

Field Safety Notice

SBN-CPS-2017-012

CPS / Serum Work Area
Version 1
05-Ju1-2017

Mixed-up sample results in immunochemistry modules

Product Name / Device Identifier	MODULAR <i>ANALYTICS</i> <E170> (GMMI 03617505001) MODULAR <i>ANALYTICS</i> EVO <E170> (GMMI 04998642001) cobas e 601 module (GMMI 04745922001) cobas e 602 module (GMMI 05990378001)
Product Description	MODULAR <i>ANALYTICS</i> <E170> (GMMI 03617505001) MODULAR <i>ANALYTICS</i> EVO <E170> (GMMI 04998642001) cobas e 601 module (GMMI 04745922001) cobas e 602 module (GMMI 05990378001)
Production Identifier (Lot No./Serial No.)	Not applicable
SW Version	All SW versions
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Due to a software limitation, sample mismatch may occur in the immunochemistry modules (**cobas e** 602, **cobas e** 601 and E170 modules). All of the clinical chemistry modules (**cobas c** 501, **cobas c** 502, **cobas c** 701 and **cobas c** 702 modules, P 800) are not affected by this software limitation.

The sample mismatch occurs when the following conditions are simultaneously met:

- 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 its turn.
- The Gripper (T/V Carrier) fails to pick up the last vessel (cup) on Rack A. Consequently, the test measurement of the cup that 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.

Mixed-up sample results in immunochemistry modules

When all of the above mentioned conditions are met, the sample orders in Rack B are mixed up in the following way:

- Test (or tests) requested for the sample in the 2nd rack position will be run with the sample in the 1st position.
- After sample in 4th rack position is processed (with the test order requested for the sample in the 5th position), the rack is moved to the L-line's rack output position. At this time, the module will recognize (through a no signal from the rack position sensor) the wrong rack position and issue the Sampling Stop alarm "**Abnormal L2-Line Movement**". With this 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 detection of the software limitation and the sample results mismatch is by the generation of two alarms within a few minutes of each other:

1. "**Tip/Cup pick up error**" (Caution Level)
Alarm code for **cobas** 8000 is 301-000002 or 301-000015
Alarm code for **cobas** 6000 and MODULAR *ANALYTICS* is 301-0002 or 301-0015
2. "**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

Risk Assessment

Frequency of Occurrence

The failure has been reported one time out of 17982 modules (Installed capacity base year end 2016) installations.

Detectability

The failure may happen if the two alarms below occur within a few minutes:

- Tip/Cup pick up error (Caution Level)
- Abnormal L2-line Movement (S.Stop Level)

Severity (HHE Summary)

The issue described above can lead to result mismatch (wrong test order and wrong result reporting). All tests that are run on the affected systems are potentially affected whereas the extent of the bias cannot be predicted. Both erroneous increased/positive and decreased/negative results are possible. From a medical point of view, the most relevant immediate impact is related to results which are triggering directly medical therapy such as cardiac markers. Also, in case of false negative results for infectious diseases a spread of infection cannot be excluded. Considering the poor detectability of the issue and unknown extent of erroneous results, relevant medical risk cannot be entirely excluded.

Mixed-up sample results in immunochemistry modules

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. The new software version will be installed as a mandatory update to the system.

Actions to be taken by the customer

Until the new software version is available, you must change the **“Module Rack Buffer setting”** to **1**. The change in setting

- Is only required for the immunochemistry modules (**cobas e 602**, **cobas e 601** and **E170** modules) and
- Will ensure that only one rack will go in the idling/processing line (L-Line)
- May impact the throughput of the system. The impact is dependent on the configuration and workload of the system.

Please see

- Attachment A for the step by step instructions for e602 module
- Attachment B for the step by step instructions for e601 module
- Attachment C for the step by step instructions for E170 modules.

Should the lab encounter the two alarms, **“Abnormal L2-line Movement”** (S.Stop Level) and **“Tip/Cup pick up error”**, within a few minutes of each other before the change in the **“Module Rack Buffer setting”**, please do the following steps:

1) Collect the remaining racks in the system.

For Standalone systems:

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

For Lab automation connected systems:

- a) Stop sending racks from the lab automation, then wait until all results are out.
- b) Press “Stop” button to make system status turns to Stand-By.
- c) Perform “Reset or Rack Reset” to collect racks to Unloader.

2) Locate the rack and mismatched samples

- a) **See Attachment 1** “How to identify and deal with potential mixed sample results on **cobas e602**”
- b) **See Attachment 2** “How to identify and deal with potential mixed sample results on **cobas e601**”
- c) **See Attachment 3** “How to identify and deal with potential mixed sample results on **E170**”

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

4) Run measurements for the identified samples again.

Mixed-up sample results in immunochemistry modules

Communication of this Field Safety Notice

This notice must be passed on to all those who need to be aware within your organization or to any other organization/individual where the potentially affected devices have been distributed/supplied. Please pass on this notice to the Chairman Medical Board and Head of Department as well, as required by HSA. Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action

We apologize for any inconvenience this may cause and thank you for your understanding and support.

Sincerely,

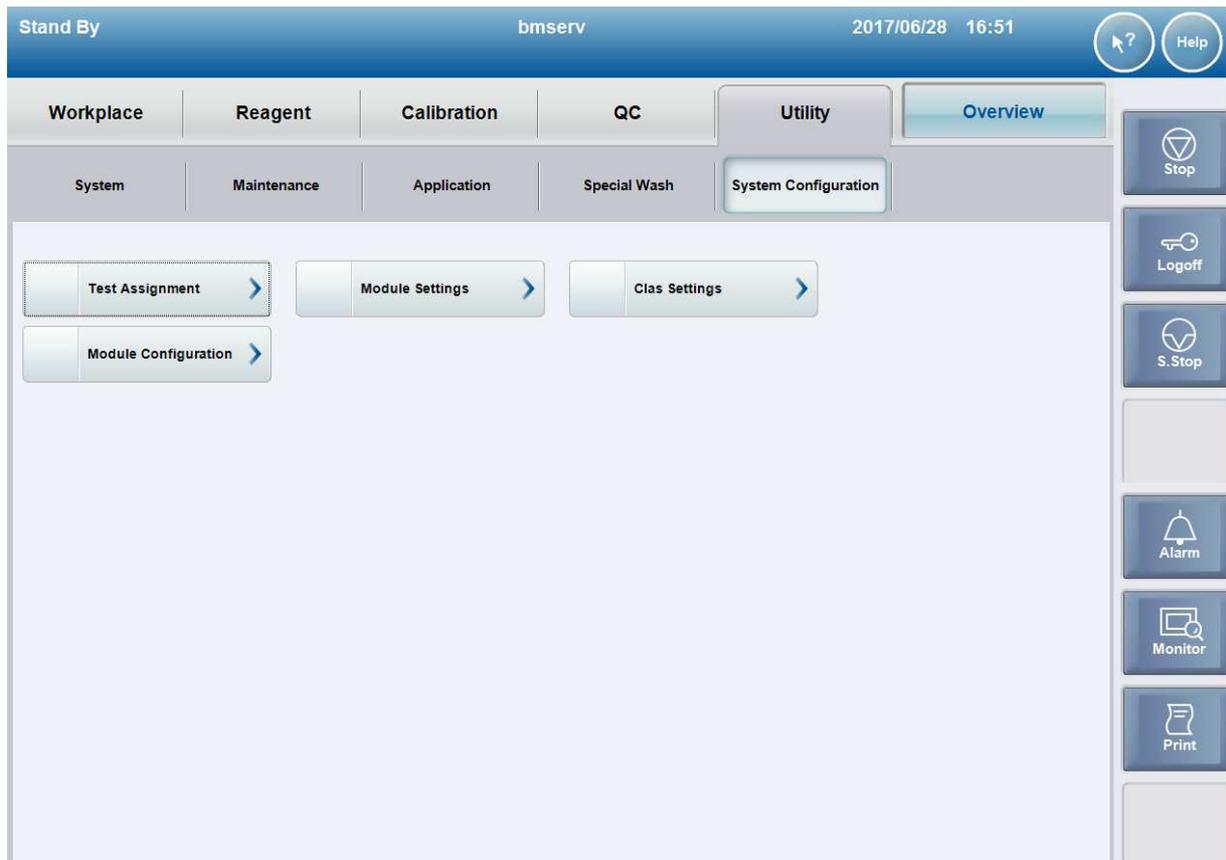
Roche Diagnostics Asia Pacific Pte Ltd

Email: sg.regulatory@roche.com

e602 Module Rack Buffer Setting

This screen can be accessed by an operator with administrator level password only.

