Cleveland Clinic

# Cleveland Clinic Laboratories

## Technical Update • October 2018

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

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

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

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

| Test Update Page # | Summary of Changes by Test Name | Order Code | Name Change | New Test | Test Discontinued | Special Information | Specimen Requirement | Component Change(s) | Methodology | Reference Range | Days Performed/Reported | Stability | CPT | Fee |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 3 | Alkaline Phosphatase Isoenzymes | | | | | | ■ | | | | | | | |
| 17 | Allergen, Alpha Lactalbumin IgE | | | | ■ | | | | | | | | | |
| 17 | Allergen, Beta Lactoglobulin IgE | | | | ■ | | | | | | | | | |
| 17 | Allergen, Casein IgE | | | | ■ | | | | | | | | | |
| 3, 16 | Allergen, Cow Milk Components IgE | | ■ | | | ■ | ■ | ■ | | ■ | ■ | ■ | ■ | ■ |
| 4 | Allergen, Egg Components IgE | | ■ | | | ■ | ■ | ■ | | ■ | ■ | ■ | ■ | |
| 4–5, 16 | Allergen, Peanut Components IgE | | ■ | | | ■ | ■ | ■ | | ■ | ■ | ■ | ■ | ■ |
| 5 | Anaerobe Culture | | | | | | | | | | | ■ | | |
| 5 | BCR/ABL1 Mutation Analysis for Tyrosine Kinase Inhibitor Resistance by NGS | | ■ | | | ■ | ■ | ■ | ■ | | ■ | ■ | | |
| 5 | Bromine-Total, Blood | | | | | | | | | | ■ | | | |
| 6 | Calculi (Stone) Analysis | | | | | | | ■ | | | | | | |
| 6 | Calprotectin, Fecal | | | | | ■ | | | | | | | | |
| 17 | Carnitine Free & Total, Urine | | | | ■ | | | | | | | | | |
| 13 | Carnitine, Free & Total, Urine by Tandem Mass Spectrometry | | | ■ | | | | | | | | | | |
| 6 | Cathartic Laxative, Urine | | | | | | | | ■ | | ■ | | | |
| 6 | Celiac Gluten Free Panel | | | | | | ■ | | | | | ■ | | |
| 6 | Clonazepam & Metabolite, Urine | | | | | ■ | | | | | ■ | | | |
| 6 | Clostridium difficile Toxin by PCR | | | | | ■ | | | | | | | | |
| 6 | Cobalt, Blood | | | | | | | | | | ■ | | | |
| 6 | Colchicine Level | | | | | ■ | | | | | ■ | ■ | | |

| 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 7 | Cortisol, Plasma | | | | | ■ | ■ | | | | ■ | ■ | | |
| 13–14 | Cystic Fibrosis Pathogenic Variant Analysis | | | ■ | | | | | | | | | | |
| 17 | Cystic Fibrosis Screen139 Variant Assay | | | | ■ | | | | | | | | | |
| 7 | Diphenhydramine | | | | | ■ | | | ■ | | ■ | | | |
| 7 | Diphenhydramine, Urine | | | | | | | | ■ | | ■ | | | |
| 7–8 | Enterovirus by PCR | | ■ | | | ■ | ■ | | | | | | | |
| 17 | Enterovirus, Miscellaneous Sites, PCR | | | | ■ | | | | | | | | | |
| 17 | Enterovirus PCR Plasma | | | | ■ | | | | | | | | | |
| 8, 16 | Familial Mediterranean Fever (MEFV) Sequencing | | ■ | | | ■ | ■ | ■ | ■ | | ■ | ■ | ■ | ■ |
| 8 | Fluoride | | | | | | | | | | ■ | | | |
| 17 | Herpesvirus 6 PCR, Quant, CSF | | | | ■ | | | | | | | | | |
| 17 | Herpesvirus 6 PCR, Quant, Plasma | | | | ■ | | | | | | | | | |
| 8 | Histone IgG Antibody | | | | | | | | | | ■ | | | |
| 17 | HLA-B27 | | | | ■ | | | | | | | | | |
| 14 | Human Herpesvirus 6 (HHV-6A and HHV-6B) by Quantitative PCR | | | ■ | | | | | | | | | | |
| 8 | Insulinoma Associated Antibody 2 | | | | | | | | | | | ■ | | |
| 8 | Ketamine & Metabolite, Serum/Plasma | | | | | ■ | | | | | ■ | | | |
| 9 | Ketorolac | | | | | ■ | | | | | ■ | | | |
| 9 | Levamisole | | | | | ■ | ■ | | | | ■ | | | |
| 9 | Levetiracetam | | | | | ■ | | | | | | | | |
| 17 | Lindane | | | | ■ | | | | | | | | | |
| 9 | LSD, Urine | | | | | ■ | ■ | | | | ■ | | | |
| 9 | Mephenytoin & Normephenytoin | | | | | ■ | | | | | ■ | | | |
| 9 | Metformin | | | | | ■ | | | ■ | | ■ | | | |
| 10, 16 | Methadone & Metabolite | | | | | ■ | ■ | | ■ | ■ | ■ | ■ | | ■ |
| 17 | Methazolamide | | | | ■ | | | | | | | | | |
| 10 | Methyl Ethyl Ketone, Urine | | | | | ■ | | | | | ■ | | | |
| 10 | Metoprolol, Serum/Plasma | | | | | ■ | | | | | ■ | | | |
| 17 | Monoclonal Protein, Blood | | | | ■ | | | | | | | | | |
| 15 | Monoclonal Protein with Immunoglobulins and Free Light Chains, serum | | | ■ | | | | | | | | | | |
| 16 | Mycobacterium tuberculosis (MTB) and Rifampin Resistance Detection by PCR | | | ■ | | | | | | | | | | |
| 10 | Neisseria gonorrhoea Antibodies, Total | | | | | ■ | ■ | | | | | | | |
| 17 | Peroxisomal Panel | | | | ■ | | | | | | | | | |
| 17 | Phenelzine | | | | ■ | | | | | | | | | |
| 17 | Phenylpropanolamine | | | | ■ | | | | | | | | | |
| 10 | Platinum | | | | | ■ | | | | | ■ | | | |
| 10 | Propylene Glycol | | | | | ■ | | | | | ■ | | | |
| 11 | Protein Electrophoresis, Serum, with IFE | | | | | ■ | | ■ | | | | | | |
| 11 | Silver, Urine | | | | | ■ | | | | | ■ | | | |
| 11 | Synthetic Cannabinoid Metabolites – Expanded, Urine (Qualitative) | | | | | | | | | | ■ | | | |

