Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • April 2025

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 Laboratory Customer Service 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
3	Acanthamoeba species Molecular Detection, PCR, Ocular						■						
12	Adenovirus Antibody				■								
12	ALLOGEN Chimerism NGS			■									
3	Amiodarone and Metabolite		■			■	■	■	■	■	■	■	
3	APC Resistance						■			■			
4	Aspergillus fumigatus Antibody IgG					■				■			
4	Autoimmune Pediatric CNS Disorders, CSF					■		■					
4	Autoimmune Pediatric CNS Disorders, Serum					■		■					
5	Blood Parasite Microscopy smear, including % parasitemia												■
5	Bordetella pertussis and parapertussis DNA, NAAT, Nasopharyngeal Swab					■	■		■			■	
12	CA 27.29				■								
6	Copeptin proAVP, Plasma		■			■	■		■	■	■	■	
6	Dermatomyositis Autoantibody Panel						■		■				■
6	Des-gamma-carboxy Prothrombin		■			■	■						
6	G6PD Quantitative	■	■				■					■	
7	Glutathione Total						■						
7	Hepatitis Delta Virus by Quantitative PCR					■	■						
7	HIV 1 Drug Resistance by Next Generation Sequencing						■						

Test Update Page #		Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT
7	Homovanillic Acid (HVA), 24 Hour Urine		■			■	■						
12	Hops, IgE allergen				■								
7	Human Herpesvirus 6 (HHV-6A and HHV-6B) by Quantitative PCR					■		■					
8	Hypercoagulation Diagnostic Interpretive Panel							■		■			■
8	Hypersensitivity Pneumonitis Evaluation							■		■			■
8	Lipid Panel, Fasting					■							
8	Lipid Panel, Nonfasting					■							
9	Lupus Anticoagulant Diagnostic Interpretive Panel					■		■		■			■
9	Mycoplasma genitalium NAAT											■	
9	Neuronal Nuclear Antibodies (Hu, Ri, Yo, Tr/DNER) IgG by Immunoblot, Serum					■		■					
10	Polymyositis and Dermatomyositis Panel						■		■				■
10	Prothrombin Time Mixing Study									■			
10	Rabies Antibody						■						
10	Routine, Prenatal Group B Streptococcus by PCR		■							■			
12	UBA1 Mutation Detection by ddPCR for VEXAS Syndrome Blood			■									
12	UBA1 Mutation Detection by ddPCR for VEXAS Syndrome Bone Marrow			■									
12	UBA1 Mutation Detection by ddPCR for VEXAS Syndrome Other			■									
12	UBA1 Mutation Testing for VEXAS Syndrome				■								
10–11	Vanillylmandelic Acid (VMA) and Homovanillic Acid (HVA), Random Urine		■			■	■	■		■			■
11	Varicella Zoster IgG Ab, CSF									■			
11	Vitamin B2					■	■					■	

Test Changes

Test Name	Order Code	Change	Effective Date
Acanthamoeba species Molecular Detection, PCR, Ocular	ACARPO	**Specimen Requirement:** 10 mm square of eye tissue in sterile container; Refrigerated; Specimen source required. Submit 5–10 mm fresh eye tissue in a sterile container with 1 mL of sterile saline, minimal essential media (MEM), or viral transport media. *OR* 1 mL eye tissue in sterile container; Refrigerated; Specimen source required. Ocular or cornea scrapings. Collect scrapings using a scalpel or other sharp device to remove the outer layer of cells from the eye. Swish the collection device in 1 mL of sterile saline, minimal essential media (MEM), or viral transport media. Remove the collection device from the collection container before submitting to the lab. Minimum 0.5mL *OR* one sterile container of contact lens; **Refrigerated**; Specimen source required. Contact lens. Indicate Right or Left in the specimen source. Place entire contact lens in a sterile container with 1 mL sterile saline, viral transport media, or minimal essential media (MEM). Additional contact lens must be ordered and submitted separately. *OR* one sterile container of contact lens case (without lens); Specimen source required. Indicate Right or Left chamber in the specimen source. If right and left chambers are separate and both must be tested, separate orders must be submitted. **Note:** *swabs are no longer acceptable specimens*	effective immediately
Amiodarone and Metabolite	AMIOD	**For interface clients only–Test build may need to be modified** **Name:** Previously Amiodarone **Includes:** Amiodarone **N-Desethyl-Amiodarone** **Special Information: Critical Frozen. Protect from light. Collect predose (trough) draw–at steady state concentration. Additional specimens must be submitted when multiple tests are ordered. This test is New York state approved.** **Clinical Information: This test is useful to optimize drug therapy and monitor patient adherence.** **Specimen Requirement: 1** mL serum from no additive (Red) tube; Minimum: **0.5** mL; **Critical** Frozen; **Collect predose (trough) specimen.** Separate serum from cells **ASAP or within 2 hours of collection and transfer to amber standard transport tube to protect from light. Additional specimens must be submitted when multiple tests are ordered.** *OR* **1 mL plasma from EDTA (Lavender) tube; Minimum: 0.5 mL; Critical Frozen; Collect predose (trough) specimen. Separate plasma from cells ASAP or within 2 hours of collection and transfer to amber standard transport tube to protect from light. Additional specimens must be submitted when multiple tests are ordered.** **Stability:** Ambient: **After separation from cells: Unacceptable** Refrigerated: **After separation from cells: Unacceptable** Frozen: **After separation from cells: 1 year** **Methodology: Quantitative Liquid Chromatography–Tandem Mass Spectrometry** **Reference Range:** Amiodarone: **Therapeutic Range: 0.5-2.0 µg/mL** **Toxic Level: Greater than 2.5 µg/mL** **Days Performed: Mon,** Tue, Thu, **Fri, Sat** **Reported: 2–8** days	5/20/25
