Cleveland Clinic

# Cleveland Clinic Laboratories

## Technical Update • December 2022

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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 8 | Anti-cN-1A (NT5c1A) IBM | | | ■ | | | | | | | | | | |
| 10 | Chromosome Analysis, Amniotic Fluid | | | | | | | | | | | | ■ | ■ |
| 10 | Chromosome Analysis, Chorionic Villus | | | | | | | | | | | | ■ | ■ |
| 2 | Coenzyme Q10, Leukocytes | | | | | ■ | ■ | | | | ■ | ■ | | |
| 2–3 | Cytomegalovirus, Newborn Saliva | | | | | | | | ■ | | | | | |
| 3 | EBV Ab to Viral Capsid Antigen, IgG | | | | | | | | ■ | | | | | |
| 3 | EBV Ab to Viral Capsid Antigen, IgM | | | | | | | | ■ | | | | | |
| 4 | EBV Antibody Panel | | | | | | | ■ | ■ | | | | | |
| 10 | EBV Antibody to Early Antigens | | | | ■ | | | | | | | | | |
| 4 | EBV Antibody to Nuclear Antigen | | | | | | | | ■ | | | | | |
| 8 | Fentanyl Screen w/Reflex, Qualitative, Urine | | | | | | | | | | | | ■ | ■ |
| 10 | FISH Insight Analysis | | | | | | | | | | | | ■ | ■ |
| 4 | Fluvoxamine, Serum and Plasma | | | | | ■ | ■ | | ■ | | ■ | ■ | ■ | |
| 4 | Group A Streptococcus by PCR | | | | | | ■ | | | | | | | |
| 10 | Helicobacter pylori Ab, IgA | | | | ■ | | | | | | | | | |
| 10 | Helicobacter pylori Antibodies, IgG and IgA | | | | ■ | | | | | | | | | |
| 4 | Hemoglobin A1C | | | | | | ■ | | | | | | | |
| 8 | High Sensitivity Troponin T | | | ■ | | | | | | | | | | |
| 4 | Lead, Blood | | | | | | ■ | | | | | | | |
| 10 | LRP4 Autoantibody Test | | | | ■ | | | | | | | | | |

| 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 | Mycoplasma Cult Non Urogenital | | | | ■ | | | | | | | | | |
| 10 | Mycoplasma genitalium | | | | | | | | | | | | | ■ |
| 10 | Mycoplasma pneumoniae IgA | | | | ■ | | | | | | | | | |
| 10 | Mycoplasma pneumoniae IgM Antibody | | | | ■ | | | | | | | | | |
| 5 | Platelet Aggregation | | | | | | | ■ | | | | | | |
| 8 | Primary Membranous Nephropathy Diagnostic Cascade, Serum | | | | | | | | | | | | ■ | ■ |
| 5 | Rabies Antibody | | | | | ■ | ■ | | | ■ | ■ | ■ | | |
| 5 | Stool Gastrointestinal Panel by PCR (STGIPR) | | | | | | | ■ | | | | | | |
| 5–6 | Supersaturation Profile, 24 Hour Urine | | | | | ■ | | ■ | ■ | ■ | | | | |
| 10 | Thyroglobulin, Serum | | | | ■ | | | | | | | | | |
| 9 | Thyroglobulin, Serum with Reflex to IA or LC-MS/MS | | | ■ | | | | | | | | | | |
| 10 | Thyroid Cancer (Thyroglobulin) Monitoring | | | | ■ | | | | | | | | | |
| 10 | Trazodone | | | | | | | | | | | | | ■ |
| 10 | Troponin T | | | | ■ | | | | | | | | | |
| 7 | Urinalysis Only | | | | | | | | | ■ | | | | |
| 7 | Urinalysis with Microscopic | | | | | | | | | ■ | | | | |
| 7 | Urinalysis with Reflex to Microscopic | | | | | | | | | ■ | | | | |

