Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • October 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
2	Adenovirus by Qualitative PCR											■	
2	Alpha-Galactosidase Enzyme Activity, Leukocytes						■				■		
2	Aripiprazole and Metabolite									■			
3	Cortisol Binding Globulin					■	■		■		■	■	
3	Cortisol, Saliva						■						
3	Diuretic Survey, Urine							■					
3	Fluphenazine					■				■			
3	Gastric Parietal Cell IgG Serum						■						
4	Glucagon					■	■		■	■		■	
4	Haloperidol					■				■			
4	Hantavirus IgG & IgM Abs					■	■				■		
4	Intrinsic Factor Blocking Antibody					■	■	■	■	■	■	■	
5–6	Meningitis Encephalitis Panel by PCR		■			■	■						
9	Norovirus Group 1 and 2 Detection by PCR				■								
9	Norwalk-Like Virus Antigen				■								
6	Phospholipids, Serum or Plasma						■						
6	Pneumocystis jirovecii PCR		■			■	■		■				
6	Polymyositis and Dermatomyositis Panel						■						
6	Pseudocholinesterase Phenotype						■						
7	Pseudocholinesterase, Total						■						

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	PTH, Intact					■				■			
7	PTH Intact, Fluid						■						
7	Quetiapine					■							
7	RBC Band 3 Protein Reduction in Hereditary Spherocytosis					■							
9	Rotavirus Antigen Detection				■								
7	RPR											■	
7	Send Out MTB Detection and Rifampin Resistance by PCR (CSF, Pleural fluid)		■			■	■						
7	Specific Gravity, Body Fluid											■	
8	Staphylococcus aureus & MRSA Screen, PCR, Nasal					■							
8	Thyroglobulin by LC-MS/MS, Serum or Plasma, for Thyroglobulin Antibody Interference						■						
9	Trypanosoma cruzi, IgG, Purified Antigen		■			■					■		
9	Volatile Screen, Urine				■								

Test Changes

Test Name	Order Code	Change	Effective Date
Adenovirus by Qualitative PCR	ADEPCR	**Stability:** Ambient: 24 hours (whole blood, plasma, serum, BAL, CSF, swab, sputum); **3 days (urine);** Unacceptable (tissue) Refrigerated: 5 days (whole blood, plasma, serum, BAL, CSF, swab, sputum); **14 days (urine);** Unacceptable (tissue) Frozen: 1 year (plasma, serum, BAL, CSF, swab, sputum); **14 days (urine);** 3 months (tissue)	10/20/25
Alpha-Galactosidase Enzyme Activity, Leukocytes	AGALAC	**Specimen Requirement:** 6 mL whole blood in acid citrate dextrose (ACD) B (Yellow) tube; Minimum: **4** mL; Refrigerated; Collect Monday–Wednesday only. Do not collect specimen on the day before a major holiday. Specimen must be sent to Cleveland Clinic Laboratories on the same day as collection. Send specimen in original tube. Do not transfer to other containers. *OR* 6 mL whole blood in acid citrate dextrose (ACD) A (Yellow) tube; Minimum: **4** mL; Refrigerated; Collect Monday–Wednesday only. Do not collect specimen on the day before a major holiday. Specimen must be sent to Cleveland Clinic Laboratories on the same day as collection. Send specimen in original tube. Do not transfer to other containers. *OR* 6 mL whole blood in EDTA (Lavender) tube; Minimum: **4** mL; Refrigerated; Collect Monday–Wednesday only. Do not collect specimen on the day before a major holiday. Specimen must be sent to Cleveland Clinic Laboratories on the same day as collection. Send specimen in original tube. Do not transfer to other containers. **Days Performed: Mon, Thu** **Reported: 3–6** days	10/14/25
Aripiprazole and Metabolite	ARPRZL	**Reference Range:** Therapeutic: 150.0–**350.0** ng/mL Toxic: >/= 1000.0 ng/mL	10/20/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cortisol Binding Globulin	CBG	**Clinical Information:** *removed* **Specimen Requirement:** 1 mL serum from red plain tube; Frozen; **Separate serum from cells within one hour of collection. Transfer specimen to a plastic transport tube before freezing. Separate specimens must be submitted when multiple tests are ordered.** *OR* 1 mL serum from gold serum separator tube; Frozen; **Separate serum from cells within one hour of collection. Transfer specimen to a plastic transport tube before freezing. Separate specimens must be submitted when multiple tests are ordered.** **Stability:** Ambient: **48 hours** Refrigerated: **48 hours** Frozen: **300 days** **Methodology: Radioimmunoassay (RIA)** **Days Performed: Varies** **Reported: 7–11** days	effective immediately
