June 3, 2021

URGENT: FIELD SAFETY NOTICE

FSCA 5183

Increased risk of false negative Adenovirus results using BioFire® FilmArray® Pneumonia *plus* (PN *plus)* Panel (Part No.: RFIT-ASY-0142 and RFIT-ASY-0143) within 6 months of expiration.

The purpose of this letter is to inform you that BioFire Diagnostics, LLC has identified a potential for obtaining elevated rates of false negative Adenovirus results when using the BioFire® PN *plus* Panel.

These potential Adenovirus false negatives are due to a 10-100x reduction in sensitivity specifically for adenovirus species C when using all BioFire® PN *plus* Panel kits within 6 months of expiration.

- The test performance is **NOT** impacted if kits are more than 6 months from expiration date.
- Performance for other adenovirus species (e.g. A, B, D, E, F, and G) is **NOT** affected
- The adenovirus assays on all other BioFire® Respiratory Panels are **NOT** affected.

The potential impact of a false negative Adenovirus result for mild to moderate illness caused by adenovirus C in immunocompetent persons is serious if the false negative result influences patient care such that the patient remains on or is placed on unnecessary antimicrobial therapy (i.e. the clinician cannot rule out bacterial infection). A continuation on unnecessary antibiotics and/or extended treatment with antibiotics may have risks associated with the medication. Additionally, if the medication is given by IV, the site can become infected or cause a blood clot. Medication-associated risks are common, but usually not life threatening and are reversible. Sometimes adverse events can prolong hospital stay.

The overall risk for immunocompromised patients, in particular transplant patients, is critical. A false negative result could lead to increased morbidity and potentially death due to lack of appropriate antiviral therapy which is considered the standard practice for treatment of severe, progressive, or disseminated adenovirus disease in most transplant centers. Note that the performance of this test has not been established for immunocompromised individuals.

If using a BioFire® PN *plus* Panel kit that is within 6 months of expiration, please confirm all negative Adenovirus results from patients suspected of adenovirus C infection via another method prior to reporting those results (e.g. consider results from testing a nasopharyngeal swab with a different BioFire respiratory panel such as the BioFire® Respiratory 2.1 *plus* Panel), **or alternatively, the BioFire PN *plus* Panel Adenovirus negative result should not be reported**.

Actions to be taken by customer:

- Immediately examine your inventory for product identified in this recall.
    - If you identify any affected BioFire PN *plus* Panels in your inventory (i.e. BioFire PN *plus* Panels within 6 months of shelf-life), you may continue using the affected product; however, when adenovirus C infection is suspected, negative results for Adenovirus should be confirmed by another method prior to reporting test results to clinicians, or alternatively, the BioFire PN *plus* Panel Adenovirus negative result should not be reported.

- If you have further distributed this product, please identify your customers and notify them at once of this product recall.

- Please complete the enclosed Acknowledgement of Receipt Form as soon as possible and return it to your local bioMérieux representative.

Actions to be taken by BioFire:

- BioFire is currently investigating this issue and closely monitoring field reports. If additional, pertinent information is uncovered, you will be notified.

If you have any questions or concerns, please don't hesitate to contact your local bioMérieux representative. The competent (regulatory) authority of your country has been informed about this communication to customers.

Thank you for your understanding and patience in this matter.

Sincerely,

Aneta Waliszewski
Senior Quality Director
BioFire Diagnostics, LLC