Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • August 2020

Cleveland Clinic Laboratories is dedicated to keeping you updated and informed about recent testing changes. This Technical Update is provided on a monthly basis to notify you of any changes to the tests in our catalog.

Recently changed tests are bolded, and they could include revisions to methodology, reference range, days performed, or CPT code. Deleted tests and new tests are listed separately. For your convenience, tests are listed alphabetically and order codes are provided.

To compare the new information with previous test information, refer to the online Test Directory at clevelandcliniclabs.com. Test information is updated in the online Test Directory on the Effective Date stated in the Technical Update. Please update your database as necessary.

For additional detail, contact Client Services at 216.444.5755 or 800.628.6816, or via email at clientservices@ccf.org.

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
3	Acetylcholine Receptor Antibodies with reflex											■		
3	Acetylcholine Receptor Binding Aby											■		
3	ACTH					■			■	■	■	■		
3	ACTH Stimulation, 2 Time Points					■	■		■	■		■		
4	ACTH Stimulation, 3 Time Points					■	■		■	■		■		
4	Albumin, CSF								■	■	■			
4	Antibiotic Assay Flucytosine										■			
21	Antimony, Blood				■									
4	APC Resistance									■				
4–5	Apolipoprotein, A-1						■		■	■	■	■		
5	Apolipoprotein A-1 & B						■	■	■	■	■	■		
6	Apolipoprotein, B						■		■	■	■	■		
6	Aspergillus Antibodies, Immunodiffusion										■			
6	Autoimmune Dysautonomia Evaluation, Serum						■							
6	B Cell CD20 Expression					■		■						
7	Beta Globin (HBB) Gene Sequencing					■						■		
7	Blastomyces Antigen							■						
7	B Type Natriuretic Peptide						■					■		
21	Calpain 3 DNA Sequencing Test				■									
21	Candida albicans Eval				■									
7	C. difficile Culture w/ reflex Cytotoxin Cell Assay					■					■			
7	Celiac Comprehensive Panel								■	■				
8	Celiac Screen with Reflex								■	■				

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
8	Chromogranin A						■							
8	Cortisol					■	■		■	■		■		
8	Coxsackie A Abs					■				■		■		
21	DNA Content/Cell Cycle Analysis, Hydatidiform Mole				■									
9	Factor XII Assay									■				
9	Fungal Antibodies with Reflex to Blastomyces dermatitidis Antibodies by Immunodiffusion, CSF						■							
9	Hexagonal Phase Phospholipid Neutralization									■				
21	Histoplasma Abs, CF+ID, CSF				■									
9	IgA						■		■	■	■	■		
9	IgG						■		■	■	■	■		
10	IgM						■		■	■	■	■		
10	IgG, CSF								■	■	■	■		
10	IgG,CSF / Albumin, CSF Ratio		■						■	■	■	■		
11	IgG Subclasses							■	■	■				
12	IgG Synthesis, CSF (Tourtellotte and Index)		■				■		■	■	■			
12–13	Immunoglobulins						■		■	■	■	■		
13	Insulin Autoantibody											■		
13	Insulin, Free, Serum									■				
13	Lipoprotein (a)						■		■	■	■	■		
14	Monoclonal Protein with Immunoglobulins and Free Light Chains, serum								■	■				
14	Mycophenolic Acid					■								
14–15	Neuronal Nuclear Abs IgG by Immunoblot					■	■	■	■	■	■	■	■	
15	N-Methylhistamine, Random, Urine											■		
15	N-Methylhistamine, Urine											■		
15	Pancreatic Elastase, Fecal					■	■		■	■	■	■		
16	Paraneoplastic Syndrome Ab Panel with Reflex					■	■	■		■	■			
16	P/Q-Type Voltage-Gated Calcium Channel (VGCC) Antibody					■								
18	Prometheus Anser ADA			■										
18	Prometheus Anser IFX			■										
19	Prometheus Anser UST			■										
19	Prometheus Anser VDZ			■										
20	Prometheus Monitr Crohn's Disease			■										
16	Protein S Clottable									■				
16	Prothrombin Time Mixing Study							■						
16	Strongyloides IgG Abs, Serum						■							
17, 21	Tularemia Antibodies, IgG and IgM					■	■	■	■	■		■		■

Test Changes

Test Name	Order Code	Change	Effective Date
Acetylcholine Receptor Antibodies with reflex	ACHABS	**Stability:** Ambient: 1 day Refrigerated: 7 days Frozen: **1 year (2 freeze/thaw cycles are acceptable)**	8/4/20
Acetylcholine Receptor Binding Aby	ACHRAB	**Stability:** Ambient: 1 day Refrigerated: 7 days Frozen: **1 year (2 freeze/thaw cycles are acceptable)**	8/4/20
ACTH	ACTH	**Special Information: 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.** **Clinical Limitation: Under ACTH 1-24 medication, ACTH measurement is not recommended due to negative interference with the sandwich assay.** **Note:** *Adrenocorticotropic Hormone Plasma will be added as an alias name.* **Stability:** Ambient: **4** hours Frozen: **4 weeks** **Methodology: Electro** Chemiluminescence Immunoassay **(ECLIA)** **Reference Range: Morning hours 7:00 to 10:00 am: 7.2–63.3 pg/mL** **Days Performed: Sunday–Saturday** **Reported: 8 hours**	9/8/20
ACTH Stimulation, 2 Time Points	ACTHS2	**Special Information: 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.** **Clinical Limitation: During metyrapon tests, 11 deoxycortisol levels are elevated. Falsely elevated cortisol values may be determined due to cross reactions. In samples from patients who have been treated with prednisolone, 6-alpha-Methylprednisolone or prednisone, falsely elevated concentrations of cortisol may be determined.** **Clinical Information: Diagnosis of adrenal insufficiency** **Note:** *Cortisol Stimulation 2 Time Points and Cortrosyn Stimulation will be removed as alias names.* **Specimen Requirement:** 1 mL **plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: 0.3 mL; Collect a baseline specimen, **then collect specimens at 30 minutes and 60 minutes after intravenous/intramuscular administration of cortrosyn (cosyntropin);** Refrigerated *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Collect a baseline specimen, **then collect specimens at 30 minutes and 60 minutes after intravenous/intramuscular administration of cortrosyn (cosyntropin);** Refrigerated *OR* 1 mL **plasma from an EDTA lavender** tube; Minimum: 0.3 mL; Refrigerated **Stability:** Ambient: 24 hours Refrigerated: **4** days Frozen: **12 months** **Methodology: Electro** Chemiluminescence Immunoassay **(ECLIA)** **Reference Range:** Normal response to cortrosyn: A peak value of at least **15 µg/dL**	9/8/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
