Urgent Field Safety Notice
SBN-CPS-2019-007

CPS / Infectious Diseases
Version 1
May-2019

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

Product Name	Elecsys Syphilis (200 test/kit)
System	MODULAR ANALYTICS E170, **cobas e** 411, **cobas e** 601, **cobas e** 602
GMMI / Part No **Device Identifier**	07802960 190
Production Identifier **(Product name/Product code)**	Elecsys Syphilis
SW Version	n/a
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**

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 product has been distributed/supplied.

Please transfer this notice to other organizations/individuals on which this action has an impact.

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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,

Contact Details

To be completed locally:
Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com