FSN: 01 – FSCA 2025-04

FIELD SAFETY NOTICE

Medical Product: Anti-GBM
Product code: ORG 550

10.11.2025

Sender: ORGENTEC Diagnostika GmbH, Carl-Zeiss-Str. 49 – 51, 55129 Mainz, Germany
Addressee: To all customers and users

Dear Valued Customer,

This letter contains important information that requires your immediate and urgent attention. ORGENTEC Diagnostika GmbH is conducting a Field Safety Corrective Action for the product identified below.

Identification of the affected medical devices:

Product Name:	Anti-GBM
Product Code:	ORG 550
Lot Number:	2502555
Intended Use:	Anti-GBM is an ELISA test system for the quantitative measurement of IgG class autoantibodies to glomerular basement membrane (GBM) in human serum or plasma. This product is intended for professional in vitro diagnostic use only. Determination of circulating autoantibodies against the Goodpasture-antigen in the glomerular basement membrane is intended to aid in the diagnosis of Anti-GBM disease (Goodpasture syndrome). The test is to be used in conjunction with standard clinical assessment for the differential diagnosis of autoimmune vasculitis.

Description of the problem:
A customer reported a high number of non-plausible low positive results obtained with Anti-GBM (ORG 550) lot #2502555. The outcome of an internal evaluation showed a clinical **specificity** of **86.0% instead of 99.3%** as claimed in the IFU. The possible cause including corrective and preventive actions (CAPA) are under investigation.

Impact on the patient:
Due to the reduced specificity of the product, there is a possibility of false positive results. False elevated or false positive anti-GBM results may lead the doctor to assume that the patient has anti-GBM disease mistakenly. This may lead to inappropriate therapy with glucocorticosteroids, cyclophosphamide or plasma exchange. Due to immunosuppression, potential adverse events especially include serious and opportunistic infections. Furthermore, plasmapheresis itself can cause side effects related to the procedure of central vascular access, as well as hypotension, thrombosis and infections.

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Commerzbank AG
IBAN: DE13 5504 0022 0200 8670 00
BIC: COBADEFFXXX

VAT Reg NO: DE149058799
Mainz 14 HRB 4300

Managing Director
Jean-Marc Chermette

What measures are to be taken by the addressee?

- Identify product
- Reviewing patient results that have been already obtained with the lot mentioned above is recommended to identify if positive results could be affected by the described issue.
- In case of positive results (>20 U/ml): Confirm the positive Anti-GBM results obtained with the afore mentioned ORGENTEC kit lot number using an alternative method. If you have no access to an alternative method, please contact your local distributor or Sebia subsidiary in your country.
- Negative results (<20 U/ml) are not affected by the described issue and can be reported as usual.
- The use of the affected kit lot can be continued as described in the instruction for use (IFU) and following the afore-described recommendations.
- Please inform and forward this notice to affected persons and institutions on which this action has an impact.
- End users should confirm receipt of this Urgent Field Safety Notice to the local distributor or Sebia subsidiary within 5 business days.

Action Being Taken by The Manufacturer
Corrective and Preventive Actions (CAPA) have been initiated.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred. Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. In case of further questions, contact your local distributor or Sebia subsidiary.

Please note that the relevant European Regulatory Agency has been advised of this Field Safety Corrective Action.

Yours sincerely:

On behalf of the PMS Manager

Margarethe Weise
Telefax: +49(0) 6131 9258733
E-Mail: vigilance@orgentec.com
ORGENTEC Diagnostika GmbH, Carl-Zeiss-Str. 49 – 51,
55129 Mainz, Deutschland

Field Safety Notice
Customer Reply Form

<Layout can be adapted by Distributor/Sebia Subsidiary according to local communication procedures>

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN: 01 – FSCA 2025-14
FSN Date*	07.11.2025
Product/ Device name*	Anti-GBM
Product Code(s)	ORG 550
UDI-DI	04260157080553
Batch/Serial Number (s)	2502555

2. Customer Details	
Customer Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

Mandatory fields are marked with *

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
☐	All measures described in the the Field Safety Notice have been implemented	Customer to complete or enter N/A
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
☐	I have a query please contact me	Customer to enter contact details if different from above and brief description of query

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Print Name	Customer print name here
Signature	Customer sign here
Date	

4. Return acknowledgement to sender	
Email	<Pre-filled by Distributor/Sebia Subsidiary>
Postal Address	<Pre-filled by Distributor/Sebia Subsidiary>
Fax	<Pre-filled by Distributor/Sebia Subsidiary>

Please return this form within 5 business days of receipt, even if you do not have any of the affected products.

It is important that your organisation takes the actions detailed in the FSN an confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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