Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • May 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
5	6-Monoacetylmorphine (6-MAM) Confirmation, Urine						■		■		■			
32	Adalimumab Activity and Neutralizing Antibody				■									
5	Alpha-1 Antitrypsin Genotyping						■	■		■		■	■	
5	Alpha 1 Antitrypsin Phenotype and Genotype							■		■		■	■	
6	Alpha Thalassemia Gene Deletion							■				■	■	
6	Amphetamine Confirmation, Urine						■		■		■			
6	ANA by IFA Screen											■		
7	Aspergillus Antibodies, Immunodiffusion						■	■	■			■	■	■
7	B-Cell Clonality Using BIOMED-2 PCR Primers							■				■	■	
7	BCR/ABL p190 RT-PCR, Quantitative							■		■		■	■	
7	BCRABL p210 RTPCR Quantitative							■				■	■	
8	BCR-ABL Qualitative Multiplex RT-PCR							■				■	■	
8	Benzodiazepines Conf, Ur						■		■		■			
9	Benzoylecgonine Confirmation/Quantitation						■		■		■			
9	BRAF Gene Analysis											■		■
9	Bromine-Total, Blood		■				■	■		■		■	■	
10	Buprenorphine Quant, Urine						■		■		■			
10	C1 Esterase Inhibitor Functional						■	■				■		
38	Cadmium, Blood					■								
32–33	Cadmium, Whole Blood				■									
33	CALR (Calreticulin) Exon 9 Mutation Analysis Marrow				■									

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
10, 38	CALR (Calreticulin) Exon 9 Mutation Blood		■				■	■	■		■	■		■
11	Cannabinoid Confirmation, Ur					■		■		■				
11	Carbohydrate Deficient Transferrin, pediatric					■	■				■	■		
12	Carotene					■	■							
12, 38	CEBPA Mutation Analysis						■		■		■	■		■
33	CEBPA Mutation Analysis Marrow			■										
34	Chikungunya Antibodies, IgG and IgM			■										
38	Chikungunya Antibodies with Reflex(es) to Titer				■									
12	Cholinesterase, RBC					■					■			
12	Chromium, Urine					■				■	■			
13	Chymotrypsin, Stool										■			
13	Cocaine Confirmation, Urine					■		■		■				
13	Colon Cancer Hotspot Panel v2 NGS										■		■	
13	Complement C 2					■	■			■		■		
14	Coxiella Burnetii IgG Abs					■	■	■	■	■	■	■		
38	Coxiella Burnetii IgM Abs				■									
34	Coxiella burnetii (Q-Fever) Antibodies, IgG and IgM, Phase I and II with Reflex to Titer			■										
38	Coxiella IgG, IgM & IgA				■									
14	Creatine, Urine					■	■							
14	Cystic Fibrosis Screen139 Variant Assay										■	■		
15	Echovirus Antibodies					■	■	■	■	■	■	■		
15	EGFR Gene Analysis										■		■	
15	Factor V Leiden						■		■		■	■		
16	Familial Mediterranean Fever, Complete						■		■		■			
16	Fentanyl and Metabolite, Urine					■		■		■				
16	FISH for Bladder Cancer with Urinary Cytology										■			
35	FLT3 Tyrosine Kinase Domain Mutation, Bone Marrow			■										
17	Fluoride					■	■		■	■	■			
38	Fluoride, Urine				■									
17	Fluoxetine/Norfluoxetine										■	■		
17	Fluvoxamine, Serum and Plasma					■	■						■	
17	Fragile X Syndrome DNA Analysis by PCR, Blood						■				■	■		
17	Glutamic Acid Decarboxylase Antibody											■		
35	Hematologic Neoplasm Next Generation Sequencing Panel Marrow			■										
35	Hematologic Neoplasm Next Generation Sequencing Panel Peripheral Blood			■										
17	Hepatitis Delta Antibody										■			
17	Heterophile Ab (Inf. Mono) LA w/Titer RFLX					■	■		■		■			
18	Hexagonal Phase Phospholipid Neutralization									■				
18	HFE (Hemochromatosis)								■		■	■		

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
18	HIV-1 Western Blot					■					■	■		
18	HTLV I/II Ab Screen					■	■					■		
19	IDH1 & IDH2 Gene Analysis										■		■	
19	IDH1 Gene Analysis										■		■	
19	IDH2 Gene Analysis										■		■	
19	Immunoglobulin Heavy Chain using Biomed-2 PCR Primers						■				■	■		
19	Immunoglobulin Kappa Chain using Biomed-2 PCR Primers						■				■	■		
35	JAK2 Exon 12-15 Mutation Detection Bone Marrow			■										
19, 38	JAK2 Exon 12-15 Sequencing Blood		■				■		■		■	■		■
20, 38	JAK2 V617F Mutation Detection Blood		■				■		■		■	■		■
36	JAK2 V617F Mutation Detection Bone Marrow			■										
20	KIT (D816V) Mutation by PCR					■	■					■		
20	KIT Gene Analysis										■		■	
20	KRAS Gene Analysis										■		■	
20	Liver Fibrosis, FibroTest-ActiTest					■	■				■			
20	Lung Cancer Hotspot Gene Panel										■		■	
21	Manganese, Urine					■				■	■			
38	Meconium Drug Screen 5				■									
21	Melanocyte Stimulation Hormone, Alpha (a-MSH)										■			
21	Melanoma Hotspot Panel v2 NGS										■		■	
21	MET Gene Analysis										■		■	
21–22	Methadone Quantitation, Urine					■		■		■				
22	MPL Mutation Analysis Blood		■			■	■				■	■		
36	MPL Mutation Analysis Marrow			■										
22	Mycophenolic Acid and Metabolite		■			■		■			■	■		
22	MYD88 L265P Mutation Analysis											■		
22	Myelin Associated Glycoprotein (MAG) Ab, IgM					■	■		■					
38	Myeloid NGS Panel				■									
36	Myeloproliferative Neoplasm Panel Marrow			■										
36	Myeloproliferative Neoplasm Panel Peripheral Blood			■										
23	Neutrophil Oxidative Burst, Blood					■	■	■	■	■		■	■	
37	NPM1 Mutation Detection Bone Marrow			■										
23	NRAS Gene Analysis										■		■	
23, 38	Nucleophosmin Gene (NPM1) Mutation						■				■	■		■
24	Opiate Confirmation, Urine					■		■		■				
24	Osmotic Fragility, Erythrocyte					■		■						
25	Ova and Parasite Examination					■								
25–26	Oxycodone Confirmation, Urine					■		■		■				

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
26	Parvovirus B-19 Antibodies											■		
26	Parvovirus B19 IgG Antibodies											■		
26	Parvovirus B19 IgM Antibodies											■		
26	Protein/Creatinine Ratio											■		
26	Prothrombin Antibody					■	■		■	■				
26	Prothrombin Gene Mutation						■		■		■	■		
27	PTT Incubated Mixing Study									■				
27–28	Quantitative Pain Panel, Urine					■		■		■				
29	Skeletal Muscle Antibodies, IgG with Reflex to Titer					■	■	■	■		■	■		
29	Strongyloides IgG Abs, Serum					■			■	■	■			
29	T-Cell Clonality Using Biomed-2 PCR Primers						■				■	■		
30	T-Cell Receptor Beta Biomed-2 PCR						■				■	■		
30	TCR-G (PCR)						■				■	■		
30, 38	Toxocara Antibodies					■	■		■		■	■		■
30	TPMT Genotype Assay						■					■		
31	Tramadol and Metabolite, Quantitation					■		■		■				
31	Vitamin D 25 Hydroxy											■		
31	West Nile Virus Antibody Panel CSF					■								

Test Changes

Test Name	Order Code	Change	Effective Date
6-Monoacetylmorphine (6-MAM) Confirmation, Urine (continued)	U6AMCO	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** 6-Acetylmorphine, Ur **Specimen Validity Specific Gravity, Urine** **Specimen Validity Creatinine, Urine** **Specimen Validity Nitrite, Urine** **Specimen Validity pH, Urine** **Specimen Validity Oxidant, Urine** **Specimen Validity Chromate, Urine** **Specimen Quality, Urine** **Special Information:** For medical purposes only; not valid for forensic use. **Specimen Validity Testing (SVT) analytes have a stability of up to 5 days at 2–8 °C as stated in the Instructions for Use (IFU). Based on the laboratory's studies, this stability is based on samples that have reached an equilibrium. Introduction of oxidants to a urine sample will not be stable until an equilibrium is achieved. Time to reach equilibrium will vary dependent on the type and amount of oxidant used as an adulterant.** **Clinical Information: For Specimen Validity Interpretations, the following rules are applied:** **Diluted: Creatinine of ≥ 2 mg/dL but < 20 mg/dL and Specific Gravity of > 1.0010 but < 1.0030** **Substituted: Creatinine of < 2 mg/dL and Specific Gravity of ≤ 1.0010 or ≥ 1.0200** **Adulterated: pH < 3.0 or ≥ 11.0, or Nitrites ≥ 500 mg/L, or Oxidants ≥ 200 mg/L, or Chromate ≥ 50 mg/L** **Reference Range:** 6-Acetylmorphine, Ur: < 5 ng/mL **Specimen Validity Specific Gravity, Urine: 1.002–1.030** **Specimen Validity Creatinine, Urine** **18–99 Years (Male): 46.8–314.5 mg/dL** **18–99 Years (Female): 42.2–237.9 mg/dL** **Specimen Validity Nitrite, Urine: ≤ 50 mg/L** **Specimen Validity pH, Urine: 4.5–8.0** **Specimen Validity Oxidant, Urine: < 200 mg/L** **Specimen Validity Chromate, Urine: < 50 mg/L**	Effective immediately
Alpha-1 Antitrypsin Genotyping	HA1AT	**Note:** *A1ADNA and A1ATPG are being added as new alias names.* **Specimen Requirement: 4 mL** whole blood in an EDTA (lavender) tube; Minimum: 1 mL; Ambient **Stability:** Ambient: **48** hours Refrigerated: **7** days Frozen: Unacceptable **Methodology:** High Resolution Melt Analysis **Real-Time Polymerase Chain Reaction (RT-PCR)** **Days Performed: 2 days** per week **Reported: 7 days**	5/1/18
Alpha 1 Antitrypsin Phenotype and Genotype	A1ATPG	**Specimen Requirement: 4 mL** whole blood in an EDTA (lavender) tube; **Ambient** *AND* 1 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Refrigerated **Stability:** Ambient: Whole Blood: **48** hours; Plasma/Serum: After separation from cells: 7 days Refrigerated: Whole Blood: **7** days; Plasma/Serum: After separation from cells: 3 months Frozen: Whole Blood: Unacceptable; Plasma/Serum: After separation from cells: 3 months **Methodology:** **Fluorescence Monitoring** High Resolution Melt Analysis **Real-Time** Polymerase Chain Reaction **(RT-PCR)** **Days Performed: 2 days** per week **Reported:** 7 days	6/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Alpha Thalassemia Gene Deletion	ATHALS	**Specimen Requirement: 4 mL** whole blood in an EDTA (lavender) tube; Minimum: **2 mL;** Ambient **Stability:** Ambient: **48** hours Refrigerated: 7 days Frozen: Unacceptable **Days Performed:** 1 day per week **Reported:** 10 days	5/1/18
Amphetamine Confirmation, Urine	UAMPC	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Amphetamine, Urine Methamphetamine, Ur **Specimen Validity pH, Urine** **Specimen Validity Specific Gravity, Urine** **Specimen Validity Creatinine, Urine** **Specimen Validity Nitrites, Urine** **Specimen Validity Oxidants, Urine** **Specimen Validity Chromate, Urine** **Specimen Validity Specimen Quality, Urine** **Special Information:** For medical purposes only; not valid for forensic use. **Specimen Validity Testing (SVT) analytes have a stability of up to 5 days at 2–8 °C as stated in the Instructions for Use (IFU). Based on the laboratory's studies, this stability is based on samples that have reached an equilibrium. Introduction of oxidants to a urine sample will not be stable until an equilibrium is achieved. Time to reach equilibrium will vary dependent on the type and amount of oxidant used as an adulterant.** **Clinical Information: For Specimen Validity Interpretations, the following rules are applied:** **Diluted: Creatinine of ≥ 2 mg/dL but < 20 mg/dL and Specific Gravity of > 1.0010 but < 1.0030** **Substituted: Creatinine of < 2 mg/dL and Specific Gravity of ≤ 1.0010 or ≥ 1.0200** **Adulterated: pH < 3.0 or ≥ 11.0, or Nitrites ≥ 500 mg/L, or Oxidants ≥ 200 mg/L, or Chromate ≥ 50 mg/L** **Reference Range:** Amphetamine, Urine: < 5 ng/mL Methamphetamine, Ur: < 8 ng/mL **Specimen Validity pH, Urine: 4.5–8.0** **Specimen Validity Specific Gravity, Urine: 1.002–1.030** **Specimen Validity Creatinine, Urine** **18–99 Years (Male): 46.8–314.5 mg/dL** **18–99 Years (Female): 42.2–237.9 mg/dL** **Specimen Validity Nitrites, Urine: ≤ 50 mg/L** **Specimen Validity Oxidants, Urine: < 200 mg/L** **Specimen Validity Chromate, Urine: < 50 mg/L**	Effective immediately
ANA by IFA Screen	ANAIFS	**Days Performed:** Monday–Friday **Reported:** 1–**4** days	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Aspergillus Antibodies, Immunodiffusion	ASPER	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** **Aspergillus spp. Abs, Precipitin** **Special Information: This test uses culture filtrates of Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger, and Aspergillus terreus. Body fluids are unacceptable. This test is New York DOH approved.** **Clinical Information: Not recommended for the diagnosis of invasive aspergillosis. In general, immunodiffusion measures IgG, and a positive result may suggest past infection. The test is positive in about 90% of sera from patients with aspergilloma and 50–70% of patients with allergic bronchopulmonary aspergillosis. A result of none detected does not exclude aspergillosis.** **Specimen Requirement: 0.5 mL** serum from a **serum separator (gold) tube;** Minimum: **0.15 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated** **Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: **After separation from cells: 2 weeks** Frozen: **After separation from cells: 1 year (Avoid repeated freeze/thaw cycles)** **Days Performed: Sunday–Friday** **Reported: 3–5** days **CPT:** 86606 **x 1**	6/26/18
B-Cell Clonality Using BIOMED-2 PCR Primers	BCBMD	**Specimen Requirement:** 10 mm square **formalin-fixed** paraffin-embedded (FFPE) tissue **block** in a clean container; Paraffin-embedded tissue should be delivered to Cleveland Clinic Laboratories for accessioning and cutting; **Ambient** *OR* 2 mL bone marrow in an EDTA (lavender) tube; **Ambient** *OR* 8 mL whole blood in an EDTA (lavender) tube; **Ambient** **Stability:** Ambient: **Whole blood–48 hours; Bone Marrow–48 hours; Paraffin-embedded tissue–indefinitely** Refrigerated: **Whole blood–7 days; Bone marrow–7 days; Paraffin-embedded tissue–unacceptable** Frozen: **Whole blood–unacceptable; Bone marrow–unacceptable; Paraffin-embedded tissue–unacceptable** **Days Performed: 2 days per week** **Reported: 7** days	6/26/18
BCR/ABL p190 RT-PCR, Quantitative	190PCR	**Specimen Requirement:** 10 mL whole blood in an EDTA (lavender) tube; Minimum: **4 mL; Ambient** *OR* 5 mL bone marrow in an EDTA (lavender) tube; Minimum: **2 mL; Ambient** **Stability:** Ambient: **48 hours** Refrigerated: **7 days** Frozen: **Unacceptable** **Methodology: Real-Time Polymerase Chain Reaction (RT-PCR)** **Days Performed: 1 day per week** **Reported: 8** days	6/26/18
BCRABL p210 RTPCR Quantitative	BCRPCR	**Specimen Requirement:** 10 mL whole blood in an EDTA (lavender) tube; Minimum: **4 mL; Ambient** *OR* 5 mL bone marrow in an EDTA (lavender) tube; Minimum: **2 mL; Ambient** **Stability:** Ambient: **48 hours** Refrigerated: **7 days** Frozen: **Unacceptable** **Days Performed: 2 days per week** **Reported:** 7 days	6/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
BCR-ABL Qualitative Multiplex RT-PCR	BCRQL	**Specimen Requirement:** 10 mL whole blood in an EDTA (lavender) tube; Minimum: 5 mL; **Ambient** *OR* 5 mL bone marrow in an EDTA (lavender) tube; Minimum: **3 mL; Ambient** **Stability:** Ambient: **48 hours** Refrigerated: **7 days** Frozen: Unacceptable **Days Performed: 3 days** per week **Reported: 5** days	6/26/18
Benzodiazepines Conf, Ur	UBENZC	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** 7-aminoclonazepam, Urine Alpha-hydroxytriazolam, Urine Oxazepam, Urine Alpha-hydroxyalprazolam, Urine Lorazepam, Urine Nordiazepam, Urine Temazepam, Urine **Specimen Validity pH, Urine** **Specimen Validity Specific Gravity, Urine** **Specimen Validity Creatinine, Urine** **Specimen Validity Nitrites, Urine** **Specimen Validity Oxidants, Urine** **Specimen Validity Chromate, Urine** **Specimen Validity Specimen Quality, Urine** **Special Information: Specimen Validity Testing (SVT) analytes have a stability of up to 5 days at 2–8 °C as stated in the Instructions for Use (IFU). Based on the laboratory's studies, this stability is based on samples that have reached an equilibrium. Introduction of oxidants to a urine sample will not be stable until an equilibrium is achieved. Time to reach equilibrium will vary dependent on the type and amount of oxidant used as an adulterant.** **Clinical Information: For Specimen Validity Interpretations, the following rules are applied:** **Diluted: Creatinine of ≥ 2 mg/dL but < 20 mg/dL and Specific Gravity of > 1.0010 but < 1.0030** **Substituted: Creatinine of < 2 mg/dL and Specific Gravity of ≤ 1.0010 or ≥ 1.0200** **Adulterated: pH < 3.0 or ≥ 11.0, or Nitrites ≥ 500 mg/L, or Oxidants ≥ 200 mg/L, or Chromate ≥ 50 mg/L** **Reference Range:** 7-aminoclonazepam, Urine 0–99 Years: < 40 ng/mL Alpha-hydroxytriazolam, Urine 0–99 Years: < 40 ng/mL Oxazepam, Urine 0–99 Years: < 40 ng/mL Alpha-hydroxyalprazolam, Urine 0–99 Years: < 60 ng/mL Lorazepam, Urine 0–99 Years: < 40 ng/mL Nordiazepam, Urine 0–99 Years: < 40 ng/mL Temazepam, Urine 0–99 Years: < 40 ng/mL **Specimen Validity pH, Urine: 4.5–8.0** **Specimen Validity Specific Gravity, Urine: 1.002–1.030** **Specimen Validity Creatinine, Urine** **18–99 Years (Male): 46.8–314.5 mg/dL** **18–99 Years (Female): 42.2–237.9 mg/dL** **Specimen Validity Nitrites, Urine: ≤ 50 mg/L** **Specimen Validity Oxidants, Urine: < 200 mg/L** **Specimen Validity Chromate, Urine: < 50 mg/L**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Benzoylecgonine Confirmation/ Quantitation	BECGO	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Benzoylecgonine, Ur **Specimen Validity pH, Urine** **Specimen Validity Specific Gravity, Urine** **Specimen Validity Creatinine, Urine** **Specimen Validity Nitrites, Urine** **Specimen Validity Oxidants, Urine** **Specimen Validity Chromate, Urine** **Specimen Validity Specimen Quality, Urine** **Special Information:** For medical purposes only; not valid for forensic use. **Specimen Validity Testing (SVT) analytes have a stability of up to 5 days at 2–8 °C as stated in the Instructions for Use (IFU). Based on the laboratory's studies, this stability is based on samples that have reached an equilibrium. Introduction of oxidants to a urine sample will not be stable until an equilibrium is achieved. Time to reach equilibrium will vary dependent on the type and amount of oxidant used as an adulterant.** **Clinical Information: For Specimen Validity Interpretations, the following rules are applied:** **Diluted: Creatinine of ≥ 2 mg/dL but < 20 mg/dL and Specific Gravity of > 1.0010 but < 1.0030** **Substituted: Creatinine of < 2 mg/dL and Specific Gravity of ≤ 1.0010 or ≥ 1.0200** **Adulterated: pH < 3.0 or ≥ 11.0, or Nitrites ≥ 500 mg/L, or Oxidants ≥ 200 mg/L, or Chromate ≥ 50 mg/L** **Reference Range:** Benzoylecgonine, Ur: < 24 ng/mL **Specimen Validity pH, Urine: 4.5–8.0** **Specimen Validity Specific Gravity, Urine: 1.002–1.030** **Specimen Validity Creatinine, Urine** **18–99 Years (Male): 46.8–314.5 mg/dL** **18–99 Years (Female): 42.2–237.9 mg/dL** **Specimen Validity Nitrites, Urine: ≤ 50 mg/L** **Specimen Validity Oxidants, Urine: < 200 mg/L** **Specimen Validity Chromate, Urine: < 50 mg/L**	Effective immediately
BRAF Gene Analysis		**Days Performed: 3 days per week** **Reported: 7 days** **CPT:** 81210 x 1, **88381 x 1,** G0452 x 1	6/4/18
Bromine-Total, Blood	BROMWB	**Test Name:** Previously Bromide, Blood **Special Information:** Exposure Monitoring. **Category: Environmental/Occupational toxin. Avoid exposure to gadolinium or iodine-based contrast media for 96 hours prior to sample collection. Do not use disinfectants containing iodine, such as Betadine®, during venipuncture. Sodium fluoride/potassium oxalate (gray) tubes and EDTA (lavender) tubes will be rejected.** **Clinical Information:** The general range of normal levels is usually **between 1.4 and 8.8 mg/L (2.5th–97.5th percentiles).** Background concentrations are diet dependent. Workers exposed to methyl bromide with blood bromide concentrations greater than **12 mg/L** have shown 3.5 times higher risk of electroencephalogram disturbances than compared to those with normal levels. Reporting limit: **0.5 mg/L** **Specimen Requirement: 2 mL** whole blood in an **EDTA (royal blue) tube;** Minimum: **0.7 mL;** Refrigerated **Stability:** Ambient: 30 days Refrigerated: 30 days Frozen: **12 months** **Methodology: ICP/Mass Spectrometry** **Days Performed: Tuesday** **Reported: 7–12** days	4/30/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Buprenorphine Quant, Urine	UQNTBU	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Buprenorphine, Ur Norbuprenorphine, Ur **Specimen Validity pH, Urine** **Specimen Validity Specific Gravity, Urine** **Specimen Validity Creatinine, Urine** **Specimen Validity Nitrite, Urine** **Specimen Validity Oxidant, Urine** **Specimen Validity Chromate, Urine** **Specimen Validity Specimen Quality, Urine** **Special Information:** For medical purposes only; not valid for forensic use. Confirmation testing is not included with this analysis. **Specimen Validity Testing (SVT) analytes have a stability of up to 5 days at 2–8 °C as stated in the Instructions for Use (IFU). Based on the laboratory's studies, this stability is based on samples that have reached an equilibrium. Introduction of oxidants to a urine sample will not be stable until an equilibrium is achieved. Time to reach equilibrium will vary dependent on the type and amount of oxidant used as an adulterant.** **Clinical Information: For Specimen Validity Interpretations, the following rules are applied:** **Diluted: Creatinine of ≥ 2 mg/dL but < 20 mg/dL and Specific Gravity of > 1.0010 but < 1.0030** **Substituted: Creatinine of < 2 mg/dL and Specific Gravity of ≤ 1.0010 or ≥ 1.0200** **Adulterated: pH < 3.0 or ≥ 11.0, or Nitrites ≥ 500 mg/L, or Oxidants ≥ 200 mg/L, or Chromate ≥ 50 mg/L** **Reference Range:** Buprenorphine, Ur 0–99 Years: < 20 ng/mL Norbuprenorphine, Ur 0–99 Years: < 20 ng/mL **Specimen Validity pH, Urine: 4.5–8.0** **Specimen Validity Specific Gravity, Urine: 1.002–1.030** **Specimen Validity Creatinine, Urine** **18–99 Years (Male): 46.8–314.5 mg/dL** **18–99 Years (Female): 42.2–237.9 mg/dL** **Specimen Validity Nitrite, Urine: ≤ 50 mg/L** **Specimen Validity Oxidant, Urine: < 200 mg/L** **Specimen Validity Chromate, Urine: < 50 mg/L**	Effective immediately
C1 Esterase Inhibitor Functional	C1EFUN	**Special Information: CRITICAL FROZEN.** Separate samples must be submitted for multiple tests. Unfrozen samples are not acceptable. **This test is New York DOH approved.** **Specimen Requirement: 0.5 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;** Freeze **immediately;** 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	5/21/18
CALR (Calreticulin) Exon 9 Mutation Blood	CALR	**For Interfaced Clients Only: Test build may need to be modified** **Test Name:** Previously CALR (Calreticulin) Exon 9 Mutation Analysis **Specimen Requirement:** 4 mL whole blood in an EDTA (lavender) tube; Minimum: 2 mL; **Ambient** **Stability:** Ambient: **48** hours Refrigerated: **7** days Frozen: Unacceptable **Methodology: Next Generation DNA Sequencing** **Days Performed: Twice** per week **Reported:** 7 days	6/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cannabinoid Confirmation, Ur	UTHCC	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Cannabinoid, Urine **Specimen Validity pH, Urine** **Specimen Validity Specific Gravity, Urine** **Specimen Validity Creatinine, Urine** **Specimen Validity Nitrites, Urine** **Specimen Validity Oxidants, Urine** **Specimen Validity Chromate, Urine** **Specimen Validity Specimen Quality, Urine** **Special Information:** For medical purposes only; not valid for forensic use. **Specimen Validity Testing (SVT) analytes have a stability of up to 5 days at 2–8 °C as stated in the instructions for Use (IFU). Based on the laboratory's studies, this stability is based on samples that have reached an equilibrium. Introduction of oxidants to a urine sample will not be stable until an equilibrium is achieved. Time to reach equilibrium will vary dependent on the type and amount of oxidant used as an adulterant.** **Clinical Information: For Specimen Validity Interpretations, the following rules are applied:** **Diluted: Creatinine of ≥ 2 mg/dL but < 20 mg/dL and Specific Gravity of > 1.0010 but < 1.0030** **Substituted: Creatinine of < 2 mg/dL and Specific Gravity of ≤ 1.0010 or ≥ 1.0200** **Adulterated: pH < 3.0 or ≥ 11.0, or Nitrites ≥ 500 mg/L, or Oxidants ≥ 200 mg/L, or Chromate ≥ 50 mg/L** **Reference Range:** Cannabinoid, Urine: < 16 ng/mL **Specimen Validity pH, Urine: 4.5–8.0** **Specimen Validity Specific Gravity, Urine: 1.002–1.030** **Specimen Validity Creatinine, Urine** **18–99 Years (Male): 46.8–314.5 mg/dL** **18–99 Years (Female): 42.2–237.9 mg/dL** **Specimen Validity Nitrites, Urine: ≤ 50 mg/L** **Specimen Validity Oxidants, Urine: < 200 mg/L** **Specimen Validity Chromate, Urine: < 50 mg/L**	Effective immediately
Carbohydrate Deficient Transferrin, pediatric	CDTRAP	**Special Information: Patient's age and reason for referral are required. Must submit Biochemical Genetics Patient Information form with the specimen. Grossly hemolyzed specimens will be rejected.** This test is for congenital disorders of glycosylation. If looking for evaluation of alcohol abuse, please order Carbohydrate Deficient Transferrin (CDTRAN). **This test is New York State approved. Informed consent is required for New York clients.** **Specimen Requirement:** 0.1 mL serum from a **plain no additive (red) tube;** Minimum: 0.05 mL; **Must submit Biochemical Genetics Patient Information form with the specimen;** Patient age is required; **Centrifuge and transfer serum into standard plastic aliquot tube;** Frozen *OR* 0.1 mL serum from a **serum separator (gold) tube;** Minimum: 0.05 mL; **Must submit Biochemical Genetics Patient Information form with the specimen;** Patient age is required; **Centrifuge and transfer serum into standard plastic aliquot tube;** Frozen **Stability:** Ambient: **7 days** Refrigerated: **28 days** Frozen: **45 days** **Days Performed:** Monday, Thursday **Reported:** 6–**11** days	5/1/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Carotene	CAROT	**Special Information:** Patient Preparation: 12 hour fast prior to collection is preferred, but not required. **CRITICAL:** Protect from light during collection, storage, and shipment, and use amber transport tubes. Separate specimens must be submitted when multiple tests are ordered. Unacceptable conditions: Any specimen other than serum, hemolyzed or icteric specimens. This test is New York DOH approved. **Specimen Requirement: 3 mL** serum from a serum separator (gold) tube; Minimum: 0.6 mL; **CRITICAL:** Protect specimen from light during collection, storage and shipment; **Transfer 3 mL serum** into amber transport tube; Separate specimens MUST be submitted when multiple tests are ordered; **Draw 2 tubes to ensure adequate volume;** Frozen	5/21/18
CEBPA Mutation Analysis	CEBPA	**Specimen Requirement: 4 mL** whole blood in an EDTA (lavender) tube; Minimum: **2 mL;** Ambient **Stability:** Ambient: **48** hours Refrigerated: **7** days Frozen: Unacceptable **Methodology: Next Generation DNA** Sequencing **Days Performed: 2 days per week** **Reported:** 10 days	6/26/18
Cholinesterase, RBC	CHORBC	**Special Information:** DO NOT FREEZE. Frozen, clotted or hemolyzed specimens are unacceptable. **Sodium or lithium heparin (green) tubes will be rejected. This test is New York DOH approved.** **Clinical Information: This is an acceptable test for determining chronic exposure to organophosphate insecticides.** **Days Performed:** Monday–Friday **Reported:** 2–**5** days	Effective immediately
Chromium, Urine	UCHRO	**Special Information:** Diet, medication and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, nonessential over-the-counter medications (upon the advice of their physician). High concentrations of iodine may interfere with elemental testing. Collection of urine specimens from patients receiving iodinated or gadolinium (Gd)-based contrast media should be avoided for a **minimum of 72 hours post-exposure. Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post contrast media exposure.** ARUP studies indicate that refrigeration of urine alone, during and after collection, preserves specimens adequately, if tested within 14 days of collection. Urine collected within **72 hours** after administration of **iodinated or** gadolinium (Gd)-based contrast media and acid preserved samples are unacceptable. Specimens contaminated with blood or fecal material are not acceptable. Specimens transported in non-trace element-free transport tubes (with the exception of the original device) are unacceptable. Include total volume and collection interval with specimen. This test is New York DOH approved. **Reference Range:** Chromium, urine–per volume: 0.0–**2.0 µg/L** Chromium, urine (24 hrs): 0.0–**2.0 µg/d** Chromium, Urine ratio to CRT: 0.0–**10.0 µg/g crt** Creatinine, Urine–per 24 h Male 3–8 Years: 140–700 mg/d 9–12 Years: 300–1300 mg/d 13–17 Years: 500–2300 mg/d 18–50 Years: 1000–2500 mg/d 51–80 Years: 800–2100 mg/d 81 Years and older: 600–2000 mg/d Female 3–8 Years: 140–700 mg/d 9–12 Years: 300–1300 mg/d 13–17 Years: 400–1600 mg/d 18–50 Years: 700–1600 mg/d 51–80 Years: 500–1400 mg/d 81 Years and older: 400–1300 mg/d **Days Performed: Sunday**–Saturday **Reported:** 2–**4** days	5/21/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Chymotrypsin, Stool	CHYMO	**Days Performed: Wednesday** **Reported: 4–12** days	Effective immediately
Cocaine Confirmation, Urine	UCOCC	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Benzoylecgonine, Ur **Specimen Validity pH, Urine** **Specimen Validity Specific Gravity, Urine** **Specimen Validity Creatinine, Urine** **Specimen Validity Nitrites, Urine** **Specimen Validity Oxidants, Urine** **Specimen Validity Chromate, Urine** **Specimen Validity Specimen Quality, Urine** **Special Information:** For medical purposes only; not valid for forensic use. **Specimen Validity Testing (SVT) analytes have a stability of up to 5 days at 2–8 °C as stated in the Instructions for Use (IFU). Based on the laboratory's studies, this stability is based on samples that have reached an equilibrium. Introduction of oxidants to a urine sample will not be stable until an equilibrium is achieved. Time to reach equilibrium will vary dependent on the type and amount of oxidant used as an adulterant.** **Clinical Information: For Specimen Validity Interpretations, the following rules are applied:** **Diluted: Creatinine of ≥ 2 mg/dL but < 20 mg/dL and Specific Gravity of > 1.0010 but < 1.0030** **Substituted: Creatinine of < 2 mg/dL and Specific Gravity of ≤ 1.0010 or ≥ 1.0200** **Adulterated: pH < 3.0 or ≥ 11.0, or Nitrites ≥ 500 mg/L, or Oxidants ≥ 200 mg/L, or Chromate ≥ 50 mg/L** **Reference Range:** Benzoylecgonine, Ur: < 24 ng/mL **Specimen Validity pH, Urine: 4.5–8.0** **Specimen Validity Specific Gravity, Urine: 1.002–1.030** **Specimen Validity Creatinine, Urine** **18–99 Years (Male): 46.8–314.5 mg/dL** **18–99 Years (Female): 42.2–237.9 mg/dL** **Specimen Validity Nitrites, Urine: ≤ 50 mg/L** **Specimen Validity Oxidants, Urine: < 200 mg/L** **Specimen Validity Chromate, Urine: < 50 mg/L**	Effective immediately
Colon Cancer Hotspot Panel v2 NGS		**Days Performed: 3 days per week** **Reported: 7** days **CPT:** 81210 x 1, 81275 x 1, 81276 x 1, 81311 x 1, **88381 x 1,** G0452 x 1	6/4/18
Complement C 2	COMPC2	**Special Information:** Unacceptable Conditions: Samples left to clot at 2–8 °C, samples subjected to repeated freeze/thaw cycles, or non-frozen samples. **This test is New York DOH approved.** **Clinical Information:** Decreased C2 levels may be associated with increased susceptibility to infection, systemic lupus erythematosus-like disease, rashes, arthritis, nephritis and with C1-Esterase deficiency. Increased C2 levels are associated with the acute phase response. **This is a follow-up test for complement activity screening when CH50 is low or absent and AH50 is normal and high suspicion remains for complement deficiency.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Allow specimen to clot for one hour at ambient temperature; Then separate serum from cells ASAP **or within 2 hours of collection and transfer into standard aliquot tube;** Freeze **immediately;** 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 **Reference Range: 1.6**–4.0 **mg/dL**	5/21/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Coxiella Burnetii IgG Abs	COXIGG	**For Interfaced Clients Only: Test build may need to be modified** **Note:** *C. burnetii Ab IgG, Phase I and II with Reflex to Titer has been added as an alias name.* **Special Information: Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. If either C. Burnetii Abs IgG Phase I and/or Phase II result is indeterminate or positive, then titer(s) will be added at an additional cost. Contaminated, hemolyzed, or severely lipemic specimens are unacceptable. This test is New York DOH approved.** **Clinical Information: Useful to confirm infectious agent as C. burnetii** (Q-fever) **in symptomatic patients. Testing of acute and convalescent sera is recommended. Single phase II IgG titers of 1:256 and greater are considered evidence of C. burnetii infection at some time prior to the date of the serum specimen. Phase I antibody titers of 1:16 and greater are consistent with chronic infection or convalescent phase of Q-fever.** **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' and '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:** IgG Phase 1: **Negative** IgG Phase 2: **Negative** **Days Performed: Monday,** Wednesday, **Friday** **Reported:** 2–**7** days	6/26/18
Creatine, Urine	UCRT24	**Special Information:** Indicate total volume on requisition. For random or timed specimens other than 24 hours, the result represents the total milligrams of creatine excreted during the collection period. Reference ranges for creatine have been established for random urine collections, in mmol/mol creatinine. **Specimens exposed to more than one freeze/thaw cycle are unacceptable. This test is New York DOH approved.** **Specimen Requirement:** 2 mL random urine in a clean container; Minimum: 0.5 mL; Freeze immediately; Frozen *OR* 2 mL 24-hour urine (well-mixed) in a clean container; Minimum: 0.5 mL; **Refrigerate during collection; Mix well and transfer 2 mL urine into standard aliquot tube;** Freeze immediately; Frozen	Effective immediately
Cystic Fibrosis Screen139 Variant Assay	CFNGS	**Stability:** Ambient: **48** hours Refrigerated: **7** days Frozen: Unacceptable **Days Performed: 1 day per week** **Reported:** 10 days	5/1/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Echovirus Antibodies	ECHOV	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** **Echovirus Type 6 Ab** Echovirus Type 7 Ab Echovirus Type 9 Ab Echovirus Type 11 Ab Echovirus Type 30 Ab **Special Information: Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of acute specimens. Plasma is unacceptable. This test is New York DOH approved.** **Clinical Information: This test detects neutralizing antibodies to echovirus types 6,** 7, 9, 11, and 30. **Single positive antibody titers of ≥ 1:80 may indicate past or current infection. Seroconversion or an increase in titers** between acute and convalescent sera of at least fourfold **is considered strong evidence of current or recent infection.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of acute specimens; Label samples plainly as 'acute' or 'convalescent;' Separate serum from cells within 2 hours of collection and transfer into sterile aliquot tube;** Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: **0.3 mL; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of acute specimens; Label samples plainly as 'acute' or 'convalescent;' Separate serum from cells within 2 hours of collection and transfer into sterile aliquot tube;** Refrigerated *OR* 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: **0.3 mL; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of acute specimens; Label samples plainly as 'acute' or 'convalescent;'** Refrigerated **Stability:** Ambient: **48 hours** Refrigerated: 2 weeks Frozen: **1 year (Avoid repeated freeze/thaw cycles)** **Methodology: Serum Neutralization Assay** **Reference Range:** **Echovirus Type 6 Ab: < 1:10** Echovirus Type 7 Ab: **< 1:10** Echovirus Type 9 Ab: **< 1:10** Echovirus Type 11 Ab: **< 1:10** Echovirus Type 30 Ab: **< 1:10** **Days Performed:** Monday–Friday **Reported: 7**–10 days	6/28/18
EGFR Gene Analysis		**Days Performed: 3 days per week** **Reported: 7 days** **CPT:** 81235 x 1, **88381 x 1,** G0452 x 1 (Client Bill Only)	6/4/18
Factor V Leiden	FVLEI	**Specimen Requirement:** 4 mL whole blood in an EDTA (lavender) tube; Minimum: **1 mL; Ambient** **Stability:** Ambient: **48 hours** Refrigerated: **7** days Frozen: **Unacceptable** **Methodology:** **High Resolution Melt Analysis** **Real-Time** Polymerase Chain Reaction **(RT-PCR)** **Days Performed: 2 days per week** **Reported: 5** days	5/1/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Familial Mediterranean Fever, Complete	FAMMED	**Specimen Requirement: 5 mL** whole blood in an EDTA (lavender) tube; **Collection of 2–5 mL is preferred;** Minimum: 1 mL; Also include reason for testing; Ambient *OR* Buccal swab; Please include reason for testing; Ambient **Methodology: Capillary Sequencing** **Days Performed:** Monday–**Saturday** **Reported: 23–24 days**	5/1/18
Fentanyl and Metabolite, Urine	UFENT	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Fentanyl, Urine Norfentanyl, Urine **Specimen Validity pH, Urine** **Specimen Validity Specific Gravity, Urine** **Specimen Validity Creatinine, Urine** **Specimen Validity Nitrite, Urine** **Specimen Validity Oxidant, Urine** **Specimen Validity Chromate, Urine** **Specimen Validity Specimen Quality, Urine** **Special Information:** For medical purposes only; not valid for forensic use. Confirmation testing is not included with this analysis. **Specimen Validity Testing (SVT) analytes have a stability of up to 5 days at 2–8 °C as stated in the Instructions for Use (IFU). Based on the laboratory's studies, this stability is based on samples that have reached an equilibrium. Introduction of oxidants to a urine sample will not be stable until an equilibrium is achieved. Time to reach equilibrium will vary dependent on the type and amount of oxidant used as an adulterant.** **Clinical Information: For Specimen Validity Interpretations, the following rules are applied:** **Diluted: Creatinine of ≥ 2 mg/dL but < 20 mg/dL and Specific Gravity of > 1.0010 but < 1.0030** **Substituted: Creatinine of < 2 mg/dL and Specific Gravity of ≤ 1.0010 or ≥ 1.0200** **Adulterated: pH < 3.0 or ≥ 11.0, or Nitrites ≥ 500 mg/L, or Oxidants ≥ 200 mg/L, or Chromate ≥ 50 mg/L** **Reference Range:** Fentanyl, Urine: < 6 ng/mL Norfentanyl, Urine: < 6 ng/mL **Specimen Validity pH, Urine: 4.5–8.0** **Specimen Validity Specific Gravity, Urine: 1.002–1.030** **Specimen Validity Creatinine, Urine** **18–99 Years (Male): 46.8–314.5 mg/dL** **18–99 Years (Female): 42.2–237.9 mg/dL** **Specimen Validity Nitrite, Urine: ≤ 50 mg/L** **Specimen Validity Oxidant, Urine: < 200 mg/L** **Specimen Validity Chromate, Urine: < 50 mg/L**	Effective immediately
FISH for Bladder Cancer with Urinary Cytology		**Days Performed:** Tuesday, Thursday **Reported: 7** days	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Fluoride	BFLUOR	**Special Information: Sodium fluoride/potassium oxalate (gray) tubes are unacceptable. Polymer gel separation tubes (SST or PST) will be rejected.** **Clinical Information:** Overexposure/Poisoning Determination. The reference range is dependent on level of water fluoridation and its consumption. **Reporting limit: 0.05 mg/L** **Specimen Requirement: 2 mL** plasma from an EDTA (lavender) tube; Minimum: **0.6 mL;** Promptly centrifuge and transfer plasma into a **plastic screw-capped vial;** Do not use plasma separator tubes; Refrigerated *OR* **2 mL** serum from a plain no additive (red) tube; Minimum: **0.6 mL;** Promptly centrifuge and transfer serum into a **plastic screw-capped vial;** Do not use serum separator tubes; Refrigerated **Methodology: Ion Selective Electrode (ISE)** **Reference Range: Generally < 0.13 mg/L** **Days Performed:** Wednesday **Reported: 4–9** days	4/30/18
Fluoxetine/ Norfluoxetine	FLUOX	**Stability:** Ambient: **2 weeks** Refrigerated: 2 weeks Frozen: **9** months **Days Performed:** Varies **Reported: 4–11** days	5/21/18
Fluvoxamine, Serum and Plasma	FLUVOX	**Special Information: Separator tubes are unacceptable. This test is New York DOH approved.** **Specimen Requirement:** 3 mL serum from a plain no additive (red) tube; Minimum: **1.2 mL;** Do not use serum separator tubes; **Transfer serum into standard aliquot tube;** Refrigerated *OR* 3 mL plasma from an EDTA (lavender) tube; Minimum: **1.2 mL;** Do not use plasma separator tubes; **Transfer plasma into standard aliquot tube;** Refrigerated **CPT: 80332 x 1, (G0480, if appropriate)**	5/1/18
Fragile X Syndrome DNA Analysis by PCR, Blood	FRAX	**Specimen Requirement: 4 mL** blood in an EDTA (lavender) tube; Minimum: **1 mL;** Ambient **Stability:** Ambient: **48** hours Refrigerated: **7** days Frozen: Unacceptable **Days Performed:** 1 day per week **Reported:** 7 days	5/1/18
Glutamic Acid Decarboxylase Antibody	GADCAB	**Stability:** Ambient: 24 hours Refrigerated: **7** days Frozen: **14 days**	5/29/18
Hepatitis Delta Antibody	AHD	**Days Performed: Monday, Wednesday,** Friday **Reported:** 2–6 days	5/21/18
Heterophile Ab (Inf. Mono) LA w/Titer RFLX	HETAB	**Special Information:** If Heterophile Antibody is detected, then a titer will be added. Additional charges apply. **Cerebrospinal fluid (CSF) is unacceptable. This test is New York DOH approved.** **Clinical Information: This test may be used as an initial serologic test to detect acute Epstein-Barr virus infectious mononucleosis.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.15 mL;** Separate serum from cells ASAP or within 2 hours of collection **and transfer into standard aliquot tube;** Refrigerated *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: **0.15 mL;** Separate plasma from cells ASAP or within 2 hours of collection **and transfer into standard aliquot tube;** Refrigerated **Methodology:** Latex Agglutination (LA) **Days Performed: Tuesday, Thursday,** Saturday **Reported:** 2–**5** days	5/3/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hexagonal Phase Phospholipid Neutralization	STACLT	**Reference Range:** Hexagonal Phase Screen 0–99 Years: **45.0–59.9 sec** Hexagonal Phase Confirm 0–99 Years: **41.8–54.9 sec** Hexagonal Phase Delta 0–99 Years: **< 9.1**	Effective immediately
HFE (Hemochromatosis)	HEMDNA	**Stability:** Ambient: **48** hours Refrigerated: **7** days Frozen: Unacceptable **Methodology:** **Fluorescence Monitoring** High Resolution Melt Analysis **Real-Time** Polymerase Chain Reaction **(RT-PCR)** **Days Performed: 1 day per week** **Reported:** 7 days	5/1/18
HIV-1 Western Blot	HIV1CO	**Special Information:** Order this assay only when a specimen is repeatedly reactive for HIV 1 or HIV 1-2 antibodies. **Hemolyzed or lipemic specimens are unacceptable. This test is New York DOH approved.** **Stability:** Ambient: **After separation from cells:** Up to 1 week is acceptable, but not preferred Refrigerated: After separation from cells: 1 week Frozen: After separation from cells: Indefinitely (Avoid repeated freeze/thaw cycles) **Days Performed: Varies** **Reported:** 2–4 days	5/21/18
HTLV I/II Ab Screen	HTLVSC	**Special Information: Specimens containing particulate matter are unacceptable. This assay should not be used for blood donor screening, associated re-entry protocols, or for screening Human Cell, Tissues and Cellular and Tissue-Based Products (HCT/P). This test is New York DOH approved.** **Clinical Information:** Screening and initial diagnosis of HTLVI/II infection. If **repeatedly** reactive, confirmation by Western Blot will be performed at an additional cost. **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Separate serum from cells ASAP or within 2 hours of collection **and transfer into standard aliquot tube;** Centrifuge, aliquot and refrigerate ASAP *OR* 0.5 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Separate plasma from cells ASAP or within 2 hours of collection **and transfer into standard aliquot tube;** Centrifuge, aliquot and refrigerate ASAP *OR* 0.5 mL plasma from a **sodium citrate (light blue) tube;** Minimum: 0.5 mL; Separate plasma from cells ASAP or within 2 hours of collection **and transfer into standard aliquot tube;** Centrifuge, aliquot and refrigerate ASAP *OR* 0.5 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 0.5 mL; Separate plasma from cells ASAP or within 2 hours of collection **and transfer into standard aliquot tube;** Centrifuge, aliquot and refrigerate ASAP **Stability:** Ambient: **After separation from cells:** Unacceptable Refrigerated: After separation from cells: 1 week Frozen: After separation from cells: Indefinitely **(Avoid repeated freeze/thaw cycles)**	6/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
IDH1 & IDH2 Gene Analysis		**Days Performed: 3 days** per week **Reported: 7** days **CPT:** 81120 x 1, 81121 x 1, **88381 x 1,** G0452 x 1	6/4/18
IDH1 Gene Analysis		**Days Performed: 3 days** per week **Reported: 7** days **CPT:** 81120 x 1, **88381 x 1,** G0452 x 1 (Client Bill Only)	6/4/18
IDH2 Gene Analysis		**Days Performed: 3 days** per week **Reported: 7** days **CPT:** 81121 x 1, **88381 x 1,** G0452 x 1 (Client Bill Only)	6/4/18
Immunoglobulin Heavy Chain using Biomed-2 PCR Primers	IGHPCR	**Specimen Requirement:** 10 mm square **formalin-fixed** paraffin-embedded (FFPE) tissue **block** in a clean container; Paraffin-embedded tissue should be delivered to Cleveland Clinic Laboratories for accessioning and cutting; **Ambient** *OR* 2 mL bone marrow in an EDTA (lavender) tube; **Ambient** *OR* 8 mL whole blood in an EDTA (lavender) tube; **Ambient** *OR* 6 μg extracted DNA in an EDTA (lavender) tube; **Ambient** **Stability:** Ambient: **Whole blood–48 hours; Bone Marrow–48 hours; Paraffin-embedded tissue–indefinitely; Extracted DNA–24 hours** Refrigerated: **Whole blood–7 days; Bone marrow–7 days; Paraffin-embedded tissue–unacceptable; Extracted DNA–3 years** Frozen: **Whole blood–unacceptable; Bone marrow–unacceptable; Paraffin-embedded tissue–unacceptable; Extracted DNA–unacceptable** **Days Performed: 2 days per week** **Reported: 7** days	5/1/18
Immunoglobulin Kappa Chain using Biomed-2 PCR Primers	IGKPCR	**Specimen Requirement:** 10 mm square **formalin-fixed** paraffin-embedded (FFPE) tissue **block** in a clean container; Paraffin-embedded tissue should be delivered to Cleveland Clinic Laboratories for accessioning and cutting; **Ambient** *OR* 2 mL bone marrow in an EDTA (lavender) tube; **Ambient** *OR* 8 mL whole blood in an EDTA (lavender) tube; **Ambient** *OR* 6 μg extracted DNA in a clean container; **Ambient** **Stability:** Ambient: **Whole blood–48 hours; Bone Marrow–48 hours; Paraffin-embedded tissue–indefinitely; Extracted DNA–24 hours** Refrigerated: **Whole blood–7 days; Bone marrow–7 days; Paraffin-embedded tissue–unacceptable; Extracted DNA–3 years** Frozen: **Whole blood–unacceptable; Bone marrow–unacceptable; Paraffin-embedded tissue–unacceptable; Extracted DNA–unacceptable** **Days Performed: 2 days per week** **Reported: 7** days	5/1/18
JAK2 Exon 12-15 Sequencing Blood	JAKNON	**Test Name:** Previously JAK2 Exon 12-15 Sequencing **Specimen Requirement:** 8 mL whole blood in an EDTA (lavender) tube; Minimum: **3 mL; Ambient** **Stability:** Ambient: **48 hours** Refrigerated: **7 days** Frozen: Unacceptable **Methodology: Next Generation DNA Sequencing** **Days Performed: 2 days** per week **Reported:** 10 days	6/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
