Field Safety Notice

SBN-CPS-2019-007

CPS / Infectious Diseases
Version 1
03-Jun-2019

Elecsys Syphilis: Erroneous Values used for Interference of IgM and IgG

Product Name	Elecsys Syphilis (200 test/kit)	
Product Description	MODULAR ANALYTICS E170, **cobas e** 411, **cobas e** 601, **cobas e** 602	
GMMI / Part No Device Identifier	07802960190	Affected identifier not available in Singapore
Production Identifier (Product name/Product code)	Elecsys Syphilis	
SW Version	Not applicable	
Type of Action	Field Safety Corrective Action (FSCA)	

Dear Valued Customer,

Description of Situation

We regret to inform you that erroneous values were stated in the method sheet (version 1.0 and 2.0) of Elecsys Syphilis, 200 test/kit on MODULAR ANALYTICS E170, cobas e 411, cobas e 601 and cobas e 602, section "limitations – interference" where the potential interference of "IgG" and "IgM" is listed.

In the column "Concentration tested" "32 g/dL" is written instead of the correct "3.2 g/dL" for "IgG" and "10 g/dL" is written instead of the correct "1.0 g/dL" for "IgM".

Note: The method sheets of Elecsys Syphilis, 100 test/kit (GMMI 06923348 190) on MODULAR ANALYTICS E170, **cobas e** 411, **cobas e** 601 and **cobas e** 602 and Elecsys Syphilis, 300 test/kit (GMMI 07251378 190) on **cobas e** 801 are **not** affected.

Consequently, the interference may remain undetected, considering the incorrect higher concentrations shown in the table in the current method sheet. A corrected version of this table is provided in the "Actions required by the Customer/User section.

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Medical risk:
If due to an incorrect high interference level of IgG and IgM the interference starts at a lower level than expected, a negative bias may result and may remain undetected. This may lead to incorrect negative results and therefore to the missed diagnosis of the disease, missed treatment and spread of infection. The risk is mitigated as the interference as claimed happens at levels of IgG / IgM which do not occur in healthy human beings. IgG ≤ 3.2 g/dL (normal range: 0.7-1.6 g/dL). IgM ≤ 1.0 g/dL (normal range: 0.04-0.28 g/dL).
For specific patient populations (e.g. Multiple Myeloma Stage II with IgG > 7.0 g/dL, M. Waldenstroem, Waldenstroem`s Macroglobulinemia) a medical risk cannot be excluded.

Actions taken by Roche Diagnostics

This issue was caused by a typographical error during the creation of the method sheet which was not detected in the review process. The method sheet has been corrected and version 3 is expected to be available from mid of July 2019 onwards.

Actions to be taken by the customer/user

Until the corrected version 3 of the method sheet is available, please consider the correct table in section "limitations – interference" where the potential interference of "Endogenous Substances" is listed:

Compound	**Concentration tested (corrected)**
Bilirubin	≤ 1129 µmol/L or ≤ 66 mg/dL
Hemoglobin	≤ 0.310 mmol/L or ≤ 0.5 g/dL
Intralipid	≤ 2000 mg/dL
Biotin	≤ 246 nmol/L or ≤ 60 ng/mL
Rheumatoid factors	≤ 1500 IU/mL
Human serum albumin	≤ 10 g/dL
IgG	**≤ 3.2 g/dL**
IgA	≤ 2.8 g/dL
IgM	**≤ 1.0 g/dL**

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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 hope for your understanding and your support.

Sincerely,

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