Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • May 2021

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	Achondroplasia (FGFR3) 2 Mutations						■					■		
3	Anti-Platelet Factor 4										■			
3	Apolipoprotein E (APOE) Genotyping, Alzheimer Disease Risk						■					■		
3	Apolipoprotein E (APOE) Genotyping, Cardiovascular Risk						■					■		
3	Ashkenazi Jewish Diseases						■					■		
3–4	Autoimmune Dysautonomia Evaluation, Serum						■		■	■			■	
4–5	Autoimmune Encephalopathy Evaluation, Serum						■		■	■			■	
5	Chronic Lymphoproliferative Disorder NGS Peripheral Blood												■	
5	Colon Cancer Hotspot Gene Panel Tissue		■					■	■	■		■		
5	CSF3R Mutation Analysis Blood												■	
5	CSF3R Mutation Analysis Bone Marrow												■	
5	CYP2C19 (Cytochrome P450 2C19)						■							
5	CYP2D6 (Cytochrome P450 2D6)						■							
5	Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants						■					■		
6	DNA Autoantibodies, Double Stranded										■			
6	Duchenne/Becker Muscular Dystrophy (DMD) Deletion/Duplication with Reflex to Sequencing						■							
6	Ethyl Glucuronide, Urine Confirm/Quant											■		
6	Ethyl Glucuronide, Urine reflex to Confirm/Quant											■		
12	FLT3 ITD Mutation Analysis Bone Marrow			■										

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6	Gastrointestinal Stromal Tumor (GIST) Hotspot Panel Tissue		■				■	■				■		
6	Glycoproteins					■						■		
6	Head and Neck Next Generation Sequencing							■						
6	HIV-1 RNA, Qualitative, TMA					■	■				■	■		
7	Ketamine & Metabolite, Serum/Plasma					■	■	■			■			
7	Lipoprotein Fractionation NMR with Lipids						■							
7	Lipoprotein Fractionation NMR without Lipids						■							
7	Lung Cancer Hotspot Gene Panel Tissue		■				■					■		
7	Melanoma Hotspot Gene Panel Tissue		■				■	■				■		
7	Methylenetetrahydrofolate Reductase (MTHFR) Mutation, 2 Variants					■						■		
14	Myasthenia Gravis Evaluation, Adult				■									
12–13	Myasthenia Gravis Evaluation with Muscle-Specific Kinase (MuSK) Reflex, Serum			■										
14	Myasthenia Gravis/Lambert-Eaton Syndrome				■									
13–14	Myasthenia Gravis (MG)/Lambert-Eaton Syndrome (LES) Evaluation, Serum			■										
8	Narcolepsy Associated Ag, HLA-DQB1 Typing					■						■		
8	NMP22 Bladder Tumor Marker					■	■			■		■		
8	PAI-1 Genotype 5G/4G					■						■		
8–9	Paraneoplastic Autoantibody Evaluation, Serum					■	■	■	■				■	
14	Peripheral Blood Low Grade Leuk Markers				■									
9	PNH Panel by FCM					■	■	■		■				
10	Prader-Willi/Angelman Methylation					■						■		
10	Protein, Body Fluid											■		
14	Rett Syndrome				■									
10	Sarcoma Fusion NGS							■						
10	Supersaturation Profile, 24 Hour Urine									■				
14	Surface/Cytoplasmic IgM by FCM				■									
11	Thiopurine Metabolites by LC-MS/MS					■	■			■	■	■		
11	Warfarin Sensitivity (CYP2C8, CYP2C9, CYP4F2, VKORC1) Genotyping					■								

Test Changes

Test Name	Order Code	Change	Effective Date
Achondroplasia (FGFR3) 2 Mutations	ADPLAS	**Special Information: Plasma, serum, hemolyzed, and frozen specimens in glass collection tubes will be rejected. This test is New York DOH approved.** **Stability:** Ambient: **72 hours** Refrigerated: 1 week Frozen: **1 month**	5/17/21
Anti-Platelet Factor 4	PLATF4	**Reference Range:** Anti-Platelet Factor 4 (0–99 Years): < 0.400 OD PF4 Interpretation: Negative **Urgent Range:** Anti-Platelet Factor 4 (0–99 Years): > 0.400 OD reading with more than 50% inhibition with excess heparin after Pathologist review **PF4 Interpretation: Positive**	Effective immediately
Apolipoprotein E (APOE) Genotyping, Alzheimer Disease Risk	ALZHEI	**Special Information:** Genetic counseling and informed consent are strongly recommended prior to ordering and post test to discuss results. NOTE: Testing of fetal specimens or specimens from patients under the age of 18 years is not offered. **Plasma, serum and frozen specimens in glass collection tubes will be rejected. This test is New York DOH approved.** **Stability:** Ambient: 72 hours Refrigerated: **1 week** Frozen: 1 month	5/17/21
Apolipoprotein E (APOE) Genotyping, Cardiovascular Risk	APOEG	**Special Information:** This test is not recommended for nonsymptomatic patients under 18 years of age. **Plasma, serum and frozen specimens in glass collection tubes will be rejected. This test is New York DOH approved.** **Stability:** Ambient: 72 hours Refrigerated: **1 week** Frozen: 1 month	5/17/21
Ashkenazi Jewish Diseases	AJPWO	**Special Information:** An ARUP Patient History Form for Molecular Genetic Testing is recommended but not required. Plasma, serum **and frozen specimens in glass collection tubes will be rejected. This test is New York DOH approved.** **Stability:** Ambient: 72 hours Refrigerated: **1 week** Frozen: 1 month	5/17/21
