



URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Ref No: EFSN Elecsys Troponin T hs SBN-CPS-2019-022
Date: 31/10/19
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

Software Version: N/A

Product No	Material No	Lot No
Elecsys Troponin T hs (cobas e 801, 300 tests)	08469873190	419260, 436777
Elecsys Troponin T hs (cobas e 411/601/602, 200 tests)	08469717190	419250
Elecsys Troponin T hs STAT (cobas e 411/601/602, 100 tests)	08469814190	419254

Summary of Issue

Elecsys Troponin T hs: non reproducible elevated results with certain lots

Reason for Notice

Dear Valued Customer,

Description of Situation

Recently, we have observed an increase in complaints concerning non-reproducible elevated results (so called “Highflyers”) for Elecsys Troponin T hs with increased biotin tolerance on **cobas e** 801.

The issue appears as follows:

Either result (in the majority of cases it is the 1st result) of multiple results is discrepant-high compared to the other results of the same sample aliquot.

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The issue has been observed with both plasma and serum samples. So far, the increased frequency of non-reproducible elevated results has only been reported for the lot 419260 (2nd production lot of Elecsys Troponin T hs with increased biotin tolerance).

No significant increase has been reported in respect to:

- the previous lot 396685 (1st production lot of Elecsys Troponin T hs with increased biotin tolerance).
- the Troponin T hs lot number 436777 (3rd production lot of Elecsys Troponin T hs with increased biotin tolerance) run on **cobas e 801**.
- Troponin T hs and Troponin T hs **STAT** with increased biotin tolerance run on **cobas e 411**, **cobas e 601** and **cobas e 602** (respectively lots 419250 and 419254 / 2nd production lot).

The afore mentioned is currently subject of ongoing investigation and additional data is needed. The issue can lead to non-reproducible elevated Troponin T hs results and therefore affect clinical interpretation.

Due to the residual medical risk associated with this issue, customers must be informed using this FSN.

Actions to be taken by Roche Diagnostics

Further investigations are currently ongoing to understand the underlying root cause of the issue. Elecsys Troponin T hs lot **419260** has been blocked globally.

Action Required

Actions to be taken by the customer/user

For Troponin T hs lot **419260** run on **cobas e 801**:

Customers are advised to **stop using this lot (419260) and discard it locally**.

For Troponin T hs (08469717 190) and Troponin T hs STAT (08469814 190) using lots **419250** and **419254** (2nd production lot) run on **cobas e 411**, **cobas e 601**, **cobas e 602** and for Troponin T hs lot **436777** run on **cobas e 801**:

Although we have currently no indications based on customer complaints, we cannot entirely rule out that those reagent lots are affected.

In order to increase the detectability of possible non-reproducible elevated results (highflyers) and to facilitate the root cause investigation by increasing data volume, customers are advised to perform double determinations from the same tube until further notice.

If discrepant results are observed within a repetition, check the sample quality and if necessary re-centrifuge samples before a third measurement and contact your local point of contact at Roche Diagnostics to report the discrepant result.

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As an alternative, customers may use Troponin T hs (product number 07028075 190) on **cobas e 801**, Troponin T hs (product number 05092744 190) on **cobas e 411**, **cobas e 601** and **cobas e 602**, or Troponin T hs STAT (product number 05092728 190) on **cobas e 411**, **cobas e 601** and **cobas e 602**.

Taking into account the typical indications for the determination of cardiac troponins and the half-life, and kinetic of Troponin, no specific recommendations with respect to timelines of patient review and follow up are given. Any specific questions raised by the users should be addressed individually, considering all relevant clinical information.

General reminder:

Pre-analytical handling is crucial for a correct performance of all assays. This includes compliance to the individual specifications of the primary tube manufacturers for all tubes in use (in particular, the centrifugation conditions are important and the elimination of foam, and for serum, sufficient clotting time are important).

Please complete and return the **Acknowledgement Form** which accompanies this **Field Safety Notice** by **14th November 2019**.

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 SBN-CPS-2019-022 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 the IVD Directive 98/79 EC

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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