Urgent Field Safety Notice

MY-FSN-RDS-CoreLab-2023-001

RDS/ CoreLab/ Immunology
Version 1
Jasmine Tiow
January 2023

Elecsys® Troponin T hs / Elecsys Troponin T hs STAT: discrepant elevated results with certain plasma EDTA primary tubes

Product Name	Elecsys Troponin T hs Elecsys Troponin T hs STAT
Device Identifier **GMMI / Part No / UDI**	Elecsys Troponin T hs (**cobas**® e 411, 601, 602; 200 tests) GMMI: 08469717190 UDI: 7613336001199X Elecsys Troponin T hs STAT (**cobas** e 411, 601, 602; 100 tests) GMMI: 08469814190 UDI: 7613336001209G Elecsys Troponin T hs (**cobas** e 402, 801, 300 tests) GMMI: 08469873190 UDI: 7613336001219J
Production Identifier **(Lot No./Serial No.)**	n/a
SW Version	n/a
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

During internal studies with the Elecsys Troponin T hs (high sensitive) / Elecsys Troponin T hs STAT assay, discrepant elevated assay results were observed for K_2 EDTA plasma samples. Further investigation confirmed that for certain K_2/K_3 EDTA primary tubes, TnT hs results are elevated compared to serum samples when measured from the primary tube after processing the sample according to the tube manufacturers' instructions. This observation was confirmed for tubes from several manufacturers.

The reproducibility of the falsely elevated results and the fact that not all investigated primary tubes show this phenomenon indicate that an interference mechanism caused by pre-analytical issues with the affected primary tubes is the likely root cause.

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In some cases, affected samples showed observable turbidity and a pellet fraction was visible after centrifugation of affected samples. In this regard, it is important to remind to the users the sample handling guidance given in the Elecsys Troponin T hs / STAT assay method sheet:

Specimen collection and preparation

Only the specimens listed below were tested and found acceptable.

Serum collected using standard sampling tubes or tubes containing separating gel.

K_2-EDTA, K_3-EDTA, Li-heparin and Na-heparin plasma.

Plasma tubes containing separating gel can be used.

Plasma (EDTA, heparin) and serum samples should not be used interchangeably.

Criterion: Slope 0.90-1.10 + coefficient of correlation ≥ 0.95.

Stable for 24 hours at 2-8 °C, 12 months at -20 °C (± 5 °C). Freeze only once.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

Do not use samples and controls stabilized with azide.

Ensure the samples, calibrators and controls are at 20-25 °C prior to measurement.

Due to possible evaporation effects, samples, calibrators and controls on the analyzers should be analyzed/measured within 2 hours.

Materials provided

Based on the current status of the investigation, no general assay and/or Elecsys technology related issue was identified. No related customer complaints were received.

The root cause investigation is still ongoing to identify the exact mechanism of interference. Current results indicate that pre-analytical aspects (e.g. presence of micro-clots) are contributing to the issue.

In this situation, incorrectly elevated TnT hs concentrations were observed with specific K_2-EDTA and K_3-EDTA primary tubes. This can affect interpretation of the results and influence decisions regarding diagnosis and treatment. Due to the residual medical risk, customers using affected products must be informed via FSN-RDS-CoreLab-2023-001.

Actions taken by Roche Diagnostics

Current observations will be shared with the manufacturers of the primary tubes. Root cause analysis will be continued to further gain understanding of the underlying interference mechanisms and if needed to define corrective and preventive measures.

Actions to be taken by customers/users

Customers using K_2/K_3 EDTA plasma for TnT hs quantification are required to (temporarily) perform the following additional pre-analytical measure:

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Re-centrifuge K_2/K_3 EDTA plasma samples in a secondary tube for 5 min at 3'000 x g or 30 sec at 10'000 x g prior to measurement.

This action is required until further notice.
This additional pre-analytical measure has been assessed by Roche internally and was proven effective with the samples tested.

Note: Any specific questions regarding impacted results raised by the customers should be investigated individually, considering all relevant information. Customers are advised to consult their facility's physician and/or pathologist to determine any clinical implications (including retrospective review and/or re-testing) specific to their patients.

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.

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-RDS-CoreLab-2023-001: Elecsys® Troponin T hs / Elecsys Troponin T hs STAT: discrepant elevated results with certain plasma EDTA primary tubes

I acknowledge I have received notification on MY-FSN-RDS-CoreLab-2023-001: Elecsys® Troponin T hs / Elecsys Troponin T hs STAT: discrepant elevated results with certain plasma EDTA primary tubes and will proceed to take the action suggested.

_____

Name:
Organization:
Stamp:
Date: