BIOMÉRIEUX

FIELD ACTION NOTIFICATION

GENERAL INFORMATION

FSCA - FIELD SAFETY CORRECTIVE ACTION			
Field Action Number:	FA-TWD-000084	**Field Action rev. n°:**	1
CRM Number	FA-055242 | Field Action | Salesforce		
Subject:	False Positive KPC Results on BIOFIRE® FILMARRAY® Pneumonia Panel, BIOFIRE® FILMARRAY® Pneumonia *plus* Panel, and BIOFIRE® Joint Infection Panel		
Type of Required Actions:	**Manufacturer action(s)**	**User action(s)**	
	Customer information only Other Identify any product affected by Product Stop Ship 5936 and release product for distribution/sale.	Identify Device Other The user is required to confirm KPC positive results on affected product.	
Manufacturing Site:	BioFire Diagnostics, LLC 515 Colorow Drive Salt Lake City, Utah 84108		
CI n°:	CI-005165		
Other FA / CSN n°:	PSS 5936		
Date of decision to take action in the field	27-JUL-2026		
Issue Date:	**12-AUG-2026**	**Due Date:**	**12-AUG-2027**

SECTION A: DETAILS

Impacted product

System	Product	Ref #	Lot / SN #	Expiry	Software version(s)	Firmware version(s)	Catalog profile	Manufacturing Start & End Date	Shipment Start & End Date	Qty of products released by manuf. site	Unit name	Business unit	GMDN Code	EMDN Code	Unique Device Identifier
BIOFIRE FILMARRAY	PNEUMONIA PANEL, 30-PACK	RFIT-ASY-0144	See Appendix A	N/A	N/A	N/A	B46	N/A	N/A	N/A	Molecular	Diagnostic	61527	N/A	00815381020178
BIOFIRE FILMARRAY	PNEUMONIA PLUS PANEL, 30-PACK	RFIT-ASY-0143	See Appendix A	N/A	N/A	N/A	B46	N/A	N/A	N/A	Molecular	Diagnostic	61527	N/A	00815381020314
BIOFIRE FILMARRAY	PNEUMONIA PLUS PANEL, 6-PACK	RFIT-ASY-0142	See Appendix A	N/A	N/A	N/A	B46	N/A	N/A	N/A	Molecular	Diagnostic	61527	N/A	00815381020321
BIOFIRE	JOINT INFECTION PANEL, 30-PACK	RFIT-ASY-0138	See Appendix A	N/A	N/A	N/A	B46	N/A	N/A	N/A	Molecular	Diagnostic	65914	W0105070502	00815381020192
BIOFIRE	JOINT INFECTION PANEL, 6-PACK	RFIT-ASY-0135	See Appendix A	N/A	N/A	N/A	B46	N/A	N/A	N/A	Molecular	Diagnostic	65914	W0105070502	00815381020208
BIOFIRE FILMARRAY	PNEUMONIA PANEL, 6-PACK	RFIT-ASY-0145	See Appendix A	N/A	N/A	N/A	B46	N/A	N/A	N/A	Molecular	Diagnostic	61527	N/A	00815381020185
BIOFIRE FILMARRAY	PNEUMOVERIFICATION KIT*	FLM1-ASY-0150	See Appendix A	N/A	N/A	N/A	B46	N/A	N/A	N/A	Molecular	Diagnostic	N/A	N/A	03573026611941

*The verification kit lots (FLM1-ASY-0150) consumed kits from panel lots (RFIT-ASY-0144). The verification kit is included for the purposes of identification of customers with the customer management system. This is a sales configuration and is not registered with competent authorities.

Name & Address of Legal Manufacturer

Name & Address of Recalling Firm : BioFire Diagnostics, LLC
515 Colorow Drive
Salt Lake City, Utah 84108

Name & Address of Manufacturing site: BioFire Diagnostics, LLC
515 Colorow Drive
Salt Lake City, Utah 84108

SIG Code of Manufacturing site: NA009

Product Intended Use

Pneumonia Panel:
The BIOFIRE® FILMARRAY® Pneumonia Panel (BIOFIRE Pneumonia Panel) is a multiplexed nucleic acid test intended for use with BIOFIRE® FILMARRAY® 2.0 (BIOFIRE 2.0) or BIOFIRE® FILMARRAY® TORCH (BIOFIRE TORCH) systems for the simultaneous detection and identification of multiple respiratory viral and bacterial nucleic acids, as well as select antimicrobial resistance genes, in sputum-like specimens (induced or expectorated sputum, or endotracheal aspirates) or bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL) obtained from individuals suspected of lower respiratory tract infection.

