

Urgent Field Safety Notice



SBN-CPS-2019-022

CPS / Immunology

Version 2

November 2019

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

Product Name	Elecsys Troponin T hs
System	cobas e 801
GMMI / Part No	Elecsys Troponin T hs (cobas e 801, 300 tests) - 08469873 190
Device Identifier	Elecsys Troponin T hs (cobas e 801, 300 tests) - 07028075 190
Production Identifier (Product name/Product code)	08469873 190: 419260, 436777 07028075 190: 429178
SW Version	n/a
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

Description of Situation

In the version 1 of this SBN, we informed about an increase in complaints concerning non-reproducible elevated results (so called "Highflyers") for Elecsys Troponin T hs lot 419260 on **cobas e 801**.

The issue appears as follows:

Either result of multiple determinations is non-reproducible elevated compared to the other results of the same sample aliquot.

The issue has been observed with both plasma and serum samples.

As described in the version 1 of the SBN-CPS-2019-022, increase in complaints has been initially observed only for the lot 419260 of Elecsys Troponin T hs (08569873 190). Additional investigation and customer complaints, however, revealed that also Elecsys Troponin T hs (08569873 190) lot number 436777 and Elecsys Troponin T hs (07028075 190) lot 429178 are affected by the issue.

Meanwhile, it was confirmed that Troponin T hs (08469717 190 and 05092744 190) and Troponin T hs STAT (08469814 190 and 05092728190) running on **cobas e 411/601/602** do not show an increased rate of non-reproducible elevated results and can be considered not impacted by the issue.

The issue can lead to non-reproducible elevated Troponin T hs results and therefore affect clinical interpretation.

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



Due to the residual medical risk associated with this issue, customers must be informed using the **FSN-CPS-2019-022 version 2**.

Actions to be taken by Roche Diagnostics

Further investigations are currently ongoing to understand the underlying root cause of the issue.

Based on the current status of investigation, the advice to the customers will be updated and Elecsys Troponin T hs lot 419260 can be used again upon publication of the SBN-CPS-2019-022 version 2 if not yet discarded based on the advice provided in the SBN-CPS-022 version 1.

Actions to be taken by the customer/user

Troponin T hs (08469717 190 and 05092744 190) and Troponin T hs STAT (08469814 190 and 05092728190) running on **cobas e** 411/601/602 can be used without restrictions. As a result, double determinations per sample are not necessary.

Elecsys Troponin T hs (08469873 190) lots 419260 and 436777 and Elecsys Troponin T hs (07028075 190) lots 429178 running on **cobas e** 801 are affected. Please note that lot 419260 can be used again if not yet being discarded based on the advice in the version 1 of this SBN-CPS-2019-022.

Wherever possible, customers are asked to switch Elecsys Troponin T-hs from **cobas e** 801 to **cobas e** 411/ 601/602. In case this is not possible, customers using **cobas e** 801 are advised to perform the following actions for the affected lots:

1. In order to reduce the frequency of non-reproducible elevated results, please ensure not to invert or shake the ePacks prior to loading to the analyzer and discard each ePack of the affected lots after the first 200 determinations (for technical details, refer to Q&A).
2. Perform double determinations from the same tube for all results $\geq 14\text{ng/L}$ in order to increase the detectability of possible non-reproducible elevated results (highflyers)*.
3. Customers using algorithms for accelerated rule-in and rule-out decisions (e.g. the 0h/1h algorithm according to the 2015 ESC NSTEMI Guideline) are advised to perform double determinations for all results*.

*Important: Delays due to double determination can be reduced to a very minimum when ordering the two Troponin T hs applications (TnT hs ACN 10011 and TnT hs STAT ACN 10012) on **cobas e** 801 for two simultaneous measurements per sample.

This advice is valid until further notice.

For better overview of current reagents lots, please see table 1.

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 timeline 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).

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Table 1

Overview of reagent lots:

Product number	Description	Instrument	Lot numbers	Recommendation	
Elecsys Troponin T hs with increased biotin tolerance					
08469873 190	Troponin T hs - 300 tests	cobas e 801	396685 (1 st lot production)	Use as usual	
			419260 (2 nd lot production)		Use double measurement for values ≥ 14 ng/L & only the first 200 determinations ¹
			436777 (3 rd lot production)		
08469717 190	Troponin T hs - 200 tests	cobas e 411/ 601/ 602	396736 (1 st lot production)	Use as usual	
			419250 (2 nd lot production)		
			436909 (3 rd lot production)		
08469814 190	Troponin T hs STAT - 200 tests	cobas e 411/ 601/ 602	396678 (1 st lot production)	Use as usual	
			419254 (2 nd lot production)		
			436773 (3 rd lot production)		
Elecsys Troponin T hs					
07028075 190	Troponin T hs - 300 tests	cobas e 801	345850 & 370695	Use as usual	
			429178		Use double measurement for values ≥ 14 ng/L & only the first 200 determinations ¹
05092744 190	Troponin T hs STAT-200 tests	cobas e 411/ 601/ 602	429066 & 381547 & 345852	Use as usual	

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



05092728 190	Troponin T hs STAT- 100 tests	cobas e 411/ 601/ 602	416797 & 381539 & 345888	Use as usual
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1. Customer using algorithms for accelerating rule-in & rule-out approach (0/1-h algorithm of the ESC 2015 guidelines for NSTEMI) are advised to perform double determinations regardless of the initial results

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.

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