Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • September 2023

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
3	14.3.3 eta Protein, Serum					■	■				■	■	
3	Alkaline Phosphatase Isoenzymes					■							
3	Allergen, Respiratory Disease Profile Region 5, with Reflex						■	■					
11	Amylase, Pancreatic				■								
4	Aquaporin-4 Receptor Antibody, IgG by CBA-IFA, CSF with Reflex to Titer					■					■		
4	Aquaporin-4 Receptor Antibody, IgG by CBA-IFA with Reflex to Titer, Serum					■							
4	Arsenic, Fractionated Urine							■			■	■	
4	Chromosome Breakage for Fanconi Anemia					■	■		■		■		
5	Complement, Alternate Pathway (AH50), Functional					■	■	■	■		■	■	
5	Copper, Liver					■	■				■		
5	COVID & Influenza A/B NAAT, Routine		■										
11	COVID NAAT, Lower Respiratory, Routine			■									
5	COVID NAAT, Upper Respiratory, Routine		■										
5	DNAse-B Antibody					■					■	■	
6	Drug Detection Panel, Meconium, Qualitative							■					
7	Drug Detection Panel, TOF-MS, Umbilical Cord Tissue									■			
11	EGFR Mutation Analysis, Tissue				■								
7	Everolimus						■						

Test Update Page #		Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT
7	Expanded Respiratory Pathogen Panel by PCR (with COVID), Expedited		■										
11	FLT3 ITD Mutation Analysis Blood			■									
8	Heparin Anti Xa Assay						■	■	■			■	
8	HIV-1 Western Blot				■								
8	Iron, Liver					■	■				■		
8	LMW Anti Xa Assay						■					■	
8	Mycoplasma genitalium, NAAT											■	
9	N-methyl-D-Aspartate Receptor Ab, IgG, CSF, Reflex to Titer					■					■		
9	N-methyl-D-Aspartate Receptor Antibody, IgG					■					■		
9	Pneumococcal IgG Antibodies, 14 Serotypes					■	■		■			■	
10	Pneumococcal IgG Antibodies, 23 Serotypes					■	■		■			■	
11	Pregabalin, urine			■									
10	Proinsulin, Intact					■				■		■	
10	Rufinamide										■	■	
10	Streptococcal Antibody Panel											■	
10	Tapentadol Quant, Urine		■			■		■					
10	Triglycerides Body Fluid with Reflex to Chylomicron Electrophoresis										■		

Test Changes

Test Name	Order Code	Change	Effective Date
14.3.3 eta Protein, Serum	1433P	**Special Information: Hemolyzed or lipemic specimens will be rejected.** **Clinical Information:** 14-3-3 eta protein **is a joint-derived, proinflammatory mediator that is implicated in the joint erosion process and pathogenesis of RA. Serum 14-3-3 eta is elevated in both early and established RA.** **Specimen Requirement:** 1 mL serum from no additive (Red) tube; **Frozen; Allow specimen to clot completely** at room temperature. **Separate serum from cells ASAP or within 45 minutes of collection. Transfer serum to standard aliquot tube.** *OR* **1 mL serum from serum separator (Gold) tube; Frozen; Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 45 minutes of collection. Transfer serum to standard aliquot tube.** **Stability:** Ambient: **3** days Refrigerated: **3** days Frozen: **7 days (stable 6 freeze/thaw cycles)** **Days Performed: Varies** **Reported: 7–13** days	10/17/23
Alkaline Phosphatase Isoenzymes	ALKISO	**Special Information:** *special information has been removed* **Specimen Requirement:** 2 mL serum from serum separator (Gold) tube; Refrigerated; **Patient should be fasting. Patients who have B or O blood group and are secretors may have an elevated ALP about two hours after a fatty meal. Age and sex of patient are necessary for interpretation of results.**	9/5/23
Allergen, Respiratory Disease Profile Region 5, with Reflex	RESP5X	**For interface clients only–Test build may need to be modified** **Includes:** Alternaria tenuis Aspergillus fumigatus Bermuda grass **Birch Tree** Cat dander Cladosporium herbarum (Hormodendrum) **Cocklebur** Cockroach Cottonwood Tree Dermatophagoides farinae Dermatophagoides pteronyssinus Dog dander Elm tree **English Plantain (Ribwort)** Hickory/Pecan tree Johnson grass Lamb's quarters (goosefoot) Maple(Box Elder) Tree Mouse Urine **Mulberry** Oak tree **Pigweed** **Rough Marshelder** **Sheep sorrel** Short (common) ragweed **Sycamore Tree** Timothy Grass White Ash Tree **Specimen Requirement: 3** mL serum from serum separator (Gold) tube; **Collect Ambient;** Transport Refrigerated *OR* **3** mL plasma from EDTA (Lavender) tube; **Collect Ambient;** Transport Refrigerated *OR* **3** mL plasma from lithium heparin plasma separator (Light Green) tube; **Collect Ambient;** Transport Refrigerated; Minimum **1.5** mL Submitting the minimum volume will not allow for repeat testing or addons. Required volume of **3** mL is preferred when possible.	