Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • August 2019

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

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

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

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

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
3	6-Monoacetylmorphine (6-MAM) Confirmation, Urine						■							
3	Albumin/Creatinine Ratio, Urine									■				
3	Albumin/Creatinine Ratio, Urine Timed									■				
17	Albumin, Random Urine					■								
3	Albumin Urine, Quantitative									■				
4	Aldosterone 24 hr, Urine		■				■	■			■	■		
4	Aldosterone with Na and K, 24hr Urine		■				■	■			■	■		
4	Alkaline Phosphatase, Bone Specific						■	■						
4	Amphetamine Confirmation, Urine						■							
5	Anti-Neut Cyto Ab with Rfx to Titer and MPO/PR3 Ab		■				■			■	■	■		
5	Ashkenazi Jewish Diseases						■		■					
5	Benzodiazepines Conf, Ur						■							
5	Buprenorphine Quant, Urine						■							
17	Canavan Disease Mutation, Fluid					■								
6	Cannabinoid Confirmation, Ur						■							
6–7	Catecholamines Fractionated by LC-MS/MS, Urine Free						■				■			
7	Cocaine Confirmation, Urine						■							
17	Collagen Screen					■								
7	Cytology, SurePath Liquid-Based Pap test and Human Papillomavirus (HPV), High Risk by PCR, SurePath (for routine co-testing in women over 30)						■							

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
8	Dermatomyositis Panel						■				■	■		
8	Endomysial IgA Antibody						■							
15	Epi ProColon			■										
8	Fentanyl and Metabolite, Urine						■							
8	FIBROSpect HCV		■											
8	FLT3 ITD and TKD Mutation Detection by PCR						■	■				■		
8	G-6-PD Quantitative						■	■						
8	Gentamicin, Post Dose						■							
9	Gentamicin, Pre Dose						■							
9	Gentamicin, Random						■							
9	Hepatitis Be Antibody						■	■			■	■		
9	HIV-2 DNA/RNA PCR		■				■	■				■		
9–10	HIV PhenoSense GT						■	■				■		
10	HSP-70 Antibody (Anti-68 kd Antigen)										■			
10	IDH1/IDH2 Mutation, Blood/Bone marrow						■	■			■	■		
10	Insulin, Free, Serum										■			
10	JC Polyoma Virus Quantitative PCR						■							
10	KIT (D816V) Mutation by PCR						■	■				■		
11	Liver Fibrosis, FibroTest-ActiTest									■				
11	Methadone Quantitation, Urine						■							
11	Mitochondrial Antibody Panel						■							
11	Mitochondrial Antibody Screen						■							
17	Mitochondrial DNA Deletion Analysis				■									
11	Monoclonal Protein with Immunoglobulins and Free Light Chains, serum						■							
11	Myasthenia Gravis/Lambert-Eaton Syndrome						■				■			
11	Mycoplasma Cult Non Urogenital						■	■				■		
12	Neutrophil Oxidative Burst, Blood						■							
12	Opiate Confirmation, Urine						■							
12	Organic Acids, Plasma						■	■				■		
12	Oxycodone Confirmation, Urine						■							
12, 17	Pancreatitis Panel												■	■
12	Parietal Cell Antibody Panel						■							
12	Parietal Cell Antibody Screen						■							
12	Parvovirus B19 IgM Antibodies						■							
15	PD-L1 22C3 IHC with Tumor Proportion Score (TPS) Interpretation, pembrolizumab (KEYTRUDA)			■										
13	PML/RARA RTPCR						■	■				■		
13	Polymyositis and Dermatomyositis Panel						■				■			
17	PTT Incubated Mixing Study													■
13	Quantitative Pain Panel, Urine						■							
13	Rufinamide										■			
13	Smooth Muscle Antibody Panel						■							

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
13	Smooth Muscle Antibody Screen						■							
17	Syphilis IgG (T pallidum)					■								
17	Syphilis IgG with Confirmation					■								
16	Syphilis Total with reflex				■									
14, 17	Thyroid Stimulating Immunoglobulin	■					■	■	■	■	■	■		■
14	TP53 Somatic Mutation, Prognostic										■			
14	Tramadol and Metabolite, Quantitation						■							
14, 17	TSH Receptor Antibody							■		■		■		■
14	Vitamin B1 (Thiamine), Whole Blood							■			■	■		
16	Zika Virus by PCR, Blood			■										
16	Zika Virus by PCR, Urine			■										
16	Zika Virus IgM Antibody Capture (MAC), by ELISA			■										

