Gesellschaft für Biochemica
und Diagnostica mbH

Max-Planck-Ring 21
65205 Wiesbaden · Germany

Telefon +49 6122 9988-0
Telefax +49 6122 9988-100

Urgent Field Safety Notice

Advice

URIC ACID liquicolor^{plus}

20.02.2015

Attention:
Distributors of HUMAN and end users of:

Details on affected devices
Cat. No. 10694, Lots 13004, 14001, 14002, 14003, 15001
Enzymatic colorimetric test with LCF, PAP method with ascorbate oxidase (520 nm, 546 nm)

Cat. No. 10694150, Lots 13007, 13008, 14001, 14002, 14003, 14004
System Reagent for HumaStar 150SR - Enzymatic colorimetric test with LCF, PAP method with ascorbate oxidase

Cat. No. 10694600, Lots 13005, 13006, 13007, 13008, 13009, 14001, 14002, 14003, 14004, 14005
System Reagent for HumaStar 600 - Enzymatic colorimetric test with LCF, PAP method with ascorbate oxidase

Description of the problem:
In the cause of stability monitoring our quality control has identified a URIC ACID liquicolor^{plus} reagent stability issue.

Testing of all Multipurpose, System and Bulk reagent lots for URIC ACID liquicolor^{plus} , which are currently in the market, revealed that 8-9 months after production an interference for ascorbic acid occurred, although it should typically be avoided by the integrated ascorbate oxidase.

Advice on action to be taken by:

Distributor:
Please inform the end user of the above product lots about the problem described above and the potential risk of ascorbic acid interference. Depending on concentration ascorbic acid leads to reduced uric acid concentration findings in patient samples. This might be seen in samples from patients after vitamin C intake, e.g. vitamin C dietary supplement.

All affected lots can still be used, when considering the potential interference of ascorbic acid and when uric acid results are checked for plausibility. As the root cause is still under investigation, also newer lots might be affected.

Please fill in the attached reply form confirming receipt and send it to customer-support@human.de

User:
End users should confirm receipt of the customer information to their 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 transfer this notice to other organisations 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 National Competent Authorities of European countries which are affected by the recall 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):

Frank Minich
Customer Support & Applications
e-mail: customer-support@human.de
Telephone: +49-6122-9988-280

We regret the inconvenience.

With kind regards,

Frank Minich

Manager Customer Support & Applications

Gabriele Moos

Product Manager

Attachment
Reply Form