ACTH Stimulation, 3 Time Points	ACTHST	**Special Information: 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.** **Clinical Limitation: During metyrapon tests, 11 deoxycortisol levels are elevated. Falsely elevated cortisol values may be determined due to cross reactions. In samples from patients who have been treated with prednisolone, 6-alpha-Methylprednisolone or prednisone, falsely elevated concentrations of cortisol may be determined.** **Specimen Requirement:** 1 mL **plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: 0.3 mL; Collect a baseline specimen, then collect specimens at 30 minutes and 60 minutes after **intravenous**/intramuscular **administration** of cortrosyn **(cosyntropin);** Refrigerated *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Collect a baseline specimen, then collect specimens at 30 minutes and 60 minutes after **intravenous**/intramuscular **administration** of cortrosyn **(cosyntropin);** Refrigerated *OR* 1 mL **plasma from an EDTA (lavender)** tube; Minimum: 0.3 mL; Collect a baseline specimen, then collect specimens at 30 minutes and 60 minutes after **intravenous**/intramuscular **administration** of cortrosyn **(cosyntropin); Centrifuge, aliquot and refrigerate** **Stability:** Ambient: 24 hours Refrigerated: **4** days Frozen: **12 months** **Methodology:** Electro **Chemiluminescence Immunoassay** (ECLIA) **Reference Range:** Normal response to cortrosyn: A peak value of at least **15 µg/dL**	9/8/20
Albumin, CSF	CSFALB	**Methodology: Immunoturbidimetric Assay** **Reference Range:** **Albumin, CSF** **3–47 Months: < 45 mg/dL** **4–99 Years: 10–30 mg/dL** **Days Performed:** Monday–**Friday** **Reported:** 1–**4** days	9/8/20
Antibiotic Assay Flucytosine	FLCYT	**Days Performed:** Sunday–Saturday **Reported:** 3–**4** days	8/17/20
APC Resistance	APC	**Note:** *Reference range changes previously announced in the May Technical Update will go live on 8/4/20.*	8/4/20
Apolipoprotein, A-1	APOA	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL serum from a **plain no additive (red)** tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL **plasma from a lithium heparin (green)** tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL **plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: **0.3 mL;** Refrigerated **Stability:** Ambient: 1 day Refrigerated: **8** days Frozen: **2 months** **Methodology: Immunoturbidimetric Assay** **Reference Range:** Female (**19**–99 Years) Low Risk: **> 124 mg/dL** Male (**19**–99 Years) Low Risk: **> 114 mg/dL** *(continued on page 5)*	9/8/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Apolipoprotein, A-1 *(continued from page 4)*		**0–18 Years** **Low Risk: > 120 mg/dL** **Moderate Risk: 115–120 mg/dL** **High Risk: < 115 mg/dL** **Days Performed:** Monday–**Friday** **Reported:** 1–**4** days	
Apolipoprotein A-1 & B	APOAB	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Apolipoprotein A-1 **Apolipoprotein B/A-1 Ratio** Apolipoprotein B **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL serum from a **plain no additive (red)** tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL **plasma from a lithium heparin (green)** tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL **plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: **0.3 mL;** Refrigerated **Stability:** Ambient: 1 day Refrigerated: **8** days Frozen: **2 months** **Methodology: Immunoturbidimetric Assay** **Reference Range:** Apolipoprotein A-1 Female (**19**–99 Years) Low Risk: **> 124 mg/dL** Male (**19**–99 Years) Low Risk: **> 114 mg/dL** **0–18 Years** **Low Risk: > 120 mg/dL** **Moderate Risk: 115–120 mg/dL** **High Risk: < 115 mg/dL** **Apolipoprotein B/A-1 Ratio** **Female (19–99 Years)** **Low Risk: < 0.6** **Moderate Risk: 0.6–0.8** **High Risk: > 0.8** **Male (19–99 Years)** **Low Risk: < 0.7** **Moderate Risk: 0.7–0.9** **High Risk: > 0.9** **0–18 Years** **Low Risk: < 0.8** Apolipoprotein B Female **(19**–99 Years) Low Risk: **< 90 mg/dL** **Moderate Risk: 90–129 mg/dL** High Risk: **> 130 mg/dL** Male **(19**–99 Years) Low Risk: **< 90 mg/dL** **Moderate Risk: 90–119 mg/dL** High Risk: **> 120 mg/dL** **0–18 Years:** **Low Risk: < 90 mg/dL** **Moderate Risk: 90–109 mg/dL** **High Risk: ≥ 110 mg/dL** **Days Performed:** Monday–**Friday** **Reported:** 1–**4** days	9/8/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Apolipoprotein, B	APOB	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL serum from a **plain no additive (red)** tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL **plasma from a lithium heparin (green)** tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL **plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: **0.3 mL;** Refrigerated **Stability:** Ambient: 1 day Refrigerated: **8** days Frozen: **2 months** **Methodology: Immunoturbidimetric Assay** **Reference Range:** Female (**19**–99 Years) Low Risk: **< 90 mg/dL** **Moderate Risk: 90–129 mg/dL** High Risk: **> 130 mg/dL** Male (**19**–99 Years) Low Risk: **< 90 mg/dL** **Moderate Risk: 90–119 mg/dL** High Risk: **> 120 mg/dL** **0–18 Years** **Low Risk: < 90 mg/dL** **Moderate Risk: 90–109 mg/dL** **High Risk: ≥ 110 mg/dL** **Days Performed:** Monday–**Friday** **Reported:** 1–**4** days	9/8/20
