January 25, 2021

URGENT: FIELD SAFETY NOTICE

FSCA 5046

Increased risk of false positive *Pseudomonas aeruginosa* results using BioFire® FilmArray® Blood Culture Identification (BCID) Panel (Part No.: RFIT-ASY-0126 and RFIT-ASY-0127) and BioFire® Blood Culture Identification 2 (BCID2) Panel (Part No.: RFIT-ASY-0147) with BD BACTEC™ blood culture vials

The purpose of this letter is to inform you that BioFire Diagnostics, LLC has identified an increased risk of false positive *P. aeruginosa* results when the BioFire BCID or BCID2 Panel is used with certain types of BD BACTEC™ blood culture vials (see Table 1) with expiration dates of 31Jul2021 and 31Aug2021.

Table 1. Affected media types

BD Blood Culture Media Catalog No.	Description
442023	BD BACTEC™ Plus Aerobic medium in plastic vials
442020	BD BACTEC™ Peds Plus medium in plastic vials

The most probable cause for this risk is the presence of an increased level of nucleic acid from non-viable *P. aeruginosa* in BD BACTEC™ blood culture vials (Table 1). **The presence of non- viable organism does not compromise the intended function of the blood culture vials (culturing viable microorganisms)**. However, the BioFire BCID and BCID2 Panels detect nucleic acid from viable and non-viable organisms alike. Observed *P. aeruginosa* false positives are typically seen as multiple positives with the BioFire BCID and BCID2 Panels because a positive blood culture is a prerequisite to a BCID or BCID2 test.

The BioFire BCID and BCID2 Panel product literature includes the following limitations:

- Blood culture media may contain non-viable organisms and/or nucleic acid at levels that can be detected by the BioFire BCID/BCID2 Panel, leading to false positive test results. Typically, these false positives will be present with one or more additional true positive results because the BioFire BCID/BCID2 Panel will also detect the organism that is growing in the culture bottle.

- In some cases, the Gram stain result and results of the BioFire BCID/BCID2 Panel may be discrepant (for example, detection of gram-positive cocci by the BioFire BCID/BCID2 Panel when gram-positive cocci were not observed in the Gram stain). In these cases, the BioFire BCID/BCID2 Panel results should be confirmed (e.g. by culture) before reporting, unless the result is concordant with other laboratory, epidemiological, or clinical findings.

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Actions to be taken by customer:

- If the BioFire BCID or BCID2 Panel is used to test BD BACTEC™ blood culture vials (Table 1), with an expiration date of 31Jul2021 and 31Aug2021, positive results for *P. aeruginosa* should be confirmed by another method prior to reporting the test results.
- Please complete the Acknowledgment Form accompanied with this Field Safety Notice and return it to your local bioMérieux representative.

Actions to be taken by BioFire:

- BioFire BD teams are coordinating efforts to resolve this issue.

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,

Mari Hoidal
Sr. Global Marketing Director
BioFire Diagnostics, LLC

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