

Urgent Field Safety Notice



SBN-CPS-2019-022

CPS / Immunology

Version 1

October 2019

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

Product Name	Elecsys Troponin T hs, Elecsys Troponin T hs STAT
System	cobas e 801 / 601 / 602/ 411
GMMI / Part No	Elecsys Troponin T hs (cobas e 801, 300 tests) - 08469873 190
Device Identifier	Elecsys Troponin T hs (cobas e 411, cobas e 601, cobas e 602, 200 tests) - 08469717 190 Elecsys Troponin T hs STAT (cobas e 411, cobas e 601, cobas e 602, 100 tests) - 08469814 190
Production Identifier (Product name/Product code)	08469873 190: 419260, 436777 08469717 190: 419250 08469814 190: 419254
SW Version	n/a
Type of Action	Field Safety Corrective Action

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.

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).

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



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.

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.

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).

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).

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



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.

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