

# Field Safety Notice

## FSN-CPS-2017-012

CPS / Serum Work Area

Version 2

30-Aug-2017

## Mixed-up sample results in immunochemistry modules

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

Dear Valued Customer,

In this 2<sup>nd</sup> version of the notice, changes and additional information are highlighted in yellow.

### Description of Situation

Due to a software limitation, sample mismatch may occur (i.e orders are shifted) 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. Based on new information received we would like to give you an update.

#### **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) for the last order of the last sample on Rack A. Consequently, the test measurement of the last order of the cup that 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.

# 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 2<sup>nd</sup> rack position will be run with the sample in the 1<sup>st</sup> position.
- After sample in 4<sup>th</sup> rack position is processed (with the test order requested for the sample in the 5<sup>th</sup> 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 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).

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

## 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)

# Mixed-up sample results in immunochemistry modules

## 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.

## 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).

## 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:

# Mixed-up sample results in immunochemistry modules

## 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.

## 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,

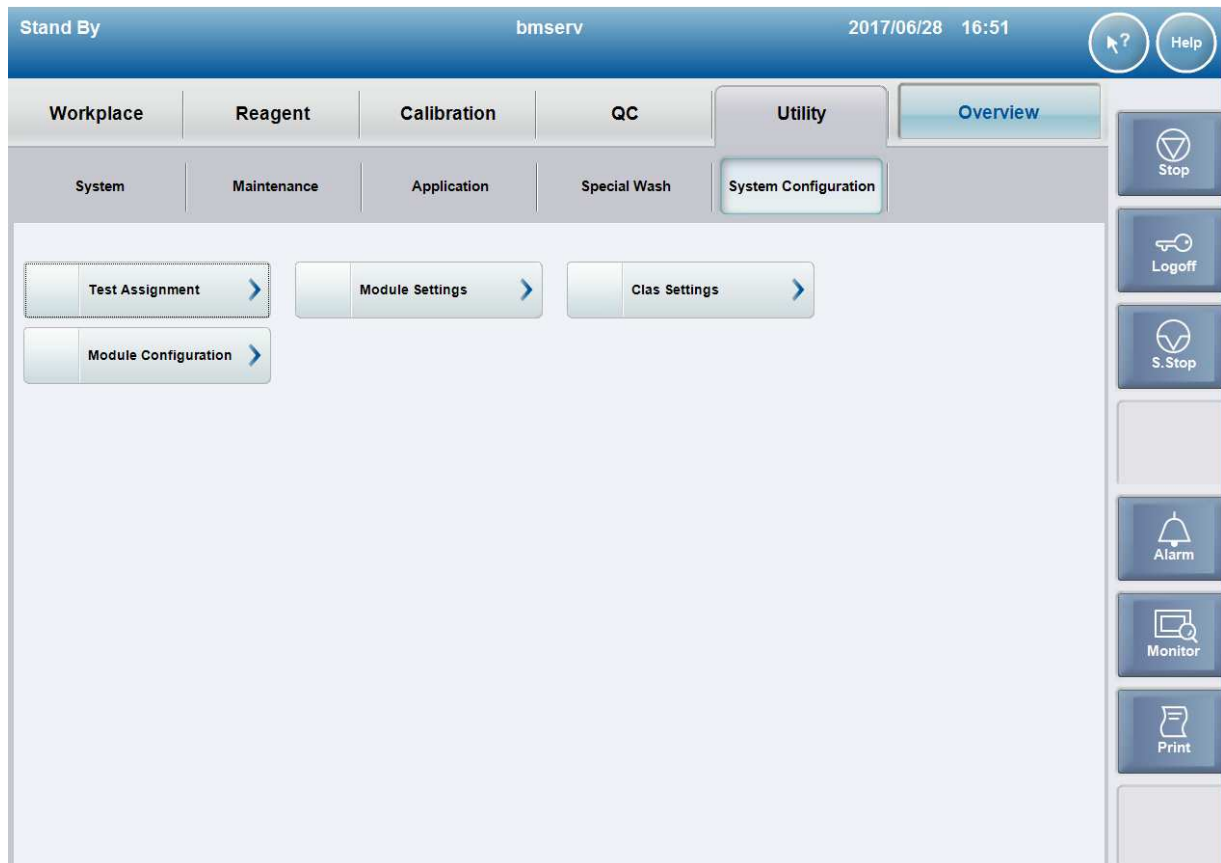
**Roche Diagnostics Asia Pacific Pte Ltd**