10/17/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Aquaporin-4 Receptor Antibody, IgG by CBA-IFA, CSF with Reflex to Titer	AQPCSF	**Special Information: If AQP4 antibody IgG is positive, then an AQP4 antibody IgG titer is reported. Additional charges apply.** Hemolyzed, contaminated specimens or severely lipemic specimens are unacceptable. This test is New York DOH approved. **Clinical Information: This test is useful in the initial evaluation of neuromyelitis optica (NMO) spectrum disorders. NMO commonly presents with optic neuritis or longitudinally extensive transverse myelitis**. Approximately 75% percent of patients with NMO **have** antibodies to the aquaporin-4 (AQP4) receptor. While the absence of AQP4 receptor antibodies does not rule out a diagnosis of NMO, presence of this antibody is diagnostic for NMO. **Days Performed: Mon,** Wed, **Fri** **Reported:** 2–**7** days	effective immediately
Aquaporin-4 Receptor Antibody, IgG by CBA-IFA with Reflex to Titer, Serum	NMOIFA	**Clinical Information: This test is useful in the initial evaluation of neuromyelitis optica (NMO) spectrum disorders. NMO commonly presents with optic neuritis or longitudinally extensive transverse myelitis. Approximately 75% of patients with NMO have antibodies to the aquaporin-4 (AQP4) receptor. While the absence of AQP4 receptor antibodies does not rule out a diagnosis of NMO, presence of this antibody is diagnostic for NMO.**	effective immediately
Arsenic, Fractionated Urine	UASFR	**For interface clients only–Test build may need to be modified** **Includes:** Organic Arsenic Inorganic Arsenic Methylated Arsenic **Arsenic Fractionation Interpretation** **Stability:** Ambient: **2** weeks Refrigerated: 2 weeks Frozen: **2 months** **Days Performed:** Tue, **Fri**	effective immediately
Chromosome Breakage for Fanconi Anemia	CBREAK	**Special Information: Collect Monday through Friday only. Specimen MUST be received in the Send Out Laboratory by noon on Fridays. If WBC or lymphocyte percentage (%L) are below normal, please contact laboratory customer service regarding minimum specimen requirements (216-444-5755).** **Clinical Information: Chromosome breakage analysis is a test for assessing genomic instability. The most common syndrome for which this test is diagnostic is Fanconi anemia (FA). FA is characterized by bone marrow failure, increased risk for cancer, and physical abnormalities. Progressive bone marrow failure is responsible for the most significant morbidity and mortality. Clinically heterogeneous, FA individuals are at increased risk for acute myelogenous leukemia, myelodysplastic syndrome, and solid tumors of the neck, head, oral cavities, and genitourinary system. Congenital abnormalities are present in approximately 70% of FA patients and include: café au lait spots or hypopigmentation; short stature; radial ray defects; eye defects such as microphthalmia; malformations of the kidney, genitalia, heart, gastrointestinal tract, ears, and feet. Currently, 21 genes have been identified that, when mutated, can cause FA or an FA-like phenotype.** **The first step in FA diagnosis is to perform a breakage analysis on peripheral blood. However, some FA patients undergo a self-correction of cells in the hematopoietic lineage, resulting in a normal blood breakage study. In such a case, breakage analysis of skin fibroblasts is necessary to detect the increased breakage and radial formation. This phenomenon is known as somatic mosaicism. Fibroblast breakage studies may also be preferable for patients with very low white blood cell counts.