

Urgent Field Safety Notice

SBN-CPS-2018-005

CPS / Immunology Application
Version 1
xx-Apr-2018

Elecsys Vitamin D total II: Non-reproducible, false high results

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| Product Name | Vitamin D total II Elecsys Vitamin D total II |
| Product Description / GMMI | Elecsys Vitamin D total II (100 tests) 07464215190 Elecsys Vitamin D total II (100 tests) 07464215160 (US Only) Elecsys Vitamin D total II (300 tests) 07028148190 |
| Production Identifier (Lot No./Serial No.) | N/A |
| SW Version | N/A |
| Type of Action | Field Safety Corrective Action (FSCA) |

Dear valued Customer,

We wish to inform you that Roche has received a number of reports of performance issues during the implementation of the Elecsys Vitamin D total II assay on MODULAR ANALYTICS E 170, **cobas e** 601 and **cobas e** 602 systems.

Description of Situation

During the implementation of the Elecsys Vitamin D total II assay on MODULAR ANALYTICS E 170, **cobas e** 601 and **cobas e** 602 systems, customers reported non-reproducible, false high results. These observations were made in duplicate measurements during assay validation of Elecsys Vitamin D total II or in method comparisons with Elecsys Vitamin D total, where the falsely-elevated discrepant value did not fit the expected result. When repeated, the elevated results were not confirmed in reruns. The issue manifests as follows:

- The first result is elevated, either above the upper end of the measuring range (>100 ng/ml or >250 nmol/mL) or within the measuring range; and repeats are significantly lower.

A medical risk for the population at the greatest risk due to the issue cannot entirely be excluded.

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Since the launch of the assay, the issues have been seen on MODULAR ANALYTICS E 170, **cobas e 601** and **cobas e 602** systems with an occurrence of between 1/100.000 and 1/1.000.000 tests sold. Rare cases have been reported on **cobas e 411** and **cobas e 801**.

Actions taken by Roche Diagnostics (if applicable)

Roche temporarily blocked the distribution of the Elecsys Vitamin D total II (07464215190 and 07464215160 USA only) assay on MODULAR ANALYTICS E 170, **cobas e 601** and **cobas e 602** systems to investigate with the highest priority.

A technical task force with all relevant functions, including members from Case Investigations and Resolution, Research and Development and Product Management has been working to identify the root cause and solve the problem.

We carried out experiments where pre-analytical errors were provoked and we could reproduce the issue for plasma samples, and finally elaborated measures to eliminate the issue in samples tested. We are carrying out further investigations to understand the underlying root cause and conditions under which this issue arises and we will inform you immediately when the investigations are conclusive.

However, the experiments revealed that the pre-analytical sample quality and compliance to the specifications of the primary tube manufacturer is very important in order to assure a good sample quality and to minimize the risk of occurrence.

We are now resuming the distribution of the Elecsys Vitamin D total II assay on MODULAR ANALYTICS E 170, **cobas e 601** and **cobas e 602** systems.

Actions to be taken by the customer/user

We strongly advise you to do the following actions prior to measurements with Elecsys Vitamin D total II on all analyzers.

These actions represent a step-by-step approach to improve sample quality prior to the measurement with Elecsys Vitamin D total II and are to be carried out temporarily until further information is provided:

1. Do a thorough inspection of your pre-analytical handling for a correct assay performance of Elecsys Vitamin D total II and to comply to the individual specifications of the primary tube manufacturers for all tubes in use (in particular the centrifugation conditions are important and the elimination of foam).
2. If the issue persists, switch from plasma to serum.
3. If you still encounter the issue on plasma or serum, do a re-centrifugation in a secondary tube for 10 min at 2000 x g prior to measurement with Elecsys Vitamin D total II.

If suggestions 1, 2 and 3 did not improve the issue, please consider switching to Vitamin D total (06506780160) or Elecsys Vitamin D total (05894913190) and contact your local point of contact at Roche Diagnostics.

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 devices have been distributed/supplied. (If appropriate).

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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