Autoimmune Dysautonomia Evaluation, Serum	AIDYSA	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Dysautonomia Interpretation AChR Ganglionic Neuronal Ab ANNA-1 **CASPR2-IgG CBA** **CRMP-5-IgG** DPPX Ab IFA **LGI1-IgG CBA** **Purkinje Cell Cytoplasmic Ab Type 2** **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 Purkinje Cell Cytoplasmic Ab, the appropriate antibody will be 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 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 additional cost. If IFA patterns suggest DPPX Ab, then DPPX Ab CBA and DPPX titer are performed at an additional cost. Include ordering provider name, number, address, and email. Include relevant clinical information. *(continued on page 4)*	5/11/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Autoimmune Dysautonomia Evaluation, Serum *(continued from page 3)*		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. **Methodology:** Cell Binding Assay (CBA) Indirect Immunofluorescence Assay (IFA) Radioimmunoassay (RIA) **CPT:** 83519 **x 1,** 86255 **x 6**	
Autoimmune Encephalopathy Evaluation, Serum	ENCSER	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Encephalopathy Interpretation, S AMPA-R Ab CBA, S Amphiphysin Ab, S AGNA-1, S ANNA-1, S ANNA-2, S ANNA-3, S CASPR2-IgG, CBA, S CRMP-5-IgG, S DPPX Ab IFA, S GABA-B-R Ab CBA, S GAD65 Ab Assay, S GFAP IFA, S IgLON5 IFA, S LGI1-IgG CBA, S mGluR1 Ab IFA, S NIF IFA, S NMDA-R Ab CBA, S PCA-1, S PCA-2, S PCA-Tr, S *(Note: AChR Ganglionic Neuronal Ab, S, N-Type Calcium Channel Ab, and P/Q-Type Calcium Channel Ab will be removed.)* **Special Information:** Reflex Algorithm: Each reflex test performed incurs additional charge. If immunofluorescence (IFA) patterns suggest CRMP-5-IgG, then CRMP-5-IgG Western blot, and ACh receptor (muscle) binding antibody are performed. If IFA patterns suggest amphiphysin antibody, then amphiphysin immunoblot is performed. If IFA pattern suggests AGNA-1 antibody, then AGNA-1 immunoblot is performed. If IFA pattern suggests ANNA-1 antibody, then ANNA-1 immunoblot is performed. If IFA pattern suggests ANNA-2 antibody, then ANNA-2 immunoblot is performed. If IFA pattern suggests PCA-1 antibody, then PCA-1 immunoblot is performed. If IFA pattern suggests PCA-Tr antibody, then PCA-Tr immunoblot is performed. If IFA pattern suggests IgLON5 antibody, then IgLON5 IFA titer and IgLON5 cell-binding assay (CBA) is performed. If AMPA-receptor antibody CBA is positive, then CRMP-5-IgG Western blot, and acetylcholine (Ach) receptor (muscle) binding antibody are performed. If IFA pattern suggests AMPA-receptor antibody, and AMPA-receptor antibody CBA is positive, then AMPA-receptor antibody IFA titer assay is performed. If AMPA-receptor antibody CBA is positive, then CRMP-5-IgG Western blot, and ACh receptor (muscle) binding antibody are performed. If CASPR2-receptor antibody CBA is positive, then CRMP-5-IgG Western blot and ACh receptor (muscle) binding antibody are performed. If IFA pattern suggests GABA-B-receptor antibody, and GABA-B-receptor antibody is positive, then GABA-B-receptor antibody IFA titer assay is performed. If IFA pattern suggests GFAP antibody, then GFAP IFA titer and GFAP CBA are performed. If IFA pattern suggests NMDA-receptor antibody, and NMDA-receptor antibody CBA is positive, then NMDA-receptor antibody IFA titer assay is performed. *(continued on page 5)*	5/11/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Autoimmune Encephalopathy Evaluation, Serum *(continued from page 4)*		If IFA pattern suggests DPPX antibody, then DPPX antibody CBA and DPPX titer are performed. If IFA pattern suggests mGluR1 antibody, then mGluR1 antibody CBA and mGluR1 titer are performed. If IFA pattern suggests NIF antibody, then alpha internexin CBA, NIF heavy chain CBA, NIF light chain CBA, and NIF titer are performed. If immunofluorescence (IFA) patterns suggest collapsin response-mediator protein-5-IgG (CRMP-5-IgG), then CRMP-5-IgG Western blot, and ACh receptor (muscle) binding antibody. For optimal antibody detection, specimen collection is recommended prior to initiation of immunosuppressant medication. This test should not be requested in patients who have recently received radioisotopes because of potential assay interference. 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 drugs in the previous 24 hours. Grossly hemolyzed, lipemic or icteric specimens will be rejected. **Methodology:** Cell Binding Assay (CBA) Indirect Immunofluorescence Assay (IFA) Radioimmunoassay (RIA) **CPT:** 86255 x 19, 86341 x 1	
Chronic Lymphoproliferative Disorder NGS Peripheral Blood	LPPNGS	**CPT:** 81450 x 1	6/13/21