Step 1: Select Utility > System Configuration > Module Configuration



ATTACHMENT A

Step 2: For Module Type e602 only, change the number under “Module Rack Buffer” to 1 and click OK.

Module Configuration

System: Serial No.:

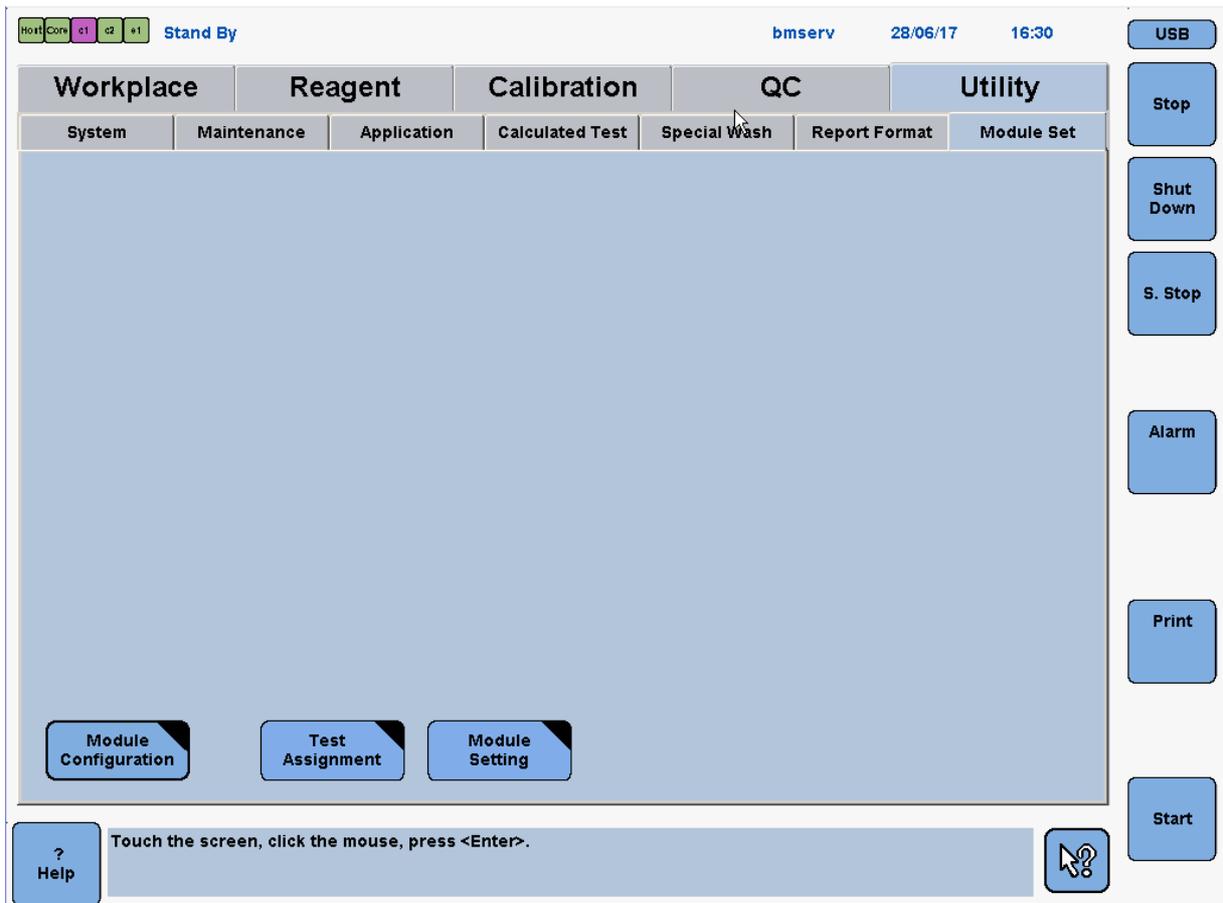
	Module Type	Module Name	Short Name	Serial No.	Module Rack Buffer
ISE 1	ISE	ISE1	I1	0800-40	
ISE 2	Inactive				
Buffer 1		MSB1	B1	1129-09	
Module 1	c 702	AU1	A1	1129-09	3
Buffer 2		MSB2	B2	0800-39	
Module 2	c 701	AU2	A2	0800-39	3
Buffer 3		MSB3	B3	0907-01	
Module 3	c 502	AU3	A3	0907-01	
Buffer 4		MSB4	B4	2254-08	
Module 4	e 602	AU4	A4	2254-08	1

Module Type Setting OK Cancel

e601 Module Rack Buffer Setting

This screen can be accessed by an operator with administrator level password only.

Step 1: Select Utility > Module Set > Module Configuration



ATTACHMENT B

Step 2: For Module Type e601 only, change the field under “Module Rack Buffer” to 1 and click OK.

The screenshot displays the 'Module Configuration' window within a software interface. The window has a top navigation bar with tabs for 'Workplace', 'Reagent', 'Calibration', 'QC', and 'Utility'. Below this is a sub-menu bar with 'System', 'Maintenance', 'Application', 'Calculated Test', 'Special Wash', 'Report Format', and 'Module Set'. The main area contains a table with the following data:

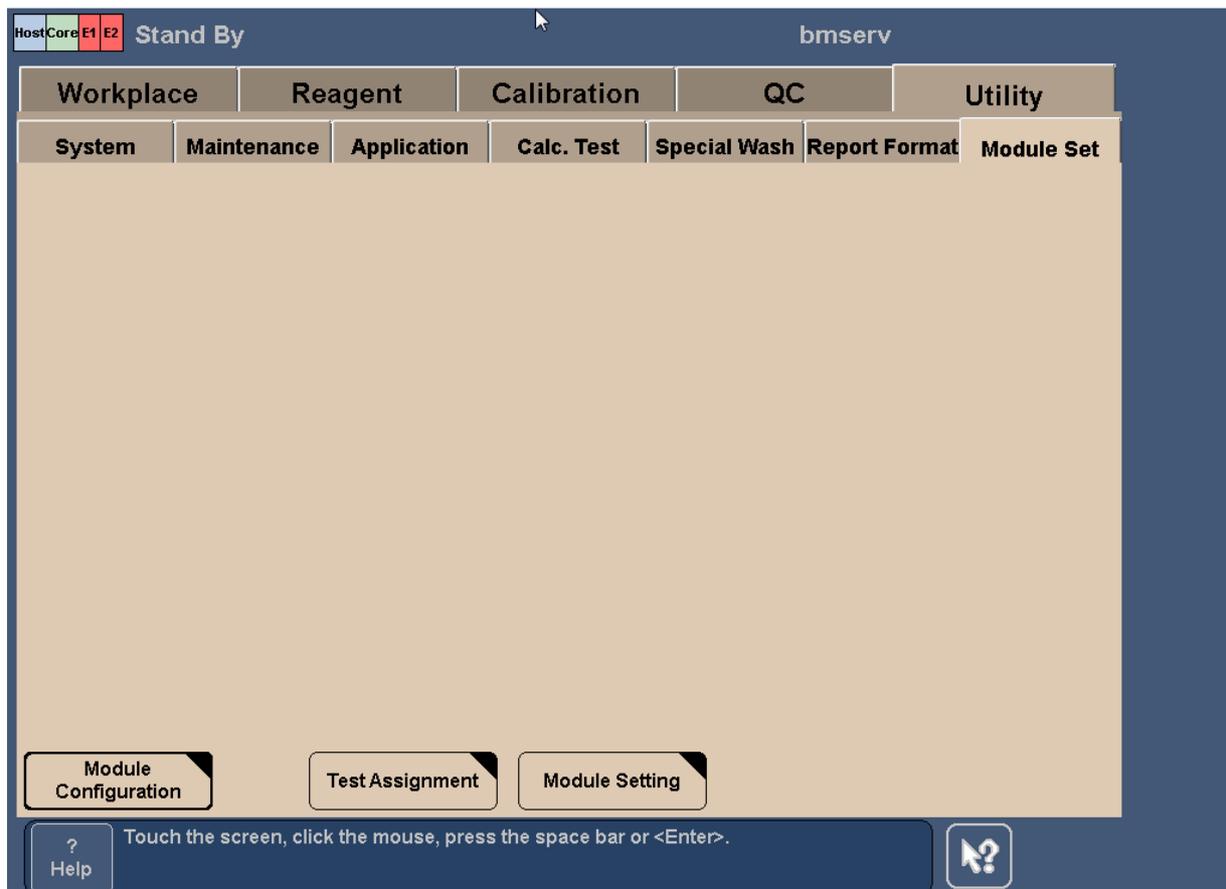
	Module Type	Module Name	Short Name	Serial No.	Module Rack Buffer
Module 1	c501	<input type="text" value="c1"/>	<input type="text" value="c1"/>	<input type="text" value="1155-20"/>	<input type="text" value="1"/>
Module 2	c501	<input type="text" value="c2"/>	<input type="text" value="c2"/>	<input type="text" value="1156-01"/>	<input type="text" value="1"/>
Module 3	e601	<input type="text" value="e1"/>	<input type="text" value="E"/>	<input type="text" value="2298-13"/>	<input type="text" value="1"/>

At the bottom of the window are buttons for 'Cancel', 'Module Type Setting', and 'OK'. A help bar at the bottom left contains a question mark icon and the text: 'Type the serial number with up to 12 characters, then press <Enter>.' On the right side of the interface, there is a vertical column of control buttons: 'USB', 'Stop', 'Shut Down', 'S. Stop', 'Alarm', 'Print', and 'Start'.

E170 Module Rack Buffer Setting

This screen can be accessed by an operator with administrator level password only.

Step 1: Select Utility > Module Set > Module Configuration



ATTACHMENT C

Step 2: For Module Type E only, change the number under “Module Rack Buffer” to 1 and click OK.

Host Core E1 E2 Stand By bmserv 17/06/28 (Wed) 17

Workplace Reagent Calibration QC Utility

System Maintenance Application Calc. Test Special Wash Report Format Module Set

Module Configuration

	Module Type	Module Name	Short Name	Serial No.	Module Rack Buffer
Module 1	E	E-1	E1		1
Module 2	E	E-2	E2		1
Module 3	Inactive				
Module 4	Inactive				
ISE 1	Inactive				
ISE 2	Inactive				

Cancel Module Type Setting OK

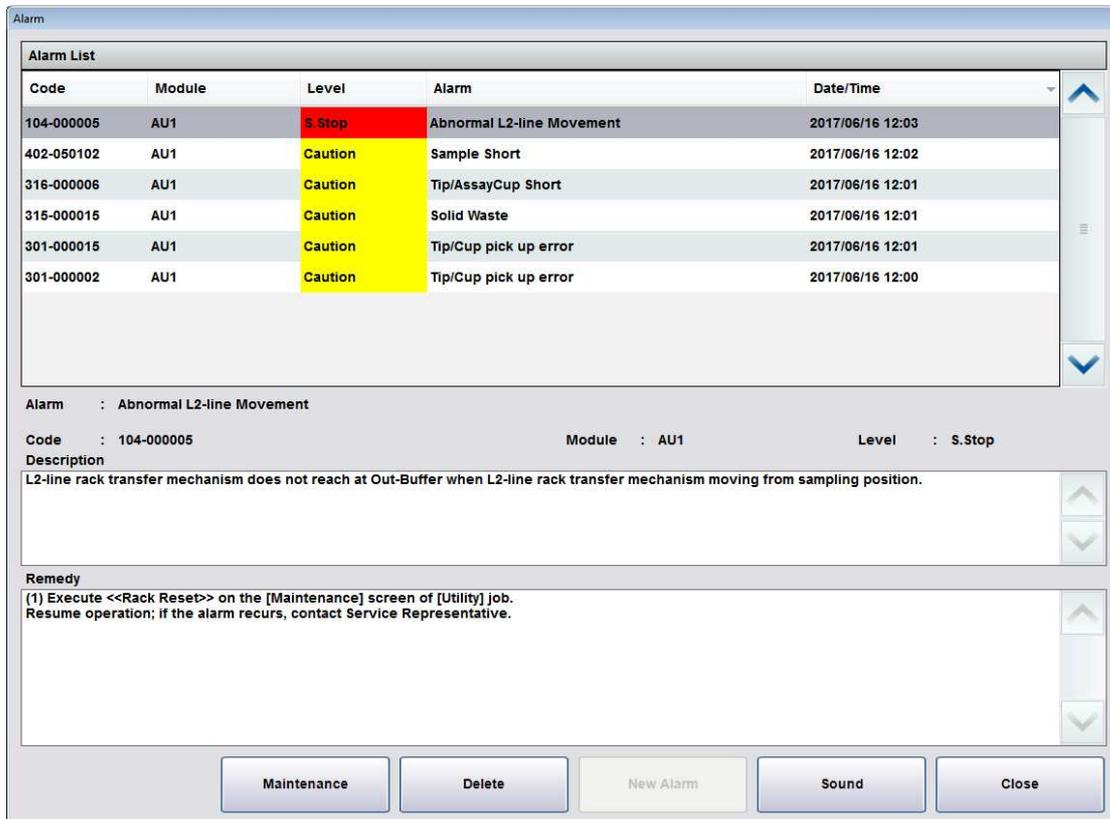
? Help Type the module name with up to 4 characters, then press <Enter>. ?

Attachment 1 QN-CPS-2017-172 “How to identify and deal with potential mixed sample results on cobas e602”

1. Identification of the software malfunction

Whenever an Abnormal L2-line Movement 104-000005 (S.Stop Level) is issued by the system, check whether Tip/Cup pick up error 301-000002 and / or 301-000015 (Caution Level) is also issued earlier on the Alarm screen.

1. Check Alarm screen and make sure the alarm “104-000005 Abnormal L2-line Movement (S.Stop Level)” occurs.



The screenshot shows the Alarm screen with the following data:

Code	Module	Level	Alarm	Date/Time
104-000005	AU1	S.Stop	Abnormal L2-line Movement	2017/06/16 12:03
402-050102	AU1	Caution	Sample Short	2017/06/16 12:02
316-000006	AU1	Caution	Tip/AssayCup Short	2017/06/16 12:01
315-000015	AU1	Caution	Solid Waste	2017/06/16 12:01
301-000015	AU1	Caution	Tip/Cup pick up error	2017/06/16 12:01
301-000002	AU1	Caution	Tip/Cup pick up error	2017/06/16 12:00

Alarm : Abnormal L2-line Movement
Code : 104-000005 Module : AU1 Level : S.Stop
Description
L2-line rack transfer mechanism does not reach at Out-Buffer when L2-line rack transfer mechanism moving from sampling position.
Remedy
(1) Execute <<Rack Reset>> on the [Maintenance] screen of [Utility] job. Resume operation; if the alarm recurs, contact Service Representative.

Maintenance Delete New Alarm Sound Close

2. Collect the remained racks in the **cobas** e602 module.
 - Standalone system:
 - 2-1) Wait until system status turns to Stand-By.
 - 2-2) Perform “Reset or Rack Reset” to collect racks to Unloader.
 - CLAS connected system:
 - 2-1) Stop sending racks from CLAS, then wait until all results are out.
 - 2-2) Press “Stop” button to make system status turns to Stand-By.
 - 2-3) Perform “Reset or Rack Reset” to collect racks to Unloader.

Attachment 1 QN-CPS-2017-172 “How to identify and deal with potential mixed sample results on cobas e602”

3. Print “Daily Alarm Trace” and check if the alarm “301-000002 Tip/Cup pick up error” or “301-000015 Tip/Cup pick up error” occurs within a short time from time alarm “104-000005 Abnormal L2-line Movement”. If yes, go to the next procedure for identifying of rack with potential mixed sample results.

2017/06/16	12:03:23	10	1 E	PC	0013-000001	Rack Collect End
2017/06/16	12:03:23	13	2 E	SU	0741-000002	Rack Collect Complete
2017/06/16	12:03:19	5	1 A	A1	104-000005-342	Abnormal L2-line Movement
2017/06/16	12:02:12	5	1 A	A1	402-050102-276	Sample Short
2017/06/16	12:01:42	5	1 A	A1	316-000006-091	Tip/AssayCup Short
2017/06/16	12:01:42	5	1 A	A1	315-000015-091	Solid Waste
2017/06/16	12:01:11	5	1 A	A1	301-000015-315	Tip/Cup pick up error
2017/06/16	12:00:50	5	2 A	A1	301-000002-315	Tip/Cup pick up error
2017/06/16	11:59:35	8	1 E	PC	0011-000001	Rack Supply End
2017/06/16	11:58:33	7	1 E	PC	0010-000001	Operation
2017/06/16	11:58:33	11	1 E	SU	0510-000001	Change to Operation Request

2. Identification of rack with mixed sample results on cobas e602

2.1. Sample Barcode mode

2.1.1. Go to Workplace > Data Review screen, search Sample ID of the samples on the racks collected at Unloader after "Reset or Rack Reset" is completed.

