Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • July 2018

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

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

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

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

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
15	Acylglycines, Quantitative Analysis, Urine			■										
17	Acylglycines, Quantitative Urine				■									
3	Allergen, Almond IgG					■	■		■	■	■	■		
15	Allergen, Mouse Urine Proteins IgE			■										
15	Allergen, Phoma Betae IgE			■										
3–4, 17	Allergen, Respiratory Disease Profile Region 5						■	■		■			■	■
4	Ammonia					■						■		
5	Antibiotic Assay Flucytosine					■	■		■	■	■	■		
5	B-Hydroxybutyrate											■		
5	Brucella Ab Total					■	■					■		
17	Brucella IgG/IgM Confirmation				■									
5	Carbamazepine and Metabolite						■				■	■		
6	Carbamazepine, Free					■	■		■	■		■		
6	Carbamazepine, Free and Total					■	■		■	■		■		
6	Cardiolipin Antibodies					■	■							
6	Cardiolipin IgA Antibodies					■	■							
7	Cardiolipin IgG Antibodies					■	■							
7	Cardiolipin IgM Antibodies					■	■							
15	CD19 Count			■										
7	Celiac Comprehensive Panel					■	■							
8	Complement, Alternate Pathway (AH50), Functional					■	■		■	■	■	■	■	

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	Cyanide, Blood					■	■		■	■	■	■		
9	Des-Gamma-Carboxy Prothrombin, Serum					■	■		■	■	■	■		
17	Endocrine Auto Antibodies				■									
16	Fat, Fecal Qualitative			■										
9, 17	FBN1 Gene Sequencing Analysis					■			■		■			■
17	Fecal Fat, Qualitative				■									
9	FLT3 Mutation Detection by PCR					■	■							
9	G-6-PD Quantitative					■	■			■	■			
10, 17	Giardia lamblia IgG, IgA, IgM						■		■		■			■
10	Hepatitis B Core Antibody, IgM					■								
10	Hepatitis B Surface Antigen					■								
10	Hepatitis B Surface Antigen Conf					■								
10	Hepatitis C Antibody IA					■								
11	Hepatitis C Antibody IA w/Confirm					■								
16	High Sensitivity Total Testosterone			■										
11	HIV 1 2 Combo (Antigen/Antibody)					■					■			
11	HSV PCR, Miscellaneous Specimen Types						■					■		
11	Human Epididymis Protein 4					■								
11	Human Erythrocyte Ag												■	
12	Legionella pneumophila Antibody (Types 1-6), IgG by IFA		■			■	■		■	■	■	■		
12	Listeria Antibody, CSF					■			■		■	■		
13	Mexiletine					■	■				■			
17	M. tuberculosis Amplified, CSF													■
16	Myeloma Prognostic Risk Signature (MyPRS)			■										
17	Myocardial Total Autoantibodies				■									
13	Oxalate		■			■	■		■	■	■	■		
13	Phenytoin, Free					■	■		■			■		
14	Schistosoma IgG Ab					■	■		■	■	■	■		
14	Valproic Acid, Free					■	■		■	■		■		
14	Valproic Acid, Total and Free					■	■		■	■	■	■		
14	Varicella Zoster by PCR					■	■							

Test Changes

Test Name	Order Code	Change	Effective Date
Allergen, Almond IgG	ALMIGG	**Special Information: Hemolyzed, icteric, or lipemic specimens will be rejected. Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.** **Clinical Information: Values < 2.00 mcg/mL represent absent or undetectable levels of allergen–specific IgG antibody. Values ≥ 2.00 mcg/mL indicate progressive increases in the relative concentration of allergen–specific IgG. Note: The units of measure mcg/mL and mgA/L are interchangeable. 1 mg/L = 1000 mcg/1000 mL** **Specimen Requirement: 0.5 mL** serum from a serum separator (gold) tube; Minimum: 0.2 mL; **Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated** **Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: **After separation from cells: 2 weeks** Frozen: **After separation from cells: 1 year** **Methodology: Quantitative** ImmunoCAP **Fluorescent Enzyme Immunoassay** **Reference Range: < 15.21 mcg/mL** **Days Performed:** Sunday **Reported:** 2–**9** days	9/6/18
Allergen, Respiratory Disease Profile Region 5	RESPR5	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Alternaria tenuis Aspergillus fumigatus Bermuda grass Cat dander Cladosporium herbarum (Hormodendrum) Cockroach Dermatophagoides farinae Dermatophagoides pteronyssinus Dog dander Elm tree Hickory/Pecan tree Johnson grass June grass (Kentucky blue/meadow) Lamb's quarters (goosefoot) Oak tree Short (common) ragweed Walnut tree **Cottonwood Tree** **Timothy Grass** **White Ash Tree** **Maple (Box Elder) Tree** **Mouse Urine** **Specimen Requirement: 2.5 mL** serum from a serum separator (gold) tube; Minimum: **1.4 mL;** Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of **2.5 mL** is preferred when possible; Refrigerated *OR* **2.5 mL** plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: **1.4 mL;** Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of **2.5 mL** is preferred when possible; Refrigerated *OR* **2.5 mL** plasma from an EDTA (lavender) tube; Minimum: **1.4 mL;** Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of **2.5 mL** is preferred when possible; Refrigerated *(continued on page 4)*	8/28/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Respiratory Disease Profile Region 5 *(continued from page 3)*		**Reference Range:** Allergen, Alternaria tenuis (alternata) IgE: < 0.35 kU/L Allergen, Alternaria tenuis (alternata) Class (0–99 Years): 0 Allergen, Aspergillus fumigatus IgE: < 0.35 kU/L Allergen, Aspergillus fumigatus Class: 0 Allergen, Bermuda Grass IgE: < 0.35 kU/L Allergen, Bermuda Grass Class: 0 Allergen, Cat Dander IgE: < 0.35 kU/L Allergen, Cat Dander Class: 0 Allergen, Cladosporium herbarum (Hormodendrum) IgE: < 0.35 kU/L Allergen, Cladosporium herbarum (Hormodendrum) Class: 0 Allergen, Cockroach IgE: < 0.35 kU/L Allergen, Cockroach Class: 0 Allergen, Dermatophagoides farinae IgE: < 0.35 kU/L Allergen, Dermatophagoides farinae Class: 