Cortisol, Saliva	SCORT	**Specimen Requirement:** Entire collection of saliva on swab; Refrigerated; Transfer saturated swab to Salivette® collection device (ARUP Supply #52056)**, available through Client Services at 216.444.5755.** Swab must be completely saturated to ensure sufficient volume for testing. **Collection should follow ARUP instructions provided with Salivete.** Record collection time on container and requisition. **Do not centrifuge Salivete. Full Salivette device must be returned: blue stopper, swab, insert, and tube.** Patient Preparation: Do not collect specimen within 60 minutes after eating a meal, within 12 hours after consuming alcohol, immediately after brushing teeth, **using mouthwash,** or after any activity that may cause gums to bleed. **Avoid using lipstick, ChapStick, and other lip items prior to sample collection. Avoid use of exogenous sources of cortisol (e.g., topical or oral hydrocortisone) or similar products during collection to reduce contamination.** Rinse mouth thoroughly with water 10 minutes before collecting specimen. Recommended collection time is between 11:00 p.m.–1:00 a.m.	10/20/25
Diuretic Survey, Urine	UDIU	**For interface clients only–Test build may need to be modified** **Reference Range:** Chlorothiazide: Refer to report Hydrochlorothiazide: Refer to report Hydroflumethiazide: Refer to report Chlorthalidone: Refer to report Metolazone: Refer to report Furosemide: Refer to report Bumetanide: Refer to report **Note:** *Benzthiazide has been removed*	effective immediately
Fluphenazine	FLUPH	**Clinical Information:** This test is useful to optimize drug therapy and monitor patient adherence. The therapeutic range is based on serum pre-dose (trough) draw at steady-state concentration. Adverse effects **to fluphenazine therapy** may include extrapyramidal symptoms, seizures and neuroleptic malignant syndrome. **Reference Range:** Therapeutic Range pre-dose (trough) draw at steady-state concentration: 1.0-10.0 ng/mL Toxic: Greater than or equal to **15.0** ng/mL	10/20/25
Gastric Parietal Cell IgG Serum	PARIES	**Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Minimum: **0.5** mL; Refrigerated	11/18/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Glucagon	GLUCA	**Special Information:** Fast **8**–12 hours prior to collection. Hemolyzed, **lipemic, icteric or clotted** specimens are unacceptable. Separate specimens must be submitted when multiple tests are ordered. This test is New York DOH approved. **Clinical Information:** Aid in **diagnosis and monitoring of glucagonoma.** **Specimen Requirement: 2 mL plasma from Lavender EDTA tube; Frozen; Fast 8 -12 hours prior to collection. Mix well. Separate from cells within 1 hour of collection and transfer plasma to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered.** **Stability:** Ambient: **After seperation from cells: 4 Hours** Refrigerated: **After separation from cells: 72** hours Frozen: **After separation from cells: 1** month **Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)** **Reference Range: < or = 150 pg/mL**	10/20/25
Haloperidol	HALOP	**Clinical Information:** Adverse effects **to haloperidol therapy** may include drowsiness, blurred vision, tardive dyskinesia, tachycardia, nausea and vomiting. **Reference Range:** Therapeutic range: **1.0–10.0** ng/mL Toxic: **> or = 15.0** ng/mL	10/20/25
Hantavirus IgG & IgM Abs	HANTAB	**Special Information:** This test is New York **State** approved. **Clinical Information: Hantavirus Antibody (IgG, IgM)–Two major groups of hantaviruses are recognized based on clinical presentation. The first group includes Sin Nombre Virus (SNV), which causes hantavirus pulmonary syndrome, a severe and sometimes fatal form of acute respiratory distress. A second group of hantaviruses (including Seoul, Hantaan, Dobrava, and Puumala) causes hemorrhagic fever with renal syndrome, a condition not typically seen in the United States. Sera are initially screened for IgG and IgM antibodies recognizing the nucleocapsid protein common to all hantaviruses.** All Hanta IgM positive samples from US residents will be sent to a Public Health Laboratory for SNV-specific IgM. **Specimen Requirement:** 0.5 mL serum from no additive (Red) tube; Minimum: **0.1** mL; Refrigerated; Centrifuge, aliquot and refrigerate. **Grossly hemolyzed, icteric, or lipemic samples will be rejected.** *OR* 0.5 mL serum from serum separator (Gold) tube; Minimum: **0.1** mL; Refrigerated; Centrifuge, aliquot and refrigerate. **Grossly hemolyzed, icteric, or lipemic samples will be rejected.** **Reported:** 2–**4** days	11/18/25
