

# **Cleveland Clinic Laboratories**

#### Technical Update • March 2024

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.

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5–6	Trichomonas vaginalis, NAAT												
6	von Willebrand Diagnostic Interpretive Panel (Limited)												
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### Test Changes

Test Name	Order Code	Change	Effective Date
C-Peptide	CPEPT	For interface clients only—Test build may need to be modified	4/18/24
		Special Information: Specimen collection should occur preferably from patients fasting for at least 8 hours and at minimum 8 hours after administration of multivitamins or dietary supplements, especially containing biotin (Vitamin B7).	
		Clinical Limitation: For diagnostic purposes, the results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings.	
		Clinical Information: The assay is intended for use as an aid in the diagnosis and treatment of patients with abnormal insulin secretion.	
		Specimen Requirement: $1$ mL serum from serum separator (Gold) tube; Minimum 0.5 mL; Refrigerated	
		Stability: Ambient: 24 hours Refrigerated: 7 days Frozen: 30 days	
		Methodology: Electro Chemiluminescence Immunoassay (ECLIA)	
		Reference Range: 1.1–4.4 ng/mL	
		Days Performed: Mon–Fri	
		Reported: 1–3 days	
Collagen Type II Antibody	CIIAB	Special Information: This test is New York State approved. Specimen Requirement: 3 mL serum from serum separator (Gold) tube; Minimum 1 mL; Refrigerated *OR* 3 mL serum from no additive (Red) tube; Minimum 1 mL; Refrigerated	4/16/24
		Stability: Ambient: 7 days Refrigerated: 7 days Frozen: 1 year	
		Reported: 5–19 days	

Test Name	Order Code	Change	Effective Date
Estriol, Serum	ESTRIO	Clinical Information: Screening test for fetal aneuploidy in conjunction with other biomarkers and ultrasonography. Indicator of fetal well-being and placental function. 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) Reference Range: Gestational age 25 weeks: 2.1–7.4 ng/mL Gestational age 25 weeks: 2.2–8.0 ng/mL Gestational age 27–29 weeks: 2.3–10.0 ng/mL Gestational age 30–31 weeks: 2.7–11.7 ng/mL Gestational age 32–37 weeks: 2.9–18.4 ng/mL Nonpregnant female: < 0.20 ng/mL Male: < 0.22 ng/mL	2/5/24
Growth Hormone Suppression	GHSUP	For interface clients only—Test build may need to be modified Includes: Growth Hormone Basal Growth Hormone 30 min Growth Hormone 60 min Growth Hormone 90 min Growth Hormone 120 min Glucose Basal Glucose 30 min Glucose 30 min Glucose 90 min Glucose 90 min Glucose 120 min Special Information: Patient Preparation: "Patient should be fasting at least 10 hours prior to the test. Collect a baseline specimen, then administer 75 grams of dextrose within 5 minutes. Collect specimens at 30, 60, 90, and 120 minutes post dextrose administration." Specimen Requirement: 1 mL plasma from potassium oxalate/sodium fluoride (Gray) tube; Refrigerated AND 1 mL serium from serum separator (Gold) tube; Refrigerated; Patient should be fasting at least 10 hours prior to the test. Collect a baseline specimen, then administer 75 grams of dextrose within 5 minutes. Collect specimens at 30, 60, 90, and 120 minutes post dextrose administration." Stability: Ambient: SST (Gold) and Potassium oxalate/sodium fluoride (Gray): 24 hours Refrigerated: SST (Gold): 7 days Potassium oxalate/sodium fluoride (Gray): 24 hours Frozen: SST (Gold): 14 days Potassium oxalate/sodium fluoride (Gray): Unacceptable	4/18/24
Hepatitis Be Antigen	HBEAG	<b>Specimen Requirement:</b> 1 mL serum from serum separator (Gold) tube; Refrigerated *OR* 1 mL serum from red plain tube; Refrigerated *OR* 1 mL plasma from EDTA (Lavender) tube; Refrigerated; Separate plasma from cells within 2 hours of collection. *OR* 1 mL plasma from lithium heparin plasma separator (Light Green) tube; Refrigerated	2/13/24
Herpes Simplex Virus (HSV-1 & HSV-2), Qualitative PCR, CSF	HSPCRC	For interface clients only—Test build may need to be modified Name: Previously Herpes Simplex Virus by PCR, CSF Clinical Limitation: Negative results do not preclude HSV-1 or HSV-2 infection and should not be used as the sole basis for treatment or other patient management decisions, especially if performed very early in the course of illness. For encephalitis patients with a negative herpes simplex PCR result, consideration should be given to repeating the test 3–7 days later for patients demonstrating a compatible clinical syndrome or temporal lobe localization on neuroimaging. As with other tests, false-positive results may occur. Repeat testing or testing with a different device may be indicated in some settings. A positive result by this test cannot rule out infections caused by other viral or bacterial pathogens. Viral nucleic acids may persist in vivo independent of virus viability. Detection of target analyte(s) does not imply that the corresponding viruses are infectious or are the causative agent for clinical symptoms. (continued on page 4)	4/18/24

