Urgent Field Safety Notice
SBN-CPS-2017-012

CPS / Serum Work Area
Version 1
21-June-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
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We regret to inform you that a sample mismatch may occur in the immunochemistry modules (**cobas e** 602**, cobas e** 601 and E170 modules) due to a software limitation.

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).
- The **"Module Rack Buffer setting"** ≠"1" à Two or more sample racks stay in the idling/processing line (L-Line) consecutively during operation.

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- 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) on Rack A. As a consequence, the measurement for 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.
- Sample position 1 of the following rack (Rack B) is empty or has 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 c**702 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 two alarms below must occur within a few minutes time difference in between both alarms

- **"Tip/Cup pick up error"** (Caution Level)
  Alarm code for cobas 8000 is 301-000002 or 301-000015
  Alram code for cobas 6000 and MODULAR *ANALYTICS* is 301-0002 or 301-0015
- **"Abnormal L2-line Movement"** (S.Stop Level)
  Alarm code for cobas 8000 is 104-000005
  Alarm code for cobas 6000 and MODULAR *ANALYTICS* is 104-0005

Actions taken by Roche Diagnostics

The root cause has been clearly identified and a new software version fixing that issue will be released by November 2017

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).

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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"**).

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 and deal with potential mixed sample results on **cobas e**602"
Att 2 "How to identify and deal with potential mixed sample results on **cobas e**601"
Att 3 "How to identify and deal with potential mixed sample results on E170"

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

4) Run measurements for the identified samples again.

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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,

Contact Details

To be completed locally:
Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com