Colon Cancer Hotspot Gene Panel Tissue	NGSCOL	**Includes:** **KRAS** **NRAS** **BRAF** *(Note: Test directory update for components)* **Test Name:** Previously Colon Cancer Hotspot Panel v2 NGS **Specimen Requirement:** 10 mm square **formalin-fixed paraffin-embedded (FFPE) tissue block; FFPE tissue slides;** Transport and store slides at ambient temperature; 10 unstained sections FFPE tissue on charged, unbaked slides plus one H&E stained section with best tumor area circled by a pathologist; Ambient **Stability:** Ambient: Indefinitely for FFPE slides; FFPE slides can be transported at ambient temperature Refrigerated: **Unacceptable** Frozen: Unacceptable **Methodology:** Next Gen Sequencing **Next Generation DNA Sequencing**	5/3/21
CSF3R Mutation Analysis Blood	CSF3RP	**CPT: 81479 x 1**	6/13/21
CSF3R Mutation Analysis Bone Marrow	CSF3RM	**CPT: 81479 x 1**	6/13/21
CYP2C19 (Cytochrome P450 2C19)	2C19CY	**Special Information:** Plasma, serum **and frozen specimens in glass collection tubes will be rejected.** Specimens collected in sodium heparin or lithium heparin are unacceptable. Whole blood is the preferred specimen. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting.	5/17/21
CYP2D6 (Cytochrome P450 2D6)	2D6GTP	**Special Information:** Plasma, serum **and frozen specimens in glass collection tubes will be rejected.** Specimens collected in sodium heparin or lithium heparin are unacceptable. Whole blood is the preferred specimen. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting.	5/17/21
Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants	5FUDPD	**Special Information:** Plasma, serum **and frozen specimens in glass collection tubes will be rejected.** Heparinized specimens are unacceptable. This test is New York DOH approved. **Stability:** Ambient: 72 hours Refrigerated: **1 week** Frozen: 1 month	5/17/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
DNA Autoantibodies, Double Stranded	DSDNA	**Days Performed:** Monday–Friday **Reported: 8–11** days	Effective immediately
Duchenne/Becker Muscular Dystrophy (DMD) Deletion/ Duplication with Reflex to Sequencing	DBMDYS	**Special Information:** Deletion/Duplication analysis is performed on all samples. If no large deletions or duplications are detected and/or results do not explain the clinical scenario, then sequencing of the DMD gene will be added. Additional charges apply. **Plasma, serum, hemolyzed and frozen specimens will be rejected.**	5/17/21
Ethyl Glucuronide, Urine Confirm/Quant	UEGQNT	**Stability:** Ambient: **1 week** Refrigerated: 20 days Frozen: 20 days	5/17/21
Ethyl Glucuronide, Urine reflex to Confirm/Quant	UEGLUC	**Stability:** Ambient: **1 week** Refrigerated: **1 month** Frozen: **1 month**	5/17/21
Gastrointestinal Stromal Tumor (GIST) Hotspot Panel Tissue	GISTHS	**Includes:** **BRAF** **KIT** **PDGFRA** *(Note: Test directory update for components)* **Test Name:** Previously Gastrointestinal Stromal Tumor (GIST) Hotspot Panel v2 NGS **Specimen Requirement:** 10 mm square **formalin-fixed paraffin-embedded (FFPE) tissue block; FFPE tissue slides;** Transport and store slides at ambient temperature; 10 unstained sections FFPE tissue on charged, unbaked slides plus one H&E stained section with best tumor area circled by a pathologist; Ambient **Stability:** Ambient: Indefinitely for formalin-fixed paraffin-embedded tissue (FFPET) slides; FFPET can be transported at ambient temperature Refrigerated**:** Unacceptable Frozen: Unacceptable	5/3/21
Glycoproteins	GLYCO	**Special Information: Hemolyzed specimens will be rejected. This test is New York DOH approved.** **Stability:** Ambient: 8 hours Refrigerated: 8 days Frozen: **3 months**	5/17/21
Head and Neck Next Generation Sequencing	HDNK	**Note:** *MAML2 gene will be added.*	Effective immediately
HIV-1 RNA, Qualitative, TMA	HIVTMA	**Special Information: Improper specimen handling can cause false negatives or contamination.** **Clinical Information: Reference Interval: Not detected. This test detects human immunodeficiency virus type 1 (HIV-1) RNA from Group M, N and O subtypes; it does not detect HIV-1 proviral DNA. A result of 'Not Detected' does not rule out HIV-1 RNA concentrations below the limit of detection of the assay or the presence of inhibitors in the patient specimen. The diagnosis of HIV-1 infection should not be made based solely on a single HIV-1 test result. Diagnosis requires repeat and confirmatory testing as recommended by U.S. Health and Human Services Guidelines. This assay should not be used for blood donor screening, associated re-entry protocols, or for screening Human Cell, Tissues and Cellular Tissue-Based Products (HCT/P).