FIELD SAFETY NOTICE

Date: 18.11.2025

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

Identification of the affected medical devices:

Product Name:	GBM-Ab
Product Code:	DE7130
Intended Use:	GBM Ab 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.
Lot number:	2506494 2502566

Description of the problem:
Internal evaluation of the affected lots 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.

What measures are to be taken by the addressee?

- Identify product
- Reviewing patient results that have been already obtained with the lots 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 Demeditec kit lot numbers using an alternative method. Please contact Demeditec in case you need some more help.
- 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 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 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.

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

Contact person for further information:

ppa. Dr. Manfred Czapp
Authorized Signatory / Responsible Person
Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel
Tel: +49-(0)431-71922-32
Fax: +49-(0)431-71922-55
E-mail: czapp@demeditec.de
Web: www.demeditec.com

Signature:

Field Safety Notice –
Customer Response Form

Return acknowledgement to sender
Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2, 24145 Kiel, Germany
Email: czapp@demeditec.de (preferred)
FAX: +49 (0)431-71922-55

Product name: GBM Ab
Product code: DE7130
Product lot: 2506494 and 2502566
FSN Date: 18.11.2025

Distributor Details

Company Name	
Company Address	
Contact Person	
Title or Function	
Email Address	
Telephone number	
Date	
Signature	

Distributors		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	Customer to complete or enter N/A
☐	All measures described in 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
Print Name		Distributor print name here
Signature		Distributor sign here
Date		

Please return this form within 10 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 and confirms that you have received the FSN.

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