URGENT FIELD SAFETY NOTICE
IMMEDIATE ACTION REQUIRED

Ref No:	EFSN Elecsys PTH (1-84) SBN-CPS-2020-006
Date:	16/07/2020
Type of Action:	Field Safety Corrective Action (FSCA)

Product Affected:	Elecsys PTH (1-84)
System Affected:	cobas e 601 cobas e 602 cobas e 801

Software Version:	N/A

Product Name	Material No	Lot No
Elecsys PTH (1-84) (cobas e 601/cobas e 602)	05608546190	All lots
Elecsys PTH (1-84) (cobas e 801)	07027745190	All lots

Summary of Issue

Discrepant results with Elecsys PTH (1-84) on cobas e 601, e 602 and e 801.

Reason for Notice

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 analysers.

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 Control allegations included borderline & out-of-range results towards both ends: under- and over-recovery. Despite calibrator and QC the issue can also

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Registered No 571546

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 analysers 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.

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.

Action Required

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.

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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.

Please complete and return the Acknowledgement Form which accompanies this Field Safety Notice by Friday 31st July 2020.

Please bring this notice to the attention of all personnel in your hospital or Health Care facility who need to be aware of this safety issue.

If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this notice to them.

Attachments EFSN Elecsys PTH (1-84) SBN-CPS-2020-006 Acknowledgement Form

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This action is being conducted with the knowledge of the Medicines and Healthcare Products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

Roche Diagnostics operates a vigilance system that complies with the IVD Directive 98/79 EC

A copy of this notice can also be found on the Roche Dialog Portal

If you require any further information please contact our

Technical Support Hotline

UK: 0808 100 19 20
Ireland: 1800 40 95 64

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ACKNOWLEDGEMENT

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Field Safety Notice Ref No: EFSN Elecsys PTH (1-84) SBN-CPS-2020-006
Acknowledgement Form
Date: 16/07/2020
Type of Action: Field Safety Corrective Action (FSCA)

Kindly complete and return this form to the e mail address shown on the footer before Friday 31st July 2020.

Product Catalogue No:	Elecsys PTH (1-84) (cobas e 601/cobas e 602) 05608546190 Elecsys PTH (1-84) (cobas e 801) 07027745190
System:	cobas e 601 cobas e 602 cobas e 801
Customer Name & Dept:	
Address:	

Are the above contact details correct? (Please circle) Yes No (If no please insert correct details below)

Contact Name:

Department:

Telephone:

If you require an electronic copy of this field safety notice in addition to the hard copy please print your e-mail address below:

Email:

Please acknowledge receipt of information and awareness of any required actions described within the accompanying Field Safety Notice.

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email to burgesshill.techsupportdocs@roche.com

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Acknowledgement Form
Date: 16/07/2020
Type of Action: Field Safety Corrective Action (FSCA)

I acknowledge receipt of this Field Safety Notice and have read, understood and implemented its content.

Name:

Signed:

Date:

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