Cleveland Clinic

# Cleveland Clinic Laboratories

## Technical Update • May 2020

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 | Acetylcholine Receptor Antibodies with Reflex | | | | | | ■ | | | | | | | |
| 19 | Acetylcholine Receptor Binding Ab | | | | | ■ | | | | | | | | |
| 15 | Acetylcholine Receptor Binding Aby | | | | ■ | | | | | | | | | |
| 19 | Acetylcholine Receptor Blocking Ab | | | | | ■ | | | | | | | | |
| 15 | Acetylcholine Receptor Blocking Aby | | | | ■ | | | | | | | | | |
| 3 | Aminolevulinic Acid Dehydratase (ALAD), Whole Blood | | | | | | | ■ | | | ■ | ■ | | |
| 3 | Angiotensin Converting Enzyme, CSF | | | | | | ■ | | | | | | | |
| 3 | APC Resistance | | | | | | | | | ■ | | | | |
| 3–4 | Autoimmune Dysautonomia Evaluation, Serum | | | | | | ■ | | ■ | ■ | | | | |
| 4 | Bartonella quintana Antibodies, IgG & IgM | | | | | | ■ | ■ | | | | | | |
| 4, 18 | BCR/ABL1 p210 Quantitative PCR Bone Marrow | | | | | | ■ | | | | | | | ■ |
| 4 | Brucella Ab Total | | | | | | | ■ | | | | | | |
| 4, 18 | Cathartic Laxative, Stool | | | | | | | ■ | | | | | ■ | ■ |
| 15 | Chromosome Analysis, Neoplastic Tissue | | | | ■ | | | | | | | | | |
| 4 | Coccidioides IgG and IgM Antibodies | | | | | | | ■ | | | | | | |
| 4 | Colchicine Level | | | | | | | | | | ■ | ■ | | |
| 5 | Coxiella Burnetii IgG Abs | | | | | | | ■ | | | | | | |
| 5 | Coxiella burnetii (Q-Fever) Antibodies, IgG and IgM, Phase I and II with Reflex to Titer | | | | | | | ■ | | | | | | |
| 5 | Cytology, SurePath Liquid-Based Pap test and HPV, High Risk with 16 and 18 Genotype by PCR, SurePath (for routine co-testing in women over 30) | | ■ | | | | ■ | | ■ | | | ■ | | |

| Test Update Page # | Summary of Changes by Test Name | Order Code | Name Change | New Test | Test Discontinued | Special Information | Specimen Requirement | Component Change(s) | Methodology | Reference Range | Days Performed/Reported | Stability | CPT | Fee |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 5 | Cytology, SurePath Liquid-Based Pap Test with Reflex to human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, SurePath | | ■ | | | | ■ | | ■ | | | ■ | | |
| 5–6, 18 | Digitoxin | | | | | | ■ | ■ | | ■ | ■ | ■ | ■ | ■ | ■ |
| 6 | Dilute Russell Viper Venom Time | | | | | | | | | | ■ | | | | |
| 6 | Disopyramide (Norpace) | | | | | | ■ | ■ | | ■ | ■ | ■ | ■ | | |
| 6 | Ehrlichia chaffeensis IgG & IgM Abs by IFA | | | | | | | ■ | | | | | | | |
| 6 | Hexagonal Phase Phospholipid Neutralization | | | | | | | | | | ■ | | | | |
| 6 | Hypercoagulation Diagnostic Interpretive Panel | | | | | | | | | | ■ | | | | |
| 15 | HLA-B58 | | | ■ | | | | | | | | | | | |
| 19 | HPV DNA, High Risk, Anal-Rectal | | | | ■ | | | | | | | | | | |
| 6 | Immunofixation Screen, Serum | | | | | | | | | | | ■ | | | |
| 19 | Insulin Antibody | | | | ■ | | | | | | | | | | |
| 16 | Insulin Autoantibody | | | ■ | | | | | | | | | | | |
| 7 | Interleukin 2 | | | | | | ■ | ■ | | ■ | ■ | ■ | | | |
| 7 | Interleukin-2 Receptor, Soluble | | | | | | ■ | ■ | | | ■ | ■ | | | |
| 8 | Interleukin 4 | | | | | | ■ | ■ | | ■ | ■ | ■ | | | |
| 8 | Interleukin 5 | | | | | | ■ | ■ | | | ■ | ■ | | | |
| 9 | Interleukin-6 | | | | | | ■ | ■ | | ■ | ■ | ■ | | | |
| 19 | Librium & Metabolite | | | | ■ | | | | | | | | | | |
| 19 | Limulus Amebocyte Lysate | | | | ■ | | | | | | | | | | |
| 9 | Lupus Anticoagulant Diagnostic Interpretive Panel | | | | | | | | | | ■ | | | | |
| 9 | Monoclonal Protein, 24 Hour Urine | | | | | | | | | | | ■ | | | |
| 9 | Monoclonal Protein, Urine | | | | | | | | | | | ■ | | | |
| 9 | Monoclonal Protein with Immunoglobulins and Free Light Chains, serum | | | | | | | | | | | ■ | | | |
| 19 | Nitrazepam | | | | ■ | | | | | | | | | | |
| 16 | N-Methylhistamine, Random, Urine | | | ■ | | | | | | | | | | | |
| 9–10 | N-Methylhistamine, Urine | | | | | | ■ | ■ | ■ | ■ | | | ■ | | |
| 10 | Oligoclonal Banding | | | | | | | | | | | ■ | | | |
| 10 | Paraneoplastic Autoantibody Evaluation, CSF | | | | | | ■ | | ■ | ■ | | ■ | | | |
| 11 | Paraneoplastic Autoantibody Evaluation, Serum | | | | | | ■ | | ■ | ■ | | | | | |
| 12 | Phosphatidylethanol (PEth) | | | | | | ■ | ■ | ■ | | ■ | ■ | ■ | | |
| 12 | PNH Panel by FCM | | | | | | ■ | ■ | | | | | | | |
| 13 | Proinsulin, Intact | | | | | | ■ | ■ | | | | | ■ | | |
| 13 | Protein Electrophoresis, Ur 24 Hr w/M Protein Quant | | | | | | | | | | | ■ | | | |
| 13 | Protein Electrophoresis, Urine Random | | | | | | | | | | | ■ | | | |
| 13 | Protein Electrophoresis, Urine, with IFE | | | | | | | | | | | ■ | | | |
| 13 | Protein S Clottable | | | | | | | | | | ■ | | | | |
| 13, 18 | Reducing Substances, Stool | | | | | | ■ | | | | ■ | | ■ | | ■ |
| 17 | Respiratory Panel by Rapid PCR | | | ■ | | | | | | | | | | | |
| 19 | Reticulin IgA and IgG Antibodies | | | | ■ | | | | | | | | | | |

| Test Update Page # | Summary of Changes by Test Name | Order Code | Name Change | New Test | Test Discontinued | Special Information | Specimen Requirement | Component Change(s) | Methodology | Reference Range | Days Performed/Reported | Stability | CPT | Fee |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 13 | Serotonin, Serum | | | | | | ■ | ■ | | | | | | |
| 19 | TSH Binding Inhibition | | | | | ■ | | | | | | | | |
| 14 | TSH Receptor Antibody | | | | | | ■ | | ■ | | ■ | | | |
| 18 | TSH Receptor Total Autoantibody | | | ■ | | | | | | | | | | |
| 14 | Tumor Necrosis Factor | | | | | | ■ | ■ | | | ■ | ■ | | |
| 14 | Urticaria-Induced Basophil Activation | | | | | | ■ | ■ | | | | ■ | | |