# Test Changes

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Coenzyme Q10, Leukocytes | LEUK10 | **Clinical Information: This test is used for diagnosis of Coenzyme Q10(CoQ10) deficiency that is inherited or acquired.**<br>**Specimen Requirement:** 5 mL whole blood in Acid Citrate Dextrose A or B (Yellow) tube; **Minimum 2 mL**; Ambient<br>**Stability:**<br>Ambient: 5 days<br>Refrigerated: **5 days**<br>Frozen: Unacceptable<br>**Reported: 11–15** days | 12/13/22 |
| Cytomegalovirus, Newborn Saliva | CMVSAL | **Special Information:** Testing will be performed daily, 7 days per week. Results should generally be available within 1-2 days of receipt in **Molecular** Microbiology.<br>**Clinical Limitation:**<br>**1.** Saliva sample should be obtained at least one-hour after breast feeding to avoid contamination from cytomegalovirus which may result in a false positive result. Current treatment guidelines suggest waiting at least an hour after breastfeeding to obtain the sample.<br>**2.** Samples containing mucin at concentrations >25 mg/mL may produce invalid results with the CMV assay.<br>*(continued on page 3)* | effective immediately |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Cytomegalovirus, Newborn Saliva<br>*(continued from page 2)* | | **3.** The results of the CMV assay are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions.<br>**4**. The CMV assay is a qualitative assay and does not provide quantitative values or information about viral load.<br>**5.** Viral nucleic acid may persist in vivo, independent of viability. The CMV assay does not distinguish between viable and nonviable virus.<br>**Clinical Information:** The CMV DNA Amplification Assay, performed on the **cobas 8800 system,** is a qualitative, in **a lab-developed** diagnostic test system for the direct detection of cytomegalovirus (CMV) DNA in saliva samples from neonates younger than 21 days of age. The test is used as an aid in the diagnosis of congenital CMV infection. **Patients with CMV detected in saliva should have urine testing for confirmation.** The results of this test should be used in conjunction with the results of other clinical findings.<br>**Specimen Requirement: 3** mL saliva swab in Universal Transport Media (UTM); Ambient; Collect saliva swab samples and place into a transport tube with transport media according to established laboratory methods. No special preparation of the neonate is required in order to collect the sample.<br>**Stability:**<br>Ambient: Saliva swabs specimens may be stored for up to 48 hours at 19-30 C<br>Refrigerated: Saliva swabs specimens may be stored for up to 7 days refrigerated (2-8 C)<br>Frozen: Saliva swab specimens should be frozen immediately at -20 C and may be stored up for to 14 days. **Saliva samples may be frozen and thawed up to 2 times after storage at -20 C.**<br>**Methodology: Real-Time PCR**<br>**Days Performed:** 7 days a week; **24 hours** | |
| EBV Ab to Viral Capsid Antigen, IgG | EBVG | **Clinical Limitation:** Assay performance has not been established for immunocompromised or immunosuppressed patients. Assay performance has not been established for cord blood, neonatal specimens or infants. There is a possibility of assay cross-reactivity with specimens containing anti E-coli antibody. **Assay performance has not been established for the diagnosis of nasopharyngeal carcinoma, Burkitt's lymphoma, other EBV-associated lymphomas, and other EBV associated diseases other than EBV related mononucleosis. Testing should not be performed as a screening procedure for the general population. It should only be performed when clinical evidence suggests the diagnosis of EBV-associated infectious mononucleosis. If the marker is negative and exposure to EBV is suspected, a second sample should be collected and tested no less than one-two weeks later. In cases of equivocal results, a second freshly collected sample should be obtained and tested.