Urgent Field Safety Notice

SBN-CPS-2019-012

CPS / Immunology

Version 1

Jul 2019

Elecsys Anti-CCP: lot-specific false high results on plasma samples

Product Name	Elecsys Anti-CCP
System	**cobas e** 411 / 601/ 602/ 801 Modular Analytics E170
GMMI / Part No **Device Identifier**	Elecsys Anti-CCP (Modular Analytics E170, cobas e411, cobas e 601, cobas e 602, 100 tests) 05031656190 Elecsys Anti-CCP (Modular Analytics E170, cobas e 411, cobas e 601, cobas e 602, 100 tests) 05031656160 (US Only) Elecsys Anti-CCP (cobas e 801, 100 tests) 07251670190
Production Identifier (Product name/Product code)	05031656190: 368033, 376804, 389152 05031656160: 358545, 368037, 376808, 389165 07251670190: 368029, 376648, 388800
SW Version	n/a
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

We wish to inform you that Roche has received a number of reports of performance issues with certain lots of the Elecsys Anti-CCP assay when using plasma samples on the **cobas e** 601 and **cobas e** 602 systems. Sporadically cases have been reported on the **cobas e** 411 analyzer and **cobas e** 801 analytical unit. Therefore we would like to support you with handling recommendations.

Description of Situation

Based on the current reports, the following 3 main patterns are observed:

1) Discrepant results between serum and plasma samples from the same blood draw of a given patient: negative results (< cutoff) on serum and positive results on plasma samples.

2) Decreasing concentration of anti-CCP with the same plasma sample tube over time: starting from a positive result (>cutoff) and becoming negative within 24 hours.

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3) Discrepant concentrations obtained on plasma samples depending on the reagent lots used.

Customer reports alleged issues only with plasma samples.
Subsequent Roche internal investigations could only confirm pattern 1) and 3) as listed above; these issues could only be reproduced with plasma samples. **Serum samples are not affected and thus do not require a workaround.** Pattern 2) could not be confirmed yet**.**
To date no definite root cause has been identified; investigations are ongoing.

Irrespective of the sample type, we would like to remind you of the importance of pre-analytical handling and sample quality when running Elecsys Anti-CCP or any other immunoassay.
The issue can lead to a wrong Anti-CCP result in plasma samples and therefore affect clinical interpretation.

Due to the residual medical risk associated with this issue, customers using the affected product with plasma samples must follow the "Actions to be taken" as described below.

Actions taken by Roche Diagnostics

Until the root cause has been identified, an additional Quality Control step (QC testing with plasma) is being implemented for future reagent lots, thus preventing potentially affected lots being released.

Actions to be taken by the customer/user

We strongly advise you to take the following actions when measuring with Elecsys Anti-CCP on all analyzers.
These actions are to be carried out until further information is provided.

Actions to be taken:
Please note: Serum samples are not affected.

- We advise you to use the Elecsys Anti-CCP with serum samples only until further notice on the affected lots.
- If you cannot use serum samples in your laboratory, we advise you to use a not affected lot (GMMI 05031656190: #400794, #400782; GMMI 07251670190: #399875).
- Please reach out to your local Roche Diagnostics point of contact, if you cannot use serum samples in order to identify the best solution for your routine

General reminder:

- We advise you to perform maintenance according to the operator manual (e.g. Liquid Flow Cleaning (LFC)) to ensure proper functioning of the analyzer
- We remind you that sample quality can be affected by fibrin clots and this can significantly impact results
- If implausible result constellation occurs while using plasma samples and a high anti-CCP result does not match the patient's clinical picture, we advise you to re-measure the sample

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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 devices have been distributed/supplied. (If appropriate).

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.

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com