# Test Changes

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Acetylcholine Receptor Antibodies with Reflex | ACHABS | **Note:** *Changes for this test were previously announced in the April Technical Update with a go-live of 5/5/20. Please note that the effective date for changes has been moved to 6/9/20. We apologize for any inconvenience this may have caused.* | 6/9/20 |
| Aminolevulinic Acid Dehydratase (ALAD), Whole Blood | ALADWB | **For Interfaced Clients Only: Test build may need to be modified**<br>**Stability:**<br>Ambient: **4 days**<br>Refrigerated: **7 days (preferred)**<br>Frozen: Unacceptable<br>**Days Performed: Tuesday, Thursday**<br>**Reported:** 4–5 days | 5/7/20 |
| Angiotensin Converting Enzyme, CSF | CACE | **Special Information: Cerebrospinal fluid (CSF) containing gadolinium-based contrast agents are unacceptable.** Hemolyzed or xanthochromic samples will be rejected. This test is New York DOH approved.<br>**Clinical Information:** Support diagnosis of neurosarcoidosis. May be used to evaluate treatment response. **Gadolinium contrast agents have been reported to inhibit angiotensin converting enzyme (ACE) activity. Therefore, cerebrospinal fluid containing gadolinium-based contrast agents should not be submitted to the laboratory for evaluation.** | 5/18/20 |
| APC Resistance | APC | **Reference Range:**<br>**0–999 Years: > 1.96 Ratio** | 6/25/20 |
| Autoimmune Dysautonomia Evaluation, Serum | AIDYSA | **For Interfaced Clients Only: Test build may need to be modified**<br>**Special Information:** Reflex Algorithm: **If indirect immunofluorescence assay (IFA) patterns suggest amphyphysin Ab, amphiphysin immunoblot (IB) is performed at an additional cost. If IFA patterns suggest ANNA-1 Ab, ANNA-1 IB and ANNA-2 IB are performed at an additional cost. If IFA patterns suggest PCA-1 Ab, PCA-1 IB is performed at an additional cost. If IFA patterns suggest PCA-Tr Ab, PCA-Tr IB is performed at an additional cost.** If IFA patterns suggest Purkinje cell cytoplasmic Ab type 1, type 2, or type trace, the appropriate antibody specific IFA is performed at an additional cost. If IFA patterns suggest CRMP-5-IgG, CRMS and/or CRMP-5-IgG Western blot is performed at an additional cost. If IFA patterns suggest NMDA-R, NMDA-R cell-binding assay (CBA) and NMDA-R titer are performed at an additional cost. If IFA patterns suggest AMPA-R, AMPA-R CBA and AMPA-R titer are performed at an additional cost. If IFA patterns suggest GABA-B-R, GABA-B-R CBA and GABA-B-R titer are performed at an<br>*(continued on page 4)* | 5/14/20 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Autoimmune Dysautonomia Evaluation, Serum *(continued from page 3)* | | additional cost. If IFA patterns suggest DPPX Ab, then DPPX Ab CBA and DPPX titer are performed at an additional cost. If acetylcholine (ACh) receptor binding Ab is > 0.02, then ACh receptor modulating antibodies and CRMP-5-IgG Western blot are performed at an additional cost. If VGKC is above 0.00, LGI1-IgG CBA and CASPR2-IgG CBA are performed at an additional cost. Include ordering provider name, number, address, and email. Include relevant clinical information. Patient Prep: For optimal antibody detection, collection of specimen before initiation of immunosuppressant medication is recommended. This test should not be requested in patients who have recently received radioisotopes, therapeutically or diagnostically, because of potential assay interference. The specific waiting period before specimen collection will depend on the isotope administered, the dose given, and the clearance rate in the individual patient. Specimens will be screened for radioactivity prior to analysis. Radioactive specimens received in the laboratory will be held 1 week and assayed if sufficiently decayed, or canceled if radioactivity remains. Patient should have no general anesthetic or muscle-relaxant medications in the previous 24 hours. Grossly hemolyzed, grossly lipemic, or grossly icteric specimens will be rejected.<br>**Methodology:**<br>Cell Binding Assay (CBA), if indicated<br>Cell-Based Assay<br>Enzyme Immunoassay (EIA)<br>**Immunoblot (IB)**<br>Immunoprecipitation<br>Indirect Immunofluorescence Assay (IFA)<br>Radioimmunoassay (RIA)<br>Western Blot (WB), if indicated | |
| Bartonella quintana Antibodies, IgG & IgM | BARQAB | **Special Information:** Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as 'acute' or 'convalescent.' **Hemolyzed, contaminated, or severely lipemic specimens will be rejected. This test is New York DOH approved.**<br>**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL;** Separate serum from cells **ASAP or** within 2 hours of collection **and transfer into a standard aliquot tube; Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' or 'convalescent;'** Refrigerated | 5/18/20 |
| BCR/ABL1 p210 Quantitative PCR Bone Marrow | P210BM | **Special Information:** External client shipping instructions: Ship "Priority Overnight;" do not ship on Fridays or the day preceding a holiday. | 4/30/20 |
| Brucella Ab Total | BRUAGG | **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL;** Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' or 'convalescent;' Refrigerated | 5/18/20 |
| Cathartic Laxative, Stool | STCATH | **Specimen Requirement:** 10 g solid stool in a clean container **(No preservatives);** Minimum: **10 g; Refrigerated**<br>*OR* 10 mL liquid stool in a clean container **(No preservatives);** Minimum: **10 mL; Refrigerated**<br>**CPT:** 80375 x 1, 84100 x 1, **(G0480, if appropriate)** | Effective immediately |
| Coccidioides IgG and IgM Antibodies | COCIMG | **Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL;** Separate serum from cells ASAP or within 2 hours of collection and transfer serum to standard aliquot tube; Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of the acute specimens; Please mark specimens plainly as 'acute' or 'convalescent;' Refrigerated | 5/18/20 |
| Colchicine Level | COLCH | **Stability:**<br>Ambient: 1 day<br>Refrigerated: 30 days<br>Frozen: **6** months<br>**Days Performed:** Monday–Sunday<br>**Reported:** 9–**10** days | 7/13/20 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Coxiella Burnetii IgG Abs | COXIGG | **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL**; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' or 'convalescent;' Refrigerated | 5/18/20 |
| Coxiella burnetii (Q-Fever) Antibodies, IgG and IgM, Phase I and II with Reflex to Titer | COXGMR | **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL**; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' or 'convalescent;' Refrigerated | 5/18/20 |
| **Cytology, SurePath Liquid-Based Pap test and HPV, High Risk with 16 and 18 Genotype by PCR, SurePath (for routine co-testing in women over 30)** | SPHPV | **For Interfaced Clients Only: Test build may need to be modified**<br>**Test Name:** Previously Cytology, SurePath Liquid-Based Pap test and Human Papillomavirus (HPV), High Risk by PCR, SurePath (for routine co-testing in women over 30)<br>**Special Information:** Transport cervical specimen in the original collection kit. For specific collection instructions, contact Cleveland Clinic Laboratories Client Services at 800.628.6816. Note: In addition to the SurePath Pap Test, **Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, SurePath** will be performed and reported under a separate accession. The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate. Pap Test Pathology Review reflex testing may also be added. Additional charges apply. Unacceptable conditions: Specimens not collected in a SurePath collection kit. Expired preservative vials or vials received without the collection devices.<br>**Stability:**<br>Ambient: **1 month**<br>Refrigerated: **6 months**<br>Frozen: Unacceptable | 5/18/20 |
| **Cytology, SurePath Liquid-Based Pap Test with Reflex to human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, SurePath** | SPLBP | **For Interfaced Clients Only: Test build may need to be modified**<br>**Test Name:** Previously Cytology, SurePath Liquid-Based Pap Test with Reflex to human Papillomavirus (HPV), High Risk by PCR, SurePath<br>**Special Information:** Transport cervical specimen in the original collection kit. For specific collection instructions, contact Cleveland Clinic Laboratories Client Services at 800.628.6816. If the SurePath Liquid-Based Pap Test is interpreted as atypical squamous cells of undetermined significance (ASC-US), then **Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, SurePath** will be added. Pap Test Pathology Review reflex testing may also be added. Additional charges apply. Unacceptable conditions: Specimens not collected in a SurePath collection kit. Expired preservative vials or vials received without the collection devices.<br>**Stability:**<br>Ambient: **1 month**<br>Refrigerated: **6 months**<br>Frozen: Unacceptable | 5/18/20 |
| Digitoxin | | **Special Information: Separate specimens must be submitted when multiple tests are ordered. Separator tubes will be rejected. This test is New York DOH approved.**<br>**Specimen Requirement:** 1 mL serum from a plain no additive (red) tube; Minimum: **0.4 mL;** Do not use serum separator tubes; Separate serum from cells **ASAP or** within 2 hours of collection **and transfer into a standard aliquot tube; Separate specimens must be submitted when multiple tests are ordered;** Refrigerated<br>*OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: **0.4 mL;** Do not use plasma separator tubes; Separate plasma from cells **ASAP or** within 2 hours of collection **and transfer into a standard aliquot tube; Separate specimens must be submitted when multiple tests are ordered;** Refrigerated<br>*(continued on page 6)* | 5/18/20 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Digitoxin<br>*(continued from page 5)* | | **Stability:**<br>Ambient: **Undetermined**<br>Refrigerated: **1 week**<br>Frozen: **3 months**<br>**Methodology:** Immunoassay (IA)<br>**Reference Range: Refer to report**<br>**Days Performed: Varies**<br>**Reported: 6–9** days<br>**CPT: 80375 x 1, (G0480, if appropriate)** | |
| Dilute Russell Viper Venom Time | DRVVT | **Reference Range:**<br>DRVVT Screen (0–99 Years): **32.0–45.7 sec**<br>DRVVT 1:1 Mix (0–99 Years): **32.0–45.7 sec**<br>DRVVT Confirm Ratio (0–99 Years): **< 1.32** | 6/25/20 |
| Disopyramide (Norpace) | DISOP | **Special Information:** Do not use gel separator tubes.<br>**Clinical Information: Disopyramide is useful in treating patients with cardiac arrhythmias and tachycardia. Therapeutic drug monitoring is useful for avoiding toxicity and optimizing dosage.**<br>**Specimen Requirement:** 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Do not use serum separator tubes; Separate from cells **immediately** and transfer into a standard plastic aliquot tube; **Ambient**<br>*OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Do not use plasma separator tubes; Separate from cells **immediately** and transfer into a standard plastic aliquot tube; **Ambient**<br>*OR* 1 mL plasma from a **sodium heparin (green)** tube; Minimum: 0.5 mL; Do not use plasma separator tubes; Separate from cells **immediately** and transfer into a standard plastic aliquot tube; **Ambient**<br>**Stability:**<br>Ambient: **5** days<br>Refrigerated: **14 days**<br>Frozen: **35 days**<br>**Methodology:** Immunoassay (IA)<br>**Reference Range:** 2.0–**5.0 mg/L**<br>**Days Performed: Monday–Saturday**<br>**Reported:** 2–**3** days | 5/18/20 |
| Ehrlichia chaffeensis IgG & IgM Abs by IFA | ECHAFF | **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL;** Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' or 'convalescent;' Refrigerated | 5/18/20 |
| Hexagonal Phase Phospholipid Neutralization | STACLT | **Reference Range:**<br>Hexagonal Phase Screen (0–99 Years): **46.2–57.4 sec**<br>Hexagonal Phase Confirm (0–99 Years): **43.0–52.3 sec**<br>Hexagonal Phase Delta (0–99 Years): **< 11.1** | 6/25/20 |
| Hypercoagulation Diagnostic Interpretive Panel | HYPER | **Reference Range:**<br>**Note:** *Refer to reference range changes for APC Resistance (APC) and Protein S Clottable (PRSCLT).* | 6/25/20 |
| Immunofixation Screen, Serum | IFESC | **Days Performed:** Monday–Friday<br>**Reported:** 1–**7** days | Effective immediately |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Interleukin 2 | INT2 | **Special Information: Critical frozen. Separate specimens must be submitted when multiple tests are ordered. Contaminated or heat-inactivated specimens will be rejected. Refrigerated specimens are unacceptable. This test is New York DOH approved.**<br>**Clinical Information: Cytokine levels may demonstrate diurnal variation. For longitudinal comparison, it is recommended that cytokine levels be determined at the same time of day. Results are used to understand the pathophysiology of immune, infectious, or inflammatory disorders, or may be used for research purposes.**<br>**Specimen Requirement:** 1 mL **serum** from a serum separator (gold) tube; Minimum: **0.4 mL;** Place specimen on ice after draw; Centrifuge, **transfer into a standard aliquot tube** and freeze ASAP or within 2 hours of collection; **Separate specimens must be submitted when multiple tests are ordered; Critical frozen**<br>*OR* 1 mL **serum** from a plain no additive (red) tube; Minimum: **0.4 mL;** Place specimen on ice after draw; Centrifuge, **transfer into a standard aliquot tube** and freeze ASAP or within 2 hours of collection; **Separate specimens must be submitted when multiple tests are ordered; Critical frozen**<br>**Methodology: Quantitative Multiplex Bead Assay**<br>**Reference Range: ≤ 2.1 pg/mL**<br>*(Note: There is a clinically significant charting name change associated with this test. Change the charting name for the component to Interleukin 2, Serum.)*<br>**Days Performed: Sunday–Saturday**<br>**Reported:** 2–5 days | 5/18/20 |
| Interleukin-2 Receptor, Soluble | SIL2R | **Special Information: Critical frozen. Separate specimens must be submitted when multiple tests are ordered. Contaminated or heat-inactivated specimens will be rejected. Refrigerated specimens are unacceptable. This test is New York DOH approved.**<br>**Clinical Information: Cytokine levels may demonstrate diurnal variation. For longitudinal comparison, it is recommended that cytokine levels be determined at the same time of day.** Results are to be used for research purposes or in attempts to understand the pathophysiology of immune, infectious, or inflammatory disorders.<br>**Specimen Requirement:** 1 mL **serum** from a serum separator (gold) tube; Minimum: **0.4 mL;** Separate serum from cells ASAP or within 2 hours of collection, **transfer into a standard aliquot tube and freeze; Separate specimens must be submitted when multiple tests are ordered;** Critical Frozen<br>*OR* 1 mL **serum** from a plain no additive (red) tube; Minimum: **0.4 mL;** Separate serum from cells ASAP or within 2 hours of collection, **transfer into a standard aliquot tube and freeze; Separate specimens must be submitted when multiple tests are ordered;** Critical Frozen<br>**Reference Range: 175.3–858.2 pg/mL**<br>*(Note: There is a clinically significant charting name change associated with this test. Change the charting name for the component to Interleukin- 2 Receptor, Soluble, Serum.)*<br>**Days Performed: Sunday–Saturday**<br>**Reported:** 2–5 days | 5/18/20 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Interleukin 4 | INT4 | **Special Information: Critical frozen. Separate specimens must be submitted when multiple tests are ordered. Contaminated or heat-inactivated specimens will be rejected. Refrigerated specimens are unacceptable. This test is New York DOH approved.**<br>**Clinical Information: Cytokine levels may demonstrate diurnal variation. For longitudinal comparison, it is recommended that cytokine levels be determined at the same time of day.** Results are to be used for research purposes or in attempts to understand the pathophysiology of immune, infectious or inflammatory disorders.<br>**Specimen Requirement:** 1 mL **serum** from a serum separator (gold) tube; Minimum: **0.4 mL;** Separate serum from cells ASAP or within 2 hours of collection, **transfer to a standard aliquot tube and freeze; Separate specimens must be submitted when multiple tests are ordered; Critical frozen**<br>*OR* 1 mL **serum** from a plain no additive (red) tube; Minimum: **0.4 mL;** Separate serum from cells ASAP or within 2 hours of collection, **transfer to a standard aliquot tube and freeze; Separate specimens must be submitted when multiple tests are ordered; Critical frozen**<br>**Methodology: Quantitative Multiplex Bead Assay**<br>**Reference Range: ≤ 2.2 pg/mL**<br>*(Note: There is a clinically significant charting name change associated with this test. Change the charting name for the component to Interleukin 4, Serum.)*<br>**Days Performed: Sunday–Saturday**<br>**Reported:** 2–5 days | 5/18/20 |
| Interleukin 5 | INT5 | **Special Information: Critical frozen. Separate specimens must be submitted when multiple tests are ordered. Contaminated or heat-inactivated specimens will be rejected. Refrigerated specimens are unacceptable. This test is New York DOH approved.**<br>**Clinical Information: Cytokine levels may demonstrate diurnal variation. For longitudinal comparison, it is recommended that cytokine levels be determined at the same time of day.** Results are to be used for research purposes or in attempts to understand the pathophysiology of immune, infectious, or inflammatory disorders.<br>**Specimen Requirement:** 1 mL **serum** from a serum separator (gold) tube; Minimum: **0.4 mL; Separate specimens must be submitted when multiple tests are ordered;** Separate serum from cells **ASAP or** within 2 hours of collection, **transfer into a standard aliquot tube and freeze;** Critical Frozen<br>*OR* 1 mL **serum** from a plain no additive (red) tube; Minimum: **0.4 mL; Separate specimens must be submitted when multiple tests are ordered;** Separate serum from cells **ASAP or** within 2 hours of collection, **transfer into a standard aliquot tube and freeze;** Critical Frozen<br>**Reference Range: ≤ 2.1 pg/mL**<br>*(Note: There is a clinically significant charting name change associated with this test. Change the charting name for the component to Interleukin 5, Serum.)*<br>**Days Performed: Sunday–Saturday**<br>**Reported:** 2–5 days | 5/18/20 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Interleukin-6 | INT6 | **Special Information: Critical frozen. Separate specimens must be submitted when multiple tests are ordered. Contaminated or heat-inactivated specimens will be rejected. Refrigerated specimens are unacceptable. This test is New York DOH approved.**<br>**Clinical Information: Cytokine levels may demonstrate diurnal variation. For longitudinal comparison, it is recommended that cytokine levels be determined at the same time of day. Results are used to understand the pathophysiology of immune, infectious, or inflammatory disorders, or may be used for research purposes.**<br>**Specimen Requirement:** 1 mL **serum** from a serum separator (gold) tube; Minimum: **0.4 mL; Separate specimens must be submitted when multiple tests are ordered;** Separate serum from cells ASAP or within 2 hours of collection, **transfer to a standard aliquot tube** and freeze; Critical Frozen<br>*OR* 1 mL **serum** from a plain no additive (red) tube; Minimum: **0.4 mL; Separate specimens must be submitted when multiple tests are ordered;** Separate serum from cells ASAP or within 2 hours of collection, **transfer to a standard aliquot tube** and freeze; Critical Frozen<br>**Methodology: Quantitative Multiplex Bead Assay**<br>**Reference Range: ≤ 2.0 pg/mL**<br>*(Note: There is a clinically significant charting name change associated with this test. Change the charting name for the component to Interleukin 6, Serum.)*<br>**Days Performed: Sunday–Saturday**<br>**Reported:** 2–5 days | 5/18/20 |
| Lupus Anticoagulant Diagnostic Interpretive Panel | LUPUSP | **Reference Range:**<br>**Note:** *Refer to reference range changes for Hexagonal Phase Phospholipid Neutralization (STACLT ) and Dilute Russell Viper Venom Time (DRVVT).* | 6/25/20 |
| Monoclonal Protein, 24 Hour Urine | U24MPA | **Days Performed:** Monday–Friday<br>**Reported:** 1–**7** days | Effective immediately |
| Monoclonal Protein, Urine | URMPA | **Days Performed:** Monday–Friday<br>**Reported:** 1–**7** days | Effective immediately |
| Monoclonal Protein with Immunoglobulins and Free Light Chains, serum | SERMPA | **Days Performed:** Monday–Friday<br>**Reported:** 1–**7** days | Effective immediately |
| N-Methylhistamine, Urine | MHISTA | **For Interfaced Clients Only: Test build may need to be modified**<br>**Includes:**<br>**N-Methylhistamine, 24 Hr**<br>**Creatinine, 24 Hr Urine mg/24 h**<br>Collection Duration<br>Urine Volume<br>**Creatinine Concentration, 24 Hr Urine mg/dL**<br>**Special Information: Patient must not be taking monoamine oxidase inhibitors (MAOIs) or aminoguanidine as these medications increase N-methylhistamine (NMH) levels. Random urine collections are preferred for patients with episodic symptoms, for example in the context of allergic reactions, brought on by specific environmental factors. Please refer to N-Methylhistamine, Random, Urine (UMHISR).**<br>**Clinical Information: This test is useful for screening and monitoring mastocytosis and disorders of systemic mast-cell activation, such as anaphylaxis and other forms of severe systemic allergic reactions using 24-hour urine collection specimens. Monitoring therapeutic progress in conditions that are associated with secondary, localized, low-grade persistent, mast-cell proliferation and activation such as interstitial cystitis. Cautions: While an average North American diet has no effect on urinary NMH levels,** mild elevations (approximately 30%) may be observed on very histamine-rich diets. This problem is more pronounced if **random**<br>*(continued on page 10)* | 4/30/20 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| N-Methylhistamine, Urine<br>*(continued from page 9)* | | urine specimens are used and collected following a histamine-rich meal. NMH levels may be depressed in individuals who have **an alteration** in the histamine-N-methyl transferase gene, which encodes the enzyme that catalyzes NMH formation. **This alteration** results in an amino acid change that decreases the rate of NMH synthesis. **When N-acetylcysteine is administered at levels sufficient to act as an antidote for the treatment of acetaminophen overdose, it may lead to falsely decreased creatinine results.**<br>**Specimen Requirement:** 5 mL **24-hour** urine (well-mixed) in a clean container; Minimum: 3 mL; Refrigerate during collection; Please include volume and hours of collection; Refrigerated<br>**Stability:**<br>Ambient: **28 days**<br>Refrigerated: **28 days (preferred)**<br>Frozen: **28 days**<br>**Methodology:**<br>**Colorimetric Enzyme Assay**<br>Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) | |
| Oligoclonal Banding | OLIGO | **Days Performed:** 3 days per week<br>**Reported: 1–7** days | Effective immediately |
| Paraneoplastic Autoantibody Evaluation, CSF | PARCSF | **For Interfaced Clients Only: Test build may need to be modified**<br>**Special Information: Reflex algorithm: If indirect immunofluorescence assay (IFA) patterns suggest AGNA-1 Ab, AGNA-1 Immunoblot (IB) is performed at an additional cost. If IFA patterns suggest amphiphysin antibody, amphiphysin IB is performed at an additional cost. If IFA patterns suggest ANNA-1 antibody, ANNA-1 IB is performed at an additional cost. If IFA patterns suggest ANNA-2 antibody, ANNA-2 IB is performed at an additional cost. If IFA patterns suggest PCA-1 antibody, PCA-1 IB is performed at an additional cost. If IFA patterns suggest PCA-Tr antibody, PCA-Tr IB is performed at an additional cost.** If IFA patterns suggest CRMP-5-IgG, CRMP-5-IgG Western blot is performed at an additional cost. If IFA patterns suggest GAD65 antibody, GAD65 Ab radioimmunoassay is performed at an additional cost. If IFA patterns suggest neuronal voltage-gated potassium channel-complex autoantibody, VGKC-complex Ab IPA is performed at an additional cost. If VGKCC > 0.00 nmol/L, LGI1-IgG CBA, CSF (Leucine-Rich Glioma Inactivated Protein-1 IgG, CSF) and CASPR2-IgG CBA, CSF (Contactin-Associated Protein-Like-2-IgG, CSF) are performed at an additional cost. If IFA patterns suggest NMDA-Receptor Ab and NMDA-Receptor Ab CBA are positive, NMDA-Receptor Ab IF titer assay is performed at an additional cost. If IFA patterns suggest AMPA-Receptor Ab and AMPA-Receptor Ab CBA are positive, AMPA-Receptor Ab IF titer assay is performed at an additional cost. If IFA patterns suggest GABA-B-Receptor Ab and GABA-B-R Receptor Ab are positive, GABA-B-R Receptor Ab IF titer assay is performed at an additional cost. If IFA patterns suggest DPPX, DPPX antibody CBA and DPPX titer are performed at an additional cost. If IFA patterns suggest mGluR1, mGluR1 Ab CBA and mGluR1 titer are performed at an additional cost. Include name, number, address, and email of ordering physician. In patients with a history of tobacco use or other lung cancer risk, or if thymoma is suspected, Paraneoplastic Autoantibody Evaluation, Serum (PARNEO) is also recommended. Causes for rejection: Grossly hemolyzed, grossly lipemic, grossly icteric<br>**Methodology:**<br>Cell Binding Assay (CBA), if indicated<br>**Immunoblot (IB)**<br>Immunoprecipitation<br>Indirect Immunofluorescence Assay (IFA)<br>Radioimmunoassay (RIA)<br>Western Blot (WB), if indicated<br>**Days Performed:** Monday–Sunday<br>**Reported:** 9–**12** days | 5/14/20 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Paraneoplastic Autoantibody Evaluation, Serum | PARNEO | **For Interfaced Clients Only: Test build may need to be modified**<br>**Special Information: Reflex Algorithm: If IFA patterns suggest AGNA-1 antibody, AGNA-1 immunoblot (IB) is performed at an additional cost. If IFA patterns suggest amphiphysin antibody, amphiphysin immunoblot is performed at an additional cost. If IFA patterns suggest ANNA-1 antibody, ANNA-1 immunoblot is performed at an additional cost. If IFA patterns suggest ANNA-2 antibody, ANNA-2 immunoblot is performed at an additional cost. If IFA patterns suggest PCA-1 antibody, PCA-1 immunoblot is performed at an additional cost. If IFA patterns suggest PCA-Tr antibody, PCA-Tr immunoblot is performed at an additional cost.** If client requests or if IFA patterns suggest CRMP-5-IgG, CRMP-5-IgG Western blot is performed at an additional cost. If IFA patterns suggest GAD65 antibody, GAD65 Ab radioimmunoassay is performed at an additional cost. If IFA patterns suggest NMDA-R, NMDA-R Ab CBA and/or NMDA-R Ab IF Titer Assay is performed at an additional cost. If IFA patterns suggest AMPA-R, AMPA-R Ab CBA and/or AMPA-R Ab IF Titer Assay is performed at an additional cost. If IFA patterns suggest GABA-B-R, GABA-B-R Ab CBA and/or GABA-B-R Ab IF Titer Assay is performed at an additional cost. If IFA patterns suggest DPPX, DPPX antibody CBA and DPPX antibody titer are performed at an additional cost. If IFA patterns suggest mGluR1, mGluR1 Ab CBA and mGluR1 Ab titer are performed at an additional cost. If CRMP IFA is positive, ACh receptor binding antibody, CRMP-5-IgG Western blot, and ACh receptor (muscle) modulating antibody will be performed at an additional cost. If striational striated muscle antibody is 1:7,680 or greater, ACh receptor binding Ab, CRMP-5-IgG Western blot, and ACh receptor (muscle) modulating Ab will be performed at an additional cost. Testing should be requested in cases of subacute basal ganglionic disorders (chorea, Parkinsonism), cranial neuropathies (especially loss of vision, taste, or smell) and myelopathies. If VGKC > 0.00, LGI1-IgG CBA, S (Leucine-Rich Glioma Inactivated Protein-1 IgG, Serum) and CASPR2-IgG CBA, S (Contactin-Associated Protein-Like-2-IgG, Serum) are performed at an additional cost. Provide relevant clinical information and name, phone number, address, and email of ordering provider. Patient Prep: For optimal antibody detection, it is recommended to collect the specimen prior to initiation of immunosuppressant medication. This test should not be requested in patients who have recently received radioisotopes, therapeutically or diagnostically, because of potential assay interference. The specific waiting period before specimen collection will be dependent upon the isotope administered, the dose given, and the clearance rate in the individual patient. Specimens will be screened for radioactivity prior to analysis. Radioactive specimens received in the laboratory will be held for 1 week and assayed if sufficiently decayed, or canceled if radioactivity remains. Patient should have no general anesthetic or muscle-relaxant drugs in the previous 24 hours. Causes for specimen rejection: Grossly hemolyzed, grossly lipemic, grossly icteric.<br>**Methodology:**<br>Cell Binding Assay (CBA), if indicated<br>Enzyme-Linked Immunosorbent Assay (ELISA)<br>IFA Titer Assay (if indicated)<br>**Immunoblot (IB)**<br>Indirect Immunofluorescence Assay (IFA)<br>Radioimmunoassay (RIA)<br>Western Blot (WB), if indicated | 5/14/20 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Phosphatidylethanol (PEth) | PETH | **For Interfaced Clients Only: Test build may need to be modified**<br>**Includes:**<br>PEth 16:0/18.1 (POPEth)<br>**PEth 16:0/18.2 (PLPEth)**<br>**Special Information: Gel separator tubes will be rejected. Also unacceptable are plain (no additive) red tubes, citrate (light blue) tubes, or SPS or ACD solution (yellow) tubes.**<br>**Clinical Information: Phosphatidylethanol (PEth) homologues/Interpretation–PEth 16:0/18.1 (POPEth): < 10 ng/mL not detected; < 20 ng/mL abstinence or light alcohol consumption; 20–200 ng/mL moderate alcohol consumption; > 200 ng/mL heavy alcohol consumption or chronic alcohol use. For PEth 16:0/18.2 (PLPEth)–Reference ranges are not well established (Reference: W. Ulwelling and K Smith 2018 J. Forensic Sci). PEth is a group of phospholipids formed in the presence of ethanol, phospholipase D and phosphatidylcholine. PEth is known to be a direct alcohol biomarker. The predominant PEth homologues are PEth 16:0/18:1 (POPEth) and PEth 16:0/18:2 (PLPEth), which account for 37–46% and 26–28% of the total PEth homologues, respectively. PEth is incorporated into the phospholipid membrane of red blood cells and has a general half-life of 4–10 days and a window of detection of 2–4 weeks. However, the window of detection is longer in individuals who chronically or excessively consume alcohol. The limit of quantification is 10 ng/mL. Serial monitoring of PEth may be helpful in monitoring alcohol abstinence over time. PEth results should be interpreted in the context of the patient's clinical and behavioral history. Patients with advanced liver disease may have falsely elevated PEth concentrations (Nguyen VL et al 2018, Alcoholism Clinical & Experimental Research).**<br>**Specimen Requirement:** 1 mL whole blood in an EDTA (lavender) tube; Minimum: 0.5 mL; Refrigerated<br>*OR* 1 mL whole blood in a **lithium heparin (green)** tube; Minimum: 0.5 mL; Refrigerated<br>*OR* 1 mL whole blood in a **potassium oxalate/sodium fluoride (gray)** tube; Minimum: 0.5 mL; Refrigerated<br>**Stability:**<br>Ambient: Unacceptable<br>Refrigerated: 2 weeks<br>Frozen: **1 month**<br>**Reference Range:**<br>PEth 16:0/18.1 (POPEth): **< 10 ng/mL**<br>*[Reference ranges are not well established for PEth 16:0/18.2 (PLPEth)]*<br>**Days Performed: Sunday–Saturday**<br>**Reported: 2–5** days | 5/18/20 |
