None detected** **ABPA A. fumigatus #6 Ab, Precipitin: None detected** **Days Performed: Sun–Sat** **Reported:** 4–**8** days **CPT:** 86003x1; 82785x1; **86606x2**	
Aminolevulinic Acid (ALA) Urine	UAMINO	**Special Information:** Patient Prep: Refrain from alcohol consumption 24 hours prior to collection. Specimen preservation with acid or base is discouraged and may cause assay interference. Record total volume and collection time interval on transport tube **for 24-hour urine specimens**. Unacceptable conditions: Body fluids other than urine. This test is New York DOH approved. **Specimen Requirement:** 4 mL random urine in clean container (No preservatives); Refrigerated; Patient should refrain from alcohol consumption 24 hours prior to collection. Transfer 4mL aliquot to a standard transport tube. *OR* ***alternate specimen*** 4 mL 24-hour (well-mixed) urine; Refrigerate during collection. Transport Refrigerated; Patient should refrain from alcohol consumption 24 hours prior to collection. Transfer 4mL aliquot to a standard transport tube. Record total volume and collection time interval on specimen.	6/20/24
B Cell CD20 Expression	CD20	**Includes:** **CD19+ Percent of Lymphocytes** **CD19+ Count of Lymphocytes** **CD20+ Percent of CD19+ Cells** **CD20+ Count of CD19+ Cells** **Cell Viability** **Special Information:** Provide clinical history, differential diagnosis, and any relevant pathology reports. Clotted, hemolyzed, or frozen specimens will be rejected. This test is New York State approved. **Clinical Information:** Monoclonal antibody-based therapies, such as rituximab that target the CD20 antigen, are being used to treat patients with a variety of **autoimmune disorders.** The effectiveness of **this therapy is dependent on the degree of B-cell suppression and varies by disease state. This assay is designed to detect low levels of B cells and provide quantitative cell numbers in the setting of rituximab-treated patients using both CD20 and CD19.** **Specimen Requirement:** 5 mL whole blood in sodium heparin (Green) tube; **Minimum 1 mL;** Ambient *OR* 5 mL whole blood in EDTA (Lavender) tube; **Minimum 1 mL**; Ambient **Stability:** Ambient: **72** hours Refrigerated: **72** hours Frozen: Unacceptable **Methodology: Flow Cytometry (FC)**	5/20/24
Bartonella Species by PCR	BARPCR	**Name:** Previously Bartonella PCR	6/25/24
Cell Count/Diff, Body Fluid	CCBF	**Specimen Requirement:** 2 mL body fluid in EDTA (Lavender) tube; Refrigerated *OR* **2 mL body fluid in sterile container; Refrigerated**	6/18/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cryoglobulin, Qual w Reflex to IgG, IgA, IgM	CRYQL	**Special Information:** The sample is examined daily for the presence of cryoglobulin. If after 3 days cryoprecipitate is observed, then quantitative immunoglobulins (IgG, IgA, IgM) will be added at an additional cost. **Fasting for a minimum of 8 hours is required. Do not use serum separator tubes. Collect in a pre-warmed (37C), no additive (Red) tube. Immediately after collection, place tube in heel warmer or 37°C (warm, not hot) water. Keep sample warm at 37C until clotting is complete (up to 1 hour). Grossly hemolyzed or lipemic specimens will be rejected. This test is New York state approved.** **Clinical Information: This test is useful in evaluation of patients with vasculitis, macroglobulinemia, or multiple myeloma in whom symptoms occur with exposure to cold.** **Specimen Requirement:** 3 mL serum from no additive (Red) tube; Ambient; Fasting **for a minimum of 8 hours is required. Do not use serum separator tubes.** Collect in a pre-warmed **(37C), no additive (**Red**) tube. Immediately after collection, place tube in heel warmer or 37°C (warm, not hot) water. Keep sample warm** at 37C until clotting is complete (up to 1 hour). Separate serum from cells **and transfer to standard aliquot tube.** **Stability:** Ambient: After separation from cells: 1 week Refrigerated: After separation from cells: **1 week** Frozen: After separation from cells: Uncacceptable	6/20/24
FLT3 ITD and TKD Mutation Detection by PCR	FLT3IT	**Special Information:** Plasma, serum, FFPE tissue blocks/slides, or frozen tissue will be rejected. Clotted or grossly hemolyzed specimens will be rejected. This test is New York DOH approved. **Specimen Requirement:** 5 mL whole blood in EDTA (Lavender) tube; Refrigerated *OR* 3 mL bone marrow in EDTA (Lavender) tube; Refrigerated *OR* **5 mL whole blood in sodium heparin (Green) tube; Refrigerated** **Stability:** Ambient: **Unacceptable** Refrigerated: **7** days Frozen: Unacceptable **Methodology: Capillary Electrophoresis (CE)**	5/20/24
