FSCA
FIELD SAFETY CORRECTIVE ACTION

BIOMÉRIEUX

**IMPORTANT:**

**URGENT FIELD SAFETY NOTICE**

**EBV R-GENE (Ref. 69-002B) - BK Virus R-GENE (Ref. 69-013B)**

**Aspecific Signals**

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 5773

**Table 1: 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 | Product Expiration Date |
|---|---|---|---|
| EBV R-GENE® | 69-002B | N/A | N/A |
| BK Virus R-GENE® | 69-013B | Lots starting from: 1009358720 and manufactured after 13-SEP-2022 | N/A |

Dear bioMérieux Customer,

Our records indicate that your laboratory received products listed in table above.

The aim of this new communication is to inform you about potential low positive signals, in FAM channel (530nm) for the negative control (IC2W0 and/or R0) and/or negative sample when using lots of BK Virus R-GENE® (ref. 69-013B, lots starting from: 1009358720 and manufactured after 13-SEP-2022) and EBV R-GENE® (ref. 69-002B) listed in Table 1.

This new communication cancels and replaces a first Field Safety Notice associated to the FSCA #5763-1 released on 26 May 2023, that you may have received, due to the scope extension of the affected products.

**Required actions**

In this context, we recommend you take the following actions. Please:

- Do not consider low positive signal (above 38 Ct) for the validation of your runs and results of patient samples testing: If IC2W0 and/or R0 are > 38Ct, the run can be validated and analysed.
- You can continue to use the impacted references BK Virus R-GENE® (ref. 69-013B, lots starting from: 1009358720 and manufactured after 13-SEP-2022) and EBV R-GENE® (ref. 69-002B)
- Keep a critical eye on patients' results: all results must be interpreted with other clinical and biological tests results to define patient status.
- In case of doubt about a low positive result > 38Ct, we advise you to retest the patient's sample.
- Distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, 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 *your local bioMérieux representative (to be adapted at local level)* to confirm receipt of this notice. It is important that you return the acknowledgement form to bioMérieux even if you determine that this urgent product correction notice/information/recommendation *(to be adapted based on issue)* does not impact your facility.

**Description of the issue**

Following complaints from the field related to low positive signals (aspecific signals below Ct corresponding to the limit of detection), in FAM channel (530nm) for the negative control (IC2W0 and/or R0) and/or negative sample when using BK Virus R-GENE® (ref. 69-013B) and EBV R-GENE® (ref. 69-002B), bioMérieux has initiated an investigation to confirm product issue and identify the root cause.

While the investigation is still ongoing, the following were identified:

- During the initial investigation, low positive signals (above 38 Ct) in FAM channel (530nm) for the negative controls (IC2W0 and/or R0) and/or negative samples were confirmed when using BK Virus R-GENE® (ref. 69-013B, starting from lot: 1009358720 and manufactured after 13-SEP-2022) and EBV R-GENE® (ref. 69-002B, lot 1009621440 and 1009270270).

- At that time, lots of BK Virus R-GENE® (ref. 69-013B) manufactured before 13-SEP-2022 were tested and confirmed within their specifications. Also, lot #1009827240 of EBV R-GENE® (ref. 69-002B) available on the market was conform to its specifications.
- Since the root cause(s) was not confirmed, we could not exclude that lots of BK Virus R-GENE® (ref. 69-013B) manufactured after 13-SEP-2022 could be impacted by the issue. Lots of BK Virus R-GENE® (ref. 69-013B) manufactured before this date are conform.
- After the publication of FSCA #5763-1, new complaints were reported especially on others lots of EBV (ref. 69-002B) reference for which no complaints were received before and that were not included in the scope of the first FSCA #5763-1. Investigation confirmed low positive signals (above 38 Ct) in FAM channel (530nm) with another lot of EBV (ref. 69-002B).
- Therefore, it was decided to include all lots available on the market and future lots of EBV (Ref: 69-002B) in the scope of this new Field Safety Notice #5773 until the exact root-cause is determined.
- These low aspecific signals are above 38 Ct (corresponding to 50 cop/ml for BKV and 100 cop/ml for EBV, i.e. below the limit of detection of the 2 references), therefore this issue has no impact on patient follow up/treatment.
- The only risk that may be encountered due to this issue is a potential delay in reporting results because the analysis should be repeated.

**Impact to Customer/Patients**

There is only a risk of delay in reporting results due to an invalid run because the IC2W0 (mandatory negative extraction control) and R0 (optional negative control) must be negative to validate the entire run.

| |
|---|
| *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 #5773
## EBV R-GENE (Ref. 69-002B) - BK Virus R-GENE (Ref. 69-013B)
## Aspecific Signals

---

**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 FSCA issue)*

☐ Yes ☐ No

**DATE**…….....**SIGNATURE**……

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