| PNH Panel by FCM | PNHPNL | **Special Information:** Do not draw on Fridays, weekends or holidays. **The clinical significance of results on specimens 24–48 hours old should be evaluated in the context of other clinical and laboratory findings.** Specimens greater than 48 hours old will be rejected.<br>**Specimen Requirement:** 4 mL whole blood in an EDTA (lavender) tube; Minimum: 2 mL; Peripheral blood must be kept at room temperature and delivered to the flow cytometry laboratory at Cleveland Clinic Laboratories within 24 hours of draw time; **The clinical significance of results on specimens 24–48 hours old should be evaluated in the context of other clinical and laboratory findings;** Samples greater than 48 hours old will be rejected; Do not draw on Fridays, weekends or holidays; Ambient | 6/2/20 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Proinsulin, Intact | IPROIN | **Special Information: Critical frozen.** Patient must fast 12–15 hours prior to collection. **Separate specimens must be submitted when multiple tests are ordered. Grossly hemolyzed specimens will be rejected. This test is New York DOH approved.**<br>**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.2 mL; Patient MUST fast 12–15 hours prior to collection; **Separate specimens must be submitted when multiple tests are ordered;** Separate from cells ASAP or within 2 hours of collection, transfer into a standard aliquot tube and freeze; **Critical Frozen**<br>*OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.2 mL; Patient MUST fast 12–15 hours prior to collection; **Separate specimens must be submitted when multiple tests are ordered;** Separate from cells ASAP or within 2 hours of collection, transfer into a standard aliquot tube and freeze; **Critical Frozen**<br>*OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.2 mL; Patient MUST fast 12–15 hours prior to collection; **Separate specimens must be submitted when multiple tests are ordered;** Separate from cells ASAP or within 2 hours of collection, transfer into a standard aliquot tube and freeze; **Critical Frozen**<br>**Stability:**<br>Ambient: After separation from cells: Unacceptable<br>Refrigerated: After separation from cells: **48 hours**<br>Frozen: After separation from cells: 2 months | 5/18/20 |
| Protein Electrophoresis, Ur 24 Hr w/M Protein Quant | UEPG24 | **Days Performed:** Monday–Friday<br>**Reported:** 1–**7** days | Effective immediately |
| Protein Electrophoresis, Urine Random | UEPG | **Days Performed:** Monday–Friday<br>**Reported:** 1–**7** days | Effective immediately |
| Protein Electrophoresis, Urine, with IFE | UEPGRX | **Days Performed:** Monday–Friday<br>**Reported:** 1–**7** days | Effective immediately |
| Protein S Clottable | PRSCLT | **Reference Range:**<br>0–1 Days: **14–90%**<br>2–5 Days: **14–90%**<br>6–30 Days: **14–90%**<br>1–3 Months: **49–114%**<br>4–11 Months: **50–116%**<br>1–5 Years: **43–167%**<br>6–10 Years: **45–150%**<br>11–16 Years: **53–133%**<br>17–**999** Years: **59–152%** | 6/25/20 |
| Reducing Substances, Stool | STRED | **Special Information:** Samples in preservatives **or media will be rejected.** Diapers are unacceptable. **Stool containing barium is unacceptable. This test is New York DOH approved.**<br>**Clinical Information: A normal result is negative or trace. An abnormal result is 1+ through 4+.**<br>**Stability:**<br>Ambient: Unacceptable<br>Refrigerated: **1 week**<br>Frozen: **2 weeks**<br>**Reference Range: Normal** | 5/18/20 |
| Serotonin, Serum | SERTON | **Special Information:** Patient Prep: Abstain from medications for 72 hours prior to collection. **Separate specimens must be submitted when multiple specimens are ordered.** Specimens other than serum are unacceptable. Non-frozen specimens will not be accepted. This test is New York DOH approved.<br>**Specimen Requirement: 0.5 mL** serum from a serum separator (gold) tube; Minimum: **0.2 mL; Separate specimens must be submitted when multiple specimens are ordered;** Centrifuge and transfer serum into an **amber transport tube** within 1 hour of collection; Frozen | 5/18/20 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| TSH Receptor Antibody | TRAB | **For Interfaced Clients Only: Test build may need to be modified**<br>**Includes:**<br>**TSH Receptor Autoantibody**<br>**TSH Receptor Autoantibody, qualitative**<br>Thyroid Stimulating Immunoglobulin<br>TSI Qualitative<br>**Note:** *Special Information will be removed.*<br>**Reference Range:**<br>**TSH Receptor Autoantibody: < 1.01 IU/L**<br>**TSH Receptor Autoantibody, qualitative: Negative**<br>Thyroid Stimulating Immunoglobulin: < 0.55 IU/L<br>TSI Qualitative: Negative | 6/9/20 |
| Tumor Necrosis Factor | TNFA2 | **Clinical Information: Cytokine levels may demonstrate diurnal variation. For longitudinal comparison, it is recommended that cytokine levels be determined at the same time of day.** Results are used to understand the pathophysiology of immune, infectious, or inflammatory disorders, or may be used for research purposes.<br>**Specimen Requirement:** 1 mL **serum** from a serum separator (gold) tube; Minimum: **0.4 mL;** Separate serum from cells ASAP or within 2 hours of collection; Transfer into standard aliquot tube and freeze; Additional specimens must be submitted when multiple tests are ordered; Critical Frozen<br>*OR* 1 mL **serum** from a plain no additive (red) tube; Minimum: **0.4 mL;** Separate serum from cells ASAP or within 2 hours of collection; Transfer into standard aliquot tube and freeze; Additional specimens must be submitted when multiple tests are ordered; Critical Frozen<br>**Reference Range: ≤ 7.2 pg/mL**<br>*(Note: There is a clinically significant charting name change associated with this test. Change the charting name for the component to Tumor Necrosis Factor–alpha, Serum.)*<br>**Days Performed: Sunday–Saturday**<br>**Reported:** 2–5 days | 5/18/20 |
| Urticaria-Induced Basophil Activation | UTBAS | **Special Information: Contaminated, grossly hemolyzed, or lipemic specimens will be rejected. Specimens other than serum are unacceptable. Separate specimens must be submitted when multiple tests are ordered. This test is New York DOH approved.**<br>**Specimen Requirement:** 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; **Separate specimens must be submitted when multiple tests are ordered;** Separate serum from cells ASAP or within 2 hours of collection, **transfer into a standard aliquot tube and freeze;** Critical Frozen<br>**Days Performed:** Monday, Friday<br>**Reported: 8–11** days | 5/18/20 |

