Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • February 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
11	ABO/Rh and Antigen Testing													■
12	ADmark PS-1 Analysis, Symptomatic				■									
3	Anti IgE					■	■				■			
3	Anti-Nuclear Antibodies by IFA, Synovial Fluid		■			■	■				■			
8–9	Autoimmune Encephalopathy Evaluation, CSF			■										
9–11	Autoimmune Encephalopathy Evaluation, Serum			■										
11	Beta-Glucosidase, Leukocytes													■
3–4	Bordetella pertussis and Bordetella parapertussis by Molecular Detection		■			■	■	■			■	■	■	
12	Carbohydrate, Urine													■
4	Complement Deficiency Assay					■					■			
4	Complement Factor B					■					■			
4	Copper, Urine 24 Hour					■				■	■	■		
4	Copper, Urine Random										■	■		
4	Cortisol, Plasma					■			■					
12	DNA Content, Cell Cycle Analysis, Ploidy and S-Phase				■									
12	Encainide				■									
4	Ethanol												■	
12	Fibrinogen Panel				■									
12	FISH Neuroblastoma 2p24 MYCN Amp				■									
4	Fluphenazine					■			■	■				

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
11	Growth Differentiation Factor 15 (GDF15), Plasma													■
12	Growth Hormone, 60 Minutes				■									
4	Haloperidol					■			■	■				
5	Hexagonal Phase Phospholipid Neutralization									■				
5	Humoral Immunity Panel I						■	■	■	■		■		
5–6	Immunoglobulin A Subclasses 1 & 2					■	■		■	■		■		
6	Immunoglobulin D					■	■		■			■		
6	Inhibin A (Dimer) and Inhibin B, Tumor Markers, Serum					■				■		■		
6	Inhibin B					■				■		■		
12	Interleukin 28B Associated Variants, 2 SNPs				■									
12	Ipecac Biomarkers				■									
12	IPF1 (NDM) DNA Sequencing Test				■									
12	KCNJ11 (CH) DNA Sequencing Test				■									
6	LSD, Urine					■								
6	Magnesium, Urine 24 Hour										■	■		
7	Magnesium, Urine Random									■	■	■		
7	Mannose Binding Lectin					■	■					■		
7	Maternal Serum Screen, First Trimester, hCG, PAPP-A, NT							■				■		
11	Methylenetetrahydrofolate Reductase (MTHFR) Mutation, 2 Variants			■										
12	MTHFR Gene Analysis				■									
12	Neoencephalitis Paraneoplastic Profile with Recombx				■									
7	NTRK Next Generation Sequencing												■	
11	Orexin A, Spinal Fluid													■
12	Organic Acids, Plasma				■									
12	PINK1 DNA Sequencing				■									
12	Pipecolic Acid, Urine				■									
7	Platelet Function Screen					■								
7	PML/RARA RTPCR							■						
7, 12	Prometheus Anser ADA												■	■
7, 12	Prometheus Anser IFX												■	■
7, 12	Prometheus Anser UST												■	■
7, 12	Prometheus Anser VDZ												■	■
7, 11	Prometheus Monitr Crohn's Disease								■				■	■
7	Prothrombin Time and PTT Elevation Diagnostic Panel					■								
7	Prothrombin Time Elevation Diagnostic Panel					■								
12	Reptilase Time with Reflex to Reptilase Time 1:1 Mix				■									
12	Respiratory Chain Complexes, Fibroblast				■									

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
7	SF3B1 Mutation Analysis Blood												■	
8	SF3B1 Mutation Analysis Bone Marrow												■	
12	Specific Gravity, Synovial Fluid					■								
8	Tapentadol and Metabolite Confirm/Quantitation, Urine						■				■			
11	Warfarin Sensitivity (CYP2C8, CYP2C9, CYP4F2, VKORC1) Genotyping													■

Test Changes

Test Name	Order Code	Change	Effective Date
Anti IgE	ANTIGE	**Note:** *Qualitative Anti IgE will be added as an alias name.* **Special Information: Blood should be collected and allowed to clot prior to centrifugation. This test is New York DOH approved.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.1 mL; Allow specimen to clot prior to centrifugation;** Ambient *OR* 1 mL serum from a plain no additive (red) tube; Minimum: **0.1 mL; Allow specimen to clot prior to centrifugation;** Ambient **Days Performed:** Wednesday **Reported:** 6–**8** days	3/11/21