**<br>**Clinical Information: The test is used to investigate the evidence of recent or past EBV infection.**<br>**Methodology: Chemiluminescence Immunoassay (CLIA)**<br>**Reference Range:**<br>EBV Ab to Viral Capsid Antigen, IgG (EBVGX): Refer to report **U/mL**<br>EBV Viral Capsid IgG, Qual (EBVGQ): Negative | 1/5/23 |
| EBV Ab to Viral Capsid Antigen, IgM | EBVM | **Clinical Limitation:** Assay performance has not been established for immunocompromised or immunosuppressed patients. Assay performance has not been established for cord blood, neonatal specimens or infants. Due to a degree of observed cross-reactivity in some CMV and Toxo IgM positive samples, samples positive for these analytes should be interpreted with caution. **Assay performance has not been established for the diagnosis of nasopharyngeal carcinoma, Burkitt's lymphoma, other EBV-associated lymphomas, and other EBV associated diseases other than EBV related mononucleosis. Testing should not be performed as a screening procedure for the general population. It should only be performed when clinical evidence suggests the diagnosis of EBV-associated infectious mononucleosis. In cases of equivocal results, a second freshly collected sample should be obtained and tested.**<br>**Clinical Information: The test is used as an aid in diagnosing recent EBV infection. It should ne done in conjunction with EBV VCA IgG and EBV nuclear antigen IgG tests. Clinical correlation is required.**<br>**Methodology: Chemiluminescence Immunoassay (CLIA)**<br>**Reference Range:**<br>EBV Ab to Viral Capsid Antigen, IgM (EBVMX): Refer to report **U/mL**<br>EBV Viral Capsid IgM, Qual (EBVMQ): Negative | 1/5/23 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| EBV Antibody Panel | EBVPNL | **For interface clients only–Test build may need to be modified**<br>**Methodology: Chemiluminescence Immunoassay (CLIA)**<br>**Reference Range:**<br>EBV Viral Capsid IgG, Qual (EBVGQ): Negative<br>EBV Ab to Viral Capsid Antigen, IgG (EBVGX): Refer to report **U/mL**<br>EBV Viral Capsid IgM, Qual (EBVMQ): Negative<br>EBV Ab to Viral Capsid Antigen, IgM (EBVMX): Refer to report **U/mL**<br>EBV Aby Nuclear Ag, Qual (EBVNAQ): Negative<br>EBV Antibody to Nuclear Antigen (EBVNAX): Refer to report **U/mL** | 1/5/23 |
| EBV Antibody to Nuclear Antigen | EBVNA | **Clinical Limitation:** Assay performance has not been established for immunocompromised or immunosuppressed patients. Assay performance has not been established for cord blood, neonatal specimens or infants. There is a possibility of assay cross-reactivity with specimens containing anti E-coli antibody. **Assay performance has not been established for the diagnosis of nasopharyngeal carcinoma, Burkitt's lymphoma, other EBV-associated lymphomas, and other EBV associated diseases other than EBV related mononucleosis. Testing should not be performed as a screening procedure for the general population. It should only be performed when clinical evidence suggests the diagnosis of EBV-associated infectious mononucleosis. If the marker is negative and exposure to EBV is suspected, a second sample should be collected and tested no less than one-two weeks later. In cases of equivocal results, a second freshly collected sample should be obtained and tested.