

Urgent Field Safety Notice

FSN-CPS-2020-007

CPS / Immunology

Version 1

July 2020



Elecsys® Anti-TPO assay: change in rheumatoid factors interference claim

| | |
|--|--|
| Product Name | Elecsys Anti-TPO |
| System | cobas e 411, cobas e 601, cobas e 602 |
| GMMI / Part No | Elecsys Anti-TPO 06368590 190 |
| Device Identifier | |
| Production Identifier (Product name/Product code) | Elecsys Anti-TPO: all lots |
| SW Version | n/a |
| Type of Action | Field Safety Corrective Action |

Dear Valued Customer,

The internal documentation of the Elecsys Anti-TPO assay on **cobas e 411, cobas e 601** and **cobas e 602** platforms was checked as part of ongoing preparations for the new EU IVD Regulation (IVDR). During internal verification studies it was found that the current method sheet claim for RF interference (no RF interference ≤ 1500 IU/mL) was not met. Re-testing showed that there is no RF interference ≤ 450 IU/mL (specifications of $\pm 10\%$ difference in recovery). For this reason the method sheet of the assay will be updated accordingly as follows:

Table 1:

| cobas e 411 and cobas e 601/602 | | |
|--|---|------------------------------------|
| | Previous Claim | Updated Claim |
| | No interference of Rheumatoid Factor ≤ 1500 IU/mL | ≤ 450 IU/mL |

Elecsys Anti-TPO on **cobas e801** is not affected and therefore no method sheet change is necessary.

Elecsys® Anti-TPO assay: change in rheumatoid factors interference claim



Due to the residual medical risk associated with this issue, customers must be informed using the FSN-CPS-2020-007.

Actions to be taken by Roche Diagnostics

Claim for rheumatoid factors will be changed and respective method sheets will be updated. The changed claim is applicable for all current and upcoming lots. Updated method sheets (V8) are expected to be available from September 2020.

Actions to be taken by the customer/user

Customers are advised to consider the updated claim for rheumatoid factors interference (no RF interference ≤ 450 IU/mL). Please make sure to refer to the latest version of the method sheet (V8) as soon as it becomes available.

Note:

In this case, no general recommendations with respect to the review of previous results are given, taking into account that the issue occurs only under special circumstances. Any specific questions raised by the users should be addressed individually, considering all relevant clinical information.

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization where the devices have been distributed/supplied (if appropriate).

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

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

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

Elecsys® Anti-TPO assay: change in rheumatoid factors interference claim



Tel. +xx-xxx-xxxx xxxx

Email name@roche.com