Aspergillus Antibodies, Immunodiffusion	ASPER	**Days Performed:** Sunday–Friday **Reported: 4–7** days	8/17/20
Autoimmune Dysautonomia Evaluation, Serum	AIDYSA	**Specimen Requirement:** 4 mL serum from a plain no additive (red) tube; Minimum: 2.5 mL **(serum); Draw 2 tubes to ensure adequate serum volume;** Patient should have no general anesthetic or muscle-relaxant medications in the previous 24 hours; Specimen collection is recommended before initiation of immunosuppressant medication; This test should not be requested in patients who have recently received radioisotopes (refer to Special Information); Refrigerated *OR* 4 mL serum from a serum separator (gold) tube; Minimum: 2.5 mL **(serum); Draw 2 tubes to ensure adequate serum volume;** Patient should have no general anesthetic or muscle-relaxant medications in the previous 24 hours; Specimen collection is recommended before initiation of immunosuppressant medication; This test should not be requested in patients who have recently received radioisotopes (refer to Special Information); Refrigerated	9/10/20
B Cell CD20 Expression	CD20	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Interpretation **Special Information:** Specimen should be received by performing lab within 48 hours of collection for optimal viable testing. Provide CBC, Wright's stained smear, clinical history, differential diagnosis and any relevant pathology reports. **Frozen, clotted, or hemolyzed specimens will be rejected. Specimens greater than 48 hours old are unacceptable. This test is New York DOH approved.**	8/17/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Beta Globin (HBB) Gene Sequencing	BGHBBB	**Clinical Information:** Useful for molecular confirmation of a suspected structural hemoglobinopathy or beta thalassemia. Characteristics: Structural hemoglobinopathies or thalassemias (insufficient or absent beta-chain production). Incidence: Varies with ethnicity. Inheritance: Usually autosomal recessive, infrequently autosomal dominant. Cause: Pathogenic mutations in the HBB gene. Clinical Sensitivity: Up to 97%, depending on ethnicity. Methodology: Bidirectional sequencing of the HBB coding regions, intron-exon boundaries, **5'** proximal promoter and untranslated region, **3' polyadenylation signal,** and intronic variants **c.93-21 (IVS-I-110), c.316-197** (IVS-II-654), **c.316-146** (IVS-II-705), **c.316-106** (IVS-II-745), **and c.316-86_316-85 (IVS-II-765 L1).** Analytical sensitivity: 99% **Stability:** Ambient: **1 week** Refrigerated: **1 month;** Note: Extracted DNA samples must be shipped refrigerated Frozen: **6 months**	8/17/20
Blastomyces Antigen	BLAS	**For Interfaced Clients Only: Test build may need to be modified**	8/4/20
B Type Natriuretic Peptide	BNP	**Specimen Requirement:** 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Separate plasma from cells and freeze within **12** hours; Frozen **Stability:** Ambient: **8** hours Refrigerated: **8** hours Frozen: 9 months	10/6/20
C. difficile Culture w/ reflex Cytotoxin Cell Assay	CDCULT	**Special Information:** If Clostridium difficile culture is positive, then Clostridium difficile–Cytotoxin Cell assay will be added at an additional charge. **Positive results will be reported as soon as they are detected. Multiple specimens (more than one in 24 hours), stool in PVA or formalin, or formed stools will be rejected. This test is New York DOH approved.** **Days Performed:** Sunday–Saturday **Reported:** 5–**6** days	8/17/20
Celiac Comprehensive Panel	CELCMP	**Methodology:** Enzyme-Linked Immunosorbent Assay (ELISA) **Immunoturbidimetric Assay** Indirect Immunofluorescence Assay (IFA) Polymerase Chain Reaction (PCR) Sequence Specific Oligonucleotide Probe (SSOP) **Reference Range:** Celiac Risk Haplotype: Negative HLA-DQ2: Refer to report HLA-DQ8: Refer to report Celiac Category: Refer to report IgA **0–11 Months: < 83 mg/dL** **1–3 Years: 20–100 mg/dL** **4–6 Years: 27–195 mg/dL** **7–9 Years: 34–305 mg/dL** **10–11 Years: 53–204 mg/dL** **12–13 Years: 58–358 mg/dL** **14–15 Years: 47–249 mg/dL** **16–19 Years: 61–348 mg/dL** **20–99 Years: 70–400 mg/dL** Transglutaminase Ab, IgA Moderate Positive to Strong Positive: > 30 U Negative: < 20 U Weak Positive: 20–30 U	9/8/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Celiac Screen with Reflex	CELSCR	**Methodology:** Enzyme Immunoassay (EIA) **Immunoturbidimetric Assay** **Reference Range:** IgA **0–11 Months: < 83 mg/dL** **1–3 Years: 20–100 mg/dL** **4–6 Years: 27–195 mg/dL** **7–9 Years: 34–305 mg/dL** **10–11 Years: 53–204 mg/dL** **12–13 Years: 58–358 mg/dL** **14–15 Years: 47–249 mg/dL** **16–19 Years: 61–348 mg/dL** **20–99 Years: 70–400 mg/dL** Transglutaminase Ab, IgA Moderate Positive to Strong Positive: > 30 U Negative: < 20 U Weak Positive: 20–30 U	9/8/20
Chromogranin A	CHROMA	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Refrigerated	Effective immediately
Cortisol	COR	**Special Information: 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.** **Clinical Limitation: During metyrapon tests, 11 deoxycortisol levels are elevated. Falsely elevated cortisol values may be determined due to cross reactions. In samples from patients who have been treated with prednisolone, 6-alpha-Methylprednisolone or prednisone, falsely elevated concentrations of cortisol may be determined.** **Specimen Requirement:** 1 mL **plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: 0.3 mL; Indicate collection time on specimen; Refrigerated *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Refrigerated *OR* 1 mL **plasma from an EDTA (lavender) tube;** Minimum: 0.3 mL; **Centrifuge, aliquot and refrigerate** **Stability:** Ambient: 24 hours Refrigerated: **4** days Frozen: **12 months** **Methodology: Electro** Chemiluminescence Immunoassay **(ECLIA)** **Reference Range:** **Morning hours 6:00 to 10:00 am: 4.8–19.5 µg/dL** **Afternoon hours 4:00 to 8:00 pm: 2.5–11.9 µg/dL**	9/8/20
Coxsackie A Abs	COXAAB	**Special Information:** Severely lipemic, hemolyzed or contaminated samples are unacceptable. Acute and convalescent specimens should be labeled as such; parallel testing is preferred, and convalescent specimens MUST be received within 30 days from receipt of the acute specimens. **This test is New York DOH approved.** **Clinical Information:** Single positive titers of **> 1:32** may indicate past or current infection. **Seroconversion or an increase in titers between the acute and convalescent sera of at least fourfold is considered strong evidence of a current or recent infection.** **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** **Reference Range: < 1.8**	8/17/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Factor XII Assay	FXIIC	**Note:** *Reference range changes previously announced in the June Technical Update will go live on 8/4/20.*	8/4/20
Fungal Antibodies with Reflex to Blastomyces dermatitidis Antibodies by Immunodiffusion, CSF	FANCSF	**Specimen Requirement:** 1 mL cerebrospinal fluid (CSF) in a clean container; Minimum: **0.6 mL;** Transfer 1 mL CSF into a standard aliquot tube; Refrigerated	8/17/20
Hexagonal Phase Phospholipid Neutralization	STACLT	**Note:** *Reference range changes previously announced in the June Technical Update will go live on 8/4/20.*	8/4/20
IgA	IGA	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL **plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: **0.3 mL;** Refrigerated *OR* 1 mL **plasma from a lithium heparin (green)** tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL serum from a **plain no additive (red)** tube; Minimum: **0.3 mL;** Refrigerated **Stability:** Ambient: **8 months** Refrigerated: **8 months** Frozen: **8 months** **Methodology: Immunoturbidimetric Assay** **Reference Range:** **0–11 Months: < 83 mg/dL** **1–3 Years: 20–100 mg/dL** **4–6 Years: 27–195 mg/dL** **7–9 Years: 34–305 mg/dL** **10–11 Years: 53–204 mg/dL** **12–13 Years: 58–358 mg/dL** **14–15 Years: 47–249 mg/dL** **16–19 Years: 61–348 mg/dL** **20–99 Years: 70–400 mg/dL** **Days Performed:** Monday–**Friday** **Reported:** 1–**4** days	9/8/20
IgG	IGG	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL serum from a **plain no additive (red)** tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL **plasma from a lithium heparin (green)** tube; Minimum: **0.3 mL;** Refrigerated **Stability:** Ambient: **4 months** Refrigerated: **8 months** Frozen: **8 months** **Methodology: Immunoturbidimetric Assay** **Reference Range:** **0–11 Months: 232–1411 mg/dL** **1–3 Years: 453–916 mg/dL** **4–6 Years: 504–1465 mg/dL** **7–9 Years: 572–1474 mg/dL** **10–11 Years: 698–1560 mg/dL** **12–13 Years: 759–1550 mg/dL** **14–15 Years: 716–1711 mg/dL** **16–19 Years: 549–1584 mg/dL** **20–99 Years: 700–1600 mg/dL** **Days Performed:** Monday–**Friday** **Reported:** 1–**4** days	9/8/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
IgM	IGM	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL serum from a **plain no additive (red)** tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL **plasma from a lithium heparin (green)** tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL **plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: **0.3 mL;** Refrigerated **Stability:** Ambient: **2 months** Refrigerated: **4 months** Frozen: **6 months** **Methodology: Immunoturbidimetric Assay** **Reference Range:** **0–11 Months: < 145 mg/dL** **1–3 Years: 19–146 mg/dL** **4–6 Years: 24–210 mg/dL** **7–9 Years: 31–179 mg/dL** **10–11 Years: 31–179 mg/dL** **12–13 Years: 35–239 mg/dL** **14–15 Years: 15–188 mg/dL** **16–19 Years: 23–259 mg/dL** **20–99 Years: 40–230 mg/dL** **Days Performed:** Monday–**Friday** **Reported:** 1–**4** days	9/8/20
IgG, CSF	CSFG	**Stability:** Ambient: **24** hours Refrigerated: **7** days Frozen: **30 days** **Methodology: Immunoturbidimetric Assay** **Reference Range** **IgG, CSF: 1.0–3.0 mg/dL** **Days Performed:** Monday–**Friday** **Reported:** 1–**4** days	9/8/20
IgG,CSF / Albumin, CSF Ratio	CGALB	**Test Name:** Previously IgG/Albumin Ratio, CSF **Stability:** Ambient: 8 hours Refrigerated: **7** days Frozen: **14 days** **Methodology: Immunoturbidimetric Assay** **Reference Range:** **IgG, CSF: 1.0–3.0 mg/dL** **Albumin, CSF** **3–47 Months: < 45 mg/dL** **4–99 Years: 10–30 mg/dL** **IgG, CSF / Albumin, CSF Ratio:** 0.06–0.17 **Days Performed:** Monday–**Friday** **Reported:** 1–**4** days	9/8/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
IgG Subclasses]	IGGSUB	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** IgG Subclass 1 **Total IgG** IgG Subclass 2 IgG Subclass 3 IgG Subclass 4 **Methodology:** **Immunoturbidimetric Assay** Turbidimetry (TURB) **Reference Range:** IgG Subclass 1 0–2 Years: 194.0–842.0 mg/dL 2–4 Years: 315.0–945.0 mg/dL 4–6 Years: 306.0–945.0 mg/dL 6–8 Years: 288.0–918.0 mg/dL 8–10 Years: 432.0–1020.0 mg/dL 10–12 Years: 423.0–1060.0 mg/dL 12–14 Years: 342.0–1150.0 mg/dL 14–18 Years: 315.0–855.0 mg/dL 18–99 Years: 382.4–928.6 mg/dL **Total IgG** **0–11 Months: 232–1411 mg/dL** **1–3 Years: 453–916 mg/dL** **4–6 Years: 504–1465 mg/dL** **7–9 Years: 572–1474 mg/dL** **10–11 Years: 698–1560 mg/dL** **12–13 Years: 759–1550 mg/dL** **14–15 Years: 716–1711 mg/dL** **16–19 Years: 549–1584 mg/dL** **20–99 Years: 700–1600 mg/dL** IgG Subclass 2 0–2 Years: 22.5–300.0 mg/dL 2–4 Years: 36.0–225.0 mg/dL 4–6 Years: 60.5–345.0 mg/dL 6–8 Years: 44.0–375.0 mg/dL 8–10 Years: 72.0–430.0 mg/dL 10–12 Years: 76.0–355.0 mg/dL 12–14 Years: 100.0–455.0 mg/dL 14–18 Years: 64.0–495.0 mg/dL 18–99 Years: 241.8–700.3 mg/dL IgG Subclass 3 0–2 Years: 18.6–85.3 mg/dL 2–4 Years: 17.3–67.6 mg/dL 4–6 Years: 9.9–122.1 mg/dL 6–8 Years: 15.5–85.3 mg/dL 8–10 Years: 12.7–85.3 mg/dL 10–12 Years: 17.3–173.0 mg/dL 12–14 Years: 28.3–125.0 mg/dL 14–18 Years: 23.0–196.0 mg/dL 18–99 Years: 21.8–176.1 mg/dL IgG Subclass 4 0–2 Years: 0.5–78.4 mg/dL 2–4 Years: 1.0–53.7 mg/dL 4–6 Years: 1.8–112.5 mg/dL 6–8 Years: 0.4–99.2 mg/dL 8–10 Years: 1.9–93.2 mg/dL 10–12 Years: 1.6–115.0 mg/dL 12–14 Years: 3.7–136.0 mg/dL 14–18 Years: 11.0–157.0 mg/dL 18–99 Years: 3.9–86.4 mg/dL	9/8/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
IgG Synthesis, CSF (Tourtellotte and Index)	TOURT	**Test Name:** Previously IgG CSF Index **Specimen Requirement:** 1 mL cerebrospinal fluid (CSF) in a clean container; Minimum: 0.2 mL; **Collect cerebrospinal fluid (CSF) and blood within same 24-hour period;** Refrigerated *AND* 1 mL serum from a serum separator (gold) tube; Minimum: 0.2 mL; Collect cerebrospinal fluid (CSF) and blood within same 24-hour period; Refrigerated *OR* 1 mL cerebrospinal fluid (CSF) in a clean container; Minimum: 0.2 mL; **Collect cerebrospinal fluid (CSF) and blood within same 24-hour period;** Refrigerated *AND* 1 mL serum from a **plain no additive (red)** tube; Minimum: 0.2 mL; Refrigerated **Methodology:** **Bromocresol Green** **Immunoradiometric Assay** **Reference Range:** **IgG, CSF: 1.0–3.0 mg/dL** **Albumin, CSF** **3–47 Months: < 45 mg/dL** **4–99 Years: 10–30 mg/dL** **IgG, Serum** **0–11 Months: 232–1411 mg/dL** **1–3 Years: 453–916 mg/dL** **4–6 Years: 504–1465 mg/dL** **7–9 Years: 572–1474 mg/dL** **10–11 Years: 698–1560 mg/dL** **12–13 Years: 759–1550 mg/dL** **14–15 Years: 716–1711 mg/dL** **16–19 Years: 549–1584 mg/dL** **20–99 Years: 700–1600 mg/dL** **Albumin, Serum** **0–4 Days: 2800–4400 mg/dL** **5–364 Days: 3800–5400 mg/dL** **1–14 Years: 3200–5400 mg/dL** **15–17 Years: 3200–4500 mg/dL** **18–99 Years: 3900–4900 mg/dL** **IgG,CSF / Albumin,CSF Ratio:** 0.06–0.17 **IgG Synthesis, CSF (Tourtellotte):** 0–3.0 mg/d **IgG Index, CSF:** 0–0.61 **Days Performed:** Monday–**Friday** **Reported:** 1–**4** days	9/8/20
Immunoglobulins	SERIMM	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL serum from a **plain no additive (red)** tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL **plasma from a lithium heparin (green)** tube; Minimum: **0.3 mL;** Refrigerated *OR* 1 mL **plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: **0.3 mL;** Refrigerated **Stability:** Ambient: **2 months** Refrigerated: **4 months** Frozen: **6 months** **Methodology: Immunoturbidimetric Assay** **Reference Range:** IgG **0–11 Months: 232–1411 mg/dL** **1–3 Years: 453–916 mg/dL** **4–6 Years: 504–1465 mg/dL** **7–9 Years: 572–1474 mg/dL** **10–11 Years: 698–1560 mg/dL** *(continued on page 13)*	9/8/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Immunoglobulins *(continued from page 12)*		**12–13 Years: 759–1550 mg/dL** **14–15 Years: 716–1711 mg/dL** **16–19 Years: 549–1584 mg/dL** **20–99 Years: 700–1600 mg/dL** IgA **0–11 Months: < 83 mg/dL** **1–3 Years: 20–100 mg/dL** **4–6 Years: 27–195 mg/dL** **7–9 Years: 34–305 mg/dL** **10–11 Years: 53–204 mg/dL** **12–13 Years: 58–358 mg/dL** **14–15 Years: 47–249 mg/dL** **16–19 Years: 61–348 mg/dL** **20–99 Years: 70–400 mg/dL** IgM **0–11 Months: < 145 mg/dL** **1–3 Years: 19–146 mg/dL** **4–6 Years: 24–210 mg/dL** **7–9 Years: 31–179 mg/dL** **10–11 Years: 31–179 mg/dL** **12–13 Years: 35–239 mg/dL** **14–15 Years: 15–188 mg/dL** **16–19 Years: 23–259 mg/dL** **20–99 Years: 40–230 mg/dL** **Days Performed: Monday–Friday** **Reported:** 1–**4 days**	
Insulin Autoantibody	INSLAB	**Stability:** Ambient: 1 day Refrigerated: 7 days Frozen: **1 year (2 freeze/thaw cycles are acceptable)**	8/4/20
Insulin, Free, Serum	FINS	**Reference Range: 3.0–25.0 mU/L**	10/6/20
Lipoprotein (a)	LPA	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Allow specimen to clot completely at room temperature; Recommended to separate serum from cells within 2 hours of collection; Refrigerated *OR* 1 mL serum from a **plain no additive (red)** tube; Minimum: 0.5 mL; Refrigerated *OR* 1 mL **plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: 0.5 mL; Refrigerated *OR* 1 mL **plasma from a lithium heparin (green)** tube; Minimum: 0.5 mL; Refrigerated **Stability:** Ambient: **8** hours Refrigerated: 7 days Frozen: **1 month** **Methodology: Immunoturbidimetric Assay** **Reference Range: < 30 mg/dL** **Days Performed: Monday–Friday** **Reported:** 1–**4** days	9/8/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Monoclonal Protein with Immunoglobulins and Free Light Chains, serum	SERMPA	**Methodology:** Immunofixation Electrophoresis **Immunoturbidimetric Assay** **Reference Range:** Lambda, Free, Serum: 5.7–26.3 mg/L Kappa, Free, Serum: 3.30–19.40 mg/L Kappa/Lambda Ratio: 0.26–1.65 MPA Result: No M protein is identified MPA Serum IgG **0–11 Months: 232–1411 mg/dL** **1–3 Years: 453–916 mg/dL** **4–6 Years: 504–1465 mg/dL** **7–9 Years: 572–1474 mg/dL** **10–11 Years: 698–1560 mg/dL** **12–13 Years: 759–1550 mg/dL** **14–15 Years: 716–1711 mg/dL** **16–19 Years: 549–1584 mg/dL** **20–99 Years: 700–1600 mg/dL** Immunofixation Screen, Serum: Refer to report MPA Serum IgM **0–11 Months: < 145 mg/dL** **1–3 Years: 19–146 mg/dL** **4–6 Years: 24–210 mg/dL** **7–9 Years: 31–208 mg/dL** **10–11 Years: 31–179 mg/dL** **12–13 Years: 35–239 mg/dL** **14–15 Years: 15–188 mg/dL** **16–19 Years: 23–259 mg/dL** **20–99 Years: 40–230 mg/dL** MPA Serum IgA **0–11 Months: < 83 mg/dL** **1–3 Years: 20–100 mg/dL** **4–6 Years: 27–195 mg/dL** **7–9 Years: 34–305 mg/dL** **10–11 Years: 53–204 mg/dL** **12–13 Years: 58–358 mg/dL** **14–15 Years: 47–249 mg/dL** **16–19 Years: 61–348 mg/dL** **20–99 Years: 70–400 mg/dL**	9/8/20
Mycophenolic Acid	MYCOPH	**Special Information:** Do not collect in a gel separator tube. **Draw immediately before next dose.**	Effective immediately
Neuronal Nuclear Abs IgG by Immunoblot	HURIYO	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** **Neuronal nuclear Ab Hu, IgG** **Neuronal nuclear Ab Ri, IgG** **Neuronal nuclear Ab Yo, IgG** **Neuronal nuclear Ab Tr/DNER, IgG** **Special Information: Plasma will be rejected. Grossly hemolyzed, heat-inactivated, contaminated, or lipemic specimens are unacceptable.** **Clinical Information:** This assay detects IgG **antineuronal** antibodies to Hu, Ri, Yo **and Tr (DNER) antigens. Antineuronal antibodies serve as markers that aid in discriminating between a true paraneoplastic neurological disorder (PND) and other inflammatory disorders of the nervous system.** Anti-Hu (antineuronal nuclear antibody, type I) is associated with small cell lung cancer. Anti-Ri (antineuronal nuclear antibody, type II) is associated with fallopian tube and breast cancer in adults and neuroblastoma in children. Anti-Yo (anti-Purkinje cell cytoplasmic antibody) is associated with ovarian and breast cancer. **Anti-Tr(DNER) is associated with Hodgkin's lymphoma.** Presence of one or more of these antineuronal antibodies supports a clinical diagnosis of **PND** and should lead to a focused search for the underlying neoplasm. *(continued on page 15)*	8/17/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Neuronal Nuclear Abs IgG by Immunoblot *(continued from page 14)*		**Note**: *Neuronal Nuclear Abs (Hu, Ri, Yo) IgG, Immunoblot will be removed as an alias name, and Neuronal Nuclear Abs (Hu, Ri, Yo, Tr/DNER) IgG, Immunoblot will be added.* **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 a 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 month** **Methodology:** Immunoblot (IB), **Qualitative** **Reference Range:** **Neuronal nuclear Ab Hu, IgG: Negative** **Neuronal nuclear Ab Ri, IgG: Negative** **Neuronal nuclear Ab Yo, IgG: Negative** **Neuronal nuclear Ab Tr/DNER, IgG: Negative** **Days Performed: Monday,** Thursday, **Saturday** **Reported:** 2–**5** days **CPT: 84182 x 4**	
N-Methylhistamine, Random, Urine	UMHISR	**Stability:** Ambient: **14** days Refrigerated: 28 days (preferred) Frozen: 28 days	Effective immediately
N-Methylhistamine, Urine	MHISTA	**Stability:** Ambient: **14** days Refrigerated: 28 days (preferred) Frozen: 28 days	Effective immediately
Pancreatic Elastase, Fecal	PANCEF	**Special Information:** When ordering Pancreatic Elastase along with Fecal Fat, Qualitative **(FFATQL),** please submit two separate specimens. Pancreatic Elastase should be sent **refrigerated,** and Fecal Fat, Qualitative should be sent **frozen.** Unacceptable conditions: Stool in media or preservative; Swabs. This test is New York DOH approved. **Clinical Information:** Screen for exocrine pancreatic insufficiency. Reference range does not apply for infants less than one month old. Note: Enzyme substitution therapy does not influence the determination of pancreatic elastase-1. **Note:** *Pancreatic Elastase, Fecal by ELISA will be removed as an alias name, and Pancreatic Elastase, Fecal by Immunoassay will be added.* **Specimen Requirement:** 5 g stool in a clean container (No preservatives); Minimum: 1 g; Do not collect in media or preservative; Do not use swabs; **Refrigerated** **Stability:** Ambient: **Unacceptable** Refrigerated: **2 weeks** Frozen: **30 days** **Methodology: Quantitative Chemiluminescent Immunoassay** **Reference Range:** **≥ 200 µg/g: Normal** **100 to < 200 µg/g: Moderate to mild exocrine pancreatic insufficiency** **< 100 µg/g: Severe exocrine pancreatic insufficiency** **Note: Reference range does not apply for infants < 1 month old** **Days Performed:** Sunday–**Saturday** **Reported:** 2–**4** days	8/17/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Paraneoplastic Syndrome Ab Panel with Reflex	PARSYN	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Purkinje Cell/Neuronal Nuclear IgG Ab Screen Neuronal Nuclear Ab (ANNA) IFA Titer, IgG (if indicated) Neuronal Nuclear Abs (Hu,Ri, Yo, **Tr/DNR**) IgG, Immunblot (if indicated) Purkinje Cell Ab Titer (if indicated) **Special Information:** Purkinje Cell (PCCA) antibody and Neuronal Nuclear (ANNA) antibody IgG are screened by IFA. If the IFA screen is indeterminate, then a Neuronal Nuclear Antibodies (Hu, Ri, Yo, **and Tr/DNER)** IgG by Immunoblot will be added. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu, Ri, Yo, **and Tr/DNER)** IgG by Immunoblot will be added. Additional charges apply. Unacceptable conditions: Contaminated, heat-inactivated, hemolyzed, or lipemic specimens **Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: **0.75 mL;** Separate serum from cells **ASAP or** within two hours of collection **and transfer into a standard aliquot tube; Refrigerated** **Reference Range:** **Note:** *Please refer to changes to Neuronal Nuclear Abs IgG by Immunoblot (HURIYO).* **Days Performed: Sunday,** Wednesday, **Friday** **Reported:** 2–**7** days	8/17/20