Glutathione Total	GLUTAT	**For interface clients only–Test build may need to be modified** **Special Information:** Hemolyzed specimens **will be rejected. This test is New York state approved.** **Specimen Requirement: 10 mL whole** blood in acid citrate dextrose B (Yellow) tube; **Minimum: 8.5 mL; Place specimen on ice after draw. Transport Refrigerated; Critical Refrigerated. Transport whole blood in original collection container.** *OR* **8.5 mL whole** blood in acid citrate dextrose A (Yellow) tube; **Minimum: 6.5 mL; Place specimen on ice after draw. Transport Refrigerated; Critical Refrigerated. Transport whole blood in original collection container.** **Stability:** Ambient: **Unacceptable** Refrigerated: **3** weeks Frozen: **Unacceptable** **Methodology: Quantitative, Kinetic** **Reference Range: Refer to report** **Days Performed: Varies** **Reported: 4–7** days	7/9/24
Hypersensitivity Pneumonitis Evaluation	HYPNE2	**For interface clients only–Test build may need to be modified** **Special Information: Contaminated, hemolyzed, or severely lipemic specimens will be rejected. This test is New York state approved.** **Clinical Information: This test is used to evaluate patients suspected of having** hypersensitivity pneumonitis **induced by exposure. 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.** *(continued on page 6)*	7/2/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hypersensitivity Pneumonitis Evaluation *(continued from page 5)*		**Specimen Requirement: 5** mL serum from serum separator (Gold) tube; **Minimum: 3 mL (1.5 mL per aliquot tube);** Refrigerated; **Draw 2 tubes to ensure adequate volume.** Separate serum from cells ASAP or within 2 hours of collection. Transfer **2.5 mL** serum **in two aliquot tubes.** **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:** **Immunodiffusion (ID)** **Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay** **Reference Range:** **A. fumigatus #1 Ab, Precipitin: None detected** **A. fumigatus #6 Ab, Precipitin: None detected** **A. pullulans Ab, Precipitin: None detected** **Pigeon Serum Ab, Precipitin: None detected** **M. faeni Ab, Precipitin: None detected** **A. flavus Ab, Precipitin: None detected** **A. fumigatus #2 Ab, Precipitin: None detected** **A. fumigatus #3 Ab, Precipitin: None detected** **S. viridis Ab, Precipitin: None detected** **T. candidus Ab, Precipitin: None detected** **Allergen, Fungi/Mold, Phoma betae IgE: </= 0.34 kU/L** **Allergen, Food, Beef IgE: </= 0.34 kU/L** **Allergen, Food, Pork IgE: </= 0.34 kU/L** **Allergen, Animal, Feather Mix IgE: Negative** **Allergen, Interp, Immunocap Score IgE: Refer to report** **Days Performed: Sun–Sat** **Reported: 4**–8 days **CPT: 86003x3; 86005x1; 86606x5; 86331x5**	
Lead, Blood	LEAD2	**Specimen Requirement:** 1 mL whole blood in EDTA (Royal blue) tube; Refrigerated *OR* **1 mL whole blood in EDTA (Tan) tube; Refrigerated**	effective immediately
Lipoprotein Fractionation by NMR, Particle Count only	NMRPRT	**For interface clients only–Test build may need to be modified** **Name:** Previously Lipoprotein Fractionation NMR without Lipids **Special Information:** Patient **must** be fasting 12 hours. **Do not use gel separator tubes. Non-fasting or** lipemic specimens will be rejected. **This test is New York state approved.** **Clinical Information:** This test is used **in appropriate high-risk patients (eg, type 2 diabetes mellitus) in whom LDL particle number is being used to guide therapy. Not recommended for cardiovascular disease risk assessment in most individuals.** **Specimen Requirement:** 2 mL serum from no additive (Red) tube; Minimum: **1** mL**;** Refrigerated; Patient must be fasting 12 hours. Do not use gel separator tubes. Gently invert **tube to mix. Allow specimen to clot completely at room temperature. Separate serum from cells within 8 hours of collection.** Transfer serum to standard aliquot tube. **Stability:** Ambient: **2 days** Refrigerated: **1 month** Frozen: **Unacceptable** **Reference Range:** LDL-P: Refer to report Small LDL-P: Refer to report LDL Size: Refer to report HDL-P: Refer to report Large HDL-P: Refer to report HDL Size: Refer to report Large VLDL-P: Refer to report VLDL Size: Refer to report **EER LipoFit by NMR, Particle Count Only: Refer to report** **Days Performed: Sun–Sat** **Reported: 4–7** days	7/2/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Lipoprotein Fractionation by NMR with Lipids	NMRLPD	**For interface clients only–Test build may need to be modified** **Special Information:** Patient must be fasting 12 hours prior to collection. **Non-fasting or** lipemic specimens will be rejected. **This test is New York state approved.** **Clinical Information:** This test is used **in appropriate high-risk patients (eg, type 2 diabetes mellitus) in whom LDL particle number is being used to guide therapy. Not recommended for cardiovascular disease risk assessment in most individuals.** **Specimen** Requirement: 4 mL serum from no additive (Red) tube; Refrigerated; Patient must be fasting 12 hours. Do not use gel separator tubes. Gently invert **tube to mix. Allow specimen to clot completely at room temperature. Separate serum from cells within 8 hours of collection.** Transfer serum to standard aliquot tube. **Stability:** Ambient: **24 hours** Refrigerated: **2 weeks** Frozen: **Unacceptable** **Methodology:** **Detergent Solubilization** **Enzymatic** Nuclear Magnetic Resonance Spectroscopy **Reference Range:** LDL-P: Refer to report Small LDL-P: Refer to report LDL Size: Refer to report HDL-P: Refer to report Large HDL-P: Refer to report HDL Size: Refer to report Large VLDL-P: Refer to report VLDL Size: Refer to report LDL Chol Calculated:Refer to report HDL Cholesterol: Refer to report Triglycerides: Refer to report Cholesterol, Total: Refer to report **EER LipoFit by NMR: Refer to report** **Days Performed: Sun–Sat** **Reported: 4–7** days	7/2/24
Malignancy Risk Assessment, Pelvic Mass, OVA1 Plus	OVA1	**For interface clients only–Test build may need to be modified** **Name:** Previously OVA1® Test **Special Information: Menopausal Status required at time of ordering. This test is New York state approved.** **Clinical Information: This test is useful to assess risk of ovarian cancer in women who present with an adnexal mass. OVA1 Biomarkers: CA-125 II, Apoliproprotein A1 (Apo A-1), Beta-2 Microglobulin (B2M), Transferrin, and Prealbumin. OVERA Biomarkers: Apolipoprotein A1 (Apo A-1), HE4 (Human Epididymis protein 4), CA-125 II, FSH (Follicle Stimulating Hormone), and Transferrin.** **Specimen Requirement:** 2.2 mL serum from serum separator (Gold) tube; **Frozen; Menopausal Status required at time of ordering. Separate serum from cells and transfer to standard aliquot tube.** **Stability:** Ambient: Unacceptable Refrigerated: 8 days Frozen: **9 weeks** **Reference Range:** **EER Malignancy Assessment, OVA1 Plus: Refer to report** **Malignancy Assessment, CA 125 II: Refer to report** **Malignancy Assessment, OVA1 Score: Refer to report** **Malignancy Assessment, OVERA Score: Refer to report** **Days Performed: Varies** **Reported:** 5–**9** days	6/25/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Mucopolysaccharides, Urine	UMUCPO	**For interface clients only–Test build may need to be modified** **Special Information: Morning void preferred. This test is New York state approved.** **Clinical Information: This test is used to evaluate symptomatic patients for mucopolysaccharidoses (MPS). Mucopolysaccharides (Glycosaminoglycans) include: Keratan Sulfate, Heparan Sulfate, Dermatan Sulfate, and Chondroitin Sulfates 4 and 6. The excretion of Heparan Sulfate is variable. A normal mucopolysaccharides screen does not exclude Sanfilippo Syndrome (Mucopolysaccharidosis Type III).** **Specimen Requirement: 20** mL random urine in clean container; Minimum: **10** mL; **Critical** Frozen; **Morning void preferred. Freeze specimen immediately.** **Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: **1 month (avoid repeated freeze/thaw cycles)** **Methodology:** Electrophoresis **Spectrophotometry (S)** **Reference Range:** Mucopolysaccharides, Urine: **0 Months to 5 Months: 14.6–47.8 mg/mmol CRT** **6 Months to 11 Months: 3.7–35.5 mg/mmol CRT** **1 Year to 2 Years: 5.4–30.8 mg/mmol CRT** **3 Years to 6 Years: 5.2–16.7 mg/mmol CRT** **7 Years to 13 Years: 2.4–10.2 mg/mmol CRT** **14 Years to 99 Years: 0.0–7.1 mg/mmol CRT** **MPS Electrophoresis: Refer to report** **Days Performed: Tue** **Reported: 5–15 days** **CPT:** 82664x1; 83864x**1**	6/25/24
Mumps Virus by PCR, Qualitative	MUMPCR	**For interface clients only–Test build may need to be modified** **Name:** Previously Mumps Virus RNA, Qualitative Real-Time PCR **Special Information: Urine and Nasopharyngeal swab specimens will be rejected. This test is New York state approved.** **Clinical Information: Detect mumps virus in buccal swab specimens.** **Specimen Requirement:** Buccal **swab in Viral Transport Media; Minimum: 0.5** mL; **Frozen; Patient should not eat, drink, smoke or chew gum for 30 minutes before collecting oral sample.** Place oral/buccal swab in sterile, leak-proof container in 3 mL **Viral Transport Media.** **Stability:** Ambient: 48 hours Refrigerated: **1 week** Frozen: **1 week** **Methodology: Qualitative Polymerase Chain Reaction** **Reference Range: Not detected** **Days Performed: Mon, Wed, Fri, Sat** **Reported:** 2–**5** days	6/18/24
Myotonic Dystrophy Type 1 (DMPK) CTG Expansion	DM1DNA	**For interface clients only–Test build may need to be modified** **Name:** Previously DMPK Repeat Analysis **Includes:** **Myotonic Dystrophy (DM1)–Specimen** **Myotonic Dystrophy (DM1)–Allele 1** **Myotonic Dystrophy (DM1)–Allele 2** **Myotonic Dystrophy (DM1) Interpretation** **Clinical Information: This test is used to diagnose myotonic dystrophy type 1 (DM1) in symptomatic individuals. May be used to screen for DM1 for adults with a family history. Specific allele sizing estimates cannot be determined for expanded alleles with greater than 150 CTG repeats.** *(continued on page 9)*	6/25/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Myotonic Dystrophy Type 1 (DMPK) CTG Expansion *(continued from page 8)*		**Specimen Requirement: 3** mL whole blood in EDTA (Lavender) tube; **Minimum 1 mL; Refrigerated** **Stability:** Ambient: **1 week** Refrigerated: **1 month** Frozen: Unacceptable **Methodology:** **Capillary Electrophoresis (CE)** **Polymerase Chain Reaction (PCR)** **Reference Range:** **Myotonic Dystrophy (DM1) Interpretation: Refer to report** **Days Performed: Varies** **Reported: 8–11** days	
Neisseria meningitidis Tetravalent Antibodies, IgG (Vaccine Response)	NMEN	**For interface clients only–Test build may need to be modified** **Name:** Previously Neisseria meningitidis IgG Vaccine Response **Special Information: Postimmunization specimen must be collected 30 days after preimmunization specimen. Label specimens plainly as 'postimmunization' or 'preimmunization' so that specimens will be saved and tested simultaneously. Postimmunization specimen must be received within 60 days of preimmunization specimen. Contaminated, hemolyzed or severely lipemic specimens will be rejected. This test is New York state approved.** **Clinical Information: This test is useful to assess immunocompetence following Neisseria meningitidis vaccination. To assess suspected immunodeficiency, use pre- and postvaccination serology. Do not use for diagnosis of infection or serotyping.** **Responder status is determined according to the ratio of the one month post-vaccination concentration to pre-vaccination concentration of IgG antibodies to N. meningitidis (Types A, C, Y, and W-135) as follows:** **1. If the one month post-vaccination concentration is less than 3.0 μg/mL, the patient is considered to be a non-responder.** **2. If the one-month post-vaccination concentration is greater than or equal to 3.0 μg/mL, a patient with a ratio of greater than or equal to 4 is a good responder, a ratio of 2-4 is a weak responder, and a ratio of less than 2 is considered a non-responder.** **Specimen Requirement: 1.5** mL serum from serum separator (Gold) tube; **Minimum: 0.25** mL; Refrigerated; **Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube. Postimmunization specimen must be collected 30 days after preimmunization specimen. Label specimens plainly as 'postimmunization' or 'preimmunization' so that specimens will be saved and tested simultaneously. Postimmunization specimen must be received within 60 days of preimmunization specimen.** **Stability:** Ambient: **48 hours** Refrigerated: 2 weeks Frozen: **1 year (avoid repeated freeze/thaw cycles)** **Methodology: Quantitative Multiplex Bead Assay** **Reference Range:** **N.meningitidis Type A IgG: Refer to report** **N.meningitidis Type C IgG: Refer to report** **N.meningitidis Type Y IgG: Refer to report** **N.meningitidis Type W-135 IgG: Refer to report** **Days Performed: Mon** **Reported:** 2–**9** days **CPT: 86741x4**	6/18/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Pemphigoid Antibody Panel	PEMGUS	**For interface clients only–Test build may need to be modified** **Name:** Previously Pemphigus Basic Screen **Includes:** **Pemphigoid Antibody Panel** **Basement Membrane Zone (BMZ) IgG, IgG4, IgA** **Bullous Pemphigoid (BP) 180 and BP230 IgG** **IgG Type VII Collagen Antibody Level** **Comments** **Special Information: Hemolyzed or lipemic specimens will be rejected. This test is New York state approved.** **Clinical Information: This test is used to assess and monitor pemphigoid, pemphigoid variants, and linear IgA disease and to discriminate among the immunobullous diseases with epithelial basement membrane zone antibodies.** **Specimen Requirement: 2** mL serum from serum separator (Gold) tube; Minimum **0.5** mL; Refrigerated *OR* **2** mL serum from no additive (Red) tube; Minimum **0.5** mL; Refrigerated **Stability:** Ambient: **1 week** Refrigerated: **2 weeks** Frozen: **Indefinitely** **Methodology:** Indirect Immunofluorescence Assay (IFA) **Semi Quantitative Enzyme Linked Immunosorbent Assay** **Reference Range:** Pemphigoid Antibody Panel: Refer to report **EER Pemphigoid Antibody Panel: Refer to report** **Days Performed: Varies** **Reported: 5–10** days	7/2/24
PM-Scl-100 Antibody, IgG by Immunoblot	PM1AB	**Special Information: Contaminated, hemolyzed, or severely lipemic specimens will be rejected.** This test is New York DOH approved. **Stability:** Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 14 days Frozen: After separation from cells: **1 month (avoid repeated freeze/thaw cycles)** **Methodology:** Immunoblot (IB), **Qualitative**	5/20/24
Porphobilinogen, Urine Quant	UPBGQT	**For interface clients only–Test build may need to be modified** **Includes:** Porphobilinogen**, Qn, Random Ur** Creatinine**, U** **PBG/Creatinine Ratio** **Special Information: Patient should avoid excessive fluid intake. Do not collect first morning void or after 8pm.** Protect from light. **Clinical Information:** This test is useful to rule out acute intermittent porphyria (AIP) and other acute attack types of porphyrias associated with neurologic and/or psychiatric symptoms. If testing for an acute porphyria, please consider ordering PBG, Screen (SQUPBG). If testing for a cutaneous porphyria, please consider ordering Porphyrins, Urine (SQUPORFR). If testing for erythropoietic porphyria, please consider ordering Total Erythrocyte Porphyrins (SQPROPOR). **Specimen Requirement: 3** mL random urine in clean container; **Minimum: 1** mL **(Does not allow for repeat testing);** Frozen; **Patient should avoid excessive fluid intake. Do not collect first morning void or after 8pm.** Protect from light. Transfer aliquot to amber transport tube and freeze. **Stability:** Ambient: Unacceptable Refrigerated: **24 hours (protected from light)** Frozen: 1 month **(protected from light)** *(continued on page 11)*	6/20/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Porphobilinogen, Urine Quant *(continued from page 10)*		**Methodology:** **Chromatography** **Spectrophotometry (S)** **Reference Range:** **PBG/Creatinine Ratio: 0.2–2.2 mg/g Creat** **Days Performed: Varies** **Reported: 4–7** days **CPT: 82570,** 84110	
Protoporphyrins, Total, RBC	PROPOR	**Name:** Previously Total Erythrocyte Porphyrins	6/20/24
Thiocyanate	THIOCY	**Specimen Requirements:** 2 mL serum from no additive (Red) tube; Refrigerated; Collect immediately prior to next dose. Allow sample to clot. Then, centrifuge and immediately separate serum specimens from the cells into transport tube. *OR* ***alternate specimen*** 2 mL plasma from EDTA (Lavender) tube; Refrigerated; Collect immediately prior to next dose. Centrifuge and immediately separate plasma specimens from the cells into transport tube	effective immediately
U3RNP Fibrillarin Ab	U3RNP	**Stability:** Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: **1 month (avoid repeated freeze/thaw cycles)**	5/20/24
Y-Chromosome Microdeletion	YCMICR	**Special Information:** Counseling and informed consent are recommended for genetic testing. Do NOT freeze. Severely hemolyzed specimens **will be rejected.** This test is New York DOH approved. **Clinical Information:** Aids in determining the cause of azoospermia or oligospermia and helps predict effectiveness of assisted reproductive technologies in men with Y chromosome microdeletions. **Specimen Requirement: 2** mL whole blood in EDTA (Lavender) tube; Refrigerated *OR* **2** mL whole blood in Acid Citrate Dextrose (ACD) A or B (Yellow) tube; Refrigerated **Stability:** Ambient: **1 week** Refrigerated: **1 month** Frozen: Unacceptable **Days Performed: Varies**	effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Allergen, Food, Anchovy IgE allergen	ANCHVY	**Includes:** Allergen, Food, Anchovy IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported**: 2–4 days **CPT:** 86003	6/25/24
Allergen, Food, Carob Gum/Locust Bean IgE	CRBGUM	**Includes:** Allergen, Food, Carob Gum IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported**: 2–4 days **CPT:** 86003	6/27/24

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Food, Eggplant IgE	EGPLNT	**Includes:** Allergen, Food, Eggplant IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported**: 2–4 days **CPT:** 86003	6/25/24
Allergen, Food, Ginger IgE	GINGER	**Includes:** Allergen, Food, Ginger IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported**: 2–4 days **CPT:** 86003	6/20/24

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Food, Lamb, IgE	LMBIGE	**Includes:** Allergen, Food, Lamb IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported**: 2–4 days **CPT:** 86003	6/20/24
Allergen, Food, Sardine IgE	SARDIN	**Includes:** Allergen, Food, Sardine IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported**: 2–4 days **CPT:** 86003	6/25/24

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Insect and Venum, Bumble Bee Venom IgE	BMBLBE	**Includes:** Allergen, Insect, Bumble Bee Venom IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported**: 2–4 days **CPT:** 86003	6/27/24
Allergen, Insects and Venom, Fire Ant (Solenopsis invicta), IgE	FIRANT	**Includes:** Allergen, Insect, Fire Ant, Imported IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported**: 2–4 days **CPT:** 86003	6/25/24

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Region 3 Respiratory Panel IgE, South Atlantic	SALNTC	**Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 4 mL serum from serum separator (Gold) tube; Minimum: 1.3 mL; Refrigerated; Draw 2 tubes to ensure adequate serum volume. Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Immunoglobulin E (South Atlantic Panel): 0 Months to 5 Months: 13 or less kU/L 6 Months to 12 Months: 34 or less kU/L 1 Year to 2 Years: 97 or less kU/L 3 Years: 199 or less kU/L 4 Years to 6 Years: 307 or less kU/L 7 Years to 8 Years: 403 or less kU/L 9 Years to 12 Years: 696 or less kU/L 13 Years to 15 Years: 629 or less kU/L 16 Years to 17 Years: 537 or less kU/L 18 Years to 99 Years: 214 or less kU/L Allergen, Fungi/Mold, A. alternata IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Tree, Box Elder/Maple Tree IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Animal, Cat Dander IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Tree, Mountain Cedar Tree IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Weed, Pigweed IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High *(continued on page 17)*	7/2/24

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Region 3 Respiratory Panel IgE, South Atlantic *(continued from page 16)*		**Reference Range (continued):** Allergen, Grass, Timothy Grass IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Fungi/Mold, Hormodendrum IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Tree, Elm Tree IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Tree, Oak Tree IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Tree, Birch Tree IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Fungi/Mold, A. fumigatus IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Mites, D. pteronyssinus IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Mites, D. farinae IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Grass, Bermuda Grass IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High *(continued on page 18)*	

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Region 3 Respiratory Panel IgE, South Atlantic *(continued from page 17)*		**Reference Range (continued):** Allergen, Fungi/Mold, P. notatum IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Weed, Common/Short Ragweed IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Insect, Cockroach, German IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Tree, Pecan Tree IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Grass, Bahia IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Animal, Mouse Epithelium IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Fungi/Mold, M. racemosus IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Animal, Dog Dander IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High Allergen, Weed, Nettle IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High *(continued on page 19)*	

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Region 3 Respiratory Panel IgE, South Atlantic *(continued from page 18)*	SALNTC	**Reference Range (continued):** Allergen, Weed, Sheep Sorrel IgE: Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported:** 2–4 days **CPT:** 86003x24; 82785x1	7/2/24
Allergen, Tree, Palm/ Queen Tree IgE	PALMQN	**Includes:** Allergen, Tree, Palm/Queen Tree IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported**: 2–4 days **CPT:** 86003	6/27/24
Annatto Seed, IgE allergen	ANNATO	**Includes:** Allergen, Food, Annatto Seed IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state approved. **Specimen Requirement:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.34 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered. **Stability:** Ambient: 1 month Refrigerated: 1 month Frozen: 1 year **Methodology:** Enzyme Immunoassay (EIA) **Reference Range:** Refer to report **Days Performed:** Varies **Reported**: 4–7 days **CPT:** 86003	6/25/24

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Cauliflower IgE allergen	CLFLWR	**Includes:** Allergen, Food, Cauliflower IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported**: 2–4 days **CPT:** 86003	6/18/24
Cocaine Metabolite, Serum or Plasma, Quantitative	COCRFX	**Special Information:** This test may be ordered, or may be a reflex from Drug Screen 9 Panel, Serum or Plasma (DRGSC9). Specimens that are hemolyzed or collected in gel separator tubes will be rejected. This test is New York DOH approved. **Clinical Information:** This test is useful to detect exposure to cocaine. **Specimen Requirement:** 1 mL plasma from potassium oxalate/sodium fluoride (Gray) tube; Minimum 0.5 mL; Refrigerated; Do not use gel separator tubes. Separate plasma from cells ASAP or within 2 hours of collection. Transfer plasma to standard aliquot tube. *OR* 1 mL serum from no additive (Red) tube; Minimum 0.5 mL; Refrigerated; Do not use gel separator tubes. Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. *OR* 1 mL plasma from sodium heparin (Green) tube; Minimum 0.5 mL; Refrigerated; Do not use gel separator tubes. Separate plasma from cells ASAP or within 2 hours of collection. Transfer plasma to standard aliquot tube. *OR* 1 mL plasma from EDTA (Lavender) tube; Minimum 0.5 mL; Refrigerated; Do not use gel separator tubes. Separate plasma from cells ASAP or within 2 hours of collection. Transfer plasma to standard aliquot tube. **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:** Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** Benzoylecgonine S/P, Quant: Refer to report **Days Performed:** Sun–Sat **Reported:** 2–7 days **CPT:** 80353 / G0480	7/9/24

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Goat Milk IgE allergen	GOTMLK	**Includes:** Allergen, Food, Goat Milk IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported**: 2–4 days **CPT:** 86003	6/18/24
Lima Bean/White Bean Allergen, IgE	LIMAWT	**Includes:** Allergen, Food, Lima Bean/White Bean IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported**: 2–4 days **CPT:** 86003	6/20/24

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Navy Bean, IgE allergen	NAVYBN	**Includes:** Allergen, Food, Navy Bean IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported**: 2–4 days **CPT:** 86003	6/20/24
Olives, IgE, allergen	BLOLIV	**Includes:** Allergen, Food, Black Olive IgE **Special Information:** Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state 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:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High **Days Performed:** Sun–Sat **Reported**: 2–4 days **CPT:** 86003	6/18/24

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Ustekinumb Quantitation with Antibodies, Serum	USTEKQ	**Special Information:** Collect immediately before the next dose of drug administration (trough level). Heat-inactivated specimens will be rejected. This test is New York State approved. **Clinical Limitation:** This assay does not measure immunocomplexes of UTK bound to antibodies-to-ustekinumab (ATU). Presence of UTK at concentrations greater than 1 mcg/mL may impair detection of ATU, as the ATU assay is not drug tolerant. Elevated rheumatoid factor (RF) may falsely increase results of ATU. During validation studies, negative ATU samples remained negative and positive ATU samples remained positive; however, the quantitative result differed by more than 20% when compared to the non-RF spiked original samples. If patients are positive for RF, clinical correlation is recommended for ATU test interpretation. **Clinical Information:** This assay measures free ustekinumab (UTK) and free antibodies to ustekinumab (ATU). This test is most useful in the evaluation of loss of response to therapy. A gradual decrease in efficacy over time following an initial response to biologics is common. In many cases, antibodies generated to the biologic are responsible for treatment failure, as they bind to the drug creating an immunocomplex and clear the drug faster from circulation. USTEKINUMAB QN, S: Limit of quantitation is 0.3 mcg/mL. In inflammatory bowel disease, at post-induction measurement (week 8), concentrations above 3.5 mcg/mL are associated with good outcomes. For maintenance stages: Concentrations > or =1.0 mcg/mL are associated with clinical response and clinical remission; Concentrations > or =4.5 mcg/mL are associated with mucosal healing. USTEKINUMAB AB, S: Limit of quantitation is 10 AU/mL. Absent: <10 