Test Name	Order Code	Change	Effective Date
Herpes Simplex Virus (HSV-1 & HSV-2), Qualitative PCR, CSF (continued from page 4)		Clinical Information: Herpes simplex viruses (HSV-1 and HSV-2) are enveloped DNA viruses that are members of the alpha-herpesviridae subfamily. HSV causes about 5–10% of all encephalitis cases, and is one of the most common causes of identified sporadic encephalitis is more common in neonates. Clinical features involved with HSV encephalitis include fever, hemicranial headache, language and behavioral abnormalities, memory impairment, and seizures. HSV can also be associated with meningitis. Nucleic acid amplification testing of CSF specimens has greatly increased the ability to diagnose infections of the CNS, especially viral infections caused by the herpesviruses. The FDA-cleared DiaSorin Molecular Simplexa HSV 1 & 2 Direct is a multiplex qualitative real-time PCR assay that targets HSV-1 and HSV-2 DNA polymerase genes, and is intended for use as an aid in the diagnosis of HSV-1 and HSV-2 infections of the CNS. For encephalitis patients with a negative herpes simplex PCR result, consideration should be given to repeating the test 3–7 days later for patients demonstrating a compatible clinical syndrome or temporal lobe localization on neuroimaging. This standalone HSV-1 and HSV-2 PCR test has been shown to have greater analytic sensitivity for HSV detection as compared to large multiplex panels, and should be considered for patients with high pre-test probability of HSV encephalitis. Specimen Requirement: 0.5 mL cerebrospinal fluid (CSF) in sterile container; Minimum 0.2 mL; Refrigerated; Collect CSF using standard protocol. 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: Refrigerated: 7 days at 2-8C Frozen: 1 month at -70C Methodology: Qualitiative Real-Time PCR	
Histoplasma Antigen Quantitative by EIA, Serum	SHISTO	For interface clients only—Test build may need to be modified Name: Previously Histoplasma capsulatum Antigen Clinical Information: The quantitative range of this assay is 0.19-60.0 ng/mL. Antigen concentrations less than 0.19ng/mL ;greater than 60.0 ng/mL fall outside the linear range of the assay and cannot be accurately quantified. This EIA test should be used in conjunction with other diagnostic procedures, including microbiological culture, histological examination of biopsy samples, serology and/or radiographic evidence, to aid in the diagnosis of histoplasmosis. Cross-reactivity with Blastomyces dermatiditis, Coccidioides immitis, and possibly Talaromyces marneffei have been observed with this EIA. Other clinically and geographically relevant endemic mycoses should be considered in the case of a positive test result. Specimen Requirement: 2 mL serum from serum separator (Gold) tube; Refrigerated *OR* 2 mL serum from no additive (Red) tube; Refrigerated *OR* 2 mL serum from no additive (Red) tube; Refrigerated *Trozen: 1 month Reference Range: Histoplasma Antigen, Serum: Not detected Histoplasma Antigen, Serum Interp: Refer to report Days Performed: Mon, Wed, Fri Reported: 2–5 days	4/25/24
Lupus Anticoagulant Diagnostic Interpretive Panel	LUPUSP	For interface clients only—Test build may need to be modified Reference Range: Refer to individual components New components and reference ranges will be added	4/16/24

