Cleveland Clinic

# Cleveland Clinic Laboratories

## Technical Update • December 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 6 | ADAMTS13 Antibody Test | | | | ■ | | | | | | | | |
| 2 | Allergen, Food, Pepper C. annum IgE | | | | | ■ | ■ | | ■ | | ■ | ■ | |
| 6 | Dabigatran Assay | | | | ■ | | | | | | | | |
| 4 | Dilute Thrombin Time Panel | | | ■ | | | | | | | | | |
| 2 | Enterovirus by PCR | | | | | | ■ | | | | | | |
| 2 | F2 Isoprostane/Creatinine Ratio | | | | | ■ | | | | | | ■ | |
| 2 | G6PD Quantitative | | | | | | ■ | ■ | | | | ■ | |
| 3 | Herpes Simplex Virus (HSV-1 & HSV-2) and Varicella Zoster Virus (VZV), NAAT, Lesion Swab | | | | | ■ | | | ■ | | | ■ | |
| 4–5 | Herpes Simplex Virus (HSV-1/2) PCR, Non-Lesion | | | ■ | | | | | | | | | |
| 3 | Lipid Panel, Nonfasting | | | | | ■ | | | | | | | |
| 6 | Micro lab use only HSV PCR - Miscellaneous Specimen Types | | ■ | | ■ | | | | | | | | |
| 6 | Micro lab use only Varicella Zoster by PCR | | ■ | | ■ | | | | | | | | |
| 3 | Protein C Functional | | | | | | ■ | | | | | | |
| 3 | Trofile Co-receptor Tropism Assay | | | | | | ■ | | | | | | |
| 3 | Universal PCR, Acid Fast Bacilli | | | | | ■ | | | | | | | |
| 5–6 | Varicella Zoster Virus (VZV) PCR, Non-Lesion | | | ■ | | | | | | | | | |
| 3 | Voriconazole | | | | | ■ | | | | | | | |

# Test Changes

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Allergen, Food, Pepper C. annum IgE | CAYENN | **Special Information: An extra 50uL will be required for each additional allergen ordered.**<br>**Clinical Information:** *removed*<br>**Specimen Requirement:** 0.5 mL serum from serum separator (Gold) tube; Minimum: **0.3** mL; Refrigerated; **An extra 50uL will be required for each additional allergen ordered.** *OR* **0.5 mL plasma from EDTA (Lavender) tube; Minimum: 0.3 mL** *OR* **0.5 mL plasma from lithium heparin plasma separator (Light Green) tube; Minimum: 0.3 mL**<br>**Stability:**<br>Ambient: **1 day**<br>Refrigerated: **30 days**<br>Frozen: **30 days**<br>**Methodology:** Fluorescent Enzyme Immunoassay (FEIA) by ImmunoCAP<br>**Reference Range: < 0.35 kU/L**<br>**Reported: 1–2** days | 1/20/26 |
| Enterovirus by PCR | ENTNAS | **Specimen Requirement:** 1 mL plasma from EDTA (Lavender) tube; Frozen; Separate plasma from cells and transfer into sterile aliquot tube. Must indicate specimen source. *OR* 1 mL serum from serum separator (Gold) tube; Frozen; Separate serum from cells and transfer into sterile aliquot tube. Must indicate specimen source. *OR* one nasopharyngeal swab in viral transport media; Frozen; Must indicate specimen source. *OR* **1 mL cerebrospinal fluid (CSF) in sterile container; Frozen; Must indicate specimen source.** | 12/16/25 |
| F2 Isoprostane/ Creatinine Ratio | F2 | **Special Information:** Ship specimen on the day of collection. Testing is not performed on major holidays. Specimens other than preservative-free urine will be rejected. Samples received outside of stability limits are unacceptable. Specimens that are improperly labeled or stored will be rejected. **This test is New York DOH approved.**<br>**Stability:**<br>Ambient: **1 week**<br>Refrigerated: 1 week<br>Frozen: **28 days** | 12/15/25 |
| G6PD Quantitative | QNG6PD | **For interface clients only–Test build may need to be modified**<br>**Includes:**<br>G-6-PD Quantitative<br>Hemoglobin**, G-6-PD**<br>**Specimen Requirement:** 3 mL whole blood in EDTA (Lavender) tube; Refrigerated; Collect **one** tube. Do NOT freeze.<br>**Stability:**<br>Ambient: 24 hours<br>Refrigerated: 7 days<br>Frozen: Unacceptable | 1/20/26 |