Follow 1 through 4 in the Figure 1 below.

Stand By 2017/04/27 18:16

Workplace Reagent Calibration QC Utility Overview

Test Selection Data Review Calib. Review

Data: Routine View Filter: ON OFF Filter Search Sample Count: 4870

DM	C	St	S. ID	Rack No. - Pos.	S. Type	Col.	Date/Time
H			1736340381	50068-1	Ser/PI		04/07 10:06:35
H			1736359811	50068-4	Ser/PI		04/07 10:06:55
H			1736362831	50068-5	Ser/PI		04/07 10:06:55
H			1736379531	50082-2	Ser/PI		04/07 10:07:24
H			1736531111	50025-5	Ser/PI		04/07 10:26:40
H			1736372391	50062-1	Ser/PI		04/07 10:06:35
H	I		1736489941	50062-2	Ser/PI		04/07 10:06:35
H	I		1736520561	50006-4	Ser/PI		04/07 10:06:35
H	I		1736377501	50016-1	Ser/PI		04/07 10:48:30
H	I		1736525401	50079-2	Ser/PI		04/07 10:50:49
H	I		1736542811	50079-4	Ser/PI		04/07 10:50:51
H	I		1736527771	50049-5	Ser/PI		04/07 10:51:28
H	I		1736566351	50094-4	Ser/PI		04/07 11:15:20
H	I		1736400601	50001-4	Ser/PI		04/07 11:22:29
H			1736354151	50024-1	Ser/PI		04/07 13:40:19
H			1736367411	50024-3	Ser/PI		04/07 13:40:21
H	O		1736368391	50039-2	Ser/PI		04/07 13:40:31
H			1736359641	50039-5	Ser/PI		04/07 13:40:33

Search Sample

Find: 1736340381

Search Option: Match Case

Focus Move: Up Down

Close

Sample information Unload Rack Change Priority Send to DM Delete Record Delete All Backup Data Test Review Reaction Monitor

Touch the screen, click the mouse or press a key.

Figure 1. Data Review screen

Attachment 1 QN-CPS-2017-172 “How to identify and deal with potential mixed sample results on cobas e602”

2.1.2. Select the searched Sample ID and then, open "Test Review" screen.
Verify corresponding **cobas** e602 module and sampling time.

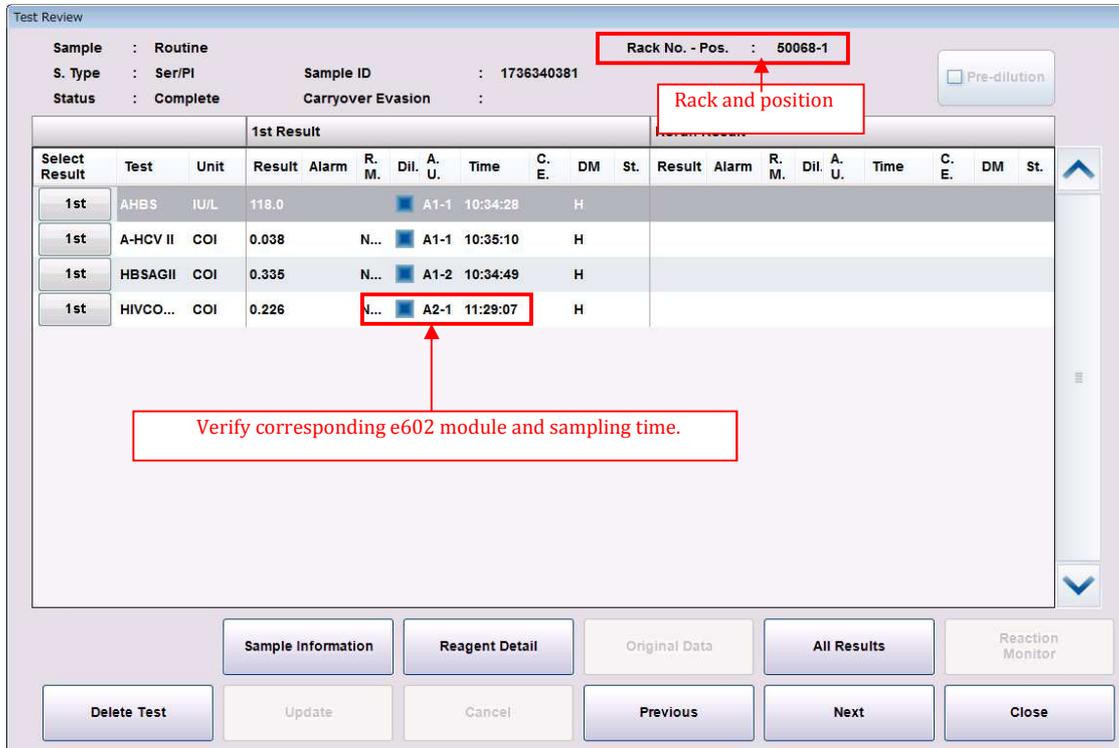


Figure 2. Test Review screen

2.1.3. Repeat step 2.1.1. and 2.1.2. for all samples on the collected racks.

2.1.4. The rack with the samples that are mismatched can be identified by the sample with sampling time that is the closest to the Tip/Cup pick up error alarm generation time.

2.2. Rack position number mode

2.2.1. Go to Workplace > Data Review screen, search by “Rack No.”

Note: If the rack is used repeatedly used, search by "Date/Time".

The screenshot displays the 'Data Review' screen. At the top, it shows 'Stand By', 'bmserv', and the date/time '2017/06/13 16:47'. Below this are navigation tabs for 'Workplace', 'Reagent', 'Calibration', 'QC', 'Utility', and 'Overview'. Under 'Workplace', there are sub-tabs for 'Data Review' and 'Calib. Review'. The 'Data Review' sub-tab is active, showing a 'Routine View' and a 'Filter' set to 'OFF'. A 'Sample Count' of 50 is displayed. The main area contains a table of test results:

DW	C. E.	St.	Seq. No.	S. ID	Rack No.	S. Type	Comment	Date/Time
	O		000203		50037-3	er/PI		06/13 15:28:41
H	O		000204		50037-4	er/PI		06/13 15:28:41
H	O		000205		50037-5	er/PI		06/13 15:28:41
	O		000206			er/PI		
O			000207		50102-2	er/PI		06/13 15:28:49
O			000208		50102-3	er/PI		06/13 15:28:49
H			000209		50102-4	er/PI		06/13 15:28:50
H			000210		50102-5	er/PI		06/13 15:28:50
H			000211		50037-1	er/PI		06/13 16:16:50
H			000212		50037-2	er/PI		06/13 16:16:50
O			000213		50037-3	er/PI		06/13 16:16:51
O			000214		50037-4	er/PI		06/13 16:16:51
O			000215		50037-5	er/PI		06/13 16:16:51
O			000216			er/PI		
H			000217		50102-2	er/PI		06/13 16:16:59
H			000218		50102-3	er/PI		06/13 16:16:59
H			000219		50102-4	er/PI		06/13 16:17:00
H			000220		50102-5	er/PI		06/13 16:17:00

To the right of the table, a detailed view for 'TSH' is shown with a result of '0.275 IU/mL' and 'A1-1'. At the bottom, there are buttons for 'Sample Information', 'Unload Rack', 'Change Priority', 'Send to DM', 'Delete Record', 'Delete All', 'Backup Data', 'Test Review', and 'Reaction Monitor'. A 'Start' button is also present on the far right.

Figure 3. Data Review screen

Attachment 1 QN-CPS-2017-172 “How to identify and deal with potential mixed sample results on cobas e602”

2.2.2. Select the sample on the searched racks, then open "Test Review" screen.
Verify corresponding **cobas** e602 module and sampling time.