** **Specimen Requirement: 10** mL whole blood in sodium heparin (Green) tube; **Minimum 5** mL; Ambient; Collect Monday **through Friday** only. Specimen MUST be received **in the Main Campus Send Out Laboratory by noon on Fridays.** **Stability:** Ambient: **48 hours** Refrigerated: Unacceptable Frozen: Unacceptable **Methodology:** **Chromosome Analysis** Stress test induced by mitomycin C (MMC) or diepoxybutane (DEB) **Days Performed: Mon–Sat** **Reported: 8–11 days**	10/17/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Complement, Alternate Pathway (AH50), Functional	COMAP	**Special Information:** CRITICAL FROZEN. **Locations without a -70°C freezer should not collect this test. Do not use gel separator tubes.** Separate specimens must be submitted when multiple tests are ordered. Unacceptable conditions include specimen types other than serum, specimens left to clot at refrigerated temperature, specimens exposed to repeated freeze/thaw cycles, **or specimens that are grossly hemolyzed, lipemic or icteric.** **Clinical Information: This test is useful as initial screening for suspected deficiency in the alternative complement pathway.** **Specimen Requirement:** 1 mL serum from no additive (Red) tube; Critical Frozen; CRITICAL FROZEN **(-70°C). Locations without a -70°C freezer should not collect this test. Do not use gel separator tubes.** Allow specimen to clot for 1 hour at room temperature. **Centrifuge (at refrigerated temperature if possible) and** separate serum from cells ASAP or within 2 hours of collection. Transfer into standard aliquot tube and freeze **immediately in a -70°C freezer.** Separate specimens must be submitted when multiple tests are ordered. **Note:** *Serum separator (Gold) tube is no longer acceptable.* **Stability:** Ambient: After separation from cells: **Unacceptable** Refrigerated: After separation from cells: Unacceptable Frozen: After separation from cells: **30 days at -70 degrees C** (Avoid multiple freeze/thaw cycles) **Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)** **Reference Range: >= 31** % normal **Days Performed: Sun, Wed**	effective immediately
Copper, Liver	LIVCOP	**Clinical Information:** This test may be useful when related serum or urine assessments are inconclusive. Hepatic copper concentrations approach or exceed 250 µg/g in untreated Wilson disease. Elevated hepatic copper is also seen with chronic biliary obstruction and cholestasis. Results inconsistent with other findings may reflect heterogeneity in hepatic copper distribution. **Special Information:** Specimens less than 0.25 mg (dry weight) are unacceptable. **Routine existing paraffin block can be used.** Paraffin blocks that have been processed with Hollandes or other copper-containing stain will be rejected. This test is New York DOH approved. **Specimen Requirement:** 1 cm long liver tissue; Obtain **a minimum of two liver cores, at least 1 cm in length per core,** with an 18 gauge needle. Tissue can be fresh, dried, paraffin-embedded, **or formalin-fixed (refer to stability for transport temperature). If formalin-fixed, the tissue should immediately be placed in the same container with formalin. Create a surgical pathology order for liver biopsy and include the comment "QUANTITATIVE COPPER."** Specimens other than paraffin-embedded should be stored and transported in a metal-free container (e.g., royal blue with no additive). **Days Performed:** Wed **Reported: 4–11** days	effective immediately
COVID & Influenza A/B NAAT, Routine	COVFLU	**Name:** Previously COVID with FLU A+B, Routine	9/12/23
COVID NAAT, Upper Respiratory, Routine	COVID	**Name:** Previously Coronavirus 2019	9/12/23
