Date: 2025-02-26

Urgent Field Safety Notice

Anti-TPO IgG

For Attention of*: all distributors, end users, medical practitioners using concerned reagent or results obtained with concerned device

Contact details of local representative (name, e-mail, telephone, address etc.)*
DIALAB - Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H. IZ-NOE Sued, Hondastrasse, Objekt M55 2351 - Wr. Neudorf, AUSTRIA **Contact:** **Lorenz Miller (Reporting Officer in order of the PRRC)** **E-Mail: safety@dialab.at** **Phone: +43-2236-660910-48** **Website: www.dialab.at**

Urgent Field Safety Notice (FSN)

Anti-TPO IgG

Decreased sensitivity

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Enzyme Linked Immunosorbent Assay for the quantitative determination of IgG-autoantibodies against Thyroid peroxidase (TPO) in human serum or plasma.
1.	2. Commercial name(s)
	Anti-TPO IgG
1.	3. Unique Device Identifier(s) (UDI-DI)
	-
1.	4. Primary clinical purpose of device(s)*
	DIALAB Anti-TPO IgG is an ELISA test system for the quantitative measurement of IgG class autoantibodies against thyroid peroxidase (TPO) in human serum or plasma. Autoimmune diseases of the thyroid are associated with the appearance 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, e.g. Hashimoto's thyroiditis, Graves' disease.
1.	5. Device Model/Catalogue/part number(s)*
	REF: **R97401**
1.	6. Software version
	-
1.	7. Affected serial or lot number range
	Kit Lot. 06230029, Exp. 2025-05-31 **Kit Lot. 06230050, Exp. 2025-05-31** **Kit Lot. 06230057, Exp. 2025-11-30**
1.	8. Associated devices
	-

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Following a performance evaluation, it was confirmed that the performance claims of the product were not met. The result of an internal evaluation showed a clinical sensitivity and an overall agreement that was too low.
2.	2. Hazard giving rise to the FSCA*
	Due to the reduced sensitivity of the product, there is a possibility of false negative results which may lead to delayed treatment.
2.	3. Probability of problem arising
	All product is concerned.
2.	4. Predicted risk to patient/users
	Without treatment, symptoms such as fatigue, weight gain, depression, cold intolerance, and cognitive problems may worsen over time.
2.	5. Further information to help characterise the problem
	The result of an internal evaluation showed a clinical sensitivity of 65.2% instead of 97.7%. The overall agreement is 71.2 % instead of 98.2 %.
2.	6. Background on Issue
	Please see at point 2.1
2.	7. Other information relevant to FSCA
	-

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***

☒ **Identify Device** ☐ Quarantine Device ☐ Return Device
☒ **Destroy Device**

☐ On-site device modification/inspection

☒ **Follow patient management recommendations**

☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☒ **Other:** ☐ None

- **Ensure that the Field Safety Notice for this FSCA reaches all affected customers and end users.**
- **Make sure that Anti-TPO IgG of the mentioned Lot. numbers is no longer sold or used: Destruction of the product.**

	Final customers: - **Discontinue further measurements with Anti-TPO IgG reagent of the affected Lot. numbers immediately.** - **It is highly recommended to review and confirm previous results that were obtained by the affected lots, please see further details in section 3.3.**	
3.	2. By when should the action be completed?	**2025-03-25**
3.	3. Particular considerations for: Is follow-up of patients or review of patients' previous results recommended? **Yes** **Consider the review of recent measurements performed with affected goods with regard to a possible influence on patient decisions. If symptoms suggest thyroid dysfunction but the anti-TPO IgG test is negative, doctors may consider additional tests, such as anti-TG antibodies or anti-TSH receptor antibodies. Doctors may also focus on thyroid function tests (TSH, Free T3, T4) and clinical examinations. Please inform the affected persons and institutions affected by this measure and forward this communication.**	
3.	4. Is customer Reply Required? *	**Yes**
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other: ☐ None Destruction of all concerned DIALAB product on the Market via FSCA. Replacement: Credit note for remaining kits at customers.	
3	6. By when should the action be completed?	**Please send the FSN confirmation form until 2025-03-25**
3.	7. Is the FSN required to be communicated to the patient /lay user?	Product for professional use only (not for lay users).
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	-	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	-
4.	**3.** For Updated FSN, key new information as follows:	
	-	

4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet.
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	-	
4.	6. Anticipated timescale for follow-up FSN	-
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN.)	
	a. Company Name	DIALAB - Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
	b. Address	IZ-NOE Sued, Hondastrasse, Objekt M55 2351 - Wr. Neudorf, AUSTRIA
	c. Website address	http://www.dialab.at/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * * Distributors outside the EU/EEA are responsible for reporting to their authorities in compliance with national regulations.	
4.	9. List of attachments/appendices:	FSN Confirmation Form
4.	10. Name/Signature	Lorenz Miller, MSc.

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) **Please transfer this notice to other organisations on which this action has an impact. (As appropriate)** **Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.** **Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.***

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

FSN CONFIRMATION FORM

Product Name: Anti-TPO IgG

Identifier: FSN: FSN_2025_02_Anti-TPO IgG

☒ **Destruction** ☐ **Return**

☐ **Modification** ☒ **others:**

Please see description in FSN_2025_02_Anti-TPO IgG, section 3.1 'Action to be taken by the user'.

Distributor/Customer Details

Company Name:	
Address:	

Tick received REFs and Lots / SNs!

REF **R97401:**

☐ Lot. 06230029, Exp. 2025-05-31

☐ Lot. 06230050, Exp. 2025-05-31

☐ Lot. 06230057, Exp. 2025-11-30

Please list the counts of concerned units (add details, if required)

Total Quantity of IVDs received from DIALAB:	
Quantity of Kits in your storage for destruction / Quantity of Kits already destructed:	
Quantity of Kits already distributed to your end customers: In case of end customers in (other) European/EEA countries please note the involved countries:	

Quantity of Kits at end customer already used up:	
Quantity of Kits at end customer, currently in stock, for destruction / Quantity of Kits at end customer, already destructed:	

The undersigned confirms that all required actions have been implemented, and all concerned parties have been made aware of this Field Safety Notice.

The undersigned confirms that all data listed above is correct and complete to the best of his/her knowledge.

Completed By	
Telephone / E-Mail	
Date	
Original Signature	

Please complete this form and send it via e-mail until **2025-03-25** to safety@dialab.at.

Thank you for your efforts!

Your DIALAB Team