APC Resistance	APC	**Specimen Requirement:** 2 mL plasma from sodium citrate (Light Blue) tube; **Centrifuge, aliquot and freeze ASAP. Collection tube must be filled to total fill volume. Inadequately filled tubes will be rejected. Invert to mix 3-4 times. Non-Testing Sites: Centrifuge sample; Aliquot plasma into a separate tube and label with Epic Beaker labels. Specimens should be frozen (-20C or colder).** **Stability:** Ambient: Main Campus: **ACCEPTABLE for Whole Blood. (Must be delivered ambient to testing lab less than** 4 hours **post collection). Non-Testing Sites: UNACCEPTABLE.** Refrigerated: Unacceptable Frozen: **For Non-Testing Sites: Frozen Plasma is ACCEPTABLE. Centrifuge sample, then aliquot plasma into a separate tube and label with Epic Beaker label. Specimen should be frozen (-20 C or colder) and is stable for 2 months.** **Reference Range: >=2.90** Ratio	5/20/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Aspergillus fumigatus Antibody IgG	ASPIGG	**Special Information:** This test is New York DOH approved. **Clinical Information:** This test aids in the diagnosis of allergic bronchopulmonary aspergillosis (ABPA) and is not appropriate for diagnosing invasive aspergillosis. **A positivity cutoff of 40 μg/mL was established based on a comparison study to precipitin assay results. Note that elevated specific IgG concentrations to Aspergillus fumigatus are not disease specific and could be found in healthy individuals. Results must be interpreted in the context of patient's clinical, laboratory, and radiologic findings, and in concordance with current practice guidelines.** **Reference Range: Less than or equal to 40.0 μg/mL**	4/21/25
Autoimmune Pediatric CNS Disorders, CSF	APCNSC	**For interface clients only–Test build may need to be modified** **Special Information:** Reflex Algorithm: Each reflex test performed incurs additional charge. If NMDA CSF antibody IgG is positive, then titer will be performed. PCCA/ANNA antibody IgG is screened by IFA. If the IFA screen is indeterminate, then a Neuronal Nuclear Antibodies (Hu andTr/DNER) IgG by Immunoblot will be performed. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu and Tr/DNER) IgG by Immunoblot will be performed. If LGI1 CSF antibody IgG is positive, then titer will be added. If CASPR2 CSF antibody IgG is positive, then titer will be added. If AQP4/NMO CSF antibody IgG by IFA is positive, then titer will be added. If GABA-BR CSF antibody IgG by IFA is positive, then titer will be added. If DPPX CSF antibody IgG by IFA is positive, then titer will be added. If mGluR1 CSF antibody IgG by IFA is positive, then titer will be added. If GABA-AR CSF antibody IgG by IFA is positive, then titer will be added. **If AMPA CSF antibody is positive, then titer will be added.** Grossly hemolyzed specimens will be rejected. This test is New York state approved. **Reference Range:** Paraneoplastic Abs (PCCA/ANNA) IgG, CSF: None detected Glutamic Acid Decarboxylase Antibody CSF: 0.0–5.0 IU/mL DPPX Ab IgG CBA-IFA Screen, CSF: Less than 1:1 mGluR1 Ab IgG CBA-IFA Screen, CSF: Less than 1:1 NMO/AQP4 Ab IgG CBA-IFA Screen, CSF: Less than 1:1 NMDA Receptor Ab IgG CBA-IFA, CSF: Less than 1:1 GABA-BR Ab IgG CBA-IFA Screen, CSF: Less than 1:1 CASPR2 Ab IgG CBA-IFA Screen, CSF: Less than 1:1 LGI1 Ab IgG CBA-IFA Screen, CSF: Less than 1:1 GABA-AR Ab IgG CBA-IFA Screen, CSF: Less than 1:1 **AMPA Receptor Ab IgG CBA-IFA Screen, CSF: Less than 1:1**	4/21/25
Autoimmune Pediatric CNS Disorders, Serum	APCNSS	**For interface clients only–Test build may need to be modified** **Special Information:** Reflex Algorithm: Each reflex test performed incurs additional charge. If NMDA antibody IgG is positive, then titer will be performed. PCCA/ANNA antibody IgG is screened by IFA. If the IFA screen is indeterminate, then a Neuronal Nuclear Antibodies (Hu and Tr/DNER) IgG by Immunoblot will be performed. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu and Tr/DNER) IgG by Immunoblot will be performed. If LGI1 antibody IgG is positive, then titer will be added. If CASPR2 antibody IgG is positive, then titer will be added. If AQP4/NMO antibody IgG by IFA is positive, then titer will be added. If GABA-BR antibody IgG by IFA is positive, then titer will be added. If MOG antibody IgG by IFA is positive, then titer will be added. If DPPX antibody IgG by IFA is positive, then titer will be added. If mGluR1 antibody IgG by IFA is positive, then titer will be added. If GABA-AR antibody IgG by IFA is positive, then titer will be added. **If AMPA antibody IgG by IFA is positive, then titer will be added.