fb-8.3.3.0.0 Revisionsstand 1

Customer Notification



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.

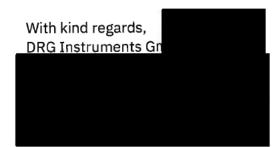
For this reason, it was decided to discontinue the product.

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.





Freigegebenes Originaldokument siehe Ablage QMB/QA: "QMH Kapitel 1 – 8"

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