**<br>**Clinical Information: EBV nuclear antigen (EBNA-1) IgG typically appears from several weeks to several months after primary EBV infection and may remain elevated for life but it may become equivocal or undetectable in certain immunocompromised individuals. The final interpretation should be done in the context of other EBV serology panel results.**<br>**Methodology: Chemiluminescence Immunoassay (CLIA)**<br>**Reference Range:**<br>EBV Antibody to Nuclear Antigen (EBVNAX): Refer to report **U/mL**<br>EBV Aby Nuclear Ag, Qual (EBVNAQ): Negative | 1/5/23 |
| Fluvoxamine, Serum and Plasma | FLUVOX | **Includes:**<br>**Fluvoxamine Quant, Serum or Plasma**<br>**Special Information: Do not use serum separator tubes. Separate serum from cells ASAP or within 2 hours of collection and transfer serum into standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered.**<br>**Clinical Information: Reporting Limit: 10 ng/mL**<br>**Specimen Requirement: 1** mL serum from no additive (Red) tube; **Minimum 0.4** mL; Refrigerated; Do not use serum separator tubes. **Separate serum from cells ASAP or within 2 hours of collection and** transfer serum into standard aliquot tube. **Separate specimens must be submitted when multiple tests are ordered.** *OR* **1** mL plasma from EDTA (Lavender) tube; **Minimum 0.4** mL; Refrigerated; Do not use serum separator tubes. **Separate serum from cells ASAP or within 2 hours of collection and** transfer serum into standard aliquot tube. **Separate specimens must be submitted when multiple tests are ordered.**<br>**Stability:**<br>Ambient: **Unacceptable**<br>Refrigerated: **1 month**<br>Frozen: **3** months<br>**Methodology: High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)**<br>**Reported: 5–8** days<br>**CPT:** 80332 / **G0480** | effective immediately |
| Group A Streptococcus by PCR | GASPCR | **Specimen Requirement: E-**swab of throat; ambient<br>**Days Performed:** 7 days a week; **24 hours** | 1/11/23 |
| Hemoglobin A1C | HBA1C | **Specimen Requirement:** 2 mL whole blood in EDTA (Lavender) tube; Minimum 0.1 mL; Refrigerated<br>**Note:** *Lithium heparin (Green) tube is no longer acceptable.* | 1/12/23 |
| Lead, Blood | LEAD2 | **Specimen Requirement:** 1 mL whole blood in EDTA (Royal blue) tube; Minimum 0.5 mL; Refrigerated<br>**Note:** *EDTA (Lavender) tube is no longer acceptable* | effective immediately |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Platelet Aggregation | AGGPLP | **For interface clients only–Test build may need to be modified**<br>**Reference Range:**<br>ADP Aggregation (ADP): 65-93% Max<br>ATP Rel by ADP (ADPREL): 0.1-1.3 nM<br>ADP 20 Max Aggreg (ADP20): 71-94% Max<br>ATP Rel by ADP 20 (AD20RE): 0.1-1.4 nM<br>Arach Max Aggreg (ARACA): 75–100% Max<br>ATP Rel by Aracha (ARAREL): 0.4-2.0 nM<br>Collagen Max Aggreg (COLLAG): 74-99% Max<br>ATP Rel by Collagen (COLREL): 0.4–1.7 nM<br>EPIN Max Aggreg (EPIN): 70-97% Max<br>ATP Rel by Epineph (EPIREL): 0.2-1.6 nM<br>Epin 100 Max Aggreg (EPI100): 70-99% Max<br>ATP Rel by Epineph 100 (EP100R): 0.2–1.7 nM<br>Risto 1500 Max Agg (RIST15): 76–100% Max<br>Risto 1200 Max Agg (RIST12): 76-100% Max<br>Risto 900 Max Agg (RIST9): 50-100% Max<br>**Risto 500 Max Agg (RIST5): 0-9% Max** | 1/12/23 |