** Contaminated, hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state approved. **Reference Range:** Purkinje Cell/Neuronal Nuclear IgG Scrn: None detected DPPX Ab IgG CBA-IFA Screen, Serum: Less than 1:10 Glutamic Acid Decarboxylase Antibody: 0.0–5.0 IU/mL mGluR1 Ab IgG CBA-IFA Screen, Serum: Less than 1:10 NMDA Receptor Ab IgG CBA-IFA, Serum: Less than 1:10 CASPR2 Ab IgG CBA-IFA Screen, Serum: Less than 1:10 LGI1 Ab IgG CBA-IFA Screen, Serum: Less than 1:10 GABA-BR Ab IgG CBA-IFA Scrn, Ser: Less than 1:10 NMO/AQP4 Ab IgG CBA-IFA Screen, Serum: Less than 1:10 MOG Ab IgG CBA-IFA Screen, Serum: Less than 1:10 GABA-AR Ab IgG CBA-IFA Screen, Serum: Less than 1:10 **AMPA Receptor Ab IgG CBA-IFA Scrn, Serum: Less than 1:10**	4/21/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Blood Parasite Microscopy smear, including % parasitemia	BPMSM	**CPT: 87015**; 87207	5/20/25
Bordetella pertussis and parapertussis DNA, NAAT, Nasopharyngeal Swab	BORAMP	**Includes:** Bordetella pertussis DNA Bordetella parapertussis DNA **Clinical Limitation:** The IS481 **insertional element can also be present in B. holmesii and B. bronchiseptica. Specimens collected from patients with respiratory infection caused by B. pertussis, B. holmesii or B. bronchiseptica may yield positive test results in IS481 assays.** B. holmesii infection may cause clinical illness similar to B. pertussis, and mixed outbreaks involving both B. pertussis and B. holmesii infection have been reported. Additional testing should be performed if necessary to differentiate B. holmesii and B. pertussis. B. bronchiseptica is a rare cause of infection in humans. When clinical factors suggest that B. pertussis may not be the cause of respiratory infection, other clinically appropriate investigation(s) should be carried out in accordance with published guidelines. Environmental contamination of an exam room from a prior patient or a recent pertussis vaccination administration may result in false-positive test results. As with any nucleic acid amplification test, positive results do not rule out coinfection with other organisms, detected organisms may not be the definite cause of disease, and negative results do not rule out infection. **Clinical Information:** Bordetella pertussis (BP), a gram-negative bacterium, is the predominant causative agent of whooping cough or pertussis, a vaccine-preventable, highly infectious disease that is reportable to public health organizations. Pertussis occurs most commonly in children but also occurs in adolescents and adults and outbreaks have been documented in fully vaccinated populations due to waning immunity (immunity has been shown to decrease 5-10 years after vaccination). Early (catarrhal) pertussis disease is non-specific, and classic signs of pertussis (paroxysmal coughing, inspiratory 'whoop', post-tussive emesis, as well as apnea or cyanosis in infants) do not arise until approximately two weeks after the initial onset of symptoms. Bordetella parapertussis (BPP) is known to cause a milder pertussis-like disease. For diagnosis of pertussis, NAAT performed on a nasopharyngeal swab collected within 2-3 weeks of symptom onset is the most sensitive method. The Simplexa Bordetella **Direct** Assay is an in vitro diagnostic test for the qualitative detection **and differentiation** of Bp and BPP nucleic acids from nasopharyngeal specimens from patients **with signs and symptoms of Bordetella infection of the respiratory tract.** The assay uses **real-time PCR** to target the IS481 and IS1001 sequence of BP and BPP genomes respectively. Both targets can exhibit cross reactivity with other members of the Bordetella genus. **Specimen Requirement:** 3 mL nasopharyngeal swab in Universal Transport Media (UTM); Refrigerated; 1. Tilt patient's head back 70 degrees. 2. Gently and slowly insert a mini-tipped flocked swab with a flexible shaft through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. 3. Gently rub and roll the swab. 4. Leave swab in place for several seconds to absorb secretions. 5. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril. 6. Place swab, tip first, into the transport tube provided. Break the swab shaft at the score line, discard the top portion of the stem, and close the cap. *OR* 3 mL nasopharyngeal swab in Viral transport Media; Refrigerated; Viral transport media (including VTM, M4RT, M5, or M6) may be used if UTM cannot be sourced. *OR* **1 mL nasopharyngeal swab in E-Swab; Refrigerated; Liquid Amies (E-Swab) may be used if UTM cannot be sourced.** **Stability:** Refrigerated: **7 days** Frozen: **Indefinite** at or below -70C **Methodology: Qualitative Real-Time PCR**	5/20/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Copeptin proAVP, Plasma	ADH	**For interface clients only–Test build may need to be modified** **Name:** Previously Arginine Vasopressin **Special Information: This test is New York DOH approved.** **Clinical Information: This test is useful for Investigating the differential diagnosis for patients with water balance disorders, including diabetes insipidus, in conjunction with osmolality and hydration status. May aid in the evaluation of cardiovascular disease in conjunction with other cardiac markers.** **Specimen Requirement: 2** mL plasma from EDTA (Lavender) tube; Minimum: **1** mL; **Refrigerated; Separate** plasma from cells **ASAP or** within 2 hours of collection **and transfer to standard aliquot tube.** **Stability:** Ambient: After separation from cells: **7 days** Refrigerated: **After separation from cells: 7 days** Frozen: After separation from cells: 1 month **Methodology: Immunofluorescence** **Reference Range: 1.0–13.0 pmol/L** **Days Performed: Sun–Sat** **Reported: 2–5** days	4/21/25
Dermatomyositis Autoantibody Panel	DERMYO	**Specimen Requirement: 4** mL serum from serum separator (Gold) tube; Minimum: **1** mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. **Methodology:** Immunoblot (IB), Qualitative Immunoprecipitation **Qualitative Particle-Based Multianalyte Technology (PMAT)** Semi-Quantitative Indirect Fluorescent Antibody **CPT:** 83516x**6**; 86039x1	4/21/25
Des-gamma-carboxy Prothrombin	PIVKA	**Name:** Previously Des-Gamma-Carboxy Prothrombin, Serum **Special Information:** Plasma is unacceptable. This test is New York **state** approved. **Clinical Limitation: Medication containing vitamin K preparations may cause a negative bias of the DCP values. Medication containing vitamin K antagonist or antibiotic may cause a positive bias of the DCP values.** **Clinical Information:** The μTASWako method is used. Results obtained with different assay methods or kits cannot be used interchangeably. The des-gamma-carboxy prothrombin (DCP) assay is intended as a risk assessment for the development of hepatocellular carcinoma in patients with chronic liver diseases. Elevated DCP values have been shown to be associated with an increased risk for developing hepatocellular carcinoma. Patients with elevated serum DCP should be more intensely evaluated for evidence of hepatocellular carcinoma. **Specimen Requirement:** 1 mL serum from no additive (Red) tube; Refrigerated; Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection and transfer **to** standard aliquot tube. *OR* 1 mL serum from serum separator (Gold) tube; Refrigerated; Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection and transfer **to** standard aliquot tube.	4/24/25
G6PD Quantitative	QTG6PD	**For interface clients only–Test build may need to be modified** **Order Code:** Previously QTG6PD **Name:** Previously G-6-PD Quantitative **Specimen Requirement:** 3 mL whole blood in EDTA (Lavender) tube; Refrigerated; **Collect two tubes.** Do NOT freeze. **Stability:** Ambient: 24 hours **for Hemoglobin;** 24 hours **for G6PD** Refrigerated: **48 hours for Hemoglobin;** 7 days **for G6PD** Frozen: Unacceptable **for both Hemoglobin and G6PD** **Methodology:** **Automated Cell Counter** Colorimetric, Kinetic Quantitative Enzymatic	5/20/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Glutathione Total	GLUTAT	**Specimen Requirement:** 10 mL whole blood in acid citrate dextrose (ACD) B (Yellow) tube; Place specimen on ice after draw. Transport refrigerated; **ACD tube must be filled to maintain ratio of blood-to-liquid anticoagulant.** Critical Refrigerated. Transport whole blood in original collection container **or transfer at least 1 mL to standard aliquot tube.** *OR* 8.5 mL whole blood in acid citrate dextrose (ACD) A (Yellow) tube; Place specimen on ice after draw. Transport refrigerated; **ACD tube must be filled to maintain ratio of blood-to-liquid anticoagulant.** Critical Refrigerated. Transport whole blood in original collection container **or transfer at least 1 mL to standard aliquot tube.**	effective immediately
Hepatitis Delta Virus by Quantitative PCR	HDVPCR	**Special Information:** Specimen source is required. **This test is New York DOH approved.** **Specimen Requirement: 2** mL serum from serum separator (Gold) tube; Frozen; Specimen source required. Separate serum from cells and transfer into sterile aliquot tube.	4/21/25
HIV 1 Drug Resistance by Next Generation Sequencing	HIVNGS	**Specimen Requirement:** 3 mL plasma from EDTA (Lavender) tube; Frozen; Separate plasma from cells within 24 hours and transfer plasma to a standard aliquot tube. Please submit most recent viral load and test date, if available. *OR* **3 mL plasma from white plasma preparation (PPT) EDTA tube; Frozen; Separate plasma from cells within 24 hours and transfer plasma to a standard aliquot tube. Please submit most recent viral load and test date, if available.**	effective immediately