** **Specimen Requirement: 1 mL plasma** from an **EDTA (lavender)** tube; Minimum: **0.4 mL; Refrigerated** **Stability:** Ambient: **Unacceptable** Refrigerated: **1 week** Frozen: **1 week** **Days Performed: Tuesday–Saturday** **Reported:** 3–6 days	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Ketamine & Metabolite, Serum/ Plasma	KETMIN	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Norketamine, Serum/Plasma Ketamine, Serum/Plasma **Note:** *Ketalar will be added as an alias name.* **Special Information:** Polymer gel separation tubes (serum separator tubes or plasma separator tubes) will be rejected. Reporting limit: 20 ng/mL for both Norketamine and Ketamine. **This test is New York DOH approved.** **Specimen Requirement:** 3 mL serum from a plain no additive (red) tube; Minimum: 1.2 mL; Do not use serum separator tube; Promptly centrifuge and separate serum into a plastic screw-capped vial; Refrigerated *OR* 3 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 1.2 mL; **Do not use plasma separator tube;** Promptly centrifuge and separate plasma into a plastic screw-capped vial; Refrigerated *OR* 3 mL plasma from an EDTA (lavender) tube; Minimum: 1.2 mL; Please collect two EDTA lavender top tubes; Promptly centrifuge and separate plasma into a plastic screw-capped vial; Refrigerated **Days Performed:** Monday–Sunday **Reported:** 6–**7** days	6/7/21
Lipoprotein Fractionation NMR with Lipids	NMRLPD	**Specimen Requirement:** 4 mL serum from a plain no additive (red) tube; Minimum: 2 mL; Patient should be fasting 12 hours; Do not use gel separator tubes; **Gently invert specimen five times (DO NOT SHAKE)** and allow to clot at room temperature for 30 **to 60 minutes; Centrifuge for 10 minutes** and transfer serum to a standard aliquot tube; Refrigerated	4/29/21
Lipoprotein Fractionation NMR without Lipids	NMRPRT	**Specimen Requirement:** 2 mL serum from a plain no additive (red) tube; Minimum: 2 mL; Patient should be fasting 12 hours; Do not use gel separator tubes; **Gently invert specimen five times (DO NOT SHAKE)** and allow to clot at room temperature for 30 **to 60 minutes; Centrifuge for 10 minutes** and transfer serum to a standard aliquot tube; Refrigerated	4/29/21
Lung Cancer Hotspot Gene Panel Tissue	LNG550	**Test Name:** Previously Lung Cancer Hotspot Gene Panel **Specimen Requirement:** 10 mm square **formalin-fixed paraffin-embedded (FFPE) tissue block; FFPE tissue slides;** Transport and store slides at ambient temperature; 10 sections FFPE tissue on charged, unbaked slides plus one H&E stained section with best tumor area circled by a pathologist; Provide the percentage of tumor cells present; Ambient **Stability:** Ambient: Indefinitely for FFPE slides; FFPE slides can be transported at ambient temperature Refrigerated: **Unacceptable** Frozen: Unacceptable	5/3/21
Melanoma Hotspot Gene Panel Tissue	NGSMEL	**Includes:** **KIT** **BRAF** **NRAS** *(Note: Test directory update for components)* **Test Name:** Previously Melanoma Hotspot Panel v2 NGS **Specimen Requirement:** 10 mm square **formalin-fixed paraffin-embedded (FFPE) tissue block; FFPE tissue slides;** Transport and store slides at ambient temperature; 10 unstained sections FFPE tissue on charged, unbaked slides plus one H&E stained section with best tumor area circled by a pathologist; Ambient **Stability:** Ambient: Ambient: Indefinitely for FFPE slides; FFPE slides can be transported at ambient temperature Refrigerated: **Unacceptable** Frozen: Unacceptable	5/3/21
Methylenetetra-hydrofolate Reductase (MTHFR) Mutation, 2 Variants	MTHFRM	**Special Information: Plasma, serum and frozen specimens in glass collection tubes will be rejected.** This test is New York DOH approved. **Stability:** Ambient: 72 hours Refrigerated: **1 week** Frozen: 1 month	5/17/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Narcolepsy Associated Ag, HLA-DQB1 Typing	NARCAB	**Special Information:** Counseling and informed consent are recommended for genetic testing. **Plasma, serum and frozen specimens in glass collection tubes will be rejected.** This test is New York DOH approved. **Stability:** Ambient: 72 hours Refrigerated: 1 week Frozen: **1 month**	5/17/21