| 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 11 | Thiopurine Metabolites by LC-MS/MS | | | | | | ■ | ■ | | ■ | ■ | ■ | ■ | |
| 17 | Tier 2 B-Cell Clonality Using BIOMED2 Primers | | | | | ■ | | | | | | | | |
| 11 | Toluene, Blood | | | | | | | | | | ■ | | | |
| 11 | Torsemide, Serum/Plasma | | | | | | ■ | | | | ■ | | | |
| 17 | TP53 Sequencing (Exons 5-8) | | | | | ■ | | | | | | | | |
| 12 | VRE Culture Screen | | | | | | | ■ | | | | | | |
| 12 | West Nile Virus IgM, CSF | | | | | | ■ | | | ■ | | | | |

# Test Changes

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Alkaline Phosphatase Isoenzymes | ALKISO | **Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: **1.5 mL**; Refrigerated | Effective immediately |
| **Allergen, Cow Milk Components IgE** | MILKE | **For Interfaced Clients Only: Test build may need to be modified**<br>**Test Name:** Previously Allergen, Food, Milk (Cow's) Components IgE<br>**Note:** *The following alias names will be added: Alpha-lactalbumin, Beta-lactoglobulin, Casein, Cow Milk. Special Information will be removed.*<br>**Includes:**<br>Allergen, Casein IgE<br>Allergen, Alpha Lactalbumin IgE<br>Allergen, Beta Lactoglobulin IgE<br>**Allergen Class Guide**<br>**Clinical Information:** Alpha-lactalbumin, beta-lactoglobulin, and casein are the allergens included in this panel. Allergen results of 0.10–0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.<br>**Specimen Requirement: 0.8 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 0.8 mL is preferred; An extra 50 µL will be required** for each additional allergen ordered; Refrigerated<br>*OR* **0.8 mL plasma from an EDTA (lavender) tube;** Minimum: 0.5 mL; **Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.8 mL is preferred; An extra 50 µL will be required** for each additional allergen ordered; Refrigerated<br>*OR* **0.8 mL plasma from a lithium heparin (green) tube;** Minimum: 0.5 mL; **Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.8 mL is preferred; An extra 50 µL will be required** for each additional allergen ordered; Refrigerated<br>**Stability:**<br>Ambient: **1 day**<br>Refrigerated: **7 days**<br>Frozen: **14 days**<br>**Reference Range:**<br>Allergen, Casein IgE: **< 0.35 kU/L**<br>Allergen, Alpha Lactalbumin IgE: **< 0.35 kU/L**<br>Allergen, Beta Lactoglobulin IgE: **< 0.35 kU/L**<br>**Days Performed:** Sunday–Saturday<br>**Reported:** **1**–2 days<br>**CPT:** 86008 x 3 | 11/27/18 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| **Allergen, Egg Components IgE** | EGGIGE | **For Interfaced Clients Only: Test build may need to be modified**<br>**Test Name:** Previously Allergen, Food, Egg Components IgE<br>**Note:** *The following alias names will be added: Egg white, Ovalbumin, Ovomucoid. Special Information will be removed.*<br>**Includes:**<br>Ovomucoid<br>Ovalbumin<br>**Allergen Class Guide**<br>**Clinical Information:** Ovomucoid and ovalbumin are the allergens included in this panel. Allergen results of 0.10–0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.<br>**Specimen Requirement: 0.5 mL** serum from a serum separator (gold) tube; Minimum: **0.3 mL; Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.5 mL is preferred; An extra 50 µL will be required** for each additional allergen ordered; Refrigerated<br>*OR* **0.5 mL plasma from an EDTA (lavender) tube;** Minimum: **0.3 mL; Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.5 mL is preferred; An extra 50 µL will be required** for each additional allergen ordered; Refrigerated<br>*OR* **0.5 mL plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: **0.3 mL; Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.5 mL is preferred; An extra 50 µL will be required** for each additional allergen ordered; Refrigerated<br>**Stability:**<br>Ambient: **1 day**<br>Refrigerated: **7 days**<br>Frozen: **14 days**<br>**Reference Range:**<br>Ovomucoid: **< 0.35 kU/L**<br>Ovalbumin: **< 0.35 kU/L**<br>**Days Performed:** Sunday–Saturday<br>**Reported: 1**–2 days<br>**CPT:** 86008 x 2 | 11/27/18 |
| **Allergen, Peanut Components IgE** | PNUTCP | **For Interfaced Clients Only: Test build may need to be modified**<br>**Test Name:** Previously Allergen, Food, Peanut Components IgE<br>**Note:** *The following alias names will be added: Peanut, Peanut IgE, rAra h 1, rAra h 2, rAra h 3, rAra h 8, rAra h 9. Special Information will be removed.*<br>**Includes:**<br>Ara h 1 Ab IgE<br>Ara h 2 Ab IgE<br>Ara h 3 Ab IgE<br>Ara h 9 Ab IgE<br>Ara h 8 Ab IgE<br>ALGN Food Pnut Components Interp<br>**Allergen Class Guide**<br>**Clinical Information:** Allergen results of 0.10–0.34 kU/L for whole peanut are intended for specialist use as the clinical relevance is undetermined. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.<br><br>*(continued on page 5)* | 11/27/18 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| **Allergen, Peanut Components IgE** *(continued from page 4)* | | **Specimen Requirement: 0.8 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 0.8 mL is preferred; An extra 50 µL will be required** for each additional allergen ordered; Refrigerated<br>*OR* **0.8 mL plasma from an EDTA (lavender) tube;** Minimum: **0.5 mL; Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.8 mL is preferred; An extra 50 µL will be required** for each additional allergen ordered; Refrigerated<br>*OR* **0.8 mL plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: **0.5 mL; Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.8 mL is preferred; An extra 50 µL will be required** for each additional allergen ordered; Refrigerated<br>**Stability:**<br>Ambient: **1 day**<br>Refrigerated: **7 days**<br>Frozen: **14 days**<br>**Reference Range:**<br>Ara h 1 Ab IgE: **< 0.1 kU/L**<br>Ara h 2 Ab IgE: **< 0.1 kU/L**<br>Ara h 3 Ab IgE: **< 0.1 kU/L**<br>Ara h 9 Ab IgE: **< 0.1 kU/L**<br>Ara h 8 Ab IgE: **< 0.1 kU/L**<br>**Days Performed:** Sunday–Saturday<br>**Reported: 1**–2 days<br>**CPT:** 86008 x 5 | |
