# Urgent Field Safety Notice

*SBN-CPS-2020-001*

CPS / Immunology
Version 3
July 2020

# Elecsys CA 19-9: non-reproducible elevated results with reagent lots 416245 and 464449 on cobas e 801

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| **Product Name** | Elecsys CA 19-9 |
| **System** | **cobas e** 801 |
| **GMMI / Part No**<br>**Device Identifier** | Elecsys CA 19-9 (**cobas e** 801, 300 tests) – 07027028 190 |
| **Production Identifier (Product name/Product code)** | 07027028 190: Lot 416245 and 464449 (not affected: 483123) |
| **SW Version** | n/a |
| **Type of Action** | Field Safety Corrective Action |

Dear Valued Customer,

## Description of Situation

As described in FSN-CPS-2020-001 version 1 and 2, Elecsys CA 19-9 lot 416245 and 464449 on **cobas e** 801 showed in internal investigations and customer complaints an increased rate of non-reproducible elevated results.

The issue appears as follows:
Either result of multiple determinations is non-reproducibly 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 been reported for reagent lot 416245 and could be also confirmed for the following lot 464449 which was released with restrictions in SBN-CPS-2020-001 version 2. The issue is reagent lot-specific and not related to **cobas e** 801 instrument.
The issue can lead to non-reproducible elevated Elecsys CA 19-9 results and therefore may affect clinical interpretation. Reagents filled for **cobas e** 411/**e** 601/**e** 602 are unaffected.
Due to the residual medical risk associated with this issue, customers were informed using the Field Safety Notice version 1 and 2.

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. Unique root cause/source for this contamination was not identified yet. A multifactorial background is assumed. However, multiple countermeasures to prevent contamination with (para-)magnetic particles are

implemented on the basis of the risk analysis of the filing process. Furthermore, an additional QC release criteria has been defined and put in place to assess if a production lot is affected by an increased high-flyer frequency or not.

For the now upcoming Elecsys CA 19-9 lot 483123 internal QC tests did not show an increased rate of non-reproducible elevated results after the 14 weeks maturation period. For that, this lot was released and can be used without restrictions.
Customers must be informed regarding the updated workaround using the FSN-CPS-2020-001 version 3

## Actions to be taken by Roche Diagnostics

Immediate corrections were already taken and countermeasures to prevent contamination with (para-)magnetic particles were implemented based on the risk analysis of the filling process.
Upcoming lots undergo extensive quality control measurements and if passed, will be released without restrictions.

## Actions to be taken by the customer/user

Reagent lot 483123 - based on the results of the quality control measurements – is considered as non affected and can therefore be used without restrictions. No double determinations are needed, the restriction to 200 determinations per ePack can be lifted.

All reagent lots CA 19-9 (11776193 122) running on **cobas e** 411/**e** 601/**e** 602 can be used without restrictions.
Customers using Elecsys CA 19-9 (07027028 190) lots 416245 and 464449 (which run on **cobas e** 801) are advised to perform the following actions for the affected lots:

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).

The contamination of two Elecsys CA 19-9 assay lots with (para)magnetic particles is only one of the known causes of non-reproducible results. Although corrections have been made to prevent the contamination, other causes may still lead to a sporadic occurrence of non-reproducible results in the future.

General reminder regarding occurrence of high flyers:
Some of the most important aspects are:

- Correct and good sample preanalytic according to the specifications of the respective primary tube manufacturer (e.g. centrifugation time, speed, temperature)
- Avoidance or complete elimination of foam on or clots in the samples
- Regular and complete equipment maintenance according to the manufacturer's specifications
- Regular visual checks of e.g. the sample carriers to ensure correct positioning of the tubes on the analyzers.

Due to these alternative causes, flyers may continue to appear in the future at the frequency typical of the laboratory before the product problem.

## Communication of this Field Safety Notice (if appropriate)

# Elecsys CA 19-9: non-reproducible elevated results with reagent lots 416245 and 464449 on cobas e 801

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

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Email name@roche.com