NMP22 Bladder Tumor Marker	NMP22	**Special Information: Follow instructions provided in the Urine Stabilization kit.** Stabilized specimen should be blue/green in color. **Clinical Information:** The NMP22 test is intended as an aid in the management of patients with transitional cell carcinoma of the urinary tract (TCC/UT) and is used after surgical treatment to identify patients with residual or rapidly recurring TCC/UT. NMP22 testing should not be performed on patients who have had a total cystectomy or within five days of an invasive procedure, such as cystoscopy or catheterization of the urethra. **Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.** Values obtained with different assay methods should not be used interchangeably. This assay uses a kit which is an enzyme immunoassay (EIA) method. **Specimen Requirement: 10 mL** random urine in an NMP22 Urine Stabilizer Vial; Minimum: 5 mL; **Follow instructions provided in the Urine Stabilization kit; Stabilized specimen should be blue/green in color; Refrigerated** **Stability:** Ambient: Stabilized urine in NMP22 collection kit: **4** days Refrigerated: Stabilized urine in NMP22 collection kit: **7** days Frozen: Stabilized urine in NMP22 collection kit: **60 days** **Reference Range:** 0–99 Years: **< 10.0 U/mL**	5/17/21
PAI-1 Genotype 5G/4G	PAIGEN	**Special Information: Plasma, serum and frozen specimens in glass collection tubes will be rejected.** This test is New York DOH approved. **Stability:** Ambient: 72 hours Refrigerated: 1 week Frozen: **1 month**	5/17/21
Paraneoplastic Autoantibody Evaluation, Serum	PARNEO	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** **Interpretive Comments** AChR Ganglionic Neuronal Ab Amphiphysin Ab Anti-Glial Nuclear Ab, Type 1 Anti-Neuronal Nuclear Ab, Type 1 Anti-Neuronal Nuclear Ab, Type 2 Anti-Neuronal Nuclear Ab, Type 3 CRMP-5-IgG Neuronal (V-G) K+ Channel Ab Calcium Channel Bind Ab, P/Q Type and N-Type Purkinje Cell Cytoplasmic Ab Type 1 Purkinje Cell Cytoplasmic Ab Type 2 Purkinje Cell Cytoplasmic Ab Type Tr {*Note: Striational (Striated Muscle) Ab and Calcium Channel Binding Antibody, N-Type will be removed.*} **Special Information:** Reflex Algorithm: If IFA patterns suggest AGNA-1 Ab, AGNA-1 immunoblot is performed at an additional cost. If IFA patterns suggest amphiphysin Ab, amphiphysin immunoblot is performed at an additional cost. If IFA patterns suggest ANNA-1 Ab, ANNA-1 immunoblot is performed at an additional cost. If IFA patterns suggest ANNA-2 Ab, ANNA-2 immunoblot is performed at an additional cost. If IFA patterns suggest PCA-1 Ab, PCA-1 immunoblot is performed at an additional cost. If IFA patterns suggest PCA-Tr Ab, 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 Ab, GAD65 Ab RIA 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. *(continued on page 9)*	5/11/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Paraneoplastic Autoantibody Evaluation, Serum *(continued from page 8)*		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 Ab CBA and DPPX Ab 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 Ab, CRMP-5-IgG Western blot 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. **Specimen Requirement:** 4 mL serum from a plain no additive (red) tube; Minimum: 2 mL; Draw 2 tubes to ensure adequate serum volume; **Patient should have no general anesthetic or muscle-relaxant medications in the previous 24 hours; Specimen collection is recommended before initiation of immunosuppressant medication; This test should not be requested in patients who have recently received radioisotopes (refer to Special Information);** Refrigerated *OR* 4 mL serum from a serum separator (gold) tube; Minimum: 2 mL; Draw 2 tubes to ensure adequate serum volume; **Patient should have no general anesthetic or muscle-relaxant medications in the previous 24 hours; Specimen collection is recommended before initiation of immunosuppressant medication; This test should not be requested in patients who have recently received radioisotopes (refer to Special Information);** Refrigerated **Methodology:** Indirect Immunofluorescence Assay (IFA) Radioimmunoassay (RIA) **CPT:** 83519 **x 3,** 86255 x 9	
PNH Panel by FCM	PNHPNL	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** % CD24-/FLAER- Granulocytes **PNH RBC clone-partial Ag loss (Type II)** **PNH RBC clone-complete Ag loss (Type III)** **PNH RBC clone sum** *(Note: % CD59- Red cells will be removed.)* **Special Information:** Do not draw on Fridays, weekends or holidays. Specimens greater than 48 hours old will be rejected. **Clinical Information:** The presence of paroxysmal nocturnal hemoglobinuria (PNH) clones in the erythrocyte and granulocyte populations is assessed in this procedure. For erythrocytes, antibodies to Glycophorin A are used to specifically gate red cells, and PNH clones are identified by **complete or partial loss** of CD59 expression. For granulocytes, CD15 and CD 33 are used to specifically gate granulocytes. The PNH-type granulocytes are then identified by lack of expression of CD24 and lack of reactivity to Fluorescent Aerolysin (FLAER). The lower limit of detection for this assay is 0.01% PNH-type cells. The presence of a PNH clone occurs in classical hemolytic PNH, generally at levels above 1%. PNH clones may be seen in other disorders such as aplastic anemia and myelodysplastic syndrome. Thus, these results must be put in context of the clinical findings. **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; Samples greater than 48 hours old will be rejected; Do not draw on Fridays, weekends or holidays; Ambient **Reference Range: < 0.01%-Negative.** No PNH clone detected.	6/19/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Prader-Willi/Angelman Methylation	PRADER	**Special Information:** Counseling and informed consent are recommended for genetic testing. **Plasma, serum and frozen specimens in glass collection tubes will be rejected.** This test is New York DOH approved. **Stability:** Ambient: 72 hours Refrigerated: 1 week Frozen: **1 month**	5/17/21
Protein, Body Fluid	BFPROT	**Stability:** Ambient: **7 days** Refrigerated: **7 days** Frozen: **Unacceptable**	Effective immediately
Sarcoma Fusion NGS	SRCNGS	**Note:** *MAML2 gene will be added.*	Effective immediately
Supersaturation Profile, 24 Hour Urine	SSAT24	**Reference Range:** Calcium Oxalate Crystal (0–99 Years): Reference Mean = 1.77 DG Brushite Crystal (0–99 Years): Reference Mean = 0.21 DG Hydroxyapatite Crystal (0–99 Years): Reference Mean = 3.96 DG Uric Acid Crystal (0–99 Years): Reference Mean = 1.04 DG Sodium Urate Crystal (0–99 Years): Reference Mean = 1.76 DG Sodium, Urine **0–17 Years: Not established** **18–99 Years: 22–328 mmol/24 hr** Potassium, Urine **0–17 Years: Not established** **18–99 Years: 16–105 mmol/24 hr** Calcium,Urine Male 0–17 Years: Not established 18–83 Years: < 250 mg/24 hrs 84–99 Years: Not established Female 0–17 Years: Not established 18–83 Years: < 200 mg/24 hrs 84–99 Years: Not established Magnesium,Urine 0–17 Years: Not established **18–99 Years: 51–269 mg/24 hrs** Chloride, Urine **0–17 Years: Not established** **18–99 Years: 34–286 mmol/24 hr** Phosphorus, Urine **0–17 Years: Not established** **18–99 Years: 266–1797 mg/24 hrs** Sulfate, Urine (0–99 Years): 7–47 mmol/24 hr Citrate Excretion, Urine: Refer to report Oxalate, U mmol/spec (0–99 Years): 0.11–0.46 mmol/24 hr Oxalate,U mg/spec (0–99 Years): 9.7–40.5 mg/24 hrs pH, Urine (0–99 Years): 4.5–8.0 Uric Acid, Urine **Male** **0–17 Years: Not established** **18–99 Years: 200–1000 mg/24 hrs** **Female** **0–17 Years: Not established** **18–99 Years: 250–750 mg/24 hrs** Creatinine, Urine **Male** **0–17 Years: Not established** **18–99 Years: 930–2955 mg/24 hrs** **Female** **0–17 Years: Not established** **18–99 Years: 603–1783 mg/24 hrs**	4/29/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Thiopurine Metabolites by LC-MS/MS	THIMET	**Special Information: Grossly hemolyzed, lipemic, icteric and clotted specimens will be rejected. This test is New York DOH approved.** **Clinical Information: This test is primarily used to verify compliance, optimize therapy, and identify elevated metabolite concentrations that may result in toxicity after initiation of thiopurine drug therapy for the treatment of inflammatory bowel disease. Recommended time points for monitoring include: 4 weeks after starting treatment to verify patient compliance and look for early risk of toxicity; 12 to 16 weeks after starting therapy when 6-thioguanine nucleotides have reached steady-state; and annually. It may also be ordered in patients who do not respond to therapy as expected or as needed for dose changes, flare-ups, signs of toxicity, or suspicion of noncompliance. The test will measure 6-methylmercaptopurine (6-MMP) and 6-thioguanine nucleotides (6-TGN) in erythrocytes. Target 6-thioguanine (6-TGN) concentrations are 235 to 450 pmol/8x10(8) RBC with lower levels suggesting suboptimal dosing and higher levels associated with increased risk of myelotoxicity and leukopenia. High 6-methylmercaptopurine (6-MMP) levels (greater than 5700 pmol/8x10[8] RBC) suggest an increased risk for hepatotoxicity and potentially 'thiopurine hypermethylation.'** **Specimen Requirement: 3 mL** whole blood in an EDTA (lavender) tube; Minimum: **1.5 mL; Separate specimens must be submitted when multiple tests are ordered;** Refrigerated **Stability:** Ambient: **24** hours Refrigerated: **8** days Frozen: Unacceptable **Reference Range:** **6-Thioguanine: 235–450 pmol/8x10(8) RBC** **6-CH3-mercaptopurine: ≤ 5700 pmol/8x10(8) RBC** **Days Performed: Monday**–Saturday **Reported: 1**–5 days	9/21/21
Warfarin Sensitivity (CYP2C8, CYP2C9, CYP4F2, VKORC1) Genotyping	WRFSEN	**Special Information:** Plasma, serum **and frozen specimens in glass collection tubes will be rejected.** Whole blood is the preferred specimen. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting.	5/17/21

New Tests

Test Name	Order Code	Change	Effective Date
FLT3 ITD Mutation Analysis Bone Marrow	F3ITDM	**Clinical Information:** This assay detects internal tandem duplication (ITD) mutations in FLT3. The presence of a FLT3 ITD mutation is associated with an adverse prognosis in acute myeloid leukemia. **Specimen Requirement:** 4 mL bone marrow aspirate in an EDTA (lavender) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Fragment Analysis Polymerase Chain Reaction (PCR) **Days Performed:** Varies **Reported:** 2 days **CPT:** 81245 x 1 **Price:** $441.00 (non-discountable)	Effective immediately
Myasthenia Gravis Evaluation with Muscle-Specific Kinase (MuSK) Reflex, Serum	MYSGRV	**Includes:** MG with MuSK Interpretation, S ACh Receptor (Muscle) Binding Ab Reflex test if indicated: AChR Modulating Flow Cytometry, S Reflex test if indicated: MuSK Autoantibody, S **Special Information:** Reflex Algorithm: If acetylcholine receptor (AChR)-binding antibodies are greater than 0.02 nmol/L, then AChR muscle modulating antibody will be performed at an additional charge. If AChR-binding antibodies are 0.02 nmol/L or less, then muscle-specific kinase (MuSK) autoantibody will be performed at an additional charge. If unable to report AChR binding antibody due to interfering substances, then AChR muscle modulating antibody will be performed at an additional charge. If unable to report AChR binding antibody due to interfering substances and AChR muscle modulating antibody is negative, then MuSK autoantibody will be performed at an additional charge. For optimal antibody detection, specimen collection is recommended prior to initiation of immunosuppressant medication. This test should not be requested in patients who have recently received radioisotopes because of potential assay interference. 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 drugs in the previous 24 hours. Grossly hemolyzed, lipemic or icteric specimens will be rejected. **Clinical Limitation:** AChR modulating antibodies will only be performed if AChR binding antibodies are present or if there is an interfering substance present which precludes testing for AChR binding antibodies. Positive muscle acetylcholine receptor (AChR) may occur in autoimmune liver disorders and in patients with graft-versus-host disease and recipients of D-penicillamine. The presence of alpha-bungarotoxin antibodies may interfere with the AChR muscle binding antibody assay and therefore if detected, AChR binding results will not be reported. **Clinical Information:** This test is useful in diagnosing autoimmune myasthenia gravis (MG) and distinguishing autoimmune from congenital MG in adults and children or other acquired forms of neuromuscular junction transmission disorders. It can be used for establishing a quantitative baseline value that allows comparison with future levels if weakness is worsening. These results should only be interpreted in the appropriate clinical and electrophysiological context and are not diagnostic in isolation. Weakly positive results may occur with hypergammaglobulinemia and should be interpreted with caution in the appropriate clinical context. Seropositive rates and quantitative results differ across laboratories and patient results tested at different laboratories should not be treated equivalently. **Specimen Requirement:** 3 mL serum from a plain no additive (red) tube; Minimum: 2 mL; Draw 2 tubes to ensure adequate serum volume; Patient should have no general anesthetic or muscle-relaxant medications in the previous 24 hours; Specimen collection is recommended before initiation of immunosuppressant medication; This test should not be requested in patients who have recently received radioisotopes (refer to Special Information); Refrigerated *(continued on page 13)*	5/11/21

New Tests (Con't)

Test Name	Order Code	Change	Effective Date
Myasthenia Gravis Evaluation with Muscle-Specific Kinase (MuSK) Reflex, Serum *(continued from page 12)*		*OR* 3 mL serum from a serum separator (gold) tube; Minimum: 2 mL; Draw 2 tubes to ensure adequate serum volume; Patient should have no general anesthetic or muscle-relaxant medications in the previous 24 hours; Specimen collection is recommended before initiation of immunosuppressant medication; This test should not be requested in patients who have recently received radioisotopes (refer to Special Information); Refrigerated **Stability:** Ambient: 72 hours Refrigerated: 28 days Frozen: 28 days **Methodology:** Radioimmunoassay (RIA) **Days Performed:** Sunday–Saturday **Reported:** 4–5 days **CPT:** 83519 x 1	
Myasthenia Gravis (MG)/Lambert-Eaton Syndrome (LES) Evaluation, Serum		**Includes:** MG Lambert-Eaton Interpretation, S ACh Receptor (Muscle) Binding Ab P/Q-Type Calcium Channel Ab Reflex test if indicated: AChR Modulating Flow Cytometry, S Reflex test if indicated: MuSK Autoantibody, S **Special Information:** Reflex Algorithm: If acetylcholine receptor (AChR)-binding antibodies are greater than 0.02 nmol/L, then AChR muscle modulating antibody will be performed at an additional charge. If AChR-binding antibodies are 0.02 nmol/L or less, then muscle-specific kinase (MuSK) autoantibody will be performed at an additional charge. If unable to report AChR binding antibody due to interfering substances, then AChR muscle modulating antibody will be performed at an additional charge. If unable to report AChR binding antibody due to interfering substances and AChR muscle modulating antibody is greater than 0.02 nmol/L, then MuSK autoantibody will be performed at an additional charge. For optimal antibody detection, specimen collection is recommended prior to initiation of immunosuppressant medication. This test should not be requested in patients who have recently received radioisotopes because of potential assay interference. 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 drugs in the previous 24 hours. Grossly hemolyzed, lipemic or icteric specimens will be rejected. **Clinical Limitation:** AChR modulating antibodies will only be performed if AChR binding antibodies are present or if there is an interfering substance present which precludes testing for AChR binding antibodies. The presence of alpha-bungarotoxin antibodies may interfere with the AChR muscle binding antibody assay and therefore if detected, AChR binding results will not be reported. **Clinical Information:** This test is useful for confirming the autoimmune basis of a defect in neuromuscular transmission, distinguishing Lambert-Eaton myasthenic syndrome from autoimmune forms of myasthenia gravis, and providing a quantitative autoantibody baseline for future comparisons in monitoring a patient's clinical course and response to immunomodulatory treatment. Results should only be interpreted in the appropriate clinical and electrophysiological context and are not diagnostic in isolation. Positive muscle acetylcholine receptor (AChR) may occur in autoimmune liver disorders and in patients with graft-versus-host disease and recipients of D-penicillamine. Weakly positive results may occur with hypergammaglobulinemia and should be interpreted with caution in the appropriate clinical context. Seropositive rates and quantitative results differ across laboratories and patient results tested at different laboratories should not be treated equivalently. **Specimen Requirement:** 3 mL serum from a plain no additive (red) tube; Minimum: 2 mL; Draw 2 tubes to ensure adequate serum volume; Patient should have no general anesthetic or muscle-relaxant medications in the previous 24 hours; Specimen collection is recommended before initiation of immunosuppressant medication; This test should not be requested in patients who have recently received radioisotopes (refer to Special Information); Refrigerated *(continued on page 14)*	

New Tests (Con't)

Test Name	Order Code	Change	Effective Date
Myasthenia Gravis (MG)/Lambert-Eaton Syndrome (LES) Evaluation, Serum *(continued from page 13)*		*OR* 3 mL serum from a serum separator (gold) tube; Minimum: 2 mL; Draw 2 tubes to ensure adequate serum volume; Patient should have no general anesthetic or muscle-relaxant medications in the previous 24 hours; Specimen collection is recommended before initiation of immunosuppressant medication; This test should not be requested in patients who have recently received radioisotopes (refer to Special Information); Refrigerated **Stability:** Ambient: 72 hours Refrigerated: 28 days Frozen: 28 days **Methodology:** Radioimmunoassay (RIA) **Days Performed:** Sunday–Saturday **Reported:** 4–5 days **CPT:** 83519 x 2	

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Myasthenia Gravis Evaluation, Adult	MYGRAV	This test will no longer be available. Suggest ordering Myasthenia Gravis Evaluation with Muscle-Specific Kinase (MuSK) Reflex, Serum (MYSGRV)	5/11/21
Myasthenia Gravis/ Lambert-Eaton Syndrome	LAMBRT	This test will no longer be available. Suggest ordering Myasthenia Gravis (MG)/ Lambert-Eaton Syndrome (LES) Evaluation, Serum (MGLESE)	5/11/21
Peripheral Blood Low Grade Leuk Markers	PBLGLY	This test will no longer be available. Suggest ordering Flow Cytometric Immunophenotyping for Leukemia/Lymphoma (RLLLIP)	6/19/21
Rett Syndrome	RETT	This test will no longer be available.	5/17/21
Surface/Cytoplasmic IgM by FCM	IGMCYT	This test will no longer be available.	6/19/21