Human

Gesellschaft für Biochemica
und Diagnostica mbH

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Urgent Field Safety Notice

IMTEC-CIC IgG
Recall

28.02.2023

Attention:
Distributors of HUMAN and end users of:

Details on affected devices:
REF ITC59031, Lot 21003

Description of the problem:
Investigations by our Quality Control department after a customer complaint regarding duplicate determinations of one calibrator value of the IMTEC-CIC IgG ELISA, which differ too much from each other, have confirmed varying OD values during multiple determinations of e.g. the positive control with the above-mentioned lot. This can either lead to invalid sample runs due to missed validation criteria or to apparently valid sample runs (fulfilled validation criteria) with the risk for incorrect results. The absorbance differences can result in too high, correct or too low values of patient samples.
Therefore, kits of the above-mentioned lot should not be used any longer. We will replace all affected kits.
HUMAN does recommend reviewing previous achieved results, especially ones in measuring values in the borderline value range.
Until now intense quality control measurements have not shown any indications that newer produced lots are affected by this issue in a similar way. Of course, future lots are tightly monitored with respect to this quality issue.

Advice on action to be taken by:
Distributor:
Please inform your customers about this issue of the affected lots, based on this Urgent Field Safety Notice. Dispose the affected kits in accordance with your local legal regulations.

Please fill in the attached Reply Form confirming receipt of this Urgent Field Safety Notice and send it to support@human.de

User:
End users should ensure that the instructions resulting from this Urgent Field Safety Notice are implemented in the laboratory accordingly.
They should confirm receipt of this Urgent Field Safety Notice to the local distributor, stop using the affected kits and report the number of kits as well as disposal of affected kits to the local distributor.

Transmission of this Field Safety Notice:
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of this corrective action.

The Federal Institute for Drugs and Medical Devices (BfArM) and National Competent Authorities of European countries, which are affected by the recall, receive a copy of this Urgent Field Safety Notice.

Contact reference person:
(for distributors only. Distributors should provide their own detailed contact information to their end users):

Petzold, Tony
e-mail: support@human.de
Telephone: +49-6122-9988-383

We regret the inconvenience.

With kind regards,

[redacted]

Tony Petzold
Customer Support & Applications

[redacted]

Product Manager

Attachment
Reply Form

Reply Form

Urgent Field Safety Notice

IMTEC-CIC IgG
REF ITC59031, Lot 21003

Please return by e-mail this filled in and signed Reply Form latest until March 10, 2023 to:

support@human.de

I confirm receipt of this Urgent Field Safety Notice and have informed all end users, who have obtained the affected lots, in writing about the problem and the HUMAN recommendations.

If requested by national regulations I have informed the respective authorities about the problem (Note: to comply with MEDDEV requirements HUMAN will inform European competent authorities directly).

I confirm that the affected kits in my stock and those kits, which will be returned from my customers, will be destroyed according to local regulations.

For distributors in the European Economic Area (EEA):
Please also provide the Urgent Field Safety Notice in your national language, which you have sent out to your end customers, as HUMAN will be approached by your national competent authority to provide this.

Number of kits of REF ITC59031 of Lot 21003 to be replaced: _____

Company: _____ Name: _____

Date: _____ Signature: _____