EKF-diagnostic GmbH • Ebendorfer Chaussee 3 • 39179 Barleben

Document Reference: SI-250020FSN

Barleben, 10.10.2025

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Dear Valued Customer,

At EKF-diagnostic GmbH (EKF), patient safety and product quality are our highest priorities. We are issuing this Field Safety Notice (FSN) to inform you of an important issue related to the product listed below:

Details of affected products:

Impacted Product:	Biosen Linearity Test Kit / REF 0209-0102-391
Impacted Product Lot:	LS2507

Upon review of our records indicate, we confirmed that your organization purchased the identified product and corresponding affected lot of the Linearity Test Kit.

Description of the problem:
The Biosen Linearity Test Kit contains Glucose/Lactate solutions in three (3) different concentrations, packaged in color-coded micro test tubes.
As previously communicated in support information SI-250018 and the accompanying product insert, the 2 mmol/L (blue) and 7 mmol/L (green) solutions are temporarily filled in 2.0 mL micro test tubes instead of standard 1.5 mL micro test tubes. This deviation shall only affect the blue micro test tubes (2 mmol/L) and green micro test tubes (7 mmol/L) of the kit. The 18 mmol/L (red) solution was intended to remain in the red 1.5 mL micro test tubes.

However, internal investigations have identified that some of the 18 mmol/L solution were inadvertently filled in red 2.0 mL micro test tubes.

The Multi Standard Solution used for calibrating the Biosen Glucose/Lactate analyzer is also packaged in red 2.0 mL micro test tubes. This creates a risk of confusion, as the test solution is visually similar and difficult to distinguish once removed from its packaging.

Calibration of the Biosen Glucose/Lactate analyzer using the incorrectly concentrated 18mmol/L may lead to falsely low patient sample measurements.

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

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If the 18 mmol/L solution is mistakenly used for calibration, the analyzer may produce falsely low glucose or lactate readings. This could lead to misclassification of patient glycemic / lactatemic status, for example, normoglycemic / normolactatemic individuals may be incorrectly identified as hypoglycemic / hypolactatemic, or hyperglycemia / hyperlactatemia may go undetected. While clinical decisions are rarely based on a single data point, such discrepancies could contribute to inappropriate or delayed therapeutic interventions.

Action Taken by EKF:

- EKF has identified all affected customers and product lots placed on the market.
- EKF has quarantined any remaining inventory to prevent further distribution.

If you have further questions, 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 lot.
2. Please ensure this information is shared with your 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 the 'Customer Response Form' and return it to EKF.
6. The enclosed '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.
8. Upon receipt of the fully completed and signed 'Customer Response Form', we will contact you to process the product replacement or refund.

Your cooperation is appreciated, and we sincerely apologize for any inconvenience this issue may cause and reaffirm our commitment to supporting you in upholding the highest standards of patient safety, quality and regulatory compliance

Sincerely,

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

FSN RESPONSE FORM

Document Reference: SI-250020FSN

To satisfy regulatory requirements for reporting, please complete this 'Customer Response Form' and return it to EKF using one of the below methods.
Please enter the following in the subject: RESPONSE TO SI-250020FSN - <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 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 product?
☐ Yes / ☐ No

If yes, please provide further information:

The following has been verified (SELECT ALL THAT APPLY):
We attest that;

☐ 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. **Indicate lots and quantities below**.
☐ We have appropriately disposed of the product. **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	