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und Diagnostica mbH

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Urgent Field Safety Notice

Recall
BILIRUBIN liquicolor

23.09.2022

Attention:
Distributors of HUMAN and end users of:

Details on affected devices:
REF 10012; LOTs 21001, 21002, 21003, 22001 and 22002

Description of the problem:
Based on customer complaints and subsequent internal investigations, we have identified a problem with BILIRUBIN liquicolor reagent of the above mentioned LOT numbers with some raw material.
The recovery and linearity of the reagent is impaired in large parts of the measuring range, resulting in low test results.

The controls SERODOS / SERODOS plus and HumaTrol N / P were, however, correctly found in the acceptable range for all lots. These controls check total bilirubin concentrations of approx. 0.8 and 4.0 mg/dl (13.7 and 68.4 µmol/l). Thus, this problem cannot be reliably detected from these control measurements.
Therefore, kits of BILIRUBIN liquicolor (REF 10012) lots 21001, 21002, 21003, 22001 and 22002 should not be used any longer. We will replace all affected kits.

We are working intensively on solving the raw material problem. As an alternative temporary solution we can offer BILIRUBIN D+T liquicolor, REF 10740 as a replacement product. Applications for this kit are available on HumaLyzer 2000, 3000, Primus and 4000.

For use on automated analyzers we recommend to use auto-BILIRUBIN-T liquicolor, REF: 10742 to determine total bilirubin. There is also an application for auto-BILIRUBIN-T liquicolor available for the HumaLyzer 4000.

Determined total bilirubin results should be checked if an unexpected (or unplausible) low concentration has been measured.

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.

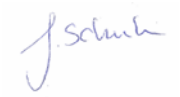
The Federal Institute for Drugs and Medical Devices (BfArM) and National Competent Authorities of European countries, which are affected by the recall, receive a copy of this Urgent Field Safety Notice.

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

Schuh, Jasmin
Customer Support & Applications
e-mail: support@human.de
Telephone: +49-6122-9988-333

We regret the inconvenience.

With kind regards,



Jasmin Schuh
Customer Support & Applications

Gabriele Moos
Product Manager

Attachment
Reply Form

Reply Form

Urgent Field Safety Notice

for BILIRUBIN liquicolor
REF 10012; Lots 21001, 21002, 21003, 22001 and 22002

Please return by e-mail this filled in and signed reply form latest until October 07, 2022 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 IVDR 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 REF 10012 of

Lot 21001 to be replaced: _____

Lot 21002 to be replaced: _____

Lot 21003 to be replaced: _____

Lot 22001 to be replaced: _____

Lot 22002 to be replaced: _____

Company: _____ Name: _____

Date: _____ Signature: _____