# Test Changes (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Herpes Simplex Virus (HSV-1 & HSV-2) and Varicella Zoster Virus (VZV), NAAT, Lesion Swab | HSVVZV | **Special Information:** *removed*<br>**Clinical Information:** Herpes simplex virus types 1 and 2 (HSV□1 and HSV□2), and varicella-zoster virus (VZV), are DNA viruses of the family Herpesviridae. HSV infections in humans can cause lesions at a variety of cutaneous and mucocutaneous sites. These lesions can be a result of the primary infection by the virus or they can result from a reactivation of the latent virus, causing recurrent episodes of the disease. Primary VZV infection results in chickenpox (varicella), which may rarely result in complications including encephalitis or pneumonia. Even when clinical symptoms of chickenpox have resolved, VZV remains dormant in the nervous system of the infected person (virus latency). In approximately 10 to 20% of cases, VZV reactivates later in life producing shingles. **This lab-developed multiplex real-time PCR assay simultaneously qualitatively detects and differentiates HSV-1, HSV-2, and VZV DNA targets. Viral nucleic acid is extracted from clinical samples using the EZ2 Connect (Qiagen). Viral DNA is amplified and detected using the RealStar alpha Herpesvirus PCR kit 1.0 (Altona) using species-specific primers and fluorescently labeled hydrolysis probes on a RotorGene Q (Qiagen) thermocycler. This specific procedure code (HSVVZV) can be used to order this test on mucocutaneous lesion swabs. Utilize HSPCRC for HSV testing on CSF; HSVNEO for HSV testing on neonatal surface swabs; HSVPCR for HSV testing on all other non-lesional specimen types; and VZVPCR for VZV testing on all other non-lesional specimen types.**<br>**Stability:**<br>Ambient: **24** hours<br>Refrigerated: 7 days<br>Frozen: **30** days<br>**Methodology: Real-Time Polymerase Chain Reaction (RT-PCR)** | 1/20/26 |
| Lipid Panel, Nonfasting | LIPNF | **Special Information:** The Direct LDL-Cholesterol measurement will **not** 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. | effective immediately |
| Protein C Functional | PRCFUN | **Specimen Requirement: 1** 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. Non-testing sites: Centrifuge sample, aliquot plasma into a separate tube and label with Epic Beaker labels. Specimens should be frozen (-20C or colder).** | 1/20/26 |
| Trofile Co-receptor Tropism Assay | TROFLE | **Specimen Requirement:** 4 mL whole blood in EDTA (Lavender) tube; Critical Frozen; CRITICAL FROZEN. **Transport** 4mL whole blood **in the original collection tube.** Separate specimens must be submitted when multiple tests are ordered. | effective immediately |
| Universal PCR, Acid Fast Bacilli | AFBPCR | **Clinical Information: M. tuberculosis complex, M. avium complex and other non-tuberculous mycobacteria may be detected with this test.** | 1/20/26 |
| Voriconazole | VORCON | **Clinical Limitation: Trough levels should generally not exceed 4.0 mcg/mL due to toxicity risk. However, the treating physician may target trough levels up to 6.0 mcg/mL in patients with severe infections without signs/symptoms of voriconazole toxicity. The treating physician must determine appropriate target levels/dosing based on the specific clinical situation. The therapeutic, prophylactic, and toxic ranges were based on the 2016 Infectious Disease Society of America's (IDSA) Clinical Practice Guidelines for the Management of Aspergillosis and Candidiasis and consultation from Cleveland Clinic's Department of Infectious Disease. Reference ranges and high/low indicator flags are provided as general guidelines only.** | effective immediately |