AU/mL; Present: > or =10 AU/mL **Specimen Requirement:** 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.35 mL; Refrigerated; Collect immediately before the next dose of drug administration (trough level). Separate serum from cells and transfer to standard aliquot tube. *OR* 0.5 mL serum from no additive (Red) tube; Minimum 0.35 mL; Refrigerated; Collect immediately before the next dose of drug administration (trough level). Separate serum from cells and transfer to standard aliquot tube. **Stability:** Ambient: Unacceptable Refrigerated: 3 weeks Frozen: 3 weeks **Methodology:** Enzyme-Linked Immunosorbent Assay (ELISA) **Reference Range:** Ustekinumab QN, S: Refer to report Ustekinumab Ab, S: Refer to report **Days Performed:** Mon, Wed, Fri **Reported:** 3–6 days **CPT:** 80299; 83520	5/28/24
Vedolizumab Quantitation with Antibodies, Serum	VEDOLZ	**Special Information:** Avoid multivitamins and dietary supplements containing biotin for 12 hours before collection. Nivolumab (Opdivo) must be discontinued at least 4 weeks prior to collection. Collect immediately before next scheduled dose (trough specimen). This test is New York State approved. **Clinical Limitation:** The presence of high concentrations of vedolizumab might inhibit the antibodies to vedolizumab (ATV) assay yielding false-negative results. Samples containing more than 100 ng/mL biotin (vitamin B7) may interfere with ATV (in the form of depressed signal) for VEMAB / Vedolizumab Antibodies, Serum. **Clinical Information:** This test includes both quantitation and antibody testing. This test is useful in assessing for primary or secondary loss of response to therapy with vedolizumab, or as an aid to achieving desired serum concentrations of vedolizumab. The therapeutic thresholds for vedolizumab and optimal concentrations associated with good outcomes are not well established. Currently the American Gastroenterology Association does not have a formal guideline on optimal thresholds for vedolizumab. *(continued on page 24)*	5/28/24

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Vedolizumab Quantitation with Antibodies, Serum *(continued from page 23)*		**Specimen Requirement:** 1.5 mL serum from no additive (Red) tube; Minimum: 0.75 mL; Refrigerated; Avoid multivitamins and dietary supplements containing biotin for 12 hours before collection. Nivolumab (Opdivo) must be discontinued at least 4 weeks prior to collection. Collect immediately before next scheduled dose (trough specimen). Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. *OR* 1.5 mL serum from serum separator (Gold); Minimum: 0.75 mL; Refrigerated; Avoid multivitamins and dietary supplements containing biotin for 12 hours before collection. Nivolumab (Opdivo) must be discontinued at least 4 weeks prior to collection. Collect immediately before next scheduled dose (trough specimen). Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. **Stability:** Ambient: Unacceptable Refrigerated: 28 days Frozen: 28 days **Methodology:** Electrochemiluminescent Bridging Immunoassay Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** Vedolizumab QN, S: Refer to report Vedolizumab Ab, S: Refer to report VEMAB Interpretation: Refer to report **Days Performed:** Mon–Fri **Reported:** 6–9 days **CPT:** 80280; 82397	

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Adenovirus DFA	DADNO	Test will no longer be orderable. Recommended replacement test is Adenovirus PCR (ADEPCR).	6/18/24
Allergen, Jalapeno Pepper	JLPENO	Test will no longer be orderable. Recommended replacement test is Allergen, Cayenne Pepper (CAYENN).	7/11/24
Bartonella PCR, tissue	TBART	Test will no longer be orderable. Recommended replacement test is Bartonella Species by PCR (BARPCR).	7/11/24
Cocaine & Benzoylecgonine, Quant	COCAIN	Test will no longer be orderable. Recommended replacement test is Cocaine Metabolite, Serum or Plasma, Quantitative (COCRFX).	7/11/24
IDH1/IDH2 Mutation, Blood/Bone marrow	IDH12	Test will no longer be orderable. There is no recommended replacement.	5/20/24
PAI-1 Genotype 5G/4G	PAIGEN	Test will no longer be orderable. There is no recommended replacement.	7/16/24
PD-L1 22C3 IHC with Tumor Proportion Score (TPS) Interpretation, pembrolizumab (KEYTRUDA)	PDL1KE	Test will no longer be orderable. Recommended replacement test is Immunohistochemistry, Quantitative.	5/20/24
Sezary Cell Staging	SEZSTG	Test will no longer be orderable. Recommended replacement test is Flow Cytometry for Leukemia/Lymphoma (FCLL).	6/18/24
Sezary Cells	BUFSEZ	Test will no longer be orderable. Recommended replacement test is Flow Cytometry for Leukemia/Lymphoma (FCLL).	6/18/24