Urgent Field Safety Notice
SBN-CPS-2017-001

CPS / Immunology
Version 2
03-February-2017

The use of lot number 185522 for TSH and PTH (1-84) on cobas e 602 module leads to inappropriate reagent kit information for TSH

Product Name	TSH (Lot No. 185522) PTH (1-84) (Lot No. 185522)
Product Description	Elecsys TSH assay Elecsys PTH assay
GMMI / Part No **Device Identifier**	TSH (GMMI 11731459122) PTH (1-84) (GMMI 05608546190)
Instrument/System Affected	cobas e 602 module
SW Version	Not applicable
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We regret to inform you that in case the Elecsys PTH (1-84) assay lot 185522 (expiry date May 2016) and Elecsys TSH assay lot 185522 (expiry date June-2017) were ever used on the same cobas 8000 modular analyzer series configuration (which includes **cobas e** 602 module), this will lead to the following consequences to the TSH:

- Ø a reduced number of tests per kit (100 instead of 200)
- Ø low recovery of PC Universal level 2 (independent from the lot number) < -3SD
- Ø high recovery of PreciControl TSH and PreciControl Thyro Sensitive (TS) (independent from the lot number) > +3SD

Note: The issue may not be detected if only PCU level 1 is measured. Recovery of samples is decreased in high concentration and increased in low concentration for TSH.

As the expiry date for Elecsys PTH (1-84) assay lot 185522 was May 2016, so it was available in the market before the release of Elecsys TSH assay lot 185522, accordingly the Elecsys PTH (1-84) assay lot 185522 is not affected (i.e. the appropriate reagent kit information for Elecsys PTH (1-84) assay lot 185522 was used).
The root cause is that the same lot number (185522) was assigned to Elecsys TSH assay and Elecsys PTH (1-

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84) assay. The **cobas e** 602 module uses the lot number as the unique identifier for the reagent kit information.

The quality of Elecsys TSH assay and Elecsys PTH (1-84) assay is not affected.

All of the other immunochemistry modules/systems (**cobas e** 411, MODULAR *ANALYTICS* E 170, **cobas e** 601 module, **cobas e** 801 module) are not affected.

Results of TSH below or above the normal ranges lead at initial diagnostics to further examinations (e.g. laboratory results, imaging); no immediate therapeutic measure is likely and no immediate invasive diagnostic is necessary. Therefore a medical risk with respect to harm of patients is very unlikely. For false normal results it cannot be excluded, that the patient will be diagnosed with a delay, as normal results of TSH do not lead to further investigation, except clinical symptoms or clinical history are contradictory.
If for newborn screening TSH only is used, incorrect TSH results could lead to an incorrect diagnosis and with inadequate treatment subsequently.
If TSH is used for pre-interventional diagnostic for verification of regular thyroid function to allow for application of iodinated contrast media and a risk for a specific patient group is related.
In case clinical symptoms or medical history of decreased TSH points to hyperthyroidism, iodinated contrast media should not be given to patients with manifest hyperthyroidism. In selected high-risk patients, prophylactic treatment may be given. Patients at risk should be closely monitored by endocrinologists after iodine-based contrast medium injection. Intravenous cholangiographic contrast media should not be given to patients at risk.
If decreased TSH is tested falsely within the normal range and no clinical symptoms nor clinical history contradict, patients with undetected hyperthyroidism may receive iodine-based contrast medium injection putting the patients at risk for thyrotoxicosis.

Correct result of TSH (µIU/mL)	False result (µIU/mL)	Clinical interpretation
0.27 or > 0.27	>0.36	euthyreot (correct)
0.15 – 0.26	0.26 – 0.36	euthyreot (incorrect)
< 0.15	< 0.26	hyperthyreot (correct)

If hyperthyroidism is excluded by measuring of TSH only, retesting of results 0.26 – 0.36 µIU/mL should be considered if clinical symptoms point to hyperthyroidism.

Actions taken by Roche Diagnostics

The distribution of Elecsys TSH assay lot 185522 was stopped to customers using **cobas e** 602 module.

Roche Diagnostics have taken all of the necessary measures with immediate effect to ensure that any product lot number is unique.

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Actions to be taken by the customer/user

Please do not use Elecsys TSH assay lot 185522 in any cobas 8000 modular analyzer series configuration (which includes **cobas e** 602 module) where the Elecsys PTH (1-84) assay lot 185522 have been previously used. Please switch to the next available Elecsys TSH assay lots 189279 and 212491.

In case you have not used in the cobas 8000 modular analyzer series configuration (which includes **cobas e** 602 module) Elecsys PTH (1-84) assay lot 185522, you can use the Elecsys TSH assay lot 185522 without any restrictions.

If you are affected by the issue:
If hyperthyroidism is excluded by measuring of TSH only, retesting of results 0.26 – 0.36 µIU/mL should be considered if clinical symptoms point to hyperthyroidism.

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 or to any organization/individual where the potentially affected devices have been distributed/supplied.

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.

Best regards,

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Contact Details

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