

Urgent Field Safety Notice

SBN-CPS-2017-026

CPS / Urinalysis
Version 1
21-Dec-2017

cobas u 601 / cobas u 701: Possible sample mismatch within a rack

Product Name / GMMI	cobas u 601 urine analyzer	06390498001
	cobas u 701 microscopy analyzer	06390501001
Production Identifier (Lot No./Serial No.)	n.a.	
Type of Action	Field Safety Corrective Action (FSCA)	

Dear Valued Customer,

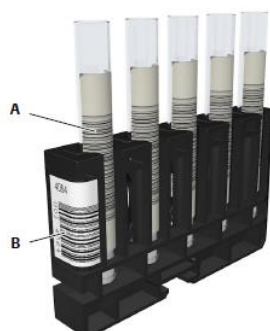
Description of Situation

With this Notification we would like to inform you about the possible sample mismatch within one rack. The analyzer may not transport the rack correctly, so that tubes might be detected twice. As a consequence, the same tube barcode label is read twice and the last tube barcode label is interpreted as the Rack ID. Hence, a sample mismatch is possible between samples processed on the same rack, because the tubes are pipetted in the order given by the rack position and the test result assigned to the wrong sample ID.

The sample ID read twice is thus listed in duplicate in the sample order list and test result list. The orders/test results have different Rack IDs. The consecutive sample ID's are also affected, since they are listed only once. As a consequence, they have an incorrect rack position displayed.

The issue can lead to sample ID mismatch. All tests that are run on the affected analyzers are potentially affected and the extent of the bias cannot be predicted. Both erroneous increased/positive and decreased/negative results are possible. Considering unreliable detectability of the issue, a relevant medical risk cannot be entirely excluded.

A Sample barcode with sample ID



B Rack barcode with Rack ID

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Impact of different configurations:

The issue can only occur when using tubes labeled with barcodes.

The **cobas** 6500 analyzer series (**cobas u 601** urine analyzer connected with **cobas u 701** microscopy analyzer) and **cobas u 601** urine analyzer or **cobas u 701** microscopy analyzer in stand-alone mode can be affected.

Actions taken by Roche Diagnostics

The issue is being addressed by proactive check of the sensor adjustment and proper functioning of affected instruments in the field. The system software will be modified to ensure automatic detection of the issue. Release is planned for Q2/2018.

Actions to be taken by the customer / user

We kindly ask you to perform the below described procedure in order to verify the systems proper function.

Checks to be performed by operator

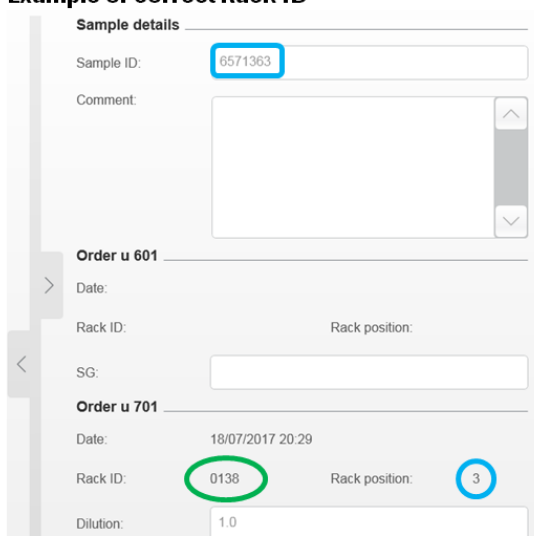
Please verify in the detail panel of the result details screen, if the displayed Sample ID, Rack ID, and Rack position corresponds to the Sample ID, Rack ID, and Rack position the tube is physically placed on. Therefore:

1. Choose Routine > Manage test results
2. In the main panel, choose the entry of a sample
3. In the detail panel, choose the sample button at the top of the panel.

If the displayed Sample ID, Rack ID, and Rack position is not consistent with the physical condition, the test result must not be used and the sample has to be rerun. If the issue occurs contact Technical Support.

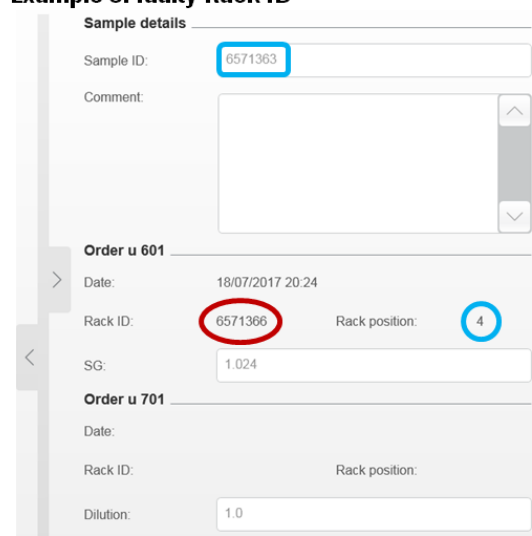
Note: A typical rack ID consists of four digits.

Example of correct Rack ID



The screenshot shows the 'Sample details' panel for a sample with ID 6571363. Below this, there are two order sections: 'Order u 601' and 'Order u 701'. In the 'Order u 701' section, the 'Rack ID' is 0138 (circled in green) and the 'Rack position' is 3 (circled in blue). The 'Date' is 18/07/2017 20:29 and 'Dilution' is 1.0.

Example of faulty Rack ID



The screenshot shows the 'Sample details' panel for a sample with ID 6571363. Below this, there are two order sections: 'Order u 601' and 'Order u 701'. In the 'Order u 601' section, the 'Rack ID' is 6571366 (circled in red) and the 'Rack position' is 4 (circled in blue). The 'Date' is 18/07/2017 20:24 and 'SG' is 1.024. In the 'Order u 701' section, the 'Rack ID' and 'Rack position' fields are empty. The 'Date' is empty and 'Dilution' is 1.0.

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To check analyzer's operation:

Note: This test has to be performed **with barcode labels** on sample tubes, even if in normal routine no barcode labels are used for sample identification.

1. Prepare 15 tubes labeled with barcodes and filled with tap water.
2. Place the tubes on 3 grey racks and put them on a rack tray.
3. Place the rack tray on the input buffer.
→ Measurement starts automatically.
4. Check after the measurements that
 - a. for all tubes sufficient results are generated and correctly displayed.
 - b. Sample ID (tube barcode), Rack ID, and Rack position are correctly displayed according to the set-up on the 3 racks, especially double check the Rack ID.
 - c. no Sample ID (result) is missing, displayed twice, or pending in order list.
 - d. no alarm or error occurred.

If all four tests (a-d) passed, the analyzer is in operational condition. Otherwise the analyzer **must not be used** and Technical Support must be contacted for tube detection sensor adjustments.

Communication of this Field Safety Notice

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

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.

Best regards,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com