

Test Bulletin



Dear Healthcare Provider,

The information contained here may be very important to your practice. Please take a moment to review this document.

BIOFIRE FILMARRAY Gastrointestinal Panel: Updated Assay Limitation March 2025

For qualitative detection of gastrointestinal pathogens by PCR, it is possible for increased incidences of false positive Norovirus GI/GII results. **See page 2 for details.**

HIV-1 Viral Load by PCR: Updated Assay Limitation March 2025

For quantitative viral load testing of HIV-1 by PCR, it is possible for patients who have received certain gene therapies that utilize HIV-1 based lentiviral vectors to have a false detection of HIV-1. **See page 2 for details.**

Legionella Antigen Urine March 2025

Testing for Legionella antigen in urine (Soft code LEGAG) should only be ordered on patients ≥ 21 years of age. **See page 2 for details.**

Type & Screen Follow-Up Testing March 2025

If a blood bank antibody screen is resulted as positive, patients should be directed to their local hospital for any necessary follow-up testing. Patients should not return to a Patient Service Center for follow-up laboratory testing. **See page 3 for details.**

Client Supply Ordering March 2025

Beginning in early March, Alverno will launch supply ordering via the online Client Community. **See page 3 for details**.

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UTILIZATION GUIDES

BIOFIRE FILMARRAY Gastrointestinal Panel: Updated Assay Limitation March 2025

Alverno Laboratories performs qualitative detection for several gastrointestinal (GI) pathogens using the BIOMÉRIEUX BIOFIRE FILMARRAY Gastrointestinal Panel (Soft codes BFGI and BFGI2). BIOMÉRIEUX has updated the analytical and clinical specificity for Norovirus GI/GII based on recent investigations into reported false positive results. The clinical specificity (or negative percent agreement) decreased to 96.5% from 98.8% for this panel target. If Norovirus is the suspected causative agent, please consider ordering Norovirus 1 & 2 by PCR (Soft code NOROA) for verification.

HIV-1 Viral Load by PCR: Updated Assay Limitation March 2025

Alverno Laboratories performs quantitative viral load testing for HIV-1 using the Abbott Alinity m HIV PCR assay (Soft code HIVAL). Abbott Molecular has extended the limitations of this assay for patients who have received gene therapies, such as chimeric antigen receptor (CAR) T-cells or hematopoietic stem cells. These therapies may utilize HIV-1 based lentiviral vectors to deliver therapeutic genes to patients with hereditary or acquired diseases resulting in the Alinity m HIV-1 assay to falsely detect HIV-1 in these patients. The Alinity m HIV-1 assay is not intended to be used as a screening test for HIV-1.

Legionella Antigen Urine March 2025

Testing for Legionella antigen in urine (Soft code LEGAG) is performed by the Microbiology Department at Alverno Laboratories using the TRU Legionella® rapid immunoassay. This test is not approved for use on specimens from patients less than 21 years of age. **Please only order this test for patients** ≥ **21 years of age.**

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UTILIZATION GUIDES

Type & Screen Follow-Up Testing March 2025

For ambulatory patients who have a positive antibody screen, please send patients directly to their local hospital for any necessary follow-up testing, including antibody identification. **Patients should not return to a Patient Service Center for follow-up laboratory testing.** If the testing is pre-natal in nature, direct patients to the hospital where they will deliver.

Antibody identification is not performed directly at the Central Laboratory. Rather, it is referred to Versiti. Additionally, it is important for a pregnant patient to have a blood bank history at the hospital where they will deliver to expedite preparation of blood products, if needed.

Client Supply Ordering March 2025

Alverno is pleased to announce a better online supply ordering process for our valued clients. Beginning in early March, Alverno will launch supply ordering via the online Client Community. The Client Community portal can be accessed via our website at www.alvernolabs.com/client-community. Instructions will be posted once this functionality is live.