Test Changes

Test Name	Order Code	Change	Effective Date
6-Monoacetylmorphine (6-MAM) Confirmation, Urine	U6AMCO	**Clinical Information:** For Specimen Validity Interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2 mg/dL but less than 20 mg/dL and specific gravity is greater than 1.0010 but less than 1.0030. Substituted: Creatinine is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200. Adulterated: pH is **less than 4** or greater than or equal to 11; Nitrite is greater than or equal to 500 mg/L; Chromate is greater than or equal to 50 mg/L; Oxidant is greater than or equal to 200 mg/L	Effective immediately
Albumin/Creatinine Ratio, Urine	UACR	**Reference Range:** Creatinine Urine 0–99 Years: 20–300 mg/dL Albumin/Creat Ratio 0–99 Years: **< 30 mg/g** *(Note: The reference range for Albumin, Urine will be removed)*	10/1/19
Albumin/Creatinine Ratio, Urine Timed	UACRT	**Reference Range:** Albumin/Creat Ratio 0–99 Years: **< 30 mg/g** Albumin, Urine Timed 0–99 Years: **< 20 µg/min** Creatinine, Urine 0–99 Years: 20–300 mg/dL *(Note: The reference range for Albumin, Urine will be removed)*	10/1/19
Albumin Urine, Quantitative	UALBQ	**Reference Range:** Albumin Urine Rate: 0–99 Years: **< 20 µg/min** Albumin Urine 24 hr: 0–99 Years: **< 30 mg/24 hrs** *(Note: The reference range for Albumin Urine will be removed)*	10/1/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Aldosterone 24 hr, Urine	UALDO1	**Test Name:** Previously Aldosterone, Urine **Special Information: Additives are not needed; however, samples with up to 1 g of boric acid added per 100 mL of urine are also acceptable for testing. Please indicate on the sample tube that boric acid has been added.** **Specimen Requirement: 1 mL** 24-hour urine (well-mixed) in a clean container; Minimum: 0.5 mL; **Additives are not needed; however, samples with up to 1 g of boric acid added per 100 mL of urine are also acceptable for testing; Please indicate on the sample tube that boric acid has been added; Refrigerated** **Stability:** Ambient: **4 days** Refrigerated: **7** days Frozen: **90 days** **Days Performed:** Monday–Thursday **Reported: 3–7** days	8/27/19
Aldosterone with Na and K, 24hr Urine	UALDOS	**Test Name:** Previously Aldosterone, Urine 24 Hour **Clinical Limitation: Samples with additives are NOT acceptable.** **Note:** *Urine aldosterone, urine potassium and urine sodium will be added as alias names. Special Information will be removed.* **Specimen Requirement: 1 mL** 24-hour urine (well-mixed) in a clean container; Minimum: 0.5 mL; **Samples with additives are NOT acceptable; Refrigerated** **Stability:** Ambient: **4 days** Refrigerated: **7** days Frozen: **90 days** **Days Performed:** Monday–**Thursday** **Reported:** 3–7 days	8/27/19
Alkaline Phosphatase, Bone Specific	APBONE	**Special Information: Critical frozen. Grossly hemolyzed specimens will be rejected. Urine is unacceptable. This test is New York DOH approved.** **Clinical Information:** Liver alkaline phosphatase can affect the measurement of bone specific alkaline phosphatase in this assay. Each 100 U/L of liver alkaline phosphatase contributes an additional 2.5 to 5.8 µg/L to the bone specific alkaline phosphatase result. **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Remove serum from cells ASAP, **transfer to standard aliquot tube** and freeze; **Separate specimens must be submitted when multiple tests are ordered; Critical Frozen** *OR* 0.5 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 0.3 mL; Remove plasma from cells ASAP, **transfer to standard aliquot tube** and freeze; **Separate specimens must be submitted when multiple tests are ordered; Critical Frozen**	8/19/19
Amphetamine Confirmation, Urine	UAMPC	**Clinical Information:** For Specimen Validity Interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2 mg/dL but less than 20 mg/dL and specific gravity is greater than 1.0010 but less than 1.0030. Substituted: Creatinine is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200. Adulterated: pH is **less than 4** or greater than or equal to 11; Nitrite is greater than or equal to 500 mg/L; Chromate is greater than or equal to 50 mg/L; Oxidant is greater than or equal to 200 mg/L	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Anti-Neut Cyto Ab with Rfx to Titer and MPO/PR3 Ab	NCYTO	**Test Name:** Previously Anti-Neut Cyto Ab with Rfx to Titer and MPO/PR-3 Ab **Special Information: Contaminated, hemolyzed or severely lipemic specimens will be rejected. Cerebrospinal fluid (CSF), plasma, urine or other body fluids are unacceptable. This test is New York DOH approved.** **Clinical Information:** Neutrophil cytoplasmic antibodies (C-ANCA = granular cytoplasmic staining, P-ANCA = perinuclear staining) are found in the serum of over 90% of patients with certain necrotizing systemic vasculitides, and usually in less than 5% of patients with collagen vascular disease or arthritis. Approximately 90% of patients with a P-ANCA pattern by IFA have antibodies specific for myeloperoxidase (MPO). Approximately 85% of patients with a C-ANCA pattern by IFA have antibodies specific for **PR3.** Specimens are screened by IFA on ethanol-fixed neutrophils, formalin-fixed neutrophils, and HEp-2 slides that allow differentiation of C- and P-ANCA patterns. If screen is positive, then titer and MPO/**PR3** antibodies will be added to aid in antibody determination. Additional charges apply. **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:** **Note:** *There will be a clinically significant charting name change: Serine Protease 3, IgG will be changed to Serine Proteinase 3, IgG.*	8/19/19
Ashkenazi Jewish Diseases	AJPWO	**For Interfaced Clients Only: Test build may need to be modified** **Note:** *Ashkenazi Jewish Diseases, 16 Genes will be added as an alias name. The directory will be updated to indicate the associated diseases/genes as shown below.* **Includes:** **ABCC8-related hyperinsulinism (ABCC8)** Bloom syndrome (BLM) Canavan disease (ASPA) Familial dysautonomia (IKBKAP) Fanconi anemia group C (FANCC) Gaucher disease (GBA) **Glycogen storage disease type 1A (G6PC)** **Joubert syndrome type 2 (TMEM216)** **Lipoamide dehydrogenase deficiency (DLD)** **Maple syrup urine disease type 1B (BCKDHB)** Mucolipidosis type IV (MCOLN1) **NEB-related nemaline myopathy (NEB)** Niemann-Pick disease type A (SMPD1) Tay-Sachs disease (HEXA) **Usher syndrome type 1F (PCDH15)** **Usher syndrome type 3 (CLRN1)**	8/19/19