0 Allergen, Dermatophagoides pteronyssinus IgE: < 0.35 kU/L Allergen, Dermatophagoides pteronyssinus Class: 0 Allergen, Dog Dander IgE: < 0.35 kU/L Allergen, Dog Dander Class: 0 Allergen, Elm Tree IgE: < 0.35 kU/L Allergen, Elm Tree Class: 0 Allergen, Hickory/Pecan Tree IgE: < 0.35 kU/L Allergen, Hickory/Pecan Tree Class: 0 Allergen, Johnson Grass IgE: < 0.35 kU/L Allergen, Johnson Grass Class: 0 Allergen, June Grass (Kentucky Blue, Meadow) IgE: < 0.35 kU/L Allergen, June Grass (Kentucky Blue, Meadow) Class: 0 Allergen, Lamb's Quarters (Goosefoot) IgE: < 0.35 kU/L Allergen, Lamb's Quarters (Goosefoot) Class: 0 Allergen, Oak Tree IgE: < 0.35 kU/L Allergen, Oak Tree Class: 0 Allergen, Short (Common) Ragweed IgE: < 0.35 kU/L Allergen, Short (Common) Ragweed Class: 0 Allergen, Walnut IgE: < 0.35 kU/L Allergen, Walnut Class: 0 **Allergen, Cottonwood Tree IgE: < 0.35 kU/L** **Allergen, Cottonwood Tree Class: 0** **Allergen, Timothy Grass IgE: < 0.35 kU/L** **Allergen, Timothy Grass Class: 0** **Allergen, White Ash Tree IgE: < 0.35 kU/L** **Allergen, White Ash Tree Class: 0** **Allergen, Box Elder (Maple) Tree IgE: < 0.35 kU/L** **Allergen, Box Elder (Maple) Tree Class: 0** **Mouse Urine IgE: < 0.35 kU/L** **Mouse Urine–Class: 0** **CPT:** 86003 **x 22**	
Ammonia	NH3	**Special Information:** EDTA is the only acceptable specimen type. All others will be refused. **Collect blood from a stasis–free vein (e.g., no tourniquet) with fist clenching avoided. Smoking should be avoided prior to collection. Tubes should be filled completely and kept tightly stoppered.** **Stability:** Ambient: Not acceptable Refrigerated: After separation from cells: **4** hours Frozen: After separation from cells: 21 days	7/10/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Antibiotic Assay Flucytosine	FLCYT	**Special Information: Required information: Time and date of collection, time of last dose, and list of all antibiotics that the patient is receiving or has received in the past 48 hours. Plasma is unacceptable. This test is New York DOH approved.** **Clinical Information: Normal peak serum concentration for 5-fluorocytosine is 30–45 μg/mL with a 2 g PO dose or 60–80 μg/mL with a 100 mg/kg/day PO dose. Trough serum concentration is not well established. Toxicity may be seen with sustained levels greater than 100 μg/mL. For bioassay measurements, the presence of other antimicrobial agents may interfere with the assay. Other factors that may influence antimicrobial levels include inherent differences among patients and their underlying physical conditions as well as the dose and route of administration of the antimicrobial agent.** **Specimen Requirement: 2 mL** serum from a **plain no additive (red) tube;** Minimum: **1 mL; Required information: Time and date of collection, time of last dose, and list of all antibiotics that the patient is receiving or has received in the past 48 hours; Aseptically remove 2 mL serum to a sterile aliquot tube and freeze;** Frozen **Stability:** Ambient: **2 hours** Refrigerated: **24 hours** Frozen: **1 week** **Methodology: Bioassay** **Reference Range: Refer to report** **Days Performed: Sunday–Saturday** **Reported: 2**–3 days	9/11/18
B-Hydroxybutyrate	BHB	**Stability:** Ambient: **48 hours** Refrigerated: **48 hours** Frozen: **48 hours**	8/28/18
Brucella Ab Total	BRUAGG	**Special Information:** Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as 'acute' or 'convalescent.' **Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens will be rejected. This test is New York DOH approved.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.2 mL; Separate serum from cells ASAP or within 2 hours of collection **and transfer into standard aliquot tube; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens;** Label specimens plainly as 'acute' or 'convalescent;' Refrigerated **Stability:** Ambient: **After separation from cells:** 48 hours Refrigerated: **After separation from cells:** 2 weeks Frozen: **After separation from cells:** 6 months **(Avoid repeated freeze/thaw cycles)**	8/30/18
Carbamazepine and Metabolite	CARBME	**Specimen Requirement:** 3 mL plasma from a sodium or lithium heparin (green) tube; Minimum: **1 mL;** Collect immediately prior to next dose; **Do not collect in a gel separator tube; Centrifuge and transfer plasma to a CCL tube and refrigerate;** Refrigerated *OR* 3 mL **serum from a plain no additive (red) tube;** Minimum: **1 mL;** Collect immediately prior to next dose; **Do not collect in a gel separator tube; Centrifuge and transfer serum to a CCL tube and refrigerate;** Refrigerated **Stability:** Ambient: **Unacceptable** Refrigerated: After separation from cells: **1 week** Frozen: After separation from cells: **1 month** **Days Performed: Monday**–Friday **Reported:** 1–**4** days	7/31/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Carbamazepine, Free	CARBFR	**Special Information: Do not collect in a gel separator tube.** **Specimen Requirement:** 2 mL **serum from a plain no additive (red) tube;** Minimum: 1.5 mL; **Do not collect in a gel separator tube; Centrifuge and transfer serum to a CCL tube and refrigerate;** Refrigerated **Stability:** Ambient: **After separation from cells: 7 days** Refrigerated: After separation from cells: **7 days** Frozen: After separation from cells: **14 days** **Methodology: Kinetic Interaction of Microparticles in a Solution** **Reference Range:** **0–99 Years: 0.8**–2.4 µg/mL	8/28/18
