Cleveland Clinic

# Cleveland Clinic Laboratories

## Technical Update • October 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 3 | (1,3) B-D Glucan | | | | | | ■ | | | | | | | |
| 3 | 5-Hydroxyindoleacetic Acid, Urine 24 Hour | | | | | | ■ | | | | | | | |
| 3 | 5-Hydroxyindoleacetic Acid, Urine Random | | | | | | ■ | | | | | | | |
| 9 | Anaplasma phagocytophilum & E. chaffeensis Ab Panel | | | | ■ | | | | | | | | | |
| 3 | Aspergillus galactomannan BAL | | | | | | ■ | | | | | | | |
| 3 | Aspergillus galactomannan Serum | | | | | | ■ | | | | | | | |
| 3 | Bilirubin, Fluid | | | | | | | | | | | ■ | | |
| 6 | BRAF V600E Mutation Detection Blood | | | | | | | | | | | | ■ | ■ |
| 6 | BRAF V600E Mutation Detection Bone Marrow | | | | | | | | | | | | ■ | ■ |
| 6 | BRAF V600E Mutation Detection Other | | | | | | | | | | | | ■ | ■ |
| 3–4 | C Telopeptide, Beta Cross Linked | | | | | | ■ | ■ | | | ■ | | ■ | |
| 4 | Celiac Comprehensive Panel | | | | | | ■ | | | | | | | |
| 4 | Celiac Screen with Reflex | | | | | | ■ | | | | | | | |
| 9 | Cell Count/Diff, Body Fluid | | | | | | | | | | | | | ■ |
| 9 | CYP2D6 (Cytochrome P450 2D6) | | | | | | | | | | | | | ■ |
| 6 | Fentanyl Screen, Qualitative, Urine | | | ■ | | | | | | | | | | |
| 6–7 | Fentanyl Screen w/Reflex, Qualitative, Urine | | | ■ | | | | | | | | | | |
| 7 | FISH for CRLF2 Blood | | | | | | | | | | | | ■ | ■ |
| 7 | FISH for CRLF2 Bone Marrow | | | | | | | | | | | | ■ | ■ |
| 4 | FSH | | | | | | | ■ | | | ■ | | | |

| 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 9 | Giardia Antigen, Stool, EIA | | | | ■ | | | | | | | | | |
| 9 | Herpes Simplex IgM, Abs | | | | ■ | | | | | | | | | |
| 9 | Herpes Simplex Virus 1/2 Antibody (IgM), IFA with Reflex to Titer, Serum | | | | ■ | | | | | | | | | |
| 9 | HIV-1 Integrase Genotype | | | | ■ | | | | | | | | | |
| 9 | Hypersensitivity Pneumonitis Evaluation | | | | | | | | | | | | ■ | ■ |
| 9 | KIT (D816V) Mutation by PCR | | | | ■ | | | | | | | | | |
| 7 | Kit D816V Mutation Detection Other | | | | | | | | | | | | ■ | ■ |
| 7 | Lymphogranuloma Venereum PCR | | | | | | | | | | | | ■ | ■ |
| 4 | LPT to Beryllium, BAL | | | | | ■ | | | | | | | | |
| 4 | LPT to Beryllium, Blood | | | | | ■ | | | | | | | | |
| 4 | Lymphocyte Transformation Test to Candida Antigen | | | | | ■ | | | | | | | | |
| 4 | Metanephrines, Free Plasma | | | | | ■ | | | | | | | | |
| 4 | Metanephrines, Urine 24 hour | | | | | ■ | | | | | | | | |
| 5 | Metanephrines, Urine Random | | | | | ■ | | | | | | | | |
| 9 | Methylenetetrahydrofolate Reductase (MTHFR) Mutation - 2 Variants | | | | ■ | | | | | | | | | |
| 5 | Mitogen LTT | | | | | ■ | | | | | | | | |
| 7 | Monkeypox Virus Qualitative PCR | | | ■ | | | | | | | | | | |
| 5 | Mycoplasma genitalium | | | | | | ■ | ■ | | | ■ | | | |
| 9 | Phospholipase A2 Receptor Ab, IgG | | | | ■ | | | | | | | | | |
| 9 | Plasma Thymidine Determination | | | | | | | | | | | | ■ | ■ |
| 5 | Plasminogen Activator Inhibitor Antigen | | | | | | ■ | | | ■ | | ■ | | |
| 8 | Primary Membranous Nephropathy Diagnostic Cascade, Serum | | | ■ | | | | | | | | | | |
| 9 | Procainamide/NAPA | | | | | | | | | | | | | ■ |
| 5 | Protein Electrophoresis, Serum | | | | | | | | ■ | ■ | | | | |
| 5 | Protein Electrophoresis, Serum, with IFE | | | | | | | | ■ | ■ | | | | |
| 6 | Send Out Mycobacterium tuberculosis Complex and Rifampin Resistance by PCR (Respiratory specimens, CSF, Pleural fluid) | | ■ | | | | | | | | | | | |
| 6 | Vanillylmandelic Acid, Urine 24 Hour | | | | | ■ | | | | | | | | |
| 6 | Vanillylmandelic Acid, Urine Random | | | | | ■ | | | | | | | | |

# Test Changes

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| (1,3) B–D Glucan | BDGLUC | **Specimen Requirement:** 0.5 mL serum from Serum Separator (Gold) tube; Refrigerated; **Sample should be collected in a sterile container using aseptic technique. If aliquoting is necessary, sterile aliquot tubes must be used. The sample should be transported to the laboratory as soon as possible or within 2 hours of collection.** The sample should be centrifuged to separate the serum from the cells **and then immediately placed into refrigerated storage pending delivery to the testing laboratory.** Heel and fingerstick collections are unacceptable. **Test is limited to in–patients only. This test cannot be added on to other testing. Sample cannot be shared with other testing.** | effective immediately |
| 5–Hydroxyindoleacetic Acid, Urine 24 Hour | UHIAAD | **Clinical Limitation: 5–Hydroxyindoleacetic Acid (5–HIAA) test performed by Liquid Chromatography Tandem Mass Spectrometry (LC–MS/MS). Results obtained with different methods or kits cannot be used interchangeably.** | 11/15/22 |
| 5–Hydroxyindoleacetic Acid, Urine Random | UHIAR2 | **Clinical Limitation: 5–Hydroxyindoleacetic Acid (5–HIAA) test performed by Liquid Chromatography Tandem Mass Spectrometry (LC–MS/MS). Results obtained with different methods or kits cannot be used interchangeably.** | 11/15/22 |
| Aspergillus galactomannan BAL | ASGALB | **Specimen Requirement:** 2 mL Bronch (BAL) in sterile container; Refrigerated; **Collect sample in a sterile container using aseptic technique.** If aliquoting is necessary, sterile aliquot tubes must be used. **Sample cannot be shared with other testing. This test cannot be added on to other testing.** | effective immediately |
| Aspergillus galactomannan Serum | ASGALS | **Specimen Requirement:** 1.5 mL serum from Serum Separator (Gold) tube; Refrigerated; **Collect sample in a sterile container using aseptic technique. If aliquoting is necessary, sterile aliquot tubes must be used. Sample cannot be shared with other testing. This test cannot be added on to other testing.** *OR* 1.5 mL serum from no additive (Red) tube; Refrigerated; **Collect sample in a sterile container using aseptic technique. If aliquoting is necessary, sterile aliquot tubes must be used. Sample cannot be shared with other testing. This test cannot be added on to other testing.** | effective immediately |
| Bilirubin, Fluid | FLBIL | **Stability:**<br>Ambient: 1 day if care is taken to prevent exposure to light.<br>Refrigerated: **5** days if care is taken to prevent exposure to light.<br>Frozen: Unacceptable | 10/13/22 |
| C Telopeptide, Beta Cross Linked | CTELO | **Special Information:** CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. Morning fasting specimen preferred. **Heparin plasma** and hemolyzed specimens are unacceptable. This test is New York DOH approved.<br>**Specimen Requirement:** 1 mL serum from Serum Separator (Gold) tube; Minimum 0.5 mL; Frozen, Critical; Morning fasting specimen **is** preferred. Separate specimens must be submitted when multiple tests are ordered. Allow tube to sit for 15–20 minutes at room temperature to form clot. Centrifuge and separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. *OR* 1 mL plasma from EDTA (Lavender) tube; Minimum 0.5 mL; Frozen, Critical; Morning fasting specimen **is** preferred. Separate specimens must be submitted when multiple tests are ordered. Centrifuge and separate plasma from cells ASAP or within 2 hours of collection. Transfer plasma to standard aliquot tube.<br>**Stability:**<br>Ambient: After separation from cells: **24** hours<br>Refrigerated: After separation from cells: **48** hours<br>Frozen: After separation from cells: 3 months<br>**Reference Range:**<br>Female:<br>6 months to 6 years: 500–1800 pg/mL<br>7 to 9 years: 566–1690 pg/mL<br>10 to 12 years: 503–2077 pg/mL<br>13 to 15 years: 160–1590 pg/mL<br>16 to 17 years: 167–933 pg/mL<br>Premenopausal: 136–689 pg/mL<br>Postmenopausal: 177–1015 pg/mL<br>*(continued on page 4)* | effective immediately |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| C Telopeptide, Beta Cross Linked<br>*(continued from page 3)* | | Male:<br>6 months to **6** years: **500–1700** pg/mL<br>**7–9 years: 522–1682 pg/mL**<br>**10–12 years: 553–2071 pg/mL**<br>**13–15 years: 485–2468 pg/mL**<br>**16–17 years: 276–1546 pg/mL**<br>18–29 years: 238–1019 pg/mL<br>30 to 39 years: 225–936 pg/mL<br>40 to 49 years: 182–801 pg/mL<br>50 to 59 years: 161–737 pg/mL<br>60 to 69 years: 132–752 pg/mL<br>70 to 99 years: 118–776 pg/mL | |
| Celiac Comprehensive Panel | CELCMP | **Clinical Information:** Comprehensive panel of tests useful to screen patients suspected of celiac disease. This panel should not be the first choice in screening patients for celiac disease. Presence of celiac–specific alleles helps assess a patient's risk of developing celiac disease when serology is negative. | 10/4/22 |
| Celiac Screen with Reflex | CELSCR | **Clinical Information: This panel is recommended when Celiac disease is clinically suspected. Positive results can be seen in asymptomatic individuals. Correlation with HLA status and biopsy results, where indicated, are advised.** | 10/4/22 |
| FSH | FSH | **Special Information:**<br>**Note:** *Special instructions related to biotin interference have been removed.*<br>**Reference Range:**<br>Female: See Clinical Information<br>**<1 years old: 1.6 to 19 mIU/mL**<br>**1 to 8 years old: 0.7 to 5.8 mIU/mL**<br>**9 to 11 years old: 0.5 to 7.6 mIU/mL**<br>**12 to 17 years old: 0.9 to 9.1 mIU/mL**<br>Follicular: 3.5–12.5 mIU/mL<br>**Ovulation: 4.7 to 21.5 mIU/mL**<br>Luteal: 1.7–7.7 mIU/mL<br>Postmenopausal: 25.8–134.8 mIU/mL<br>Male:<br>**<1 years old: <3.3 mIU/mL**<br>**1 to 8 years old: <2.1 mIU/mL**<br>**9 to 11 years old: 0.4 to 4.2 mIU/mL**<br>**12 to 17 years old: 0.9 to 7.1 mIU/mL**<br>**18 to 99 years old:** 1.5–12.4 mIU/mL | 11/15/22 |
| LPT to Beryllium, BAL | BALBE | **Specimen Requirement:** 200 mL Bronch (BAL) in clean container; Ambient; Collect Monday–Thursday only. Deliver the specimen to **the lab within 24 hours post collection.** Do not aliquot. Specimen must remain at ambient temperature. Do not refrigerate. Do not freeze. **Collect sample in a sterile container using aseptic technique. Sample cannot be shared with other testing. This test cannot be added on to other testing.** | effective immediately |
| LPT to Beryllium, Blood | BLDBE | **Specimen Requirement:** 30 mL whole blood in sodium heparin (Green) tube; Ambient; Collect Monday–Thursday only. Deliver the specimen to the lab within 48 hours post collection. Do not aliquot. Specimen must remain at ambient temperature. Do not refrigerate. Do not freeze. **Collect sample in a sterile container using aseptic technique. Sample cannot be shared with other testing. This test cannot be added on to other testing.** | effective immediately |
| Lymphocyte Transformation Test to Candida Antigen | LTT | **Specimen Requirement:** 20 mL whole blood in sodium heparin (Green) tube; Ambient; Collect Monday–Thursday only. Deliver the specimen to the lab within 24 hours post collection. Do not aliquot. Specimen must remain at ambient temperature. Do not refrigerate. Do not freeze. **Collect sample in a sterile container using aseptic technique. Sample cannot be shared with other testing. This test cannot be added on to other testing. Minimum: 10 mL; Minimum volume only applies to pediatric patients; lower volumes may be considered on a case by case basis at the discretion of the medical director.** | effective immediately |
| Metanephrines, Free Plasma | PMETAN | **Clinical Limitation: Plasma Free Metanephrine test performed by Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS). Results obtained with different methods or kits cannot be used interchangeably.** | 11/15/22 |
| Metanephrines, Urine 24 hour | UMETAN | **Clinical Limitation: Urine Metanephrine test performed by Liquid Chromatography Tandem Mass Spectrometry (LC–MS/MS). Results obtained with different methods or kits cannot be used interchangeably.** | 11/15/22 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Metanephrines, Urine Random | UMETRA | **Clinical Limitation: Urine Metanephrine test performed by Liquid Chromatography Tandem Mass Spectrometry (LC–MS/MS). Results obtained with different methods or kits cannot be used interchangeably.** | 11/15/22 |
| Mitogen LTT | LTTMS | **Specimen Requirement:** 20 mL whole blood in sodium heparin (Green) tube; Ambient; Collect Monday–Thursday only. Deliver the specimen to the lab within 24 hours post collection. Do not aliquot. Specimen must remain at ambient temperature. Do not refrigerate. Do not freeze. **Collect sample in a sterile container using aseptic technique. Sample cannot be shared with other testing. This test cannot be added on to other testing. Minimum:** 10 mL; **Minimum volume only applies to pediatric patients; lower volumes may be considered on a case by case basis at the discretion of the medical director.** | effective immediately |
| Mycoplasma genitalium | MYGPCR | **Includes:**<br>Mycoplasma genitalium Result<br>**Note:** Specimen Source removed<br>**Specimen Requirement:** One Endocervical specimen on APTIMA Collection Unisex swab; **Ambien**t *OR* One Urethral specimen on APTIMA Collection Unisex swab; **Ambient** *OR* 2 mL **first–catch** urine in APTIMA Urine specimen collection kit; **Ambient** *OR* One Genital specimen in Aptima Multitest Collection Kit; **Ambient**<br>**Days Performed:** Mon–**Sun** | 11/15/22 |
| Plasminogen Activator Inhibitor Antigen | PAI1M | **Special Information:** Spin down, remove plasma, and spin again. Freeze **double–centrifuged platelet poor plasma** immediately at < or = **–40** degrees C. Each coagulation test should have its own vial.<br>**Specimen Requirement:** 1 mL plasma from sodium citrate (Light Blue) tube; **Minimum 0.5 mL**; Frozen; Spin down, remove plasma, and spin again. Freeze **double–centrifuged platelet poor plasma** immediately at < or = **–40** degrees C. Each coagulation test should have its own vial.<br>**Stability:**<br>Frozen: **2** years<br>**Reference Range:** 3.**0**–72.**0** ng/mL<br>**Days Performed: Varies** | effective immediately |
| Protein Electrophoresis, Serum | SEPG | **Special Information:** Avoid hemolysis.<br>**Clinical Information: The test is used as an aid in diagnosing monoclonal gammopathies**. However, immunofixation electrophoresis (IFE) is a more sensitive test for the detection of small M–proteins. **For treatment follow up, IFE is superior to SPEP.**<br>**Methodology: Capillary Electrophoresis (CE)**<br>**Reference Range:**<br>Total protein (TPSPE): 18 Years to 99 Years: 6.3–8.0 g/dL<br>Albumin (ALBE): **3.43–5.41** g/dL<br>Alpha–1 globulin (A1GL): **0.18–0.43** g/dL<br>Alpha–2 globulin (A2GL): **0.42–0.98** g/dL<br>Beta globulin (BEGL): **0.61–1.17** g/dL<br>Gamma globulin (GAGL): **0.53–1.51** g/dL<br>M Spike Concentration (LOC): 0.00 g/dL | 11/15/22 |
| Protein Electrophoresis, Serum, with IFE | SEPGRX | **Special Information:** Avoid hemolysis. If indicated, Monoclonal Protein analysis by immunofixation electrophoresis will be performed and charged.<br>**Clinical Information:**Serum protein electrophoresis is useful as a screening procedure in the detection of **monoclonal** gammopathies. If an M protein is identified, it will be reflexed for confirmation using immunofixation electrophoresis (IFE). **IFE is superior to SPEP.**<br>**Methodology: Capillary Electrophoresis (CE)**<br>**Reference Range:**<br>Total protein (TPSPE): 18 Years to 99 Years: 6.3–8.0 g/dL<br>Albumin (ALBE): **3.43–5.41** g/dL<br>Alpha–1 globulin (A1GL): **0.18–0.43** g/dL<br>Alpha–2 globulin (A2GL): **0.42–0.98** g/dL<br>Beta globulin (BEGL): **0.61–1.17** g/dL<br>Gamma globulin (GAGL): **0.53–1.51** g/dL<br>M Spike Concentration (GPERDL): 0.00 g/dL | 11/15/22 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Send Out Mycobacterium tuberculosis Complex and Rifampin Resistance by PCR (Respiratory specimens, CSF, Pleural fluid) | MTBAM1 | **Test Name:** Previously Mycobacterium tuberculosis Complex and Rifampin Resistance by PCR | 11/15/22 |
| Vanillylmandelic Acid, Urine 24 Hour | UVMA24 | **Clinical Limitation: Urine Vanillylmandelic Acid (VMA) test performed by Liquid Chromatography Tandem Mass Spectrometry (LC–MS/MS). Results obtained with different methods or kits cannot be used interchangeably.** | 11/15/22 |
| Vanillylmandelic Acid, Urine Random | UVMAR | **Clinical Limitation: Urine Vanillylmandelic Acid (VMA) test performed by Liquid Chromatography Tandem Mass Spectrometry (LC–MS/MS). Results obtained with different methods or kits cannot be used interchangeably.** | 11/15/22 |

