MIKROGEN
DIAGNOSTIK

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Date
Neuried, 15.12.2021

Field Safety Notice (reply required, please refer to page 3)

Product: ***ampli*Cube HEV 2.0 Quant., Article no. 55002**

Batch No.: **AHEQ042101, AHEQ042102, AHEQ102101; IFU: GAACHEQ002EN_2019-10**

Subject: **incorrect information in the instructions for use regarding handling of internal control (IC)**

Dear Customer and Partner,

With this letter we would like to inform you about a mistake in the instructions for use of our ***ampli*Cube HEV 2.0 Quant (Art. no. 55002) of the lots AHEQ042101, AHEQ042102 und AHEQ102101**. The corresponding, enclosed instructions for use bear the version number GAACHEQ002EN_2019-10. They contain the following note under chapter 7.2 “Extraction of nucleic acids” in subsection 2. on the handling of the IC:

…For the extraction, add 5 µl (for 50 µl eluate) IC to each patient sample and the NC. The IC can be added to the **sample/lysis buffer mix or directly to the sample material**…

Attached to this letter are the updated instructions for use (GAACHEQ003EN_2021-12), which now include the following note in the same location:

…For the extraction, add 5 µl (for 50 µl eluate) IC to each patient sample and the NC. The IC should be added to the sample/lysis buffer mix **and not directly to the sample material**…

If you do not add the IC to the sample material during routine testing, the processing of the affected test kits is not affected in any way by the mistake in the instructions for use.

If it is your laboratory's practice to add the IC directly to the sample material, please follow these recommended measures:

- From now on, please follow to the note in the updated instructions for use (GAACHEQ003EN_2021-12).
- Please no longer add the IC directly to the sample material

Direct addition of the IC to the patient material may result in late ct values of the IC or failure of the IC signal, thus requiring unnecessary test repetitions.

The affected test kits may be used without further restrictions under immediate application of the updated instructions for use (GAACHEQ003EN_2021-12). The affected test kits do not have to be destroyed or sent back.
The mistake in the instructions for use has no influence on the results of patients that were obtained with the affected lots.

In delimitation, the new lot AHEQ122101 available from 15.12.2021 is equipped with valid instructions for use (GAACHEQ003EN_2021-12) and is not affected by this Field Safety Notice.

Please ensure, that all staff members of your enterprise working with the product are informed about this Field Safety Notice accordingly. We kindly ask you to confirm receipt of this letter by returning the reply form on page 3 by e-mail to **vigilance@mikrogen.de** or by **fax +49 89 54801-100** until **31.12.2021.**

Mikrogen apologizes for any inconvenience caused. For any further questions please feel free to contact us.

Sincerely,

[redacted]

Martina Wild
Deputy Safety Representative of Medical Devices

Fax reply for Distributors to Field Safety Notice

Please fill in and return until 31.12.2021 to: vigilance@mikrogen.de or Fax +49 89-54801-100

Confirm of receipt of Field Safety Notice from 15.12.2021 regarding the product *ampli*Cube HEV 2.0 Quant of lots AHEQ042101, AHEQ042102 and AHEQ102101.

1.	I have read and understood the recommendations	☐ Yes	☐ No
2.	I have followed the recommended measures (no addition of the IC directly to the sample material) to all relevant employees in the enterprise who work with the product.	☐ Yes	☐ No

Name

Position

Company

Street

Postal Code/City

Date and Signature

Account for payments in US Dollar: