

Urgent Field Safety Notice

SBN-CPS-2017-012

CPS / Serum Work Area
Version 2
17-Aug-2017

Mixed sample results in immunochemistry modules

Product Name	MODULAR ANALYTICS <E170> (GMMI 03617505001) MODULAR ANALYTICS EVO <E170> (GMMI 04998642001) cobas e 601 module (GMMI 04745922001) cobas e 602 module (GMMI 05990378001)
Product Description	MODULAR ANALYTICS <E170> (GMMI 03617505001) MODULAR ANALYTICS EVO <E170> (GMMI 04998642001) cobas e 601 module (GMMI 04745922001) cobas e 602 module (GMMI 05990378001)
GMMI / Part No Device Identifier	MODULAR ANALYTICS <E170> (GMMI 03617505001) MODULAR ANALYTICS EVO <E170> (GMMI 04998642001) cobas e 601 module (GMMI 04745922001) cobas e 602 module (GMMI 05990378001)
Instrument/System Affected	MODULAR ANALYTICS MODULAR ANALYTICS EVO cobas 6000 analyzer series cobas 8000 modular analyzer series
SW Version	All of the software versions
Reason for Version 2	Updated information based on input from HHT. Changes highlighted in yellow, <i>[the yellow background can be removed in final local version]</i>
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We have informed you in the previous version of this document that a sample mismatch may occur (i.e orders are shifted) in the immunochemistry modules (**cobas e** 602, **cobas e** 601 and E170 modules) due to a software limitation. Based on new information received we would like to give you an update.

The sample mismatch is caused by a software limitation and only occurs if the following conditions are simultaneously met (i.e. very rare occurrence):

- Immunochemistry module (**cobas e** 602, **cobas e** 601 and E170 modules) is included in its respective system (cobas 8000 modular analyzer series, cobas 6000 analyzer series, MODULAR ANALYTICS, MODULAR ANALYTICS EVO).

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- The **“Module Rack Buffer setting”** ≠”1” → Two or more sample racks stay in the idling/processing line (L-Line) consecutively during operation.
- One rack (Rack A) is undergoing sampling and the following rack (Rack B) is waiting for measurement.
- The Gripper (T/V Carrier) fails to pick up the last vessel (cup) for the last order of the last sample on Rack A. As a consequence, the measurement for the last order of the sample in the last vessel which failed to be picked up is canceled and the warning **“Tip/Cup pick up error”** (Caution Level) is issued.
- First or more leading positions of the following rack (Rack B) are empty or have no test order for the immunochemistry module.

cobas e 801 module, cobas e 411 and all of the clinical chemistry modules (cobas c 501, cobas c 502, cobas c 701 and cobas c702 modules, P 800, D 2400) are not affected by this software limitation.

The software limitation occurs only when all of the above mentioned conditions are met simultaneously (i.e. very rare occurrence):

The sample orders are shifted by one position; the immunochemistry module performs the test order requested for the sample in the 2nd rack position of Rack B with the sample material in the 1st position of Rack B. After processing the 4th sample position (with the test order requested for the sample in the 5th position) the rack is moved in the L-line to the rack output position. At that time, the module will recognize (as no signal from the rack position sensor) the wrong rack position and issue the Sampling Stop alarm **“Abnormal L2-Line Movement”**. With the occurrence of that alarm, no further samples will be pipetted but the measurement for the samples already in process/pipetted (before the alarm occurred) will be completed.

The software limitation described above and the sample mismatch caused by that limitation can be detected as follows:

The alarm "Abnormal L2-line Movement" (S.Stop level) always occurs if this software failure occurs, and when Rack (B) is carried out of the immunochemistry module due to incorrect rack stop position (one position shifted).

Associated error messages:

Alarm	Level	Alarm codes E170/cobas e 601	Alarm codes cobas e 602
Tip/Cup pick up error	Caution Level	301-0002 or 301-0015	301-000002 or 301-000015
Abnormal L2-line Movement	S.Stop Level	104-0005	104-000005

Time between the two alarms above:

The time between the two alarms depends on the test orders and samples in rack B. Theoretically it could be in the worst case up to 70 minutes between the two alarms (4 samples x 25 Tests x 42sec = 4200 sec = 70 minutes).

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Therefore it might happen that wrongly measured test results are already uploaded to the LIS.

Actions taken by Roche Diagnostics

The root cause has been clearly identified and a new software version fixing that issue will be released in:

- September 2017 for cobas 8000 modular analyzer series (cobas e 602 module).
- November 2017 for cobas 6000 analyzer series (cobas e 601 module) and MODULAR ANALYTICS/MODULAR ANALYTICS EVO (E 170).

Meanwhile and until the new software version is available, your local Roche Diagnostics service organization will contact you and change the setting for the **“Module Rack Buffer setting”** to 1, this setting

- is only required for the immunochemistry modules (**cobas e 602**, **cobas e 601** and E170 modules).
- will ensure that only one rack will go in the idling/processing line (L-Line).

Note:

- The throughput of the system maybe impacted by that setting change. The impact is dependent on the configuration and workload used.

When the new software version is available it will be installed as a mandatory update to the system.

Actions to be taken by the customer/user

Use the following interim solution until your local Roche Diagnostics service organization changes the setting for the **“Module Rack Buffer setting”** to 1:

Whenever an **“Abnormal L2-line Movement”** (S.Stop Level) is issued by the system and the immunochemistry module (**cobas e 602**, **cobas e 601** and E170 module) goes in “Sampling Stop,” perform the following steps to determine if a sample result mismatch occurred (provided that the alarm **“Tip/Cup pick up error”** occurred a few minutes before the alarm **“Abnormal L2-line Movement”**).

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1) Collect the remaining racks in the system.

Standalone systems:

- a) Wait until system status turns to Stand-By.
- b) Perform "Reset or Rack Reset" to collect racks to Unloader.

Lab automation connected systems:

- a) Stop sending racks from the lab automation, then wait until all results for measuring samples output.
- b) Press "Stop" button to make system status turns to Stand-By.
- c) Perform "Reset or Rack Reset" to collect racks to Unloader.

2) Identify the wrong software behavior and locate the rack and mismatched samples

Att 1 "How to identify potential mixed sample results on **cobas e602_V3**"

Att 2 "How to identify potential mixed sample results on **cobas e601_V4**"

Att 3 "How to identify potential mixed sample results on **E170_V4**"

3) Delete sample measurement results that were identified as mismatched from Workplace > Data Review screen.

4) Run measurements for the identified samples again.

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 or to any organization/individual where the potentially affected devices have been distributed/supplied.

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.

Best regards,

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Contact Details

To be completed locally:

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