Anti-Nuclear Antibodies by IFA, Synovial Fluid	BFANA	**Test Name:** Previously Anti-Nuclear Antibodies by IFA, Body Fluid **Note:** *ANA Body Fluid will be removed as an alias name, and ANA Synovial Fluid will be added.* **Special Information:** This test reflexes to ANA Titer and Pattern **Synovial** Fluid if ANA by IFA is positive in order to rule out false positive ANA by IFA. Bacterial contamination, gross hemolysis, lipemic or icteric specimens, and specimens other than **synovial fluid** are unacceptable. **Specimen Requirement:** 1 mL **synovial fluid** in a sterile container; Minimum: 0.3 mL; Note: This volume does NOT allow for repeat testing; Frozen **Days Performed: Varies** **Reported:** 8–15 days	Effective immediately
Bordetella pertussis and Bordetella parapertussis by Molecular Detection	BORAMP	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Bordetella Pertussis **Bordetella parapertussis** **Test Name:** Previously BORDETELLA PERTUSSIS DETECTION BY NAAT **Clinical Limitation: The Solana Bordetella Complete Assay is an HDA-based duplex assay that targets** the IS481 **and IS1001** sequence of Bordetella pertussis (BP) **and Bordetella parapertussis (BPP) genomes, respectively.** This sequence may also be found in other species of Bordetella. B. holmesii may cause clinical illness similar to B. pertussis, and mixed outbreaks have been reported. B. bronchiseptica is a rare cause of human infection. Additional testing should be performed if needed to differentiate B. pertussis from B. holmesii. **Specimen Requirement:** 2–3 mL nasopharyngeal swab in Universal Transport Media (UTM); Dry swabs, lower respiratory tract specimens (bronchoalveolar lavage, bronch washings) or other upper respiratory specimens (sputum, throat) will be rejected; Calcium-alginate swabs are not acceptable; UTM is the preferred transport media; Refrigerated *(continued on page 4)*	3/9/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Bordetella pertussis and Bordetella parapertussis by Molecular Detection *(continued from page 3)*		**Stability:** Ambient: **Specimens are stable up to 49 hours at 15–30 °C** Refrigerated: Specimens are stable up to **97 hours** at 2–8 °C before testing Frozen: **Specimens are stable at up to 5 months at minus 70 °C** **Days Performed: 7 days per week** **Reported:** 1–3 days **CPT:** 87798 **x 2**	
Complement Deficiency Assay	COMPD	**Clinical Information: The test is used as an aid to assess the functional performance of the classical pathway of the complement system. Clinical correlation is required.** This assay is performed on the Binding Site Optilite turbidimetric analyzer. **Days Performed:** Monday, **Thursday** **Reported:** 1–**5** days	2/2/21
Complement Factor B	C3PA	**Special Information:** Allow specimen to clot for 30 minutes to one hour at refrigerated temperature. **This test is New York DOH approved.** **Clinical Information: Follow-up test for complement activity screening when CH50 is normal and AH50 is low.** **Days Performed:** Monday **Reported: 11–15** days	2/16/21
Copper, Urine 24 Hour	UCOPD	**Clinical Information:** Confirmation of Wilson's Disease, copper toxicology. **Urine copper results > 100 µg/24h may be indicative of Wilson's Disease.** **Stability:** Ambient: **30 days** Refrigerated: **30 days** Frozen: **30 days** **Reference Range:** 0–99 Years: **< 40 µg/24h** **Days Performed: Wednesday** **Reported:** 1–**8** days	3/9/21
Copper, Urine Random	UCOPR	**Stability:** Ambient: **30 days** Refrigerated: **30 days** Frozen: **30 days** **Days Performed: Wednesday** **Reported:** 1–**8** days	3/9/21
Cortisol, Plasma	PCORT	**Note:** *Dexamethasone Suppression will be removed as an alias name.* **Methodology: Quantitative** Liquid Chromatography–Tandem Mass Spectrometry	Effective immediately
Ethanol	ALCO	CPT: 82077 x 1	Effective immediately
Fluphenazine	FLUPH	**Special Information:** Measure at least 2 weeks after initiating treatment. Specimen should be collected prior to next dose–at steady state concentration. **Hemolyzed specimens will be rejected. This test is New York DOH approved.** **Clinical Information: The therapeutic range is based on serum pre-dose (trough) draw at steady state concentration. Adverse effects may include extrapyramidal symptoms, seizures and neuroleptic malignant syndrome.** **Methodology: Quantitative** Liquid Chromatography–Tandem Mass Spectrometry **Reference Range:** **Therapeutic Range pre-dose (trough) draw at steady-state concentration: 1.0–10.0 ng/mL** **Critical Range: > 15 ng/mL (Toxic)**	2/16/21
Haloperidol	HALOP	**Clinical Information: Adverse effects may include drowsiness, blurred vision, tardive dyskinesia, tachycardia, nausea and vomiting.** **Methodology: Quantitative** Liquid Chromatography–Tandem Mass Spectrometry **Reference Range:** 0–99 Years: Therapeutic range: 5.0–20.0 ng/mL **Critical Range:** **0–99 Years: > 50 ng/mL (Toxic)**	2/16/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hexagonal Phase Phospholipid Neutralization	STACLT	**Reference Range:** Hexagonal Phase Screen (0–99 Years): **34.0–51.8 sec** Hexagonal Phase Confirm (0–99 Years): **34.2–47.9 sec** Hexagonal Phase Delta (0–99 Years): **< 7.1 sec**	Effective immediately
Humoral Immunity Panel I	HUMOR1	**Includes:** Diphtheria Antibody, IgG Tetanus Antibody, IgG Pneumo serotype 1 IgG (P13,PNX) Pneumo serotype 3 IgG (P13,PNX) Pneumo serotype 4 IgG (P7,P13,PNX) Pneumo serotype 5 IgG (P13,PNX) Pneumo serotype 6B IgG (P7,P13,PNX) Pneumo serotype 7F IgG (P13,PNX) Pneumo serotype 8 IgG (PNX) Pneumo serotype 9N IgG (PNX) Pneumo serotype 9V IgG (P7,P13,PNX) Pneumo serotype 12F IgG (PNX) Pneumo serotype 14 IgG (P7,P13,PNX) Pneumo serotype 18C IgG (P7,P13,PNX) Pneumo serotype 19F IgG (P7,P13,PNX) Pneumo serotype 23F IgG (P7,P13,PNX) Pneumo Serotype Interpretation Immunoglobulin G Immunoglobulin A Immunoglobulin M Immunoglobulin G Subclass 1 Immunoglobulin G Subclass 2 Immunoglobulin G Subclass 3 Immunoglobulin G Subclass 4 *(Note: This is only a test directory update for components)* **Specimen Requirement: 5.5 mL** serum from a serum separator (gold) tube; Minimum: **2.5 mL total;** Draw 2 serum separator (gold) tubes; Separate serum from cells ASAP or within 2 hours of collection; Transfer serum to individual standard transport tubes; Refrigerated **Stability:** Ambient: After separation from cells: **Unacceptable** Refrigerated: After separation from cells: **14** days Frozen: After separation from cells: **6 months** (Avoid repeated freeze/thaw cycles) **Methodology:** **Quantitative Immunoturbidimetric** Semi-Quantitative Multiplex Bead Assay **Reference Range: Refer to report**	2/16/21
Immunoglobulin A Subclasses 1 & 2	IGA12	**Special Information: Grossly hemolyzed or lipemic specimens will be rejected. This test is New York DOH approved.** **Clinical Information: Secondary test in suspected immunoglobulin deficiency.** **Specimen Requirement:** 2 mL **serum** from a serum separator (gold) tube; Minimum: **0.7 mL;** Centrifuge, aliquot and **refrigerate serum immediately; Refrigerated** **Stability:** Ambient: After separation from cells: **Unacceptable** Refrigerated: After separation from cells: **14** days Frozen: After separation from cells: 6 months **Methodology: Quantitative Immunoturbidimetric** **Reference Range:** Immunoglobulin A **0–2 Years: 2–126 mg/dL** **3–4 Years: 14–212 mg/dL** **5–9 Years: 52–226 mg/dL** **10–14 Years: 42–345 mg/dL** **15–18 Years: 60–349 mg/dL** **≥ 19 Years: 68–408 mg/dL** *(continued on page 6)*	2/16/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Immunoglobulin A Subclasses 1 & 2 *(continued from page 5)*		IgA, Subclass 1 **0–2 Years: 3–145 mg/dL** **3–4 Years: 22–278 mg/dL** **5–9 Years: 43–337 mg/dL** **10–14 Years: 37–430 mg/dL** **15–18 Years: 76–394 mg/dL** **≥ 19 Years: 60–294 mg/dL** IgA, Subclass 2 **0–2 Years: 1–15 mg/dL** **3–4 Years: 3–44 mg/dL** **5–9 Years: 7–56 mg/dL** **10–14 Years: 1–109 mg/dL** **15–18 Years: 14–54 mg/dL** **≥ 19 Years: 6–61 mg/dL**	
Immunoglobulin D	IGDQNT	**Special Information: Grossly** hemolyzed or lipemic specimens are unacceptable. This test is New York DOH approved. **Note:** *IgD, Total by Nephelometry will be removed as an alias name.* **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; **Refrigerated** **Stability:** Ambient: After separation from cells: **Unacceptable** Refrigerated: After separation from cells: **14 days** Frozen: After separation from cells: **6 months** **Methodology: Quantitative Immunoturbidimetric**	2/16/21
Inhibin A (Dimer) and Inhibin B, Tumor Markers, Serum	INHABP	**Clinical Information: For premenopausal females, collection is preferred during the follicular phase of the menstrual cycle.** **Stability:** Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: **72** hours Frozen: After separation from cells: 1 month **Reference Range:** *Please refer to reference range changes for Inhibin B (INHIBB).*	2/16/21
Inhibin B	INHIBB	**Special Information: For premenopausal females, collection is preferred during the follicular phase of the menstrual cycle.** Room temperature specimens, and **grossly** hemolyzed specimens will be rejected. This test is New York DOH approved. **Stability:** Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: **72** hours Frozen: After separation from cells: 1 month **Reference Range:** **Female** **1 Day–12 Years: 1–182 pg/mL** **13–41 Years (regular cycle, follicular phase): 8–223 pg/mL** **42–51 Years (regular cycle, follicular phase): 1–107 pg/mL** **51–76 Years (postmenopausal): 1–11 pg/mL** **Male** **< 15 Days: 68–373 pg/mL** **15 Days–6 Months: 42–516 pg/mL** **7 Months–7 Years: 24–300 pg/mL** **8–30 Years: 47–383 pg/mL** **31–72 Years: 10–357 pg/mL**	2/16/21
LSD, Urine	ULSD	**Special Information:** Specimens received at room temperature or in glass containers will be rejected. If positive, turnaround time may be extended **to 16 days.**	2/16/21
Magnesium, Urine 24 Hour	UMAGD	**Stability:** Ambient: **30 days** Refrigerated: **30 days** Frozen: **30 days** **Days Performed: Wednesday** **Reported:** 1–8 days	3/9/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Magnesium, Urine Random	UMAGR	**Stability:** Ambient: **30 days** Refrigerated: **30 days** Frozen: **30 days** **Reference Range:** 0–99 Years: ≤ **23.2 mg/dL** **Days Performed: Wednesday** **Reported:** 1–8 days	3/9/21
Mannose Binding Lectin	MANNO	**Special Information: Separate specimens must be submitted when multiple tests are ordered. This test is New York DOH approved.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.2 mL; Separate serum from cells within two hours of collection; Separate specimens must be submitted when multiple tests are ordered; **Critical Frozen** *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.2 mL; Separate serum from cells within two hours of collection; Separate specimens must be submitted when multiple tests are ordered; **Critical Frozen** *OR* 1 mL plasma from a lithium heparin (green) tube; Minimum: 0.2 mL; Separate plasma from cells within two hours of collection; Separate specimens must be submitted when multiple tests are ordered; **Critical Frozen** **Stability:** Ambient: **Unacceptable** Refrigerated: **Unacceptable** Frozen: After separation from cells: 1 year **(Avoid repeated freeze/thaw cycles)**	2/16/21
Maternal Serum Screen, First Trimester, hCG, PAPP-A, NT	MATFIR	**For Interfaced Clients Only: Test build may need to be modified** *(Note: Add component Donor Egg Age at Harvest)* **Stability:** Ambient: After separation from cells: 72 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: **1 year** (Avoid repeated freeze/thaw cycles)	2/16/21
NTRK Next Generation Sequencing	NTRK	CPT: 81194 x 1	Effective immediately
Platelet Function Screen	PLTSCP	**Note:** *The go-live date is TBD for changes previously announced in the January Technical Update.*	TBD
PML/RARA RTPCR	APLPCR	**For Interfaced Clients Only: Test build may need to be modified** *(Note: Add component PML-RARA Translocation Source)*	2/16/21
Prometheus Anser ADA	ANSADA	CPT: 80145 x 1, 82542 x 1	Effective immediately
Prometheus Anser IFX	ANSIFX	CPT: 80230 x 1, 82542 x 1	Effective immediately
Prometheus Anser UST	ANSUST	CPT: 80299 x 1, 82542 x 1	Effective immediately
Prometheus Anser VDZ	ANSVDZ	CPT: 80280 x 1, 82542 x 1	Effective immediately
Prometheus Monitr Crohn's Disease	MCROHN	**Methodology:** **Chemiluminescence (CL)** Multiplex Bead Assay Nephelometry (NEPH) **CPT: 82397 x 1,** 83520 **x 11,** 86141 x 1	Effective immediately
Prothrombin Time and PTT Elevation Diagnostic Panel	PTPTTE	**Note:** *The go-live date is TBD for changes previously announced in the January Technical Update.*	TBD
Prothrombin Time Elevation Diagnostic Panel	PTEPNL	**Note:** *The go-live date is TBD for changes previously announced in the January Technical Update.*	TBD
SF3B1 Mutation Analysis Blood	SF3B1P	**CPT: 81347 x 1**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
SF3B1 Mutation Analysis Bone Marrow	SF3B1M	**CPT: 81347 x 1**	Effective immediately
Tapentadol and Metabolite Confirm/ Quantitation, Urine	TAPENU	**Specimen Requirement:** 2 mL random urine in a clean container; Minimum: 1 mL; **Refrigerated** **Days Performed: Monday** **Reported:** 2–**9** days	2/16/21

New Tests

Test Name	Order Code	Change	Effective Date
Autoimmune Encephalopathy Evaluation, CSF	ENCCSF	**Includes:** Encephalopathy Interpretation, CSF AMPA-R Ab CBA, CSF Amphiphysin Ab, CSF Anti-Glial Nuclear Ab, Type 1 Anti-Neuronal Nuclear Ab, Type 1 Anti-Neuronal Nuclear Ab, Type 2 Anti-Neuronal Nuclear Ab, Type 3 CASPR2-IgG CBA, CSF CRMP-5-IgG, CSF DPPX Ab IFA, CSF GABA-B-R Ab CBA, CSF GAD65 Ab Assay, CSF GFAP IFA, CSF IgLON5 IFA, CSF LGI1-IgG CBA, CSF mGluR1 Ab IFA, CSF NIF IFA, CSF NMDA-R Ab CBA, CSF Purkinje Cell Cytoplasmic Ab Type Tr Purkinje Cell Cytoplasmic Ab Type 1 Purkinje Cell Cytoplasmic Ab Type 2 **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 is 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 IgLON5 cell-binding assay (CBA) is 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 IFA pattern suggests GABA-B-receptor antibody, and GABA-B-receptor antibody CBA 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. 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. Relevant clinical information, ordering provider name, phone number, mailing address, and e-mail address are required. Grossly hemolyzed, lipemic or icteric specimens will be rejected. *(continued on page 9)*	3/23/21

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Autoimmune Encephalopathy Evaluation, CSF *(continued from page 8)*		**Clinical Information:** Aids in evaluating new onset encephalopathy (noninfectious or metabolic) comprising confusional states, psychosis,delirium, memory loss, hallucinations, movement disorders, sensory or motor complaints, seizures, dyssomnias, ataxias, nausea, vomiting, inappropriate antidiuresis, coma, dysautonomias, or hypoventilation in spinal fluid specimens. A diagnosis of autoimmune encephalopathy should be suspected on the basis of clinical course, coexisting autoimmune disorder (e.g., thyroiditis, diabetes), serological evidence of autoimmunity, spinal fluid evidence of intrathecal inflammation, neuroimaging or electroencephalographic abnormalities, and favorable response to trial of immunotherapy. Detection of one or more neural autoantibodies aids the diagnosis of autoimmune encephalopathy and may guide a search for cancer. Importantly, autoimmune encephalopathies are reversible. Misdiagnosis as a progressive (currently irreversible) neurodegenerative condition is not uncommon and has devastating consequences for the patient. Clinicians must consider the possibility of an autoimmune etiology in the differential diagnoses of encephalopathy. **Specimen Requirement:** 4 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 2 mL; Relevant clinical information, ordering provider name, phone number, mailing address, and e-mail address are required; Refrigerated **Stability:** Ambient: 72 hours Refrigerated: 28 days Frozen: 28 days **Methodology:** Cell Binding Assay (CBA) Immunoblot (IB) Indirect Immunofluorescence Assay (IFA) Radioimmunoassay (RIA) Western Blot (WB) **Days Performed:** Sunday–Saturday **Reported:** 9–12 days **CPT:** 86255 x 19, 86341 x 1 **Price:** $859.00 (non-discountable)	
Autoimmune Encephalopathy Evaluation, Serum	ENCSER	**Includes:** Encephalopathy Interpretation, S AChR Ganglionic Neuronal Ab, 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 N-Type Calcium Channel Ab P/Q-Type Calcium Channel Ab PCA-1, S PCA-2, S PCA-Tr, S **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, ACh receptor (muscle) binding antibody, and ACh receptor (muscle) modulating antibody are performed. If IFA patterns suggest amphiphysin antibody, then amphiphysin immunoblot is performed. *(continued on page 10)*	3/23/21

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Autoimmune Encephalopathy Evaluation, Serum *(continued from page 9)*		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 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, ACh receptor (muscle) binding antibody, and ACh receptor (muscle) modulating antibody are performed. If CASPR2-receptor antibody CBA is positive, then CRMP-5-IgG Western blot, ACh receptor (muscle) binding antibody, and ACh receptor (muscle) modulating 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. 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. 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 Information:** This test is useful for evaluating new onset encephalopathy (noninfectious or metabolic) comprising confusional states, psychosis, delirium, memory loss, hallucinations, movement disorders, sensory or motor complaints, seizures, dyssomnias, ataxias, nausea, vomiting, inappropriate antidiuresis, coma, dysautonomias, or hypoventilation in serum specimens. Diagnosis of autoimmune encephalopathy should be suspected on the basis of clinical course, coexisting autoimmune disorder (e.g., thyroiditis, diabetes), serological evidence of autoimmunity, spinal fluid evidence of intrathecal inflammation, neuroimaging or electroencephalographic abnormalities, and favorable response to trial of immunotherapy. Detection of one or more neural autoantibodies aids the diagnosis of autoimmune encephalopathy and may guide a search for cancer. Importantly, autoimmune encephalopathies are reversible. Misdiagnosis as a progressive (currently irreversible) neurodegenerative condition is not uncommon and has devastating consequences for the patient. Clinicians must consider the possibility of an autoimmune etiology in the differential diagnoses of encephalopathy. Neurological accompaniments of neural autoantibodies are generally not syndromic, but diverse and multifocal. **Specimen Requirement:** 4 mL serum from a plain no additive (red) tube; Minimum: 2.5 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: 2.5 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 11)*	

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Autoimmune Encephalopathy Evaluation, Serum *(continued from page 10)*		**Stability:** Ambient: 72 hours Refrigerated: 28 days Frozen: 28 days **Methodology:** Cell Binding Assay (CBA) Immunoblot (IB) Indirect Immunofluorescence Assay (IFA) Radioimmunoassay (RIA) Western Blot (WB) **Days Performed:** Sunday–Saturday **Reported:** 11–14 days **CPT:** 83519 x 3, 86255 x 19, 86341 x 1 **Price:** $1085.00 (non-discountable)	
Methylenetetrahydrofolate Reductase (MTHFR) Mutation, 2 Variants	MTHFRM	**Special Information:** This test is New York DOH approved. **Clinical Information:** Reference Interval: Negative, Neither of the MTHFR variants tested, c.665C>T (previously designated C677T) and c.1286A>C (previously designated A1298C), were detected. Other causes of elevated homocysteine levels were not evaluated. This test determines genetic contribution to hyperhomocysteinemia for individuals with elevated plasma homocysteine. It is not recommended for recurrent pregnancy loss, thrombophilia screening, neural tube defect risk assessment, or testing of family members of individuals with identified MTHFR variants. **Specimen Requirement:** 3 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; Refrigerated *OR* 3 mL whole blood in an ACD A (yellow) or ACD B (yellow) tube; Minimum: 1 mL; Refrigerated **Stability:** Ambient: 72 hours Refrigerated: 2 weeks Frozen: 1 month **Methodology:** Fluorescence Monitoring Polymerase Chain Reaction (PCR) **Days Performed:** Sunday–Saturday **Reported:** 3–7 days **CPT:** 81291 x 1 **Price:** $209.00 (non-discountable)	3/16/21

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
ABO/Rh and Antigen Testing	ABOAG	$56.00 (non-discountable)	86900, 86901	Effective immediately
Beta-Glucosidase, Leukocytes	GAUCHD	$466.00 (non-discountable)	82963	Effective immediately
Growth Differentiation Factor 15 (GDF15), Plasma	GDF15	$166.00 (non-discountable)	83520	Effective immediately
Orexin A, Spinal Fluid	ORXCSF	$952.00 (non-discountable)	83519	Effective immediately
Prometheus Monitr Crohn's Disease	MCROHN	$570.00 (non-discountable)	82397, 83520 x 11, 86141	Effective immediately
Warfarin Sensitivity (CYP2C8, CYP2C9, CYP4F2, VKORC1) Genotyping	WRFSEN	$355.00 (non-discountable)	81227, 81355, 81479	Effective immediately

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Carbohydrate, Urine	UCARB	$103.00 (non-discountable)	84377	Effective immediately
Prometheus Anser ADA	ANSADA	$900.00 (non-discountable)	80145, 82542	Effective immediately
Prometheus Anser IFX	ANSIFX	$900.00 (non-discountable)	80230, 82542	Effective immediately
Prometheus Anser UST	ANSUST	$900.00 (non-discountable)	80299, 82542	Effective immediately
Prometheus Anser VDZ	ANSVDZ	$900.00 (non-discountable)	80280, 82542	Effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
ADmark PS-1 Analysis, Symptomatic	PS1SY	This test will no longer be available.	4/6/21
DNA Content, Cell Cycle Analysis, Ploidy and S-Phase	DNAMIS	This test will no longer be available.	4/6/21
Encainide	ENCAIN	This test will no longer be available.	4/6/21
Fibrinogen Panel	FIBPN	This test will no longer be available.	4/6/21
FISH Neuroblastoma 2p24 MYCN Amp	MYCNFB	This test will no longer be available.	Effective immediately
Growth Hormone, 60 Minutes	GH60MN	This test will no longer be available.	4/6/21
Interleukin 28B Associated Variants, 2 SNPs	IL28B	This test will no longer be available.	2/16/21
Ipecac Biomarkers	IPECAC	This test will no longer be available.	4/6/21
IPF1 (NDM) DNA Sequencing Test	IPFNDM	This test will no longer be available.	4/6/21
KCNJ11 (CH) DNA Sequencing Test	KCNJCH	This test will no longer be available.	4/6/21
MTHFR Gene Analysis	MTHF	This test will no longer be available. Suggest ordering Methylenetetrahydrofolate Reductase (MTHFR) Mutation, 2 Variants (MTHFRM)	3/16/21
Neoencephalitis Paraneoplastic Profile with Recombx	CEPHAL	This test will no longer be available. Suggest ordering alternative test Autoimmune Encephalopathy Evaluation, Serum (ENCSER)	3/23/21
Organic Acids, Plasma	ORGACS	This test will no longer be available.	2/16/21
PINK1 DNA Sequencing	PINK1	This test will no longer be available.	4/6/21
Pipecolic Acid, Urine	UPIPE	This test will no longer be available.	4/6/21
Reptilase Time with Reflex to Reptilase Time 1:1 Mix	REPMIX	This test will no longer be available.	4/6/21
Respiratory Chain Complexes, Fibroblast	RCCF	This test will no longer be available.	4/6/21
Specific Gravity, Synovial Fluid	SFSPGV	This test will no longer be available.	3/11/21