FSN: 01 – FSCA 2025-02

FIELD SAFETY NOTICE

Medical Product: Anti-TPO
Product code: ORG 503

12.02.2025

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-TPO
Product Code:	ORG 503
Intended Use:	Anti-TPO 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, ORGENTEC Diagnostika 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.

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

VAT Reg NO: DE149058799
Mainz 14 HRB 4300

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 or Sebia subsidiary within 5 business days.

Action Being Taken by The Manufacturer

All remaining inventory of the affected kits have been quarantined at ORGENTEC Diagnostika GmbH.
The assay kits will be reimbursed by the local distributor or Sebia subsidiary 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 or Sebia subsidiary.

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

Yours sincerely:

PMS Manager

[redacted]

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 2025-02
FSN Date*	12.02.2025
Product/ Device name*	Anti-TPO
Product Code(s)	ORG 503
UDI-DI	04260157080027
Batch/Serial Number (s)	all lots affected

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
☐	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 destroyed affected products – enter number destroyed and date complete.	please fill table below
☐	I do not have any affected products.	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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	(e.g. need for replacement of the product).	
Print Name		Customer print name here
Signature		Customer 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 units received**	**Number of units used up**	**Number of units discarded**	**Number of units requested to be reimbursed by Distributor/Sebia Subsidiary**
Anti-TPO ORG 503	2306995 (expiry 12.02.2025)				
Anti-TPO ORG 503	2314958 (expiry 01.06.2025)				
Anti-TPO ORG 503	2404300 (expiry 27.10.2025)				

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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Field Safety Notice
Distributor/Sebia Subsidiary Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN: 01 – FSCA 2025-02
FSN Date*	12.02.2025
Product/ Device name*	Anti-TPO
Product Code(s)	ORG 503
UDI-DI	04260157080027
Batch/Serial Number (s)	all lots affected

2. Distributor/ Sebia Subsidiary Details	
Company Name*	
Address*	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

Mandatory fields are marked with *

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

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VAT Reg NO: DE149058799
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Print Name	Distributor/ Sebia Subsidiary print name here
Signature	Distributor/ Sebia Subsidiary 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 units received**	**Number of units used up**	**Number of units discarded**	**Number of units requested to be reimbursed**
Anti-TPO ORG 503	2306995 (expiry 12.02.2025)				
Anti-TPO ORG 503	2314958 (expiry 01.06.2025)				
Anti-TPO ORG 503	2404300 (expiry 27.10.2025)				

4. Return acknowledgement to sender	
Email (preferred)	vigilance@orgentec.com
Postal Address	Postfach 100352, 55134 Mainz
Fax	+49(0) 6131 9258733

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 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.