

Urgent Field Safety Notice

Biosen Glucose/Lactate Consumables
FSN reference: EKF102016

Barleben, den 24.10.2016

Dear valued customer,

We, EKF-diagnostic GmbH, manufacturer of the Biosen Glucose/Lactate Analyzers and corresponding consumables have been made aware of possible counterfeit products being made available to the Russian market. The products in question are provided in the following table.

Affected products:

Reference number	Product description
0201-0002-026	System Solution
5206-3011	Chip-Sensor Glucose, Type II
5206-3029	Chip-Sensor Lactate, Type II
0209-0100-012	Hemolyzing Solution
5211-3017	Multi Standard Solution

If you have received any of the above product bearing the following lot numbers, the product should be quarantined at once pending further instruction from EKF.

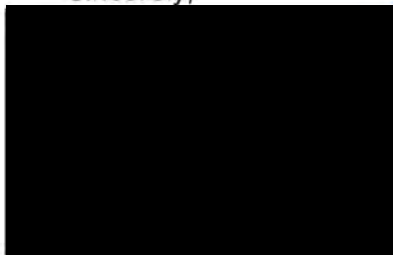
Known fake lot numbers
S17043, expiry 2017-12
CG1732, expiry 2017-09
H17021G, expiry 2018-02
M16068, expiry 2017-09

Should any of this product have already been used, EKF advise you to review any results obtained from its use and any consequential clinical actions taken. EKF-diagnostic GmbH cannot guarantee the safety and efficacy of consumables not originally produced by EKF-diagnostic GmbH.

If you have any doubt about the products you have received, please quarantine them at once and contact your EKF Service department (support@ekf-diagnostic.de).

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the affected products have been transferred.

Sincerely,



General Terms and Conditions of EKF-diagnostic GmbH, which you can view at any time in our offices, shall apply. We would also send it to you upon your request.

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BIC DEUTDE8MXXX
 Commerzbank Magdeburg
IBAN DE42 8104 0000 0209 6006 00
BIC COBADEFFXXX

FSN RESPONSE FORM

Biosen Glucose/Lactate Consumables
FSN reference: EKF102016

This response form is to confirm receipt of the enclosed Urgent Field Safety Notice dated 24th October 2016 regarding the Biosen Glucose/Lactate Consumables.

Please fax or email a scanned copy of this completed form to EKF-diagnostic GmbH until 30th November 2016.

Fax: +49 (0) 39203 511 171
Email: support@ekf-diagnostic.de

I have read and understood the Urgent Field Safety Notice instructions provided in this letter.

Please mark as applicable

Yes, we have received affected products as indicated in the Field Safety Notice.
If Yes, please answer the following questions to enable further investigation.

Who supplied the products to you?	
Which products were supplied? (please indicate reference number and lot number)	

No, we have not received affected products as indicated in the Field Safety Notice.

Signature	
Date	
Name	
Company name	
Address	