

## Urgent Field Safety Notice

*Medi-Test URYXXON® Stick 10, REF 93068.005, LOT 683502*

May 08, 2024

MACHEREY-NAGEL GmbH & Co. KG  
Valenciener Str. 11  
52355 Düren, Germany.

### Addressee:

This safety information is addressed to users and distributors of Medi-Test URYXXON® Stick 10, REF 93068.005, LOT 683502

### Affected medical device:

MACHEREY-NAGEL issues an Urgent Field Safety Notice for Medi-Test URYXXON® Stick 10, REF 93068.005, LOT 683502

### Description of the problem and the cause:

Medi-Test URYXXON® Stick 10 is a urine test strip for measuring blood, urobilinogen, bilirubin, protein, nitrite, ketone, glucose, pH, density and leucocytes. The test strip can be evaluated visually by comparing with a color scale or with a reflectometer (URYXXON® Relax and URYXXON® 500).

It was discovered that the functionality of the Urobilinogen and Bilirubin test pads is affected for the above mentioned batch.

If a defect test strip is evaluated visually or reflectometrically, the assignment of the test strip color may be impacted, so that "false negative" or "false positive" results for Urobilinogen and Bilirubin are possible.

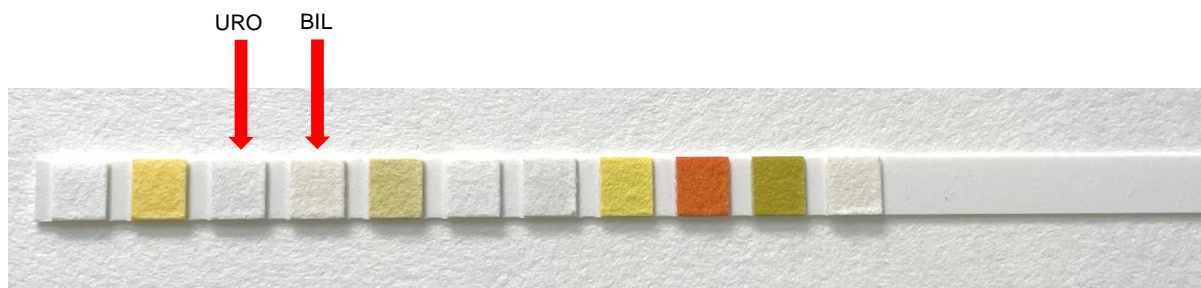


Figure 1: Position of the Urobilinogen and Bilirubin test papers

## Which measures have to be taken?

### *For distributors*

- The product named in this safety information must not longer be sold.
- Confirm the receipt of the information with the attached confirmation of receipt form by May 17, 2024.
- Pass this safety information on to customers of the affected product.
- Have the receipt of the information confirmed with the attached confirmation of receipt form. Forward the confirmation forms to our attention using the contact information below.

### *For users*

- If you have a product Medi-Test URYXXON® Stick 10, REF 93068.005, LOT 683502, the product named in this safety information must not longer be used
- Pass the information on to other people and departments who may be working with the product Medi-Test URYXXON® Stick 10, REF 93068.005, LOT 683502.
- Confirm the receipt of the information with the attached confirmation of receipt form by May 17, 2024.
- If your product is affected, please send the product to your local distributor and arrange for replacement or contact MACHEREY-NAGEL directly.

Please make sure in your organization that all users of the above products and other persons to be informed become aware of this Urgent Field Safety Notice. Please keep this information at least until all measures have been completed.



## **Additional measures taken by MACHEREY-NAGEL**

This case is being investigated as part of the quality control processes, corrective action is being taken.

We sincerely apologize for any inconvenience this may cause and thank you in advance for your support and cooperation.

## **Contact persons**

### ***Contact for sales / marketing***

Dr. Sarah Geenen  
Product Management Rapid Tests  
Email: [sgeenen@mn-net.com](mailto:sgeenen@mn-net.com)  
Tel.: +49-(0)2421 969 340

### ***Regulatory contact***

Dr. Dominik Lange  
Person Responsible for Regulatory Compliance (PRRC; IVDR 2017/746)  
Email: [dlange@mn-net.com](mailto:dlange@mn-net.com)  
Tel. +49 (0) 2421 969 294



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## Confirmation of receipt

Please fill out this form and send it to us by email by May 17, 2024 to support@mn-net.com. Please use the following confirmation of receipt text:

I hereby confirm that I have received, read and understood the enclosed urgent safety information for the Medi-Test URYXXON® Stick 10, REF 93068.005, LOT 683502 dated May 08, 2024. We have taken the necessary measures specified in this safety information.

We note that this document may be submitted to supervisory and regulatory authorities abroad, depending on the applicable legal requirements.

Name of the laboratory:

Address:

Name of the contact person:

Position:

Email:

Telephone:

Date:

Signature:

