

Urgent Field Safety Notice

Recall / Replacement

IMTEC- β 2-Glycoprotein I-Antibodies IgG

04.12.2018

Attention:

Distributors of HUMAN and end users of:

Details on affected devices

Cat. No. ITC59150 Lots 17004 and 18004

Description of the problem:

According to our records you have received the above listed products. As a result of an earlier Field Safety Notice for ITC59150 Lot 17002 in March 2018 we routinely monitored all following Lots of ITC59150. In the course of these studies we now noticed for the Lot 17004 the same issue with stability of reagents. The results of positive sera are not affected and the positive control is in range. Signals of negative sera are found higher than usually, however, and may provide false positive results, which are not recognized by the negative control.

Additionally we recognized borderline results for Lot 18004, which could be an indication for the same issue with stability of reagents. With continued use this could in future lead to false positive results as well.

HUMAN thus recommends not using the above mentioned product Lots anymore and offers replacement.

All other Lots of the product are not affected by this stability problem. Furthermore HUMAN optimized the production process for subsequent Lots to avoid further issues with stability of reagents.

Advice on action to be taken by:Distributor:

Please inform the end user of the above product Lots about the problem described here, based on this customer information.

Please destroy all kits of the above mentioned lots, which you still may have on stock and those kits, which will be returned from the customers, according to local regulations.

Please fill in the attached reply form confirming receipt and request the number of kits to be replaced. Send the reply form to support@human.de

User:

End users should stop using the affected lots and should confirm receipt of the customer information to the local distributor

Conspicuous results obtained with an affected Lot should be retested with a different Lot or with another diagnostic procedure.

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The Federal Institute for Drugs and Medical Devices (BfArM) and National Competent Authorities of European countries, which are affected by the recall have received 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):

Tony Petzold
Customer Support & Applications
e-mail: support@human.de
Telephone: +49-6122-9988-383

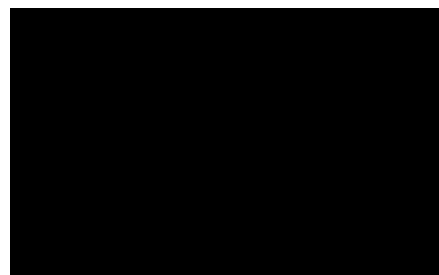
We regret the inconvenience.

With kind regards,



Tony Petzold

Customer Support & Applications



Attachment
Reply Form

Reply Form

Urgent Field Safety Notice

for IMTEC- β 2-Glycoprotein I-Antibodies IgG

Cat. No. ITC59150, Lot 17004 and 18004

Please return by e-mail this filled in and signed reply form latest until December 18th, 2018 to the following e-mail address: support@human.de

I confirm receipt of this customer information and have informed all end customers, 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 Union:

- Please also provide the Customer Information 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 ITC59150 Lot 17004 to be replaced: _____

Number of kits of ITC59150 Lot 18004 to be replaced: _____

Company: _____

Name: _____

Date: _____

Signature: _____