Intrinsic Factor Blocking Antibody	INTFCT	**For interface clients only–Test build may need to be modified** **Clinical Limitation: High serum levels of free vitamin B12 may give false positive results for intrinsic factor antibody. No sample should be collected from a patient who has received vitamin B12 injection therapy within the past week.** **Clinical Information: The test is used as an aid in diagnosing pernicious anemia. It is recommended to correlate with anti-parietal IgG antibody test result where autoimmune gastritis is clinically suspected.** **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Minimum: **0.5** mL; **Refrigerated** *OR* **1 mL serum from red plain tube; Minimum 0.5 mL; Refrigerated** **Stability:** Ambient: **24** hours Refrigerated: **7** days Frozen: **30 days** **Methodology: Immunoenzymatic Assay** **Reference Range:** Intrinsic Factor Blocking Antibody **Qualitative:** Negative **Intrinsic Factor Blocking Antibody Quantitative: <1.20 AU/mL** **Days Performed: Mon, Wed, Fri 7:00 am–3:30 pm**	11/18/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Meningitis Encephalitis Panel by PCR	MGEBF	**Name:** Previously Meningitis Encephalitis Panel **Includes:** **Escherichia coli DNA** **Haemophilus influenzae DNA** **Listeria monocytogenes DNA** **Neisseria meningitidis DNA** **Streptococcus agalactiae DNA** **Streptococcus pneumoniae DNA** **Cryptococcus neoformans/gattii DNA** **Enterovirus RNA** **Human parechovirus RNA** **Herpes simplex virus 1 (HSV-1) DNA** **Herpes simplex virus 2 (HSV-2) DNA** **Varicella zoster virus (VZV) DNA** **Cytomegalovirus (CMV) DNA** **Human herpesvirus 6 (HHV-6) DNA** **Clinical Limitation: For full limitations, refer to the assay instructions for use available on the manufacturer's website. The most important limitations are summarized as follows.** **This test is not intended for use with CSF collected from indwelling medical devices (e.g., CSF shunts).** **Only E. coli strains possessing the K1 capsular antigen will be detected by the BIOFIRE ME Panel. All other E. coli strains/serotypes will not be detected.** **Only encapsulated strains of N. meningitidis will be detected by the BIOFIRE ME Panel. Unencapsulated N. meningitidis will not be detected.** **Patients with a suspicion of cryptococcal meningitis and a negative cryptococcal PCR result, such as by the BIOFIRE ME Panel, should be tested for cryptococcal antigen (CrAg).** **Viral shedding into the CSF often occurs in cases of zoster (shingles; caused by reactivation of VZV). Detection of VZV in CSF may not indicate the cause of CNS disease in these cases.** **Herpesviruses (CMV, HHV-6, HSV-1, HSV-2, and VZV) can exist in latent forms that may be reactivated during infection by other pathogens, including agents not detected by the BIOFIRE ME Panel that may cause meningitis/encephalitis (e.g., Mycobacterium tuberculosis or HIV). HHV-6 can be chromosomally integrated into somatic cells (ciHHV-6) and into the germ cell line (iciHHV-6) allowing for persistent and sporadic reactivation in confirmed carriers or someone related to a confirmed carrier. When detected by the BIOFIRE ME Panel, herpesvirus results should be considered as the likely cause of meningitis/encephalitis only in appropriate clinical context and following expert consultation.** **In meta-analyses, this panel has been shown to be less analytically sensitive than targeted HSV-1/2 PCR testing. Standalone HSV-1/2 PCR testing should be considered for patients with a high pre-test probability of HSV encephalitis even if this panel is negative.** **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.** **Some patients may experience financial toxicity with this expanded multiplex panel, as it is variably reimbursed by insurance.** **Clinical Information: The Biofire FilmArray Meningitis/Encephalitis (ME) Panel is an FDA-approved qualitative multiplexed nucleic acid-based in vitro diagnostic test capable of simultaneous detection and identification of multiple bacterial, viral, and yeast nucleic acids directly from CSF specimens obtained via lumbar puncture from individuals with signs and/or symptoms of meningitis and/or encephalitis. The following organisms are included on the panel: E. coli (K1 strains only), Haemophilus influenzae, Listeria monocytogenes, Neisseria meningitidis (encapsulated strains only), Streptococcus agalactiae (group B Streptococcus), Streptococcus pneumoniae, cytomegalovirus (CMV), human herpesvirus 6 (HHV-6), human parechoviruses (HPeV), varicella zoster virus (VZV), enteroviruses (EV), herpes simplex viruses 1 and 2 (HSV-1, HSV-2), and Cryptococcus neoformans/gattii.** *(continued on page 6)*	11/18/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Meningitis Encephalitis Panel by PCR *(continued from page 5)*	MGEBF	**Clinical Information (continued: The assay is designed to target the most common causes of community-onset meningitis/encephalitis, and has the highest yield when use is restricted to patients with CSF pleocytosis. Severely immunocompromised patients and neonates may also benefit from testing in the absence of pleocytosis. This panel does not cover the most common pathogens in post-surgical or shunt infection, and should not be used in these settings. This assay should always be accompanied by cultures when bacterial meningitis is suspected. If there is suspicion of cryptococcal meningitis, antigen (CrAg) testing should be ordered separately due to its superior sensitivity. See clinical limitations section for additional assay limitations.** **Specimen Requirement:** 0.5 mL cerebrospinal fluid (CSF) **in sterile container**; Minimum: 0.2 mL; **Refrigerated; Collect** lumbar puncture **CSF using standard protocol. Note that CSF collected from indwelling medical devices such as shunts are not accepted because the assay does not cover the pathogens most likely to cause shunt or post-surgical infections. CSF from any tube of collection (Tubes 1-4) may be used for this assay. Make a dedicated aliquot into a sterile tube using sterile technique in a biosafety cabinet. Residual specimen from non-Microbiology laboratories is NOT acceptable.** **Stability:** Ambient: **24 hours** Refrigerated: 7 days **Methodology: Polymerase Chain Reaction (PCR)**	11/18/25
Phospholipids, Serum or Plasma	PHOLIP	**Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Refrigerated; Collect blood following a 12-hour fast. Allow specimen to clot completely at room temperature, then transfer serum into a standard aliquot tube. *OR* **1 mL serum from red plain tube; Refrigerated; Collect blood following a 12-hour fast. Allow specimen to clot completely at room temperature, then transfer serum into a standard aliquot tube.** *OR* 1 mL plasma from EDTA (Lavender) tube; Refrigerated; Collect blood following a 12-hour fast. Allow specimen to clot completely at room temperature, then transfer plasma into a standard aliquot tube. *OR* 1 mL plasma from sodium or lithium heparin (Green) tube; Refrigerated; Collect blood following a 12-hour fast. Allow specimen to clot completely at room temperature, then transfer plasma into a standard aliquot tube.	10/20/25
Pneumocystis jirovecii PCR	PJPCR	**Name:** Previously Pneumocystis jirovecii, *Real-Time PCR* **Special Information:** *will be removed* **Specimen Requirement:** 2 mL bronch (BAL) in sterile container; Refrigerated; Collect and submit the specimen in a sterile container (ie. Oracle #1012787, Covidien #2200SA). If aliquoting is necessary, sterile tubes must be used. *OR* 2 mL sputum in sterile container; Refrigerated; Collect and submit the specimen in a sterile container (ie. Oracle #1012787, Covidien #2200SA). If aliquoting is necessary, sterile tubes must be used. *OR* 2 mL bronch washings in sterile container; Collect and submit the specimen in a sterile container (ie. Oracle #1012787, Covidien #2200SA). If aliquoting is necessary, sterile tubes must be used. *OR* 2 mL tracheal aspirate in sterile container; Collect and submit the specimen in a sterile container (ie. Oracle #1012787, Covidien #2200SA). If aliquoting is necessary, sterile tubes must be used. **Note:** *lung tissue is no longer an acceptable specimen* **Methodology: Real-Time PCR**	11/18/25
Polymyositis and Dermatomyositis Panel	MYOSPL	**Specimen Requirement:** 4 mL serum from serum separator (Gold) tube; Refrigerated; **Draw 2 tubes to ensure adequate serum volume.** Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube.	11/18/25
Pseudocholinesterase Phenotype	PCHEP	**Specimen Requirement:** 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. *OR* **1 mL serum from red plain tube; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection.** *OR* 1 mL plasma from EDTA (Lavender) tube; Refrigerated; Separate plasma from cells ASAP or within 2 hours of collection. *OR* 1 mL plasma from sodium or lithium heparin (Green) tube; Refrigerated; Separate plasma from cells ASAP or within 2 hours of collection.	10/20/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Pseudocholinesterase, Total	PCHE	**Specimen Requirement:** 0.5 mL serum from serum separator (Gold) tube; Refrigerated; Specimen must be drawn prior to surgery or more than two days following surgery. Allow specimen to clot completely at room temperature. Separate serum from cells within 2 hours of collection and transfer to standard aliquot tube. *OR* **0.5 mL serum from red plain tube; Refrigerated; Specimen must be drawn prior to surgery or more than two days following surgery. Separate serum from cells within 2 hours of collection and transfer to standard aliquot tube.** *OR* 0.5 mL plasma from EDTA (Lavender) tube; Refrigerated; Specimen must be drawn prior to surgery or more than two days following surgery. Separate plasma from cells within 2 hours of collection and transfer to standard aliquot tube.	10/20/25
PTH, Intact	PTHI	**Special Information:** Note that serum specimens need to be spun immediately after the specimen clots. **Note:** *Biotin comments removed* **Reference Range:** **0 Months to 1 Month: 7–59 pg/mL** **1 Month to 1 Year: 8–61 pg/mL** **1 Year to 11 Years: 11–60 pg/mL** **11 Years to 18 Years: 15–68 pg/mL** **18 Years** to 99 Years: **18–59** pg/mL	11/18/25
PTH Intact, Fluid	FLPTH	**Special Information:** Unacceptable conditions: Specimen types other than **what is** listed, specimens too viscous to be aspirated by the instrument, grossly hemolyzed samples, grossly lipemic samples. Indicate source on test request form. **Specimen Requirement:** 0.5 mL fine needle aspirate in clean container with saline; Frozen; Specimen must be non-viscous, non-hemolyzed, and free of particulate matter. Centrifuge to remove cellular material and visible hemolysis. Indicate source of specimen. Transfer 0.5 mL saline needle rinse to a standard transport tube. **Note:** *body fluid specimens are no longer acceptable*	10/20/25
Quetiapine	QUETIA	**Clinical Information:** This test is useful to optimize drug therapy and monitor patient adherence. **The therapeutic range is based on serum pre-dose (trough) draw at steady-state concentration.** The pharmacokinetics of quetiapine are influenced by drug-drug interactions that may inhibit or induce CYP3A4 metabolism. Adverse effects **to quetiapine therapy** may include somnolence, hypotension, dizziness, **neuroleptic malignant syndrome, tardive dyskinesia, and** weight gain**.**	10/20/25
RBC Band 3 Protein Reduction in Hereditary Spherocytosis	RBCB3	**Special Information:** Specimens must be analyzed within 7 days of collection. Clotted or **grossly** hemolyzed specimens will be rejected. **Ambient samples greater than 3 days, refrigerated sample greater than 7 days, and bone marrow will be rejected.** This test is New York state approved.	10/20/25
RPR	RPR	**Stability:** Ambient: 1 day Refrigerated: **14** days Frozen: **30** days	effective immediately