Carbamazepine, Free and Total	CARBFT	**Special Information: Do not collect in a gel separator tube.** **Note:** *Clinical Information will be removed for this test.* **Specimen Requirement:** 3 mL **serum from a plain no additive (red) tube;** Minimum: **2 mL; Do not collect in a gel separator tube; Centrifuge and transfer serum to a CCL tube and refrigerate;** Refrigerated **Stability:** Ambient: **After separation from cells: 2 days** Refrigerated: After separation from cells: **7 days** Frozen: After separation from cells: **14 days** **Methodology: Kinetic Interaction of Microparticles in a Solution** **Reference Range:** Carbamazepine 0–99 Years: 4.0–12.0 µg/mL Carbamazepine, Free **0–99 Years: 0.8**–2.4 µg/mL	8/28/18
Cardiolipin Antibodies	CARDIO	**Special Information: Diagnosis cannot be made on the basis of Anti-cardiolipin antibodies (ACA) results alone. These results must be interpreted in conjunction with physical findings. A high percentage of confirmed active or seropositive syphilis patients will have elevated ACA levels. Confirmatory procedures should be performed to rule out syphilis. ACA can appear transiently during many infections. Patients positive for ACA should be retested following an appropriate wait. The presence of immune complexes or other immunoglobulin aggregates in the patient sample may cause an increased level of non-specific binding and produce false positives in this assay. Rheumatoid factor (RF) can interfere with the determination of IgM ACA.** **Clinical Limitation: Microbially contaminated, heat-treated, or specimens containing visible particulate should not be used. Grossly hemolyzed or lipemic serum or specimens should be avoided.** **Specimen Requirement: 0.5 mL** serum from a serum separator (gold) tube; Minimum: **0.25 mL;** Refrigerated	7/10/18
Cardiolipin IgA Antibodies	CARDIA	**Note:** *The following alias names will be added:* ***Anti-phospholipid, phospholipid*** **Special Information: Diagnosis cannot be made on the basis of Anti-cardiolipin antibodies (ACA) results alone. These results must be interpreted in conjunction with physical findings. A high percentage of confirmed active or seropositive syphilis patients will have elevated ACA levels. Confirmatory procedures should be performed to rule out syphilis. ACA can appear transiently during many infections. Patients positive for ACA should be retested following an appropriate wait. The presence of immune complexes or other immunoglobulin aggregates in the patient sample may cause an increased level of non-specific binding and produce false positives in this assay.** **Clinical Limitation: Microbially contaminated, heat-treated, or specimens containing visible particulate should not be used. Grossly hemolyzed or lipemic serum or specimens should be avoided.** **Specimen Requirement: 0.5 mL** serum from a serum separator (gold) tube; Minimum: **0.25 mL;** Refrigerated	7/10/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cardiolipin IgG Antibodies	CARDIG	**Note:** *The following alias names will be added:* ***Anti-phospholipid, phospholipid*** **Special Information: Diagnosis cannot be made on the basis of Anti-cardiolipin antibodies (ACA) results alone. These results must be interpreted in conjunction with physical findings. A high percentage of confirmed active or seropositive syphilis patients will have elevated ACA levels. Confirmatory procedures should be performed to rule out syphilis. ACA can appear transiently during many infections. Patients positive for ACA should be retested following an appropriate wait. The presence of immune complexes or other immunoglobulin aggregates in the patient sample may cause an increased level of non-specific binding and produce false positives in this assay.** **Clinical Limitation: Microbially contaminated, heat-treated, or specimens containing visible particulate should not be used. Grossly hemolyzed or lipemic serum or specimens should be avoided.** **Specimen Requirement: 0.5 mL** serum from a serum separator (gold) tube; Minimum: **0.25 mL;** Refrigerated	7/10/18
Cardiolipin IgM Antibodies	CARDIM	**Note:** *The following alias names will be added:* ***Anti-phospholipid, phospholipid*** **Special Information: Diagnosis cannot be made on the basis of Anti-cardiolipin antibodies (ACA) results alone. These results must be interpreted in conjunction with physical findings. A high percentage of confirmed active or seropositive syphilis patients will have elevated ACA levels. Confirmatory procedures should be performed to rule out syphilis. ACA can appear transiently during many infections. Patients positive for ACA should be retested following an appropriate wait. The presence of immune complexes or other immunoglobulin aggregates in the patient sample may cause an increased level of non-specific binding and produce false positives in this assay. Rheumatoid factor (RF) can interfere with the determination of IgM ACA.** **Clinical Limitation: Microbially contaminated, heat-treated, or specimens containing visible particulate should not be used. Grossly hemolyzed or lipemic serum or specimens should be avoided.** **Specimen Requirement: 0.5 mL** serum from a serum separator (gold) tube; Minimum: **0.25 mL;** Refrigerated	7/10/18
