

Field Safety Notice

Product: Biosen Glucose/Lactate Hemolyzing Solution

FSN reference: EKF072022

Date: 28st 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



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.

EKF-diagnostic GmbH
An EKF Diagnostics Holdings plc Company
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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	10µl glass capillaries included instead of 20µl plastic capillaries
		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			



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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:

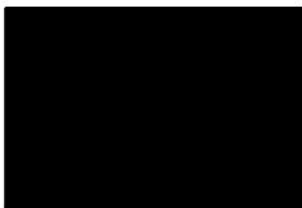
This notice needs to be communicated to all those who need to be made aware within your organization or to any organization where the affected products have been transferred.

Please complete actions by 31st 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.



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.

Signature	
Date	
Name	
Company name	
Address	



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