DNAse-B Antibody	DASEAB	**Clinical Information: This test is used to** confirm current or recent infection with group A Streptococcus in patients suspected of having a nonsuppurative complication such as acute glomerulonephritis (AGN) or acute rheumatic fever (ARF). DNase-B Antibody and Streptolysin O Antibody (ASO) are generally ordered concurrently. **Elevated titers of ASO indicate a recent group A Streptococcus infection. AntiDNase B antibodies typically remain elevated longer than ASO and may remain elevated for several months after infection. Patients suspected of having complications related to a recent Streptococcus infection such as AGN or ARF may have elevated anti-DNase B but normal ASO antibody titers. A negative or very low antiDNase B and ASO antibody titers, especially from a specimen tested 2 weeks after a suspected infection, indicates unlikely incidence of a recent Streptococcus infection.** **Stability:** Ambient: After separation from cells: **2** hours Refrigerated: After separation from cells: **8 days** Frozen: After separation from cells: **3 months** **Days Performed: Sun–Sat**	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Drug Detection Panel, Meconium, Qualitative	MECDRG	**For interface clients only–Test build may need to be modified** **Includes:** Buprenorphine Norbuprenorphine Naloxone Codeine Dihydrocodeine Fentanyl Hydrocodone Norhydrocodone Hydromorphone Meperidine Methadone Methadone metabolite 6-Acetylmorphine Morphine Methylphenidate Oxycodone Noroxycodone Oxymorphone Tapentadol Tramadol N-desmethyltramadol O-desmethyltramadol Gabapentin Amphetamine Benzoylecgonine m-OH-Benzoylecgonine Cocaethylene Cocaine MDMA (Ecstasy) Methamphetamine Phentermine Alprazolam Alpha-OH-Alprazolam Butalbital Clonazepam 7-Aminoclonazepam Diazepam Lorazepam Midazolam Alpha-OH-Midazolam Nordiazepam Oxazepam Phenobarbital Temazepam Zolpidem Phencyclidine (PCP) **Mitragynine (Kratom)**	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Drug Detection Panel, TOF-MS, Umbilical Cord Tissue	DRGTOF	**Reference Range:** Buprenorphine (BUPRE): cutoff 1 ng/g Norbuprenorphine (NORBP): cutoff 0.5 ng/g Codeine (CODEN): cutoff 0.5 ng/g Dihydrocodeine (DIHYDC): cutoff 1 ng/g Fentanyl Screen, Qualitative, Urine (FENT): Negative Hydrocodone (HYDRCO): cutoff 0.5 ng/g Norhydrocodone (NORHY): cutoff 1 ng/g Hydromorphone (HYDRMO): cutoff 0.5 ng/g Meperidine (MEPER): cutoff 2 ng/g Methadone (METHDO): cutoff 2 ng/g EDDP (EDP): cutoff 1 ng/g 6-Acetylmorphine (ACTYLM): cutoff 1 ng/g Morphine (MORPHI): cutoff 0.5 ng/g Naloxone (NALO): cutoff 1 ng/g Oxycodone (OXYD): cutoff 0.5 ng/g Noroxycodone (NOROXC): cutoff 1 ng/g Oxymorphone (OXYMP): cutoff 0.5 ng/g Noroxymorphone (NOROXM): cutoff 0.5 ng/g Propoxyphene (PROPP): cutoff 1 ng/g Tapentadol (TAPET): cutoff 2 ng/g Tramadol (TRAMA): cutoff 2 ng/g N-desmethyltramadol (NDES): cutoff 2 ng/g O-desmethyltramadol (ODESM): cutoff 2 ng/g Amphetamine (AMPHTA): cutoff 5 ng/g Benzoylecgonine (BENZYL): **cutoff 1 ng/g** m-OH-Benzoylecgonine (MOHB): cutoff 1 ng/g Cocaine (COCNE): **cutoff 1 ng/g** Cocaethylene (COCAE): cutoff 1 ng/g MDMA- Ecstasy (MDMAE): cutoff 5 ng/g Methamphetamine (MTAMPH): cutoff 5 ng/g Phentermine (PHENTE): cutoff 8 ng/g Alprazolam (ALPRAZ): cutoff 0.5 ng/g Alpha-OH-Alprazolam (AOHA): cutoff 0.5 ng/g Butalbital (BUTALB): cutoff 25 ng/g Clonazepam (CLONA): cutoff 1 ng/g Diazepam (DIAZP): cutoff 1 ng/g 7-Aminoclonazepam (7AMINO): cutoff 1 ng/g Lorazepam (LORAZ): cutoff 5 ng/g Midazolam (MIDAZO): cutoff 1 ng/g Alpha-OH-Midazolam (AOHM): cutoff 2 ng/g Nordiazepam (NORDZ): cutoff 1 ng/g Oxazepam (OXZ): cutoff 2 ng/g Phenobarbital (PHENB): cutoff 75 ng/g Temazepam (TEMZ): cutoff 1 ng/g Zolpidem (ZOLP): cutoff 0.5 ng/g Phencyclidine-PCP (PHNPCP): cutoff 1 ng/g Gabapentin (GABPTN): cutoff 10 ng/g	effective immediately
Everolimus	EVEROL	**Specimen Requirement:** 1 mLwhole blood from EDTA (Lavender) tube; Refrigerated; Collect prior to next dose. **Note:** *EDTA (Royal blue) tube is no longer acceptable.*	9/14/23