Test Name	Order Code	Change	Effective Date
Parvo B19 PCR	PARPLS	Special Information: This test is New York state approved. Clinical Information: Qualitative nucleic acid amplification testing for parvovirus B19. Specimen Requirement: 1 mL plasma from EDTA (Lavender) tube; Frozen; Separate plasma from cells and transfer to standard aliquot tube. *OR* 1 mL serum from serum separator (Gold) tube; Frozen; Separate serum from cells and transfer to standard aliquot tube. *OR* 1 mL cerebrospinal fluid (CSF) in sterile container; Frozen *OR* 1 mL amniotic fluid in sterile container; Frozen *OR* 1 mL bone marrow in EDTA (Lavender) tube; Refrigerated Stability: Ambient: 24 hours; Bone marrow: 1 week Refrigerated: 5 days; Bone marrow: 1 week Frozen: 6 months; Bone marrow: 1 week Methodology: Qualitative Polymerase Chain Reaction	effective immediately
Platelet Neutralization	PLTNEU	For interface clients only—Test build may need to be modified Specimen Requirement: 2 mL plasma from sodium citrate (Light Blue) tube; Centrifuge, aliquot and freeze ASAP. Discontinue heparin or direct thrombin inhibitor therapy 48 hours prior to collection. Reference Range: Platelet Neutralization Delta: <1.9 sec PTT LA Screen: 30.2-43.0 sec PTT LA Mix: 31.5-38.3 sec	4/16/24
Post DDAVP Monitoring	DDAPOP	For interface clients only—Test build may need to be modified Specimen Requirement: 4 mL plasma from sodium citrate (Light Blue) tube; Centrifuge samples; Aliquot plasma into a separate tube and label with Epic Beaker labels. Specimens should be frozen (-20C or colder).	4/16/24
Pre DDAVP Monitoring	DDAPRP	For interface clients only—Test build may need to be modified Specimen Requirement: 4 mL plasma from sodium citrate (Light Blue) tube; Centrifuge samples; Aliquot plasma into a separate tube and label with Epic Beaker labels. Specimens should be frozen (-20C or colder).	4/16/24
Sequential Screen Second Trimester	SEQ2	Special Information: Specimen MUST be drawn between 15.0–21.9 weeks gestation. Draw 2 tubes to ensure adequate serum volume. Specimen Requirement: 5 mL serum from serum separator (Gold) tube; Ambient; Specimen MUST be drawn between 15.0–21.9 weeks gestation. Draw 2 tubes to ensure adequate serum volume.	effective immediately
Supersaturation Profile, 24 Hour Urine	SSAT24	Stability:         Ambient: 3 days         Refrigerated: 14 days         Frozen: 14 days         Days Performed: Sun–Sat	effective immediately
Trichomonas vaginalis, NAAT		<b>Clinical Information:</b> Trichomonas vaginalis is a protozoan parasite that is a common cause of vaginitis and the most common nonviral sexually transmitted infection worldwide. The majority of persons who have trichomoniasis (70%–85%) either have minimal or no genital symptoms, and untreated infections might last from months to years, and have been associated with reproductive morbidity. Symptomatic patients can present with vaginitis, vaginal discharge, cervicitis, urethritis, and/or other genitourinary symptoms. The CDC recommends diagnostic testing for T. vaginalis in patients seeking care for vaginal discharge, as well as considering asymptomatic screening in certain high risk groups. T. vaginalis can be diagnosed via wet mount, culture, rapid antigen testing, and nucleic acid amplification testing (NAAT), with the latter having the highest sensitivity. The Aptima Trichomonas vaginalis Assay is an in vitro FDA-cleared qualitative nucleic acid amplification test (NAAT) for the detection of ribosomal RNA (rRNA) from Trichomonas vaginalis to aid in the diagnosis of trichomoniasis using the Panther System. The assay uses target capture, transcription-mediated amplification (TMA), and hybridization protection assay (HPA) technologies. The assay may be used to test the following specimens from symptomatic or asymptomatic individuals: clinician-collected endocervical swabs, clinician-collected and patient-collected vaginal swabs (in a clinical setting), female and male urine, and specimens collected in PreservCyt Solution.	

Test Name	Order Code	Change	Effective Date
Trichomonas vaginalis, NAAT (continued from page 5)	TRVAMP	Specimen Requirement (continued): *OR* One cervical Cytyc PreservCyt solution (Thin Prep); Ambient; PreservCyt Solution (ThinPrep) is an acceptable specimen when added onto a ThinPrep Pap Test and no dedicated vaginal or endocervical swab specimens are available. It is not a recommended due to lower test sensitivity for gonorrhea and chlamydia detection (often ordered on the same swab) compared to other specimen types. Due to this reason, it is not available as a selectable specimen source/type during order entry, only as a laboratory add-on. In order to place an order on this specimen type, you must place a call to lab client services. If consulted prior to specimen collection, lab client services should advise the provider to collect a separate dedicated Vaginal Multitest Swab for optimal test performance characteristics. If consulted after specimen collection, lab client services should assist the provider in placing an add on order with "Fluid, Cervix" as the specimen source, and have cytology perform the aliquot as below prior to cytology testing. Prior to cytology testing and within 30 days of collection, cytology will transfer a 1 mL aliquot into an APTIMA Specimen Transfer Tube. The specimen collection kit; Ambient; The patient should not have urinated for at least 1 hour prior to specimen collection. The patient should collect first portion of random voided urine (first part of stream) into a sterile, plastic, preservative-free container. Transfer 2 mL of urine into the Aptima urine specimen transport tube. Nork with one specimen at a time. The correct volume of urine has been added when the fluid level is between the black fill lines (window) on the urine transport tube. Do not overfill or underfill the APTIMA Urine transport tube. *CR* one vaginal Aptima Multitest Collection Kit; Ambient; Vaginal Multitest (orange tube pink swab): A vaginal swab is the recommended specimen for female patients due to this being a specimen type ideal for sharing with other testing. Carefully insert the swab into the	4/16/24
		collect first portion of random voided urine (first part of stream) into a sterile, plastic, preservative-free container. *OR* One endocervical APTIMA Collection Unisex swab; Ambient; Endocervical Unisex (white tube blue swab): Remove excess mucus from cervical os and surrounding mucosa using the white cleaning swab, then DISCARD. Insert blue swab into the endocervical canal and gently rotate clockwise for 10-30 seconds. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.	
von Willebrand Diagnostic Interpretive Panel (Limited)	VWFPR	For interface clients only—Test build may need to be modified Includes: Prothrombin Time APTT Ristocetin Cofactor Collagen Binding Assay Factor VIII assay von Willebrand Factor Antigen CBA/VWF Ratio Ristocetin Cofactor/VWF Ratio FVIII/VWF Ratio VOI Willebrand Multimer VWF:GpIbM Activity	4/16/24
VWF GPIbM Activity	VGPIBM	For interface clients only—Test build may need to be modified Clinical Information: clinical information has been removed Specimen Requirement: 0.5 mL plasma from sodium citrate (Light Blue) tube; Centrifuge samples; Aliquot plasma into a separate tube and label with Epic Beaker labels. Specimens should be frozen (-20C or colder) ASAP. Days Performed: Varies, Mon–Fri 8 hours Reported: 1–3 days	4/16/24

#### New Tests

Test Name	Order Code	Change	Effective Date
Alzheimer's Disease Biomarker Panel, Cerebrospinal Fluid	ALZCSF	Special Information: Low-binding polypropylene tubes (Sarstedt, Ref 63.614.625)MUST be used for this test. CSF samples that are collected or transported to the testing laboratory in any other tube are not acceptable and will be rejected. CSF samples that are underfilled will be rejected. Samples that are visibly hemolyzed are not acceptable. <b>Clinical Limitation:</b> A positive pTau181/Abeta42 or tTau/Abeta42 ratio result in CSF does not establish a diagnosis of Alzheimer's disease (AD) and should always be interpreted in conjunction with clinical information. The performance of the test for African-American, Asian, and other races had high uncertainty due to the limited 	4/18/24
Histoplasma Galactomannan EIA, CSF	HISCSF	<ul> <li>Special Information: Ship on dry ice for overnight delivery Monday through Friday. This test is New York State approved.</li> <li>Clinical Limitation: The clarus Histoplasma Galactomannan EIA was found to be cross-reactive with Paracoccidioides, Blastomyces, and some Candida specimens. Positive tests should be confirmed in areas or patient groups where these organisms are endemic or a risk.</li> <li>Clinical Information: The clarus Histoplasma Galactomannan EIA is not intended for monitoring therapy. Testing should not be performed as a screening procedure for the general population. The predictive value of a positive or negative result depends on the pretest likelihood of histoplasmosis disease being present. Testing should only be done when clinical evidence suggests the diagnosis of histoplasmosis. Results between different</li> <li>Histoplasma capsulatum assays cannot be compared.</li> <li>Specimen Requirement: 2 mL cerebrospinal fluid (CSF) in sterile container; Minimum 0.5 mL; Place specimen on ice after draw. Transport Frozen</li> <li>Stability:</li> <li>Ambient: Unacceptable Refrigerated: 24 hours Frozen Acceptable</li> <li>Methodology: Immunoenzymatic Assay</li> <li>Reference Range:</li> <li>Negative: &lt;0.2 ng/mL</li> <li>Positive but below the limit of quantitation: ≥0.2 but &lt;0.8 ng/mL</li> <li>Positive: ≥0.8 ng/mL</li> <li>Days Performed: Mon–Sat</li> <li>Reported: 1–4 days</li> <li>CPT: 87385</li> </ul>	4/25/24
Neurofilament light (NfL)	NFLLCP	Note: New test was announced in the February update, but financial information was not available at that time CPT: 83520	effective immediately

### New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Platelet Autoantibodies	PLTAAB	<b>Special Information:</b> Sample must be received within 4 days of collection. Ship with an ice pack. Protect whole blood from freezing by wrapping in paper towels. This test is New York State approved.	3/21/24
		<b>Clinical Information:</b> This assay detects direct and indirect glycoprotein-specific antibodies in eluates prepared from washed patient platelets. Autoantibodies to platelet glycoproteins are considered to represent a major mechanism of immune thrombocytopenia (ITP). A diagnosis of ITP is usually reached by excluding nonimmune causes of thrombocytopenia such as sepsis, fever, acute leukemia, and drug-induced thrombocytopenia. The majority of platelet autoantibodies react with platelet specific glycoproteins. Autoantibodies present at reduced levels, as in ITP responsive to therapy, may be missed in this assay. This assay detects only antibodies may be detected, causing false positive results.	
		<b>Specimen Requirement:</b> If platelet count is greater than 100,000:10 mL whole blood in acid citrate dextrose (ACD) A or B (Yellow) tube; Refrigerated; Do not collect within four days of platelet transfusion. Collect Saturday–Wednesday only. *OR* If platelet count is less than 100,000: 40 mL whole blood in acid citrate dextrose (ACD) A or B (Yellow) tube; Refrigerated; Do not collect within four days of platelet transfusion. Collect Saturday–Wednesday only.	
		Stability: Ambient: Unacceptable Refrigerated: 4 days Frozen: Unacceptable	
		Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)	
		Days Performed: Mon-Sat	
		Reported: 4–5 days	

#### **Discontinued Tests**

Test Name	Order Code	Test Information	Effective Date
ADmark Phospho-Tau CSF	PHOTAU	Test will no longer be orderable. Recommended replacement test is Alzheimer's Disease Biomarker Panel, Cerebrospinal Fluid (ALZCSF).	4/18/24
Chromosome Analysis, Amniotic Fluid	FAMCYT	Test will no longer be orderable.	3/12/24
Chromosome Analysis, Chorionic Villus or Amniotic Fluid	CVCYTO	Test will no longer be orderable.	3/12/24
Edoxaban	EDOXBN	Test will no longer be orderable. There is no recommended replacement.	4/16/24
Maternal Cell Contamination	MATRNL	Test will no longer be orderable.	3/12/24
Platelet Antibody Detection	PLTDET	Test will no longer be orderable. Recommended replacement test is Platelet Autoantibodies (PLTAAB).	effective immediately
Trichomonas Prep	TRICHO	Test will no longer be orderable. Recommended replacement test is Trichomonas vaginalis, NAAT (TRVAMP).	4/16/24