| Anaerobe Culture | ANACUL | **Stability:**<br>Ambient: **24** hours<br>Refrigerated: Unacceptable<br>Frozen: Unacceptable | 12/4/18 |
| **BCR/ABL1 Mutation Analysis for Tyrosine Kinase Inhibitor Resistance by NGS** | KINASE | **For Interfaced Clients Only: Test build may need to be modified**<br>**Test Name:** Previously BCR/ABL1, Tyrosine Kinase Inhibitor Resistance, Kinase Domain Mutation Screen, Sanger Sequencing<br>**Special Information: Serum, plasma, and specimens collected in anticoagulants other than EDTA are unacceptable. Frozen, clotted or severely hemolyzed specimens will be rejected. For specimens having no t(9;22) fusion, this test will be canceled, and an ABL1 amplification confirmation test will be ordered. This test is New York DOH approved.**<br>**Clinical Information: Order only for patients with an established diagnosis of a BCR-ABL1 positive leukemia. Used to determine if a mutation is present that would interfere with response to TKI therapy in Philadelphia chromosome positive (Ph+) lymphoblastic leukemia or chronic myelogenous leukemia (CML). This test detects all common mutations, including T315I.**<br>**Specimen Requirement: 5 mL** whole blood in an EDTA (lavender) tube; Minimum: 1 mL; **Must send to Cleveland Clinic Laboratories on the day of collection;** Refrigerated<br>*OR* **3 mL** bone marrow in an EDTA (lavender) tube; Minimum: 1 mL; **Must send to Cleveland Clinic Laboratories on the day of collection;** Refrigerated<br>**Stability:**<br>Ambient: **1 hour**<br>Refrigerated: **48 hours**<br>Frozen: Unacceptable<br>**Methodology: Massive Parallel** Sequencing<br>**Days Performed: Varies**<br>**Reported: 11–13** days | 12/6/18 |
| Bromine-Total, Blood | BROMWB | **Days Performed: Monday–Sunday**<br>**Reported: 8–9** days | 10/15/18 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Calculi (Stone) Analysis | CSA | **For Interfaced Clients Only: Test build may need to be modified**<br>**Includes:**<br>Calculi Stone Type<br>**Calculi Stone Color**<br>**Calculi Stone Size and Weight**<br>**Calculi Stone Composition**<br>Calculus Analysis | 12/6/18 |
| Calprotectin, Fecal | CALPRO | **Note:** *Changes for this test were published in the June Technical Update, and the date was changed to TBD in the August Technical Update. The new go-live date will be **10/16/18.** We apologize for any inconvenience this may have caused.* | 10/16/18 |
| Cathartic Laxative, Urine | UCATH | **Methodology: High Performance** Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)<br>**Days Performed: Monday–Sunday**<br>**Reported: 8–9** days | 10/15/18 |
| Celiac Gluten Free Panel | CELGLU | **Specimen Requirement: 1 mL** serum from a serum separator (gold) tube; Minimum: **0.5 mL;** This assay requires multiple specimen types; Ambient<br>*AND* **4 mL** whole blood in an EDTA (lavender) tube; Minimum: **4 mL;** Ambient<br>*OR* **1 mL** serum from a plain no additive (red) tube; Minimum: **0.5 mL;** This assay requires multiple specimen types; Ambient<br>*AND* 7 mL whole blood in an ACD A or B (yellow) tube; Minimum: **4 mL;** Ambient<br>**Stability:**<br>Ambient: Serum: **24** hours; Whole Blood: 1 week<br>Refrigerated: Serum: **7 days;** Whole blood: 1 week<br>Frozen: Serum: **14 days** (Multiple freeze-thaw cycles for serum are not recommended); Whole blood: Unacceptable | Effective immediately |
| Clonazepam & Metabolite, Urine | UCLONO | **Special Information: Frozen specimens will be rejected.** This test is New York State approved.<br>**Days Performed: Monday–Sunday**<br>**Reported: 5–6** days | 10/15/18 |
| Clostridium difficile Toxin by PCR | CDPCR | **Special Information: Due to the high sensitivity and negative predictive value of the PCR assay, only one sample per week is accepted for testing.** Formed stools, samples from patients < 2 years old, and specimens received in preservative, **frozen,** on swabs or wooden applicator sticks will be rejected.<br>**Clinical Information: Unformed stools** are tested for the presence of C. difficile toxin B gene **by PCR. A positive PCR result for C. difficile may represent infection or colonization. The positive predictive value of the PCR assay for C. difficile infection (CDI) is highest for patients with significant diarrhea (3 or more unformed stools in 24 hours) who do not have an alternative explanation (e.g., recent receipt of laxatives). Contact isolation is required for patients who are colonized or infected with C. difficile. Once a patient is diagnosed with CDI, therapeutic response should be based on clinical signs and symptoms; a "test of cure" should not be done since patients may remain colonized with toxin-producing strains following recovery.** | Effective immediately |
| Cobalt, Blood | COBALB | **Days Performed: Sunday–Saturday**<br>**Reported:** 2–6 days | Effective immediately |
| Colchicine Level | COLCH | **Special Information:** This test is New York State approved. **Specimens received at room temperature will be rejected. Polymer gel separation tubes are unacceptable.**<br>**Clinical Information:** Reporting limit is 0.20 ng/mL. Purpose: Therapeutic drug monitoring. **Following 1 mg p.o.: Peak plasma concentration was 5.5 ng/mL (range 4.0 to 7.6) at 1 hour**<br>**Stability:**<br>Ambient: 1 day<br>Refrigerated: **30** days<br>Frozen: 8 months<br>**Days Performed: Monday–Sunday**<br>**Reported: 8–9** days | 12/3/18 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Cortisol, Plasma | PCORT | **Special Information: Specimen should be collected between 8–10 a.m.** This test is New York DOH approved.<br>**Note:** *Clinical Information will be removed.*<br>**Specimen Requirement:** 1 mL plasma from a sodium or lithium heparin (green) tube; Minimum: **0.5 mL; Specimen should be collected between 8–10 a.m.;** Separate plasma from cells ASAP **or within 2 hours of collection and transfer into standard aliquot tube; Frozen**<br>*OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: **0.5 mL; Specimen should be collected between 8–10 a.m.;** Separate plasma from cells ASAP **or within 2 hours of collection and transfer into standard aliquot tube; Frozen**<br>**Stability:**<br>Ambient: **After separation from cells: 1 week**<br>Refrigerated: **After separation from cells: 1 week**<br>Frozen: **After separation from cells: 6 months**<br>**Days Performed: Wednesday, Saturday**<br>**Reported: 3–6** days | 11/29/18 |
| Diphenhydramine | DIPHEN | **Special Information: Polymer gel separation tubes (serum separator tubes or plasma separator tubes) will be rejected.**<br>**Methodology: High Performance** Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)<br>**Days Performed:** Monday–**Sunday**<br>**Reported:** 4–**5** days | 10/15/18 |
| Diphenhydramine, Urine | UDIPHN | **Methodology: High Performance** Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)<br>**Days Performed:** Monday–**Sunday**<br>**Reported:** 4–**5** days | 10/15/18 |
| **Enterovirus by PCR** | ENTNAS | **Test Name:** Previously Enterovirus by PCR, Nasopharyngeal Swab<br>**Special Information:** Specimen source required. **Heparinized specimens will be rejected. For cerebrospinal fluid (CSF) specimens, order Enterovirus PCR CSF (ENTPCR).** This test is New York DOH approved.<br>**Specimen Requirement: 1 mL plasma from an EDTA (lavender) tube;** Minimum: **0.5 mL; Separate plasma from cells and transfer into sterile aliquot tube; Must indicate specimen source;** Frozen<br>*OR* **1 mL serum from a serum separator (gold) tube;** Minimum: **0.5 mL; Separate serum from cells and transfer into sterile aliquot tube; Must indicate specimen source;** Frozen<br>*OR* One nasopharyngeal swab in Viral Transport Media; **Must indicate specimen source;** Frozen<br>*OR* **1 mL pericardial fluid in a sterile container;** Minimum: **0.5 mL; Please include disclaimer for approval to perform testing on this specimen type; Must indicate specimen source;** Frozen<br>*OR* **1 mL peritoneal fluid in a sterile container;** Minimum: **0.5 mL; Please include disclaimer for approval to perform testing on this specimen type; Must indicate specimen source;** Frozen<br>*OR* **1 mL pleural fluid in a sterile container;** Minimum: **0.5 mL; Please include disclaimer for approval to perform testing on this specimen type; Must indicate specimen source;** Frozen<br>*OR* **1 mL nasopharyngeal aspirate in a sterile container;** Minimum: **0.5 mL; Please include disclaimer for approval to perform testing on this specimen type; Must indicate specimen source;** Frozen<br>*OR* **1 mL tracheal aspirate in a sterile container;** Minimum: **0.5 mL; Please include disclaimer for approval to perform testing on this specimen type; Must indicate specimen source;** Frozen<br><br>*(continued on page 8)* | 12/4/18 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| **Enterovirus by PCR** *(continued from page 7)* | | *OR* **1 mL bronchoalveolar lavage (BAL) specimen in a sterile container;** Minimum: **0.5 mL; Please include disclaimer for approval to perform testing on this specimen type; Must indicate specimen source;** Frozen<br>*OR* **1 mL sputum in a sterile container;** Minimum: **0.5 mL; Please include disclaimer for approval to perform testing on this specimen type; Must indicate specimen source;** Frozen<br>*OR* **1 mL bronch washings in a sterile container;** Minimum: **0.5 mL; Please include disclaimer for approval to perform testing on this specimen type; Must indicate specimen source;** Frozen | |
| **Familial Mediterranean Fever (MEFV) Sequencing** | FAMMED | **For Interfaced Clients Only: Test build may need to be modified**<br>**Test Name:** Previously Familial Mediterranean Fever, Complete<br>**Special Information: Submit the Patient History for Periodic Fever Syndromes Testing form with the specimen. Counseling and informed consent are recommended for genetic testing. Send samples refrigerated. This test is New York DOH approved.**<br>**Clinical Limitation: Diagnostic errors can occur due to rare sequence variations. Regulatory region, intronic mutations and large deletions/duplications will not be detected.**<br>**Clinical Information: Preferred test for suspected familial Mediterranean fever. Background information: Characteristics: Recurrent episodes of inflammation, fever, abdominal pain, chest pain, joint pain, skin eruptions and the development of renal amyloidosis. Prevalence: 1 in 1,000 worldwide. Inheritance: Primarily autosomal recessive; some activating mutations appear to be autosomal dominant. Cause: Pathogenic MEFV gene mutations. Clinical Sensitivity: Approximately 80%. Methodology: Bidirectional sequencing of the entire MEFV coding region and intron-exon boundaries. Analytical Sensitivity and Specificity: 99%**<br>**Specimen Requirement: 3 mL** whole blood in an EDTA (lavender) tube; Minimum: 1 mL; **Submit the Patient History for Periodic Fever Syndromes Testing form with the specimen; Refrigerated**<br>*OR* **3 mL** whole blood in an **ACD A or B (yellow) tube;** Minimum: 1 mL; **Submit the Patient History for Periodic Fever Syndromes Testing form with the specimen; Refrigerated**<br>**Stability:**<br>Ambient: 72 hours<br>Refrigerated: **1 week**<br>Frozen: Unacceptable<br>**Methodology: Polymerase Chain Reaction**/Sequencing<br>**Days Performed: Varies**<br>**Reported: 15–22** days<br>**CPT: 81404 x 1** | 12/11/18 |