# New Tests

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| BRAF V600E Mutation Detection Blood | BRAFPB | **Note: New test was announced in the September update, but financial information was not available at that time**<br>**CPT:** 81210<br>**Price:** $270.00 | effective immediately |
| BRAF V600E Mutation Detection Bone Marrow | BRAFVBM | **Note: New test was announced in the September update, but financial information was not available at that time**<br>**CPT:** 81210<br>**Price:** $430.00 | effective immediately |
| BRAF V600E Mutation Detection Other | BRAFO | **Note: New test was announced in the September update, but financial information was not available at that time**<br>**CPT:** 81210<br>**Price:** $270.00 | effective immediately |
| Fentanyl Screen, Qualitative, Urine | UFENTS | **Special Information:** Preliminary positive results should be confirmed by another method.<br>**Clinical Information:** Evaluation of suspected acute overdose. This test should not be used for therapeutic drug or compliance monitoring; the quantitative pain panel, urine (UQNTPP) should be ordered instead.<br>**Specimen Requirement:** 3 mL urine in yellow (no additive) tube; Minimum 3 mL<br>**Stability:**<br>Ambient: 4 weeks<br>Refrigerated: 4 weeks<br>Frozen: 6 months<br>**Methodology:** Enzyme Immunoassay (EIA)<br>**Reference Range:** Negative<br>**Days Performed:** 7 days a week; 24 hours<br>**Reported:** 8 hours | 11/17/22 |
| Fentanyl Screen w/ Reflex, Qualitative, Urine | UFENTSRF | **Special Information:** All non-negative results are sent for confirmation and billed. Please see the Urine Fentanyl and Metabolite results<br>**Clinical Limitation:** Evaluation of suspected acute overdose. This test should not be used for therapeutic drug or compliance monitoring; the quantitative pain panel, urine (UQNTPP) should be ordered instead.<br>*(continued on page 7)* | 11/17/22 |