| Rabies Antibody | RABIES | **Includes: Rabies Antibody Screen**<br>**Special Information: Serum gel tubes are NOT acceptable. This test is New York DOH approved.**<br>**Clinical Information: This test is useful to measure immune response to rabies vaccination.** In humans, a result of 0.5 IU/mL or higher is considered an acceptable response to rabies vaccination according to the World Health Organization (WHO) guidelines; see WHO and Advisory Committee on Immunization Practices documents for additional guidance. Also, there is more information at www.vet.ksu.edu/rabies.<br>**Specimen Requirement: 2** mL serum from no additive (Red) tube; Minimum 1 mL; Refrigerated; Draw 2 tubes to ensure adequate specimen volume. Do NOT draw serum gel tubes. **Transfer serum to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered**<br>**Stability:**<br>Ambient: **1 week**<br>Refrigerated: **2 weeks**<br>Frozen: **1 month**<br>**Reference Range:**<br>< 0.1 IU/mL: Below detection limit<br>**>/= 0.1 IU/mL: Above detection limit**<br>**>/= 0.5 IU/mL: Acceptable response to rabies vaccination**<br>**Days Performed: Varies**<br>**Reported: 3–4** weeks | effective immediately |
| Stool Gastrointestinal Panel by PCR (STGIPR) | STGIPR | **For interface clients only–Test build may need to be modified**<br>**Note:** *C. difficile (CDREF) is no longer reported* | effective immediately |
| Supersaturation Profile, 24 Hour Urine | SSAT24 | **For interface clients only–Test build may need to be modified**<br>**Special Information: Refrigerate specimen during and after collection.** Specimens with pH > 8.0 will be rejected. **Do not attempt to adjust pH as it will adversely affect results. This test is New York DOH approved.**<br>**Clinical Information: This test is useful in diagnosis and management of patients with renal lithiasis by predicting the likely composition of the stone in patients who have a radiopaque stone or for whom stone analysis is not available. Results may help in designing a treatment program, identify specific risk factors for stones, monitor the effectiveness of therapy, evaluate kidney excretion of acid and urine pH and estimate a patient's protein intake.** Creatinine: To convert to mg/kg/24 hours, divide the mg/24 hour result by body weight in kg. CAUTIONS: Urine is often supersaturated with respect to the common crystalline constituents of stones, even in non-stone formers. Individual interpretation of the supersaturation values in light of the clinical situation is critical. In particular, treatment may reduce the supersaturation with respect to one crystal type but increase the supersaturation with respect to another. Therefore, the specific goals of treatment must be considered when interpreting the test results.<br>*(continued on page 6)* | 12/6/22 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Supersaturation Profile, 24 Hour Urine<br>*(continued from page 5)* | | **Methodology:**<br>**Calculation**<br>**Colorimetric Endpoint**<br>Colorimetric Enzyme Assay<br>Enzymatic<br>Freezing Point Depression<br>**High-Performance Ion Chromatography (HPIC)**<br>**Kinetic UV Assay**<br>**pH Meter**<br>Photometric<br>**Potentiometric, Indirect Ion-Selective Electrode (ISE)**<br>**Reference Range:**<br>Calcium Oxalate Crystal (CAOXC): Reference Mean = 1.77 DG<br>Brushite Crystal (BRCRY): Reference Mean = 0.21 DG<br>Hydroxyapatite Crystal (HYCRY): Reference Mean = 3.96 DG<br>Uric Acid Crystal ( UACRY): Reference Mean = 1.04 DG<br>Sodium,Urine (SSNA24):<br>0 Years to 17 Years: Not established<br>18 Years to 99 Years: 22-328 