Urgent Field Safety Notice

SBN-RDS-CoreLab-2022-004

RDS/CoreLab/ SWA Systems
Version 3
February 2023

PreWash failure after Preparation in Quick Start mode on cobas® e 801 and e 402

Product Name	**cobas pure e** 402 analytical unit **cobas e** 801 analytical unit **cobas pure** sample supply unit **cobas pro** sample supply unit **cobas pro** SSU **cobas** 8000 core unit	
GMMI / Part No Device Identifier	09031553001 08454345001 07682913001 09031537001 08464502001 09205632001 05641446001	**cobas pure e** 402 analytical unit **cobas e** 801 analytical unit **cobas e** 801 module **cobas pure** sample supply unit **cobas pro** sample supply unit **cobas pro** SSU **cobas** 8000 core unit
Production Identifier (Lot No./Serial No.)	n/a	
SW Version	**cobas pure** system SW 01-03 (09458115001) Modification code S_N32022/102Q SW Update version 01-03 **cobas pro** INSTALL SW V 02-03 (09400915001) Depending on the sample supply unit variant: Modification code S_S22022/093Q pro_SW_02-03 Modification code S_ZB2022/093Q pro_SW_02-03 SW Install CD c8000 V 06-10 (09976418001) Modification code S_AG2023/012Q Install CU 06-10	
Type of Action	Field Safety Corrective Action (FSCA)	

Dear Valued Customer,

Description of Situation

With version 3 of this FSN we want to inform you about an upcoming release of SW 06-10. Reason for this update are some issues which appeared when updating to SW 06-09 on certain installations.
cobas 8000 SW 06-10 is planned to be available by May 2023, to be installed together with data manager software version 1.06.10 (available since October 2022)

PreWash failure after Preparation in Quick Start mode on cobas® e 801 and e 402

As described in the former versions of this notification, we were informed by the manufacturer Hitachi High-Tech Corporation (HHT) about an internally detected operational software issue affecting **cobas pure e** 402 and **cobas pro/cobas 8000 e** 801 analytical units. With Quick Start Mode active, the issue may occur when "Rinse Pre-wash Sipper Flow Path" or "Wash Sippers Flow Path"option "Pre-Wash" is performed and the system starts afterwards. It may also occur when "Finalization", "System Wash" or "Wash Sippers Flow Paths" option "All" is performed, and the "Prime System Reagents Flow Path" option "Reagent Probe" is executed later and the system starts afterwards. This may lead to a Pre-Wash assay being washed with PreClean II M diluted with system water at run start and to potentially affected results of some Pre-Wash assays.

In summary, the chain of events causing the failure is very complex and diverse and several steps must be cumulatively present. For example, other maintenance functions (e.g. "Finalization") or actions (e.g. opening of the front cover) performed between the critical maintenance procedures mentioned above and the run start prevent this failure from occurring.

(The maintenance names mentioned here are from **cobas pro**, they can be different on different systems.)

No related customer complaints were received. The root cause is a software issue. Relevant maintenance functions were not considered during specification or inaccurately implemented for the Quick Start Mode.

The observed issue, under specific instrument conditions and sequence of laboratory actions, may lead to incorrect test results in diagnostic disease areas including cardiac, infectious diseases and endocrinology. The performance impact on patient test results was evaluated systematically using 100% water instead of PreClean II M for the Pre-Wash step of the testing procedure (mimicking the most stringent impact of the observed issue). The following assays are considered impacted by the issue: Anti-HAV 2, Anti-HBc IgM, IGF-1, PTH 1-84, Myoglobin, Rubella IgG, pTau, total P1NP, Toxo IgG Avidity, Toxo IgG and tTau. The analytical deviation in test results is largely unpredictable. The medical risk attributable to incorrect test results depends largely on the constellation of diagnostic and clinical parameters such as the degree of analytical variation of affected results, detectability by technical indices, detectability due to clinical implausibility, additional diagnostic testing results and congruence of the overall clinical picture. Together, in specific clinical scenarios, it is possible that clinical care could be influenced by incorrect test results, potentially causing adverse health consequences for patients, and therefore a medical risk cannot be excluded.

Actions taken by Roche Diagnostics

- **cobas pro** SW 02-03 and **cobas pure** SW 01-03 were both released in September 2022.
- **cobas 8000** SW 06-09 & data manager (SW 06-09 & 1.06.10) are available since October 2022.
- The new software for **cobas 8000** & data manager (SW 06-10 & 1.06.10) is planned to be available May 2023. A separate communication will be sent out to announce the availability of the corrected SW versions.

Actions to be taken by customers/users

As a short-term solution to mitigate the medical risk customers are advised to immediately implement one of the following workarounds:

1. Deactivate Quick Start Mode.

OR

2. With activated Quick Start Mode, additional maintenance functions have to be performed:

2.1 **cobas 8000 (e 801)**
If one of the following maintenance functions was performed,

- Pre-wash Sipper Rinse
- Liquid Flow Cleaning (options: PreWash and All)
- Finalization
- System Wash

one cycle of the maintenance function [37*] System Prime (**e** 602/**e** 801) is required prior to starting a run.

2.2 **cobas pro (e 801)**
If one of the following maintenance functions was performed,

- Rinse Pre-wash Sipper Flow Path
- Wash Sippers Flow Paths (options: Pre-Wash and All)
- Finalization
- System Wash

one cycle of the maintenance function [37*] Prime System Reagent Flow Paths (**e** 801) is required prior to starting a run.

2.3 **cobas pure (e 402)**
If one of the following maintenance functions was performed,

- Rinse Pre-wash Sipper Flow Path
- Wash Sippers Flow Paths (options: Pre-Wash and All))
- Finalization
- System Wash

two cycles of the maintenance function [6*] Reagent Flow Path Prime selecting the option „All“ are required prior to starting a run.

(refer to the Instructions attached to the FSN-RDS-CoreLab-2022-004)*

Detailed instructions are attached to the FSN version 1(Attachment 1).

This action is required until further notice.
Customers will be required to upgrade to the latest software version once available. This can be done remotely (**cobas pure/pro**) or during service visit (**cobas** 8000).

Note: Any specific questions regarding impacted results raised by the customers should be investigated individually, considering all relevant information. Customers are advised to consult their facility's physician and/or pathologist to determine any clinical implications (including retrospective review and/or re-testing) specific to their patients.

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

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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