Urgent Field Safety Notice

SBN-RDS-CoreLab-2021-006

RDS/Core Lab / Urinalysis
Version 2
June 2021

cobas® 6500 and u 701 standalone: possible sample mismatch software 2.2.0 – 2.2.9 and 2.3.0 – 2.3.6

Product Name	**cobas** 6500 urine analyzer series **cobas u** 701 microscopy analyzer **cobas u** 601 urine analyzer
System	**cobas** 6500 urine analyzer series (**cobas** u 701 microscopy analyzer in combination with **cobas** u 601 urine analyzer) **cobas u** 701 microscopy analyzer standalone
GMMI / Part No **Device Identifier**	**cobas u** 701 microscopy analyzer - 06390501 001 **cobas u** 601 urine analyzer - 06390498 001
Production Identifier (Product name/Product code)	Lot independent
SW Version	Software 2.2.0 – 2.2.9 (CU v1 Control Units with OS WinPOSReady2009) Software 2.3.0 – 2.3.6 (CU v2 Control Units, Win10)
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

Description of Situation

As communicated in version 1 of this Field Safety Notice, Roche had rreceived **one complaint** regarding a possible sample mismatch on the **cobas** 6500 urine analyzer series with software version 2.3.6. The mismatch was detected by the customer during manual validation of microscopy results. A number of samples were affected and reported to the treating physicians. No allegation of an adverse event was made. Results generated on **cobas u** 601 are not impacted. The issue was investigated and confirmed.

Investigation revealed that the mismatch is caused by a software limitation. A similar issue was reported recently. It was caused by the same software limitation, however in the first case, user error triggered the mismatch. The solution (software version 2.3.7 and 2.2.10) is available as a mandatory update from January 2021.

Further investigations revealed that additionally the issue might occur under rare conditions also in **cobas u** 701 microscopy analyzer as a standalone analyzer.

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Affected systems

- **cobas** 6500 urine analyzer series with software version 2.2.0 - 2.2.9 and 2.3.0-2.3.6
- **cobas u** 701 microscopy analyzer standalone with software version 2.2.0 - 2.2.9 and 2.3.0 - 2.3.6

Not affected systems:

- **cobas** 6500 urine analyzer series with software version 2.3.7 and 2.2.10
- **cobas u** 701 microscopy analyzer standalone with software version 2.3.7 and 2.2.10
- **cobas u** 601 urine analyzer

This issue can lead to a sample mismatch and therefore may affect interpretation of results.
Due to the residual medical risk associated with this issue, customers must be informed using the FSN-RDS-CoreLab-2021-006 version 2.

Actions to be taken by Roche Diagnostics

The issue was fixed in the SW version 2.3.7 and 2.2.10, available as a mandatory update.

Actions to be taken by the customer/user

As an immediate workaround, affected customers are advised to perform following:

If the analyzer is stopped because the cuvette container is empty (error 71321, Cuvette cassette error) or the cuvette waste box is full (error 70401, Solid waste container error) please perform all three steps in the described order:

1. use wizard to solve supply error
2. wait until analyzer is in “idle” status, then initialize the **u** 701. The **u** 701 only initialization can be started from Monitoring -> Analyzer -> **u** 701 page. *
3. wait until analyzer is again in “idle” status, then continue the measurement process by clicking “start” or putting a rack on the input buffer priority position.

* This will lead to warning 71634, Sample order errors. Please act as described in the warning message. The **cobas u** 601 initialization is not necessary.

This advice is valid as long as the **cobas** 6500 urine analyzer series or **cobas u** 701 microscopy analyzer standalone with software versions 2.2.0 - 2.2.9 and 2.3.0 - 2.3.6 is in 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.

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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