

## Field Safety Notice

**Product:** Biosen Glucose/Lactate Hemolyzing Solution

**FSN reference:** EKF072022

Date: 28<sup>st</sup> July 2022

**Document No.:** SI-220701

Dear Valued Customer,

This field safety notice is to inform you that the following variants and lots of Biosen Glucose/Lactate Hemolyzing Solution may contain capillaries that do not match the product specification.

### Details of affected Part Numbers and Lot Numbers:

Part Number	Product description	Lot Number	Possible issue
0209-0100-005	Glucose/Lactate hemolyzing solution with 10 µL end-to-end glass capillaries 1,000 x 0.5 mL with 10 x 100 capillaries	H22072B H22073B H22074B H220712E H22091E H22092E H22094E H22095E H22096E H22097E H22098E	20µl plastic capillaries included instead of 10µl glass capillaries
0209-0100-014	Glucose/Lactate hemolyzing solution with 20 µL end-to-end plastic capillaries 5x (200 x 1 mL with 2 x 100 capillaries)	H22069E H22072G H220610E H22073G H220611E H22074G H22075E H22075G H22076E H22077E H22077G H22078E H22078G	10µl glass capillaries included instead of 20µl plastic capillaries



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An EKF Diagnostics Holdings plc Company  
Ebendorfer Chaussee 3  
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CEO Steffen Borlich, Richard Evans

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BIC COBADEFFXXX

Part Number	Product description	Lot Number	Possible issue
0209-0100-012	Glucose/Lactate hemolyzing solution with 20 µL end-to-end plastic capillaries 1,000 x 1 mL with 10 x 100 capillaries	H22069S H22074G H22075B H22076B H22077B H22077S H22077T H22078B H22078S H22078T H22079B H22079E H22079G H22079S H22079T H220710B H220710E H220710G H220710E H220710T H220711B H220711E H220711S H220711T H220712B H220712G H220712T H22091B H220713G H220713T H22092B H220714G H22092T H22093B H220715G H22093T H22095B H220716G H22095S H22096G H22097B	10µl glass capillaries included instead of 20µl plastic capillaries



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		H22097G H22098B H22098G	
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### Description of the Problem:

Based on customer feedback EKF-diagnostic GmbH became aware that there was product released to the market that included 20µl plastic capillaries instead of 10µl glass capillaries.

Use of inappropriate sized capillaries will result in sample not being diluted to the ratio required for the correct measurement. In consequence, using 20µl capillaries with 0,5mL hemolyzing solution the measured glucose and lactate values using Biosen devices will be double the true value.

During investigation, EKF-diagnostic GmbH identified further product variants and lots, which might be affected. There is the possibility that the products listed above were supplied with 10 µL glass capillaries instead of 20µl plastic capillaries.

Using inappropriately sized capillaries, the sample will not be diluted in the ratio required for correct measurement. Using 10 µL capillaries with 1 mL hemolysis solution, the measured glucose and lactate values using Biosen devices are half ( 50%) of the true value.

### Patient Impact:

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

It is intended for use in medical practices, in clinical laboratories and hospital wards to assist in medical diagnostic investigations.

In cases where the measured glucose values are twice as high as true values, normoglycemic individuals might be wrongly identified as hyperglycemic. Conversely, hypoglycemic individuals might not be identified. Both scenarios could lead to unnecessary or omitted therapies. Although this is unlikely based on a single glucose measurement and based on other underlying clinical indications.

In cases where the measured glucose values are as half as high as true values, normoglycemic individuals might be wrongly identified as hypoglycemic and hyperglycemic individuals might not be identified. Both scenarios could lead to unnecessary or omitted therapies. Although this is unlikely based on a single glucose measurement and based on other underlying clinical indications.

### Actions to be taken by the Customer:

- Identify if you have received the above mentioned part numbers and product lot numbers
- Check the label of the capillaries and confirm if they meet the sample size as indicated on the outer label of the product package.
- If the capillaries match the outer label, you can continue to use the product.
- If the capillaries do NOT match the outer label, identify, return or discard unused products.



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Please inform EKF-diagnostic GmbH of your need for replacements of the discarded material.

Please confirm receipt and acknowledgement of this information by sending back the attached response form.

**Transmission of this Field Safety Notice:**

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

Please complete actions by 31<sup>st</sup> August 2022.

**Contact:**

Technical Support EKF-diagnostic GmbH  
Ebendorfer Chaussee 3, 39179 Barleben, Germany  
+49 (0) 39203 511 414  
support@ekf-diagnostic.de

We apologize for the inconvenience this issue has caused and thank you for your assistance.



Steffen Borlich  
CEO  
EKF-diagnostic GmbH



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### FSN RESPONSE FORM

**Product:** Biosen Glucose/Lactate Hemolyzing Solution  
**FSN reference:** EKF072022  
**Document No.:** SI-220701

This response form is to confirm that we have received and understood the enclosed Field Safety Notice.

Please fax or email a scanned copy of this completed form to EKF-diagnostic GmbH by 31.08.2022  
 Fax: +49 (0) 39203 511 171  
 Email: support@ekf-diagnostic.de

I have read and understood the Field Safety Notice.

Please mark as applicable

Yes, we have received affected products as indicated in the Field Safety Notice.

If Yes, please answer the following questions.

Lot number:		Quantity affected:	
Preferred compensation	Credit <input type="checkbox"/>	Replacement <input type="checkbox"/>	

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

<b>Signature</b>	
<b>Date</b>	
<b>Name</b>	
<b>Company name</b>	
<b>Address</b>	



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