Benzodiazepines Conf, Ur	UBENZC	**Clinical Information:** For Specimen Validity Interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2 mg/dL but less than 20 mg/dL and specific gravity is greater than 1.0010 but less than 1.0030. Substituted: Creatinine is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200. Adulterated: pH is **less than 4** or greater than or equal to 11; Nitrite is greater than or equal to 500 mg/L; Chromate is greater than or equal to 50 mg/L; Oxidant is greater than or equal to 200 mg/L	Effective immediately
Buprenorphine Quant, Urine	UQNTBU	**Clinical Information:** For Specimen Validity Interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2 mg/dL but less than 20 mg/dL and specific gravity is greater than 1.0010 but less than 1.0030. Substituted: Creatinine is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200. Adulterated: pH is **less than 4** or greater than or equal to 11; Nitrite is greater than or equal to 500 mg/L; Chromate is greater than or equal to 50 mg/L; Oxidant is greater than or equal to 200 mg/L	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cannabinoid Confirmation, Ur	UTHCC	**Clinical Information:** For Specimen Validity Interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2 mg/dL but less than 20 mg/dL and specific gravity is greater than 1.0010 but less than 1.0030. Substituted: Creatinine is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200. Adulterated: pH is **less than 4** or greater than or equal to 11; Nitrite is greater than or equal to 500 mg/L; Chromate is greater than or equal to 50 mg/L; Oxidant is greater than or equal to 200 mg/L	Effective immediately
Catecholamines Fractionated by LC-MS/MS, Urine Free	URCAT2	**Special Information:** Drugs and medications may affect results and should be discontinued for at least 72 hours prior to specimen collection, if possible. Catecholamines are not stable above pH 7. The pH of such specimens must be adjusted by the addition of 6M HCl acid or sulfamic acid prior to transport. A pH less than 2 can cause assay interference. Record total volume and collection time interval on transport tube and test request form. Specimen preservation can be extended to 1 month refrigerated by performing one of the following: Option 1: Transfer a 4 mL aliquot (Min: 2.5 mL) to an ARUP Standard Transport Tube. Adjust pH to 2.0–4.0 with 6M HCl. Option 2: Transfer a 4 mL aliquot (Min: 2.5 mL) to an ARUP Standard Transport Tube containing 20 mg sulfamic acid (ARUP supply #48098), available by contacting Client Services at 800.628.6816. **Room temperature specimens, specimens preserved with boric acid or acetic acid, or specimens with pH > 7 will be rejected.** This test is New York DOH approved. **Clinical Information: Not recommended for evaluation of paraganglioma or pheochromocytoma.** The optimal specimen for this testing is a 24-hour urine collection. Mass per day calculations are not reported for patients younger than 4 years of age and for the following specimen types: a random collection, a collection with duration of less than 20 hours, a collection with duration of greater than 28 hours, or a collection with total volume less than 400 mL (if 18 years of age or older) or greater than 5000 mL (all ages). Ratios to creatinine may be useful for these evaluations. Smaller increases in catecholamine concentrations (less than two times the upper limit) usually are the result of physiological stimuli, drugs, or improper specimen collection. Significant elevation of one or more catecholamines (three or more times the upper reference limit) is associated with an increased probability of a neuroendocrine tumor. Secreting neuroendocrine tumors are typically associated with catecholamine concentrations several times higher than the upper reference intervals. Large elevations can be seen in life-threatening illnesses and drug interferences. Common reasons for slight and moderate elevations include intense physical activity, emotional and physical stress, drug interferences, and improper specimen collection. Medications which may physiologically interfere with catecholamines and metabolites include amphetamines and amphetamine-like compounds, appetite suppressants, bromocriptine, buspirone, caffeine, carbidopa-levodopa (Sinemet), clonidine, dexamethasone, diuretics (in doses sufficient to deplete sodium), ethanol, isoproterenol, methyldopa (Aldomet), MAO inhibitors, nicotine, nose drops, propafenone (Rythmol), reserpine, theophylline, tricyclic antidepressants, and vasodilators. The effects of some drugs on catecholamine results may not be predictable. References: 1. Optimal collection and storage conditions for catecholamine measurements in human plasma and urine. (Clinical Chemistry 1993; 39: 2503-8); 2. Effect of urine pH, storage time, and temperature on stability of catecholamines, cortisol, and creatinine. (Clinical Chemistry 1998; 44: 1759-62) **Reference Range:** Epinephrine, Urine per 24h 0–3 Years: Not Established 4–**10** Years: 1–**14 µg/d** **11–17** Years: 1–**18 µg/d** **18**–99 Years: 1–**14 µg/d** Norepinephrine, Urine 24h 0–3 Years: Not Established 4–12 Years: 6–45 µg/d 13–17 Years: 15–57 µg/d 18–69 Years: 16–71 µg/d 70–99 Years: 11–60 µg/d *(continued on page 7)*	8/19/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Catecholamines Fractionated by LC-MS/MS, Urine Free *(continued from page 6)*		Dopamine, Urine 24 h 0–3 Years: Not Established 4–6 Years: 95–221 µg/d 7–12 Years: 76–371 µg/d 13–17 Years: 137–393 µg/d 18–69 Years: 77–324 µg/d 70–99 Years: 56–272 µg/d Creatinine, Urine 24h 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 81–99 Years: 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 81–99 Years: 400–1300 mg/d Epinephrine, Ur ratio to CRT 0–11 Months: 0–380 µg/g crt 1–3 Years: 0–82 µg/g crt 4–10 Years: 5–93 µg/g crt 11–17 Years: 3–58 µg/g crt 18–99 Years: 0–20 µg/g crt Norepinephrine, Ur ratio to CRT 0–11 Months: 25–310 µg/g crt 1–3 Years: 25–290 µg/g crt 4–10 Years: 27–110 µg/g crt 11–17 Years: 4–105 µg/g crt 18–99 Years: 0–45 µg/g crt Dopamine, Ur ratio to CRT 0–11 Months: 240–1290 µg/g crt 1–3 Years: 80–1220 µg/g crt 4–10 Years: 220–720 µg/g crt 11–17 Years: 120–450 µg/g crt 18–99 Years: 0–250 µg/g crt	
Cocaine Confirmation, Urine	UCOCC	**Clinical Information:** For Specimen Validity Interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2 mg/dL but less than 20 mg/dL and specific gravity is greater than 1.0010 but less than 1.0030. Substituted: Creatinine is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200. Adulterated: pH is **less than 4** or greater than or equal to 11; Nitrite is greater than or equal to 500 mg/L; Chromate is greater than or equal to 50 mg/L; Oxidant is greater than or equal to 200 mg/L	Effective immediately
Cytology, SurePath Liquid-Based Pap test and Human Papillomavirus (HPV), High Risk by PCR, SurePath (for routine co-testing in women over 30)	SPHPV	**Special Information:** Transport cervical specimen in the original collection kit. For specific collection instructions, contact Client Services at 800.628.6816. Note: **In addition to the SurePath Pap Test, Human Papillomavirus (HPV) High Risk by PCR will be performed and reported under a separate accession.** The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate. Pap Test Pathology Review reflex testing may also be added. Additional charges apply. Unacceptable conditions: Specimens not collected in a SurePath collection kit. Expired preservative vials or vials received without the collection devices.	8/19/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Dermatomyositis Panel	DERMYO	**Note:** *Clinical Information will be removed.* **Reference Range:** Mi-2 (nuclear helicase protein) Antibody: Negative P155/140 Antibody: Negative TIF-1 gamma (155 kDa) Ab: Negative SAE1 (SUMO activating enzyme) Ab: Negative MDA5 (CADM-140) Ab: Negative NXP2 (Nuclear matrix protein-2) Ab: Negative **Days Performed: Sunday–Saturday** **Reported:** 8–19 days	8/19/19
Endomysial IgA Antibody	ENDOMY	**Clinical Information: Endomysial IgA antibody assay is used as an aid in diagnosis of celiac disease in individuals who are not IgA-deficient. Clinical correlation required.**	Effective immediately
Fentanyl and Metabolite, Urine	UFENT	**Clinical Information:** For Specimen Validity Interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2 mg/dL but less than 20 mg/dL and specific gravity is greater than 1.0010 but less than 1.0030. Substituted: Creatinine is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200. Adulterated: pH is **less than 4** or greater than or equal to 11; Nitrite is greater than or equal to 500 mg/L; Chromate is greater than or equal to 50 mg/L; Oxidant is greater than or equal to 200 mg/L	Effective immediately
FIBROSpect HCV	FS2	**Test Name:** Previously FibroSpect II	8/6/19
FLT3 ITD and TKD Mutation Detection by PCR	FLT3IT	**Special Information:** DNA isolation is performed Sunday–Saturday. **Plasma, serum, fresh frozen paraffin-embedded (FFPE) tissue blocks/slides, or frozen tissue, or DNA extracted by a non-CLIA lab will be rejected. Specimens collected in anticoagulants other than EDTA or sodium heparin are unacceptable.** Clotted or grossly hemolyzed specimens will be rejected. **This test is New York DOH approved.** **Clinical Information: Aids in diagnosis and management of acute myeloid leukemia. Not intended for minimal residual disease monitoring.** **Specimen Requirement:** 5 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; **Do NOT freeze;** Refrigerated *OR* 3 mL bone marrow in an EDTA (lavender) tube; Minimum: 1 mL; **Do NOT freeze;** Refrigerated *OR* **Extracted DNA; Transport 40 µL DNA with a concentration of at least 50 ng/µL (minimum 40 µL) using a tissue transport kit (ARUP supply #47808); DNA must be extracted by a CLIA certified lab;** Refrigerated **Stability:** Ambient: Blood, bone marrow: 24 hours; **Extracted DNA: 1 month** Refrigerated: Blood, bone marrow: 5 days; **Extracted DNA: Indefinitely** Frozen: Blood, bone marrow: Unacceptable; **Extracted DNA: Indefinitely**	8/19/19
G-6-PD Quantitative	G6PDQT	**Special Information:** Do NOT freeze. Hemolyzed **or clotted** specimens are unacceptable. This test is New York DOH approved. **Specimen Requirement:** 3 mL whole blood in an **ACD A (yellow)** tube; Minimum: 1.5 mL; Enzyme most stable in acid citrate dextrose (ACD); Do NOT freeze; Refrigerated *OR* 3 mL whole blood in an EDTA (lavender) tube; Minimum: 1.5 mL; Do NOT freeze; Refrigerated *OR* 3 mL whole blood in a sodium or lithium heparin (green) tube; Minimum: 1.5 mL; Do NOT freeze; Refrigerated	8/19/19
Gentamicin, Post Dose	GENTPO	**Special Information: Do not collect in a gel separator tube. The aminoglycoside sisomicin cross-reacts with the QMS Gentamicin assay due to its structural similarity. Therefore, the results of this assay cannot be used to accurately quantify gentamicin serum or plasma levels in patients on sisomicin in combination with gentamicin.**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Gentamicin, Pre Dose	GENTPR	**Special Information: Do not collect in a gel separator tube. The aminoglycoside sisomicin cross-reacts with the QMS Gentamicin assay due to its structural similarity. Therefore, the results of this assay cannot be used to accurately quantify gentamicin serum or plasma levels in patients on sisomicin in combination with gentamicin.**	Effective immediately
Gentamicin, Random	GENTRA	**Special Information: Do not collect in a gel separator tube. The aminoglycoside sisomicin cross-reacts with the QMS Gentamicin assay due to its structural similarity. Therefore, the results of this assay cannot be used to accurately quantify gentamicin serum or plasma levels in patients on sisomicin in combination with gentamicin.**	Effective immediately
