

Urgent Field Safety Notice

FSN-CPS-2018-005

CPS / Immunology Application

Version 3

April-2019

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

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 would like to announce that we have finalized the root-cause analysis. The findings indicate that the Elecsys Vitamin D total II assays show an increased susceptibility towards pre-analytical sample handling and quality of plasma samples.

As a final corrective measure, Roche will update the respective Elecsys Vitamin D total II method sheets.

Description of Situation

There is no change to the previous version (refer to FSN-CPS-2018-005 Version 2)

Actions taken by Roche Diagnostics

Roche has finalized the root-cause analysis, which indicates that the Elecsys Vitamin D total II assay shows an increased susceptibility towards pre-analytical sample handling and quality of plasma samples. With plasma samples, non-reproducible false-high results may occur even when apparently maintaining optimal pre-analytical standards. Serum samples are not affected.

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As final corrective measure, Roche will update the respective Elecsys Vitamin D total II method sheets in section 'Specimen collection and preparation' where the following statement will be included:

“Re-centrifuge plasma samples in a secondary tube for 10 min at 2000 x g prior to measurement.”

The updated method sheets are expected to be available in Q2/2019.

Actions to be taken by the customer/user

Until the updated method sheets are available, please be reminded to do the following actions:

Re-centrifuge plasma samples (after aliquoting) in a secondary tube for 10 min at 2000 x g prior to measurement with Elecsys Vitamin D total II.

If it is not possible to re-centrifuge plasma samples, please switch to Elecsys Vitamin D (06506780160) or Elecsys Vitamin D total (05894913190) and contact your local point of contact at Roche Diagnostics.

Based on internal investigation, our initial data indicates the issue of falsely elevated results occurs only with plasma samples. Although there is no evidence that serum samples are impacted, please follow the general reminder of the importance of pre-analytical sample handling for serum samples without applying the workaround.

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). 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>,

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Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com