The following bacteria are reported semi-quantitatively with bins representing approximately 10^4, 10^5, 10^6, or ≥10^7 genomic copies of bacterial nucleic acid per milliliter (copies/mL) of specimen, to aid in estimating relative abundance of nucleic acid from these common bacteria within a specimen:

Bacteria reported with bins of 10^4, 10^5, 10^6, or ≥10^7 copies/mL
Acinetobacter calcoaceticus-baumannii complex
Klebsiella oxytoca
Enterobacter cloacae complex
Klebsiella pneumoniae group
Escherichia coli
Haemophilus influenzae
Klebsiella aerogenes
Moraxella catarrhalis
Proteus spp.
Serratia marcescens
Staphylococcus aureus
Streptococcus agalactiae
Streptococcus pneumoniae
Pseudomonas aeruginosa
Streptococcus pyogenes

The following atypical bacteria, viruses, and antimicrobial resistance genes are reported qualitatively:

Atypical Bacteria
Chlamydia pneumoniae
Legionella pneumophila
Mycoplasma pneumoniae

Viruses
Middle East respiratory syndrome coronavirus (MERS-CoV) (**Pneumonia Panel *plus* only**)
Adenovirus
Human rhinovirus/enterovirus
Coronavirus
Parainfluenza virus
Influenza A virus
Human metapneumovirus
Influenza B virus
Respiratory syncytial virus

Antimicrobial Resistance Genes
CTX-M
NDM

IMP
mecA/C and MREJ (MRSA)
OXA-48-like
KPC
VIM

The detection and identification of specific viral and bacterial nucleic acids, as well as the estimation of relative abundance of nucleic acid from common bacterial analytes, within specimens collected from individuals exhibiting signs and/or symptoms of a respiratory infection, aids in the diagnosis of lower respiratory infection if used in conjunction with other clinical and epidemiological information. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test, pathogens below the limit of detection, or in the case of bacterial analytes, present at levels below the lowest reported 10^4 copies/mL bin. Detection of analytes does not rule out co-infection with other organisms; the agent(s) detected by the BIOFIRE Pneumonia Panel may not be the definite cause of disease. Additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with a possible lower respiratory tract infection.

Detection of bacterial nucleic acid may be indicative of colonizing or normal respiratory flora and may not indicate the causative agent of pneumonia. Semi-quantitative Bin (copies/mL) results generated by the BIOFIRE Pneumonia Panel are not equivalent to CFU/mL and do not consistently correlate with the quantity of bacterial analytes compared to CFU/mL. For specimens with multiple bacteria detected, the relative abundance of nucleic acids (copies/mL) may not correlate with the relative abundance of bacteria as determined by culture (CFU/mL). Clinical correlation is advised to determine significance of semi-quantitative Bin (copies/mL) for clinical management.

The antimicrobial resistance gene detected may or may not be associated with the agent(s) responsible for disease. Negative results for these antimicrobial resistance gene assays do not indicate susceptibility to corresponding classes of antimicrobials, as multiple mechanisms of antimicrobial resistance exist.

Antimicrobial resistance can occur via multiple mechanisms. A “Not Detected” result for a genetic marker of antimicrobial resistance does not indicate susceptibility to associated antimicrobial drugs or drug classes. A “Detected” result for a genetic marker of antimicrobial resistance cannot be definitively linked to the microorganism(s) detected. Culture is required to obtain isolates for antimicrobial susceptibility testing, and BIOFIRE Pneumonia Panel results should be used in conjunction with culture results for determination of bacterial susceptibility or resistance.

Due to the genetic similarity between human rhinovirus and enterovirus, the test cannot reliably differentiate them. A positive Rhinovirus/Enterovirus result should be followed up using an alternate method (e.g., cell culture or sequence analysis) if differentiation is required.

Culture is required to identify pathogens not detected by the BIOFIRE Pneumonia Panel, to further speciate analytes in genus, complex, or group results if desired, to identify bacterial pathogens present below the 10^4 copies/mL bin if desired, and for antimicrobial susceptibility testing.

For Pneumonia Panel *plus* Only:

Positive results for MERS-CoV should be reported to state or local health departments. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Joint Infection Panel:
The BIOFIRE® Joint Infection (JI) Panel is a multiplexed nucleic-acid-based, in vitro diagnostic test intended for use with BIOFIRE® FILMARRAY® 2.0 and BIOFIRE® FILMARRAY® Torch Systems for the simultaneous qualitative detection and identification of multiple bacterial and yeast nucleic acids and select antimicrobial resistance genes from synovial fluid obtained from individuals suspected to have a joint infection.

