



bioMérieux Nordic countries
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Our Ref.: 5183 - FSCA - BioFire® -
Pneumonia Panel - Increased Risk of FN

Gothenburg, June 2021

URGENT FIELD SAFETY NOTICE
5183 - FSCA - BioFire® - Pneumonia Panel - Increased Risk of FN

Dear customer,

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.**

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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,

Regards,

Customer Service Department
bioMérieux Nordic countries

On behalf of

A handwritten signature in cursive script that reads "Aneta Waliszewski".

Aneta Waliszewski Senior Quality Director BioFire Diagnostics, LLC



Attachment A: Acknowledgement
Form

**URGENT FIELD SAFETY
NOTICE**

**FSCA - 5183 – Increased risk of false negative Adenovirus C results using the BioFire®
FilmArray®Pneumonia *plus* (PN *plus*) Panel (Part No.: RFIT-ASY-0142 and RFIT-
ASY-0143).**

Customer Information:

Customer Account Number: _____

Organization Name: _____

Street Address: _____

City, State and Postal Code: _____

Contact Name: _____

Contact Title: _____

Phone Number: _____

Product Information:

Catalog Number	Description
RFIT-ASY-0142	BioFire® FilmArray® Pneumonia <i>plus</i> Panel
RFIT-ASY-0143	BioFire® FilmArray® Pneumonia <i>plus</i> Panel

Questions:

	Yes	No
1. Did you read the enclosed Field Safety Notice regarding increased risk of falsenegative Adenovirus C results using the BioFire Pneumonia <i>plus</i> Panel (Part No.: RFIT-ASY-0142 and RFIT-ASY-0143)?		
2. Have you implemented the actions as indicated in this Field Safety Notice? If no, please indicate the reason in the Comments section below.		
3. Have you received reports of illness or injury related to the described issue?		
Comments: 		

Signature: _____

Date: _____

It is important that you complete this Acknowledgement Form and return it to

fieldactions.nordic@biomerieux.com