Celiac Comprehensive Panel	CELCMP	**Special Information:** For all Tissue Transglutaminase IgA > 20 U, Gliadin IgA and IgG and Endomysial Antibodies will be performed and billed. For all Total IgA < 7.0 mg/dL **with a Tissue Transglutaminase IgA of < 1,** a Tissue Transglutaminase IgG and Gliadin IgG will be performed and billed. **Specimen Requirement: 1 mL** serum from a serum separator (gold) tube; Minimum: **0.5 mL;** This assay requires multiple specimen types; Ambient *AND* **4 mL** whole blood in an EDTA (lavender) tube; Minimum: 4 mL; Ambient *OR* **1 mL** serum from a plain no additive (red) tube; Minimum: **0.5 mL;** This assay requires multiple specimen types; Ambient *AND* 7 mL whole blood in an ACD A or B (yellow) tube; Minimum: 4 mL; Ambient	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Complement, Alternate Pathway (AH50), Functional	COMAP	**Special Information: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. Unacceptable conditions include specimen types other than serum, refrigerated or room temperature specimens, specimens left to clot at refrigerated temperature, and specimens exposed to repeated freeze/thaw cycles.** This test is New York DOH approved. **Clinical Information: This test is intended for screening of functional activity of the alternative pathway of the complement system. Abnormal test results can be due to hereditary absence or acquired functional defect in the activity of any of the individual components of the alternative pathway. If test result is abnormal, order specific tests for evaluation of individual components of the alternative pathway.** **Specimen Requirement:** 1 mL serum from a plain no additive (red) tube; Minimum: **0.3 mL; Allow specimen to clot for 1 hour at room temperature;** Separate serum from cells ASAP **or within 2 hours of collection,** transfer into standard aliquot tube and freeze; **Separate specimens must be submitted when multiple tests are ordered; Critical Frozen** *OR* 1 mL serum from a **serum separator (gold) tube;** Minimum: **0.3 mL; Allow specimen to clot for 1 hour at room temperature;** Separate serum from cells ASAP **or within 2 hours of collection,** transfer into standard aliquot tube and freeze; **Separate specimens must be submitted when multiple tests are ordered; Critical Frozen** **Stability:** Ambient: **After separation from cells: 2 hours** Refrigerated: **After separation from cells:** Unacceptable Frozen: **After separation from cells: 2 weeks (Avoid multiple freeze/thaw cycles)** **Methodology: Radial Immunodiffusion (RID)** **Reference Range: ≥ 59% normal** **Days Performed:** Varies **Reported:** 8–**15** days **CPT: 86162 x 1**	8/30/18
Cyanide, Blood	CYANID	**Special Information: Frozen or refrigerated specimens, and clotted or hemolyzed specimens will be rejected. Serum or plasma is unacceptable. Timing of specimen collection: Dependent on time of exposure–test upon presentation to hospital. This test is New York DOH approved.** **Clinical Information: Used to monitor cyanide exposure. Cyanide poisoning can cause hypoxia, dizziness, weakness and mental and motor impairment. Elevated cyanide concentrations rarely indicate toxicity for patients on nitroprusside therapy. Thiocyanate should be monitored in patients on nitroprusside therapy for potential toxicity. Toxicity may occur with long–term nitroprusside use (longer than 7–14 days with normal renal function and 3–6 days with renal impairment at greater than 2 μg/kg/min infusion rates). Thiocyanate levels may be monitored on an every other day basis to assess potential thiocyanate toxicity and to indicate possible adjustments in dosage.** **Specimen Requirement: 4 mL** whole blood in a **sodium or lithium heparin (green) tube;** Minimum: **3 mL; Patient Prep: Timing of specimen collection is dependent on time of exposure–test upon presentation to hospital; Do NOT freeze or refrigerate specimen; Ambient** *OR* **4 mL** whole blood in an EDTA (lavender) tube; Minimum: **3 mL; Patient Prep: Timing of specimen collection is dependent on time of exposure–test upon presentation to hospital; Do NOT freeze or refrigerate specimen; Ambient** **Stability:** Ambient: 72 hours **(if tightly capped)** Refrigerated: **Unacceptable** Frozen: **Unacceptable** **Methodology: Quantitative Colorimetric** **Reference Range:** Non–smoker: **< 20 μg/dL** Smoker: **< 40 μg/dL** **Days Performed:** Sunday, **Wednesday, Friday** **Reported: 2**–6 days	9/4/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Des-Gamma-Carboxy Prothrombin, Serum	PIVKA	**Special Information: Plasma is unacceptable. This test is New York DOH approved.** **Clinical Information: The μTASWako method is used. Results obtained with different assay methods or kits cannot be used interchangeably. The des-gamma-carboxy prothrombin (DCP) assay is intended as a risk assessment for the development of hepatocellular carcinoma in patients with chronic liver diseases.** Elevated DCP values have been shown to be associated with an increased risk for developing hepatocellular carcinoma. **Patients with elevated serum DCP should be more intensely evaluated for evidence of hepatocellular carcinoma.** **Specimen Requirement: 1 mL** serum from a plain no additive (red) tube; Minimum: **0.5 mL; Allow specimen to clot completely at room temperature; Separate from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated** *OR* **1 mL** serum from a serum separator (gold) tube; Minimum: **0.5 mL; Allow specimen to clot completely at room temperature; Separate from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated** **Stability:** Ambient: **After separation from cells: 8 hours** Refrigerated: **After separation from cells: 1 week** Frozen: **After separation from cells: 3 months (Avoid repeated freeze/thaw cycles)** **Methodology:** **Quantitative Liquid Chromatography** **Immunoassay** **Reference Range: 0.0–7.4 ng/mL** **Days Performed:** Monday, **Thursday** **Reported:** 2–**6** days	9/11/18
FBN1 Gene Sequencing Analysis	FBN1	**Special Information:** Sample **must** be refrigerated if not shipped the same day. **Testing is not performed on weekends or major holidays.** **Methodology: Next Gen Sequencing** **Days Performed:** Monday–Friday **Reported: 15–30 days**	Effective immediately
FLT3 Mutation Detection by PCR	FLT3MD	**Special Information:** Must indicate specimen type. Separate specimens must be submitted when multiple tests are ordered. Unacceptable conditions: Grossly hemolyzed or clotted specimens, **and specimens in bone marrow transport media.** This test is New York DOH approved. **Specimen Requirement: 3 mL** whole blood in a sodium heparin (green) tube; Minimum: **1 mL;** Separate specimens must be submitted when multiple tests are ordered; Specimen type required; Refrigerated *OR* **1 mL** bone marrow in a sodium heparin (green) tube; Minimum: **0.25 mL;** Separate specimens must be submitted when multiple tests are ordered; Specimen type required; Refrigerated	Effective immediately
G-6-PD Quantitative	G6PDQT	**Special Information: Do NOT freeze. Hemolyzed specimens are unacceptable. This test is New York DOH approved.** **Clinical Information: Preferred initial screening test for Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency. Patients who have been recently transfused have normal donor cells that may mask G6PD deficient erythrocytes.** **Specimen Requirement:** 3 mL whole blood in an EDTA (lavender) tube; Minimum: 1.5 mL; **Do NOT freeze;** Refrigerated *OR* 3 mL whole blood in an **ACD A (yellow) tube; Enzyme most stable in acid citrate dextrose (ACD); Do NOT freeze;** Refrigerated *OR* 3 mL whole blood in a **sodium or lithium heparin (green) tube;** Minimum: 1.5 mL; **Do NOT freeze;** Refrigerated **Reference Range: 9.9–16.6 U/g Hb** **Days Performed: Sunday–Saturday** **Reported:** 2–**3** days	8/28/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Giardia lamblia IgG, IgA, IgM	GIAGAM	**Specimen Requirement: 2 mL** serum from a serum separator (gold) tube; Minimum: **0.075 mL; Ambient** *OR* **2 mL** serum from a plain no additive (red) tube; Minimum: **0.075 mL; Ambient** **Methodology:** Immunofluorescence **Days Performed: Tuesday–Saturday** **Reported:** 2–**4** days	7/31/18
Hepatitis B Core Antibody, IgM	AHBCM	**Special Information: Not intended for use in screening blood, plasma, or tissue donors. Performance has not been established for the use of cadaveric specimens or the use of body fluids other than human serum. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients.** **Clinical Limitation: Criteria for rejection: Heat inactivated, pooled, grossly hemolyzed, obvious microbial contamination** **Clinical Information:** To assess acute or recent Hepatitis B Virus (HBV) infection or exposure. **A nonreactive test result does not exclude the possibility of exposure to or infection with HBV.**	7/10/18
Hepatitis B Surface Antigen	HBSAG	**Special Information:** Hepatitis B Surface Antigen Confirmation will be performed and billed on all initially reactive Hepatitis B Surface Antigen tests. **Not intended for use in screening blood, plasma, or tissue donors. Performance has not been established for the use of cadaveric specimens or the use of body fluids other than human serum.** **Clinical Limitation: Criteria for rejection: Heat inactivated, pooled, grossly hemolyzed, obvious microbial contamination** **Clinical Information: Current methods for the detection of hepatitis B surface antigen may not detect all potentially infected individuals. A nonreactive test result does not exclude the possibility of exposure to or infection with hepatitis B virus. A nonreactive test result in individuals with prior exposure to hepatitis B may be due to antigen levels below the detection limit of this assay or lack of antigen reactivity to the antibodies in this assay. For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and chronic infection.**	7/10/18
Hepatitis B Surface Antigen Conf	HBSAGC	**Special Information:** This test should be preceded by a positive HBsAg screening assay. **Not intended for use in screening blood, plasma, or tissue donors. Performance has not been established for the use of cadaveric specimens or the use of body fluids other than human serum.** **Clinical Limitation: Criteria for rejection: Heat inactivated, pooled, grossly hemolyzed, obvious microbial contamination** **Clinical Information:** For the confirmation of an initially reactive HBsAg screening assay. **For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and chronic infection.**	7/10/18
Hepatitis C Antibody IA	AHCV	**Special Information: Not intended for use in screening blood, plasma, or tissue donors. Assay performance characteristics have not been established for newborns, infants, children, or populations of immunocompromised or immunosuppressed patients. Performance has not been established for the use of cadaveric specimens or the use of body fluids other than human serum.** **Clinical Limitation: Criteria for rejection: Heat inactivated, pooled, grossly hemolyzed, obvious microbial contamination** **Clinical Information: For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and chronic infection. Immunocompromised patients who have Hepatitis C Virus (HCV) may produce levels of antibody below the sensitivity of this assay and may not be detected as positive.**	7/10/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis C Antibody IA w/Confirm	AHCV1B	**Special Information:** If Hepatitis C Virus (HCV) antibody is positive, will reflex to a quantitative HCV RNA. **Not intended for use in screening blood, plasma, or tissue donors. Assay performance characteristics have not been established for newborns, infants, children, or populations of immunocompromised or immunosuppressed patients. Performance has not been established for the use of cadaveric specimens or the use of body fluids other than human serum.** **Clinical Limitation: Criteria for rejection: Heat inactivated, pooled, grossly hemolyzed, obvious microbial contamination** **Clinical Information: For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and chronic infection. Immunocompromised patients who have HCV may produce levels of antibody below the sensitivity of this assay and may not be detected as positive.**	7/10/18