JAK2 V617F Mutation Detection Blood	JAK2	**Test Name:** Previously JAK2 V617F Mutation Detection **Specimen Requirement:** 4 mL whole blood in an EDTA (lavender) tube; Refrigerated **Stability:** Ambient: **48** hours Refrigerated: **Refrigerated for up to 7 days** Frozen: Unacceptable **Methodology:** Next Gen Sequencing **Next Generation DNA Sequencing** **Days Performed: 2 days per week** **Reported: 5** days	6/26/18
KIT (D816V) Mutation by PCR	KIT816	**Special Information:** DNA isolation is performed Sunday–Saturday. **Fresh frozen paraffin-embedded (FFPE) tumor tissue and fresh tissue are unacceptable.** Grossly hemolyzed, frozen or clotted specimens will be rejected. **Specimen Requirement:** 5 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; Refrigerated *OR* 3 mL bone marrow in an EDTA (lavender) tube; Minimum: 1 mL; Refrigerated **Stability:** Ambient: 24 hours for whole blood or bone marrow Refrigerated: 5 days for whole blood or bone marrow Frozen: Unacceptable for whole blood or bone marrow	5/21/18
KIT Gene Analysis		**Days Performed: 3 days per week** **Reported: 7 days** **CPT:** 81272 x 1, **88381 x 1,** G0452 x 1 (Client Bill Only)	6/4/18
KRAS Gene Analysis		**Days Performed: 3 days per week** **Reported: 7 days** **CPT:** 81275 x 1, 81276 x 1, **88381 x 1,** G0452 x 1 (Client Bill Only)	6/4/18
Liver Fibrosis, FibroTest-ActiTest	LIVFIB	**Special Information:** Avoid freeze/thaw cycles of specimen. **Overnight fasting is preferred. Grossly hemolyzed and grossly lipemic specimens will be rejected. Specimens from patients less than 2 years old are unacceptable. Additionally, specimens QNS for one or more analytes will not be accepted.** **Specimen Requirement:** 3.5 mL serum from a serum separator (gold) tube; Minimum: 2 mL; Overnight fasting is preferred; Remove serum from cells ASAP **after visible clot formation (usually 15-30 minutes after collection), and transfer into standard aliquot tube; Avoid freezing and thawing;** Frozen *OR* 3.5 mL serum from a plain no additive (red) tube; Minimum: 2 mL; Overnight fasting is preferred; Remove serum from cells ASAP **after visible clot formation (usually 15-30 minutes after collection), and transfer into standard aliquot tube; Avoid freezing and thawing;** Frozen **Days Performed: Monday**–Saturday **Reported: 2**–5 days	4/26/18
Lung Cancer Hotspot Gene Panel	LNG550	**Days Performed: 3 days** per week **Reported: 7** days **CPT:** 81445 x 1, **88381 x 1,** G0452 x 1	6/1/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Manganese, Urine	UMANG	**Special Information:** Collection volume MUST be indicated. Diet, medication and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals and nonessential over-the-counter medications (upon the advice of their physician). High concentrations of iodine may interfere with elemental testing. Collection of urine specimens from patients receiving iodinated or gadolinium (Gd)-based contrast media should be avoided for a **minimum of 72 hours post-exposure. Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post contrast media exposure.** ARUP studies indicate that refrigeration of urine alone, during and after collection, preserves specimens adequately, if tested within 14 days of collection. Urine collected within **72 hours** after administration of **iodinated or** gadolinium (Gd)-based contrast media and acid preserved samples are unacceptable. Specimens contaminated with blood or fecal material and specimens transported in a non-trace element free transport tube (with the exception of the original device) are also unacceptable. This test is New York DOH approved. **Reference Range:** Manganese, Urine–ratio to CRT: 0.0–**5.0 µg/g crt** Manganese, Urine–per volume: 0.0–**5.0 µg/L** Manganese, Urine–per 24h: 0.0–**5.0 µg/d** Creatinine mg/day: Refer to report **Days Performed:** Sunday–Saturday **Reported:** 2–**4** days	5/21/18
Melanocyte Stimulation Hormone, Alpha (a-MSH)	MSHA	**Days Performed:** Varies **Reported: 8–15** days	Effective immediately
Melanoma Hotspot Panel v2 NGS		**Days Performed: 3 days per week** **Reported: 7** days **CPT:** 81210 x 1, 81272 x 1, 81311 x 1, **88381 x 1,** G0452 x 1	6/4/18
MET Gene Analysis		**Days Performed: 3 days per week** **Reported: 7 days** **CPT:** 81479 x 1, **88381 x 1,** G0452 x 1	6/4/18
Methadone Quantitation, Urine	UQMET	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Methadone, Urine EDDP, Urine **Specimen Validity pH, Urine** **Specimen Validity Specific Gravity, Urine** **Specimen Validity Creatinine, Urine** **Specimen Validity Nitrite, Urine** **Specimen Validity Oxidant, Urine** **Specimen Validity Chromate, Urine** **Specimen Quality, Urine** **Special Information:** For medical purposes only; not valid for forensic use. **Specimen Validity Testing (SVT) analytes have a stability of up to 5 days at 2–8 °C as stated in the Instructions for Use (IFU). Based on the laboratory's studies, this stability is based on samples that have reached an equilibrium. Introduction of oxidants to a urine sample will not be stable until an equilibrium is achieved. Time to reach equilibrium will vary dependent on the type and amount of oxidant used as an adulterant.** **Clinical Information: For Specimen Validity Interpretations, the following rules are applied:** **Diluted: Creatinine of ≥ 2 mg/dL but < 20 mg/dL and Specific Gravity of > 1.0010 but < 1.0030** **Substituted: Creatinine of < 2 mg/dL and Specific Gravity of ≤ 1.0010 or ≥ 1.0200** *(continued on page 22)*	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Methadone Quantitation, Urine *(continued from page 21)*		**Adulterated: pH < 3.0 or ≥ 11.0, or Nitrites ≥ 500 mg/L, or Oxidants ≥ 200 mg/L, or Chromate ≥ 50 mg/L** **Reference Range:** Methadone, Urine: < 16 ng/mL EDDP, Urine: < 6 ng/mL **Specimen Validity pH, Urine: 4.5–8.0** **Specimen Validity Specific Gravity, Urine: 1.002–1.030** **Specimen Validity Creatinine, Urine** **18–99 Years (Male): 46.8–314.5 mg/dL** **18–99 Years (Female): 42.2–237.9 mg/dL** **Specimen Validity Nitrite, Urine: ≤ 50 mg/L** **Specimen Validity Oxidant, Urine: < 200 mg/L** **Specimen Validity Chromate, Urine: < 50 mg/L**	
MPL Mutation Analysis Blood	MPL	**Test Name:** Previously MPL Mutation Analysis **Clinical Information: MPL mutation testing is useful in the workup of suspected myeloproliferative neoplasms, especially those that are negative for JAK2 V617F.** **Specimen Requirement:** 4 mL whole blood in an EDTA (lavender) tube; **Ambient** **Stability:** Ambient: **48** hours Refrigerated: **7** days Frozen: Unacceptable **Days Performed: 2 days** per week **Reported:** 7 days	6/26/18
Mycophenolic Acid and Metabolite	MYCMET	**Test Name:** Previously Mycophenolic Acid and Metabolites **For Interfaced Clients Only: Test build may need to be modified** **Includes:** Mycophenolic Acid Mycophenolic Acid Glucuronide **Special Information:** Timing of specimen collection: Pre-dose (trough) draw at steady state concentration. **Gel separator tubes, light blue (citrate), or yellow (SPS or ACD solution) are unacceptable. Whole blood will also be rejected. This test is New York DOH approved.** **Stability:** Ambient: **After separation from cells:** 6 weeks Refrigerated: **After separation from cells:** 6 weeks Frozen: **After separation from cells:** 11 months **Days Performed:** Sunday–Saturday **Reported:** 2–**3** days	5/7/18
MYD88 L265P Mutation Analysis	MYD88	**Stability:** Ambient: Blood/bone marrow: **48** hours; Formalin-fixed paraffin embedded tissue/bone marrow clot: Indefinitely Refrigerated: Blood/bone marrow: 7 days; Formalin-fixed paraffin embedded tissue/bone marrow clot: Indefinitely Frozen: Blood/bone marrow: Unacceptable; Formalin-fixed paraffin embedded tissue/bone marrow clot: Indefinitely	5/1/18
Myelin Associated Glycoprotein (MAG) Ab, IgM	MAGIGM	**Special Information: Hemolyzed, severely lipemic, contaminated or heat-inactivated specimens are unacceptable. Urine will be rejected. This test is New York DOH approved.** **Clinical Information: This is a stand-alone test for autoimmune neuropathies. The test by itself is not diagnostic, and it should be used in conjunction with other clinical parameters to confirm disease. An elevated IgM antibody concentration > 999 Titer Units (TU) against myelin-associated glycoprotein (MAG) suggests active demyelination in peripheral neuropathy. A normal concentration (< 999 TU) generally rules out an anti-MAG antibody-associated peripheral neuropathy.** **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; Refrigerated **Methodology: Semi-Quantitative** Enzyme-Linked Immunosorbent Assay	6/28/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Neutrophil Oxidative Burst, Blood	OXBRST	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Neutrophil Oxidative Burst, Blood **EER Neutrophil Oxidative Burst** **Special Information: CRITICAL AMBIENT. Patient prep: Collect control specimen from a healthy individual unrelated to patient at approximately the same time as and under similar conditions to the patient. Patient and control specimens MUST be collected within 48 hours of test performance. Do NOT refrigerate or freeze as live neutrophils are required. Refrigerated or frozen specimens will be rejected. Specimens in transport longer than 48 hours are unacceptable. This test is New York DOH approved.** **Clinical Information: Aids in screening for chronic granulomatous disease. White blood cells are incubated with dihydrorhodamine 123 (DHR) and catalase, then stimulated with Phorbol 12-Myristate 13-Acetate (PMA). Dihydrorhodamine oxidation to rhodamine by the respiratory burst of the cell is measured by flow cytometry.** **Results are reported as the ratio of the mean channel fluorescence of stimulated cells versus unstimulated cells, which yields a stimulation index (SI). If sample shows abnormal results when stimulated, and no control was sent, test should be resubmitted with control sample to validate the conditions of collection, processing and transport. Interpretation comparing the patient results to the client normal control and the laboratory control will be provided by the medical director.** **Specimen Requirement: 3 mL** whole blood in a sodium **or lithium heparin** (green) tube; Minimum: **1 mL per tube (patient and control); Prefer 3 mL per tube;** THIS TEST REQUIRES MULTIPLE SPECIMENS; Send both specimens to Cleveland Clinic Laboratories on the day of collection **by 3 p.m. EST; Critical Ambient** *AND* **3 mL** whole blood in a sodium **or lithium heparin** (green) tube; Minimum: **1 mL per tube (patient and control); Prefer 3 mL per tube;** THIS TEST REQUIRES MULTIPLE SPECIMENS; Collect this specimen from an unrelated **healthy** person; label the tube as 'Control;' Both tubes must be received in Cleveland Clinic Laboratories on the day of collection **by 3 p.m. EST; Patient and control specimens must be collected within 48 hours of test performance; Do NOT refrigerate or freeze as live neutrophils are required; Critical Ambient** **Stability:** Ambient: **48** hours Refrigerated: Unacceptable Frozen: Unacceptable **Methodology: Semi-Quantitative** Flow Cytometry **Reference Range: Refer to report** **CPT: 86352 x 1**	6/28/18
NRAS Gene Analysis		**Days Performed: 3 days per week** **Reported: 7 days** **CPT:** 81311 x 1, **88381 x 1,** G0452 x 1 (Client Bill Only)	6/4/18