Hepatitis Be Antibody	AHBE	**Special Information: This assay is not designed to test body fluids other than human serum or plasma.** Specimens containing particulate material, or grossly hemolyzed or lipemic specimens are not acceptable for testing. **The testing of heat-inactivated samples is not recommended. Serum or plasma should be separated from the clot within 2 hours of collection and placed into refrigerated storage.** **Clinical Limitation: This test has not been validated in pediatric individuals, especially less than 18 months of age, where in the latter group, passively-transferred maternal antibodies may be present.** **Clinical Information: This test should only be used in patients with a previously known and/or concurrent positive HBsAg result. Along with HBeAg test, Hepatitis Be antibody test is used for monitoring the natural history of Hepatitis B virus infection and prognostication. Clinical correlation is required.** **Specimen Requirement**: **0.5 mL** serum from a serum separator (gold) tube; Minimum: **0.3 mL; Minimum volume will not allow for repeat or additional testing; Sending 0.5 mL is preferred when possible;** Separate serum from cells ASAP or within 2 hours of collection; Transfer serum to standard aliquot tube and refrigerate; Refrigerated *OR* **0.5 mL** plasma from an EDTA (lavender) tube; Minimum: **0.3 mL; Minimum volume will not allow for repeat or additional testing; Sending 0.5 mL is preferred when possible;** Separate plasma from cells ASAP or within 2 hours of collection; Transfer plasma to standard aliquot tube and refrigerate; Refrigerated **Stability:** Ambient: Unacceptable Refrigerated: After separation from cells: 6 days Frozen: After separation from cells: **14 days** (Avoid repeated freeze/thaw cycles) **Days Performed: Monday, Thursday** **Reported: 1–5** days	10/1/19
HIV-2 DNA/RNA PCR	HIV2PC	**Test Name:** Previously HIV-2 DNA PCR **Special Information:** This test is not approved for patients residing in New York state. **Hemolyzed specimens will be rejected. Heparinized whole blood is unacceptable. Specimen must be whole blood collected in an EDTA (lavender) tube. There are no other acceptable specimens.** **Specimen Requirement:** 1 mL whole blood in an **EDTA (lavender) tube;** Minimum: 0.4 mL; Ambient **Stability:** Ambient: **7** days Refrigerated: **14** days Frozen: **30 days**	9/30/19
HIV PhenoSense GT	HIVPHS	**Special Information:** Patient's most recent viral load and viral load collection date are recommended to be sent with the sample. If this information is not supplied and the laboratory has a failed assay, they will ask for the viral load. This test is validated for testing specimens with the HIV-1 viral loads above 500 copies/mL and should be interpreted only on such specimens. **Thawed specimens will be rejected. This test is New York DOH approved.** **Clinical Information: HIV-1 combined pheno- and genotyping provides antiretroviral susceptibility information for protease inhibitors (PI) and reverse transcriptase inhibitors (NRTI, NNRTI).** *(continued on page 10)*	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
HIV PhenoSense GT *(continued from page 9)*		**Specimen Requirement:** 3 mL plasma from an EDTA (white) plasma preparation tube (PPT); Minimum: **1 mL;** Patient's most recent viral load and viral load collection date are recommended; Separate plasma from cells ASAP or within **6 hours** of collection; **Transfer into standard aliquot tube and** freeze immediately; **Separate specimens must be submitted when multiple tests are ordered; Critical Frozen** *OR* 3 mL plasma from an EDTA (lavender) tube; Minimum: **1 mL;** Collect 2 EDTA lavender top tubes; Patient's most recent viral load and collection date are recommended; Separate plasma from cells ASAP or within 6 hours of collection; **Transfer into standard aliquot tube and** freeze immediately; **Separate specimens must be submitted when multiple tests are ordered; Critical Frozen** **Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: 2 weeks	
HSP-70 Antibody (Anti-68 kd Antigen)	AB68KD	**Days Performed:** Thursday **Reported:** 2–**9** days	8/19/19
IDH1/IDH2 Mutation, Blood/ Bone marrow	IDH12	**Special Information:** Plasma, serum, **fresh frozen paraffin-embedded (FFPE) tissue blocks/slides, or frozen tissue, or DNA extracted by a non-CLIA lab will be rejected.** Specimens collected in anticoagulants other than EDTA **or sodium heparin** are unacceptable. Clotted or grossly hemolyzed specimens will be rejected. **This test is New York DOH approved.** **Specimen Requirement:** 5 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; **Do not freeze;** Refrigerated *OR* 3 mL bone marrow in an EDTA (lavender) tube; Minimum: 1 mL; **Do not freeze;** Refrigerated *OR* Extracted DNA; Transport **40 µL** extracted DNA at a concentration of 50 ng/µL **(minimum 40 µL) using a tissue transport kit (ARUP supply #47808); DNA must be extracted by a CLIA certified lab;** Refrigerated **Stability:** Ambient: **Blood, bone marrow:** 24 hours; **Extracted DNA: 1 month** Refrigerated: **Blood, bone marrow:** 5 days; **Extracted DNA: Indefinitely** Frozen: **Blood, bone marrow:** Unacceptable; **Extracted DNA: Indefinitely** **Days Performed:** Sunday, Tuesday, Thursday **Reported: 8–15** days	8/19/19
Insulin, Free, Serum	FINS	**Days Performed: Tuesday,** Friday **Reported: 3–5** days	Effective immediately
JC Polyoma Virus Quantitative PCR	JCQNT	**Special Information:** Avoid repeated freezing and thawing of specimens. **The published serum or plasma specimen types are the only acceptable specimen types; all other specimens will be rejected.**	8/26/19
KIT (D816V) Mutation by PCR	KIT816	**Special Information:** DNA isolation is performed Sunday–Saturday. **Plasma, serum,** fresh frozen paraffin-embedded (FFPE) tissue **blocks/slides, or frozen tissue, or DNA extracted by a non-CLIA lab will be rejected. Specimens collected in anticoagulants other than EDTA or sodium heparin are unacceptable.** Clotted or grossly hemolyzed specimens will be rejected. **This test is New York DOH approved.** **Clinical Information: Aids in the diagnosis of mastocytosis and provides prognostic and predictive information for tyrosine kinase inhibitor (TKI) therapy planning.** **Specimen Requirement:** 5 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; **Do not freeze;** Refrigerated *OR* 3 mL bone marrow in an EDTA (lavender) tube; Minimum: 1 mL; **Do not freeze;** Refrigerated *OR* **Extracted DNA; Transport 40 µL extracted DNA at a concentration of 50 ng/µL (minimum 40 µL) using a tissue transport kit (ARUP supply #47808); DNA must be extracted by a CLIA certified lab;** Refrigerated **Stability:** Ambient: Blood, bone marrow: 24 hours; **Extracted DNA: 1 month** Refrigerated: Blood, bone marrow: 5 days; **Extracted DNA: Indefinitely** Frozen: Blood, bone marrow: Unacceptable; **Extracted DNA: Indefinitely**	8/19/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Liver Fibrosis, FibroTest-ActiTest	LIVFIB	**Reference Range:** Fibrosis Interpretation FibroTest Score: ≥ **0 and ≤ 0.21**–Metavir Score: F0 no fibrosis FibroTest Score: > **0.21 and ≤ 0.27**–Metavir Score: F0–F1 **no fibrosis** FibroTest Score: > **0.27 and ≤ 0.31**–Metavir Score: F1 minimal fibrosis FibroTest Score: > **0.31 and ≤ 0.48**–Metavir Score: F1–F2 **minimal fibrosis** FibroTest Score: > **0.48 and ≤ 0.58**–Metavir Score: F2 moderate fibrosis FibroTest Score: > **0.58 and ≤ 0.72**–Metavir Score: F3 advanced fibrosis FibroTest Score: > **0.72 and ≤ 0.74**–Metavir Score: F3–F4 **advanced fibrosis** FibroTest Score: > **0.74 and ≤ 1.00**–Metavir Score: F4 severe fibrosis Necroinflammatory Activity Interpretation ActiTest Score: ≥ **0 and ≤ 0.17**–Metavir Score: A0 no activity ActiTest Score: > **0.17 and ≤ 0.29**–Metavir Score: A0–A1 **no activity** ActiTest Score: > **0.29 and ≤ 0.36**–Metavir Score: A1 minimal activity ActiTest Score: > **0.36 and ≤ 0.52**–Metavir Score: A1–A2 **minimal activity** ActiTest Score: > **0.52 and ≤ 0.60**–Metavir Score: A2 significant activity ActiTest Score: > **0.60 and ≤ 0.62**–Metavir Score: A2–A3 **significant activity** ActiTest Score: > **0.62 and ≤ 1.00**–Metavir Score: A3 severe activity *(Note: There will be no other reference range changes for this test)*	9/23/19
Methadone Quantitation, Urine	UQMET	**Clinical Information:** For Specimen Validity Interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2 mg/dL but less than 20 mg/dL and specific gravity is greater than 1.0010 but less than 1.0030. Substituted: Creatinine is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200. Adulterated: pH is **less than 4** or greater than or equal to 11; Nitrite is greater than or equal to 500 mg/L; Chromate is greater than or equal to 50 mg/L; Oxidant is greater than or equal to 200 mg/L	Effective immediately
Mitochondrial Antibody Panel	MITO	**Clinical Information: Anti-mitochondrial antibody test is used as an aid in diagnosis of primary biliary cirrhosis. Clinical correlation is required.**	Effective immediately
Mitochondrial Antibody Screen	MITOS	**Clinical Information: Anti-mitochondrial antibody test is used as an aid in diagnosis of primary biliary cirrhosis. Clinical correlation is required.**	Effective immediately
Monoclonal Protein with Immunoglobulins and Free Light Chains, serum	SERMPA	**Note:** *Immunoelectrophoresis, Serum and Immunofixation Electrophoresis (IFE), serum were removed as alias names.*	Effective immediately
Myasthenia Gravis/ Lambert-Eaton Syndrome	LAMBRT	**Special Information:** Reflex Algorithm: If AChR modulating antibody is ≥ 90% and striational antibodies are ≥ 1:120, AChR Ganglionic Neuronal Ab and CRMP-5-IgG Western blot will be performed at an additional charge. **Grossly hemolyzed, lipemic or icteric specimens will be rejected.** **Days Performed:** Monday–Sunday **Reported: 4**–8 days	8/1/19
Mycoplasma Cult Non Urogenital	UMPLAS	**Special Information: Transport specimen on dry ice. The following specimens are unacceptable: Non-patient specimens, specimens not in Mycoplasma/Ureaplasma transport media, M4 RT or bacterial transport media, dry swabs. Specimen source preferred. This test is New York DOH approved.** **Specimen Requirement:** 0.5 mL body fluid in M4 or Universal Transport Media (UTM); Minimum: 0.3 mL; **Transport specimen on dry ice;** Frozen *OR* Tissue in M4 or Universal Transport Media (UTM); Frozen *OR* 0.5 mL respiratory specimen in M4 or Universal Transport Media (UTM); Minimum: 0.3 mL; **Collect specimens from patients < 1 year old;** Other than lung transplant patients, this test is not appropriate for adult respiratory specimens; Frozen *OR* **0.5 mL** cerebrospinal fluid (CSF) in M4 or Universal Transport Media (UTM); Minimum: 0.3 mL; Frozen **Stability:** Ambient: 8 hours Refrigerated: **48 hours** Frozen: 1 month at minus 70 °C; **Note: Unacceptable at minus 20 °C**	8/19/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Neutrophil Oxidative Burst, Blood	OXBRST	**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. **Ambient stability is 24 hours for New York clients.** This test is New York DOH approved.	8/19/19
Opiate Confirmation, Urine	OPICON	**Clinical Information:** For Specimen Validity Interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2 mg/dL but less than 20 mg/dL and specific gravity is greater than 1.0010 but less than 1.0030. Substituted: Creatinine is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200. Adulterated: pH is **less than 4** or greater than or equal to 11; Nitrite is greater than or equal to 500 mg/L; Chromate is greater than or equal to 50 mg/L; Oxidant is greater than or equal to 200 mg/L	Effective immediately
Organic Acids, Plasma	ORGACS	**Note:** *There is a unit of measurement change associated with this test. The unit of measure has changed from nmol/mL to µmol/L.* **Specimen Requirement:** 3 mL plasma from a sodium or lithium heparin (green) tube; Minimum: **1 mL;** Separate plasma from cells within 1 hour of collection and freeze; A "Patient History for Biochemical Genetic Testing" form is recommended, but not required; **Separate specimens must be submitted when multiple tests are ordered;** Critical Frozen **Stability:** Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: Unacceptable Frozen: After separation from cells: **5 months**	Effective immediately
Oxycodone Confirmation, Urine	UOXYCC	**Clinical Information:** For Specimen Validity Interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2 mg/dL but less than 20 mg/dL and specific gravity is greater than 1.0010 but less than 1.0030. Substituted: Creatinine is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200. Adulterated: pH is **less than 4** or greater than or equal to 11; Nitrite is greater than or equal to 500 mg/L; Chromate is greater than or equal to 50 mg/L; Oxidant is greater than or equal to 200 mg/L	Effective immediately
Pancreatitis Panel	PANCPL	**CPT:** 81223 x 1, 81404 x 1, 81405 x 1	8/6/19
Parietal Cell Antibody Panel	PARIET	**Clinical Information: Anti-parietal cell antibody test is used as an aid in diagnosis of autoimmune gastritis. Clinical correlation is required.**	Effective immediately
Parietal Cell Antibody Screen	PARIES	**Clinical Information: Anti-parietal cell antibody test is used as an aid in diagnosis of autoimmune gastritis. Clinical correlation is required.**	Effective immediately
Parvovirus B19 IgM Antibodies	PARVOM	**Special Information:** Avoid using hemolyzed, icteric, lipemic or bacterially contaminated sera.	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