P/Q-Type Voltage-Gated Calcium Channel (VGCC) Antibody	VOLTCA	**Special Information: Cerebrospinal fluid (CSF) will be rejected.** Plasma is not acceptable. Hemolyzed or grossly lipemic specimens are unacceptable. **This test is New York DOH approved.**	8/17/20
Protein S Clottable	PRSCLT	**Note:** *Reference range changes previously announced in the May Technical Update will go live on 8/4/20.*	8/4/20
Prothrombin Time Mixing Study	PTMIX	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** PT Screen	8/4/20
Strongyloides IgG Abs, Serum	STRSER	**Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; **Only one tube to be collected;** Refrigerated *OR* 0.5 mL serum from a plain no additive (red) tube; Minimum: 0.3 mL; **Only one tube to be collected;** Refrigerated	8/4/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Tularemia Antibodies, IgG and IgM	TULGM	**For Interfaced Clients Only: Test build may need to be modified** **Special Information: If the initial testing is equivocal or positive for IgG and/or IgM, then Francisella tularensis Antibodies by Agglutination will be performed at an additional cost. Contaminated, heat-inactivated, or turbid specimens will be rejected. This test is New York DOH approved.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.6 mL;** Separate serum from cells ASAP or within 2 hours of collection **and transfer into a standard aliquot tube;** Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: **0.6 mL;** Separate serum from cells ASAP or within 2 hours of collection **and transfer into a 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 month** **Methodology: Semi-Quantitative** Enzyme-Linked Immunosorbent Assay **Reference Range:** F. tularensis IgG **≤ 9 U/mL; Negative–No significant level of IgG antibody to F. tularensis detected** **10–15 U/mL; Equivocal–Questionable presence of IgG antibody to F. tularensis; Repeat testing in 10–14 days may be helpful** **≥ 16 U/mL; Positive–Presence of IgG antibody to F. tularensis detected, suggestive of current or past exposure/immunization** F. tularensis IgM **≤ 9 U/mL; Negative–No significant level of IgM antibody to F. tularensis detected** **10–15 U/mL; Equivocal–Questionable presence of IgM antibody to F. tularensis; Repeat testing in 10–14 days may be helpful** **≥ 16 U/mL; Positive–Presence of IgM antibody to F. tularensis detected, suggestive of current or recent exposure/immunization**	8/17/20

New Tests

Test Name	Order Code	Change	Effective Date
Prometheus Anser ADA	ANSADA	**Includes:** Serum adalimumab (ADA) concentration Antibody to adalimumab (ATA) concentration **Clinical Information:** Serum concentrations of adalimumab (ADA) may vary among equally dosed patients, which can ultimately affect patient outcomes. Suboptimal levels of ADA have been linked to lower response rates in IBD patients. Additionally, some patients may develop immunogenicity to ADA by producing antibodies to adalimumab (ATA). The presence of ATA has also been associated with increased rates of infusion reactions and drug clearance leading to lower response rates. Therefore, the quantitative measurement of ADA and ATA levels in serum provides clinicians with valuable information to help them gain a better understanding of the factors that may be affecting a patient's loss of response. The Prometheus Anser ADA test is a next generation quantitative monitoring assay that allows healthcare providers to measure and monitor serum ADA and ATA levels at any time during therapy. Incorporating therapeutic drug monitoring may clarify what factors are contributing to a patient's loss of response and help patient management by providing information to help decide an appropriate course of action. **Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: 2 mL adult patients, 0.5 mL pediatric patients; Ship using cold pack; Refrigerated *OR* 2 mL serum from a plain no additive (red) tube; Minimum: 2 mL adult patients, 0.5 mL pediatric patients; Ship using cold pack; Refrigerated **Stability:** Ambient: 7 days Refrigerated: 9 days Frozen: Unacceptable **Methodology:** High Performance Liquid Chromatography (HPLC) **Days Performed:** Varies **Reported:** 4–5 days **CPT:** 84999 x 1 **Price:** $1825.00 (non-discountable)	8/13/20
Prometheus Anser IFX	ANSIFX	**Includes:** Serum infliximab concentration Antibody to infliximab partial concentration Antibodies to infliximab (ATI) concentration **Clinical Information:** Serum concentrations of infliximab (IFX) can vary among equally dosed patients, which can ultimately affect patient outcomes. Suboptimal levels of IFX have been linked to lower response rates in IBD patients. Additionally, some patients may develop immunogenicity to IFX by producing antibodies to infliximab (ATI). The presence of ATI has also been associated with increased rates of infusion reactions and drug clearance leading to lower response rates. Therefore, the quantitative measurement of IFX and ATI levels in serum provides clinicians with valuable information to help them gain a better understanding of the factors that may be affecting a patient's loss of response. The Prometheus Anser IFX test is a next generation and more sensitive quantitative monitoring assay that allows healthcare providers to measure and monitor serum IFX and ATI levels at any time during therapy. Incorporating therapeutic drug monitoring may clarify what factors are contributing to a patient's loss of response and help guide treatment decisions by providing information to help determine an appropriate course of action. **Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: 2 mL adult patients, 0.5 mL pediatric patients; Ship using cold pack; Refrigerated *OR* 2 mL serum from a plain no additive (red) tube; Minimum: 2 mL adult patients, 0.5 mL pediatric patients; Ship using cold pack; Refrigerated **Stability:** Ambient: 7 days Refrigerated: 9 days Frozen: Unacceptable **Methodology:** High Performance Liquid Chromatography (HPLC) **Days Performed:** Varies **Reported:** 4–5 days **CPT:** 84999 x 1 **Price:** $1825.00 (non-discountable)	8/13/20