Nucleophosmin Gene (NPM1) Mutation	NPM1	**Specimen Requirement:** 4 mL whole blood in an EDTA (lavender) tube; Minimum: **2 mL;** Ambient **Stability:** Ambient: **48** hours Refrigerated: **7** days Frozen: Unacceptable **Days Performed: 2 days per week** **Reported:** 7 days	6/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Opiate Confirmation, Urine	OPICON	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Morphine, Urine Oxymorphone, Urine Hydromorphone, Ur Dihydrocodeine, Ur Codeine, Urine 6-Acetylmorphine, Ur Oxycodone, Urine Hydrocodone, Urine **Specimen Validity pH, Urine** **Specimen Validity Specific Gravity, Urine** **Specimen Validity Creatinine, Urine** **Specimen Validity Nitrites, Urine** **Specimen Validity Oxidants, Urine** **Specimen Validity Chromate, Urine** **Specimen Validity Specimen Quality, Urine** **Special Information:** For medical purposes only; not valid for forensic use. **Specimen Validity Testing (SVT) analytes have a stability of up to 5 days at 2–8 °C as stated in the Instructions for Use (IFU). Based on the laboratory's studies, this stability is based on samples that have reached an equilibrium. Introduction of oxidants to a urine sample will not be stable until an equilibrium is achieved. Time to reach equilibrium will vary dependent on the type and amount of oxidant used as an adulterant.** **Clinical Information: For Specimen Validity Interpretations, the following rules are applied:** **Diluted: Creatinine of ≥ 2 mg/dL but < 20 mg/dL and Specific Gravity of > 1.0010 but < 1.0030** **Substituted: Creatinine of < 2 mg/dL and Specific Gravity of ≤ 1.0010 or ≥ 1.0200** **Adulterated: pH < 3.0 or ≥ 11.0, or Nitrites ≥ 500 mg/L, or Oxidants ≥ 200 mg/L, or Chromate ≥ 50 mg/L** **Reference Range:** Morphine, Urine: < 10 ng/mL Oxymorphone, Urine: < 5 ng/mL Hydromorphone, Ur: < 5 ng/mL Dihydrocodeine, Ur: < 5 ng/mL Codeine, Urine: < 11 ng/mL 6-Acetylmorphine, Ur: < 5 ng/mL Oxycodone, Urine: **< 10 ng/mL** Hydrocodone, Urine: < 8 ng/mL **Specimen Validity pH, Urine: 4.5–8.0** **Specimen Validity Specific Gravity, Urine: 1.002–1.030** **Specimen Validity Creatinine, Urine** **18–99 Years (Male): 46.8–314.5 mg/dL** **18–99 Years (Female): 42.2–237.9 mg/dL** **Specimen Validity Nitrites, Urine: ≤ 50 mg/L** **Specimen Validity Oxidants, Urine: < 200 mg/L** **Specimen Validity Chromate, Urine: < 50 mg/L**	Effective immediately
Osmotic Fragility, Erythrocyte	OSMFER	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Osmotic Fragility **Special Information:** Grossly hemolyzed specimens are unacceptable. **If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory.**	5/21/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Ova and Parasite Examination	OVAP	**Special Information: The enzyme immunoassay (EIA) (i.e., ova & parasite screen; OVAPSC) for Cryptosporidium and Giardia is the recommended test for most patients thought to have enteritis caused by a parasite. Diagnostic testing is not recommended for traveler's diarrhea unless it persists for 14 days. The potential etiology of diarrhea in immunocompromised patients encompasses a broad differential diagnosis. A full Ova & Parasitic exam (OVAP) should be reserved for individuals with significant risk factors for enteric parasitosis (e.g., immigration from or travel to an endemic area). Requests for Ova and Parasite Exam on patients who have been hospitalized for > 3 days will be blocked; requests for processing of specimens on such patients should be made through Client Services. Testing is performed weekdays on day shift. Special studies Cyclospora and Cystoisospora: If Cyclospora, Cystoisospora are diagnostic considerations, then (CRYSPO) should be ordered; this assay also detects Cryptosporidium, but the OVAPSC is the preferred test for that parasite. Microsporidia PCR is the test of choice if a microsporidial infection is considered, but the less sensitive microscopic examination for microsporidia is available upon request (MICSPO). Pinworm: Importantly, pinworm is not routinely detected on O&P examination, so pinworm exam (TAPE) should be ordered; the specimen should be collected with a pinworm collection kit, but cellophane tape, which has been used for collection that is adherent to a glass slide, is also acceptable. Parasitic Liver Cyst/Abscess Liver aspirates will be assessed for the presence of E. histolytica and Echinococcus. Paragonimus Sputum and bronchoalveolar lavage specimens will be assessed for the eggs of Paragonimus species. When paragonimiasis is considered, then a stool ova & parasite examination should also be ordered (OVAP). Worm Identification: Worms and portions of worms may be submitted for identification (PARAID).** Urinary Schistosomiasis: Twenty-four hour urine specimens for the diagnosis of urinary schistosomiasis are optimal, but single urine specimens are acceptable; **serologic studies should be considered when this diagnosis is considered.** Urine specimens > 48 hours old and urine in preservative will be rejected. **Clinical Information: The Ova and Parasite screen (OVAPSC) is more sensitive than the Ova and Parasite exam (OVAP) for the detection of Giardia, the most commonly encountered enteric parasite in this locale. The Ova and Parasite screen (OVAPSC) should be used, rather than the Ova and Parasite exam (OVAP), unless other enteric parasites are suspected. The Ova and Parasite exam (OVAP) should be ordered to detect and identify the presence of enteric protozoa and the eggs of helminths. This test should be reserved for individuals with significant risk factors for enteric parasitosis (e.g., immigration from or travel to an endemic area). In such cases, a minimum of 3 specimens collected over 3–10 days is recommended. Stool should be collected using a stool collection kit. Special studies are needed for the detection of Cryptosporidium, Cyclospora, Cystoisospora, microsporida, pinworm, worm identification, and parasites in unusual locations. Non-stool specimens should be collected using a sterile screw-top transport container.**	5/1/18
Oxycodone Confirmation, Urine	UOXYCC	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Oxymorphone, Urine Oxycodone, Urine **Specimen Validity pH, Urine** **Specimen Validity Specific Gravity, Urine** **Specimen Validity Creatinine, Urine** **Specimen Validity Nitrites, Urine** **Specimen Validity Oxidants, Urine** **Specimen Validity Chromate, Urine** **Specimen Validity Specimen Quality, Urine** **Special Information:** For medical purposes only; not valid for forensic use. **Specimen Validity Testing (SVT) analytes have a stability of up to 5 days at 2–8 °C as stated in the Instructions for Use (IFU). Based on the laboratory's studies, this stability is based on samples that have reached an equilibrium. Introduction of oxidants to a urine sample will not be stable until an equilibrium is achieved. Time to reach equilibrium will vary dependent on the type and amount of oxidant used as an adulterant.** *(continued on page 26)*	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Oxycodone Confirmation, Urine *(continued from page 25)*		**Clinical Information: For Specimen Validity Interpretations, the following rules are applied:** **Diluted: Creatinine of ≥ 2 mg/dL but < 20 mg/dL and Specific Gravity of > 1.0010 but < 1.0030** **Substituted: Creatinine of < 2 mg/dL and Specific Gravity of ≤ 1.0010 or ≥ 1.0200** **Adulterated: pH < 3.0 or ≥ 11.0, or Nitrites ≥ 500 mg/L, or Oxidants ≥ 200 mg/L, or Chromate ≥ 50 mg/L** **Reference Range:** Oxymorphone, Urine: < 5 ng/mL Oxycodone, Urine: **< 10 ng/mL** **Specimen Validity pH, Urine: 4.5–8.0** **Specimen Validity Specific Gravity, Urine: 1.002–1.030** **Specimen Validity Creatinine, Urine** **18–99 Years (Male): 46.8–314.5 mg/dL** **18–99 Years (Female): 42.2–237.9 mg/dL** **Specimen Validity Nitrites, Urine: ≤ 50 mg/L** **Specimen Validity Oxidants, Urine: < 200 mg/L** **Specimen Validity Chromate, Urine: < 50 mg/L**	
Parvovirus B-19 Antibodies	PARV	**Stability:** Ambient: **1 da**y Refrigerated: **7 day**s Frozen: 1 year	5/29/18
Parvovirus B19 IgG Antibodies	PARVOG	**Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: 1 year	5/29/18
Parvovirus B19 IgM Antibodies	PARVOM	**Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: 1 year	5/29/18
Protein/Creatinine Ratio	PRATIO	**Stability:** Ambient: **1 day** Refrigerated: **6 days** Frozen: **1 month**	Effective immediately
Prothrombin Antibody	PTABGM	**Special Information:** Preferred second-line testing for strong suspicion of seronegative antiphospholipid syndrome (APS). Order incrementally or concurrently with other non-criteria antiphospholipid antibody tests. **Hemolyzed or lipemic specimens are unacceptable.** This test is New York DOH approved. **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; **Transfer serum into standard aliquot tube;** Refrigerated *OR* 0.5 mL plasma from a sodium citrate (light blue) tube; Minimum: 0.3 mL; **Transfer plasma into standard aliquot tube;** Refrigerated **Methodology: Semi-Quantitative** Enzyme-Linked Immunosorbent Assay **Reference Range: < 20 Units**	5/21/18
Prothrombin Gene Mutation	PTGEN	**Specimen Requirement:** 4 mL whole blood in an EDTA (lavender) tube; Minimum: **1 mL; Ambient** **Stability:** Ambient: **48** hours Refrigerated: **7** days Frozen: Unacceptable **Methodology:** **High Resolution Melt Analysis** **Real-Time** Polymerase Chain Reaction **(RT-PCR)** **Days Performed:** 2 days per week **Reported: 5** days	5/1/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
PTT Incubated Mixing Study	PTTIM	**Reference Range:** PT Screen 0–1 Days: 7.9–14.8 sec 2–5 Days: 7.4–14.2 sec 6–30 Days: 7.2–13.3 sec 1–3 Months: 7.2–13.2 sec 4–11 Months: 8.3–12.9 sec 1–99 Years: 8.4–13.0 sec APTT Screen 0–1 Days: 28.7–45.1 sec 2–5 Days: 23.3–49.4 sec 6–30 Days: 23.5–45.6 sec 1–3 Months: 22.1–41.4 sec 4–11 Months: 25.8–35.5 sec 1–99 Years: 24.4–33.4 sec Immediate PTT 1:1 Mix 0–99 Years: **< 33.2 sec** Incubated PTT 1:1 Mix 0–99 Years: **< 35.0 sec** Thrombin Time 0–1 Days: < 17.4 sec 2–5 Days: < 17.9 sec 6–30 Days: < 17.9 sec 1–3 Months: < 18.2 sec 4–11 Months: < 19.1 sec 1–99 Years: < 18.6 sec Heparin Anti Xa 0–99 Years: Therapeutic range: 0.3–0.7 (standard nomogram) IU/mL 0–99 Years: < 0.10 IU/mL 0–99 Years: Stroke or low dose protocol: 0.2–0.5 IU/mL	Effective immediately
Quantitative Pain Panel, Urine	UQNTPP	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Morphine, Urine Codeine, Urine Dihydrocodeine, Ur Oxycodone, Urine Oxymorphone, Urine Hydrocodone, Urine Hydromorphone, Ur Methadone, Urine EDDP, Urine Fentanyl, Urine Norfentanyl, Urine Tramadol, Urine Desmethyltramadol, Ur Buprenorphine, Ur Norbuprenorphine, Ur Amphetamine, Urine Methamphetamine, Ur Benzoylecgonine, Ur 6-Acetylmorphine, Ur Cannabinoid, Urine **Specimen Validity Creatinine, Urine** **Specimen Validity pH, Urine** **Specimen Validity Specific Gravity, Urine** **Specimen Validity Oxidants, Urine** **Specimen Validity Nitrites, Urine** **Specimen Validity Chromate, Urine** **Specimen Validity Specimen Quality, Urine** *(continued on page 28)*	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Quantitative Pain Panel, Urine *(continued from page 27)*		**Special Information:** For medical purposes only; not valid for forensic use. **Specimen Validity Testing (SVT) analytes have a stability of up to 5 days at 2–8 °C as stated in the Instructions for Use (IFU). Based on the laboratory's studies, this stability is based on samples that have reached an equilibrium. Introduction of oxidants to a urine sample will not be stable until an equilibrium is achieved. Time to reach equilibrium will vary dependent on the type and amount of oxidant used as an adulterant.** **Clinical Information: For Specimen Validity Interpretations, the following rules are applied:** **Diluted: Creatinine of ≥ 2 mg/dL but < 20 mg/dL and Specific Gravity of > 1.0010 but < 1.0030** **Substituted: Creatinine of < 2 mg/dL and Specific Gravity of ≤ 1.0010 or ≥ 1.0200** **Adulterated: pH < 3.0 or ≥ 11.0, or Nitrites ≥ 500 mg/L, or Oxidants ≥ 200 mg/L, or Chromate ≥ 50 mg/L** **Reference Range:** Morphine, Urine: < 10 ng/mL Codeine, Urine: < 11 ng/mL Dihydrocodeine, Ur: < 5 ng/mL Oxycodone, Urine: **< 10 ng/mL** Oxymorphone, Urine: < 5 ng/mL Hydrocodone, Urine: < 8 ng/mL Hydromorphone, Ur: < 5 ng/mL Methadone, Urine: < 16 ng/mL EDDP, Urine: < 6 ng/mL Fentanyl, Urine: < 6 ng/mL Norfentanyl, Urine: < 6 ng/mL Tramadol, Urine: < 25 ng/mL Desmethyltramadol, Ur: < 20 ng/mL Buprenorphine, Ur: < 20 ng/mL Norbuprenorphine, Ur: < 20 ng/mL Amphetamine, Urine: < 5 ng/mL Methamphetamine, Ur: < 8 ng/mL Benzoylecgonine, Ur: < 24 ng/mL 6-Acetylmorphine, Ur: < 5 ng/mL Cannabinoid, Urine: < 16 ng/mL **Specimen Validity Creatinine, Urine** **18–99 Years (Male): 46.8–314.5 mg/dL** **18–99 Years (Female): 42.2–237.9 mg/dL** **Specimen Validity pH, Urine: 4.5–8.0** **Specimen Validity Specific Gravity, Urine: 1.002–1.030** **Specimen Validity Oxidants, Urine: < 200 mg/L** **Specimen Validity Nitrites, Urine: ≤ 50 mg/L** **Specimen Validity Chromate, Urine: < 50 mg/L**	

