Urgent Field Safety Notice

FSN-CPS-2020-006

CPS / Immunology

Version 1

July 2020

Discrepant results with Elecsys PTH (1-84) on cobas e 601, e602 and e801

Product Name	Elecsys PTH (1-84)
System	**cobas e** 601, **cobas e** 602, **cobas e** 801
GMMI / Part No **Device Identifier**	Elecsys PTH (1-84) (**cobas e** 601/**cobas e** 602) – 05608546 190 Elecsys PTH (1-84) (**cobas e** 801) - 07027745 190
Production Identifier (Product name/Product code)	Elecsys PTH (1-84): all lots
SW Version	n/a
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

Description of Situation

Customers complained about non-robust calibration signals of calibrator level 2 and QC recovery issues with PTH (1-84) lot 434933 on **cobas e** 601 / **e** 602 analyzers.

The issue observed is a calibration signal for calibrator level 2 varying between two signal levels: ~25'000 cts vs ~35'000 cts. The Quality Controls allegations included borderline & out-of-range results towards both ends: under- and over-recovery. Despite calibrator and QC the issue can also affect the recovery of patient samples. The above mentioned deviation might occur with a change of the ProCell M / ProCell II M lot.

Internal investigations showed that the signal level of the PTH (1-84) assay might be influenced by the ProCell M or ProCell II M lot used. The causal factors for this interaction are currently being investigated. This signal is affected differently on **cobas e** 601 / **e** 602 and **e** 801. On **cobas e** 601 / **e** 602 analyzers the signal offset may cause a deviation >30% of the reported result (ProCell M lots 421171, 425300, 426235, 426236, 426237, 421170, 425301, 425303 and 426229), on **cobas e** 801 the observed deviation can be up to 30% (ProCell II M lots 421768 and 427413).

cobas e 411 is not affected. There are no known issues with other assays.

Due to the residual medical risk associated with this issue, customers must be informed using the FSN-CPS-2020-006 version 1.

Discrepant results with Elecsys PTH (1-84) on cobas e 601, e 602 and e801

Actions to be taken by Roche Diagnostics

Further investigations are currently ongoing to understand the underlying root cause of the issue.
In order to prevent a re-occurrence of the issue Roche has implemented an additional QC test release step. All new lots of ProCell (starting from 485018 / ProCell M (starting from 484472) / ProCell II M (starting from 499311) will be tested with the PTH (1-84) assay prior to market release.

Actions to be taken by the customer/user

Customers using PTH (1-84) on cobas e 601 / e 602 are requested to perform calibration, QC and routine patient measurements with the same ProCell M lot. Perform a PTH (1-84) calibration with the ProCell M lot in use and repeat the following steps on every ProCell M lot change:

1. Bring the **cobas e** 601 / **e** 602 analyzer in **stand-by mode.**
2. Replace both ProCell M bottles with **bottles of a new lot and register both bottles.**
3. Perform calibration for all Elecsys PTH (1-84) **cobas e** packs on-board. Verify that one of these calibrations results in a **Lot Calibration**.
   If not, place a new **cobas e** pack on the reagent rotor and calibrate again.
4. Verify the new Elecsys PTH (1-84) calibration(s) by **established QC means**.

This workaround is not needed with ProCell M lots starting from lot number 484472.

Customers using PTH (1-84) with ProCell II M lots 421768 or 427413 on cobas e 801 are asked to perform calibration, quality control and routine patient measurements with the same ProCell II M lot.
To use any of the above lots, perform a new PTH (1-84) calibration and repeat the following steps the next time you change the ProCell II M lot:

1. Bring the **cobas e** 801 analytical unit in **stand-by mode**.
   If quick start mode is active or a red alarm occurred, perform “Finalization” manually.
2. Replace both ProCell II M bottles with **bottles of a new lot and register both bottles.**
3. Perform calibration for all Elecsys PTH (1-84) **cobas e** packs on-board. Ensure that one of these calibrations results in a **Lot Calibration**.
   If not, place a new **cobas e** pack on the reagent rotor and calibrate again.
4. Verify the new Elecsys PTH (1-84) calibration(s) by **established QC means**.

If you are not using the above mentioned ProCell II M lots, this workaround is not needed.

Note:
In this case, no general recommendations with respect to the review and follow up were given, taking into account different possible scenarios (e.g. detectability via QC might be given). Any specific questions raised by the users should be addressed individually, considering all relevant clinical information.

Discrepant results with Elecsys PTH (1-84) on cobas e 601, e 602 and e801

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
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com