IMPORTANT:

URGENT FIELD SAFETY NOTICE

False Positive Vibrio/Vibrio cholerae Results on the BIOFIRE GI Panel associated with Remel Cary Blair

Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Laboratory Medical Director

Date

bMx local contact information

(to be adapted at local level)

Our reference: FSCA - FIELD SAFETY CORRECTIVE ACTION - FA-TWD-000007

Impacted products ***(to be adapted at local level if necessary including for names and ref #, local license #, name and address of manufacturer)***

Product Name	**Reference Number**	**Lot Number/Serial Number/ Product version**	**Product Expiration Date (if applicable)**
BioFire® FilmArray® Gastrointestinal (GI) Panel	RFIT-ASY-0116	All unexpired lots when used with Remel Cary-Blair Transport Medium	All unexpired lots when used with Remel Cary-Blair Transport Medium
BioFire® FilmArray® Gastrointestinal (GI) Panel	RFIT-ASY-0104	All unexpired lots when used with Remel Cary-Blair Transport Medium	All unexpired lots when used with Remel Cary-Blair Transport Medium

Dear bioMérieux Customer,

Our records indicate you may be using the product identified in the above table.

The purpose of this letter is to inform you that bioMérieux has identified an increased risk of false positive *Vibrio/Vibrio Cholerae* results when the BIOFIRE GI Panel is used with certain lots of Remel™ Cary-Blair transport medium (see Appendix A - Affected Remel™ Cary-Blair Lots).

Required actions

In this context, we request you take the following actions:

- If the BIOFIRE GI Panel is used in conjunction with certain lots of Remel™ Cary-Blair (Lot # 743930, 769240, 712258, 782425, 732357, and 742049), positive results for *Vibrio/Vibrio Cholerae* should be confirmed by another method prior to reporting the test results.
- Distribute this information to all appropriate personnel in your laboratory, retain a copy for your files, post this letter in or near the laboratory, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
- Complete the Acknowledgement Form in Attachment A and return it to bioMérieux so that bioMérieux may acknowledge your receipt of this notification. It is important that you return the acknowledgment form to bioMérieux even if you determine this urgent field safety notice does not impact your facility.

Description of the issue

The cause for this risk is the presence of an increased level of non-viable organism from *Vibrio/Vibrio Cholerae* targets in Remel™ Cary-Blair transport medium. The presence of non-viable organisms does not compromise the intended function of the transport medium. However, the BIOFIRE GI Panel detects nucleic acid from viable and non-viable organisms alike.

The BIOFIRE GI Panel product literature includes the following limitation:

- Cary Blair transport medium may contain non-viable organisms and/or nucleic acid at levels that can be detected by the BIOFIRE GI Panel.

The BIOFIRE GI Panel is indicated as an aid in the diagnosis of gastrointestinal illness and results are meant to be used in conjunction with other clinical, laboratory, and epidemiological data.

Impact to User/Customer/Patients

A false positive result could lead to an inappropriate change in therapy. The patient may remain on inappropriate therapy until the *Vibrio/Vibrio Cholerae* is confirmed or not.

Local legal mentions to be added if necessary at local level (e.g. in case of recall, reporting to NCA, recall methods)

bioMérieux is committed to providing our customers with the highest quality product possible.

We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact *your local bioMérieux Customer Service representative (to be adapted at local level)*.

Yours faithfully,

Customer Service

Attachment A: Acknowledgement Form.

URGENT: Field Safety Notice

FSCA - FIELD SAFETY CORRECTIVE ACTION FA-TWD-000007 False Positive Vibrio/Vibrio cholerae Results on the BIOFIRE GI Panel associated with Remel Cary Blair

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TO BE RETURNED TO *YOUR BIOMERIEUX CUSTOMER SERVICE (TO BE ADAPTED AT LOCAL LEVEL)*
AT THE FOLLOWING
FAX NUMBER: XXXXXXXX OR EMAIL ADDRESS: XXXXXXX

Name and Address of the laboratory	
Contact information	
Customer Account Number	

Local legal mentions to be added if necessary at local level)

☐ I am not impacted by the issue. Please provide rationale: ……

☐ I have implemented the required actions.

Have you encountered impact on patients' results, or reports of illness or injury related to the identified issue ? *(to be completed based on FCA/FSCA issue)*

☐ Yes ☐ No

DATE…….....SIGNATURE……

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

Appendix A – Affected Remel™ Cary-Blair Lots

	Lot Number	Expiration Date
Remel™ Cary-Blair	743930	10/8/2024
	769240	12/3/2024
	712258	8/2/2024
	782425	12/26/2024
	732357	9/12/2024
	742049	10/4/2024