# New Tests

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Dilute Thrombin Time Panel | DTT | **Clinical Information:** The DTT is used for measuring and monitoring direct thrombin inhibitors (DTI). The expected therapeutic range for the appropriate DTI (dabigatran, bivalirudin and argatroban) will be provided based on the medication selected when placing the order. DTT is not affected by optical interferences (hemolysis, icteria, lipemia), high or low fibrinogen, coumadin, enoxaparin or direct Xa inhibitors (e.g., apixaban, rivaroxaban). However, unfractionated heparin is known to interfere with the DTT assay.<br>**Specimen Requirement:** 1 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. Non-testing sites: Centrifuge sample, aliquot plasma into a separate tube and label with Epic Beaker labels. Specimens should be frozen (-20C or colder).<br>**Stability:**<br>Ambient: 4 Hours<br>Refrigerated: 14 days at -20 C; 6 months at -70 C<br>Frozen: Unacceptable<br>**Methodology:** Clotting Assay<br>**Reference Range:**<br>Dilute Thrombin Time: <18.6 sec<br>APTT Screen:<br>0 Days to 1 Day: 28.2-47.4 sec<br>2 Days to 5 Days: 22.9-52.0 sec<br>6 Days to 30 Days: 23.1-48.0 sec<br>1 Month to 3 Months: 21.7-43.5 sec<br>4 Months to 11 Months: 25.3-37.3 sec<br>1 Year to 5 Years: 21.3-31.6 sec<br>6 Years to 10 Years: 23.1-31.6 sec<br>11 Years to 16 Years: 23.1-32.5 sec<br>17 Years to 99 Years: 24.0-35.1 sec<br>**Days Performed:** Sun–Sat 16 hours<br>**Reported:** 6 hours<br>**CPT:** 85730**;** 85670 | 1/20/26 |
| Herpes Simplex Virus (HSV-1/2) PCR, Non-Lesion | HSVPCR | **Clinical Limitation:** 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. Dilution of ocular fluid at the point of collection may decrease assay sensitivity.<br>**Clinical Information:** Herpes simplex viruses (HSV-1 and HSV-2) are enveloped DNA viruses that are members of the alpha-herpesviridae subfamily. HSV infections in humans can cause lesions at a variety of cutaneous and mucocutaneous sites. These lesions can be a result of the primary infection by the virus or they can result from a reactivation of the latent virus, causing recurrent episodes of the disease. While testing is typically performed on mucocutaneous swabs, more unusual presentations of disseminated disease, pneumonitis, central nervous system infection, or intraocular infection may require testing of alternative specimen types. Nucleic acid amplification tests are a sensitive method for detection of HSV in plasma, lower respiratory specimens, CSF, and ocular fluid.<br>This lab-developed multiplex real-time PCR assay simultaneously qualitatively detects and differentiates HSV-1 and HSV-2 DNA targets. Viral nucleic acid is extracted from clinical samples using the EZ2 Connect (Qiagen). HSV-1 and HSV-2 DNA are amplified and detected using the RealStar alpha Herpesvirus PCR kit 1.0 (Altona) using species-specific primers and fluorescently labeled hydrolysis probes on a RotorGene Q (Qiagen) thermocycler.<br>This specific procedure code (HSVPCR) can be used to order this test on plasma, bronchoalveolar lavage, bronchial wash, and ocular fluid specimens. Utilize alternative orders for the following specimen types: HSVVZV for mucocutaneous lesion swabs, HSPCRC for CSF, HSVNEO for neonatal surface swabs.<br>*(continued on page 5)* | 1/20/26 |

# New Tests (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Herpes Simplex Virus (HSV-1/2) PCR, Non-Lesion<br>*(continued from page 4)* | HSVPCR | **Specimen Requirement:** 0.5 mL ocular fluid in sterile container; Minimum: 0.25 mL; Refrigerated; Collect ocular fluid using standard protocol. An absolute minimum of 250 uL is required for testing (for HSVPCR and VZVPCR combined). For specimen volumes below 5 mL, leave the fluid inside the sterile syringe to allow maximal recovery. The needle MUST be removed and syringe capped before transport to the lab. *OR* 0.5 mL bronch (BAL) in sterile container; Minimum: 0.25 mL; Refrigerated; Collect 2-3 mL into a sterile, leak-proof, screw-cap collection cup or sterile dry container (ie. Oracle 1619591). If aliquotting is necessary, sterile aliquot tubes must be used. Do not dilute with transport media. *OR* 0.5 mL plasma from EDTA plasma preparation (White) tube; Minimum: 0.25 mL; Refrigerated; Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for a minimum of 10 minutes) within 24 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, BKQUAN, HSVPCR, or VZVPCR. *OR* 0.5 mL bronch washings in sterile container; Minimum: 0.25 mL; Refrigerated; Collect 2-3 mL into a sterile, leak-proof, screw-cap collection cup or sterile dry container (ie. Oracle 1619591). If aliquotting is necessary, sterile aliquot tubes must be used. Do not dilute with transport media. *OR* 0.5 mL plasma from EDTA (Lavender) tube; Minimum: 0.25 mL; Refrigerated; Collect EDTA plasma according to standard protocol. Centrifuge (at >1300 RCF for a minimum of 10 minutes) and aliquot into a sterile secondary tube within 24 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, BKQUAN, HSVPCR, or VZVPCR.<br>**Stability:**<br>Ambient: 24 hours<br>Refrigerated: 7 days<br>Frozen: 30 days<br>**Methodology:** Real-Time Polymerase Chain Reaction (RT-PCR)<br>**Reference Range:**<br>Herpes Simplex Virus 1 (HSV-1) DNA: Not Detected<br>Herpes Simplex Virus 2 (HSV-2) DNA: Not Detected<br>**Days Performed:** 3 days per week<br>**Reported:** 1–3 days<br>**CPT:** 87529x2 | 1/20/26 |
| Varicella Zoster Virus (VZV) PCR, Non-Lesion | VZVPCR | **Includes:** Varicella Zoster Virus (VZV) DNA<br>**Clinical Limitation:** 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. Dilution of ocular fluid at the point of collection may decrease assay sensitivity.<br>**Clinical Information:** Varicella-zoster virus (VZV) is a DNA virus of the family Herpesviridae. Primary VZV infection results in chickenpox (varicella), which may rarely result in complications including encephalitis or pneumonia. Even when clinical symptoms of chickenpox have resolved, VZV remains dormant in the nervous system of the infected person (virus latency). In approximately 10 to 20% of cases, VZV reactivates later in life producing shingles. While testing is typically performed on mucocutaneous swabs, more unusual presentations of disseminated disease, pneumonitis, central nervous system infection, or intraocular infection may require testing of alternative specimen types. Nucleic acid amplification tests are a sensitive method for detection of VZV in plasma, lower respiratory specimens, CSF, and ocular fluid.<br>This lab-developed real-time PCR assay qualitatively detects VZV DNA. Viral nucleic acid is extracted from clinical samples using the EZ2 Connect (Qiagen). VZV DNA is amplified and detected using the RealStar alpha Herpesvirus PCR kit 1.0 (Altona) using species-specific primers and fluorescently labeled hydrolysis probes on a RotorGene Q (Qiagen) thermocycler.<br>This specific procedure code (VZVPCR) can be used to order this test on plasma, bronchoalveolar lavage, bronchial wash, CSF, and ocular fluid specimens. Utilize alternative orders for the following specimen types: HSVVZV for mucocutaneous lesion swabs.<br>*(continued on page 6)* | 1/20/26 |

