Urgent Field Safety Notice

SBN-RDS-CoreLab-2025-004

RDS / CoreLab
Version 1
November 2025

Deviations of Elecsys® Anti-TSHR assay on cobas® e 411, cobas e 402 and cobas e 801

Product Name	**Elecsys** Anti-TSHR assay
BASIC UDI-DI/GMMI / Part No Device Identifier (UDI)	GMMI 08496633190 – for **cobas** e801 & 402 (E2G), UDI 7613336001239N GMMI 08496609190 – for **cobas** e411 & 60x (E1G), UDI 7613336001229
Production Identifier (Lot No./Serial No.)	All lots; Note: only 3 lots (Lot 840177, Lot 840183, and Lot 874011) are available in the market which are not already expired.
SW Version	n/a
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We've received a high number of global complaints, and our internal reviews have confirmed two related problems with the Elecsys Anti-TSHR assay (a test often used to measure results around the 1.75 IU/L medical decision point).
1. Results Vary by Instrument Platform
The test results for the same patient sample are coming out significantly different depending on which instrument is used:
On the **cobas** e 411 analyzer: Results are showing a higher reading (a "positive bias") than they should be, with the error being up to 60% around the 1.75 IU/L cutoff.
On the **cobas** e 801 and e 402 units: Results are showing a lower reading (a "negative bias") than they should be, with the error being up to approximately 50% around the 1.75 IU/L cutoff.
2. Results Vary by Calibrator Lot (on the cobas e 411)
On the **cobas** e 411 analyzer specifically, the results also change significantly when different lots of the test's calibrator are used. This causes discrepancies of up to 35 % between calibrator lots.

The cobas e 601 and cobas e 602 modules are not impacted and are within our specifications and for that can be used without restrictions for all available and future lots for the Elecsys Anti-TSHR assay.

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There are no reports of patient harm linked to this issue. In specific clinical scenarios, it is possible that clinical care could be influenced by incorrect anti-TSHR antibodies test results especially in the population at greatest risk for which the assay is intended to be used, potentially causing adverse health consequences for patients during the diagnostic workflow and therapy management.

The root cause for the variations in the **Elecsys** Anti-TSHR assay was an insufficiency of the assay's routine production process, particularly for results around the 1.75~IU/L Medical Decision Point. For the Platform-to-Platform deviation (**cobas** e 411 vs. **cobas** e 402/e 801), differences arose due to an insufficient alignment concept between the platforms. These variations were further influenced by updates to the routine production process for this assay. For the Lot-to-Lot deviation on e 411, measures taken to enhance robustness led to additional shifts.

Actions taken by Roche Diagnostics

A Corrective and Preventive Action (CAPA) investigation has been initiated to define and evaluate appropriate actions to finally solve the issue. In focus are improvements on the QC concepts. Further information will be provided after completion of the CAPA investigation, if needed.

Actions to be taken by the customer/user

Stop using the following lots of Elecsys Anti-TSHR assay and switch to the lots as indicated in the table below:

Affected Systems	Affected lots (stop using)	New unaffected lots (switch to)
cobas e 411	Lot 840177	Lot 906872
cobas e 402 cobas e 801	Lot 840183 and Lot 874011	Lot 908953

Note that cobas e 601 and cobas e 602 are not affected and can be used with all currently available lots and with the upcoming lots without restrictions.

In this case, no general recommendations with respect to the review of previous results can be given by using the Elecsys Anti-TSHR assay. Customers should follow their standard laboratory operating procedures. Any specific questions raised by the users should be addressed individually, considering all relevant clinical information.

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Communication of this Field Safety Notice (if appropriate)

<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected assay with the affected system has been distributed/supplied. (If appropriate).

Please transfer this notice to other organizations/individuals on which this action has an impact. (If appropriate).

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action. (If appropriate).>

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

Contact Details

To be completed locally:

Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com

Roche Diagnostics GmbH - SRN: DE-MF-000006260 (legal manufacturer)