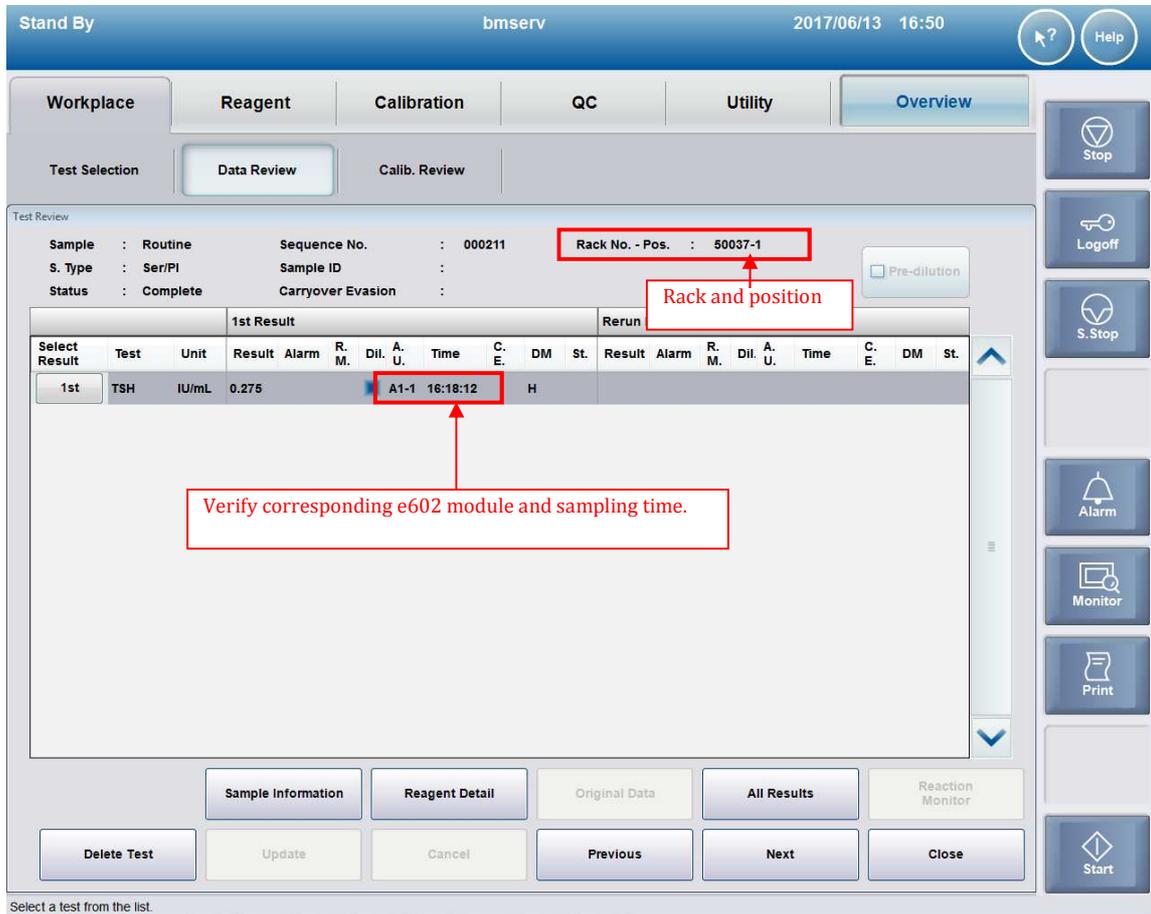


Figure 4. Test Review screen

2.2.3. Repeat step 2.2.1. and 2.2.2. for all samples on the collected racks.

2.2.4. The rack with the samples that are mismatched can be identified by the sample with sampling time that is the closest to the Tip/Cup pick up error alarm generation time.

Attachment 2 QN-CPS-2017-172 “How to identify and deal with potential mixed sample results on cobas e601”

1. Identification of the software malfunction

Whenever an Abnormal L2-line Movement 104-000005 (S.Stop Level) is issued by the system, check whether Tip/Cup pick up error 301-000002 and / or 301-000015 (Caution Level) is also issued earlier on the Alarm screen.

1. Check Alarm screen and make sure the alarm “104-000005 Abnormal L2-line Movement (S.Stop Level)” occurs.



2. Collect the remained racks in the **cobas** e601 module.
 - Standalone system:
 - 2-1) Wait until system status turns to Stand-By.
 - 2-2) Perform “Reset or Rack Reset” to collect racks to Unloader.
 - CLAS connected system:
 - 2-1) Stop sending racks from CLAS, then wait until all results are out.
 - 2-2) Press “Stop” button to make system status turns to Stand-By.
 - 2-3) Perform “Reset or Rack Reset” to collect racks to Unloader.

Attachment 2 QN-CPS-2017-172 “How to identify and deal with potential mixed sample results on cobas e601”

3. Print “Daily Alarm Trace” and check the alarm “301-000002 Tip/Cup pick up error” or “301-000015 Tip/Cup pick up error” occurs within a short time from time alarm “104-000005 Abnormal L2-line Movement”. If yes, go to the next procedure for identifying of rack with potential mixed sample results.

13/06 13:35	2	2	A	01-029-0001-065	Inc. Water Level Too Low
13/06 13:35	2	2	A	01-113-0009-063	Abnormal Temp Control
13/06 13:34	2	1	A	01-029-0001-065	Inc. Water Level Too Low
13/06 13:34	2	1	A	01-113-0009-063	Abnormal Temp Control
13/06 13:34	62	1	A	02-104-0005-342	Abnormal L2-line Movement
13/06 13:34	62	2	A	02-113-0006-281	Abnormal Temp Control
13/06 13:34	4	3	A	02-329-0003-271	Pressure Sensor Error
13/06 13:33	4	1	A	02-402-0401-276	Sample Short
13/06 13:33	4	1	A	02-315-0015-091	Solid Waste
13/06 13:32	4	1	A	02-301-0015-315	Tip/Cup pick up error
13/06 13:32	2	23	A	01-113-0009-063	Abnormal Temp Control
13/06 13:32	4	2	A	02-301-0002-315	Tip/Cup pick up error
13/06 13:31	2	30	A	01-029-0001-065	Inc. Water Level Too Low
13/06 13:31	2	7	A	01-113-0010-063	Abnormal Temp Control
13/06 13:31	4	25	A	02-113-0006-141	Abnormal Temp Control

2. Identification of rack with mixed sample results on cobas e601

2.1. Sample Barcode mode

2.1.1. Go to Workplace > Data Review screen, search Sample ID of the samples on the racks collected by performing "Reset or Rack Reset" to Unloader.

Follow 1 through 4 in the Figure 1 below.

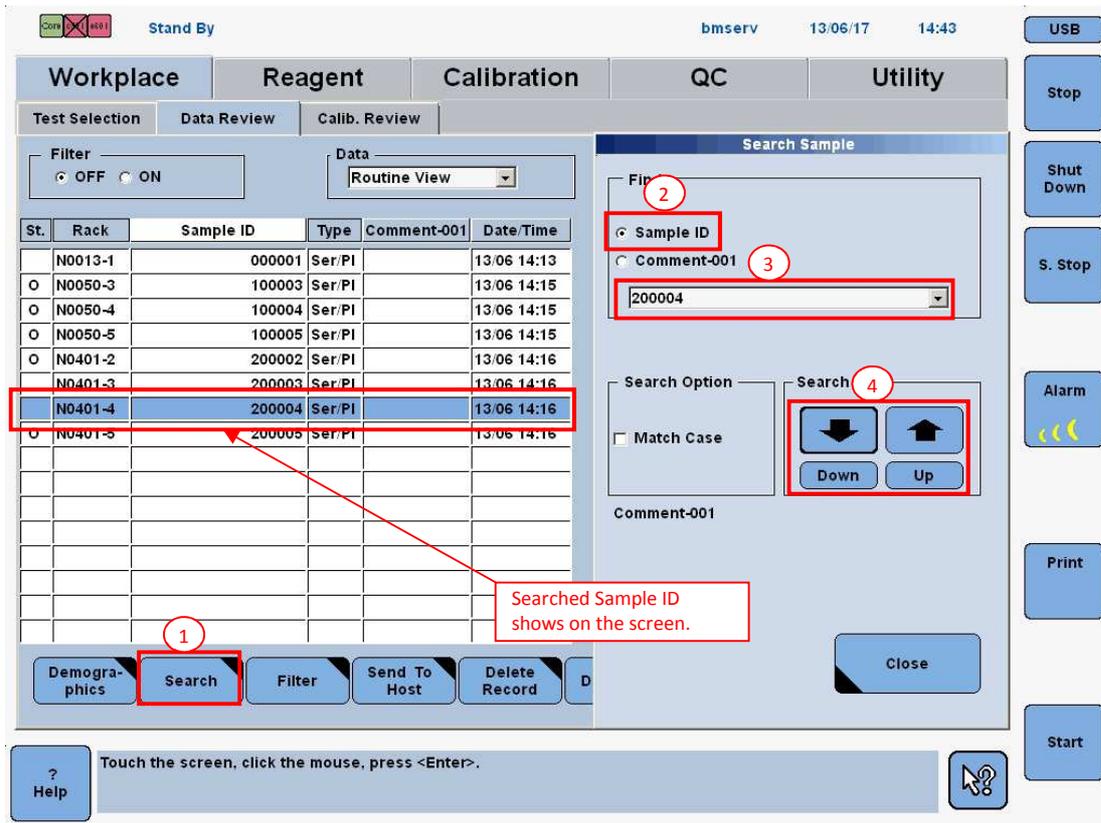


Figure 1. Data Review screen

Attachment 2 QN-CPS-2017-172 "How to identify and deal with potential mixed sample results on cobas e601"

2.1.2. Select the searched Sample ID, then open "Test Review" screen.
Verify corresponding **cobas** e601 module and sampling time.

