

FIELD SAFETY NOTICE

False negative reaction of blood in URINORM XL P

Date: 12th of October 2023
ID: FSN 2023_03
Affected product: URINORM XL, catalogue number: REG00060
Batch: 2211165

Dear Madam / Sir,

according to our internal records you have ordered and received URINORM XL (lot: 2211165, expiration: 03/2024) affected by this Filed Safety Notice. See below the details of the defect that was detected in this specific batch.

Description:

URINORM XL control urines are liquid synthetic material with concentrations of analytes and urine sediment within normal (URINORM XL N) and pathological (URINORM XL P) levels. URINORM XL control urines are designed for verification and confirmation of precision and accuracy of PHAN AUTO diagnostic urine strips as well as LAURA XL urine analyser intended for *in vitro* diagnostics.

According to our internal testing and post market surveillance data, we have confirmed for affected batch that positive level of URINORM XL control urine (URINORM XL P) provides weak reaction of blood diagnostic pad (BLD) on our diagnostic strips which can lead to **false negative result** at positive control level during the internal QC process in your laboratory. The observed issue is caused by degradation of raw material in time.

Potential impact:

The declared shelf-life of URINORM XL control urine doesn't meet defined specification. The weak reaction of blood at positive control level can affect your results during the daily internal QC process in your laboratory. Observed false negative results for blood parameter will be out of declared range as defined in IFU therefore you will not pass your regular QC check as required by LAURA XL automatic urine analyser.

Actions to be taken:

If you have affected batch of URINORM XL in your stock, Erba will request you to:

- Identify, locate and discard the affected pieces of URINORM XL on your stock.
- Contact Erba as soon as possible in order to report number of blocked pieces on your stock using Confirmation of receipt form at the end of this document. You will receive replacement by fresh lot of URINORM XL free of charge.
- Use other lots of URINORM XL on your stock until the affected lot will be replaced.
- New lot of URINORM XL is available and can be used without any risk.
- If you have already shipped the affected lot to any customer, please immediately inform them about this Field Safety Notice and instruct them to follow above described rules.

- Also forward this notice to all those who need to be aware within your organization.
- We ask customers outside the EU to handle necessary announcements to authorities in their countries.

Under current regulations, we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we would like to ask you to fill in, sign the attached confirmation, and communicate this information to all concerned customers. Please send back filled confirmation to Erba Lachema by e-mail until **15th of November 2023**.

Please accept our sincere apologies for the inconvenience caused. In case you have any questions, please do not hesitate to contact us.

Best regards,

Radim Herrmann
Quality Manager

<mailto:r.herrmann@erba.com>



Erba Lachema s.r.o.
Karásek 2219/1d, 621 00 Brno
DIČ: CZ26918846 -7-

Confirmation of receipt

Please, confirm that the customer information below has been received by your facility.

Date: 12th of October 2023
ID: FSN 2023_03
Affected product: URINORM XL, catalogue number: REG00060
Batch: 2211165

Herewith I confirm that we have received above mentioned customer notification and that all required actions have been implemented and all concerned parties have been informed about this Field Safety Notice. The use and further distribution of the affected products has been stopped until replacement by fresh URINORM XL control urines.

Number of discarded pieces of URINORM XL: boxes

Customer name:

Confirmed by:
(name and position)

Date and sign:

Please complete this form and send it back via email until 15th of November 2023.

Thank you for your efforts.

Erba Lachema, s.r.o.

Radim Herrmann
Quality Manager
<mailto:r.herrmann@erba.com>