Urgent Field Safety Notice

FSN-CPS-2020-003

CPS / Urinalysis

Version 1

April 2020

cobas 6500: possible sample mismatch software 2.2.0 – 2.2.8

Product Name	**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)
GMMI / Part No **Device Identifier**	06390501 001 (**cobas u** 701 microscopy analyzer) 06390498 001 (**cobas u** 601 urine analyzer)
Production Identifier (Product name/Product code)	n/a
SW Version	Software 2.2.0 – 2.2.8
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

Description of Situation

Roche has received **one complaint** regarding a possible sample mismatch on the **cobas**® 6500 urine analyzer series with software version 2.2.7 (Windows Embedded POSReady 2009). The mismatch was detected by the customer due to discrepant results between the **cobas u** 601 urine analyzer and **cobas u** 701 microscopy analyzer for the same sample. In this case, there was no reported adverse impact to the patient.

The issue was investigated and confirmed.

The issue appears as follows:

A mismatch of results of **cobas u** 601 urine analyzer and **cobas u** 701 microscopy analyzer for the same sample was observed after a cuvette solid waste container-full error message 70401 came up on the user interface of the **cobas**® 6500 urine analyzer series.

Although only one complaint case since 2014 has been reported to Roche, the issue can theoretically lead to wrong assignments of results and therefore may affect clinical interpretation.

Affected systems

- **cobas**® 6500 urine analyzer series with software version 2.2.0 - 2.2.8 (Windows Embedded POSReady 2009)

cobas 6500: possible sample mismatch software 2.2.0 – 2.2.8

Not affected systems

- **cobas®** 6500 urine analyzer series with software version 2.3.x (Windows 10 IoT Enterprise 2016 LTSB)
- Standalone **cobas u** 601 urine analyzer
- Standalone **cobas u** 701 microscopy 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 attached to the SBN-CPS-2020-003.

Actions to be taken by Roche Diagnostics

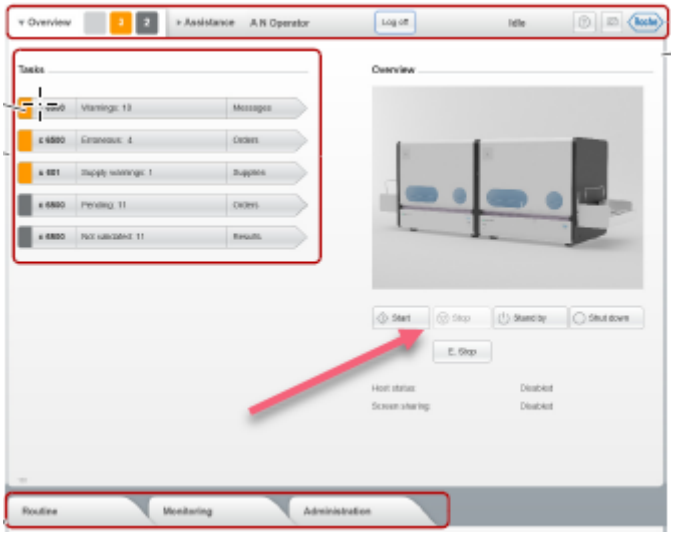
The following corrective actions have been initiated:

- development, verification, distribution and implementation of a corrected software version 2.2.9 (Windows Embedded POSReady 2009) for **cobas**® 6500 urine analyzer series, expected to be available by end Q2 2020.
- increase availability of **cobas**® 6500 urine analyzer series with software version 2.3.x (Windows 10 IoT Enterprise 2016 LTSB) including hardware.
- optional upgrade to **cobas**® 6500 urine analyzer series with software version 2.3.x (Windows 10 IoT Enterprise 2016 LTSB) including hardware.

Actions to be taken by the customer/user

Affected customers:

- shall empty the cuvette solid waste container every time a new cuvette cassette gets loaded onto the **cobas u** 701 microscopy analyzer.
- shall **not** use the *stop* button on the user interface of the **cobas**® 6500 urine analyzer series.



This advice is valid as long as the **cobas**® 6500 urine analyzer series with software versions 2.2.0 - 2.2.8 is in use. The issue will be resolved with the update to software version 2.2.9 or with the update of the **cobas**® 6500 urine analyzer series with software version 2.3.x (Windows 10 IoT Enterprise 2016 LTSB) together with new hardware.

cobas 6500: possible sample mismatch software 2.2.0 – 2.2.8

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