

Field Safety Notice

SBN-CPS-2019-012

CPS / Immunology

Version 1

15-Jul-2019

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

Product Name	Elecsys Anti-CCP
Product Description	cobas e 411 / 601/ 602/ 801
GMMI / Part No	Elecsys Anti-CCP (cobas e411, cobas e 601, cobas e 602, 100 tests)
Device Identifier	05031656190 Elecsys Anti-CCP (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 (Lot No./Serial No.)	05031656190: 368033, 376804, 389152 05031656160: 358545, 368037, 376808, 389165 07251670190: 368029, 376648, 388800
	Affected lots are not available in Singapore for 05031656160 and 07251670190
SW Version	Not applicable
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

We wish to inform you that Roche has received a number of reports of performance issues with certain lots of Elecsys Anti-CCP assay when using plasma samples on the cobas e 601 and cobas e 602 systems. Sporadic cases have been reported on the cobas e 411 analyzer and cobas e 801 analytical unit. This FSN is to provide sample type and handling recommendations.

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Description of Situation

Based on the current reports, the following 3 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.
- 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). Serum samples are not affected. 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, customers using the affected product with plasma samples must follow the "Actions to be taken by the customer/user".

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.

- As serum samples are unaffected, please use serum samples.
- If serum samples are not used in your laboratory, a not affected lot (GMMI 05031656190: #400794, GMMI 07251670190: #399875) can be ordered.

A general reminder for routine operations:

- To ensure proper functioning of the analyzer, perform maintenance according to the operator manual (e.g. Liquid Flow Cleaning (LFC)).
- Fibrin clots (poor sample quality) can significantly impact results.
- If implausible result occurs while using plasma samples or 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

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,

Roche Diagnostics Asia Pacific Pte Ltd

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