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Skeletal Muscle Antibodies, IgG with Reflex to Titer	SKELS	**For Interfaced Clients Only: Test build may need to be modified** **Special Information: If skeletal muscle antibodies are detected, a titer will be added at an additional cost. Plasma, contaminated, hemolyzed, or severely lipemic specimens are unacceptable. This test is New York DOH approved.** **Clinical Information: This test is recommended for the differential evaluation of neuromuscular junction diseases** including myasthenia gravis (MG). **When detected in the presence of acetylcholine receptor (AChR) antibody, striated muscle antibodies, which bind in a cross-striational pattern to skeletal and heart muscle tissue sections, are associated with late-onset MG. Striated muscle antibodies recognize epitopes on three major muscle proteins, including titin, ryanodine receptor (RyR) and Kv1.4 (an alpha subunit of voltage-gated potassium channel [VGKC]). Isolated cases of striated muscle antibodies may be seen in patients with certain autoimmune diseases, myocardial infarction, rheumatic fever, and following some cardiotomy procedures.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.15 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube;** Refrigerated **Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: **After separation from cells: 2 weeks** Frozen: **After separation from cells: 1 year (Avoid repeated freeze/thaw cycles)** **Methodology: Semi-Quantitative** Indirect **Fluorescent Antibody** **Days Performed:** Monday–**Friday** **Reported:** 2–**6** days	7/12/18
Strongyloides IgG Abs, Serum	STRSER	**Clinical Information:** Aid in the diagnosis of strongyloides. Positive results in patients from endemic areas may not represent active infection. **False-positive results may occur with prior exposure to other helminth infections. Testing low-prevalence populations may also result in false-positive results.** **Methodology: Semi-Quantitative** Enzyme-Linked Immunosorbent Assay **Reference Range:** 0.99 IV or less: Negative–No significant level of Strongyloides IgG antibody detected; **Recommend repeat testing in 10-14 days if clinically indicated** 1.00 IV or greater: Positive–IgG antibodies to Strongyloides detected, which may suggest current or past infection **Days Performed: Sunday**–Saturday **Reported:** 2–**4** days	5/21/18
T-Cell Clonality Using Biomed-2 PCR Primers	TCBMD	**Specimen Requirement:** 10 mm square **formalin-fixed** paraffin-embedded (FFPE) tissue **block** in a clean container; Paraffin-embedded tissue should be delivered to Cleveland Clinic Laboratories for accessioning and cutting; **Ambient** *OR* 2 mL bone marrow in an EDTA (lavender) tube; **Ambient** *OR* 8 mL whole blood in an EDTA (lavender) tube; **Ambient** **Stability:** Ambient: **Whole blood–48 hours; Bone Marrow–48 hours; Paraffin-embedded tissue–indefinitely** Refrigerated: **Whole blood–7 days; Bone marrow–7 days; Paraffin-embedded tissue–unacceptable** Frozen: **Whole blood–unacceptable; Bone marrow–unacceptable; Paraffin-embedded tissue–unacceptable** **Days Performed: 2 days per week** **Reported: 7** days	6/26/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
T-Cell Receptor Beta Biomed-2 PCR	TCRB	**Specimen Requirement:** 10 mm square **formalin-fixed** paraffin-embedded (FFPE) tissue **block** in a clean container; Paraffin-embedded tissue should be delivered to Cleveland Clinic Laboratories for accessioning and cutting; **Ambient** *OR* 2 mL bone marrow in an EDTA (lavender) tube; **Ambient** *OR* 5 mL whole blood in an EDTA (lavender) tube; **Ambient** *OR* 6 µg extracted DNA in a clean container; **Ambient** **Stability:** Ambient: **Whole blood–48 hours; Bone Marrow–48 hours; Paraffin-embedded tissue–indefinitely; Extracted DNA–24 hours** Refrigerated: **Whole blood–7 days; Bone marrow–7 days; Paraffin-embedded tissue–unacceptable; Extracted DNA–3 years** Frozen: **Whole blood–unacceptable; Bone marrow–unacceptable; Paraffin-embedded tissue–unacceptable; Extracted DNA–unacceptable** **Days Performed: 2 days per week** **Reported: 7** days	5/1/18
TCR-G (PCR)	TGAMMA	**Specimen Requirement:** 10 mm square **formalin-fixed** paraffin-embedded (FFPE) tissue **block** in a clean container; Paraffin-embedded tissue should be delivered to Cleveland Clinic Laboratories for accessioning and cutting; Ambient *OR* 8 mL whole blood in an EDTA (lavender) tube; **Ambient** *OR* 2 mL bone marrow in an EDTA (lavender) tube; **Ambient** *OR* **6 µg extracted DNA in a clean container; Ambient** **Stability:** Ambient: **Whole blood–48 hours; Bone Marrow–48 hours; Paraffin-embedded tissue–indefinitely; Extracted DNA–24 hours** Refrigerated: **Whole blood–7 days; Bone marrow–7 days; Paraffin-embedded tissue–unacceptable; Extracted DNA–3 years** Frozen: **Whole blood–unacceptable; Bone marrow–unacceptable; Paraffin-embedded tissue–unacceptable; Extracted DNA–unacceptable** **Days Performed: 2 days per week** **Reported: 7** days	6/26/18
Toxocara Antibodies	TOXCAR	**Special Information: This test is New York DOH approved.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.1 mL; Centrifuge and transfer serum into standard aliquot tube;** Refrigerated *OR* 1 mL serum from a **plain no additive (red) tube;** Minimum: **0.1 mL; Centrifuge and transfer serum into standard aliquot tube;** Refrigerated **Stability:** Ambient: **1 week** Refrigerated: 2 weeks Frozen: **1 month** **Methodology: Semi-Quantitative** Enzyme-Linked Immunosorbent Assay **Days Performed: Varies** **Reported: 4–12** days	Effective immediately
TPMT Genotype Assay	TPMTGN	**Specimen Requirement:** 4 mL whole blood in an EDTA (lavender) tube; Minimum: **1 mL;** Ambient **Stability:** Ambient: **48** hours Refrigerated: **7 days** Frozen: Unacceptable	5/1/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Tramadol and Metabolite, Quantitation	TRAQNT	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Desmethyltramadol, Ur Tramadol, Urine **Specimen Validity pH, Urine** **Specimen Validity Specific Gravity, Urine** **Specimen Validity Creatinine, Urine** **Specimen Validity Nitrites, Urine** **Specimen Validity Oxidants, Urine** **Specimen Validity Chromate, Urine** **Specimen Validity Specimen Quality, Urine** **Special Information: For medical purposes only; not valid for forensic use. Specimen Validity Testing (SVT) analytes have a stability of up to 5 days at 2–8 °C as stated in the Instructions for Use (IFU). Based on the laboratory's studies, this stability is based on samples that have reached an equilibrium. Introduction of oxidants to a urine sample will not be stable until an equilibrium is achieved. Time to reach equilibrium will vary dependent on the type and amount of oxidant used as an adulterant.** **Clinical Information: For Specimen Validity Interpretations, the following rules are applied:** **Diluted: Creatinine of ≥ 2 mg/dL but < 20 mg/dL and Specific Gravity of > 1.0010 but < 1.0030** **Substituted: Creatinine of < 2 mg/dL and Specific Gravity of ≤ 1.0010 or ≥ 1.0200** **Adulterated: pH < 3.0 or ≥ 11.0, or Nitrites ≥ 500 mg/L, or Oxidants ≥ 200 mg/L, or Chromate ≥ 50 mg/L** **Reference Range:** Desmethyltramadol, Ur: < 20 ng/mL Tramadol, Urine: < 25 ng/mL **Specimen Validity pH, Urine: 4.5–8.0** **Specimen Validity Specific Gravity, Urine: 1.002–1.030** **Specimen Validity Creatinine, Urine** **18–99 Years (Male): 46.8–314.5 mg/dL** **18–99 Years (Female): 42.2–237.9 mg/dL** **Specimen Validity Nitrites, Urine: ≤ 50 mg/L** **Specimen Validity Oxidants, Urine: < 200 mg/L** **Specimen Validity Chromate, Urine: < 50 mg/L**	Effective immediately
Vitamin D 25 Hydroxy	VITD	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	6/25/18
West Nile Virus Antibody Panel CSF	CNILE	**Special Information: Hemolyzed, contaminated, or heat-inactivated specimens are unacceptable. If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory.**	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Adalimumab Activity and Neutralizing Antibody	ADANEU	**Special Information:** Patient Prep: Collect specimens before adalimumab treatment. Hemolyzed, icteric, lipemic or contaminated specimens are unacceptable. This test is New York DOH approved. **Clinical Information:** This test measures the capacity of adalimumab to neutralize TNF-alpha activity. Additionally, adalimumab neutralizing antibodies (NAb) are titered (reporting the minimal serum dilution at which blocking of adalimumab activity is no longer observed). Testing is used to evaluate secondary response failures to adalimumab therapy. Secondary response failure is defined as loss of clinical response after initial improvement of clinical signs and symptoms. Therapeutic decision should rest on both the clinical response and the knowledge of the fate of the drug including the emergence of immunogenicity in individual patients. Circulating adalimumab levels have been shown to vary considerably between patients. These differences relate to route and frequency of administration and patient-related features such as weight, gender, age, drug metabolism, and concomitant medications such as methotrexate and other immunosuppressants. If adalimumab activity is not detected AND adalimumab neutralizing Ab titer is not detected, then a higher dosage of adalimumab or shortening the dosing interval may be appropriate. If adalimumab activity is not detected AND adalimumab neutralizing Ab titer is 1:20 or greater, then a change to another anti-TNF- drug may be appropriate. If adalimumab activity is 0.65 µg/mL or greater AND adalimumab neutralizing Ab titer is not detected, then a change to another type of therapy (not targeting TNF-) may be appropriate. If adalimumab activity is 0.65 µg/mL or greater AND adalimumab neutralizing Ab titer is 1:20 or greater, then repeat testing is suggested to rule out decreasing adalimumab activity and/or increasing adalimumab neutralizing antibodies. **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated **Stability:** Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 4 weeks Frozen: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles) **Methodology:** Cell Culture Quantitative Chemiluminescent Immunoassay Semi-Quantitative Chemiluminescent Immunoassay **Reference Range:** Adalimumab Activity: Not Detected Adalimumab Neutralizing Activity: Not Detected **Days Performed:** Monday, Wednesday, Thursday, Saturday **Reported:** 3–4 days **CPT:** 86352 x 2	5/31/18