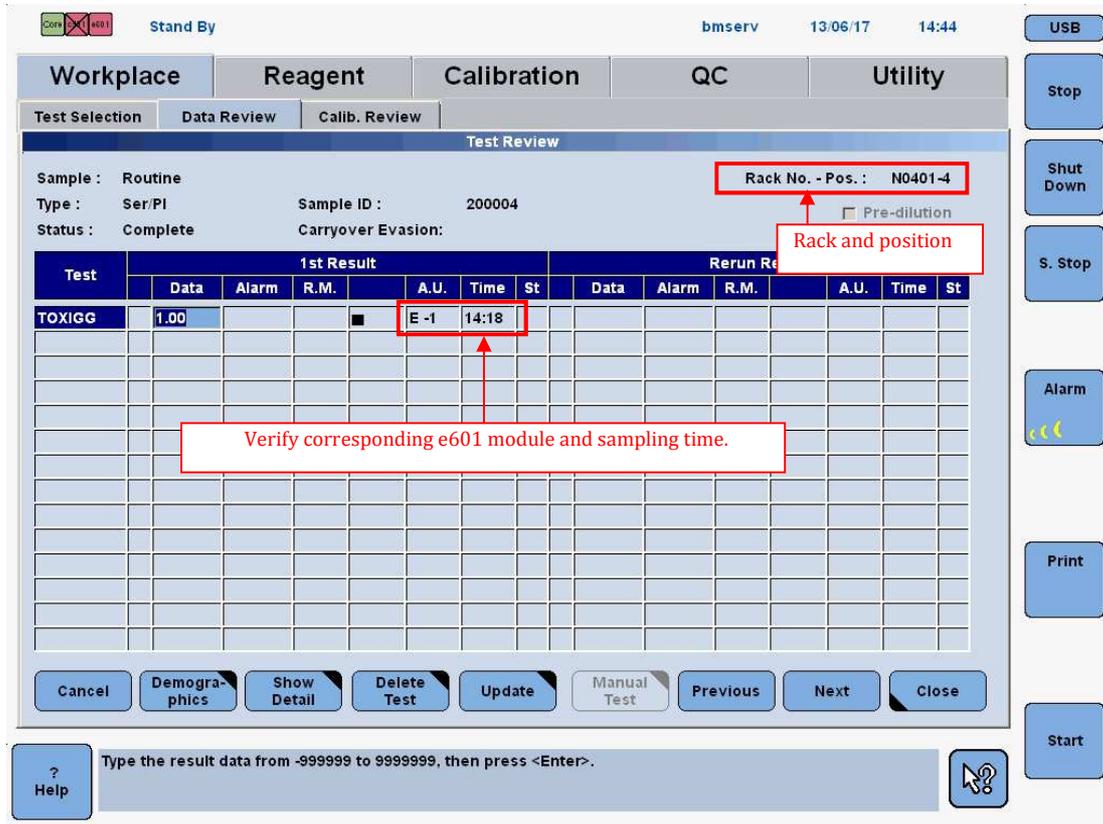


Figure 2. Test Review screen

2.1.3. Repeat step 2.1.1. and 2.1.2. for all samples on the collected racks.

2.1.4. The rack with the samples that are mismatched can be identified by the sample with sampling time that is the closest to the Tip/Cup pick up error alarm generation time.

2.2. Rack position number mode

2.2.1. Go to Workplace > Data Review screen, search by "Rack No."

Note: If the rack is used repeatedly, search by "Date/Time".

The screenshot displays the 'Data Review' screen in the 'Workplace' tab. The interface includes a top navigation bar with 'Workplace', 'Reagent', 'Calibration', 'QC', and 'Utility'. Below this is a 'Test Selection' section with 'Data Review' and 'Calib. Review' tabs. A 'Filter' section has 'OFF' and 'ON' radio buttons. A 'Data' dropdown menu is set to 'Routine View'. The 'Sample Count' is 700. The main data table has the following columns: St., Seq. No., Rack, ID, Type, Comment-001, Date/Time, Test, Result, R.M., Alarm, and Unit. A red box highlights the 'Rack' column. The 'Test' column shows 'TOXIGG' with a 'Result' of '1.00' and 'Unit' of 'IU/mL'. The bottom toolbar contains buttons for 'Demographics', 'Search', 'Filter', 'Send To Host', 'Delete Record', 'Delete All', 'Backup Data', 'Test Review', and 'Reaction Monitor'. A 'Help' button is in the bottom left, and a 'Start' button is in the bottom right.

St.	Seq. No.	Rack	ID	Type	Comment-001	Date/Time	Test	Result	R.M.	Alarm	Unit
O	N001015	N0050-5		Ser/PI		08.06 11:34					
O	N001016	N0401-1		Ser/PI		08.06 11:35					
O	N001017	N0401-2		Ser/PI		08.06 11:35					
O	N001018	N0401-3		Ser/PI		08.06 11:35					
O	N001019	N0401-4		Ser/PI		08.06 11:35					
O	N001020	N0401-5		Ser/PI		08.06 11:35					
O	N001021	N		Ser/PI							
O	N001022	N		Ser/PI							
O	N001023	N0050-3		Ser/PI		13.06 13:31					
O	N001024	N0050-4		Ser/PI		13.06 13:31					
O	N001025	N0050-5		Ser/PI		13.06 13:31					
O	N001026	N		Ser/PI							
O	N001027	N0401-2		Ser/PI		13.06 13:31					
O	N001028	N0401-3		Ser/PI		13.06 13:31					
O	N001029	N0401-4		Ser/PI		13.06 13:31					
O	N001030	N0401-5		Ser/PI		13.06 13:31					

Figure 3. Data Review screen

Attachment 2 QN-CPS-2017-172 "How to identify and deal with potential mixed sample results on cobas e601"

2.2.2. Select the sample on the searched racks, then open "Test Review" screen.
Verify corresponding **cobas** e601 module and sampling time.