PML/RARA RTPCR	APLPCR	**Special Information:** RNA isolation performed Sunday–Saturday. **The following specimens are unacceptable: Severely hemolyzed or clotted specimens, serum, plasma, cerebrospinal fluid (CSF), extracted DNA, RNA extracted by a non-CLIA lab, bone core, fresh frozen paraffin-embedded (FFPE) tissue, specimens collected in anticoagulants other than EDTA. This test is New York DOH approved.** **Specimen Requirement:** 5 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; Specimen must be delivered to Cleveland Clinic Laboratories by 3 p.m. EST on the day of collection; DO NOT collect the day before or the day of a major holiday; **Separate specimens must be submitted when multiple tests are ordered; Critical Refrigerated** *OR* 3 mL bone marrow in an EDTA (lavender) tube; Minimum: 1 mL; Specimen must be delivered to Cleveland Clinic Laboratories by 3 p.m. EST on the day of collection; DO NOT collect the day before or the day of a major holiday; **Separate specimens must be submitted when multiple tests are ordered; Critical Refrigerated** *OR* **Extracted RNA; Transport 40 µL extracted RNA at a concentration of at least 40 ng/µL (minimum 40 µL) using a tissue transport kit (ARUP supply #47808); RNA must be extracted by a CLIA certified lab; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen** **Stability:** Ambient: **Blood, bone marrow:** 1 hour; **Extracted RNA: Unacceptable** Refrigerated: **Blood, bone marrow:** 48 hours; **Extracted RNA: Unacceptable** Frozen: **Blood, bone marrow:** Unacceptable; **Extracted RNA: Indefinitely**	8/19/19
Polymyositis and Dermatomyositis Panel	MYOSPL	**Note:** *Clinical Information will be removed.* **Reference Range:** Jo-1 Antibody, IgG Negative: 29 AU/mL or less Equivocal: 30–40 AU/mL Positive: 41 AU/mL or greater PL-7 (threonyl-tRNA synthetase) Antibody: Negative PL-12 (alanyl-tRNA synthetase) Antibody: Negative EJ (glycyl-tRNA synthetase) Antibody: Negative SRP (Signal Recognition Particle) Ab: Negative OJ (isoleucyl-tRNA synthetase) Antibody: Negative Mi-2 (nuclear helicase protein) Antibody: Negative P155/140 Antibody: Negative SAE1 (SUMO activating enzyme) Antibody: Negative MDA5 (CADM-140) Antibody: Negative NXP-2 (Nuclear matrix protein-2) Ab: Negative TIF-1 gamma (155 kDa) Antibody: Negative **Days Performed: Sunday–Saturday** **Reported:** 8–19 days	8/19/19
Quantitative Pain Panel, Urine	UQNTPP	**Clinical Information:** For Specimen Validity Interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2 mg/dL but less than 20 mg/dL and specific gravity is greater than 1.0010 but less than 1.0030. Substituted: Creatinine is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200. Adulterated: pH is **less than 4** or greater than or equal to 11; Nitrite is greater than or equal to 500 mg/L; Chromate is greater than or equal to 50 mg/L; Oxidant is greater than or equal to 200 mg/L	Effective immediately
Rufinamide	RUFIN	**Reference Range:** Therapeutic Range: **5–30 µg/mL** Dose-related range (values at dosages of 800–7200 mg/day): 3–30 µg/mL	8/19/19
Smooth Muscle Antibody Panel	SMOOTH	**Clinical Information: Anti-smooth muscle antibody test is used as an aid in diagnosis of autoimmune hepatitis. Low positive titers may occasionally be seen with primary biliary cirrhosis and viral hepatitides, among others. Clinical correlation is required.**	Effective immediately
Smooth Muscle Antibody Screen	SMTHS	**Clinical Information: Anti-smooth muscle antibody test is used as an aid in diagnosis of autoimmune hepatitis. Low positive titers may occasionally be seen with primary biliary cirrhosis and viral hepatitides, among others. Clinical correlation is required.**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Thyroid Stimulating Immunoglobulin	**TSIGIM**	**For Interfaced Clients Only: Test build may need to be modified** **Note:** *TSIGIM will be the new order code (previously TSIG). Special Information will be removed.* **Includes:** Thyroid Stimulating Immunoglobulin **Thyroid Stimulating Immunoglobulin Qualitative** **Clinical Limitation: Avoid hemolysis.** **Clinical Information: The measurement of thyroid stimulating autoantibodies, in conjunction with other clinical and laboratory findings, is used as an aid in the** diagnosis of patients suspected of having Graves' disease. **Specimen Requirement: 0.5 mL** serum from a serum separator (gold) tube; Minimum: **0.35 mL; Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.5 mL is preferred when possible;** Refrigerated *OR* **0.5 mL plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: **0.35 mL; Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.5 mL is preferred when possible;** Refrigerated **Stability:** Ambient: **24** hours Refrigerated: **7** days Frozen: **1 year** **Methodology: Chemiluminescence Immunoassay (CLIA)** **Reference Range:** Thyroid Stimulating Immunoglobulin: **< 0.55 IU/L** **Thyroid Stimulating Immunoglobulin Qualitative: Negative** **Days Performed:** Monday–**Friday** **Reported:** 1–**4** days	8/28/19
TP53 Somatic Mutation, Prognostic	TP53MU	**Days Performed:** Varies **Reported: 4–12** days	8/19/19
Tramadol and Metabolite, Quantitation	TRAQNT	**Clinical Information:** For Specimen Validity Interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2 mg/dL but less than 20 mg/dL and specific gravity is greater than 1.0010 but less than 1.0030. Substituted: Creatinine is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200. Adulterated: pH is **less than 4** or greater than or equal to 11; Nitrite is greater than or equal to 500 mg/L; Chromate is greater than or equal to 50 mg/L; Oxidant is greater than or equal to 200 mg/L	Effective immediately
TSH Receptor Antibody	TRAB	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Thyroid Stimulating Immunoglobulin TSH Binding Inhibition **Thyroid Stimulating Immunoglobulin Qualitative** **Stability:** Ambient: **24** hours Refrigerated: **3** days Frozen: **30 days** **Reference Range:** Thyroid Stimulating Immunoglobulin: **< 0.55 IU/L** TSH Binding Inhibition (0–99 Years): < 1.0 U/L **Thyroid Stimulating Immunoglobulin Qualitative: Negative**	8/28/19
Vitamin B1 (Thiamine), Whole Blood	B1WB	**Specimen Requirement:** 2 mL whole blood in an EDTA (lavender) tube; Minimum: 0.6 mL; **Frozen** **Stability:** Refrigerated: 7 days Frozen: **14 days** **Days Performed:** 5 days per week **Reported: 2–7** days	8/13/19