The following organisms are identified using the BIOFIRE JI Panel:

Gram Positive Bacteria
Anaerococcus prevotii/vaginalis
Clostridium perfringens
Cutibacterium avidum/granulosum
Enterococcus faecalis
Enterococcus faecium
Finegoldia magna
Parvimonas micra
Peptoniphilus
Peptostreptococcus anaerobius
Staphylococcus aureus
Staphylococcus lugdunensis
Streptococcus spp.
Streptococcus agalactiae
Streptococcus pneumoniae
Streptococcus pyogenes

Gram Negative Bacteria
Bacteroides fragilis
Citrobacter
Enterobacter cloacae complex
Escherichia coli
Haemophilus influenzae
Kingella kingae
Klebsiella aerogenes
Klebsiella pneumoniae group
Morganella morganii
Neisseria gonorrhoeae
Proteus spp.
Pseudomonas aeruginosa
Salmonella spp.
Serratia marcescens

Yeast
Candida spp.
Candida albicans

The BIOFIRE JI Panel contains assays for the detection of genetic determinants associated with S. aureus resistance to methicillin (*mecA/C* in conjunction with the SCCmec right extremity junction (MREJ)), enterococcal resistance to vancomycin (*vanA* and *vanB*) and some mechanisms of gram-negative bacterial resistance to ß-lactams including penicillins, cephalosporins, monobactams, and carbapenems (*blaCTX-M, blaIMP, blaKPC, blaNDM, blaOXA-48-like, blaVIM*). Detection of these genetic determinants can aid in the identification of potentially antimicrobial-resistant organisms in synovial fluid samples. The antimicrobial resistance gene or marker detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene assays do not indicate susceptibility, as multiple mechanisms of resistance to methicillin, vancomycin, and ß-lactams exist.

Antimicrobial Resistance Genes
CTX-M
IMP
KPC

mecA/C and MREJ (MRSA)
NDM
OXA-48-like
vanA/B
VIM

The BIOFIRE JI Panel is indicated as an aid in the diagnosis of specific agents of joint infection and results should be used in conjunction with other clinical and laboratory findings. Negative results may be due to infection with pathogens that are not detected by this test, pathogens present below the limit of detection of the assay, or infection that may not be detected in a synovial fluid specimen. Positive results do not rule out co-infection with other organisms. The BIOFIRE JI Panel is not intended to monitor treatment for joint infections.

Culture of synovial fluid is necessary to recover organisms for susceptibility testing and epidemiological typing, to identify organisms in the synovial fluid that are not detected by the BIOFIRE JI Panel, and to further identify species in the genus, complex, or group results.

Description of the Issue

Investigation Reference No. :
CI/CAPA n° if any :
CI-005165
Associated customer complaint, if any :
Other FA/CSN, if any :
PSS 5936
PSS reference n° and issue date, if any :
Product Stop Ship 5936 was initiated for specific lots of the Pneumonia, Pneumonia *plus*, and JI Panels on June 15, 2026.

Description of the issue :
Issue Description:
Beginning April 5, 2026, elevated rates of KPC unexpected positives were observed in Reagent Final QC testing of the BIOFIRE FILMARRAY Pneumonia Panel, BIOFIRE FILMARRAY Pneumonia Panel plus, and BIOFIRE Joint Infection Panel, including in passing product that met Final QC negativity requirements. Internal testing of failing product has reproduced KPC unexpected positive results, suggesting KPC nucleic acid (organism or synthetic) contamination in the pouch at levels that can lead to false positive results. Additional testing has confirmed that an isolated component, the outer primer pellet, is sufficient for producing unexpected positive KPC results. Further component analysis of unexpected positive results has indicated that a subset of pouch lots consuming outer primer pellets manufactured from March 7, 2026, to April 16, 2026, are at risk of experiencing KPC positive assays results due to outer primer pellet contamination.

The KPC assay is included on the BIOFIRE FILMARRAY Pneumonia Panel, BIOFIRE FILMARRAY Pneumonia Panel *plus*, BIOFIRE Joint Infection Panel, and BIOFIRE Blood Culture Identification 2 Panel. Although the assay is shared across these panels, the BIOFIRE Blood Culture Identification 2 Panel is optimized for positive blood culture specimens, which typically contain higher organism titers. Data indicate that the BIOFIRE FILMARRAY Pneumonia Panel, BIOFIRE FILMARRAY Pneumonia Panel *plus*, and BIOFIRE Joint Infection Panel are approximately 10- to 100- fold more sensitive than the BIOFIRE Blood Culture Identification 2 Panel. As no impact has been observed on the BIOFIRE Blood Culture Identification 2 Panel, it is not considered affected by this issue and is therefore excluded from the scope of the error/defect evaluation.