# New Tests (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Fentanyl Screen w/ Reflex, Qualitative, Urine<br>*(continued from page 6)* | | **Clinical Information:**<br>**Specimen Requirement:** 3 mL urine in yellow (no additive) tube; Minimum 3 mL<br>**Stability:**<br>Ambient: 4 weeks<br>Refrigerated: 4 weeks<br>Frozen: 6 months<br>**Methodology:** Enzyme Immunoassay (EIA)<br>**Reference Range:** Negative<br>**Days Performed:** 7 days a week; 24 hours<br>**Reported:** 8 hours | |
| FISH for CRLF2 Blood | CRLF2B | **Note: New test was announced in the September update, but financial information was not available at that time**<br>**CPT:** 88271; 88275; 88291; 88237<br>**Price:** $596.00 | effective immediately |
| FISH for CRLF2 Bone Marrow | CRLF2M | **Note: New test was announced in the September update, but financial information was not available at that time**<br>**CPT:** 88271; 88275; 88291; 88237<br>**Price:** $596.00 | effective immediately |
| Kit D816V Mutation Detection Other | K816O | **Note: New test was announced in the September update, but financial information was not available at that time**<br>**CPT:** 81273<br>**Price:** $335.00 | effective immediately |
| Lymphogranuloma Venereum PCR | LGVPCR | **Note: New test was announced in the August update, but financial information was not available at that time**<br>**CPT:** 87491<br>**Price:** $195.00 | effective immediately |
| Monkeypox Virus Qualitative PCR | MONKEY | **Includes:**<br>Orthopoxvirus Source<br>Orthopoxvirus by PCR<br>**Special Information:** Specimen source required. Calcium alginate swabs, wooden swabs and specimens without swabs will be rejected.<br>**Clinical Limitation:** A negative result does not rule out the presence of PCR inhibitors in the patient specimen or assay specific nucleic acid in concentrations below the level of detection by the assay. This test is intended for the detection of non-variola orthopoxviruses, however high viral titer variola virus (smallpox) infections could be detected by this assay. Smallpox was declared eradicated in 1980 by the World Health Organization and the last case in humans was described in 1977.<br>**Clinical Information:** This test is used to detect members of the orthopoxviruses, including monkeypox virus and vaccinia virus. This assay does not differentiate members of the orthopoxviruses. In the United States, a detected result is most likely due to monkeypox virus or vaccinia virus. Other orthopoxviruses may be considered if appropriate. Refer to the US Centers for Disease Control and Prevention if additional confirmatory testing is needed.<br>**Specimen Requirement:** swab of lesion fluid in Universal Transport Media (UTM); Frozen; Specimen source required. *OR* swab with lesion fluid in Viral Transport Media; Frozen; Specimen source required.<br>**Stability:**<br>Ambient: 24 hours<br>Refrigerated: 7 days<br>Frozen: 7 days<br>**Methodology:** Qualitative Polymerase Chain Reaction<br>**Days Performed:** Sun - Sat<br>**Reported:** 2–4 days<br>**CPT:** 87593<br>**Price:** $166.00 | effective immediately |

# New Tests (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Primary Membranous Nephropathy Diagnostic Cascade, Serum | PMNDCS | **Includes:** Phospholipase A2 Receptor, ELISA, S<br>**Special Information:** Reflex Algorithm: The phospholipase A2 receptor (PLA2R) enzyme-linked immunosorbent assay (ELISA) is initially performed. If the PLA2R ELISA result is greater than 20 (positive), no additional testing will be performed. If the PLA2R ELISA result is less than 20 (negative or borderline), then the reflex test PLA2R immunofluorescence (PLA2RI) will be performed at an additional charge. If the reflex PLA2R immunofluorescence result is positive, no additional testing will be performed. If the reflex PLA2R immunofluorescence result is negative, the reflex test thrombospondin type-1 domain-containing 7A (THSD7A) antibody testing will be performed at an additional charge. This test is New York DOH approved.<br>**Clinical Limitation:** This test should not be used as a stand-alone test but an adjunct to other clinical information. A diagnosis of primary membranous nephropathy (pMN) or secondary membranous nephropathy (sMN) should not be made on a single test result. The clinical symptoms, results on physical examination, and laboratory tests (eg, serological tests), when appropriate, should always be taken into account when considering the diagnosis of pMN vs sMN. Absence of circulating anti-phospholipase A2 receptor autoantibodies does not rule out a diagnosis of pMN.<br>**Clinical Information:** This test is useful in distinguishing primary membranous nephropathy (pMN) from secondary membranous nephropathy (sMN), monitoring patients with MN at very low antibody titers, and screening for anti-phospholipase A2 receptor antibodies. Anti-phospholipase A2 receptor (PLA2R) antibodies are highly specific for the diagnosis of pMN. As many as 70% to 75% of patients with pMN are positive for anti-PLA2R. A titer increase, decrease, or disappearance generally precedes a change in clinical status.<br>MN is a rare disease in which immune complexes deposit at the glomerular basement membrane, causing damage to the filtration barrier, resulting in proteinuria.<br>Recent studies have shown that in approximately 70% of patients with pMN, the immune complexes consist of autoantibodies against the podocyte protein M-type PLA2R. There is also evidence that levels of anti-PLA2R autoantibodies correlate well with disease activity and progression. The presence of anti-PLA2R antibodies could also potentially be used to differentiate pMN from other causes of nephrotic syndrome if a biopsy is not possible. Among patients with chronic kidney disease awaiting kidney transplantation, higher levels of anti-PLA2R could predict those more likely to recur after transplantation. In the remaining 30% of patients with MN who are PLA2R-negative, anti-thrombospondin type-1 domain-containing 7A (THSD7A) was shown to have an approximate 10% prevalence (ie, about 3% of all primary MN patients). Additionally, THSD7A has been described as a potential tumor antigen and, thus, it has been suggested that THSD7A-positive patients merit a thorough cancer screening.<br>**Specimen Requirement:** 1 mL serum from Serum Separator (Gold) tube; Minimum 1 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. *OR* 1 mL serum from No additive (Red) tube; Minimum 1 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube.<br>**Stability:**<br>Ambient: 8 hours<br>Refrigerated: 14 days<br>Frozen: 14 days<br>**Methodology:** Enzyme-Linked Immunosorbent Assay (ELISA)<br>**Reference Range:**<br>< 14 RU/mL: Negative<br>14 to 19 RU/mL: Borderline<br>>= 20 RU/mL: Positive<br>**Days Performed:** Mon, Wed, Fri<br>**Reported:** 4–8 days | 11/15/22 |

## Fee Increases

| Test Name | Order Code | List Fee | CPT Code | Effective Date |
|---|---|---|---|---|
| Plasma Thymidine Determination | PLTHY | $255.00 | 82542 | effective immediately |

## Fee Reductions

| Test Name | Order Code | List Fee | CPT Code | Effective Date |
|---|---|---|---|---|
| Cell Count/Diff, Body Fluid | CCBF | $35.00 | 89051 | effective immediately |
| CYP2D6 (Cytochrome P450 2D6) | 2D6GTP | $515.00 | 81226 | effective immediately |
| Hypersensitivity Pneumonitis Evaluation | HYPNE2 | $200.00 | 86001x8 | effective immediately |
| Procainamide/NAPA | PROC | $45.00 | 80192 | effective immediately |

## Discontinued Tests

| Test Name | Order Code | Test Information | Effective Date |
|---|---|---|---|
| Anaplasma phagocytophilum & E. chaffeensis Ab Panel | EHRLIC | Test will no longer be orderable. Recommended replacement tests are Anaplasma phagocytophilum (HGA) Antibodies, IgG and IgM (ANIGM) and Ehrlichia chaffeensis IgG & IgM Abs by IFA (ECHAFF) | 11/15/22 |
| Giardia Antigen, Stool, EIA | GIAEIA | Test will no longer be orderable. Recommended replacement test is Cryptosporidium & Giardia Antigens by EIA (OVAPSC) | 11/15/22 |
| Herpes Simplex IgM, Abs | HSVM | Test will no longer be orderable. Recommended replacement test is Herpes Simplex IgM, Abs, with IgG Reflex (HSVGM) | 11/15/22 |
| Herpes Simplex Virus 1/2 Antibody (IgM), IFA with Reflex to Titer, Serum | HSVIFA | Test will no longer be orderable. Recommended replacement test is HSV 1 & 2 / VZV Amplification- Herpes Simplex Virus and Varicella-Zoster Virus, Molecular Detection (HSVVZV) | 11/15/22 |
| HIV-1 Integrase Genotype | HIVIGT | Test will no longer be orderable. Recommended replacement test is HIV 1 Drug Resistance by Next Generation Sequencing (HIVNGS) | 11/15/22 |
| KIT (D816V) Mutation by PCR | KIT816 | Test will no longer be orderable. Recommended replacement tests are KIT D816V Mutation Detection Blood (K816PB) or KIT D816V Mutation Detection Bone Marrow (K816BM) or Kit D816V Mutation Detection Other (K816O) | effective immediately |
| Methylenetetrahydrofolate Reductase (MTHFR) Mutation - 2 Variants | MTHFRM | Test will no longer be orderable. Recommended replacement test is Homocysteine (HOMCYS) | 11/15/22 |
| Phospholipase A2 Receptor Ab, IgG | PLA2R | Test will no longer be orderable. Recommended new replacement test is Primary Membranous Nephropathy Diagnostic Cascade, Serum (PMNDCS) | 11/15/22 |