

# Field Safety Notice

## SBN-CPS-2016-025

CPS / ClinChem fully automated / Immunology  
Version 1  
08-Dec-2016

### PreciControl Varia, Level 2 - Erroneous Target Value for Elecsys PTH assay on Elecsys 2010 / cobas e 411

|   |  |
|---|--|
| <b>Product Name</b>                               | PreciControl Varia                           |
| <b>Product Description</b>                        | PreciControl Varia                           |
| <b>GMMI / Part No</b>                             | 05618860190                                  |
| <b>Device Identifier</b>                          |  |
| <b>Production Identifier (Lot No./Serial No.)</b> | 189285-01                                    |
|   | Affected lots are not available in Singapore |
| <b>SW Version</b>                                 | Not applicable                               |
| <b>Type of Action</b>                             | Field Safety Corrective Action (FSCA)        |

Dear Valued Customer,

During our regular Quality Control activities, we have observed an error in the barcode and value sheet of PreciControl (PC) Varia lot 189285-01: erroneous target values are provided for Elecsys PTH assay (Cat. No. 11972103122) on Elecsys 2010 / **cobas e 411** for PC Varia control level 2.

**Please note:**

The following products are **NOT affected**:

- PC Varia control level 1 target values for PTH on Elecsys 2010 / **cobas e 411**
- PC Varia control level 1 and 2 target values for PTH on MODULAR ANALYTICS E170 / **cobas e 601 / cobas e 602**
- Any other bone or anemia applications also present in PC Varia

# Increased recovery of patient results with ONLINE TDM Gentamicin assay

## Description of Situation

The deviation of the correct from the erroneous target value is 20% for Elecsys PTH assay, lot 185000 and 31% for Elecsys PTH assay lot 143251. Reason for this error was a limitation in internally used software.

The issue itself can be detected easily as it will cause elevated control recoveries at customer sites. The issue will also be detected if both control levels are run together prior to the measurement of patient data.

However, if only level 2 is used and in addition a local issue occurs within the lab which causes false-low PTH-results, the control would still be within range and not invalidating results that are reported as false-low. Consequently, false-low patient results might be released.

In case of intra-operative measurement, erroneous low PTH result can lead to a wrong interpretation and conclusion that the resection was complete. In the worst case, remaining tumor/hyperplastic tissue may be left undetected. Considering unreliable detectability of the issue, relevant medical risk in the worst case cannot entirely be excluded.

## Actions taken by Roche Diagnostics

PC Varia, lot 189285-01 has been temporarily blocked for re-processing. The subsequent PC Varia lot 221451 is already available.

The software limitation in the internally used software, that caused the issue, has already been corrected.

## Actions to be taken by the customer/user

The erroneous target value is only present in PreciControl Varia, lot 189285-01, level 2 for Elecsys PTH assay on the Elecsys 2010 / **cobas e** 411. Customers have to enter the correct target value manually which are provided in a new value sheet attached to this communication:

- A reagent lot specific value has been provided for Elecsys PTH lot 143251.
- For all other Elecsys PTH lots (incl. 185000), the corrected generic PTH target values have to be used.

## Communication of this Field Safety Notice

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

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

Sincerely,

**Roche Diagnostics Asia Pacific Pte Ltd**

Email: [sg.regulatory@roche.com](mailto:sg.regulatory@roche.com)