Email: [sg.regulatory@roche.com](mailto: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.:

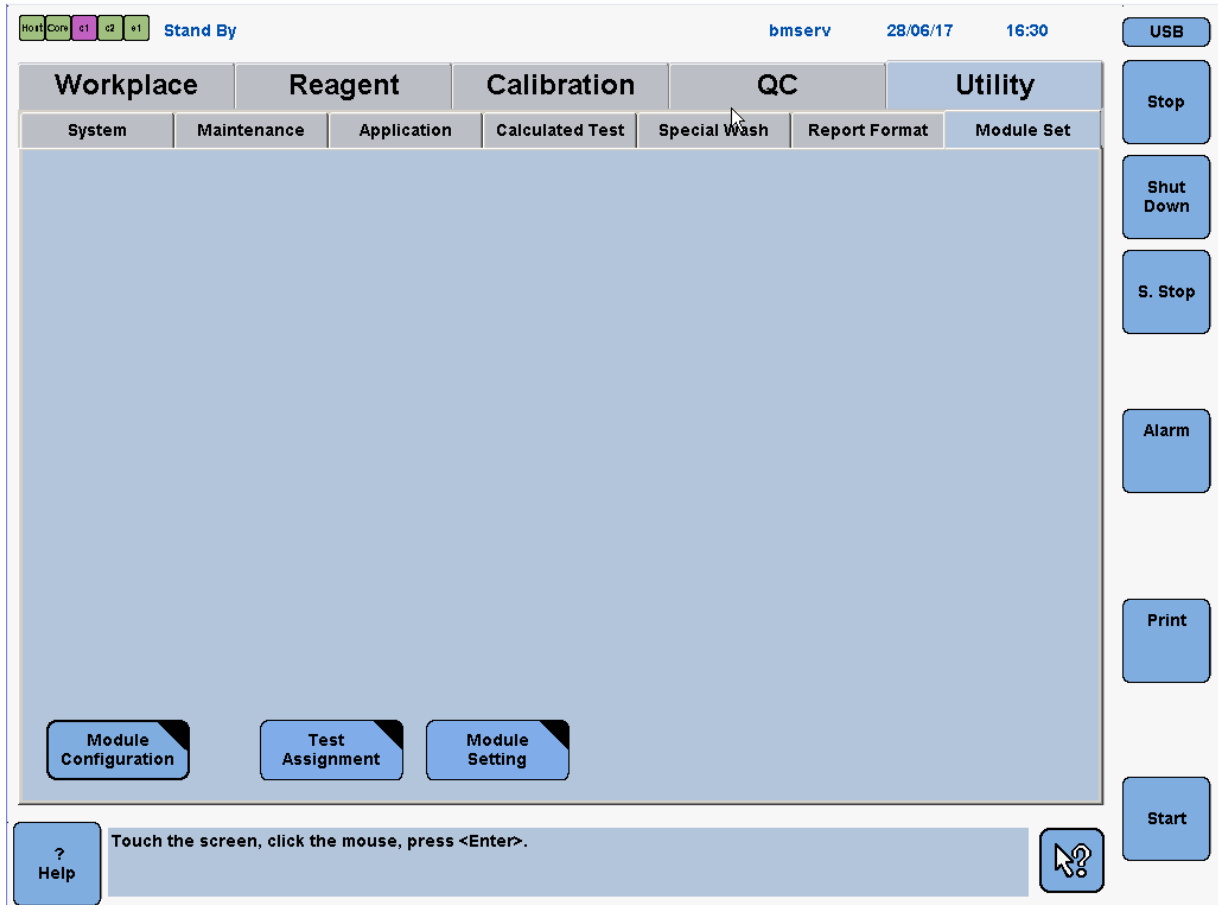
	Module Type	Module Name	Short Name	Serial No.	Module Rack Buffer
ISE 1	ISE	ISE1	I1	0800-40	
ISE 2	Inactive				
Buffer 1		MSB1	B1	1129-09	
Module 1	c 702	AU1	A1	1129-09	3
Buffer 2		MSB2	B2	0800-39	
Module 2	c 701	AU2	A2	0800-39	3
Buffer 3		MSB3	B3	0907-01	
Module 3	c 502	AU3	A3	0907-01	
Buffer 4		MSB4	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 shows a software interface for module configuration. At the top, there are status indicators for 'Host', 'Core', 'c1', 'c2', and 'e1', along with the text 'Stand By'. The system name 'bmserv' and the date/time '28/06/17 16:32' are also visible. A vertical toolbar on the right contains buttons for 'USB', 'Stop', 'Shut Down', 'S. Stop', 'Alarm', 'Print', and 'Start'. The main window has a menu bar with '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 'Module Configuration' table is as follows:

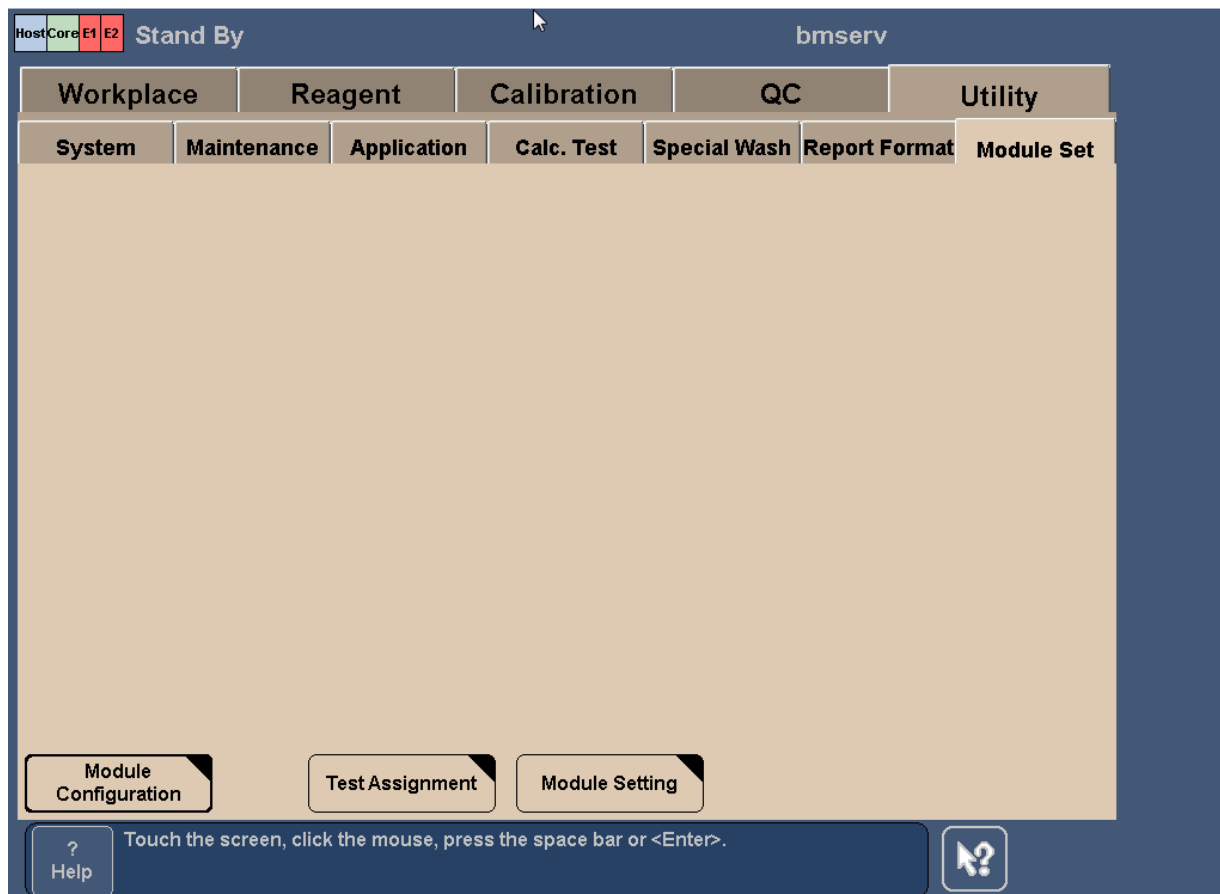
	Module Type	Module Name	Short Name	Serial No.	Module Rack Buffer
Module 1	c501	<input type="text" value="c1"/>	<input type="text" value="c1"/>	<input type="text" value="1155-20"/>	<input type="text" value="1"/>
Module 2	c501	<input type="text" value="c2"/>	<input type="text" value="c2"/>	<input type="text" 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 configuration window are buttons for 'Cancel', 'Module Type Setting', and 'OK'. A help bar at the very bottom contains a 'Help' button and the text: 'Type the serial number with up to 12 characters, then press <Enter>.' with a question mark icon.