The KPC antimicrobial resistance interpretation is only visible to the customer if it occurs with a corresponding pathogen detection. To date, KPC unexpected positives observed in Final QC have not been observed in conjunction with a positive call for a related on-panel target. However, there is risk of false positive antimicrobial resistance interpretation for KPC if a customer has a true relevant pathogen detection.

Investigation Results:
To date, the investigation has determined that unexpected KPC positive results observed in the BIOFIRE FILMARRAY Pneumonia, BIOFIRE FILMARRAY Pneumonia *plus*, and BIOFIRE Joint Infection Panels are associated with low-level KPC nucleic acid

contamination. Testing of affected product has confirmed that the outer primer pellet leads to KPC unexpected melts/positives, and analysis has linked the issue to outer primer pellets manufactured between March 7, 2026, and April 16, 2026. Data from further sub-component analysis correlates outer primer pellet lots with elevated KPC positive detections with one lot of magnesium chloride lot 0000456418; however, retains from this lot of magnesium chloride are not available for direct testing.

Root cause:
Investigation indicates contamination during reagent manufacturing with KPC nucleic acid at levels that can lead to false positive KPC results on the Pneumonia, Pneumonia *plus*, and Joint Infection Panels as the likely root cause for the false positive detections. Full investigation and investigation of root cause will be documented in CI-005165.

CI/CAPA summary:
CI-005165 was initiated to further investigate root cause of false positive KPC activity.

Description of the actions

Based on an overall risk of 'Minor' for false positive KPC results on the Pneumonia and Pneumonia *plus* Panels, a Field Safety Corrective Action is recommended. Although the overall risk for a false positive KPC result on the JI Panel is 'Irrelevant', the Field Safety Corrective Action will include JI lots as the suspected source of KPC was manufactured into JI lots and unexpected positive KPC results have been observed in QC for the JI Panel. This ensures customers are fully informed of the product issue. A letter will be issued informing customers of the risk and to confirm KPC results with another method. Additionally, given the risk profile and the proposed customer action, we will resume shipment of suspended and stop-shipped product.

At subs/distributors levels:
Identify any product affected by the Product Stop Ship 5936 and release product for distribution/sale.

Translate and send the customer letter (field safety notice), including Appendix A, to customers who have received the affected lots of the Pneumonia, Pneumonia *plus*, and JI panels.

Perform delta management at least monthly.

At customers level:
Customer should identify affected product within inventory.

Customer is required to complete and submit the Acknowledgement of Receipt form.

If a positive KPC result obtained when using the affected product is inconsistent with local resistance epidemiology and clinical data, then the customer should confirm the result with an alternative method.

At manufacturing site level:
Identify any product affected by Product Stop Ship 5936 or related product suspensions and release product for distribution/sale.

Identify root cause as part of CI-005165 and correct root cause in CAPA.

At International/regional Distribution Center(s) level:
N/A

At other internal level, if any:
N/A

Hazard Assessment

Summary of the impact on customer/patient:
The hazard associated with the issue is false positive KPC results on affected lots of BIOFIRE FILMARRAY Pneumonia Panel, BIOFIRE FILMARRAY Pneumonia Panel *plus*, and BIOFIRE Joint Infection Panel products. The false positive result could lead to inappropriate patient care.
P1 is estimated for false positive KPC results to be 'Occasional' on affected lots of the BIOFIRE Pneumonia and Pneumonia *plus* Panels.
P1 is estimated for false positive KPC results to be 'Remote' on affected lots of the BIOFIRE Joint Infection Panel.
The calculation of P1 can be found in DX-REG-192443-01-False positive KPC HHA.
False Positive KPC Results have a severity of 'Serious' for both the BIOFIRE FILMARRAY Pneumonia and Pneumonia *plus* Panels, as well as the BIOFIRE Joint Infection Panel. This severity applies to both the at-risk population group and the normal population group.
Additional details can be found in DX-REG-192443-01-False positive KPC HHA.
P2 for false positive KPC results on affected lots of the BIOFIRE Pneumonia and Pneumonia *plus* Panels is 'Occasional'.
P2 for false positive KPC results on affected lots of the BIOFIRE Joint Infection Panel is 'Remote'.
Additional details can be found in DX-REG-192443-01-False positive KPC HHA.
Per the HHA, the overall risk of a false positive KPC result is 'Minor' for affected lots of the BIOFIRE Pneumonia and Pneumonia *plus* Panels.
Per the HHA, the overall risk of a false positive KPC result is 'Irrelevant' for affected lots of the BIOFIRE Joint Infection Panel.
Additional details can be found in DX-REG-192443-01-False positive KPC HHA.