Expanded Respiratory Pathogen Panel by PCR (without COVID), Routine	RPPCR	**Name:** Previously Respiratory Panel by PCR	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Heparin Anti Xa Assay	HEPASY	**Specimen Requirement:** 1 mL platelet-poor plasma from sodium citrate (light blue) tube; **Centrifuge, aliquot and freeze ASAP. Collection tube must be filled to total fill volume. Inadequately filled tubes will be rejected. Non Testing Sites: Centrifuge within one hour of collection, aliquot platelet poor plasma into a separate tube with Epic Beaker label, freeze plasma at -20C, send frozen plasma to Main Campus on dry ice. AND 1.8 mL whole blood in sodium citrate (light blue) tube; Ambient; Centrifuge, aliquot and freeze ASAP. Collection tube must be filled to total fill volume. Inadequately filled tubes will be rejected. Non Testing Sites: Centrifuge within one hour of collection, aliquot platelet poor plasma into a separate tube with Epic Beaker label, freeze plasma at -20C, send frozen plasma to Main Campus on dry ice.** **Stability:** Ambient: Centrifuge within one hour of phlebotomy and test or freeze platelet poor plasma within four hours. Refrigerated: Unacceptable Frozen: **3 days at less than or equal to -18 degrees C (platelet poor plasma) 3 months at less than or equal to -74 degrees C (platelet poor plasma)**	9/12/23
Iron, Liver	LIVIRO	**Special Information:** Specimens less than 0.25 mg (dry weight) are unacceptable. **Existing routine paraffin blocks may be used.** Specimens stored or shipped in saline will be rejected. Age is required on test request form in order to calculate iron index. This test is New York DOH approved. **Specimen Requirement:** 1 cm long liver tissue; Obtain **a minimum of two liver cores,** at least 1 cm in length per core**, with an 18 gauge needle.** Tissue can be fresh, dried, paraffin-embedded, **or formalin-fixed (refer to stability for transport temperature). If formalin-fixed, the tissue should immediately be placed in the same container with formalin. Create a surgical pathology order for liver biopsy and include the comment "QUANTITATIVE IRON." Specimens other than paraffin-embedded should be stored and transported in a metal-free container (e.g., royal blue with no additive).** **Days Performed:** Fri **Reported: 4–11** days	effective immediately
LMW Anti Xa Assay	LMWHEP	**Specimen Requirement:** 1 mL platelet-poor plasma from sodium citrate (light blue) tube; **Centrifuge, aliquot and freeze ASAP. Collection tube must be filled to total fill volume. Inadequately filled tubes will be rejected. Non Testing Sites: Centrifuge within one hour of collection , aliquot platelet poor plasma into a separate tube with Epic Beaker label, freeze plasma at -20C, send frozen plasma to Main Campus on dry ice. AND 1.8 mL whole blood in sodium citrate (light blue) tube; Centrifuge, aliquot and freeze ASAP. Collection tube must be filled to total fill volume. Inadequately filled tubes will be rejected. Non Testing Sites: Centrifuge within one hour of collection , aliquot platelet poor plasma into a separate tube with Epic Beaker label, freeze plasma at -20C, send frozen plasma to Main Campus on dry ice.** **Stability:** Ambient: Centrifuge within one hour of phlebotomy and test or freeze platelet poor plasma within four hours. Refrigerated: Unacceptable Frozen: **3 days at less than or equal to -18 degrees C (platelet poor plasma). 3 months at less than or equal to -74 degrees C (platelet poor plasma).** **Days Performed:** Sun–Sat **24** hours	9/12/23
Mycoplasma genitalium, NAAT	MYGAMP	**Stability:** Ambient: 15˚C to 30˚C. Swab in Aptima transport media: 60 days; Urine in Aptima transport media: 30 days; Urine unprocessed: 24 hours Refrigerated: 2˚C to 8˚C. Swab in Aptima transport media: 60 days; Urine in Aptima transport media: 30 days; Urine unprocessed: 24 hours Frozen: -20˚to -70˚Swab in Aptima transport media: 4 months; Urine in Aptima transport media: 4 months; Urine unprocessed: unacceptable	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
N-methyl-D-Aspartate Receptor Ab, IgG, CSF, Reflex to Titer	NMDCSF	**Special Information:** If NMDA CSF antibody IgG is positive, then an NMDA CSF antibody IgG titer is reported. Additional charges apply. **Contaminated, hemolyzed, or severely lipemic specimens will be rejected. This test is New York DOH approved.** **Clinical Information:** NMDA receptor antibody is found in a subset of patients with autoimmune limbic encephalitis and may occur with or without associated tumor. Decreasing antibody levels may be associated with therapeutic response. **In addition, positive results have been reported in patients with nonautoimmune phenotypes.** A negative test result does not rule out a diagnosis of autoimmune limbic encephalitis. **Results should be interpreted in correlation with the patient's clinical history and other laboratory findings.** **Days Performed: Sun–Sat** **Reported:** 2–**4** days	effective immediately