Send Out MTB Detection and Rifampin Resistance by PCR (CSF, Pleural fluid)	MTBAM1	**Name:** Previously Send Out MTB Detection and Rifampin Resistance by PCR (Resp specimens, CSF, Pleural fluid) **Special Information:** Specimen source required. To perform this test it is essential to know whether or not the submitted specimen has been processed (digestion and decontamination procedure). If processed, smear results must be provided as a comment on the test order or requisition. For processed specimens, identify method used for digestion. Delayed turnaround time will occur if the required information is not provided. Unacceptable conditions: Blood, paraffin blocks, stool, swabs, tissue, **respiratory specimens** and urine. This test is New York DOH approved. **Specimen Requirement:** 10 mL cerebrospinal fluid (CSF) or pleural fluid in sterile container; Refrigerated; Unprocessed specimen: Send 5-10 mL specimen. MUST label as unprocessed. Indicate specimen source. *OR* 5 mL cerebrospinal fluid (CSF) or pleural fluid in sterile container; Refrigerated; Processed specimen: Send 2–5 mL digested/decontaminated specimen. Identify method used for digestion *AND* provide smear results. Place each specimen in an individually sealed bag. MUST label as processed. Indicate specimen source. **Note:** *Respiratory specimens are no longer acceptable*	effective immediately
Specific Gravity, Body Fluid	BFSPGV	**Stability:** Ambient: **Ambient samples must be tested within 24 hours of collection.** Refrigerated: **Refrigerated samples are stable for 5 days.**	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Staphylococcus aureus & MRSA Screen, PCR, Nasal	SAPCR	**Clinical Limitation:** The Staphylococcus aureus PCR test is a screening test for nasal carriage. A negative result does not preclude MRSA/SA colonization. **Results from the Xpert SA Nasal Complete assay should be interpreted in conjunction with other laboratory and clinical data available to the clinician, and should be used as an adjunct to nosocomial infection control efforts to identify patients needing enhanced precautions. Results should not be used to guide or monitor treatment for MRSA or SA infections. Erroneous test results might occur from improper specimen collection, failure to follow the recommended sample collection, handling and storage procedures, technical error, sample mix-up, or because the number of organisms in the specimen is too low to be detected by the test. Careful compliance with the instructions in this insert is necessary to avoid erroneous results. A positive test result does not necessarily indicate the presence of viable organisms. It is however, presumptive for the presence of MRSA or SA. The Xpert SA Nasal Complete assay positive result does not necessarily indicate intervention eradication failure since nonviable DNA may persist. A negative result following a previously positive test result may or may not indicate eradication success. The performance characteristics were not established for patients ≤ 21 years of age. Because the detection of MRSA and SA is dependent on the number of organisms present in the sample, reliable results are dependent on proper specimen collection, handling, and storage. Mutations or polymorphisms in primer or probe binding regions may affect detection of new or unknown MRSA variants resulting in a false negative result. In samples containing both MRSA and SA, the Xpert SA Nasal Complete assay may not detect the MRSA organisms. The pivotal clinical study included one sample with documented MRSA/SA mixed infection; the Xpert SA Nasal Complete assay successfully identified the sample as MRSA positive/SA positive.** **In a mixed culture, the analytical LoD of MRSA is variable when extremely high concentrations of SA are present. Competition from SA was observed at a MRSA:SA ratio of 1:1×106 in 7 of 8 SCCmec types tested. For SCCmec type VIII, competition from SA was observed at a MRSA:SA ratio of 1:1×103. Inhibition of the SA Nasal Complete assay resulting in Invalid test results has been observed in the presence of inhaled nasal steroids Flonase and Nasonex in SA negative samples at concentrations greater than 5% v/v, and 10% v/v, respectively. Inhibition of the SA Nasal Complete assay resulting in false negative test results has been observed in the presence of inhaled nasal steroids Flonase and Nasonex in MRSA positive samples at concentrations greater than 1% (v/v) and 5% (v/v), respectively. The Xpert SA Nasal Complete assay may generate a false positive MRSA result when testing a mixed infection nasal specimen containing both methicillin-resistant coagulase-negative Staphylococcus and empty cassette SA.** **The Xpert SA Nasal Complete assay may generate false negative MRSA results when testing borderline oxacillin resistant S. aureus (BORSA). The mechanism of oxacillin resistance in BORSA strains is due to an increased production of ß-lactamases, not the mecA gene. BORSA with oxacillin MICs of 4 – 8 µg/mL are considered borderline resistant but would be reported as MRSA negative by the Xpert SA Nasal Complete assay. BORSA strains are rare in the United States. The Xpert SA Nasal Complete assay may generate false negative MRSA results when testing modified S. aureus (MOD-SA). The mechanism of oxacillin resistance in MOD-SA strains is due to changes in affinity of penicillin binding proteins for oxacillin, not the mecA gene. MOD-SA with oxacillin MICs of 4 – 8 µg/mL are considered borderline resistant but, would be reported as MRSA negative by the Xpert SA Nasal Complete assay. MOD-SA strains are rare in the United States. There may be an association with false positive results in specimens containing blood. As with all PCR based in vitro diagnostic tests, extremely low levels of target below the LoD of the assay may be detected, but results may not be reproducible.**	10/7/25
Thyroglobulin by LC-MS/MS, Serum or Plasma, for Thyroglobulin Antibody Interference	TGMSMS	**Specimen Requirement:** 1.5 mL serum from serum separator (Gold) tube; Refrigerated; Separate from cells **within 2 hours of collection** and transfer into standard aliquot tube. *OR* 1.5 mL plasma from sodium or lithium heparin (Green) tube; Refrigerated; Separate from cells **within 2 hours of collection** and transfer into standard aliquot tube. *OR* 1.5 mL plasma from EDTA (Lavender) tube; Refrigerated; Separate from cells **within 2 hours of collection** and transfer into standard aliquot tube. *OR* 1.5 mL blood in no additive (Red) tube; Refrigerated; Separate from cells **within 2 hours of collection** and transfer into standard aliquot tube.	10/20/25

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Trypanosoma cruzi, IgG, Purified Antigen	TCAIGG	**Name:** previously Trypanosoma cruzi Antibody, IgG **Special Information:** Bacterially contaminated, heat-inactivated, hemolyzed, icteric, lipemic, or turbid specimens will be rejected. This assay should not be used for blood donor screening or associated re-entry protocols, or for screening Human Cell and Cellular Tissue-Based Products (HCT/Ps). This test is New York **State** approved. **Assay is performed using the Hemagen Chagas kit.** **Clinical Information:** Aid in the diagnosis of non-acute (chronic phase) Chagas disease (T. cruzi). **According to the CDC, at least two different serologic tests should be used to make the laboratory diagnosis of chronic Chagas Disease, as no single serologic test is sufficiently sensitive and specific. If results between the two assays are discrepant, repeat testing or testing by a third method may be helpful.** **Days Performed: Mon,** Wed**, Fri** **Reported:** 2–**7** days	10/20/25

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Norovirus Group 1 and 2 Detection by PCR	NORPCR	Test will no longer be orderable. Recommended replacement test is Enteric Viral Panel by PCR (EVPPCR).	11/18/25
Norwalk-Like Virus Antigen	NORWLK	Test will no longer be orderable. Recommended replacement test is Enteric Viral Panel by PCR (EVPPCR).	11/18/25
Rotavirus Antigen Detection	EROTA	Test will no longer be orderable. Recommended replacement test is Enteric Viral Panel by PCR (EVPPCR).	11/18/25
Volatile Screen, Urine	UVLTSR	Test will no longer be orderable. Recommended replacement test is Alcohols, Plasma (ALCOS).	11/18/25