mmol/24 hr<br>Potassium,Urine (SSK24U):<br>0 Years to 17 Years: Not established<br>18 Years to 99 Years: 16-105 mmol/24 hr<br>Calcium,Urine (SSCALU):<br>0 Years to 17 Years: Not established<br>Male: 18 Years to 99 Years: < 250 mg/24 hr<br>Female: 18 Years to 99 Years: < 200 mg/24 hr<br>Magnesium,Urine (SSMAGU):<br>0 Years to 17 Years: Not established<br>18 Years to 99 Years: 51–269 mg/24 hr<br>Chloride,Urine (SSCL24):<br>0 Years to 17 Years: Not established<br>18 Years to 99 Years: 34–286 mmol/24 hr<br>Phosphorus,Urine (SSPHU):<br>0 Years to 17 Years: Not established<br>18 Years to 99 Years: 266–1,797 mg/24 hr<br>Sulfate,Urine (SSSULU): 7–47 mmol/24 hr<br>Citrate Excretion,Urine (SSCITR): Refer to report<br>Oxalate,U mmol/spec (SSOXL):<br>**0 Years to 15 Years: Not established**<br>**16** Years to 99 Years: 0.11–0.46 mmol/24 hr<br>Oxalate,U mg/spec (SSOXU):<br>**0 Years to 15 Years: Not established**<br>**16** Years to 99 Years: 9.7–40.5 mg/24 hr<br>pH,Urine (SSPH): 4.5–8.0<br>Uric Acid,Urine (SSURA):<br>0 Years to 17 Years: Not established<br>Male: 18 Years to 99 Years: 200–1,000 mg/24 hr<br>Female: 18 Years to 99 Years: 250–750 mg/24 hr<br>Creatinine,Urine (SSCRE):<br>0 Years to 17 Years: Not established<br>Male: 18 Years to 99 Years: 930–2,955 mg/24 hr<br>Female: 18 Years to 99 Years: 603–1,783 mg/24 hr<br>Osmolaltiy, 24Hr, Ur (SSOSM):<br>0 Months to 11 Months: 50–750 mOsm/kg<br>1 Year to 99 Years: 150–1,150 mOsm/kg<br>Ammonium, 24Hr, Ur (AMM24):<br>0 Years to 17 Years: Not established<br>18 Years to 77 Years: 15–56 mmol/24 hr<br>78 Years to 99 Years: Not established<br>Urea Nitrogen (UN24):<br>0 Years to 17 Years: Not established<br>18 Years to 99 Years: 7–42 g/24 hr<br>Protein Catabolic Rate, Ur (PCTR): 56–125 g/24 hour | |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Urinalysis Only | UA | **Reference Range:**<br>***change for Arkray Aution AX Series Analyzers only***<br>Color (UCOL): Yellow<br>Clarity (UCLA): Clear<br>Glucose (UGLUC): Negative–**Trace**<br>Ketones (UKET): Negative–**Trace**<br>Bilirubin (UBIL): Negative<br>Specific Gravity (USPG): 1.005–1.030<br>Hemoglobin/Blood (UHGB): Negative–**Trace**<br>pH (UPH): 5.0–8.0<br>Protein (UPROT): Negative–**Trace mg/dL**<br>Urobilinogen (UUROB): 0.2-1.0 EU/dL<br>Nitrites (UNITR): Negative<br>Urine Leukocyte Esterase (ULKEST): Negative–**25 Leu/uL** | 12/13/22 |
| Urinalysis with Microscopic | UAWMIC | **Reference Range:**<br>***change for Arkray Aution AX Series Analyzers only***<br>Color (UCOL): Yellow<br>Clarity (UCLA): Clear<br>Glucose (UGLUC): Negative–**Trace**<br>Ketones (UKET): Negative–**Trace**<br>Bilirubin (UBIL): Negative<br>Specific Gravity (USPG): 1.005–1.030<br>Hemoglobin/Blood (UHGB): Negative–**Trace**<br>pH (UPH): 5.0–8.0<br>Protein (UPROT): Negative–**Trace mg/dL**<br>Urobilinogen (UUROB): 0.2-1.0 EU/dL<br>Nitrites (UNITR): Negative<br>Urine Leukocyte Esterase (ULKEST): Negative–**25 Leu/uL** | 12/13/22 |
| Urinalysis with Reflex to Microscopic | LAB1237 | **Reference Range:**<br>***change for Arkray Aution AX Series Analyzers only***<br>Color (UCOL): Yellow<br>Clarity (UCLA): Clear<br>Glucose (UGLUC): Negative–**Trace**<br>Ketones (UKET): Negative–**Trace**<br>Bilirubin (UBIL): Negative<br>Specific Gravity (USPG): 1.005–1.030<br>Hemoglobin/Blood (UHGB): Negative–**Trace**<br>pH (UPH): 5.0–8.0<br>Protein (UPROT): Negative–**Trace mg/dL**<br>Urobilinogen (UUROB): 0.2-1.0 EU/dL<br>Nitrites (UNITR): Negative<br>Urine Leukocyte Esterase (ULKEST): Negative–**25 Leu/uL** | 12/13/22 |

