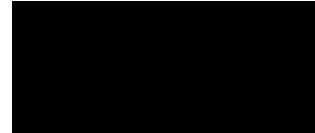




bioMérieux Deutschland GmbH · Postfach 1204 · 72602 Nürtingen

Date: 22. March 2019
Department: Scientific Customer Service
Contact:
Phone:
Fax:
Email:
Our Reference:
Your Reference:
Your Customer Number:



PLEASE DELIVER UPON RECEIPT to LAB DIRECTOR or LAB MANAGER

URGENT FIELD SAFETY NOTICE

Reply required

Increased risk of false positive *Enterobacteriaceae* and *Escherichia coli* results using the BioFire® FILMARRAY® Blood Culture Identification (BCID) Panel (Part No.: RFIT-ASY-0126 and RFIT-ASY-0127) with bioMérieux BACT/ALERT® blood culture bottles

Dear Valued bioMérieux customer,

The purpose of this letter is to inform you that BioFire Diagnostics, LLC has identified an increased risk of false positive *Enterobacteriaceae* and *Escherichia coli* results when the BioFire BCID Panel is used with bioMérieux BACT/ALERT® blood culture bottles identified in Table 1. The false positive results are primarily *Enterobacteriaceae* results with a lower rate of concurrent *E. coli* results.

Table 1. Affected media types

Description	Part Number	BACT/ALERT® Blood Culture Bottle Lot No.
BACT/ALERT® FA Plus	410851	4052663, 4052639, 4052640, 4052599, 4052598, 4052547, 4052546, 4052471, 4052472, 4052799, 4052800, 4052815, 4052816
BACT/ALERT® FN Plus	410852	4052871, 4052872, 4052459, 4052458, 4052565, 4052564, 4052705, 4052704, 4052735, 4052617, 4052616
BACT/ALERT® PF Plus	410853	4052717, 4052718, 4052503, 4052504

The most probable cause for this risk is the presence of an increased level of nucleic acid from non-viable *Escherichia coli* in select BACT/ALERT® Blood Culture Bottles (Table 1). *E. coli* is a member of the *Enterobacteriaceae* taxonomic family. Two types of false positive results have been seen with the latter being observed less frequently:

- false positive *Enterobacteriaceae* family-level assay with all *Enterobacteriaceae* species-level assays being true negatives
- *Enterobacteriaceae* family-level assay and *E. coli* assay simultaneously providing false positive results.

BioFire has confirmed the presence of *Escherichia coli* nucleic acid in BACT/ALERT bottle lots using an independent PCR/bi-directional sequencing method. **The presence of non-viable organism does not compromise the intended function of the blood culture bottles (culturing)**
bioMérieux Deutschland GmbH

viable microorganisms). However, the BioFire BCID Panel detects nucleic acid from both viable and non-viable organisms. Observed false positives are typically seen as multiple positives with the BioFire BCID Panel because a positive culture is a prerequisite to a BioFire BCID Panel test.

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

Actions:

- If the BioFire BCID Panel is used to test BACT/ALERT® blood culture bottles from the lots listed in Table 1, positive results for *Escherichia coli* and *Enterobacteriaceae* (if occurring without a specific genus/species reported other than *E. coli*; i.e. negative for all of the following: *Enterobacter cloacae* complex, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, and *Serratia marcescens*) should be confirmed by another method prior to reporting the test results. Confirmation is not required if the *Enterobacteriaceae* detected result is accompanied by a detected result for *Enterobacter cloacae* complex, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, or *Serratia marcescens* (refer to Table 2). For *Proteus* detection using BACT/ALERT® blood culture bottles, refer to Table 2 below.

Table 2. Recommended confirmation testing for *Enterobacteriaceae* assay results

BioFire BCID Panel Interpretations	Recommended Confirmation Testing
<i>Enterobacteriaceae</i> detected	Confirm by another method
<i>Enterobacteriaceae</i> detected and <i>Escherichia coli</i> detected	Confirm by another method
<i>Enterobacteriaceae</i> detected and <i>Enterobacter cloacae</i> complex or <i>Klebsiella oxytoca</i> or <i>Klebsiella pneumoniae</i> or <i>Serratia marcescens</i> detected	Confirmation not needed
<i>Enterobacteriaceae</i> detected and <i>Proteus</i> detected	Confirm by another method as per previous notice (refer to: https://www.online-ifu.com/ITBCID0270)

A copy of this notification is also available here: <https://www.online-ifu.com/ITBCID2286>.

Please fill out the attached Acknowledgement of receipt and return it to us by 04.04.2019 by fax (fax number 07022 3007-105).

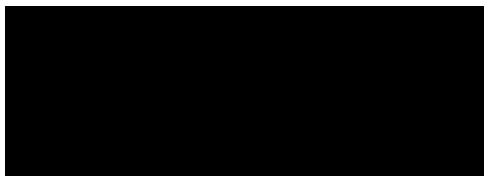
Be assured that bioMérieux is taking all necessary measures to offer you the best quality products and services. Thank you for your understanding and patience in this matter.



If you have any questions or concerns, please contact the Scientific Customer Service of bioMérieux Deutschland GmbH at +49 7022 3007-19.

Sincerely

bioMérieux Deutschland GmbH



Attachment A: Acknowledgement of receipt



Attachment A: ACKNOWLEDGEMENT FORM

URGENT FIELD SAFETY NOTICE

Reply required

To be returned to your customer service: Fax-No. 07022 3007-105

FSCA – 4292 – Increased risk of false positive *Enterobacteriaceae* and *Escherichia coli* results using the BioFire® FILMARRAY® Blood Culture Identification (BCID) Panel (Part No.: RFIT-ASY-0126 and RFIT-ASY-0127) with bioMérieux BACT/ALERT® blood culture bottles

Organization Name: _____

Contact Name: _____

City and Postal Code _____

Customer Account Number: _____

Product Information

Catalog Number	Description
RFIT-ASY-0126	FILMARRAY® Blood Culture Identification (BCID) Panel
RFIT-ASY-0127	FILMARRAY® Blood Culture Identification (BCID) Panel

By signing this document you confirm that you have received and taken note of the Urgent Product Safety Notice from bioMérieux regarding the increased risk of false positive results for *Enterobacteriaceae* and *Escherichia coli* results using the BioFire® FILMARRAY® Blood Culture Identification (BCID) Panel (Part No.: RFIT-ASY-0126 and RFIT-ASY-0127) with bioMérieux BACT/ALERT® blood culture bottles. You further acknowledge that you have followed the instructions and implemented the actions as indicated in this Urgent Product Correction Notice.

Have you received reports of illness or injury related to the described issue?

☐ **No**

☐ **Yes**

If **Yes**, would you please give us your phone number so that we can call you back:

.....

If you have not implemented the actions, please indicate the reason in the Comments section below.

Comments

DATE **SIGNATURE**