Urgent Field Safety Notice

SBN-RDS-CoreLab-2023-001

RDS/CoreLab/ Immunology
Version 2
February 2024

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 Elecsys Troponin T hs (**cobas** e 411, 601, 602; 200 tests) GMMI: 09315322190 UDI: 761333600917B3 Elecsys Troponin T hs STAT (**cobas** e 411, 601, 602; 100 tests) GMMI: 09315349190 UDI: 761333600918B5 Elecsys Troponin T hs (**cobas** e 402, 801; 300 tests) - GMMI: 09315357190 UDI: 761333600919B7
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 root cause investigation showed that the interfering agent is present in the pellet fraction after blood-to-plasma processing. Since the issue was not observed with all K3/K2 EDTA plasma primary tubes tested, it might be caused

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by micro clots (even such clots not visible with the naked eye) that seem to be predominantly present in specific primary tubes.

With this version 2 of this Field Safety Notice, we want to announce that the instructions for use (IFU) of Elecsys TnThs have been updated to add one additional centrifugation step for K2/K3 EDTA plasma samples to avoid any issue in the future. The updated IFUs will be released with this notification.
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.

Re-centrifuge K2/K3-EDTA plasma samples in a secondary tube for 5 minutes at 3000 x g or 30 seconds at 10000 x g prior to measurement.

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.

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.

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 version 2.

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Actions taken by Roche Diagnostics

As a corrective action, the additional centrifugation step was included into the Instructions for Use (see above) which will be released with this notification.

Actions to be taken by customers/users

Customers using K_2/K_3 EDTA plasma for TnT hs quantification are required to perform the following additional preanalytical measure:

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 and now part of the Instructions for Use.
This additional preanalytical 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.

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
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com

Roche Diagnostics GmbH (SRN DE-AR-000006262)