N-methyl-D-Aspartate Receptor Antibody, IgG	NMDAG	**Special Information:** If NMDA antibody IgG is positive, then an NMDA antibody IgG titer will be performed at an additional cost. **Contaminated, hemolyzed, or severely lipemic specimens will be rejected. This test is New York DOH approved.** **Clinical Information: NMDA receptor antibody is** found in a subset of patients with autoimmune limbic encephalitis and may occur with or without associated tumor. Decreasing antibody levels may be associated **with** therapeutic response. **In addition, positive results have been reported in patients with nonautoimmune phenotypes.** A negative test result does not rule out a diagnosis of autoimmune limbic encephalitis. **Results should be interpreted in correlation with the patients clinical history and other laboratory findings. Serum testing should be paired with CSF testing for improved diagnostic sensitivity.** **Stability:** Ambient: After separation from cells: **48 hours** Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year **Days Performed: Sun–Sat** **Reported:** 2–**4** days	effective immediately
Pneumococcal IgG Antibodies, 14 Serotypes	PNEUMG	**Special Information:** Post-immunization specimen should be drawn 30 days after immunization and, if shipped separately, must be received within 60 days of pre-immunization specimen. **Pre-immunization samples will be held and tested simultaneously with post-immunization samples.** Plasma or other body fluids will be rejected. Contaminated, hemolyzed, or severely lipemic specimens are unacceptable. This test is New York DOH approved. **Specimen Requirement:** 1.5 mL serum from serum separator (Gold) tube; Refrigerated; Post-immunization specimen should be drawn 30 days after immunization and must be received within 60 days of pre-immunization specimen. Label specimens clearly as 'Pre' or 'Post.' Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube. **Stability:** Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: **60 days** (Avoid repeated freeze/thaw cycles) **Methodology: Quantitative Multiplex Chemiluminescent Immunoassay**	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Pneumococcal IgG Antibodies, 23 Serotypes	PNE23	**Special Information:** Post-immunization specimen should be drawn 30 days after immunization **and, if shipped separately,** must be received within 60 days of **pre-immunization specimen. Pre-immunization samples will be held and tested simultaneously with post-immunization samples. Plasma or other body fluids will be rejected. Contaminated, hemolyzed, or severely lipemic specimens are unacceptable. This test is New York DOH approved.** **Clinical Information:** A pre- and post-vaccination comparison is required to adequately assess the humoral immune response to Prevnar 7 (P7), Prevnar 13 (P13), and/or Pneumovax 23 (PNX) Streptococcus pneumoniae vaccines. Pre-vaccination samples should be collected prior to vaccine administration. Post-vaccination samples should be obtained at least 4 weeks after immunization. Testing of post-vaccination samples alone will provide only general immune status of the individual to various pneumococcal serotypes. **Specimen Requirement:** 1.5 mL serum from serum separator (Gold) tube; Minimum **0.25** mL; Refrigerated; **Post-immunization specimen should be drawn 30 days after immunization and must be received within 60 days of pre-immunization specimen. Label specimens clearly as 'Pre' or 'Post.'** Separate serum from cells ASAP or within 2 hours of collection **and transfer into standard aliquot tube.** **Stability:** Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: **60 days** (Avoid repeated freeze/thaw cycles) **Methodology: Quantitative Multiplex Chemiluminescent Immunoassay**	effective immediately