Homovanillic Acid (HVA), 24 Hour Urine	UHVA	**Name:** Previously Homovanillic Acid (HVA), Urine **Special Information:** Indicate total volume. This test is New York DOH approved. **Clinical Information: Moderately elevated HVA (homovanillic acid) may be caused by a variety of factors such as essential hypertension, intense anxiety, intense physical exercise, and numerous drug interactions (including some over-the-counter medications and herbal products).** Medications **that** may interfere with catecholamines and their metabolites include amphetamines and amphetamine-like compounds, appetite suppressants, bromocriptine, buspirone, caffeine, chlorpromazine, clonidine, disulfiram, diuretics (in doses sufficient to deplete sodium), epinephrine, glucagon, guanethidine, histamine, hydrazine derivatives, imipramine, levodopa (L-dopa, Sinemet**(R)**), lithium, MAO inhibitors, melatonin, methyldopa (Aldomet**(R)**), morphine, nitroglycerin, nose drops, propafenone (Rythmol), radiographic agents, rauwolfia alkaloids (Reserpine), and vasodilators. The effects of some drugs on catecholamine metabolite results may not be predictable. **Interpretive Data: Homovanillic acid (HVA) results are expressed as a ratio to creatinine excretion (mg/g CRT). No reference interval is available for results reported in units of mg/L. Slight or moderate increases in catecholamine metabolites may be due to extreme anxiety, essential hypertension, intense physical exercise, or drug interactions. Significant increase of one or more catecholamine metabolites (several times the upper reference limit) is associated with an increased probability of a secreting neuroendocrine tumor. Per 24h calculations are provided to aid interpretation for collections with a duration of 24 hours and an average daily urine volume. For specimens with notable deviations in collection time or volume, ratios of analytes to a corresponding urine creatinine concentration may assist in result interpretation.** **Specimen Requirement:** 4 mL urine from 24-hour (well mixed) collection in clean container; Refrigerate during collection and transport refrigerated; Abstain from medications for 72 hours prior to collection.	4/21/25
Human Herpesvirus 6 (HHV-6A and HHV-6B) by Quantitative PCR	HHV6QT	**For interface clients only–Test build may need to be modified** **Includes:** **HHV6 Quant by PCR (copy/mL)** **HHV6 Quant by PCR (log copy/mL)** **HHV6 Quant by PCR (log IU/mL)** **HHV6 Quant by PCR (IU/mL)** **Clinical Limitation: If the assay Detected the presence of the virus but was not able to accurately quantify the number of copies, the test result will be report as "Not Quantified".** **Clinical Information:** Useful for detecting and quantifying HHV6 subtypes A and B in immunocompromised patients. The quantitative range of this assay is **2.7-6.7** log copies/mL (**500-5,000,000** copies/mL) **or 3.1-7.1 log IU/mL (1250-12,500,000 IU/mL). 1 copies/mL is approximately 2.5 IU/mL.** A negative result (**< 2.7** log copies/mL or **< 500** copies/mL**; < 3.1 log IU/mL or < 1250 IU/mL)** does not rule out the presence of PCR inhibitors in the patient specimen or HHV6 DNA in concentrations below the level of detection of the assay. Inhibition may also lead to underestimation of viral quantitation. **Reference Range: Not detected**	4/21/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hypercoagulation Diagnostic Interpretive Panel	HYPER	**For interface clients only–Test build may need to be modified** **Includes:** **Beta-2 Glycoprotein Antibodies** Cardiolipin Antibodies C-Reactive Protein APTTSC TT ANTIXA Protein C Functional PTGEN FVIIIC APC Antithrombin Assay PROT S Clot STACLOT LA **PT Screen** **Fibrinogen Activity** **Note:** *PT, APTT and Fibrinogen have been removed* **CPT:** 81240; 85240; 85300; 85303; 85307; 85384**x2;** 85390; 85520; 85598; 85610; 85670; 85730**x2**; 85732; 86140; **86146x2**; 86147x3	5/20/25
Hypersensitivity Pneumonitis Evaluation	HYPNE2	**For interface clients only–Test build may need to be modified** **Reference Range:** A. fumigatus #1 Ab, Precipitin: None detected A. fumigatus #6 Ab, Precipitin: None detected A. pullulans Ab, Precipitin: None detected Pigeon Serum Ab, Precipitin: None detected M. faeni Ab, Precipitin: None detected A. flavus Ab, Precipitin: None detected A. fumigatus #2 Ab, Precipitin: None detected A. fumigatus #3 Ab, Precipitin: None detected S. viridis Ab, Precipitin: None detected T. candidus Ab, Precipitin: None detected Allergen, Fungi/Mold, Phoma betae IgE: **Less than 0.10 kU/L: No significant level detected** **0.10–0.34 kU/L: Clinical relevance undetermined** **0.35–0.70 kU/L: Low** **0.71–3.50 kU/L: Moderate** **3.51–17.50 kU/L: High** **17.51 kU/L or Greater: Very High** Allergen, Animal, Feather Mix IgE: Negative Allergen, Interp, Immunocap Score IgE: Refer to report **Note:** *Allergen, Food, Beef IgE and Allergen, Food, Pork IgE components will be removed* **CPT:** 86003x**1**; 86005x1; 86606x5; 86331x5	4/21/25
