

Urgent Field Safety Notice

SBN-RDS-CoreLab-2021-002



RDS/Core Lab / Immunology
Version1
March 2021

Elecsys[®] Troponin I / Troponin I STAT: interaction with Elecsys[®] proBNP II / proBNP II STAT

Product Name	Elecsys Troponin I / Troponin I STAT Elecsys proBNP II / proBNP II STAT	
System	cobas e 601 / cobas e 602	
GMMI / Part No	Elecsys Troponin I STAT	05094798-160/ -190
Device Identifier	Elecsys Troponin I	05094810-160/ -190
	Elecsys proBNP II	04842464-160/-190
	Elecsys proBNP II STAT	05390109-160/-190
	Elecsys proBNP II STAT	08836744-190
	Elecsys proBNP II	08836736-190
	Elecsys proBNP II	09315268-190
	Elecsys proBNP II STAT	09315276-190
Production Identifier (Product name/Product code)	Lot independent	
SW Version	n/a	
Type of Action	Field Safety Corrective Action	

Dear Valued Customer,

Description of Situation

Recently, a customer complaint was received regarding a failed external quality survey (using native sample material) for Elecsys Troponin I, when Elecsys proBNP II was measured directly before Elecsys Troponin I assay from the same sample on the same module.

The decreased recovery of Elecsys Troponin I was confirmed internally with native sample on **cobas e 601/ e 602**. Other platforms are not affected. No further complaints were received, no allegation of an adverse event was made.

This interaction has been observed on **cobas e 60x**. Both modules, **cobas e 601** module in **cobas 6000** analyzer series and **cobas e 602** module in **cobas 8000** analyzer series, have identical hardware and the same pipetting steps. Therefore, both modules are affected. The **cobas e 411** analyzer and **cobas e 801** modules are not affected.

We can confirm there is no performance change to the Elecsys proBNP II assays.

Also, so far no other Elecsys assay besides Elecsys Troponin I assay is considered to be affected by this interaction. Due to the residual medical risk related to the issue, customers must be informed via FSN-RDS-CoreLab-2021-002.

Elecsys[®] Troponin I / Troponin I STAT: interaction

with Elecsys[®] proBNP II / proBNP II STAT

Actions to be taken by Roche Diagnostics

As a mitigation measure, the assay combination Elecsys proBNP II / proBNP II STAT and Elecsys Troponin I /Troponin I STAT will be added to the Special Wash List. Instructions for Use will be updated as follows:

Current Instructions for Use versions Elecsys Troponin I and Troponin I STAT:

05094810-190, Elecsys Troponin I, v10.0
 05094810-160, Elecsys Troponin I, v8.0
 05094798-190, Elecsys Troponin I STAT, v9.0
 05094798-160, Elecsys Troponin I STAT, v8.0

The following section was added to the Elecsys Troponin I /Troponin I STAT Instructions for Use:

cobas e 601 and **cobas e 602** modules

Note: Only required if the Elecsys Troponin I/ Troponin I STAT assay runs on the same analyzer module as the Elecsys proBNP II/ proBNP II STAT assay.

Make sure that in the Special Wash List (Screen → Utility → Special Wash → Immune) it is set as described below.

This additional wash has no effect on the instrument throughput.

From test	Step	To test	Step 0	Step 1	Step 2
Elecsys proBNP II	1	all items	x	x	x
Elecsys proBNP II STAT	1	all items	x	x	x

The described additions to the Special Wash List have to be entered manually. Please refer to the operator's manual.

Current Instructions for Use versions Elecsys proBNP II and proBNP II STAT:

04842464-190, Elecsys proBNP II, v14.0
 04842464-160, Elecsys proBNP II, v11.0
 08836736-190, Elecsys proBNP II, v2.0
 05390109-190, Elecsys proBNP II STAT, v11.0
 05390109-160, Elecsys proBNP II STAT, v9.0
 08836744-190, Elecsys proBNP II STAT, v2.0

Elecsys proBNP II /proBNP II STAT products will be launched soon:

Elecsys[®] Troponin I / Troponin I STAT: interaction

with Elecsys[®] proBNP II / proBNP II STAT

09315268-190, Elecsys proBNP II, v1.0
 09315276-190, Elecsys proBNP II STAT, v1.0

The following section was added to the Elecsys proBNP II / proBNP II STAT Instructions for Use:

cobas e 601 and **cobas e 602** modules:

Note: Only required if the Elecsys proBNP II / proBNP II STAT assay runs on the same analyzer module as the Elecsys Troponin I / Troponin I STAT assay.

Make sure that in the Special Wash List (Screen → Utility → Special Wash → Immune) the Elecsys proBNP II / proBNP II STAT assay is combined with all assays performed on the analyzer.

This additional wash has no effect on the instrument throughput.

From test	Step	To test	Step 0	Step 1	Step 2
Elecsys proBNP II / proBNP II STAT	1	all items	x	x	x

The described additions to the Special Wash List have to be entered manually. Please refer to the operator's manual.

Current Instruction for Use version ProbeWash M:

03005712190, ProbeWash M, for USA: Elecsys ProbeWash M, v20.0

The following section was added to the ProbeWash M Instruction for Use:

From test	Step	To test	Step 0	Step 1	Step 2
proBNP II	1	all items	x	x	x
proBNP II STAT	1	all items	x	x	x

Updated Instructions for Use are expected to be available in Q4 2021.

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Actions to be taken by the customer/user

Customers are advised to manually define and activate the additional wash step, as described in the Instruction attached to the FSN-RDS-CoreLab-2021-002. This step will not affect the throughput of the instruments. Once available, customers are advised to consider the updated Instructions for use.

Furthermore, customers are advised to exchange ProbeWash M bottles regularly and not later than after 4 weeks open use on board the analyzers, please refer to the instructions for use

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