# New Tests

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Anti-cN-1A (NT5c1A) IBM | CN1AAB | **Includes:** Anti-cN-1A (NT5c1A) IBM<br>**Special Information:** Grossly hemolyzed, lipemic or icteric specimens will be rejected. This test is New York DOH approved.<br>**Clinical Information:** Anti-cN-1A autoantibodies in idiopathic inflammatory myopathy (IIM) patients appear to be disease-specific for sporadic Inclusion Body Myositis (sIBM) and are rarely detected in other autoimmune conditions. Anti-cN-1A autoantibodies have a moderate sensitivity, but their high specificity for sIBM may be helpful in the diagnosis of this infrequent and difficult-to-diagnose myopathy. This assay can augment and accelerate the suspected diagnosis of sIBM using sera where muscle biopsy is delayed and/or unfeasible.<br>**Specimen Requirement:** 2 mL serum from no additive (Red) tube; Minimum 0.5 mL; Refrigerated; Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. *OR* 2 mL serum from Serum Separator (Gold) tube; Miniimum 0.5 mL; Refrigerated; Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.<br>**Stability:**<br>Ambient: 7 days<br>Refrigerated: 14 days<br>Frozen: 60 days<br>**Methodology:** Enzyme-Linked Immunosorbent Assay (ELISA)<br>**Days Performed:** Mon–Fri<br>**Reported:** 17–26 days | 12/15/22 |
| Fentanyl Screen w/ Reflex, Qualitative, Urine | UFENTSRF | **Note: New test was announced in the October update, but financial information was not available at that time**<br>**CPT:** 80307<br>**Price:** $135.00 | effective immediately |
| High Sensitivity Troponin T | HSTNT | **Clinical Information:** When assessing risk for acute coronary syndromes: In patients undergoing blood draw greater than 2° from symptom onset, with history of very low to moderate risk and non-ischemic ECG, an initial hs-Troponin T less than 12 ng/L AND a 1° delta hs-Troponin T less than 3 ng/L should be considered very low risk for 30 day MACE.<br>**Specimen Requirement:** 1 mL plasma from lithium heparin Plasma Separator (Light Green) tube; MInimum 0.3 mL; Refrigerated *OR* 1 mL plasma from lithium heparin (Green) tube; Minimum 0.3 mL<br>**Stability:**<br>Ambient: 24 hours<br>Refrigerated: 24 hours<br>Frozen: 12 months. Freeze only once.<br>**Methodology:** Electro Chemiluminescence Immunoassay (ECLIA)<br>**Reference Range:**<br><12 ng/L<br>Urgent: Greater than or equal to 52 ng/L<br>**Days Performed:** 7 days a week; 24 hours<br>**Reported:** 8 hours<br>**CPT:** 84484<br>**Price:** $109.00 | 1/24/23 |
| Primary Membranous Nephropathy Diagnostic Cascade, Serum | PMNDCS | **Note: New test was announced in the October update, but financial information was not available at that time**<br>**CPT:** 83520<br>**Price:** $300.00 | effective immediately |

# New Tests (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Thyroglobulin, Serum with Reflex to IA or LC-MS/MS | THYRORF | **Special Information:** In this test, Thyroglobulin Antibody is analyzed by the Access Thyroglobulin Antibody assay (Beckman). If the result is negative (<14.4 IU/mL), the Thyroglobulin tests will be performed by immunoassay using the Access Thyroglobulin assay (Beckman). If the antibody result is positive (≥14.4 IU/mL), the Thyroglobulin tests will be performed by LC-MS/MS. Results obtained from different assay method or kits cannot be used interchangeably.<br><br>**Clinical Information:** Serum thyroglobulin levels correlate well with the volume of differentiated thyroid tissue, hence are increased in thyrotoxicosis, thyroiditis, iodine deficiency, benign thyroid adenomas, and thyroid cancer. Thus although it is unsuitable as a screening tool for differentiated thyroid cancer (DTC), it is a highly sensitive marker for the detection of residual or recurrent disease after a total thyroidectomy and successful radioiodine remnant ablation. Presence of thyroglobulin autoantibodies interfere in the assay and thyroglobulin levels are underestimated in the antibody positive patients. In the presence of anti-thyroglobulin antibodies, thyroglobulin measurement by LC-MS/MS provides accurate thyroglobulin results.<br><br>The thyroglobulin test is intended for surveillance of patients with differentiated thyroid cancer who have had a thyroidectomy with or without radioactive ablation. The presence of thyroglobulin antibodies may interfere with thyroglobulin measurement by immunoassay and cause falsely-low results.<br><br>**Specimen Requirement:** 1 mL serum from Serum Separator (Gold) tube; Minimum 0.5 mL; Centrifuge and refrigerate. *OR* 1 mL serum from no additive (Red) tube; Minimum 0.5 mL; Centrifuge, aliquot and refrigerate.<br><br>**Stability:**<br>Ambient: 8 hours<br>Refrigerated: 7 days<br>Frozen: 7 days<br><br>**Methodology:**<br>Chemiluminescence Immunoassay (CLIA)<br>Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)<br><br>**Reference Range:**<br>Thyroglobulin, Serum (THYROS): 1.6–50.0 ng/mL<br>Thyroglobulin by LC-MS/MS, Serum (TGLCMS):<br>6 Months to 3 Years: 7.4–48.7 ng/mL<br>4 Years to 7 Years: 4.1–40.5 ng/mL<br>8 Years to 17 Years: 0.8–29.4 ng/mL<br>18 Years to 99 Years: 1.3–31.8 ng/mL<br>Thyroglobulin Antibody (TGAB): Negative: < 4.0 IU/mL<br>Thyroglobulin (THYG): 1.6-50.1 ng/mL<br>Thyroglobulin Antibody (TGABS): < 14.4 IU/mL<br><br>**Days Performed:** Mon–Fri; 16 hours<br><br>**Reported:** 1–3 days | effective immediately |