| Fluoride | BFLUOR | **Days Performed: Monday–Sunday**<br>**Reported: 8**–9 days | 10/15/18 |
| Histone IgG Antibody | HISTON | **Days Performed: Thursday**<br>**Reported:** 1–7 days | 10/23/18 |
| Insulinoma Associated Antibody 2 | IA2AB | **Stability:**<br>Ambient: **1 day**<br>Refrigerated: **7** days<br>Frozen: **14 days** | 11/27/18 |
| Ketamine & Metabolite, Serum/ Plasma | KETMIN | **Special Information: Polymer gel separation tubes (serum separator tubes or plasma separator tubes) will be rejected.** Reporting limit: 20 ng/mL for both Ketamine and Norketamine<br>**Days Performed: Monday–Sunday**<br>**Reported: 5–6** days | 10/15/18 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Ketorolac | KETOR | **Special Information: MUST protect from light. Specimens not received light-protected will be rejected. Polymer gel separation tubes (serum separator tubes or plasma separator tubes) are unacceptable.** This test is New York State approved.<br>**Days Performed: Monday–Sunday**<br>**Reported: 8–9** days | 10/15/18 |
| Levamisole | LEVAM | **Special Information: Specimens received at ambient temperature will be rejected. Polymer gel separation tubes (serum separator tubes or plasma separator tubes) are unacceptable.**<br>**Clinical Information: Reporting limit is 0.1 mcg/mL**<br>**Specimen Requirement:** 1 mL serum from a plain no additive (red) tube; Minimum: 0.4 mL; **Promptly centrifuge and transfer serum into plastic screw-capped vial; Do not use serum separator tubes;** Refrigerated<br>*OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.4 mL; **Promptly centrifuge and transfer plasma into plastic screw-capped vial; Do not use plasma separator tubes;** Refrigerated<br>**Days Performed: Monday–Sunday**<br>**Reported: 8–9** days | 10/15/18 |
| Levetiracetam | LEVET | **Special Information:** Collect specimen immediately prior to next dose. Remove plasma/serum from whole blood as soon as possible, preferably within 1 hour after collection. Hydrolysis of levetiracetam may occur in the presence of whole blood. **This test is not suitable for patients receiving treatment with the drug brivaracetam (Briviact). The drug causes an interference that may lead to falsely elevated levetiracetam results. Brivaracetam (Briviact) interferes with measurements of levetiracetam (Keppra) in the levetiracetam assay. Patients undergoing a switch in drug therapy involving Keppra and Briviact should not be monitored for levetiracetam using the assay. Brivaracetam is a chemical analog of levetiracetam. They are structurally similar, and thus immunochemical crossreactivity is possible. The circulating half-life of each drug is approximately 8 to 9 hours. Sufficient time should be allowed for clearance prior to using the Levetiracetam assay. Please contact Client Services at 800.628.6816 or 216.444.5755 for suitable testing.** | 11/13/18 |
| LSD, Urine | ULSD | **Special Information: MUST protect from light. Specimens received not light-protected will be rejected.** Do not collect in glass containers.<br>**Specimen Requirement:** 2 mL random urine in a clean container; Minimum: **0.85 mL;** Protect from light; Refrigerated<br>**Days Performed:** Monday–**Sunday**<br>**Reported: 8**–9 days | 10/15/18 |
| Mephenytoin & Normephenytoin | MEPNOR | **Special Information: Polymer gel separation tubes (serum separator tubes or plasma separator tubes) are unacceptable.** This test is New York State approved.<br>**Days Performed:** Monday–**Sunday**<br>**Reported:** 8–**9** days | 10/15/18 |
| Metformin | MTFORM | **Special Information: Polymer gel separation tubes (serum separator tubes or plasma separator tubes) will be rejected.** Oral Hypoglycemic Agent<br>**Methodology: High Performance** Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)<br>**Days Performed: Monday–Sunday**<br>**Reported: 8–9** days | 10/15/18 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Methadone & Metabolite | MMTAB | **Special Information: For medical purposes only; not valid for forensic use. Separator tubes, plasma or whole blood collected in sodium citrate (light blue) tubes, specimens exposed to repeated freeze/thaw cycles, and hemolyzed specimens will be rejected. This test is New York DOH approved.**<br>**Clinical Information: Used to monitor patient adherence. The absence of expected drug(s) and/or drug metabolite(s) may indicate non-compliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, or limitations of testing. The concentration value must be greater than or equal to the cutoff to be reported as positive.**<br>**Specimen Requirement: 1 mL plasma from a potassium oxalate/sodium fluoride (gray) tube;** Minimum: **0.5 mL; Separate plasma from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube;** Refrigerated<br>*OR* 1 mL serum from a plain no additive (red) tube; Minimum: **0.5 mL; Do not use serum separator tubes; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube;** Refrigerated<br>*OR* **1 mL plasma from a sodium heparin (green) tube;** Minimum: **0.5 mL; Do not use plasma separator tubes; Separate plasma from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube;** Refrigerated<br>*OR* **1 mL plasma from an EDTA (lavender) tube;** Minimum: **0.5 mL; Separate plasma from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube;** Refrigerated<br>**Stability:**<br>Ambient: **After separation from cells: 1 week (Avoid repeated freeze/thaw cycles)**<br>Refrigerated: **After separation from cells: 2 weeks (Avoid repeated freeze/thaw cycles)**<br>Frozen: **After separation from cells: 3 years (Avoid repeated freeze/thaw cycles)**<br>**Methodology: Quantitative** Liquid Chromatography–Tandem Mass Spectrometry<br>**Reference Range:**<br>Methadone: **cutoff: 10 ng/mL**<br>Methadone Metabolite: **cutoff: 10 ng/mL**<br>**Days Performed:** Sunday–**Saturday**<br>**Reported: 2–5** days | 12/11/18 |