New Tests

Test Name	Order Code	Change	Effective Date
Epi ProColon	EPCOL	**Special Information:** This test is not intended to replace a colonoscopy. NOT recommended for pregnant women because of a potential for false-positive results in these individuals. Accurate test performance requires following the specimen preparation instructions. Minimum volume of 4 mL is required for testing without repeats. If a repeat is necessary, an additional specimen will be requested. **Specimen Requirement:** 20 mL whole blood in an EDTA (lavender) tube; Minimum: 10 mL whole blood (4 mL plasma following centrifugation, no repeat testing); Blood collection tubes should be allowed to complete the evacuated fill; Plasma preparation should be performed ASAP or within 4 hours of collection; Centrifuge for 12 minutes at 1350 ± 150 rcf; Transfer the plasma to a 15 mL conical tube and centrifuge for an additional 12 minutes at 1350 ± 150 rcf; Ensure a minimum of 8 mL plasma is obtained following centrifugation; Transfer 4 mL plasma into 2 cryovial tubes or freezable specimen transport tubes; Frozen **Stability:** Ambient: Unacceptable Refrigerated: 72 hours Frozen: 2 weeks **Methodology:** Polymerase Chain Reaction (PCR) **Days Performed:** Sunday, Wednesday **Reported:** 8–11 days **CPT:** 81327 x 1 **Price:** $240.00 (non-discountable)	8/6/19
PD-L1 22C3 IHC with Tumor Proportion Score (TPS) Interpretation, pembrolizumab (KEYTRUDA)	PDL1KE	**Special Information:** This test code includes pathologist interpretation. At least 100 viable tumor cells are required for interpretation. Include surgical pathology report and indicate tissue site with the test order. If sending precut slides, do not oven bake. Gastric/gastroesophageal junction (GEJ) specimens are unacceptable. Paraffin block with no tumor tissue remaining will be rejected. Specimens fixed in any fixative other than 10% neutral buffered formalin, decalcified specimens, and specimens with fewer than 100 viable tumor cells are unacceptable. This test is New York DOH approved. **Clinical Information:** Use for non-small cell lung cancer (NSCLC) specimens only. Companion diagnostic testing to aid in the prediction of response to pembrolizumab (KEYTRUDA) as first- or second-line monotherapy for patients with NSCLC. **Specimen Requirement:** Tumor tissue; Formalin-fixed, paraffin-embedded (FFPE) tissue block; Formalin fix (10% neutral buffered formalin) and paraffin embed specimen; Protect paraffin block and/or slides from excessive heat; Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808 recommended); Minimum: 3 slides; Include surgical pathology report and indicate tissue site; Ambient **Stability:** Ambient: Slides: 6 months, must be stored in the dark; Paraffin block: Indefinitely Refrigerated: Slides: 6 months, must be stored in the dark; Paraffin block: Indefinitely Frozen: Slides: Unacceptable; Paraffin block: Unacceptable **Methodology:** Immunohistochemistry **Days Performed:** Monday–Friday **Reported:** 2–6 days **CPT:** 88360 x 1 **Price:** $300.00 (non-discountable)	Effective immediately

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Syphilis Total with reflex	SYPHTX	**Clinical Limitation:** Not intended for use in the screening of blood or plasma donors. A nonreactive result does not totally exclude a recent, within the past 2–3 weeks, Treponema pallidum infection. Detection of treponemal antibodies may indicate recent, past, or successfully treated syphilis infections and therefore cannot be used to differentiate between active and cured cases. Results obtained from immunocompromised individuals should be interpreted with caution. Contaminated, icteric, lipemic, hemolyzed, or heat-inactivated sera may cause erroneous results and should be avoided. **Clinical Information:** The Syphilis Total assay is a multiplex flow immunoassay intended for the qualitative detection of total (IgG/IgM) antibodies to Treponema pallidum. **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 1 mL is preferred when possible; Refrigerated **Stability:** Ambient: 24 hours Refrigerated: 7 days Frozen: 14 days **Methodology:** Multiplex Flow Immunoassay **Days Performed:** Monday–Saturday **Reported:** 1–3 days **CPT:** 86780 x 1 **Price:** $34.00 (non-discountable)	10/1/19
Zika Virus by PCR, Blood	ZKAPCR	**Note:** *This test was previously announced in the June Technical Update with a go-live date of 8/1/19. Due to unforeseen circumstances, the go-live date has been changed to 8/19/19. We apologize for any inconvenience this may have caused.*	8/19/19
Zika Virus by PCR, Urine	UZKPCR	**Note:** *This test was previously announced in the June Technical Update with a go-live date of 8/1/19. Due to unforeseen circumstances, the go-live date has been changed to 8/19/19. We apologize for any inconvenience this may have caused.*	8/19/19
Zika Virus IgM Antibody Capture (MAC), by ELISA	ZKAIGM	**Note:** *This test was previously announced in the June Technical Update with a go-live date of 8/1/19. Due to unforeseen circumstances, the go-live date has been changed to 8/19/19. We apologize for any inconvenience this may have caused.* **Special Information:** Use for patients whose symptoms began, or whose documented exposure occurred, at least 14 days prior to testing. Should also be used as follow-up for patients with negative serum and urine results from molecular testing performed less than 14 days after symptom onset. This assay is intended for in vitro diagnostic use under FDA Emergency Use Authorization (EUA). This test has not been FDA cleared or approved. The possibility of false-positive or false-negative results must be considered. RT-PCR testing on both a serum and urine specimen is recommended by the Centers for Disease Control and Prevention (CDC) to rule out false-negative IgM results in patients experiencing symptoms for less than 2 weeks. Specimens collected for IgM testing greater than or equal to 2 weeks after symptom onset do not require any additional testing. For more information, please review the current clinical guidelines for Zika virus testing at: www.cdc.gov/zika/. If the result is "Presumptive Zika," then Zika IgM Ab Capture (MAC) Confirmation will be added at no additional charge. 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,' and submit Patient History for Zika Virus testing form with the specimen. Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens are unacceptable. This test is New York DOH approved.	8/19/19

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
PTT Incubated Mixing Study	PTTIM	$388.00	85390, 85520, 85610, 85670, 85730, 85732 x 2	Effective immediately

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Pancreatitis Panel	PANCPL	$3552.00 (non-discountable)	81223, 81404 , 81405	8/6/19
Thyroid Stimulating Immunoglobulin	TSIGIM	$95.00 (non-discountable)	84445	8/28/19
TSH Receptor Antibody	TRAB	$140.00 (non-discountable)	83520, 84445	8/28/19

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Albumin, Random Urine	UALBR	This test will no longer be available. Suggest ordering Albumin/Creatinine Ratio, Urine (UACR).	10/1/19
Canavan Disease Mutation, Fluid	CANV2	This test will no longer be available.	10/3/19
Collagen Screen	COLLGN	This test will no longer be available.	10/3/19
Mitochondrial DNA Deletion Analysis	DNADEL	This test will no longer be available.	10/3/19
Syphilis IgG (T pallidum)	SYPHG	This test will no longer be available. Suggest ordering Syphilis Total with reflex (SYPHTX).	10/1/19
Syphilis IgG with Confirmation	SYPHGX	This test will no longer be available. Suggest ordering Syphilis Total with reflex (SYPHTX).	10/1/19