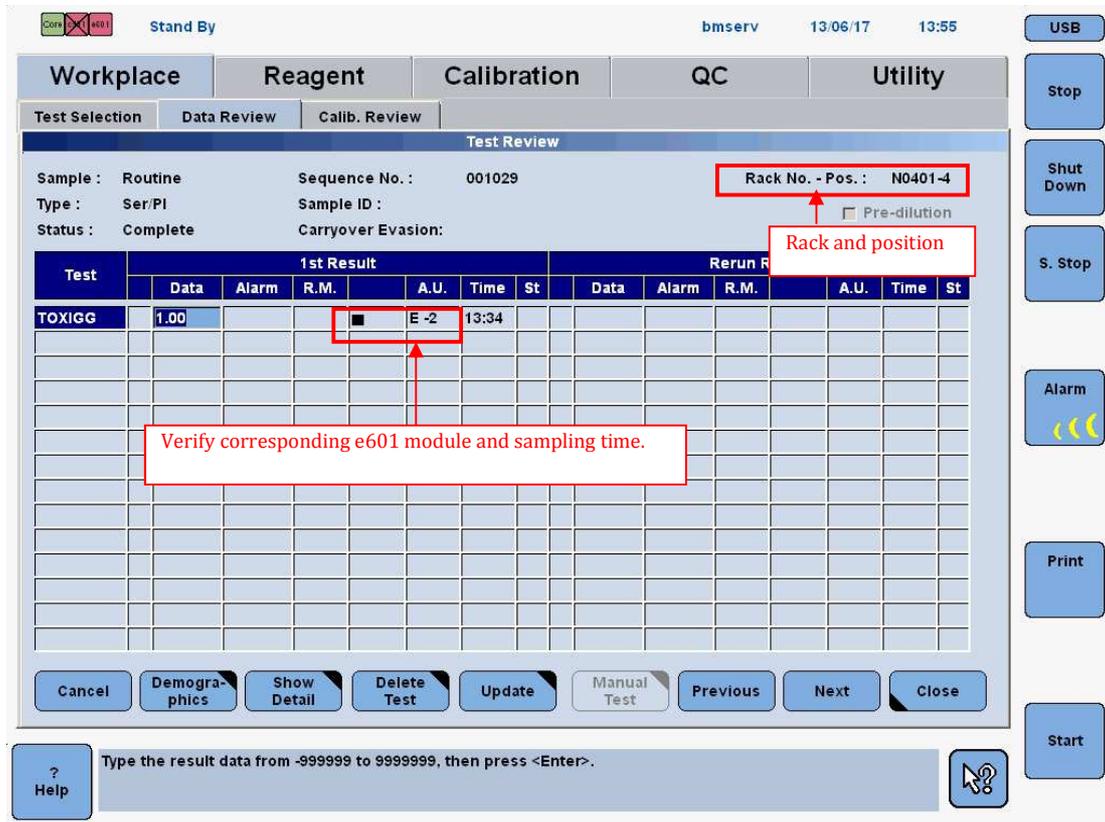


Figure 4. Test Review screen

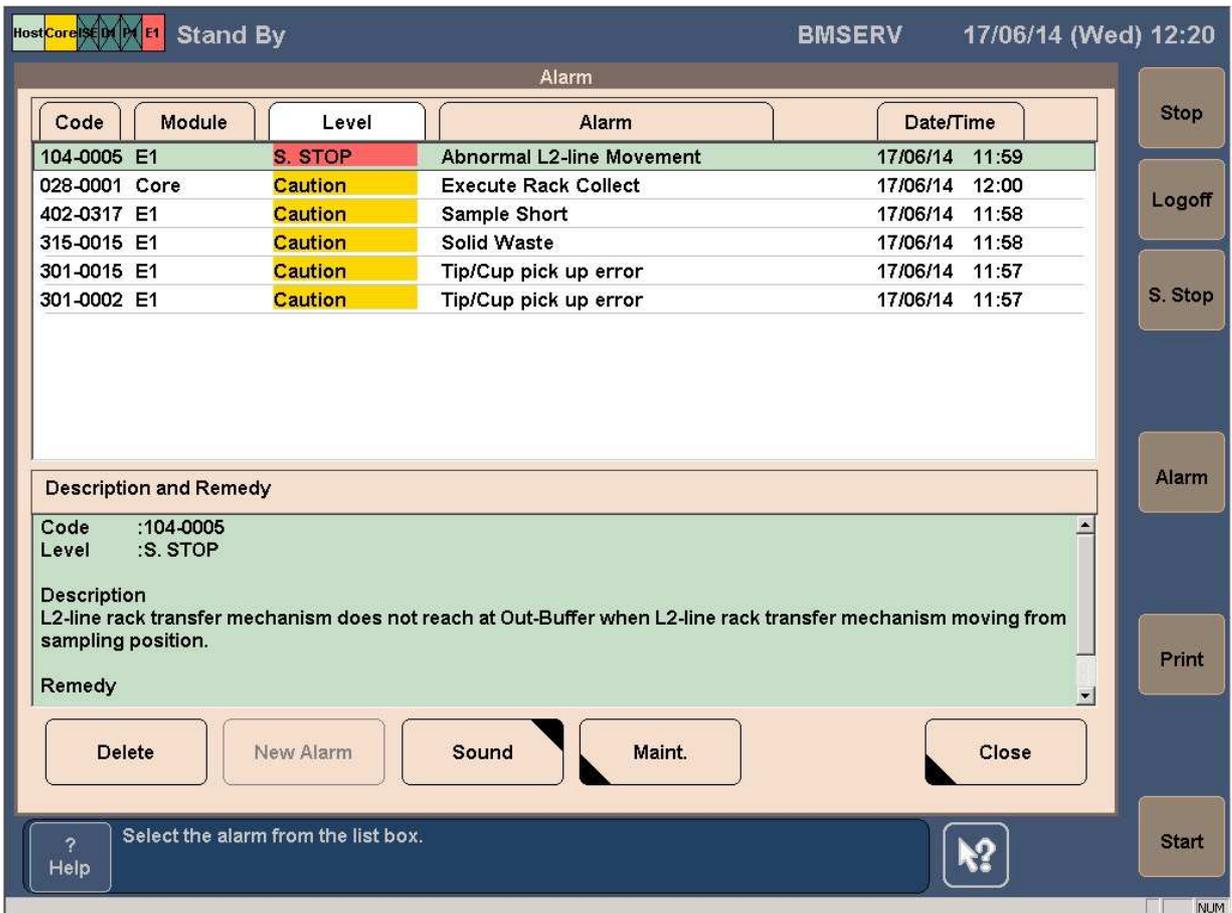
2.2.3. Repeat step 2.2.1. and 2.2.2. for all samples on the collected racks.

2.2.4. The rack with the samples that are mismatched can be identified by the sample with sampling time that is the closest to the Tip/Cup pick up error alarm generation time.

1. Identification of the software malfunction

Whenever an Abnormal L2-line Movement 104-00005 (S.Stop Level) is issued by the system, check whether Tip/Cup pick up error 301-00002 and / or 301-000015 (Caution Level) is also earlier on the Alarm screen.

- 1. Check Alarm screen and make sure the alarm “104-00005 Abnormal L2-line Movement (S.Stop Level)” occurs.



- 2. Collect the remained racks in the E170 module.
 - Standalone system:
 - 2-1) Wait until system status turns to Stand-By.
 - 2-2) Perform “Reset or Rack Reset” to collect racks to Unloader.
 - CLAS connected system:
 - 2-1) Stop sending racks from CLAS, then wait until all results are out.
 - 2-2) Press “Stop” button to make system status turns to Stand-By.
 - 2-3) Perform “Reset or Rack Reset” to collect racks to Unloader.

Attachment 3 QN-CPS-2017-172 “How to identify and deal with potential mixed sample results on E170”

3. Print “Daily Alarm Trace” and check the alarm “301-000002 Tip/Cup pick up error” or “301-000015 Tip/Cup pick up error” occurs within a short time from the time alarm time “104-000005 Abnormal L2-line Movement”. If yes, go to the next procedure for identifying of rack with potential mixed sample results.

06/14 11:59	7	1	E	15-005-0001-000	Rack Supply Complete
06/14 11:59	11	1	E	99-016-0001-000	Restart Disable (All Module)
06/14 11:59	5	1	A	03-104-0005-342	Abnormal L2-line Movement
06/14 11:59	62	1	E	03-007-0001-000	Rack Supply Complete
06/14 11:58	5	1	A	03-402-0317-276	Sample Short
06/14 11:58	5	1	A	03-316-0006-091	Tip/AssayCup Short
06/14 11:58	5	1	A	03-315-0015-091	Solid Waste
06/14 11:57	5	1	A	03-301-0015-315	Tip/Cup pick up error
06/14 11:57	5	1	A	03-301-0002-315	Tip/Cup pick up error
06/14 11:57	6	1	E	15-005-0001-000	Rack Supply Complete
06/14 11:57	43	1	E	99-017-0001-000	Barcode Read Complete
06/14 11:56	10	1	E	99-013-0001-000	Rack Supply Complete
06/14 11:56	6	1	R	15-001-0001-006	Water Reservoir Level Too Low
13/06 13:31	628	1	E	11-502-0000-000	Restart

2. Identification of rack with mixed sample results on E170

2.1. Sample Barcode mode

2.1.1. Go to Workplace > Data Review screen, search Sample ID of the samples on the racks collected at Unloader after "Reset or Rack Reset" is completed.

Follow 1 through 4 in the Figure 1 below.