Cadmium, Whole Blood	CADMWB	**Special Information:** Patient demographics form (Heavy Metal Form) is required to meet State Health Department requirements. Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, non-essential over-the-counter medications (upon the advice of their physician). Always use an alcohol swab to cleanse the venipuncture site. Avoid iodine-containing disinfectants. Use only stainless steel phlebotomy needles, and use non-powder gloves when handling and collecting. Do not collect specimens from patients who have received gadolinium- or iodine-containing contrast material within 96 hours. Gadolinium and iodine are known to interfere with most metal tests. Heparin anticoagulant is unacceptable. Frozen specimens will be rejected. This test is New York DOH approved. *(continued on page 33)*	7/12/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Cadmium, Whole Blood *(continued from page 32)*		**Clinical Information:** Blood cadmium can be used to monitor acute toxicity, and in combination with cadmium and urine and B-2 microglobulin is the preferred method for monitoring occupational exposure. Symptoms associated with cadmium toxicity vary based upon route of exposure and may include tubular proteinuria, fever, headache, dyspnea, chest pain, conjunctivitis, rhinitis, sore throat and cough. Ingestion of cadmium in high concentration may cause vomiting, diarrhea, salivation, cramps, and abdominal pain. Elevated results from noncertified trace element-free collection tubes may be due to contamination. Elevated concentrations of trace elements in blood should be confirmed with a second specimen collected in a tube designed for trace element determinations, such as a royal blue EDTA tube. **Specimen Requirement:** 7 mL whole blood in an EDTA (royal blue) tube; Minimum: 0.5 mL; Patient Prep: Diet, medication and nutritional supplements may introduce interfering substances; Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician); Send specimen in original tube; Heavy Metal Form must be submitted with the specimen to meet State Health Department requirements; Ambient **Stability:** Ambient: Preferred; If the specimen is drawn and stored in the appropriate container, the trace element values do not change with time Refrigerated: Acceptable; If the specimen is drawn and stored in the appropriate container, the trace element values do not change with time Frozen: Unacceptable **Methodology:** Inductively Coupled Plasma / Mass Spectrometry (ICP-MS) **Reference Range:** 0–99 Years: 0.0–5.0 µg/L **Days Performed:** Sunday–Saturday **Reported:** 2–4 days **CPT:** 82300 x 1 **Price:** $43.00 (non-discountable)	
CALR (Calreticulin) Exon 9 Mutation Analysis Marrow	CALRM	**Clinical Information:** CALR mutation testing is useful in the workup of suspected myeloproliferative neoplasms, especially those that are negative for JAK2 V617F. **Specimen Requirement:** 2 mL bone marrow aspirate in an EDTA (lavender) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Next Generation DNA Sequencing **Days Performed:** 2 days per week **Reported:** 7 days **CPT:** 81219 x 1, G0452 x 1, (81479, if appropriate) **Price:** $833.00 (non-discountable)	6/26/18
CEBPA Mutation Analysis Marrow	CEBPAM	**Clinical Information:** Acute myeloid leukemia (AML) with biallelic CEBPA mutation represents a distinct clinicopathologic entity in the current WHO classification of AML. **Specimen Requirement:** 2 mL bone marrow aspirate in an EDTA (lavender) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Next Generation DNA Sequencing **Days Performed:** 2 days per week **Reported:** 10 days **CPT:** 81218 x 1, G0452 x 1, (81479, if appropriate)	6/26/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Chikungunya Antibodies, IgG and IgM	CHIKGM	**Special Information:** Parallel testing is preferred and convalescent specimens MUST be received within 30 days from receipt of the acute specimens. Hemolyzed, severely lipemic, contaminated or heat-inactivated specimens are unacceptable. This test is New York DOH approved. **Clinical Information:** May aid in the diagnosis of chikungunya viral infection during the acute phase of disease (> 5 days after onset of symptoms). In endemic regions, co-testing for dengue and Zika virus is recommended because the clinical picture of these diseases is similar. **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.15 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 Enzyme-Linked Immunosorbent Assay **Reference Range:** Chikungunya Antibody, IgG ≤ 0.79 Index: Negative: No significant level of Chikungunya IgG antibody detected 0.80–1.09 Index: Equivocal: Questionable presence of Chikungunya IgG antibody detected; Repeat testing in 10-14 days may be helpful ≥ 1.10 Index: Positive: Chikungunya IgG antibody detected; suggests current or past infection Chikungunya Antibody, IgM ≤ 0.79 Index: Negative: No significant level of Chikungunya IgM antibody detected 0.80–1.09 Index: Equivocal: Questionable presence of Chikungunya IgM antibody detected; Repeat testing in 10-14 days may be helpful ≥ 1.10 Index: Positive: Chikungunya IgM antibody detected **Days Performed:** Wednesday **Reported:** 2–9 days **CPT:** 86790 x 2 **Price:** $130.00 (non-discountable)	6/28/18
Coxiella burnetii (Q-Fever) Antibodies, IgG and IgM, Phase I and II with Reflex to Titer	COXGMR	**Special Information:** Parallel testing is preferred and convalescent specimens MUST be received within 30 days from receipt of the acute specimens. Contaminated, hemolyzed, or severely lipemic specimens are unacceptable. For IgG or IgM testing, if any Phase I or Phase II screening result is indeterminate or positive, titer(s) will be added at an additional cost. This test is New York DOH approved. **Clinical Information:** Used to confirm infectious agent as C. burnetii (Q-fever) in symptomatic patients. **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.15 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' and '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:** C. burnetii (Q-Fever) Ab, Phase I IgG: Negative C. burnetii (Q-Fever) Ab, Phase II IgG: Negative C. burnetii (Q-Fever) Ab, Phase I IgM: Negative C. burnetii (Q-Fever) Ab, Phase II IgM: Negative **Days Performed:** Monday, Wednesday, Friday **Reported:** 2–7 days **CPT:** 86638 x 4 **Price:** $100.00 (non-discountable)	6/26/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
FLT3 Tyrosine Kinase Domain Mutation, Bone Marrow	FLT3TM	**Specimen Requirement:** 2 mL bone marrow aspirate in an EDTA (lavender) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Next Generation DNA Sequencing **Days Performed:** 2 days per week **Reported:** 7 days **CPT:** 81246 x 1, G0452 x 1, (81479, if appropriate)	6/26/18
Hematologic Neoplasm Next Generation Sequencing Panel Marrow	HNMNGS	**Clinical Information:** This assay is intended to detect mutations associated with hematologic neoplasms including acute myeloid leukemia, myelodysplastic syndromes, myeloproliferative neoplasms, acute lymphoblastic leukemias, and chronic lymphoid leukemias. **Specimen Requirement:** 2 mL bone marrow aspirate in an EDTA (lavender) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Next Generation DNA Sequencing **Days Performed:** 2 days per week **Reported:** 10 days **CPT:** 81455 x 1, G0452 x 1 **Price:** $3113.00 (non-discountable)	6/26/18
Hematologic Neoplasm Next Generation Sequencing Panel Peripheral Blood	HNPNGS	**Clinical Information:** This assay is intended to detect mutations associated with hematologic neoplasms including acute myeloid leukemia, myelodysplastic syndromes, myeloproliferative neoplasms, acute lymphoblastic leukemias, and chronic lymphoid leukemias. **Specimen Requirement:** 4 mL peripheral blood in an EDTA (lavender) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Next Generation DNA Sequencing **Days Performed:** 2 days per week **Reported:** 10 days **CPT:** 81455 x 1, G0452 x 1 **Price:** $3113.00 (non-discountable)	6/26/18
JAK2 Exon 12-15 Mutation Detection Bone Marrow	JAK2NM	**Specimen Requirement:** 2 mL bone marrow aspirate in an EDTA (lavender) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Next Generation DNA Sequencing **Days Performed:** 2 days per week **Reported:** 10 days **CPT:** 81270 x 1, G0452 x 1, (81479, if appropriate)	6/26/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
JAK2 V617F Mutation Detection Bone Marrow	JAK2M	**Specimen Requirement:** 2 mL bone marrow aspirate in an EDTA (lavender) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Next Generation DNA Sequencing **Days Performed:** 2 days per week **Reported:** 5 days **CPT:** 81270 x 1, G0452 x 1, (81479, if appropriate)	6/26/18
MPL Mutation Analysis Marrow	MPLM	**Clinical Information:** MPL mutation testing is useful in the workup of suspected myeloproliferative neoplasms, especially those that are negative for JAK2 V617F. **Specimen Requirement:** 2 mL bone marrow aspirate in an EDTA (lavender) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Next Generation DNA Sequencing **Days Performed:** 2 days per week **Reported:** 7 days **CPT:** 81403 x 1, G0452 x 1, (81479, if appropriate)	6/26/18
Myeloproliferative Neoplasm Panel Marrow	MPNM	**Clinical Information:** This assay is intended to detect mutations associated with myeloproliferative neoplasms including JAK2 V617F, JAK2 exon 12, MPL exon 10, and CALR exon 9 mutations. **Specimen Requirement:** 2 mL bone marrow aspirate in an EDTA (lavender) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Next Generation DNA Sequencing **Days Performed:** 2 days per week **Reported:** 10 days **CPT:** 81479 x 1, G0452 x 1	6/26/18
Myeloproliferative Neoplasm Panel Peripheral Blood	MPNP	**Specimen Requirement:** 4 mL peripheral blood in an EDTA (lavender) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Next Generation DNA Sequencing **Days Performed:** 2 days per week **Reported:** 10 days **CPT:** 81479 x 1, G0452 x 1	6/26/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
NPM1 Mutation Detection Bone Marrow	NPM1M	**Specimen Requirement:** 2 mL bone marrow aspirate in an EDTA (lavender) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Next Generation DNA Sequencing **Days Performed:** 2 days per week **Reported:** 7 days **CPT:** 81310 x 1, G0452 x 1, (81479, if appropriate)	6/26/18

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
CALR (Calreticulin) Exon 9 Mutation Blood	CALR	$472.00 (non-discountable)	81219, G0452	6/26/18
CEBPA Mutation Analysis	CEBPA	$625.00 (non-discountable)	81218, G0452	6/26/18
JAK2 Exon 12-15 Sequencing Blood	JAKNON	$605.00 (non-discountable)	81403, G0452	6/26/18
JAK2 V617F Mutation Detection Blood	JAK2	$561.00 (non-discountable)	81270, G0452	6/26/18
Nucleophosmin Gene (NPM1) Mutation	NPM1	$651.00 (non-discountable)	81310, G0452	6/26/18
Toxocara Antibodies	TOXCAR	$133.00 (non-discountable)	86682	Effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Cadmium, Blood	CADM	This test will no longer be available. Suggest ordering Cadmium, Whole Blood (CADMWB).	7/12/18
Chikungunya Antibodies with Reflex(es) to Titer	CHIKAB	This test will no longer be available. Suggest ordering Chikungunya Antibodies, IgG and IgM (CHIKGM).	6/28/18
Coxiella Burnetii IgM Abs	COXIGM	This test will no longer be available. Suggest ordering Coxiella burnetii (Q-Fever) Antibodies, IgG and IgM, Phase I and II with Reflex to Titer (COXGMR).	6/26/18
Coxiella IgG, IgM & IgA	COXIEL	This test will no longer be available. Suggest ordering Coxiella burnetii (Q-Fever) Antibodies, IgG and IgM, Phase I and II with Reflex to Titer (COXGMR).	6/26/18
Fluoride, Urine	UFLUOR	This test will no longer be available.	5/21/18
Meconium Drug Screen 5	MECDS5	This test will no longer be available. Suggest ordering Meconium Drug Screen 9 (MECDS9).	7/10/18
Myeloid NGS Panel	TCHNGS	This test will no longer be available. Suggest ordering Hematologic Neoplasm Next Generation Sequencing Panel Marrow (HNMNGS) or Hematologic Neoplasm Next Generation Sequencing Panel Peripheral Blood (HNPNGS).	6/26/18