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Prometheus Anser UST	ANSUST	**Includes:** Serum ustekinumab (UST) concentration Antibodies to ustekinumab (ATU) concentration **Clinical Information:** Serum concentrations of ustekinumab (UST) may vary among equally dosed patients, which can ultimately affect patient outcomes. Some patients may develop immunogenicity to UST by producing antibodies to ustekinumab (ATU), and the presence of persistent ATU has been observed to substantially reduce serum concentrations of UST. The quantitative measurement of UST and ATU levels in serum provides clinicians with valuable information to help them gain a better understanding of the factors that may be affecting a patient's loss of response. The Prometheus Anser UST test is a next generation and more sensitive quantitative monitoring assay that allows healthcare providers to measure and monitor serum UST and ATU levels at any time during therapy. Incorporating therapeutic drug monitoring may clarify what factors are contributing to a patient's loss of response and help guide treatment decisions by providing information to help determine an appropriate course of action. **Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: 2 mL adult patients, 0.5 mL pediatric patients; Ship using cold pack; Refrigerated *OR* 2 mL serum from a plain no additive (red) tube; Minimum: 2 mL adult patients, 0.5 mL pediatric patients; Ship using cold pack; Refrigerated **Stability:** Ambient: 7 days Refrigerated: 9 days Frozen: Unacceptable **Methodology:** High Performance Liquid Chromatography (HPLC) **Days Performed:** Varies **Reported:** 4–5 days **CPT:** 84999 x 1 **Price:** $1825.00 (non-discountable)	8/13/20
Prometheus Anser VDZ	ANSVDZ	**Clinical Information:** Serum concentrations of vedolizumab (VDZ) may vary among equally dosed patients, which can ultimately affect patient outcomes. Some patients may develop immunogenicity to VDZ by producing antibodies to vedolizumab (ATV), and the presence of persistent anti-vedolizumab antibody has been observed to substantially reduce serum concentrations of vedolizumab. The quantitative measurement of VDZ and ATV levels in serum provides clinicians with valuable information to help them gain a better understanding of the factors that may be affecting a patient's loss of response. The Prometheus Anser VDZ test is a next generation and more sensitive quantitative monitoring assay that allows healthcare providers to measure and monitor serum VDZ and ATV levels at any time during therapy. Incorporating therapeutic drug monitoring may clarify what factors are contributing to a patient's loss of response and help guide treatment decisions by providing information to help determine an appropriate course of action. **Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: 2 mL adult patients, 0.5 mL pediatric patients; Ship using cold pack; Refrigerated *OR* 2 mL serum from a plain no additive (red) tube; Minimum: 2 mL adult patients, 0.5 mL pediatric patients; Ship using cold pack; Refrigerated **Stability:** Ambient: 7 days Refrigerated: 9 days Frozen: Unacceptable **Methodology:** High Performance Liquid Chromatography (HPLC) **Days Performed:** Varies **Reported:** 4–5 days **CPT:** 84999 x 1 **Price:** $1825.00 (non-discountable)	8/13/20

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Prometheus Monitr Crohn's Disease	MCROHN	**Includes:** Ang 1 Ang 2 CEACAM 1 hsCRP EMMPRIN IL 7 MMP 1 MMP 2 MMP 3 MMP 9 SAA 1 TGFa VCAM 1 **Clinical Information:** This test measures mucosal healing status in Crohn's disease patients. The test applies an algorithm to the concentrations of 13 biomarkers in order to produce a quantitative Mucosal Healing Index Score ranging from 0–100. The Mucosal Healing Index Score is intended to aid in the assessment of active disease in Crohn's disease patients in conjunction with clinical evaluation performed by a healthcare professional. It is not validated or intended for use in diagnosing Crohn's disease. **Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: 2 mL adult patients, 0.5 mL pediatric patients; Ship using cold pack; Refrigerated *OR* 2 mL serum from a plain no additive (red) tube; Minimum: 2 mL adult patients, 0.5 mL pediatric patients; Ship using cold pack; Refrigerated **Stability:** Ambient: 24 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Multiplex Bead Assay Nephelometry (NEPH) **Days Performed:** Varies **Reported:** 4–5 days **CPT:** 83520 x 12, 86141 x 1 **Price:** $535.00 (non-discountable)	8/13/20

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Tularemia Antibodies, IgG and IgM	TULGM	$80.00 (non-discountable)	86668 x 2	8/17/20

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Antimony, Blood	ANTMBL	This test will no longer be available.	8/17/20
Calpain 3 DNA Sequencing Test	CALP3	This test will no longer be available.	9/10/20
Candida albicans Eval	CANDA	This test will no longer be available. Suggest ordering alternative tests Candida albicans Abs, IgA, IgG, IgM (CNDAGM) and Fungitell Assay for (1,3)-B-D-Glucan (BDGLUC)	8/3/20
DNA Content/Cell Cycle Analysis, Hydatidiform Mole	DNAHYD	This test will no longer be available.	9/10/20
Histoplasma Abs, CF+ID, CSF	CSFHAB	This test will no longer be available.	9/10/20