HIV 1 2 Combo (Antigen/Antibody)	HIV12C	**Clinical Limitation: Criteria for rejection: Heat inactivated, pooled, grossly hemolyzed, obvious microbial contamination** **Clinical Information:** Screening and initial diagnosis of HIV-1 infection. This assay is not intended for use with patients under 2 years of age. **Assay is not intended for use in screening blood or plasma donors.** Performance characteristics of this assay have not been established for the use of cadaveric specimens or body fluids other than serum or plasma (EDTA and heparin). **Days Performed: Sunday–Saturday** **Reported:** 1–3 days	7/10/18
HSV PCR, Miscellaneous Specimen Types	PCRHSV	**Specimen Requirement:** 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Separate plasma from cells and transfer into sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Separate serum from cells and transfer into sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL amniotic fluid in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen *OR* 1 mL bronchoalveolar lavage (BAL) specimen in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen *OR* Tissue in a sterile container; Freeze immediately; Specimen source required; Frozen *OR* 1 mL **ocular fluid in a sterile container;** Minimum: 0.5 mL; Specimen source required; Frozen **Stability:** Ambient: Tissue: Unacceptable; Plasma, serum, amniotic fluid, BAL, **ocular fluid:** 8 hours Refrigerated: Tissue: Unacceptable; Plasma, serum, amniotic fluid, BAL, **ocular fluid:** 72 hours Frozen: 3 months	Effective immediately
Human Epididymis Protein 4	HEP4	**Special Information:** Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Specimens containing HAMA may produce anomalous values when tested by this assay. **Clinical Limitation: Criteria for rejection: Heat inactivated, pooled, grossly hemolyzed, obvious microbial contamination, cadaver samples or body fluids other than human serum**	7/10/18
Human Erythrocyte Ag	HEA	**CPT: 0001U x 1,** G0452 x 1	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Legionella pneumophila Antibody (Types 1-6), IgG by IFA	SLEGAB	**Test Name:** Previously Legionella pneumophila, Antibody **Special Information: Contaminated, hemolyzed, or severely lipemic specimens will be rejected. 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: Seroconversion between acute and convalescent sera is considered strong evidence of recent infection. The best evidence for infection is a significant change on two appropriately timed specimens where both tests are done in the same laboratory at the same time. This assay may detect infection by any of the serotypes 1–6. The CDC and many state health laboratories recommend testing only for antibody to Legionella pneumophila Type 1. For equivocal or positive IFA results, the CDC protocol suggests follow–up testing for Legionella pneumophila antibody Type 1.** **Specimen Requirement: 1 mL** serum from a **serum separator (gold) tube;** Minimum: **0.1 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' or 'convalescent;'** Refrigerated **Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: **After separation from cells: 2 weeks** Frozen: **After separation from cells: 1 year (Avoid repeated freeze/thaw cycles)** **Methodology: Semi–Quantitative Indirect Fluorescent Antibody** **Reference Range:** **< 1:128 Negative–No significant level of Legionella pneumophila Type 1-6 IgG antibody detected** **1:128 Equivocal–Questionable presence of Legionella pneumophila Type 1-6 IgG antibody detected. Repeat testing in 10-14 days may be helpful** **≥ 1:256 Positive–Presence of Legionella pneumophila Type 1-6 IgG antibody detected, suggestive of current or past infection** **Days Performed: Monday–Friday** **Reported:** 2–5 days	9/6/18
Listeria Antibody, CSF	LISCSF	**Special Information: This test is New York DOH approved.** **Note:** *Clinical Information will be removed for this test.* **Stability:** Ambient: **Undefined** Refrigerated: **2 weeks** Frozen: **1 month** **Methodology: Semi-Quantitative** Complement Fixation **Days Performed: Varies** **Reported: 4–9** days	9/4/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Mexiletine	MEX	**Special Information:** Draw specimen prior to next dose–at steady state concentration. Please provide the following information if available: 1. Dose–List drug amount and include the units of measure 2. Route–List the route of administration (IV, oral, etc.) 3. Dose Frequency–Indicate how often the dose is administered (per day, per week, as needed, etc.) 4. Type of Draw–Indicate the type of blood draw (Peak, Trough, Random, etc.) **Unacceptable conditions: Whole blood, gel separator tubes, light blue (sodium citrate), or yellow (SPS or ACD solution) tubes. This test is New York DOH approved.** **Clinical Information: Used to optimize drug therapy and monitor patient adherence. The therapeutic range is based on serum pre-dose (trough) draw at steady-state concentration. Toxic concentrations may cause hypotension, tremor and cardiac abnormalities.** **Specimen Requirement:** 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; **Pre-dose (trough) draw–At a steady state concentration; Refer to Special Information;** Do not use serum separator tubes; Separate serum from cells within 2 hours of collection **and transfer to standard aliquot tube;** Refrigerated *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; **Pre-dose (trough) draw–At a steady state concentration; Refer to Special Information;** Do not use plasma separator tubes; Separate plasma from cells within 2 hours of collection **and transfer to standard aliquot tube;** Refrigerated **Days Performed:** Tuesday, Thursday, Saturday **Reported: 2–6** days	Effective immediately