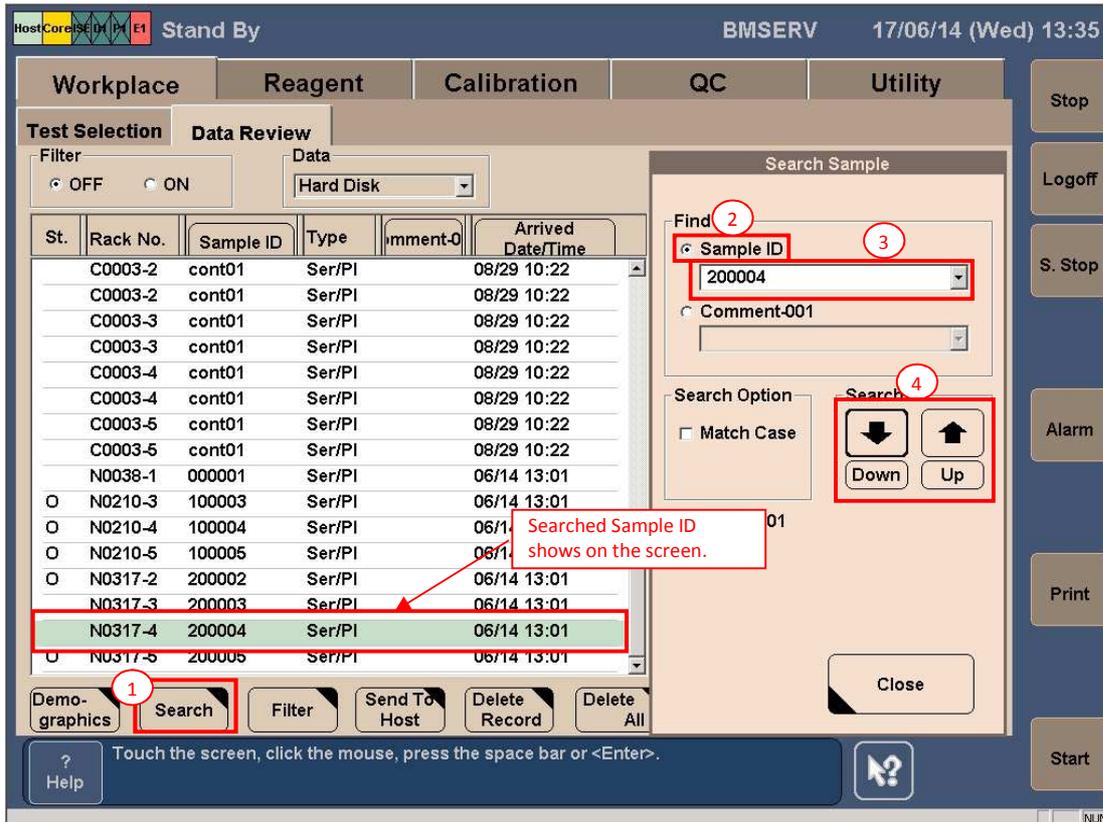
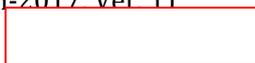
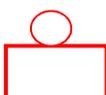


Figure 1. Data Review screen



Attachment 3 QN-CPS-2017-172 “How to identify and deal with potential mixed sample results on E170”

2.1.2. Select the searched Sample ID, then open "Test Review" screen.
Verify corresponding E170 module and sampling time.

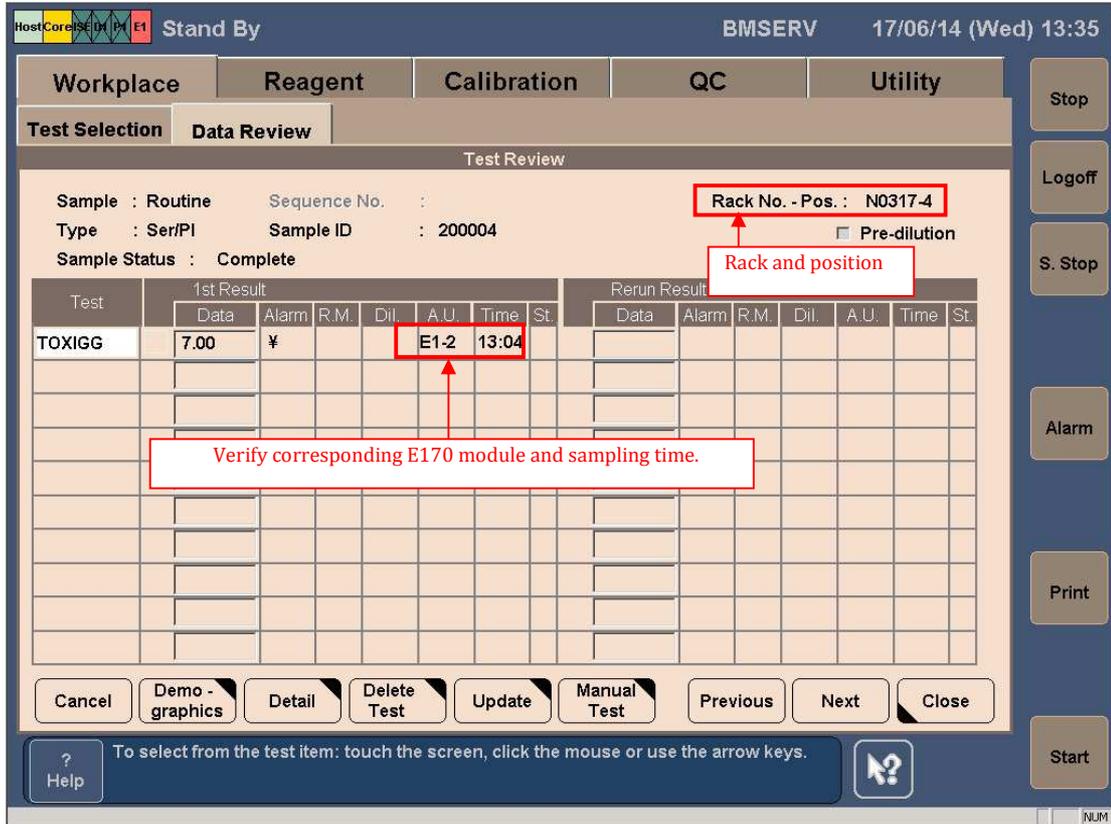


Figure 2. Test Review screen

2.1.3. Repeat step 2.1.1. and 2.1.2. for all samples on the collected racks.

2.1.4. The rack with the samples that are mismatched can be identified by the sample with sampling time that is the closest to the Tip/Cup pick up error alarm generation time.

2.2. Rack position number mode

2.2.1. Go to Workplace > Data Review screen, search by "Rack No."

Note: If the rack is used repeatedly, search by "Date/Time".

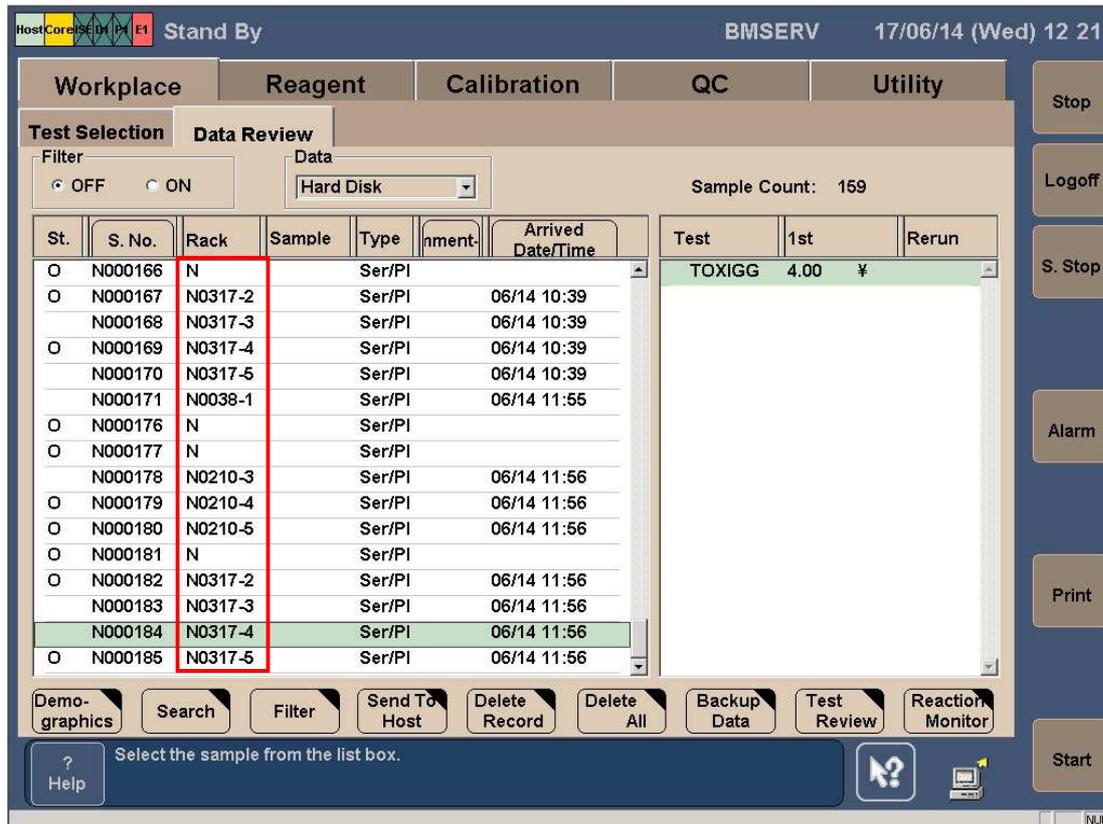


Figure 3. Data Review screen