## Fee Increases

| Test Name | Order Code | List Fee | CPT Code | Effective Date |
|---|---|---|---|---|
| FISH Insight Analysis | ISIGHT | $525.00 | 88271x5; 88274x2 | effective immediately |
| Trazodone | DESYRL | $115.00 | 80338 / G0480 | effective immediately |

## Fee Reductions

| Test Name | Order Code | List Fee | CPT Code | Effective Date |
|---|---|---|---|---|
| Chromosome Analysis, Amniotic Fluid | FAMCYT | $792.00 | 88235; 88269; 88280; 88285 | effective immediately |
| Chromosome Analysis, Chorionic Villus | CVCYTO | $789.00 | 88280; 88267; 88235; 88285 | effective immediately |
| Mycoplasma genitalium | MYGPCR | $195.00 | 87563 | effective immediately |

## Discontinued Tests

| Test Name | Order Code | Test Information | Effective Date |
|---|---|---|---|
| EBV Antibody to Early Antigens | EBVEA | Test will no longer be orderable. | 1/5/23 |
| Helicobacter pylori Ab, IgA | HPYLRA | Test will no longer be orderable. | 12/13/22 |
| Helicobacter pylori Antibodies, IgG and IgA | HPYGA | Test will no longer be orderable. Recommended replacement test is Helicobacter pylori Ab, IgG (HPYLRI). | 12/13/22 |
| LRP4 Autoantibody Test | LRP4AA | Test will no longer be orderable. | 1/12/23 |
| Mycoplasma Cult Non Urogenital | UMPLAS | Test will no longer be orderable. Recommended replacement tests are Ureaplasma Species, Molecular Detection, PCR, Fluid, Tissue (URPCRF) or Mycoplasma hominis, Molecular Detection, PCR, Fluid, Tissue (MYPCRF). | 1/12/23 |
| Mycoplasma pneumoniae IgA | MYCIGA | Test will no longer be orderable. Recommended replacement test is Respiratory Panel by PCR (RPPCR). | 1/12/23 |
| Mycoplasma pneumoniae IgM Antibody | MYCOPM | Test will no longer be orderable. Recommended replacement test is Mycoplasma pneumoniae PCR (MYCPCR). | 1/12/23 |
| Thyroglobulin, Serum | TG | Test will no longer be orderable. Recommended replacement test is Thyroglobulin, Serum with Reflex to IA or LC-MS/MS (THYRORF). | effective immediately |
| Thyroid Cancer (Thyroglobulin) Monitoring | THYMON | Test will no longer be orderable. Recommended replacement test is Thyroglobulin, Serum with Reflex to IA or LC-MS/MS (THYRORF). | effective immediately |
| Troponin T | TNT | Test will no longer be orderable. Recommended replacement test is High Sensitivity Troponin T (HSTNT). | 1/24/23 |