# New Tests (Cont.)

| Test Name | Order Code | Change | Effective Date |
|---|---|---|---|
| Varicella Zoster Virus (VZV) PCR, Non-Lesion<br>*(continued from page 5)* | VZVPCR | **Specimen Requirement:** 0.5 mL ocular fluid in sterile container; Minimum: 0.25 mL; Refrigerated; Collect ocular fluid using standard protocol. An absolute minimum of 250 uL is required for testing (for HSVPCR and VZVPCR combined). For specimen volumes below 5 mL, leave the fluid inside the sterile syringe to allow maximal recovery. The needle MUST be removed and syringe capped before transport to the lab. *OR* 0.5 mL bronch (BAL) in sterile container; Minimum: 0.25 mL; Refrigerated; Collect 2-3 mL into a sterile, leak-proof, screw-cap collection cup or sterile dry container (ie. Oracle 1619591). If aliquotting is necessary, sterile aliquot tubes must be used. Do not dilute with transport media. *OR* 0.5 mL plasma from EDTA plasma preparation (White) tube; Minimum: 0.25 mL; Refrigerated; Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for a minimum of 10 minutes) within 24 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, BKQUAN, HSVPCR, or VZVPCR. *OR* 0.5 mL cerebrospinal fluid (CSF) in sterile container; Minimum 0.25 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. *OR* 0.5 mL bronch washings in sterile container; Minimum: 0.25 mL; Refrigerated; Collect 2-3 mL into a sterile, leak-proof, screw-cap collection cup or sterile dry container (ie. Oracle 1619591). If aliquotting is necessary, sterile aliquot tubes must be used. Do not dilute with transport media. *OR* 0.5 mL plasma from EDTA (Lavender) tube; Minimum: 0.25 mL; Refrigerated; Collect EDTA plasma according to standard protocol. Centrifuge (at >1300 RCF for a minimum of 10 minutes) and aliquot into a sterile secondary tube within 24 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, BKQUAN, HSVPCR, or VZVPCR.<br>**Stability:**<br>Ambient: 24 hours<br>Refrigerated: 7 days<br>Frozen: 30 days<br>**Methodology:** Real-Time Polymerase Chain Reaction (RT-PCR)<br>**Reference Range:** Not detected<br>**Days Performed:** 3 days per week<br>**Reported:** 1–3 days<br>**CPT:** 87798x1 | 1/20/26 |

# Discontinued Tests

| Test Name | Order Code | Test Information | Effective Date |
|---|---|---|---|
| ADAMTS13 Antibody Test | ABADM | Test will no longer be orderable. Recommended replacement test is ADAMTS13 Evaluation (ADM13). | 1/20/26 |
| Dabigatran Assay | DBGTRN | Test will no longer be orderable. Recommended replacement test is Dilute Thrombin Time Panel (DTT). | 1/20/26 |
| Micro lab use only HSV PCR – Miscellaneous Specimen Types | PCRHSV | Name: Previously HSV PCR - Miscellaneous Specimen Types<br>Test will no longer be orderable. Recommended replacement test is Herpes Simplex Virus (HSV-1/2) PCR, Non-Lesion (HSVPCR). | 1/20/26 |
| Micro lab use only Varicella Zoster by PCR | VZPCR | Name: Previously Varicella Zoster by PCR<br>Test will no longer be orderable. Recommended replacement test is Varicella Zoster Virus (VZV) PCR, Non-Lesion (VZVPCR). | 1/20/26 |