## 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	<input type="text" value="E-1"/>	<input type="text" value="E1"/>	<input type="text"/>	<input type="text" value="1"/>
Module 2	E	<input type="text" value="E-2"/>	<input type="text" value="E2"/>	<input type="text"/>	<input type="text" value="1"/>
Module 3	Inactive	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Module 4	Inactive	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
ISE 1	Inactive	<input type="text"/>	<input type="text"/>	<input type="text"/>	
ISE 2	Inactive	<input type="text"/>	<input type="text"/>	<input type="text"/>	

Cancel Module Type Setting OK

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

## 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 interface. At the top, there is a title bar labeled "Alarm". Below it is a table titled "Alarm List" with the following columns: Code, Module, Level, Alarm, and Date/Time. The table contains six rows of alarm data. The first row is highlighted in red, indicating the selected alarm.

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

Below the table, the details for the selected alarm are displayed:

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.

At the bottom of the screen, there are five buttons: Maintenance, Delete, New Alarm, Sound, and 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 FSN-CPS-2017-12 "How to identify and deal with potential mixed sample results on cobas e602\_v2"**

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 **in combination** within a short time from time alarm "104-000005 Abnormal L2-line Movement" **within an immunochemistry module**. If yes, go to the next procedure for identifying of rack with potential mixed sample results.

**Note:**

**Time between the two alarms**

The time between the two alarms depends of 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).

2017/06/16 12:03:23 10 1E_PC 0013-000001 Rack Collect End	
2017/06/16 12:03:23 13 2E_SU 0741-000002 Rack Collect Complete	
2017/06/16 12:03:19 5 1A (A1) 104-000005-342 Abnormal L2-line Movement (1)	<b>(1)</b> Find L2 Line alarm and specify occurred module (circled in red)
2017/06/16 12:02:12 5 1A A1 402-050102-276 Sample Short	
2017/06/16 12:01:42 5 1A A1 316-000006-091 Tip/AssayCup Short	
2017/06/16 12:01:42 5 1A A1 315-000015-091 Solid Waste	
2017/06/16 12:01:11 5 1A (A1) 301-000015-315 Tip/Cup pick up error (3)	<b>(2)</b> Find the corresponding module (circled in red) at "start"
2017/06/16 12:00:50 5 2A (A1) 301-000002-315 Tip/Cup pick up error (3)	
2017/06/16 11:59:35 8 1E_PC 0011-000001 Rack Supply End	
2017/06/16 11:58:33 7 1E_PC 0010-000001 Operation	
2017/06/16 11:58:33 11 1E_SU 0510-000001 Change to Operation Request	
2017/06/16 11:58:33 6 1E_PC 0009-000001 Preparation (SU Wait)	
2017/06/16 11:52:26 4 1A A1 331-000013-409 Reagent Pack Masked	
2017/06/16 11:49:48 4 1A A1 317-000006-186 PreClean Short	
2017/06/16 11:49:28 6 18E_PC 0008-000018 Preparation (MSB)	
2017/06/16 11:49:28 6 95E_PC 0007-000095 Preparation (AU)	
2017/06/16 11:49:28 8 1E_SU 0001-000001 Start	
2017/06/16 11:49:28 8 1E_B1 0001-000001 Start	
2017/06/16 11:49:23 53 1E_PC 0006-000001 Preparation Start	
2017/06/16 11:49:18 2 1E (A1) 0001-000001 Start (2)	<b>(3)</b> Check whether the corresponding module (circled in red) has Tip/Cup pick up error in between (1) and (2).
2017/06/16 11:49:18 3 1E_PC 0027-000001 Operation Tm Start	
2017/06/16 11:48:53 4 1E_PC 0005-000001 Stand By	

If two alarms below occur in combination in an immunochemistry module, the failure could happen.

