

## FIELD SAFETY NOTICE

### Performance of Glucose HK 330

Date: July 10<sup>th</sup>, 2026  
ID: FSN 2026\_01  
Affected product: Glucose HK 330, catalogue number XSYS0095  
Affected LOT: 2410097, 2504018

Dear Madam / Sir,

according to our internal records you have ordered and received Glucose HK 330 affected by this Field Safety Notice. See below the details of the defect that was detected in specific batches mentioned above.

#### Description:

The kit is intended for *in vitro* photometric quantitative determination of glucose in human serum, plasma and urine on automatic systems ERBA XL. Intended for screening, monitoring and diagnosis of diabetes, hypoglycaemia. For professional use in clinical laboratory only.

#### Potential impact:

The reagent kit exhibits a non-conforming reaction curve, resulting in an elevated calibration factor. This may lead to incorrect evaluation of patient sample results, even in cases where quality control measurements remain within the specified acceptance range. Additionally, for some analyser/reagent combinations, the quality control results are either outside the acceptable range or located at the acceptance limit, indicating potential instability or performance issues of the reagent batch. This issue may therefore impact both the accuracy of patient results and the reliability of quality control performance.

#### Actions to be taken:

If you have unopened pieces of any affected LOT of Glucose HK 330 in your stock, Erba will request you to:

- Discard all affected pieces of this product.
- Contact Erba as soon as possible to report number of blocked pieces on your stock using Confirmation of receipt form at the end of this document. Credit note will be issued immediately.
- 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 **15<sup>th</sup>, September 2026**.

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

Best regards,

Jitka Augustinová  
Quality Manager

mailto: [j.augustinova@erba.com](mailto:j.augustinova@erba.com)



Erba Lachema s.r.o.

Karásek 2219/1d, 621 00 Brno

DIČ: CZ26918846 -12-