

Geneva, 14th August 2023
FSCA 5773

**Please distribute to the Laboratory Manager
– URGENT FIELD SAFETY NOTICE –
EBV R-GENE® (Ref. 69-002B) - BK Virus R-GENE® (Ref. 69-013B)
Aspecific Signals**

Acknowledgment of receipt required

Dear bioMérieux Customer,

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

Table 1: Impacted products			
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

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.

bioMérieux (Suisse) SA

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 per email to ch_support@biomerieux.com 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 Safety Notice 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.

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 the Scientific Customer Service of bioMérieux at 022 906 57 96.

Sincerely,

bioMérieux (Suisse) SA

A handwritten signature in blue ink, appearing to read "Doris Grünbart".

Doris Grünbart
Product Manager Molecular biology

Attachment A: Acknowledgement Form



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**

Response required

In compliance with legal traceability requirements, we thank you for completing this form even if you no longer have this reagent.

**Please return the form to your customer service
per email (ch_support@biomerieux.com)**

Name of the laboratory: _____

Contact person: _____

City and postal Code: _____

Customer No.: _____

With your signature you confirm that you have received the urgent field safety notice regarding the „ **FSCA 5773 - EBV R-GENE (Ref. 69-002B) - BK Virus R-GENE (Ref. 69-013B) Aspecific Signals** “.

You further confirm that you will implement the required actions, as indicated in the Urgent Field Safety Notice. If not, please indicate the reasons in the Comments section below.

Comments

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

Have you encountered impact on patients' results, or reports of illness or injury related to the identified issue?

☐ No

Yes ☐

If **YES**, please give your telephone number for contacting you:

DATE..... SIGNATURE.....