

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:

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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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with Elecsys[®] proBNP II / proBNP II STAT

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

Instruction to manually update Special wash settings in case Elecsys® proBNP II and Elecsys® Troponin I are measured on the same cobas e 601 and / or cobas e 602 module:

cobas e 601 and cobas e 602 modules:

Note: Only required if the Elecsys proBNP II (REF 04842464 160, 04842464 190; 08836736 190; 09315268 190;) and/or Elecsys proBNP II STAT assay (REF 05390109 160, 05390109 190; 08836744 190; 09315276 190) runs on the same analyzer module as the Elecsys Troponin I (REF 05094810 190, 05094810 160) or Elecsys Troponin I STAT assay (REF 05094798 190, 05094798 160)

Make sure that in the Special Wash List (Screen → Utility → Special Wash → Immune) Elecsys proBNP II and Elecsys proBNP II STAT are available, as described below.

| 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 Special Wash List in the method sheet of ProbeWash M (REF 03005712190) will be updated accordingly.

The described additions to the Special Wash List must be entered manually on **cobas e 601** and **cobas e 602** modules. Please refer to the operator's manual.

cobas e 601 module:

On the **cobas e 601** module the Special Wash List needs to be updated manually.

For this please go to Screen → Utility → Special Wash → Immune and perform the following steps:

1. Select an empty line in the **Reagent Probe** list and click on the **Edit** button on the left.
2. Select the short name of Elecsys proBNP II (*PRO-BNP, PBNP, PBNPX*) or of Elecsys proBNP II STAT assay (*PROBNPST, PBNPST, PBNPSTX*) from the **From Reagent** dropdown menu.
3. Select 1 from the **Step** dropdown menu.
4. Select all items from the **To reagent** dropdown menu
5. Check all checkboxes for the Steps and click on the yellow **OK** button.
6. The new wash rule is now active.

Detailed description including Screenshots can be found in the **cobas 6000** analyzer series operator's manual in chapter "Configuration".

cobas e 602 module:

On the **cobas e 602** module the Special Wash List has to be downloaded. This new entry needs to be entered as an interim solution manually.

For this please go to Screen → Utility → Special Wash → Reagent Probe and perform the following steps:

1. From the **Module Type** drop-down list, choose the e 602 module.
2. Select an empty line from the **User Rule** list and click on the **Edit** button on the left.
3. Within the **From Reagent** column select the short name of Elecsys® proBNP II (*PRO-BNP, PBNP, PBNPX*) or of Elecsys® proBNP II STAT assay (*PROBNPST, PBNPST, PBNPSTX*) from the from the **Test** drop-down list.
4. Select 1 from the **Step** dropdown menu.
5. Select all items from the **To Reagent** dropdown menu.
6. Check all checkboxes for the Steps and click on the yellow **OK** button.
7. The new wash rule is now active.

Detailed description including Screenshots can be found in the **cobas 8000** modular analyzer series operator's manual in chapter "Configuration".

Further Information

The additions to the Special Wash List can only be done with "Admin" level.

Please note that about 350 tests with washes can be performed from one ProbeWash M bottle. As two (2) bottles can be placed on the instrument, approximately 700 ProbeWash M steps can be carried out. Please be aware that it is not possible to exchange the ProbeWash M bottles during an active run, and that other assay combinations run on the same instruments might require Special Wash steps.

This step will not affect the throughput of the instruments.