Summary of the overall risk before implementing a Field Action:

Product name - Ref	Associated risk	P1 (Probability of hazardous situation occurring)	P2 (Probability of hazardous situation leading to harm)	P (Overall probability)	Severity	OVERALL RISK
BIOFIRE FILMARRAY PNEUMONIA PANEL - RFIT-ASY-0144*	False Positive KPC Result	Occasional	Occasional	Remote	Serious	Minor
BIOFIRE FILMARRAY PNEUMONIA PLUS PANEL - RFIT-ASY-0143	False Positive KPC Result	Occasional	Occasional	Remote	Serious	Minor
BIOFIRE FILMARRAY PNEUMONIA PLUS PANEL - RFIT-ASY-0142	False Positive KPC Result	Occasional	Occasional	Remote	Serious	Minor
BIOFIRE JOINT INFECTION PANEL -	False Positive KPC Result	Remote	Remote	Improbable	Serious	Irrelevant

RFIT-ASY-0138						
BIOFIRE JOINT INFECTION PANEL - RFIT-ASY-0135	False Positive KPC Result	Remote	Remote	Improbable	Serious	Irrelevant
BIOFIRE FILMARRAY PNEUMONIA PANEL - RFIT-ASY-0145	False Positive KPC Result	Occasional	Occasional	Remote	Serious	Minor

*The verification kit lots (FLM1-ASY-0150) consumed kits from panel lots (RFIT-ASY-0144).

Notification to Regulatory Authority

Manual creation of Local Field Actions for management of reporting to health authorities are required for the countries that are required to assess/report to health authorities for FCA-FSCA implemented outside of their country per 000584 – Field Action Reporting Matrix

Attachments

Customer Letter 1-FA-TWD-000084
FA-TWD-000084 Customer Letter Appendix A
FA-TWD-000084 Impacted Lot Numbers

SECTION B : REQUIRED ACTIONS

1. **Please immediately acknowledge receipt (AR) of this FA.**

- Subsidiaries and plants using CRM: Please manage the Acknowledgment of this FA in CRM by changing the local field action status from “new” to “Acknowledged”. Please refer to CRM 360 – Service – Global user manual – Field action 065826 for more details.
- Subsidiaries not using CRM, Export Distributors and other entities: Please complete the Acknowledgment of receipt, sign and date where indicated, then send it by email to fieldactions@biomerieux.com.

2. **Identify all customers for which you are responsible that are impacted by the scope of this notification.**

3. **Implement the following required actions (when applicable) :**

Service tasks	Subsidiaries	Export distributors and other entities	Due date
Send Initial Notification to Customer Send initial notification to impacted customer. Recipients of this notification must notify the impacted customer using the translated customer letter (if applicable), including Appendix A. Initial customer notification should be completed before the indicated due date unless local regulation specifies an earlier due date.	CRM users: Complete the date of initial customer notification and close the Service Task “Send Initial Notification to customer” from your **Local Field Action.** Please refer to the CRM 360 – Service – Global user manual – Field action 065826 for more details.	Complete the paragraph “Send initial notification to customer” of the acknowledgment of completion, then send it by email to fieldactions@biomerieux.com.	To be completed in one (1) month. **12-SEP-2026**
	Not CRM users: Complete the paragraph “Send initial notification to customer” of the acknowledgment of completion, then send it by email to fieldactions@biomerieux.com.		

Service tasks	Subsidiaries	Export distributors and other entities	Due date
<u>Send Reminder for Customer:</u> Recipients of this notification must define a customer reminder according to their local procedure. The customer reminder should be completed before the indicated due date unless local regulation specifies earlier due date.	<u>CRM users</u>: Complete the date of reminder customer notification and close the Service Task "Send Reminder for customer letter" from your **Local Field Action.** Please refer to the CRM 360 – Service – Global user manual – Field action 065826 for more details.	*Refer to your local procedure - No need to provide information in AOC*	**Refer to your local requirements**
	<u>Not CRM users:</u> Complete the paragraph "Send reminder for customer letter" of the acknowledgment form then send it by email to fieldactions@biomerieux.com.		

