URGENT FIELD SAFETY NOTICE
IMMEDIATE ACTION REQUIRED

Ref No:	EFSN Elecsys® Troponin T hs/ Elecsys® Troponin T hs STAT SBN-RDS-CoreLab-2023-001
Date:	06/01/2023
Type of Action:	Field Safety Corrective Action (FSCA)

Product Affected:	Elecsys® Troponin T hs Elecsys® Troponin T hs STAT
System Affected:	cobas® e 411 cobas® e 601 cobas® e 602 cobas® e 801 cobas® e 402
Software Version:	N/A

Product Name	Material No	Lot No
Elecsys® Troponin T hs (cobas® e 411, 601, 602; 200 tests)	08469717190	All
Elecsys® Troponin T hs STAT (cobas® e 411, 601, 602; 100 tests)	08469814190	All
Elecsys® Troponin T hs (cobas® e 402, 801, 300 tests)	08469873190	All
Elecsys® Troponin T hs (cobas® e 411, 601, 602; 200 tests)	09315322190	All
Elecsys® Troponin T hs STAT (cobas® e 411, 601, 602; 100 tests)	09315349190	All
Elecsys® Troponin T hs (cobas® e 402, 801; 300 tests)	09315357190	All

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Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Registered No 571546

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Summary of Issue

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

Reason for Notice

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.

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

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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.

Action Required

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 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 until further notice.
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.

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URGENT FIELD SAFETY NOTICE
IMMEDIATE ACTION REQUIRED

Please complete and return the Acknowledgement Form which accompanies this Field Safety Notice by Monday 23rd January 2023.

Please bring this notice to the attention of all personnel in your hospital or Health Care facility who need to be aware of this safety issue.

If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this notice to them.

Attachments — EFSN Elecsys® Troponin T hs/ Elecsys® Troponin T hs STAT SBN-RDS-CoreLab-2023-001 Acknowledgement Form

This action is being conducted with the knowledge of the Medicines and Healthcare Products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

Roche Diagnostics operates a vigilance system that complies with UK MDR 2002, IVD Directive 98/79 EC, Regulation (EU) 2017/746

A copy of this notice can also be found on the Roche Dialog Portal

If you require any further information please contact our

Technical Support Hotline

UK: 0808 100 19 20
Ireland: 1800 40 95 64

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ACKNOWLEDGEMENT

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Date: 06/01/2023
Type of Action: Field Safety Corrective Action (FSCA)

Kindly complete and return this form to the e mail address shown on the footer before Monday 23rd January 2023.

Product Catalogue No:

System:

Customer Name & Dept:

Address:

Are the above contact details correct? *(Please circle)* Yes No *(If no please insert correct details below)*

Contact Name:

Department:

Telephone:

If you require an electronic copy of this field safety notice in addition to the hard copy please print your e-mail address below:

Email:

Please acknowledge receipt of information and awareness of any required actions described within the accompanying Field Safety Notice.

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email to burgesshill.techsupportdocs@roche.com

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I acknowledge receipt of this Field Safety Notice and have read, understood and implemented its content.

Name:

Signed:

Date:

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