Lipid Panel, Fasting	LIPB	**Special Information:** Patient should be fasting for a minimum of 12 hours and on a stable diet 3 weeks prior to collection. If Triglycerides are greater than **800** mg/dL, then LDL-Cholesterol, Direct will be performed and billed. Indicate the number of hours of fasting and age of patient on requisition. **Clinical Information:** Evaluation of hyper or hypolipidemia and risk for cardiovascular disease. **LDL cholesterol is calculated using the Sampson-NIH equation.**	4/15/25
Lipid Panel, Nonfasting	LIPNF	**Special Information:** The Direct LDL-Cholesterol measurement will be performed when triglycerides are greater than **800** mg/dL. If clinically indicated, a fasting Basic Lipid Panel may be ordered. Non-HDL cholesterol is invariant to fasting status, and can be utilized to evaluate risk. **Clinical Information:** Nonfasting lipid measurements may be used to estimate initial risk of atherosclerotic cardiovascular disease (ASCVD). **LDL cholesterol is calculated using the Sampson-NIH equation.**	4/15/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Lupus Anticoagulant Diagnostic Interpretive Panel	LUPUSP	**For interface clients only–Test build may need to be modified** **Includes:** Anticardiolipin Ab IgG, IgM and IgA Beta 2 Glycoproteins IgG and IgM APTT Screen Thrombin Time Anti Xa Inhibitor Assay Dilute Russell Viper Venom Time (DRVVT) Hexagonal Phase Phospholipid Neutralization (Staclot) Platelet Neutralization (PNP) FVIIIC **PT Screen** **Note:** *Prothrombin Time (PT) and APTT components have been removed* **Special Information:** 3.2% sodium citrate is the preferred anticoagulant recommended by NCCLS. Patient preparation: Discontinue heparin therapy for 2 days prior to collection. If tests are abnormal, the following tests may be ordered and billed: PTT Mixing Study (85730), Factor II (85210), Factor V (85220), Factor VII (85230), Factor X (85260), Von Willebrand Factor Antigen (85246), Ristocetin Co-factor (85245), Factor IX Assay (85250), Factor XI Assay (85270), Factor XII Assay (85280), Reptilase Time (85635), D-Dimer (85379), Fibrinogen Ag (85385), **Fibrinogen Activity (85384),** Bethesda Assay (85335), Factor VIII Chromogenic (85240), Antithrombin Assay (85300), Protein C Functional (85303), Protein S Clottable (85306), and APC Resistance (85307). Sample must be accompanied by the completed Clinical History Form for Hemostasis and Thrombosis Evaluation. **CPT:** 85240x1; 85390x1; 85520x1; 85598x1; 85610x1; 85670x1; 85730**x1**; 86146x2; 86147x3	5/20/25
Mycoplasma genitalium NAAT	MYGAMP	**Stability:** Ambient: 15˚C to 30˚C. Swab in Aptima transport media: 60 days; Urine in Aptima transport media: 30 days; Urine unprocessed: 24 hours Refrigerated: 2˚C to 8˚C. Swab in Aptima transport media: 60 days; Urine in Aptima transport media: 30 days; Urine unprocessed: 24 hours Frozen: -20˚C to -70˚C Swab in Aptima transport media: **90 days**; Urine in Aptima transport media: **90 days**; Urine unprocessed: unacceptable	4/1/25
Neuronal Nuclear Antibodies (Hu, Ri, Yo, Tr/DNER) IgG by Immunoblot, Serum	HURIYO	**For interface clients only–Test build may need to be modified** **Includes:** Neuronal nuclear Ab Hu, IgG Neuronal nuclear Ab Ri, IgG **Purkinje Cell Ab (Yo) IgG, IB, Ser** **Purkinje Cell Ab (TR/DNER) IgG, IB, Ser** **Special Information:** This test may be a reflex from Motor and Sensory Neuropathy Evaluation with Reflex to Titer and Neuronal Immunoblot (SENMOT) or Sensory Neuropathy Antibody Panel with Reflex to Titer and Neuronal Immunoblot (SENNRO). **Reflex algorithm: Each reflex test performed incurs additional charge. If positive (low/high), then the neuronal nuclear (ANNA) antibody and Purkinje cell (PCCA) antibody IgG are screened by IFA. If the IFA screen is positive at 1:10, then a specific titer (ANNA or PCCA) will be added.** Grossly hemolyzed, heat-inactivated, contaminated, or lipemic specimens will be rejected. **Clinical Information:** This assay detects IgG antineuronal antibodies to Hu, Ri, Yo and Tr (DNER) antigens. Antineuronal antibodies serve as markers that aid in discriminating between a true paraneoplastic neurological disorder (PND) and other inflammatory disorders of the nervous system. Anti-Hu (antineuronal nuclear antibody, type I) is associated with small cell lung cancer. Anti-Ri (antineuronal nuclear antibody, type II) is associated with fallopian tube and breast cancer in adults and neuroblastoma in children. Anti-Yo (anti-Purkinje cell cytoplasmic antibody) is associated with ovarian and breast cancer. Anti-Tr(DNER) is associated with Hodgkin lymphoma. Presence of one or more of these antineuronal antibodies **detected by both immunoblot (IB) and immunofluorescence (IFA)** supports a clinical diagnosis of PND and should lead to a focused search for the underlying neoplasm. **A positive IB result but negative IFA result is of questionable clinical significance. Thus, strong clinical correlation is recommended.**	4/21/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Polymyositis and Dermatomyositis Panel	MYOSPL	**Specimen Requirement: 4** mL serum from serum separator (Gold) tube; Minimum: 1 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection **and transfer to standard aliquot tube.** **Methodology:** Immunoblot (IB), Qualitative Immunoprecipitation **Qualitative Particle-Based Multianalyte Technology (PMAT)** Semi-Quantitative Indirect Fluorescent Antibody Semi-Quantitative Multiplex Bead Assay **CPT:** 83516x**11;** 84182**x3;** 86039x1; 86235x1	4/21/25
Prothrombin Time Mixing Study	PTMIX	**Reference Range:** PT Screen: 0 Days through 1 Day: **10.8-16.4** seconds 2 Days through 5 Days: **10.2-15.8** seconds 6 Days through 29 Days: **10.0-14.7** seconds 30 Days through 3 Months: **10.3-14.6** seconds 4 Months through 11 Months: **11.5-14.3** seconds 1 Year through 5 Years: **11.2-11.7** seconds 6 Years through 10 Years: **10.7-12.4** seconds 11 Years through 16 Years: **10.8-12.3** seconds 17 Years through 99 Years: **11.6-14.4** seconds	5/20/25
Rabies Antibody	RABIES	**Specimen Requirement:** 2 mL serum from no additive (Red) tube; **Frozen**; Transfer serum to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered. *OR* 2 mL serum from serum separator (Gold) tube; **Frozen**; Transfer serum to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered.	effective immediately
Routine, Prenatal Group B Streptococcus by PCR	GBPCR	**Name:** Previously Group B Streptococcus by PCR, Routine Prenatal Screening **Reference Range:** Grp B Streptococcus DNA, **Routine Prenatal: Not detected**	effective immediately
Vanillylmandelic Acid (VMA) and Homovanillic Acid (HVA), Random Urine	UVAHA	**For interface clients only–Test build may need to be modified** **Name:** Previously Vanillylmandelic Acid (VMA) and Homovanillic Acid (HVA), Urine **Includes:** Creatinine, Urine–per volume Vanillylmandelic Acid–per volume Vanillylmandelic Acid–ratio to CRT Homovanillic Acid–per volume Homovanillic Acid–ratio to CRT VMA and HVA Interpretation **Special Information: Critical Refrigerated.** Abstain from medications 72 hours prior to collection. This test is New York **state** approved. **Clinical Information: This test is useful as the initial test for the diagnosis and monitoring of neuroblastoma.** Vanillylmandelic acid (VMA) and homovanillic acid (HVA) results are expressed as a ratio to creatinine excretion (mg/g CRT). No reference interval is available for results reported in units of mg/L. **Slight or moderate increases in catecholamine metabolites may be due to extreme anxiety, essential hypertension, intense physical exercise, or drug interactions. Significant increase of one or more catecholamine metabolites (several times the upper reference limit) is associated with an increased probability of a secreting neuroendocrine tumor.** Moderately elevated HVA (homovanillic acid) and VMA (vanillylmandelic acid) can be caused by a variety of factors such as essential hypertension, intense anxiety, intense physical exercise, and numerous drug interactions (including some over-the-counter medications and herbal products). Medications that may interfere with catecholamines and their metabolites include amphetamines and amphetamine-like compounds, appetite suppressants, bromocriptine, buspirone, caffeine, chlorpromazine, clonidine, disulfiram, diuretics (in doses sufficient to deplete sodium), epinephrine, glucagon, guanethidine, histamine, hydrazine derivatives, imipramine, levodopa (L-dopa, **Sinemet**), **lithium,** MAO inhibitors, melatonin, methyldopa (Aldomet), **morphine,** nitroglycerin, nose drops, propafenone (Rythmol), radiographic agents, rauwolfia alkaloids (Reserpine), tricyclic antidepressants, and vasodilators. The effects of some drugs on catecholamine metabolite results may not be predicable. *(continued on page 11)*	4/21/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Vanillylmandelic Acid (VMA) and Homovanillic Acid (HVA), Random Urine *(continued from page 10)*		**Specimen Requirement:** 4 mL random urine in clean container; Refrigerated; Critical Refrigerated. Abstain from medications 72 hours prior to collection. **Note:** *24-hour urine is no longer accepted* **Reference Range:** VMA, Urine mg/g CRT: 0 Years to 2 Years: 0–27 mcg/g crt 3 Years to 5 Years: 0–13 mcg/g crt 6 Years to 17 Years: 0–9 mcg/g crt 18 Years to 99 Years: 0–6 mcg/g crt HVA, Urine mg/g CRT: 0 Years to 2 Years: 0–42 mg/g crt 3 Years to 5 Years: 0–22 mg/g crt 6 Years to 17 Years: 0–15 mg/g crt 18 Years to 99 Years: 0–8 mg/g crt VMA and HVA Interpretation: **Refer to report** **CPT:** 83150; 84585	
Varicella Zoster IgG Ab, CSF	CVZVG	**Reference Range:** **< 1.00 S/Co:** Negative–No significant level of IgG antibody to varicella-zoster virus detected **>/= 1.00 S/Co:** Positive–IgG antibody to varicella-zoster virus detected, which may indicate a current or past varicella-zoster infection	4/21/25
Vitamin B2	VITB2	**Special Information: Lipemic specimens will be rejected.** Protect specimen from light during collection, storage and shipment. This test is New York DOH approved. **Specimen Requirement:** 1 mL plasma from lithium heparin plasma separator (Light Green) tube; **Refrigerated**; Protect specimen from light during collection, storage and shipment. Separate plasma from cells within 1 hour of collection and transfer to amber transport tube. **Additional** specimens must be submitted when multiple tests are ordered. *OR* 1 mL plasma from sodium heparin plasma separator (Light Green) tube; **Refrigerated**; Protect specimen from light during collection, storage and shipment. Separate plasma from cells within 1 hour of collection and transfer to amber transport tube. **Additional** specimens must be submitted when multiple tests are ordered. *OR* 1 mL plasma from sodium or lithium heparin (Green) tube; **Refrigerated**; Protect specimen from light during collection, storage and shipment. Separate plasma from cells within 1 hour of collection and transfer to amber transport tube. **Additional** specimens must be submitted when multiple tests are ordered. **Stability:** Ambient: Unacceptable Refrigerated: **2 weeks** Frozen: 1 month	4/21/25

New Tests

Test Name	Order Code	Change	Effective Date
ALLOGEN Chimerism NGS	CHMNGS	**Specimen Requirement:** 60 ml whole blood in acid citrate dextrose (ACD) A (Yellow) tube; Minimum: 40 mL; Ambient **Methodology:** Next Generation DNA Sequencing **CPT:** 81479x2	5/1/2025
UBA1 Mutation Detection by ddPCR for VEXAS Syndrome Blood	UBA1	**Clinical Information:** This assay uses Droplet Digital PCR to detect seven mutations in the ubiquitin-like modifier activating enzyme 1 (UBA1) gene that causes VEXAS syndrome. **Specimen Requirement:** 4 mL whole blood in EDTA (Lavender) tube; Minimum: 1 mL; Collection and Transport Ambient **Stability:** Ambient: Whole blood and bone marrow for 48 hours, FFPE tissue indefinitely Refrigerated: Whole blood and bone marrow up to 7 days, FFPE tissue indefinitely Frozen: Unaccaptable **Methodology:** Droplet Digital Polymerase Chain Reaction (PCR) **Days Performed:** 1 day per week 7:30 am–5:00 pm **Reported:** 7 days **CPT:** 81403	effective immediately
UBA1 Mutation Detection by ddPCR for VEXAS Syndrome Bone Marrow	UBA1M	**Clinical Information:** This assay uses Droplet Digital PCR to detect seven mutations in the ubiquitin-like modifier activating enzyme 1 (UBA1) gene that causes VEXAS syndrome. **Specimen Requirement:** 2 mL whole bone marrow in EDTA (Lavender) tube; Minimum: 0.5 mL; Collection and Transport Ambient **Stability:** Ambient: Bone marrow-up to 48 hours Refrigerated: Bone marrow-up to 7 days Frozen: Bone marrow-unacceptable **Methodology:** Droplet Digital Polymerase Chain Reaction (PCR) **Days Performed:** 1 day per week 7:30 am–5:00 pm **Reported:** 7 days **CPT:** 81403	effective immediately
UBA1 Mutation Detection by ddPCR for VEXAS Syndrome Other	UBA1O	**Special Information:** Paraffin-embedded clots should be delivered to Anatomic Pathology for accessioning and cutting. **Clinical Information:** This assay uses Droplet Digital PCR to detect seven mutations in the ubiquitin-like modifier activating enzyme 1 (UBA1) gene that causes VEXAS syndrome. **Specimen Requirement:** 10 mm square paraffin block in clean container; Collection and Transport Ambient; Paraffin-embedded tissue should be delivered to Anatomic Pathology for accessioning and cutting. **Stability:** Ambient: Paraffin-embedded tissue- indefinitely Refrigerated: Paraffin-embedded tissue-unacceptable Frozen: Paraffin-embedded tissue-unacceptable **Methodology:** Droplet Digital Polymerase Chain Reaction (PCR) **Days Performed:** 1 day per week 7:30 am–5:00 pm **Reported:** 7 days **CPT:** 81403	effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Adenovirus Antibody	SADNAB	Test will no longer be orderable. There is no recommended replacement.	effective immediately
CA 27.29	CA2729	Test will no longer be orderable. Recommended replacement test is CA 15-3 (CA153).	5/20/25
Hops, IgE allergen	HPSIGE	Test will no longer be orderable. There is no recommended replacement.	effective immediately
UBA1 Mutation Testing for VEXAS Syndrome	VEXAS	Test will no longer be orderable. Recommended replacement tests are UBA1 Mutation Detection by ddPCR for VEXAS Syndrome Blood (UBA1), UBA1 Mutation Detection by ddPCR for VEXAS Syndrome Bone Marrow (UBA1M) or UBA1 Mutation Detection by ddPCR for VEXAS Syndrome Other (UBA1O).	effective immediately