Proinsulin, Intact	IPROIN	**Clinical Information: Aids in the detection of insulinoma. Do not use to diagnose diabetes mellitus.** **Stability:** Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: **24** hours Frozen: After separation from cells: 2 months **Reference Range:** 18 Years to 99 Years: <= **7.2** pmol/L 0 Years to 17 Years: Not established	effective immediately
Rufinamide	RUFIN	**Stability:** Ambient: After separation from cells: **72 hours** Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 2 weeks **Reported:** 2–**8** days	effective immediately
Streptococcal Antibody Panel	ASODNA	**Stability:** Ambient: After separation from cells: 2 **hours** Refrigerated: After separation from cells: 8 days Frozen: After separation from cells: **3** months	effective immediately
Tapentadol Quant, Urine	TAPENU	**For interface clients only–Test build may need to be modified** **Name:** Previously Tapentadol and Metabolite Confirm/Quantitation, Urine **Clinical Information:** The absence of expected drug(s) may indicate noncompliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, diluted/adulterated urine, or limitations of testing. The concentration value must be greater than or equal to the cutoff to be reported as positive. **Reference Range:** Tapentadol (TAPEN): Positive cutoff: 50 ng/mL **Note:** *Tapentadol glucuronide, Tapentadol-O-sulfate and N-desmethyltapentadol are no longer reported*	effective immediately
Triglycerides Body Fluid with Reflex to Chylomicron Electrophoresis	FTCHYL	**Days Performed: Varies**	effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
COVID NAAT, Lower Respiratory, Routine	ITCOVD	**Specimen Requirement:** 1 mL sputum in sterile container; Refrigerated; Do not aliquot into transport media. *OR* 1 mL tracheal aspirate in sterile container; Refrigerated; Do not aliquot into transport media. *OR* 1 mL bronch (BAL) in sterile container; Refrigerated; Do not aliquot into transport media. **Stability:** Ambient: All specimens are unacceptable at ambient temperature. Refrigerated: Lower respiratory specimens are stable for 72 hours at 2 to 8 degrees Celsius. Frozen: Lower respiratory specimens are stable for 30 days at–70 degrees Celsius or lower. **Methodology:** Transcription-Mediated Amplification **Reference Range:** Negative for COVID19 (SARS CoV2) by RT-PCR or equivalent method. **Days Performed:** Sun–Sat **Reported:** 24 hours **CPT:** 87635	effective immediately
FLT3 ITD Mutation Analysis Blood	F3ITD	**Clinical Information:** This assay detects internal tandem duplication (ITD) mutations in FLT3. The presence of a FLT3 ITD mutation is associated with an adverse prognosis in acute myeloid leukemia. **Specimen Requirement:** 4 mL whole blood in EDTA (Lavender) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Fragment Analysis Polymerase Chain Reaction (PCR) **Days Performed:** Varies **Reported:** 2 days **CPT:** 81245	effective immediately
Pregabalin, urine	UPRGAB	**Clinical Information:** This test is useful for general testing in contexts of compliance and/or abuse and is not valid for forensic use. The concentration value must be greater than or equal to the cutoff (Positive cutoff: 5.0 µg/mL) to be reported as a quantitative result. **Specimen Requirement:** 1 mL random urine in clean container; Minimum 0.6 mL; Refrigerated **Stability:** Ambient: 1 month Refrigerated: 1 month Frozen: 1 month **Methodology:** Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** **Days Performed:** Wed, Sat **Reported:** 2–7 days	10/17/23

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Amylase, Pancreatic	AMYLPS	Test will no longer be orderable. Recommended replacement test is Amylase Isoenzymes (AMYISO).	effective immediately
EGFR Mutation Analysis, Tissue	EGFRTI	Test will no longer be orderable.	9/12/23
HIV-1 Western Blot	HIV1CO	Test will no longer be orderable. Recommended replacement test is HIV-1 p24 Ag + HIV-1-2 Ab, with reflex to differentiation (HIV12C)	effective immediately