

Urgent Field Safety Notice

HumaTex RF complete kit & RF Latex Reagent Recall

December 1st, 2022

Attention:

Distributors of HUMAN and end users of:

Details on affected articles:

REF 40050 (Lot 22001, Lot 22002), REF 40053 (Lot 22001, Lot 22002)

Description of the problem:

Based on notification by customers and internal investigations, we have identified an issue with the RF Latex Reagent of the above-mentioned lots (in the HumaTex RF complete test kit and alone).

When performing the test for Rheumatoid Factors (RF) with this material, there is a possibility of false negative results, due to a reduced or even missing agglutination with some RF positive patient samples. These false negative results are undetected by the control material included in the kit and we assume this also applies to other manufacturer's control reagents. It should also be noted that most RF positive patient samples will, however, still yield a correct agglutination.

Thus, kits of HumaTex RF (REF 40053; Lot 22001 and Lot 22002) as well as RF Latex Reagent (REF 40050; Lot 22001 and Lot 22002) should no longer be applied by users. According to our investigations this problem is not observed with RF Latex Reagent Lots not listed above.

We will replace all affected kits.

Advice on action to be taken by:**Distributor:**

Please inform your customers about the issue of the affected products, based on this Urgent Field Safety Notice. Dispose the affected kits in accordance with your local legal regulations.

Advise your customers to reevaluate patient results in case they have been tested negative with these Lots and if the diagnostic results were not in agreement with other clinical indications.

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

User:

Please ensure that the instructions resulting from this Urgent Field Safety Notice are implemented in the laboratory accordingly.

End users 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 Urgent 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 maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of this corrective action.

The National Competent Authorities of European countries has received a copy of this Urgent Field Safety Notice.

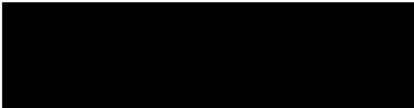
Contact reference person:

(For distributors only. Distributors should provide their own detailed contact information to their end users):

Dörschmann, Hendrik
e-mail: support@human.de
Telephone: +49-6122-9988-310

We regret the inconvenience.

With kind regards,


Hendrik Dörschmann
Customer Support & Applications

Attachment
Reply Form

Reply Form

Urgent Field Safety Notice

**RF Latex Reagent
REF 40050, Lots 22001, 22002**

**HumaTex RF complete kit
REF 40053, Lots 22001, 22002**

Please return by e-mail this filled in and signed Reply Form latest until December 15^h, 2022 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 European regulatory 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) and Turkey:
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 40050 of Lot 22001 to be replaced: _____

Lot 22002 to be replaced: _____

Number of kits of REF 40053 of Lot 22001 to be replaced: _____

Lot 22002 to be replaced: _____

Date: _____

Company: _____

Name: _____

Signature: _____