Field Safety Notice

SBN-CPS-2018-016

CPS / Immunology
Version 1
25-Sept-2018

Elecsys® FT4 III – Reduced biotin interference threshold

Product Name	Elecsys® FT4III
Product Description / GMMI	07976836190 07976887190
Production Identifier (Lot No./Serial No.)	304692 / 331797 304694 / 331807 / 356756
Instrument / System Affected	**cobas e** 411, **cobas e** 601, **cobas e** 602, MODULAR ANALYTICS E170 **cobas e** 801
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We wish to inform you about a reduced biotin interference threshold for the recently launched Elecsys® FT4 III assays. The described threshold in the method sheet is ≤ 409 nmol/L or ≤ 100 ng/mL of biotin in a sample. However, for the currently available:

- Elecsys® FT4 III (07976836190) reagent lots 304692 / 331797 (**cobas e** 411, **cobas e** 601, **cobas e** 602, MODULAR ANALYTICS E170)
- Elecsys® FT4 III (07976887190) 304694 / 331807 / 356756 (**cobas e** 801)

the threshold is ≤ 81.8 nmol/L or ≤ 20 ng/mL. In patient samples with biotin concentrations of ≥266 nmol/L or ≥ 65 ng/mL, FT4 recovery could lead to a difference of >20%.

Please note: As only patient samples that contain a high Biotin concentration of ≥266 nmol/L or ≥65 ng/mL are affected, the general patient population is not affected.

The overall performance of the Elecsys® FT4 III assays is not impacted.

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Elecsys® FT4 III – Reduced biotin interference threshold

Actions taken by Roche Diagnostics

The original claimed threshold of ≤ 409 nmol/L or ≤ 100 ng/mL for biotin will be reinstated from Elecsys® FT4 III (GMMI 07976887190) lot 378826 and Elecsys® FT4 III (GMMI 07976836190) lots 378844 / 380330 onwards.

Actions to be taken by the customer/user

It is important to adhere to the claim described in the method sheet of the assay:

"Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration."

In case a result does not match the patient's clinical picture:

1. Assess the result in conjunction with the patient's medical history, clinical examination and other findings, and rule out that the patient has taken biotin before blood draw.
2. Collect a new sample from the patient and perform a new measurement, if biotin intake has been ruled out.
3. In case of biotin intake, please wait until the end of the washout period. (According to *Grimsey P et al.: Population pharmacokinetics of exogenous biotin and the relationship between biotin serum levels and in vitro immunoassay interference. Int. J.. Pharmocokinet. Vol 2, No 4 14* https://doi.org/10.4155/ipk-2017-0013)

Communication of this Field Safety Notice

This notice must be passed on to all those who need to be aware within your organization or to any other organization/individual where the potentially affected devices have been distributed/supplied. Please pass on this notice to the Chairman Medical Board and Head of Department as well, as required by HSA.
Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action

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

Sincerely,

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