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Marburg, 2025-02-19

## **Urgent field safety notice (FSN): Anti TPO Ab ELISA, EIA-3561**

Dear Customer,

This notice is to inform you about a quality issue with DRG product Anti TPO Ab ELISA, EIA-3561, all lots.

### **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, it was decided to discontinue the product.

### **Risk assessment:**

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.

### **Action to be taken by distributors and end-users:**

- 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 testing, 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.

With kind regards,  
DRG Instruments GmbH



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