Urgent Field Safety Notice

SBN-CPS-2020-001

CPS / Immunology

Version 1

January 2020

Elecsys CA 19-9: non-reproducible elevated results with reagent lot 416245 on cobas e 801

Product Name	Elecsys CA 19-9
System	**cobas e** 801
GMMI / Part No **Device Identifier**	Elecsys CA 19-9 (**cobas e** 801, 300 tests) – 07027028 190
Production Identifier (Product name/Product code)	07027028 190: Lot 416245
SW Version	n/a
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

Description of Situation

We recently received an increased number of complaints concerning non-reproducible elevated results (so-called "high flyers") for Elecsys CA 19-9 lot 416245 on **cobas e** 801. With previous lots of CA 19-9 none to one high flyer complaints per month were reported on **cobas e** 801. However, since October 2019 we have received a total of 23 complaints.

<u>The issue appears as follows:</u>
Either result of multiple determinations is non-reproducible elevated compared to the other results of the same sample aliquot.
The issue has been observed with both plasma and serum samples.
The increased frequency of non-reproducible elevated results has only been reported for reagent lot 416245. The issue is reagent lot-specific and not related to **cobas e** 801 instrument.

The issue can lead to non-reproducible elevated CA 19-9 results and therefore affect clinical interpretation.

The investigations revealed that in this case the occurrence of non-reproducible falsely elevated results is related to a contamination with magnetic/paramagnetic particles (no beads) that occurred during the filling process for **cobas e** 801 only.
Thus, reagents filled for **cobas e** 411/**e** 601/**e** 602 are unaffected.

Due to the residual medical risk associated with this issue, customers must be informed using this Field Safety Notice.

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Actions to be taken by Roche Diagnostics

Immediate corrections were already taken and investigations are currently ongoing to:

- establish methods for recognition of affected lots during the filling process
- eliminate the contamination with particles within the filling process
- monitor and identify if other Elecsys assays are affected by the issue. So far, a similar issue was observed with certain lots of Elecsys Troponin T hs on **cobas e** 801. At this point, there is no indication that further Elecsys assays (beyond Troponin T hs and CA 19-9) are affected by this issue.

Actions to be taken by the customer/user

- Only Elecsys CA 19-9 (07027028 190) lot 416245 (which runs on **cobas e** 801) is affected.
- Wherever possible, customers are asked to switch Elecsys CA 19-9 from **cobas e** 801 to **cobas e** 411/**e** 601/**e** 602.
  All reagent lots CA 19-9 (11776193 122) running on **cobas e** 411/**e** 601/**e** 602 can be used without restrictions.
  Please Note: Reagent lot 375128 Elecsys CA 19-9 (11776193 122) running on **cobas e** 411/**e** 601/**e** 602 should not be used in combination with PreciControl Tumormarker (11776452 122) lot 415249.
  All other combinations of Elecsys CA 19-9 reagent lot/ PreciControl Tumormarker running on **cobas e** 411/**e** 601/**e** 602 can be used without any restrictions.
- In case switch from **cobas e** 801 to **cobas e** 411/**e** 601/**e** 602 is not possible, customers using **cobas e** 801 are advised to perform the following actions for the affected lot:
  1. In order to reduce the frequency of non-reproducible elevated results, please ensure not to invert or shake the ePacks prior to loading on to the analyzer and discard each ePack of the affected lot after the first 200 determinations.
  2. Perform double determinations from the same tube for all results ≥ 37 U/ml CA 19-9 in order to increase the detectability of possible non-reproducible elevated results (high flyers).

This advice is valid until further notice.

General reminder:
Pre-analytical handling is crucial for a correct performance of all assays. This includes compliance to the individual specifications of the primary tube manufacturers for all tubes in use (in particular, the centrifugation conditions are important and the elimination of foam, and for serum, sufficient clotting time are important).

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:

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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