Service tasks	Subsidiaries	Export distributors and other entities	Due date
Perform Action on Product Recipients of this notification must apply following actions before the indicated due date: • Action at Customer Level: Identify whether affected product is within their supply and confirm KPC results for affected product. • Action at Subsidiary/Distributor Level: Resume shipment of product affected by PSS 5936. • Action at Manufacturer Level: Resume shipment of product affected by PSS 5936.	CRM users: Complete the date requested and close the Service Task "Perform actions on product" from your **Local Field Action.** Please refer to the CRM 360 – Service – Global user manual – Field action 065826 for more details. Not CRM users: Complete the paragraph "Perform actions on product" of the acknowledgment form, then send it by email to fieldactions@biomerieux.com	Complete the paragraph "Perform actions on product" of the acknowledgment form, then send it by email to fieldactions@biomerieux.com.	**12-JUL-2027**

Service tasks	Subsidiaries	Export distributors and other entities	Due date
Report to Health Authority: Recipients of this notification must assess the product issue and any associated patient risk in accordance with local regulations to determine if it is reportable to their local regulatory authority. Notification to their regulatory authority must include device classification when required. Reporting decision and Initial reporting to health authorities should be completed before the indicated due date unless local regulation specifies earlier due date. If required by the local procedures and regulation, recipient of this notification must send to their regulatory authority final/closure reports before the due date specified in their local regulation.	CRM users: Complete the date and information requested in the Service task "Report to Health Authority" from your **Local Field Action.** Then, create the appropriate Health Authority Action(s) (HAA) in CRM including "Health Authority - Reporting decision" which is mandatory. NB: If reportable, the service task "Report to health Authority" must be closed when the "Health Authority - Initial report" has been completed. If not reportable, the service task "Report to health Authority" must be closed after the "Health Authority - Reporting decision" has been completed. Please refer to the CRM User Guide - Field Action - Regulatory Reporting 063702 - for more details. Not CRM users: Complete the paragraph "Report to Health Authority" of the acknowledgement form, then send it by email to fieldactions@biomerieux.com.	Complete the paragraph "Report to Health Authority" of the acknowledgement form, then send it by email to fieldactions@biomerieux.com.	To be completed in one (1) month. **12-SEP-2026**

Service tasks	Subsidiaries	Export distributors and other entities	Due date
Perform Delta Management Recipients of this notification must identify new customers that have received affected product. Delta management should be performed at least monthly until the due date indicated.	CRM users: Complete the date and close the service task "Perform Delta Management" from your **Local Field Action.** Please refer to the CRM 360 – Service – Global user manual – Field action 065826 for more details. Not CRM users: Complete the paragraph "Perform delta management" of the acknowledgment of completion, then send it by email to fieldactions@biomerieux.com.	*Refer to your local procedure - No need to provide information in AOC*	**12-JUN-2027**

4. **After all actions are completed, please:**

- Subsidiaries and plants using CRM: Close the Local Field Action. Please refer to the CRM 360 – Service – Global user manual – Field action 065826
- Subsidiaries not using CRM, Export Distributors and other entities: Complete the acknowledgment of completion at the time of each ACTION, sign it and return it by email to fieldactions@biomerieux.com.

SECTION C : CONTACT

Alexandra Sufit, Director of Vigilance and Regulatory Affairs
515 Colorow Drive
Salt Lake City, Utah
84108, USA

Email : ML-US-RecallCommLog@biomerieux.com

SECTION D: REVISION HISTORY

Revision #	Description of change
1	Creation of FA notification

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000084	**CRM number:** FA-055242 | Field Action | Salesforce	**FA type/Title: FSCA - False Positive KPC Results on BIOFIRE® FILMARRAY® Pneumonia Panel, BIOFIRE® FILMARRAY® Pneumonia plus Panel, and BIOFIRE® Joint Infection Panel**

A/ ACKNOWLEDGEMENT OF RECEIPT (AR)

Location

Account #:

Group Company or Export Distributor Name(s):

Country:

Please assess if the Field Action is applicable to your entity and fill the document, accordingly.

*If you are an Export **DISTRIBUTOR:** both Acknowledgement of Receipt and the Acknowledgement of Completion – Part 1 must be sent back to bioMérieux **within 1 month** after receiving the Field Action communication. Then, the Acknowledgment of Completion Part 2 should be fulfilled and returned **at the time of each action completion**.*

*If you are part of bioMérieux, as **SUBSIDIARY OR OTHER ENTITY not CRM users**, the Acknowledgement of Receipt must be sent back **immediately** after receiving the Field Action communication. Then, the Acknowledgment of Completion Part 1 and Part 2 should be fulfilled and returned **at the time of each action completion**.*

☐ Field Action Not Applicable

Provide justification: ……

Please, provide a justification, sign, and return the document.

☐ Field Action Applicable

If applicable, please sign and return the document.

ACKNOWLEDGEMENT FORM

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Print Name:

Sign Name:

Position:

Date (dd/MMM/yyyy):

B/ ACKNOWLEDGMENT OF COMPLETION (AC) – Part 1

Location

Account #:

Group Company or Export Distributor Name(s):

Country:

*If you are an **Export DISTRIBUTOR**: both Acknowledgement of Receipt and the Acknowledgement of Completion – Part 1 must be sent back **within 1 month** after receiving the Field Action communication.*

If you are part of bioMérieux, as SUBSIDIARY OR OTHER ENTITY not CRM users, the Acknowledgment of Completion Part 1 and Part 2 should be fulfilled and returned at the time of each action completion (before the due date indicated in the table).

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000084	CRM number: FA-055242 | Field Action | Salesforce	FA type/Title: FSCA - False Positive KPC Results on BIOFIRE® FILMARRAY® Pneumonia Panel, BIOFIRE® FILMARRAY® Pneumonia plus Panel, and BIOFIRE® Joint Infection Panel

Actions to be completed by all stakeholders

ACTIONS	Due Date	Description
Initial Notification to Customers	12-SEP-2026	☐ If applicable, please indicate the date when all customers have been notified (DD/MM/YYYY):……. ☐ If not applicable, please provide a justification: …….
Report to Health Authority	12-SEP-2026	**REPORTING DECISION** ⇨ *Please refer to your local regulation to determine if the field action must be reported to your National competent authority and indicate the decision below:* ☐ REPORTABLE ☐ NON-REPORTABLE ⇨ Please indicate when the reporting decision has been taken (DD/MM/YYYY): …… If non-reportable, please provide a justification of the decision: …… ……
	IF REPORTABLE, PLEASE COMPLETE THE SECTION BELOW	

ACKNOWLEDGEMENT FORM

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ACTIONS	Due Date	Description
	12-SEP-2026	**INITIAL REPORT** ⇨ *Please indicate the following information as soon as your initial report has been sent to your National Competent Authority (NCA)* Country: …… National Competent Authority Name: ……..…….. Reference number from your NCA, if any: ……..…….. Date of submission to your NCA (DD/MM/YYYY): …… ⇨ *In case of shorter timelines for reporting requested by your local regulation, please indicate this due date: (DD/MM/YYYY): ……..* ⇨ *Please provide the evidence of submission in attachment to this Acknowledgement of Completion*

Please sign and return the fulfilled Acknowledgement of Completion form:

Print Name:

Sign Name:

Position:

Date (DD/MM/YYYY):

ACKNOWLEDGEMENT FORM

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B/ ACKNOWLEDGMENT OF COMPLETION (AC) – Part 2

Location

Account #:

Group Company or Export Distributor Name(s):

Country:

*Please complete the **Acknowledgment of Completion – Part 2 at the time of each ACTION completion**. The due date indicates the date when the action must be completed and when the Acknowledgment of Completion must be returned to bioMérieux.*

NB 1: There is no need to complete the Acknowledgment of Completion – Part 2 if you have assessed the field action as "not applicable".

NB 2: For Export DISTRIBUTOR, it is acceptable to return the Acknowledgment of Completion – Part 2 once all the remaining actions are completed.

Actions to be completed by all stakeholders

ACTIONS	Due Date	Description
Action on Product	12-JUL-2027	☐ If applicable, please indicate the date when the action on product has been completed (DD/MM/YYYY): …….. ⇨ Please complete the following table related to the impacted products:

REF #	Product Name	Batch #	Quantity Received
RFIT-ASY-0144	PNEUMONIA PANEL, 30-PACK	See Appendix A	N/A
RFIT-ASY-0143	PNEUMONIA PLUS PANEL, 30-PACK	See Appendix A	N/A
RFIT-ASY-0142	PNEUMONIA PLUS PANEL, 6-PACK	See Appendix A	N/A

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000084	CRM number: FA-055242 | Field Action | Salesforce	FA type/Title: FSCA - False Positive KPC Results on BIOFIRE® FILMARRAY® Pneumonia Panel, BIOFIRE® FILMARRAY® Pneumonia plus Panel, and BIOFIRE® Joint Infection Panel