Oxalate	OXLATE	**Test Name:** Previously Oxalate, Serum **Special Information: CRITICAL FROZEN.** Patient Prep: Patient should avoid ingestion of vitamin C for **24 hours** prior to sample collection. **Separate specimens must be submitted when multiple tests are ordered. Samples that are not plasma will be rejected. Specimens not received frozen are unacceptable. This test is New York DOH approved.** **Clinical Information: Used to assess the body pool size of oxalate** **Specimen Requirement:** 2 mL **plasma from a lithium heparin (green) tube;** Minimum: **1.5 mL; Place specimen on ice after draw; Patient should avoid ingestion of vitamin C for 24 hours prior to sample collection; Separate plasma from cells ASAP or within 1 hour of collection, transfer to standard aliquot tube,** and freeze immediately; **Separate specimens must be submitted when multiple tests are ordered; Critical Frozen** *OR* 2 mL plasma from an **EDTA (lavender) tube;** Minimum: **1.5 mL; Place specimen on ice after draw; Patient should avoid ingestion of vitamin C for 24 hours prior to sample collection; Separate plasma from cells ASAP or within 1 hour of collection, transfer to standard aliquot tube,** and freeze immediately; **Separate specimens must be submitted when multiple tests are ordered; Critical Frozen** **Stability:** Ambient: After separation from cells: Unacceptable Refrigerated: **After separation from cells: Unacceptable** Frozen: **After separation from cells: 1 week** **Methodology: Spectrophotometry** **Reference Range: ≤ 1.9 µmol/L** **Days Performed: Monday** **Reported:** 2–9 days	9/6/18
Phenytoin, Free	PHTFR	**Special Information: Do not collect in a gel separator tube.** **Specimen Requirement:** 2 mL **serum from a plain no additive (red) tube;** Minimum: 1.5 mL; **Do not collect in a gel separator tube;** Centrifuge and transfer serum to a CCL tube and refrigerate; Refrigerated **Stability:** Ambient: **After separation from cells: 7 days** Refrigerated: After separation from cells: 7 days Frozen: **After separation from cells: 14 days** **Methodology: Kinetic Interaction of Microparticles in a Solution**	8/28/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Schistosoma IgG Ab	SCHIST	**Note:** *Clinical Information has been removed for this test* **Special Information: Grossly hemolyzed or lipemic specimens are unacceptable. This test is New York DOH approved.** **Specimen Requirement: 1 mL** serum from a serum separator (gold) tube; Minimum: **0.5 mL; Transfer 1 mL serum to standard aliquot tube;** Refrigerated *OR* **1 mL** serum from a **plain no additive (red) tube;** Minimum: **0.5 mL; Transfer 1 mL serum to standard aliquot tube;** Refrigerated **Stability:** Ambient: After separation from cells: **Unacceptable** Refrigerated: After separation from cells: **1 month** Frozen: After separation from cells: **1 month** **Methodology:** Enzyme **Immunoassay (EIA)** **Reference Range: Refer to report** **Days Performed: Varies** **Reported: 4–9** days	Effective immediately
Valproic Acid, Free	VPAFR	**Special Information: Do not collect in a gel separator tube.** **Specimen Requirement:** 2 mL **serum from a plain no additive (red) tube;** Minimum: 1.5 mL; **Do not collect in a gel separator tube; Centrifuge and transfer serum to a CCL tube and refrigerate;** Refrigerated **Stability:** Ambient: **Not acceptable** Refrigerated: **After separation from cells: 5 days** Frozen: **After separation from cells: 14 days** **Methodology: Homogenous Enzyme Immunoassay (HEIA)** **Reference Range:** 0–99 Years: 4.0–**30.0 µg/mL**	8/28/18
Valproic Acid, Total and Free	VPAFT2	**Special Information: Do not collect in a gel separator tube.** **Specimen Requirement:** 3 mL **serum from a plain no additive (red) tube;** Minimum: 1.8 mL; **Do not collect in a gel separator tube; Centrifuge and transfer serum to a CCL tube and refrigerate;** Refrigerated **Stability:** Ambient: **Not acceptable** Refrigerated: **After separation from cells: 5 days** Frozen: **After separation from cells: 14 days** **Methodology: Homogenous Enzyme Immunoassay (HEIA)** **Reference Range:** Valproic Acid 0–99 Years: 50–100 µg/mL Valproic Acid, Free 0–99 Years: 4.0–**30.0 µg/mL** **Days Performed:** Sunday–Saturday **Reported: 8 hours**	8/28/18
Varicella Zoster by PCR	VZPCR	**Special Information: Specimen source is required. Heparinized specimens are unacceptable. This test is New York DOH approved.** **Specimen Requirement:** 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Specimen source is required; Frozen *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Specimen source is required; Frozen *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Specimen source is required; Frozen *OR* Tissue in a sterile container; Snap frozen; **Specimen source is required;** Frozen *OR* 1 mL ocular fluid in a sterile container; Minimum: 0.5 mL; **Specimen source is required;** Frozen	8/28/18

New Tests

Test Name	Order Code	Change	Effective Date
Acylglycines, Quantitative Analysis, Urine	UQACYL	**Includes:** Creatinine, Urine Acylglycines, Urine Interpretation Propionylglycine Isobutyrylglycine Butyrylglycine 2-Methylbutyrylglycine Tiglylglycine 3-Methylcrotonylglycine Isovalerylglycine Hexanoylglycine Phenylpropionylglycine Suberylglycine **Special Information:** Submit Patient History for Biochemical Genetics form with specimen. Clinical information is necessary for appropriate interpretation. Additional required information includes age, gender, diet (e.g., TPN therapy), drug therapy, and family history. This test is New York DOH approved. **Clinical Information:** Diagnose and monitor for fatty acid oxidation disorders and organic acidemias. Use in conjunction with urine organic acids and plasma acylcarnitines testing. **Specimen Requirement:** 6 mL random urine in a clean container; Minimum: 3 mL; Avoid dilute urine when possible; Freeze immediately; Submit Patient History for Biochemical Genetics form with specimen; Frozen **Stability:** Ambient: Unacceptable Refrigerated: 24 hours Frozen: 2 weeks **Methodology:** Liquid Chromatography–Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** Refer to report **Days Performed:** Wednesday **Reported:** 3–14 days **CPT:** 82542 x 1 **Price:** $166.00 (non-discountable)	9/11/18
Allergen, Mouse Urine Proteins IgE	MOUUR	**Note:** *This test was previously announced in the June Technical Update.* **Price:** $33.00	7/31/18
Allergen, Phoma Betae IgE	PHOMAB	**Note:** *This test was previously announced in the June Technical Update.* **Price:** $33.00	7/31/18
CD19 Count	ABS19	**Includes:** CD19% CD19 absolute number WBC **Clinical Limitation:** This test is used for CD19 positive B–cells. It is not meant for enumeration of T–cells or NK cells. **Clinical Information:** This test is used for monitoring B–cell targeted therapy. **Specimen Requirement:** 4 mL whole blood in an EDTA (lavender) tube; Draw two 2 mL EDTA tubes: one for CD19 count and one for WBC; Ambient **Stability:** Ambient: Maintain at room temperature when transporting to laboratory **Methodology:** Flow Cytometry (FC) **Clinical Reference:** CD19+ B cell% 5–22 CD19+ B cell# 75–660 No pediatric ranges for CD19 **Days Performed:** Monday–Saturday **Reported:** 1–2 days **CPT:** 85048 x 1, 86355 x 1 **Price:** $142.00 (non-discountable)	8/23/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Fat, Fecal Qualitative	FFATQL	**Special Information:** Neutral fats include the monoglycerides, diglycerides, and triglycerides while split fats are the free fatty acids that are liberated from them. Impaired synthesis or secretion of pancreatic enzymes or bile may cause an increase in neutral fats while an increase in split fats suggests impaired absorption of nutrients. **Clinical Information:** Specimens in media or preservatives will be rejected. Diapers are unacceptable. This test is New York DOH approved. **Specimen Requirement:** 5 g random stool in a clean container (No preservatives); Minimum: 1 g; Frozen **Stability:** Ambient: 1 hour Refrigerated: 2 weeks Frozen: 2 weeks **Methodology:** Microscopy Stain **Days Performed:** Sunday–Saturday **Reported:** 2–3 days **CPT:** 82705 x 1 **Price:** $32.00 (non-discountable)	8/28/18
High Sensitivity Total Testosterone	HSTSTO	**Note:** *This test was previously announced in the June Technical Update.* **Price:** $76.00	7/31/18
Myeloma Prognostic Risk Signature (MyPRS)	MYPRST	**Special Information:** For clients not sending through Cleveland Clinic main campus, please ship with ice packs using MyPRS collection kit (Quest supply #194713) via Short Stability Process via FedEx to Quest SJC. Contact the lab prior to ordering for special logistics arrangements. Do NOT freeze. Frozen or clotted specimens are not acceptable. Specimens received > 72 hours from collection will be rejected. Collect Monday–Thursday only. Note: If specimen is collected on a Friday, please mark for Saturday delivery. Do NOT collect the day before a major holiday. **Clinical Information:** Gene Expression Risk Score will be provided. Test is for patients with newly diagnosed plasma cell myeloma or myeloma patients who present with frank relapse. It is not intended to assess minimal residual disease post treatment. **Specimen Requirement:** 3–5 mL bone marrow aspirate in an EDTA (lavender) tube; Minimum: 3 mL; Contact Cleveland Clinic Laboratories prior to ordering for special logistics arrangements; Do NOT freeze; Do NOT collect the day before a major holiday; Collect ONLY Monday–Thursday; Collect 3–5 mL bone marrow aspirate with a non-heparinized syringe and transfer into EDTA lavender tube; Deliver to Cleveland Clinic Laboratories immediately on the same day of collection; For clients not sending through Cleveland Clinic main campus, please ship with ice packs using MyPRS collection kit (Quest supply #194713) via Short Stability Process via FedEx to Quest SJC; Refrigerated **Stability:** Ambient: 72 hours Refrigerated: 72 hours Frozen: Unacceptable **Methodology:** Polymerase Chain Reaction (PCR) **Days Performed:** Sunday–Saturday **Reported:** 8–11 days **CPT:** 81599 x 1 **Price:** $2300.00 (non-discountable)	7/17/18

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Allergen, Respiratory Disease Profile Region 5	RESPR5	$506.00	86003 x 22	8/28/18
FBN1 Gene Sequencing Analysis	FBN1	$1100.00 (non-discountable)	81408	Effective immediately
Giardia lamblia IgG, IgA, IgM	GIAGAM	$99.00 (non-discountable)	86674 x 3	7/31/18
M. tuberculosis Amplified, CSF	MTBCSF	$190.00 (non-discountable)	87556, 87798	8/7/18

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Acylglycines, Quantitative Urine	UACYLG	This test will no longer be available. Suggest ordering Acylglycines, Quantitative Analysis, Urine (UQACYL).	9/11/18
Brucella IgG/IgM Confirmation	BRUCON	This test will no longer be available. Suggest ordering Brucella Ab Total (BRUAGG).	8/30/18
Endocrine Auto Antibodies	ENDOAB	This test will no longer be available.	8/30/18
Fecal Fat, Qualitative	FFAT	This test will no longer be available. Suggest ordering Fat, Fecal Qualitative (FFATQL).	8/28/18
Myocardial Total Autoantibodies	MYCABG	This test will no longer be available.	7/9/18