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

Note:

**Same alarms are put together in Daily Alarm Trace**

Daily Alarm Trace shows the first time of occurrence alarm only and the following same alarm are put together into the first alarm as shown in the example of Alarm Trace below. This showing way could make confusion as if it took longer time from the time of alarm "Tip/Cup pick up error" to the time of alarm "Abnormal L2-Line Movement". However, alarm "Tip/Cup pick up error" actually occurred (not shown i.e. being put together) much shorter from the time of occurrence of "Abnormal L2-Line Movement" alarm.

**[e.g.]**

Alarm "**301-000002** Tip/Cup pick up error" firstly occurred at 08:42:05 and then, the same alarm occurred three times within an operation status (4 times occurred totally = **4A**)

Alarm "**301-000015** Tip/Cup pick up error" firstly occurred at 08:42:50 and then, the same alarm occurred one time within an operation status (2 times occurred totally = **2A**)

```
2017/06/19 12:15:44 38 1 E SU 0001-000001 Start
2017/06/19 12:14:21 8 1A E1 315-000015-091 Solid Waste
2017/06/19 12:14:14 5 1A E1 104-000005-362 Abnormal L2-line Movement
2017/06/19 12:13:32 4 3R c5 0001-000003-012 Inc. Bath Water Level Sensor
.
.
.
2017/06/19 08:44:21 5 2A E1 315-000015-091 Solid Waste
2017/06/19 08:43:51 5 2A E1 351-000178-321 Determinations canceled
2017/06/19 08:43:50 5 2A E1 301-000015-315 Tip/Cup pick up error
2017/06/19 08:42:05 5 4A E1 301-000002-315 Tip/Cup pick up error
2017/06/19 08:40:33 8 1E PC 0025-000001 Operation (Clas)
.
.
.
2017/06/19 08:23:22 8 1E B1 0001-000001 Start
2017/06/19 08:23:22 8 1E B4 0001-000001 Start
2017/06/19 08:23:12 2 1E c7 0001-000001 Start
2017/06/19 08:23:12 2 1E c5 0001-000001 Start
2017/06/19 08:23:12 2 1E E2 0001-000001 Start
2017/06/19 08:23:12 2 1E E1 0001-000001 Start
2017/06/19 08:23:12 53 1E PC 0006-000001 Preparation Start
2017/06/19 08:23:12 2 1E ISE 0001-000001 Start
2017/06/19 08:23:12 3 1E PC 0027-000001 Operation Tm Start
2017/06/19 08:13:35 25 1 E PC 0005-000001 Stand By
```

**Time between the two alarms**

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).