<table>
<tr><th>ACTIONS</th><th>Due Date</th><th>Description</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>RFIT-ASY-0138</td><td>JOINT INFECTION PANEL, 30-PACK</td><td>See Appendix A</td><td>N/A</td></tr>
<tr><td>RFIT-ASY-0135</td><td>JOINT INFECTION PANEL, 6-PACK</td><td>See Appendix A</td><td>N/A</td></tr>
<tr><td>RFIT-ASY-0145</td><td>PNEUMONIA PANEL, 6-PACK</td><td>See Appendix A</td><td>N/A</td></tr>
<tr><td>FLM1-ASY-0150</td><td>PNEUMO VERIFICATION KIT</td><td>See Appendix A</td><td>N/A</td></tr>
</table>
☐ If not applicable, please provide a justification: ……..
</td></tr>
<tr><td rowspan="2">Report to Health Authority</td><td>Refer to your local regulation</td><td>
<u>FINAL REPORT</u>
⇨ Please refer to your local regulation to determine if a final report is required:
FINAL REPORT REQUIRED: ☐ YES ☐ NO
⇨ If required, please refer to your local regulation to determine the local due date the final report must be sent to your NCA, if any: (DD/MM/YYYY) ……..
⇨ If required, please indicate the date when the final report has been submitted to your NCA (DD/MM/YYYY): ……..
⇨ Please, provide the evidence of submission in attachment to the Acknowledgement of Completion
</td></tr>
<tr><td>Refer to your local regulation</td><td>
<u>CLOSURE</u>
⇨ Please indicate if your local procedure requires a closure of the field action.
CLOSURE REQUIRED: ☐ YES ☐ NO
⇨ If required, please indicate the date when the closure has been completed (DD/MM/YYYY): ……
⇨ Please indicate the criteria of closure: ……
</td></tr>
</table>

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000084	CRM number: FA-055242 | Field Action | Salesforce	FA type/Title: FSCA - False Positive KPC Results on BIOFIRE® FILMARRAY® Pneumonia Panel, BIOFIRE® FILMARRAY® Pneumonia plus Panel, and BIOFIRE® Joint Infection Panel

Please sign and return the fulfilled acknowledgement of completion form:

Print Name:

Sign Name:

Position:

Date (DD/MM/YYYY):

Actions to be completed only by bioMérieux entities

ACTIONS	Due Date	Description
Send reminder for customer letter	Refer to your local regulation	⇨ *Please refer to your local procedure to determine if a reminder must be sent to your customer(s)* ☐ If applicable, please complete the following table:

Reminder customer notification	Due date (as per your local procedure) (DD/MM/YYYY)	Reminder Customer Notification date (DD/MM/YYYY)	% customer answers after the reminder
Reminder #1			
Reminder #2			
Reminder #3			

☐ If not applicable, please provide a justification: ……..

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000084	CRM number: FA-055242 | Field Action | Salesforce	FA type/Title: FSCA - False Positive KPC Results on BIOFIRE® FILMARRAY® Pneumonia Panel, BIOFIRE® FILMARRAY® Pneumonia plus Panel, and BIOFIRE® Joint Infection Panel

ACTIONS	Due Date	Description
Delta Management	**12-JUN-2027**	⇨ *Please refer to your local procedure to determine if a delta management must perform.* ☐ If applicable, please indicate the date when it has been completed (dd/MMM/yyyy): …… ☐ If not applicable, please provide a justification: ……..
Report to Health Authority	Refer to your local regulation	**FOLLOW UP REPORT** ⇨ *Please refer to your local regulation to determine if a follow up report is required* **FOLLOW UP REPORT REQUIRED: ☐ YES ☐ NO** ⇨ *If required, please indicate the following information as soon as your report has been sent to your NCA:*
Report to Health Authority		**QUESTIONS/COMMUNICATION FROM NCA** ⇨ *Please indicate if you have received any question/ communication from your National Competent Authority* Questions/ Communication from NCA? ☐ YES ☐ NO

Follow-up report	Due date (as per your local procedure/ local regulation) (DD/MM/YYYY)	Submission Date(s) (DD/MM/YYYY)
Follow up #1		
Follow up #2		
Follow up #3		

⇨ *Please, provide the evidence of reporting in attachment to the Acknowledgement of completion.*

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000084	CRM number: FA-055242 | Field Action | Salesforce	FA type/Title: FSCA - False Positive KPC Results on BIOFIRE® FILMARRAY® Pneumonia Panel, BIOFIRE® FILMARRAY® Pneumonia plus Panel, and BIOFIRE® Joint Infection Panel

ACTIONS	Due Date	Description
		⇨ *If applicable, please indicate the date when you have answered to your NCA (DD/MM/YYYY): ……* ⇨ *Please, provide supporting documentation in attachment to the Acknowledgement of Completion, as applicable.*
		CHANGE REQUESTS FROM NCA ⇨ *Please indicate if you have received any change request from your National Competent Authority* Change request from NCA? ☐ YES ☐ NO *If yes, please indicate the date when you have answered to your NCA (DD/MM/YYYY): :……* ⇨ *Please, provide supporting documentation in attachment to the Acknowledgement of Completion as applicable.*

Please sign and return the fulfilled Acknowledgement of Completion form:

Print Name:

Sign Name:

Position:

Date (DD/MM/YYYY):