



Urgent Field Safety Notice

MY-FSN-CPS-2020-001

RDS/ CoreLab / Immunology

Cindy Tang

Version 9

April 2022

Elecsys CA 19-9: non-reproducible elevated results with upcoming reagent lots 598135, 598140, 599263 on cobas e 801

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| Product Name | Elecsys CA 19-9 |
| System | cobas e 801 |
| GMMI / Part No | Elecsys CA 19-9: 07027028190 |
| Device Identifier | |
| Production Identifier (Product name/Product code) | Lot 598135, 598140 and 599263 (newly identified affected lots) |
| SW Version | n/a |
| Type of Action | Field Safety Corrective Action |

Dear Valued Customer,

Description of Situation

As described in the former versions of MY-FSN-CPS-2020-001, Elecsys CA 19-9 lots 416245, 464449, 483123 (all three expired), 504743 and 568976 on **cobas e 801** showed in internal investigations and/or customer complaints an increased rate of non-reproducible elevated results.

With the MY-FSN-CPS-2020-001 version 9 we want to inform that the implemented corrective actions are currently in the evaluation phase and therefore the **upcoming CA19-9 lots 598135, 598140 and 599263** can be used on **cobas e 801** analyzers only if the already described restrictions are applied.



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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 detected for reagent lots 416245, 483123, and 504743 which were released with restrictions in the former versions of MY-FSN-CPS-2020-001.

The issue is reagent lot-specific and not related to the **cobas e 801** instrument.

The issue can lead to non-reproducible elevated Elecsys CA 19-9 results and therefore may affect clinical interpretation. Measures have been implemented to ensure consistent product quality of future lots. Until confirmation of the effectiveness of these measures, the upcoming CA 19-9 reagent lots still have to be released with restrictions: double determinations for all results ≥ 37 U/ml CA 19-9 must be applied as a precautionary measure.

For the time being, the restrictions as communicated previously for all affected lots still apply to allow for reliable detection of high flyers.

Based on the current status of investigations, the interaction of (para)magnetic particles and proteins of the assay formulation being able to trigger the Elecsys ECLIA reaction may be specific for Elecsys CA 19-9.

For the upcoming CA 19-9 lots, countermeasures to prevent contamination have been implemented. These comprise the quantitative detection of both protein aggregates and detection of (para-)magnetic particles. Production process has been further changed to deplete potential protein aggregates before filling and will be applied to the upcoming lots.

Due to residual medical risk described in the previous versions, customers using the Elecsys CA 19-9 lots 598135, 598140 and 599263 must be informed using the MY-FSN-CPS-2020-001 version 9.

Actions to be taken by Roche Diagnostics

Countermeasures to prevent contamination with (para-)magnetic particles were implemented in the filling process. Additional QC release criteria were defined and are implemented. While the Proof of Effectiveness is still ongoing, upcoming lots have to be released with restrictions to ensure the detectability of high elevated results.

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Actions to be taken by the customer/user

Customers using affected CA 19-9 lots on **cobas e 801** are advised to apply the restrictions (double determinations) described below.

Based on the complaints and our internal investigation, customers are advised to perform double determinations from the same tube for all results ≥ 37 U/ml CA 19-9 when using the reagent lots 504743, 525510, 568976, **598135, 598140 and 599263 (upcoming lots)** in order to allow the detection of possible non-reproducible elevated results (high flyers). Customers can still use the entire ePack and there is no need to restrict the number of determinations to the first 200.

All reagent lots CA 19-9 (11776193122) running on **cobas e 411 / e 601 / e 602** can be used without restrictions.

The contamination of 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.

Any specific questions raised by the users regarding review of results and possible re-testing should be addressed individually, considering all relevant clinical information.

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)

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).



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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.

Please complete and return the Customer Acknowledgement Receipt within 2 business days to acknowledge your reading and understanding of this notice.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Contact

If you have any questions, please do not hesitate to contact your sales representative or our Customer Call Centre: **1800 88 8881**

Thank you.

Best regards,

ROCHE DIAGNOSTICS (M) SDN. BHD.

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Customer Acknowledgement Receipt

Attention to: Centralized Point of Care & Customer Support Team

**Roche Diagnostics Malaysia Fax Back:
+603 7967 2399
Email: malaysia.diagnostics@roche.com**

Re: MY-FSN-CPS-2020-001 (version 9): Elecsys CA 19-9: non-reproducible elevated results with upcoming reagent lots 598135, 598140, 599263 on cobas e 801

I acknowledge I have received notification on MY-FSN-CPS-2020-001 (version 9): Elecsys CA 19-9: non-reproducible elevated results with upcoming reagent lots **598135, 598140, 599263** on cobas e 801 and will proceed to take the action suggested.

Name:
Organization:
Stamp:
Date: