bioMérieux Deutschland GmbH · Postfach 1204 · 72602 Nürtingen

Date: 26. June 2019
Department:
Contact:
Phone:
Fax:
E-mail:
Our reference :
Your reference:
Your customer account number:

PLEASE DELIVER UPON RECEIPT to LAB DIRECTOR or LAB MANAGER

URGENT: FIELD SAFETY NOTICE

Reply required

Investigation Update and Required and Recommended Customer Actions:

Modification to the BIOFIRE® FilmArray® Gastrointestinal (GI) Panel (Part No.: RFIT-ASY-0104 and RFIT-ASY-0116) BIOFIRE® FilmArray® Gastrointestinal (GI) Panel Pouch Module Software

Dear Valued Customer,

An increased incidence of non-specific chemistry interactions in BIOFIRE GI Panels performed on the BIOFIRE® FilmArray® Torch System combined with a recent change in reagent manufacturing is leading to a rate of false positive *Campylobacter* and *Cryptosporidium* results that exceeds BioFire's published product claims.

The rates of false positive results for BIOFIRE GI Panels performed on the BIOFIRE® FilmArray® 1.5 or the BIOFIRE® FilmArray® 2.0 Systems were found to be within BioFire's published product claims. BIOFIRE GI Panels performed on either of these systems no longer require previously recommended confirmatory testing for *Campylobacter* and *Cryptosporidium* (customer letter issued March 2019, https://www.online-ifu.com/ITIGI2357).

Action Taken by BioFire

BioFire has validated an updated version of the BIOFIRE GI Panel Pouch Module Software that improves temperature control during BIOFIRE GI Panel testing on the BIOFIRE Torch System and mitigates the increased risk of related false positives. *This update does **not** affect thermocycling parameters and does **not** change the claimed performance of the BIOFIRE GI Panel.* The updated software makes the BIOFIRE Torch System less susceptible to non-specific chemistry interactions by maintaining high temperatures between nested PCR steps that occur within the BIOFIRE GI Panel reagents.

Actions to Be Taken By BIOFIRE GI Panel Users

BIOFIRE Torch System Users

- **Required**: Update the BIOFIRE GI Panel Pouch Module Software.
    - The updated BIOFIRE GI Panel Pouch Module Software and a technical note with important information and instructions for installation can be downloaded here: https://www.online-ifu.com/ITIFA20GI21. Please read this technical note *before* installation.
- Once the software has been updated, previously recommended confirmatory testing for *Campylobacter* and *Cryptosporidium* may be stopped and results may be reported normally.

BIOFIRE FilmArray 2.0 System Users

- **Recommended**: Update the BIOFIRE GI Panel Pouch Module Software.
    - The updated BIOFIRE GI Panel Pouch Module Software and a technical note with important information and instructions for installation can be downloaded here: https://www.online-ifu.com/ITIFA20GI21. Please read this technical note before installation.
- Previously recommended confirmatory testing for *Campylobacter* and *Cryptosporidium* may be stopped and results may be reported normally.

BIOFIRE® FilmArray® 1.5 System Users

- No action related to the BIOFIRE® FilmArray® Gastrointestinal (GI) Panel Pouch Module Software is required. BioFire has not updated BIOFIRE GI Panel Pouch Module Software for the BIOFIRE 1.5 System.
- Previously recommended confirmatory testing for *Campylobacter* and *Cryptosporidium* may be stopped and results may be reported normally.

Please fill out the attached Acknowledgement of receipt and return it to us by 08.07.2019 by fax (fax number 07022 3007-105).

Additional Information

BioFire will continue to provide credit to BIOFIRE® FilmArray® Torch System users for the BIOFIRE® FilmArray® Gastrointestinal (GI) Panel retesting to confirm positive *Campylobacter* and *Cryptosporidium* results through July 15, 2019. This is to provide ample time for BIOFIRE Torch System users to install the updated BIOFIRE GI Panel Pouch Module Software.

BioFire will not continue to provide credit to BIOFIRE FilmArray 1.5 or BIOFIRE® FilmArray® 2.0 System users as previously recommended confirmatory testing for *Campylobacter* and *Cryptosporidium* is no longer required for BIOFIRE GI Panels performed on either of these systems.

The countdown timer displayed for the BIOFIRE GI Panel run time, which was originally set at 65 minutes, has been updated to display 75 minutes with the updated pouch module software.

If you have any questions or concerns, please don’t hesitate to contact your local bioMérieux representative.

Sincerely
bioMérieux Deutschland GmbH

[redacted]

Attachment A: Acknowledgement of receipt

Attachment A: ACKNOWLEDGEMENT FORM

URGENT PRODUCT CORRECTION NOTICE

Reply required

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

FSCA – 4280-2 – Modification to BioFire® FilmArray® Gastrointestinal (GI) Panel (RFIT-ASY-0104 and RFIT-ASY-0116) Pouch Module Software

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Organization Name: _____

Contact Name: _____

City and Postal Code _____

Customer Number: _____

Product Information

Catalog Number	Description
RFIT-ASY-0104	FilmArray® Gastrointestinal (GI) Panel (6 pack)
RFIT-ASY-0116	FilmArray® Gastrointestinal (GI) Panel (30 pack)

COMPLETE ALL APPLICABLE SECTIONS BELOW:

BIOFIRE® FilmArray® Torch System Users	**Yes**	**No**
(1) I have read and understand the instructions in the Medical Device Field Safety Notice.		
(2) **Mandatory:** I have updated all BIOFIRE® Torch systems within my organization to version 2.0.1 of the BIOFIRE® Gastrointestinal Pouch Module Software.		
(3) Have you received reports of illness or injury related to the described issue?		
BIOFIRE® FilmArray® 2.0 System Users	**Yes**	**No**
(1) I have read and understand the instructions in the Medical Device Field Safety Notice.		
(2) **Recommended:** I have updated all BIOFIRE® 2.0 systems within my organization to version 2.0.1 of the BIOFIRE® Gastrointestinal Pouch Module Software.		
(3) Have you received reports of illness or injury related to the described issue?		
BIOFIRE® FilmArray® 1.5 System Users	**Yes**	**No**
(1) I have read and understand the instructions in the Medical Device Field Safety Notice.		
(2) Have you received reports of illness or injury related to the described issue?		

DATE …… SIGNATURE ……..…