EKF-diagnostic GmbH • Ebendorfer Chaussee 3 • 39179 Barleben

SI-260019FSN

Barleben, 20 October 2026

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Dear Valued Customer,

At EKF-diagnostic GmbH (EKF), the quality and safety of our products are our highest priority, and so is the trust you place in us. The purpose of this letter is to advise you that EKF has issued a Field Safety Notice (FSN), in relation to the product(s) listed below.

REF number	Product	Impacted Product Lots	Expiry date
0209-0100-012	Glucose/Lactate hemolyzing solution 1.000x 0.5 mL in micro test tube with 10x 100 capillaries	H25348T, H25347T, H25346T, H25346E, H25345T, H25345E	31.12.2026
0209-0100-014	Glucose/Lactate hemolyzing solution 5x (200x 1 mL) in micro test tube with 2x 100 capillaries	H25342T	31.12.2026
		H252921T, H252920T, H252919T, H252918T	30.11.2026
0209-0100-022	Glucose/Lactate hemolyzing solution 1.000x 1 mL in micro test tube	H25348E, H25347E	31.12.2026

Our distribution records confirm that you received one or more lots of the impacted product. This notice has been issued to every customer identified from those records, and a completed Customer Response Form is required from you whether or not you currently hold any affected product. Please treat the response as mandatory.

Description of the Identified Observation:

Based on customer feedback, EKF became aware that the impacted product lots might contain single micro test tubes that do not contain the required fill volume. It was determined that the lot of micro test tubes used in manufacture of the product exhibit isolated defects on the lids and, consequently, do not always seal tightly.

If the micro test tube is not tightly sealed, the hemolyzing solution may leak out in large quantities or evaporate in small amounts, depending on the extent of the defect. Consequently, the required amount of hemolyzing solution is not available; thus, when the test sample is added using a capillary, the necessary 1:51 dilution ratio is not achieved. If there is an insufficient amount of hemolyzing solution, an erroneously high measurement value is obtained.

Risk to Health:
The Biosen measuring system is used for the quantitative determination of glucose and lactate in blood, plasma or serum.

In cases where the measured glucose/lactate values are falsely high compared to the true values, normoglycemic/normolactatemic individuals might be wrongly identified as hyperglycemic/hyperlactatemic. Conversely, hypoglycemic individuals might not be appropriately identified. Both scenarios could lead to unnecessary or omitted therapies resulting in a treatment decision that is hazardous to health.

Action by the Company:
EKF has identified all impacted customers and product lots placed on the market. A formal investigation has been opened under EKF's quality management system to establish root cause.

Until the investigation is finalized, if you have further questions regarding this notice, please contact Technical Support at: +49 39203 511 414 or support@ekf-diagnostic.de.

CUSTOMER REQUIRED ACTION

1. Please immediately discontinue use, quarantine, and dispose of any remaining inventory of the affected lots.
2. Please ensure this information is shared with your healthcare professionals, laboratory staff and other pertinent personnel.
3. If you are a distributor, please complete and return the 'Customer Response Form' enclosed herein. Please also forward this FSN to your end user(s) without delay for completion and return.
4. If you are the end user in receipt of this FSN from the distributor, please complete the 'Customer Response Form' and return it to the distributor.
5. If you are an end user in receipt of this FSN directly from EKF, please complete and return the 'Customer Response Form' to EKF.
6. The 'Customer Response Form' must be returned via fax or email within 10 business days.
7. Please ensure a copy of this notification is retained as part of your Quality System records.

Your cooperation is appreciated and we sincerely apologize for any inconvenience this issue may cause.

Sincerely,

i.V. [redacted]
Head of Regulatory Affairs / PPRC
EKF-diagnostic GmbH

CUSTOMER RESPONSE FORM
MEDICAL DEVICE FIELD SAFETY NOTICE FSN Reference Number: SI-260019FSN

Acknowledgement and Receipt Form
Response is Required

To satisfy regulatory requirements for reporting, please complete this 'Customer Response Form' and return it to EKF using one of the methods below.
Please enter the following in the subject: RESPONSE TO SI-260019FSN - <COMPANY NAME>

FAX +49 (0) 39203 511 171
E-Mail support@ekf-diagnostic.de

Return Response:
We acknowledge receipt of the URGENT MEDICAL DEVICE FIELD SAFETY NOTICE dated, 20 October 2026 and confirm we have read and understand the instructions provided therein.
☐ Yes / ☐ No

Are you aware of any adverse events or quality issues associated with recalled products?
☐ Yes / ☐ No

If yes, please provide further information:

The following has been verified (SELECT ALL THAT APPLY):
☐ We confirm that all areas where the product could be located have been identified and checked.
☐ We do not have any affected product.
☐ We do have affected product and have quarantined the product.
In order to receive replacement or refund indicate lots and quantities below.
☐ We have appropriately disposed of the product.
In order to receive replacement or refund indicate lots and quantities below.
☐ Product was redistributed to another facility; and the notice was forwarded.

Please provide any additional information below (if applicable).

Signature	
Date	
Name	
Company name	
Address	