| Methyl Ethyl Ketone, Urine | UMEK | **Special Information: MUST send frozen. Specimens received at ambient temperature or refrigerated will be rejected.** This test is New York State approved.<br>**Days Performed: Monday**–Sunday<br>**Reported: 5–6** days | 10/15/18 |
| Metoprolol, Serum/ Plasma | METOP | **Special Information: Polymer gel separation tubes (serum separator tubes or plasma separator tubes) will be rejected.**<br>**Days Performed: Monday–Sunday**<br>**Reported: 8–9** days | 10/15/18 |
| Neisseria gonorrhoea Antibodies, Total | NGAB | **Special Information: Label specimens plainly as 'acute' or 'convalescent.' Plasma is unacceptable. Contaminated, icteric, lipemic, or turbid specimens will be rejected. This test is New York DOH approved.**<br>**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.15 mL; Transfer 1 mL serum to standard aliquot tube;** Mark specimens plainly as 'acute' or 'convalescent;' Refrigerated | Effective immediately |
| Platinum | PLATIN | **Special Information: Polymer gel separation tubes (serum separator tubes or plasma separator tubes) will be rejected.**<br>**Days Performed: Monday–Sunday**<br>**Reported:** 8–**9** days | 10/15/18 |
| Propylene Glycol | PROPYL | **Special Information: Polymer gel separation tubes (serum separator tubes or plasma separator tubes) will be rejected.**<br>**Days Performed:** Monday–**Sunday**<br>**Reported: 8–9** days | 10/15/18 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Protein Electrophoresis, Serum, with IFE | SEPGRX | **For Interfaced Clients Only: Test build may need to be modified**<br>**Clinical Information:** Serum protein electrophoresis is useful as a screening procedure in the detection of gammopathies, dysproteinemias, and various pathophysiologic states such as inflammation, protein loss, and cirrhosis. If an M protein is identified, it will be quantitated by densitometry **and the sample will be reflexed for confirmation using immunofixation electrophoresis (IFE).** | 11/27/18 |
| Silver, Urine | UAG | **Special Information: MUST protect from light. Specimens not received light-protected will be rejected.** Avoid exposure to gadolinium-based contrast media for 48 hours prior to sample collection.<br>**Days Performed: Monday–Sunday**<br>**Reported:** 8–**9** days | 10/15/18 |
| Synthetic Cannabinoid Metabolites–Expanded, Urine (Qualitative) | K2 | **Days Performed: Monday–Sunday**<br>**Reported: 5–6** days | 10/15/18 |
| Thiopurine Metabolites by LC-MS/MS | THIMET | **Special Information: Patient Prep:** Trough collection (within 1 hour prior to the next dose) **is required. Following the determination of the RBC concentration, the thiopurine metabolites are analyzed by LC-MS/MS in the red blood cells.** Hemolyzed specimens are unacceptable. **Frozen specimens and heparinized whole blood will be rejected. MUST send refrigerated.**<br>**Clinical Information: 6-Mercaptopurine (Purinethol) and its imidazolyl derivative, Azathioprine (Imuran), are immunosuppressive drugs. 6-Mercaptopurine (6-MP) is indicated for remission induction and maintenance therapy of acute lymphoblastic leukemia (ALL). Azathioprine is indicated as an adjunct for the prevention of rejection in kidney transplant patients and for management of rheumatoid arthritis, and also for management of inflammatory bowel disease. Azathioprine is cleaved to 6-MP. 6-MP is metabolized via a series of enzymatic steps to 6-thioguanine nucleotides (6-TGNs), to 6-methyl-mercaptopurine (6-MMPNs) by the enzyme thiopurine methyltransferase (TPMT), and to 6-thiouric acid by the enzyme xanthine oxidase (XO). TPMT enzyme activity has large inter-individual variations which affect the efficacy, toxicity and variability of the treatment. Therapeutic drug monitoring of 6-MP metabolites (6-TGNs and 6-MMPNs) in erythrocytes is recommended to assist therapy, particularly in combination with TPMT enzyme activity or mutation analysis.**<br>**Specimen Requirement:** 5 mL whole blood in an EDTA (lavender) tube; Minimum: 2.5 mL; Patient Prep: Trough collection (within 1 hour prior to the next dose); **MUST send refrigerated (use cold packs); Deliver to Cleveland Clinic Laboratories on the day of collection;** Must be received in the **Send Outs laboratory** at Cleveland Clinic Laboratories **by 3 p.m. EST on Friday;** Refrigerated<br>**Stability:**<br>Ambient: **6** hours<br>Refrigerated: 5 days<br>Frozen: Unacceptable<br>**Methodology:** Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)<br>**Reference Range:**<br>6-Thioguanine: **235–400 pmol/8x10(8) RBC**<br>6-CH3-mercaptopurine: **< 5700 pmol/8x10(8) RBC**<br>**Days Performed: Tuesday–Saturday**<br>**Reported: 3–5** days | 10/16/18 |
| Toluene, Blood | TOLUEN | **Days Performed: Monday**–Sunday<br>**Reported: 5–6** days | 10/15/18 |
| Torsemide, Serum/Plasma | TORSE | **Special Information: Polymer gel separation tubes (serum separator tubes or plasma separator tubes) will be rejected.**<br>**Days Performed: Monday–Sunday**<br>**Reported: 8–9** days | 10/15/18 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| VRE Culture Screen | VRESC | **Specimen Requirement:** One rectal swab **in Amies or Stuart's media without charcoal; Collect specimen with BBL Culture swab in liquid Stuart's medium (Cardinal #4320109) or Copan swab in liquid Amies medium (Cardinal #4320147); Both swabs are made by Copan;** Ambient | 11/6/18 |
| West Nile Virus IgM, CSF | CWESTM | **Special Information: Contaminated, heat-inactivated, or hemolyzed specimens will be rejected. If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory.**<br>**Methodology: Semi–Quantitative** Enzyme–Linked Immunosorbent Assay | Effective immediately |

# New Tests

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Carnitine, Free & Total, Urine by Tandem Mass Spectrometry | UCARFT | **Special Information:** CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. Refrigerated or room temperature specimens will be rejected. This test is New York DOH approved.<br>**Clinical Information:** Useful in the diagnosis of primary carnitine deficiency (carnitine uptake defect) in conjunction with free and total plasma carnitine. The concentration of esterified carnitine is derived from a mathematical calculation using free and total carnitine.<br>**Specimen Requirement:** 5 mL random urine in a clean container; Minimum: 2 mL; Freeze immediately after collection; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen<br>**Stability:**<br>Ambient: Unacceptable<br>Refrigerated: Unacceptable<br>Frozen: 1 month<br>**Methodology:** Tandem Mass Spectrometry (MS-MS)<br>**Reference Range:**<br>Carnitine, Total, Urine<br>0–5 Months: 160–1552 µmol/g creatinine<br>6–23 Months: 231–1710 µmol/g creatinine<br>2 Years and older: 73–731 µmol/g creatinine<br>Carnitine, Free, Urine<br>0–5 Months: 16–922 µmol/g creatinine<br>6–23 Months: 37–1066 µmol/g creatinine<br>2 Years and older: 7–407 µmol/g creatinine<br>Carnitine, Esterified, Urine<br>0–5 Months: 138–525 µmol/g creatinine<br>6–23 Months: 175–613 µmol/g creatinine<br>2 Years and older: 55–317 µmol/g creatinine<br>Carnitine, E/F Ratio, Urine<br>0–5 Months: 0.4–6.8<br>6–23 Months: 0.4–5.0<br>2 Years and older: 0.5–7.3<br>**Days Performed:** Tuesday<br>**Reported:** 3–10 days<br>**CPT:** 82379 x 1<br>**Price:** $83.00 (non-discountable) | 11/29/18 |
| Cystic Fibrosis Pathogenic Variant Analysis | CFMDX | **Special Information:** This test may not be appropriate for follow-up testing of the partners of known carriers. Genetics consultation may be of benefit in determining the appropriate testing strategy in these circumstances.<br>**Clinical Limitation:** The test does not include all known pathogenic variants of CFTR. A negative result reduces but does not eliminate the risk of carrier status or cystic fibrosis. Residual risk after a negative test varies with ethnicity, which influences both the carrier rate and the test's detection rate.<br>**Clinical Information:** The test is intended for cystic fibrosis carrier screening in adults of reproductive age, in confirmatory diagnostic testing, and as an initial test to aid in the diagnosis of individuals with suspected cystic fibrosis. This test is not indicated for use for newborn screening, fetal diagnostic testing, pre-implantation testing, or for stand-alone diagnostic purposes. The test includes 142 pathogenic variants, including the 23 ACMG/ACOG recommended common CFTR variants. The increased number of variants improves the detection rate across a wider spectrum of patient ethnicities.<br>**Specimen Requirement:** 4 mL whole blood in an EDTA (lavender) tube; Blood specimens are transported and stored at room temperature no longer than 48 hours; Ambient<br>**Stability:**<br>Ambient: Blood may be transported ambient temperature within 48 hours<br>Refrigerated: Blood may be transported ambient temperature within 48 hours; After 48 hours blood must be stored at 2–8 °C for up to 7 days<br>Frozen: Frozen samples will be rejected<br>*(continued on page 14)* | 11/27/18 |

# New Tests (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Cystic Fibrosis Pathogenic Variant Analysis<br>*(continued from page 13)* | | **Methodology:**<br>Matrix-assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry (MALDI-TOF)<br>Polymerase Chain Reaction (PCR)<br>Single Nucleotide Extension (SNE)<br>**Days Performed:** 1 day per week<br>**Reported:** 10 days<br>**CPT:** 81220 x 1, G0452 x 1<br>**Price:** $268.00 (non-discountable) | |
| Human Herpesvirus 6 (HHV-6A and HHV-6B) by Quantitative PCR | HHV6QT | **Special Information:** Specimen source is required. Heparinized specimens will be rejected. This test is New York DOH approved.<br>**Clinical Information:** Useful for detecting and quantifying HHV6 subtypes A and B in immunocompromised patients. The quantitative range of this assay is 3.0–6.0 log copies/mL (1,000–999,000 copies/mL). A negative result (< 3.0 log copies/mL or < 1,000 copies/mL) does not rule out the presence of PCR inhibitors in the patient specimen or HHV6 DNA in concentrations below the level of detection of the test. Inhibition may also lead to underestimation of viral quantitation. There is no international standard currently available for calibration of this test. Caution should be taken when interpreting results generated by different methodologies. The limit of quantification for this DNA assay is 3.0 log copies/mL (1,000 copies/mL). If the assay did NOT detect the virus, the test result will be reported as "< 3.0 log copies/mL (< 1,000 copies/mL)." If the assay DETECTED the presence of the virus but was not able to accurately quantify the number of copies, the test result will be reported as "Not Quantified."<br>**Specimen Requirement:** 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Separate plasma from cells and transfer into a sterile aliquot tube; Must indicate specimen source; Frozen<br>*OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Separate serum from cells and transfer into a sterile aliquot tube; Must indicate specimen source; Frozen<br>*OR* 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Must indicate specimen source; Frozen<br>**Stability:**<br>Ambient: 24 hours<br>Refrigerated: 5 days<br>Frozen: 3 months<br>**Methodology:** Polymerase Chain Reaction (PCR), Quant<br>**Reference Range:** Not detected<br>**Days Performed:** Tuesday–Saturday<br>**Reported:** 2–5 days<br>**CPT:** 87533 x 1<br>**Price:** $188.00 (non-discountable) | 12/6/18 |

# New Tests (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Monoclonal Protein with Immunoglobulins and Free Light Chains, serum | SERMPA | **Includes:**<br>IgG<br>IgA<br>IgM<br>Lambda, Free, Serum<br>Kappa, Free, Serum<br>Kappa/Lambda Ratio<br>MPA Result<br>Immunofixation Screen, Serum<br>Staff Review<br>**Clinical Information:** Evaluation of monoclonal gammopathies<br>**Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Refrigerated<br>**Stability:**<br>Ambient: 4 days<br>Refrigerated: 2 weeks<br>Frozen: 6 months<br>**Methodology:**<br>Immunofixation Electrophoresis<br>Nephelometry (NEPH)<br>**Reference Range:**<br>IgG<br>0–6 Months: 206–676 mg/dL<br>6–9 Months: 208–868 mg/dL<br>9–12 Months: 282–1026 mg/dL<br>1–2 Years: 331–1164 mg/dL<br>2–3 Years: 407–1009 mg/dL<br>3–4 Years: 423–1090 mg/dL<br>4–5 Years: 444–1187 mg/dL<br>5–8 Years: 608–1229 mg/dL<br>8–10 Years: 584–1509 mg/dL<br>10–99 Years: 717–1411 mg/dL<br>IgA<br>0–6 Months: 8–67 mg/dL<br>6–9 Months: 11–89 mg/dL<br>9–12 Months: 16–83 mg/dL<br>1–2 Years: 14–105 mg/dL<br>2–3 Years: 14–122 mg/dL<br>3–4 Years: 22–157 mg/dL<br>4–5 Years: 25–152 mg/dL<br>5–8 Years: 33–200 mg/dL<br>8–10 Years: 45–234 mg/dL<br>10–99 Years: 78–391 mg/dL<br>IgM<br>0–6 Months: 33–97 mg/dL<br>6–9 Months: 32–120 mg/dL<br>9–12 Months: 39–142 mg/dL<br>1–2 Years: 41- 164 mg/dL<br>2–3 Years: 46–120 mg/dL<br>3–4 Years: 45–190 mg/dL<br>4–5 Years: 41–186 mg/dL<br>5–8 Years: 46–197 mg/dL<br>8–10 Years: 49–230 mg/dL<br>10–99 Years: 53–334 mg/dL<br>Lambda, Free, Serum: 5.7–26.3 mg/L<br>Kappa, Free, Serum: 3.30–19.40 mg/L<br>Kappa/Lambda Ratio: 0.26–1.65<br>MPA Result: No M protein is identified<br>Immunofixation Screen, Serum: Refer to report<br>**Days Performed:** Monday–Friday<br>**Reported:** 1–4 days<br>**CPT:** 82784 x 3, 83883 x 2, 86334 x 1<br>**Price:** $204.00 | 11/27/18 |

# New Tests (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Mycobacterium tuberculosis (MTB) and Rifampin Resistance Detection by PCR | MTBRIF | **Specimen Requirement:** 5 mL sputum in a clean, leak-proof container; 2 mL of sputum digest/concentrate for acid fast culture is also accepted; Refrigerated<br>**Stability:**<br>Ambient: Sputum specimens can be stored at a maximum of 35 °C for up to 3 days<br>Refrigerated: Sputum can be stored at 2–8 °C for up to 7 days; Sputum concentrates can be stored at 2–8 °C for up to 7 days<br>**Methodology:**<br>Culture<br>Probe and Pyrosequencing for Identification<br>Real-Time Polymerase Chain Reaction (RT-PCR)<br>Stain<br>**Reference Range:**<br>Mycobacterium tuberculosis: Not detected<br>Rifampin Resistance: Not detected<br>**Days Performed:** 7 days per week<br>**Reported:** 1–2 days<br>**CPT:** 87015 x 1, 87116 x 1, 87206 x 1, 87556 x 1, 87798 x 1 | 10/18/18 |

# Fee Increases

| Test Name | Order Code | List Fee | CPT Code | Effective Date |
|---|---|---|---|---|
| Allergen, Cow Milk Components IgE | MILKE | $55.00 | 86008 x 3 | 11/27/18 |
| Methadone & Metabolite | MMTAB | $140.00 (non-discountable) | 80358, (G0480, if appropriate) | 12/11/18 |

# Fee Reductions

| Test Name | Order Code | List Fee | CPT Code | Effective Date |
|---|---|---|---|---|
| Allergen, Peanut Components IgE | PNUTCP | $160.00 | 86008 x 5 | 11/27/18 |
| Familial Mediterranean Fever (MEFV) Sequencing | FAMMED | $707.00 (non-discountable) | 81404 | 12/11/18 |

# Discontinued Tests

| Test Name | Order Code | Test Information | Effective Date |
|---|---|---|---|
| Allergen, Alpha Lactalbumin IgE | LACALB | This test will no longer be available. Suggest ordering Allergen, Cow Milk Components IgE (MILKE). | 11/27/18 |
| Allergen, Beta Lactoglobulin IgE | BLACGL | This test will no longer be available. Suggest ordering Allergen, Cow Milk Components IgE (MILKE). | 11/27/18 |
| Allergen, Casein IgE | MCASIN | This test will no longer be available. Suggest ordering Allergen, Cow Milk Components IgE (MILKE). | 11/27/18 |
| Carnitine Free & Total, Urine | UCARN1 | This test will no longer be available. Suggest ordering Carnitine, Free and Total, Urine by Tandem Mass Spectrometry (UCARFT). | 11/29/18 |
| Cystic Fibrosis Screen139 Variant Assay | CFNGS | This test will no longer be available. Suggest ordering Cystic Fibrosis Pathogenic Variant Analysis (CFMDX). | 11/27/18 |
| Enterovirus, Miscellaneous Sites, PCR | ENTMS | This test will no longer be available. Suggest ordering Enterovirus by PCR (ENTNAS). | 12/4/18 |
| Enterovirus PCR Plasma | ENTPLA | This test will no longer be available. Suggest ordering Enterovirus by PCR (ENTNAS). | 12/4/18 |
| Herpesvirus 6 PCR, Quant, CSF | HV6QNT | This test will no longer be available. Suggest ordering Human Herpesvirus 6 (HHV-6A and HHV-6B) by Quantitative PCR (HHV6QT). | 12/6/18 |
| Herpesvirus 6 PCR, Quant, Plasma | HV6PLS | This test will no longer be available. Suggest ordering Human Herpesvirus 6 (HHV-6A and HHV-6B) by Quantitative PCR (HHV6QT). | 12/6/18 |
| HLA-B27 | HLAB27 | This test will no longer be available. Suggest ordering HLA-B27 PCR (B27PCR). | 11/28/18 |
| Lindane | LIND | This test will no longer be available. | 11/29/18 |
| Methazolamide | METHAZ | This test will no longer be available. | 11/27/18 |
| Monoclonal Protein, Blood | MPASRM | This test will no longer be available. Suggest ordering Monoclonal Protein with Immunoglobulins and Free Light Chains, serum (SERMPA). | 11/27/18 |
| Peroxisomal Panel | PEROXI | This test will no longer be available. Suggest ordering Very Long-Chain and Branched-Chain Fatty Acids Profile (FATLON). | 12/6/18 |
| Phenelzine | PHENEL | This test will no longer be available. | 11/29/18 |
| Phenylpro-panolamine | PHENYL | This test will no longer be available. | 11/29/18 |
| Tier 2 B-Cell Clonality Using BIOMED2 Primers | T2BPCR | This test will no longer be available. Suggest ordering B-Cell Clonality Using BIOMED-2 PCR Primers (BCBMD). | 11/27/18 |
| TP53 Sequencing (Exons 5-8) | | This test will no longer be available. | 11/1/18 |