

## FIELD SAFETY NOTICE

Date: 17.02.2025

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: Thyreoidal Peroxidase-Ab (TPO-Ab)

Product Code: DE7580

Intended Use: Thyreoidal Peroxidase-Ab (TPO-Ab) is an ELISA test system for the quantitative measurement of IgG class autoantibodies against thyroid peroxidase (TPO) in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

Thyroid autoimmune diseases are associated with the occurrence of autoantibodies directed against antigens of the thyroid cells: thyroglobulin (TG) and thyroid peroxidase (TPO). The test contributes to the differential diagnosis of autoimmune diseases of the thyroid gland, e.g. Hashimoto's thyroiditis, Graves' disease.

Lot number: all lots affected

### Description of the problem:

Following an internal performance evaluation it has been confirmed that performance claims in the current Instructions for Use (IFU) are not met.

The outcome of an internal evaluation showed a clinical **Sensitivity of 65.2% instead of 97.7%** as claimed in the IFU.

The Overall Agreement is 71.2% instead of 98.2% as claimed in the IFU.

For this reason, Demeditec Diagnostics GmbH has decided to **discontinue the product**.

### Impact on the patient:

Due to the reduced sensitivity of the product, there is a possibility of false negative results. A false negative result with Anti-TPO would indicate that the patient has no Hashimoto's disease or Graves' disease depending on test results with anti-TG. Hashimoto's thyroiditis is one of the most common causes of hypothyroidism (underactive thyroid), and early detection is important for managing the condition. A false negative test result could result in delayed treatment. Without treatment, symptoms such as fatigue, weight gain, depression, cold intolerance, and cognitive issues (brain fog) can worsen over time.

### What measures are to be taken by the addressee?

- Identify product
- Destroy product  
(Note: It is expected that expired products were already destroyed as per instructions for use.)
- Follow-up of patients or review of patient's previous results are recommended.  
If symptoms are suggestive of thyroid dysfunction, but Anti-TPO test is negative, doctors may consider additional testings, like Anti-TG antibodies or Anti-TSH receptor antibodies. They may also focus on thyroid function tests (TSH, Free T3, T4) and clinical examinations.
- 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.

Demeditec Diagnostics GmbH • Lise-Meitner-Straße 2 • 24145 Kiel (Germany)

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**Action Being Taken by The Manufacturer**

All remaining inventory of the affected kits have been quarantined at Demeditec Diagnostics GmbH.  
The assay kits will be reimbursed by the local distributor in your country.

Enclosed with this notice is a return protocol with relevant information.

**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.

**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  
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Web: [www.demeditec.com](http://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](mailto:czapp@demeditec.de) (preferred)  
FAX: +49 (0)431-71922-55

Product name: Thyreoidal Peroxidase-Ab (TPO-Ab)  
Product code: DE7580  
Product lot: all lots affected  
FSN Date: 17.02.2025\_V1

### Distributor Details

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

Distributors		
<input type="checkbox"/>	I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor to complete or enter N/A
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Distributor to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this product	
<input type="checkbox"/>	I have attached customer list	please provide customer list in excel format
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	I have destroyed affected products – enter number destroyed and date complete.	please fill table below
<input type="checkbox"/>	Neither I nor any of my customers has any affected products in inventory	

Print Name	Distributor print name here
Signature	Distributor sign here
Date	

**Please confirm the number of units remaining in your facility for which you would require a reimbursement.**

Please note that if you do NOT have units in use and in stock, you must still sign this form and fill out the table as zero (0) in the corresponding columns.

Product	Lot	Number of Kits received	Number of kits used up	Number of Kits discarded	Number of kits requested to be reimbursed
Thyreoidal Peroxidase-Ab (TPO-Ab) DE7580	2306995 (expiry: 12.02.2025)				
	2314969 (expiry: 01.06.2025)				
	2400663 (expiry: 01.06.2025)				
	2404311 (expiry: 27.10.2025)				

**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.**