# New Tests

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Acetylcholine Receptor Binding Aby | ACHRAB | **Special Information:** Severely lipemic, contaminated or hemolyzed specimens are unacceptable.<br>**Clinical Information:** Anti-acetylcholine receptor binding antibody test is used as an aid in diagnosis of myasthenia gravis. A negative result cannot exclude myasthenia gravis. Clinical correlation is required.<br>**Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.25 mL; Separate serum from cells as soon as possible; Refrigerated<br>**Stability:**<br>Ambient: 1 day<br>Refrigerated: 7 days<br>Frozen: 14 days<br>**Methodology:** Radioimmunoassay (RIA)<br>**Reference Range:**<br>Acetylcholine Receptor Binding Ab (0–99 Years): < 0.21 nmol/L<br>Acetylcholine Receptor Binding Ab, Qualitative: Negative<br>**Days Performed:** Thursday<br>**Reported:** 1–8 days<br>**CPT:** 84238 x 1<br>**Price:** $165.00 | 6/9/20 |
| Acetylcholine Receptor Blocking Aby | ACEBAB | **Special Information:** Grossly hemolyzed, lipemic samples, or samples containing bilirubin are unacceptable.<br>**Clinical Information:** Anti-acetylcholine receptor blocking antibody test is used as an aid in diagnosis of myasthenia gravis. A negative result cannot exclude myasthenia gravis. Clinical correlation is required.<br>**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Separate serum from cells as soon as possible; Refrigerated<br>**Stability:**<br>Ambient: 1 day<br>Refrigerated: 7 days<br>Frozen: 2 years<br>**Methodology:** Radioimmunoassay (RIA)<br>**Reference Range:**<br>Acetylcholine Receptor Blocking Ab: < 21%<br>Acetylcholine Receptor Blocking Ab, Qualitative: Negative<br>**Days Performed:** Thursday<br>**Reported:** 1–8 days<br>**CPT:** 84238 x 1<br>**Price:** $165.00 | 6/9/20 |
| Chromosome Analysis, Neoplastic Tissue | CHRNPT | **Note:** *This test was previously announced in the April Technical Update.*<br>**Price:** $864.00 (non-discountable) | 5/26/20 |
| HLA-B58 | HLAB58 | **Specimen Requirement:** 5 mL peripheral blood in an EDTA (lavender) tube; Ambient<br>*OR* 7 mL peripheral blood in an ACD A or B (yellow) tube; Ambient<br>**Stability:**<br>Ambient: 1 week<br>Refrigerated: 1 week<br>Frozen: Unacceptable<br>**Methodology:**<br>Polymerase Chain Reaction (PCR)<br>Sequence Specific Oligonucleotide Probe (SSOP)<br>**Days Performed:** Monday–Friday<br>**Reported:** 2–4 days<br>**CPT:** 81374 x 1<br>**Price:** $235.00 (non-discountable) | 7/1/20 |

# New Tests (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Insulin Autoantibody | INSLAB | **Special Information:** Patients who have been administered radioactive isotopes within the last 48 hours cannot be tested.<br>**Clinical Information:** Anti-insulin antibody test is used as an aid in diagnosis and prognosis of autoimmune diabetes mellitus in combination with other tests such as anti-GAD65 and anti-IA-2 antibody. A single negative result cannot rule out autoimmune diabetes mellitus. The test is not reliable in patients who had previously received exogenous insulin. Clinical correlation is required.<br>**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Refrigerated<br>**Stability:**<br>Ambient: 1 day<br>Refrigerated: 7 days<br>Frozen: 14 days<br>**Methodology:** Radioimmunoassay (RIA)<br>**Reference Range:**<br>Insulin Antibody (0–99 Years): < 0.4 U/mL<br>Insulin Antibody, Qualitative: Negative<br>**Days Performed:** Monday, Thursday<br>**Reported:** 2–5 days<br>**CPT:** 86337 x 1<br>**Price:** $59.00 | 6/9/20 |
| N-Methylhistamine, Random, Urine | UMHISR | **Includes:**<br>N-Methylhistamine, Random, Ur<br>Creatinine, Random, Ur<br>**Special Information:** Patient must not be taking monoamine oxidase inhibitors (MAOIs) or aminoguanidine as these medications increase N-methylhistamine (NMH) levels. Collect the random urine specimen within a few hours of onset of symptoms.<br>**Clinical Information:** Useful for screening and monitoring mastocytosis and disorders of systemic mast-cell activation, such as anaphylaxis and other forms of severe systemic allergic reactions using random urine specimens. Monitoring therapeutic progress in conditions that are associated with secondary, localized, low-grade persistent, mast-cell proliferation and activation such as interstitial cystitis. Patients with chronic mast cell activation often have chronically elevated N-methylhistamine (NMH) levels and will sometimes have intermittent NMH elevations. In these cases, a 24-hour urine collection is preferred [see N-Methylhistamine, Urine (MHISTA)]. Cautions: While an average North American diet has no effect on urinary N-methylhistamine (NMH) levels, mild elevations (approximately 30%) may be observed on very histamine-rich diets. This problem is more pronounced if random urine specimens are used and collected following a histamine-rich meal. NMH levels may be depressed in individuals who have an alteration in the histamine-N-methyl transferase gene, which encodes the enzyme that catalyzes NMH formation. This alteration results in an amino acid change that decreases the rate of NMH synthesis. When N-acetylcysteine is administered at levels sufficient to act as an antidote for the treatment of acetaminophen overdose, it may lead to falsely decreased creatinine results.<br>**Specimen Requirement:** 5 mL random urine in a clean container (No preservatives); Minimum: 3 mL; Collect within a few hours of onset of symptoms; Refrigerated<br>**Stability:**<br>Ambient: 28 days<br>Refrigerated: 28 days (preferred)<br>Frozen: 28 days<br>**Methodology:**<br>Colorimetric Enzyme Assay<br>Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)<br>**Reference Range:** Refer to report<br>**Days Performed:** Tuesday, Thursday<br>**Reported:** 4–8 days<br>**CPT:** 82542 x 1, 82570 x 1<br>**Price:** $105.00 (non-discountable) | 4/30/20 |

# New Tests (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Respiratory Panel by Rapid PCR | RPRAPD | **Special Information:** The coronaviruses detected by this panel are NOT the SARS-CoV-2 (COVID-19) virus. Nasopharyngeal swabs only. Dry swabs (swabs not received in Viral Transport Media) will be rejected. Sputum and bronchoalveolar lavage (BAL) specimens should be sent for RPPCR (Respiratory Panel by PCR) testing.<br>**Clinical Information:** This test is primarily to be used for patients who have met Cleveland Clinic criteria to rule out the novel coronavirus (COVID-19) and are going to be admitted to a Cleveland Clinic Hospital. This test may also be used in situations wherein a rapid respiratory virus panel could improve access to beds. The test is very expensive. If rapid results are not required, the RPPCR assay with next day results should be ordered.<br>**Specimen Requirement:** One nasopharyngeal (NP) swab in Universal Transport Media; 1 mL or 3 mL is accepted; Refrigerated (or on ice)<br>**Stability:**<br>Ambient: Stable for 4 hours at room temperature (15–25 °C)<br>Refrigerated: Stable for up to 3 days refrigerated (2–8 °C)<br>Frozen: Stable for up to 30 days frozen (minus 15 °C or minus 70 °C)<br>**Methodology:** Qualitative Polymerase Chain Reaction<br>**Reference Range:**<br>Adenovirus: Negative<br>Coronavirus 229E: Negative<br>Coronavirus HKU1: Negative<br>Coronavirus NL63: Negative<br>Coronavirus OC43: Negative<br>H Metapneumovirus: Negative<br>Rhino/Enterovirus: Negative<br>Influenza A Virus: Negative<br>Influenza A H1 Virus: Negative<br>Influenza A H3 Virus: Negative<br>Influenza A H1N1 2009: Negative<br>Influenza B Virus: Negative<br>Parainfluenza 1: Negative<br>Parainfluenza 2: Negative<br>Parainfluenza 3: Negative<br>Parainfluenza 4: Negative<br>RSV PCR: Negative<br>Bordetella parapertussis: Negative<br>Bordetella Pertussis: Negative<br>C. pneumoniae: Negative<br>M. pneumoniae: Negative<br>**Days Performed:** 7 days per week<br>**Reported:** 4 hours<br>**CPT:** 87486 x 1, 87581 x 1, 87631 x 1, 87798 x 2<br>**Price:** $287.00 (non-discountable) | Effective immediately |

# New Tests (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| TSH Receptor Total Autoantibody | TSHRA | **Clinical Information:** TSH receptor autoantibody test is based on a competitive ELISA and detects all TSHR binding antibodies which may be used as an aid in diagnosis of autoimmune thyroid diseases. The results may be positive in both autoimmune hypo- and hyperthyroidism. Low positive results may occasionally be seen in non-autoimmune thyroid disorders such as nodules or in other autoimmune diseases. Clinical correlation is required.<br>**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Refrigerated<br>**Stability:**<br>Ambient: 1 day<br>Refrigerated: 7 days<br>Frozen: 14 days<br>**Methodology:** Enzyme-Linked Immunosorbent Assay (ELISA)<br>**Reference Range:**<br>TSH Receptor Autoantibody, qualitative: Negative<br>TSH Receptor Autoantibody: < 1.01 IU/L<br>**Days Performed:** Monday, Thursday<br>**Reported:** 1–6 days<br>**CPT:** 83520 x 1<br>**Price:** $185.00 | 6/9/20 |

# Fee Increases

| Test Name | Order Code | List Fee | CPT Code | Effective Date |
|---|---|---|---|---|
| Digitoxin | DIGIT | $232.00 | 80375, (G0480, if appropriate) | 5/18/20 |
| Reducing Substances, Stool | STRED | $42.00 (non-discountable) | 84376 | 5/18/20 |

# Fee Reductions

| Test Name | Order Code | List Fee | CPT Code | Effective Date |
|---|---|---|---|---|
| BCR/ABL1 p210 Quantitative PCR Bone Marrow | P210BM | $746.00 (non-discountable) | 81206 | 4/30/20 |
| Cathartic Laxative, Stool | STCATH | $360.00 (non-discountable) | 80375, 84100, (G0480, if appropriate) | Effective immediately |

# Discontinued Tests

| Test Name | Order Code | Test Information | Effective Date |
|---|---|---|---|
| Acetylcholine Receptor Binding Ab | ACHRA | **Note:** *Changes to this test were previously announced in the April Technical Update. It was determined that a new order code will be needed, and ACHRA will be discontinued. We suggest ordering Acetylcholine Receptor Binding Aby (ACHRAB). We apologize for any inconvenience this may have caused.* | 6/9/20 |
| Acetylcholine Receptor Blocking Ab | ACEBLC | **Note:** *Changes to this test were previously announced in the April Technical Update. It was determined that a new order code will be needed, and ACEBLC will be discontinued. We suggest ordering Acetylcholine Receptor Blocking Aby (ACEBAB). We apologize for any inconvenience this may have caused.* | 6/9/20 |
| HPV DNA, High Risk, Anal-Rectal | HPVAR | This test will no longer be available. | 5/18/20 |
| Insulin Antibody | INSAB | **Note:** *Changes to this test were previously announced in the April Technical Update. It was determined that a new order code will be needed, and INSAB will be discontinued. We suggest ordering Insulin Autoantibody (INSLAB). We apologize for any inconvenience this may have caused.* | 6/9/20 |
| Librium & Metabolite | LIBRI | This test will no longer be available. | 6/11/20 |
| Limulus Amebocyte Lysate | LALYS | This test will no longer be available. | 6/11/20 |
| Nitrazepam | NITRAZ | This test will no longer be available. | 6/11/20 |
| Reticulin IgA and IgG Antibodies | RETAB | This test will no longer be available. Suggest ordering alternative test Celiac Screen with Reflex (CELSCR). | 4/30/20 |
| TSH Binding Inhibition | TBI | **Note:** *Changes to this test were previously announced in the April Technical Update. It was determined that a new order code will be needed, and TBI will be discontinued. We suggest ordering TSH Receptor Autoantibody (TSHRA). We apologize for any inconvenience this may have caused.* | 6/9/20 |