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

## 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.

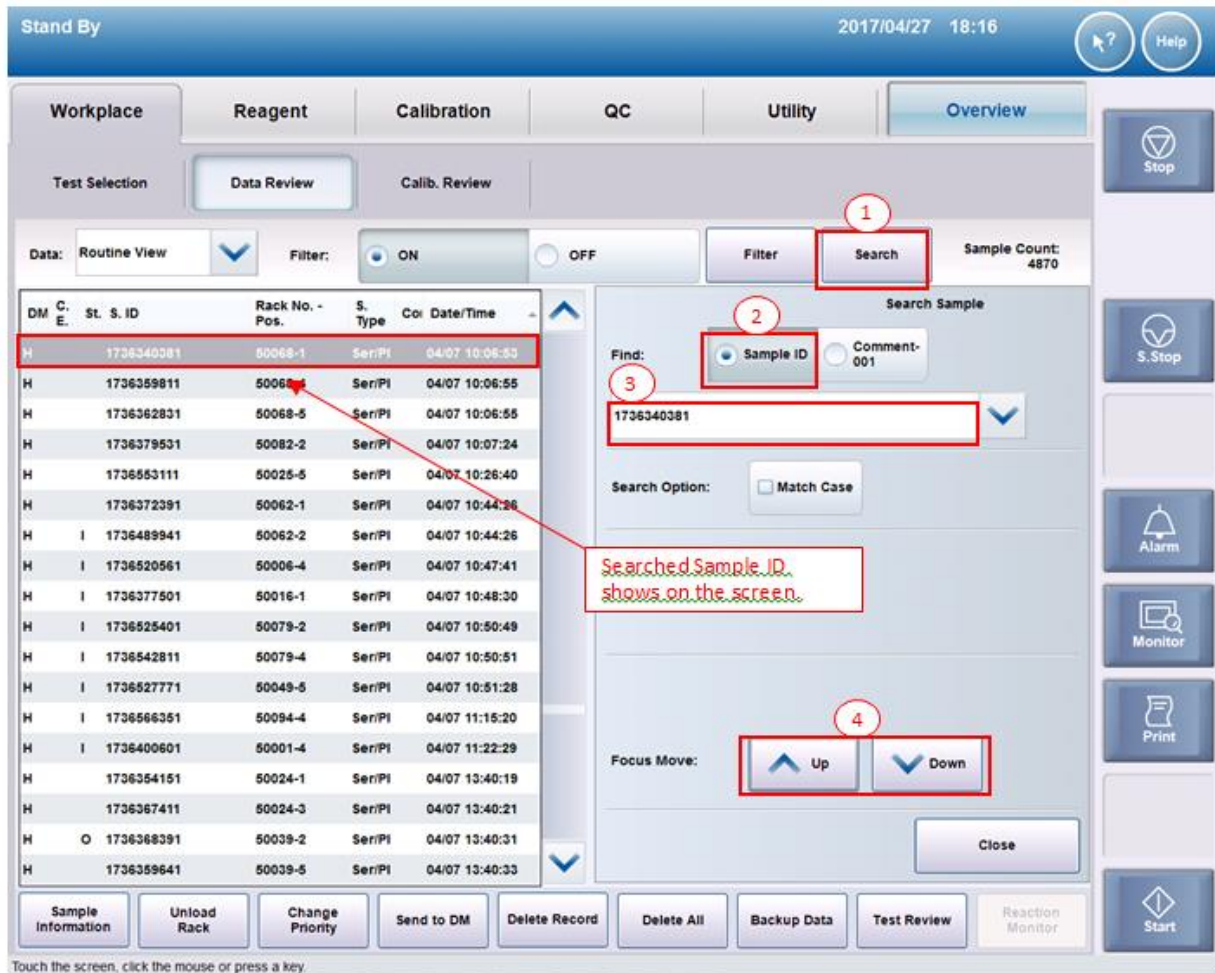


Figure 1. Data Review screen

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

The screenshot shows the 'Test Review' interface. At the top, sample information is displayed: Sample: Routine, S. Type: Ser/PI, Sample ID: 1736340381, Status: Complete, Carryover Evasion: . A red box highlights 'Rack No. - Pos. : 50068-1' with an arrow pointing to another red box labeled 'Rack and position'. Below this is a table with columns: Select Result, Test, Unit, Result, Alarm, R. M., Dil. A. U., Time, C. E., DM, St., Result, Alarm, R. M., Dil. A. U., Time, C. E., DM, St. The table contains four rows of data. The last row is highlighted with a red box around 'A2-1 11:29:07', with an arrow pointing to a red box containing the text 'Verify corresponding e602 module and sampling time.' At the bottom, there are several buttons: Sample Information, Reagent Detail, Original Data, All Results, Reaction Monitor, Delete Test, Update, Cancel, Previous, Next, and Close.

Select Result	Test	Unit	Result	Alarm	R. M.	Dil. A. U.	Time	C. E.	DM	St.	Result	Alarm	R. M.	Dil. A. U.	Time	C. E.	DM	St.
1st	AHBS	IU/L	118.0			A1-1	10:34:28			H								
1st	A-HCV II	COI	0.038		N...	A1-1	10:35:10			H								
1st	HBSAGII	COI	0.335		N...	A1-2	10:34:49			H								
1st	HIVCO...	COI	0.226		N...	A2-1	11:29:07			H								

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 shows the Data Review screen in the bmserv interface. The top bar displays "Stand By", "bmserv", and the date/time "2017/06/13 16:47". The main interface has tabs for "Workplace", "Reagent", "Calibration", "QC", "Utility", and "Overview". The "Data Review" tab is selected. Below the tabs, there are controls for "Data: Routine View", "Filter: ON/OFF", "Filter", "Search", and "Sample Count: 50".

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

Below the table, there is a detailed view for a selected sample (TSH) showing "Result: 0.275 IU/mL" and "Alarm: 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".

Figure 3. Data Review screen

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

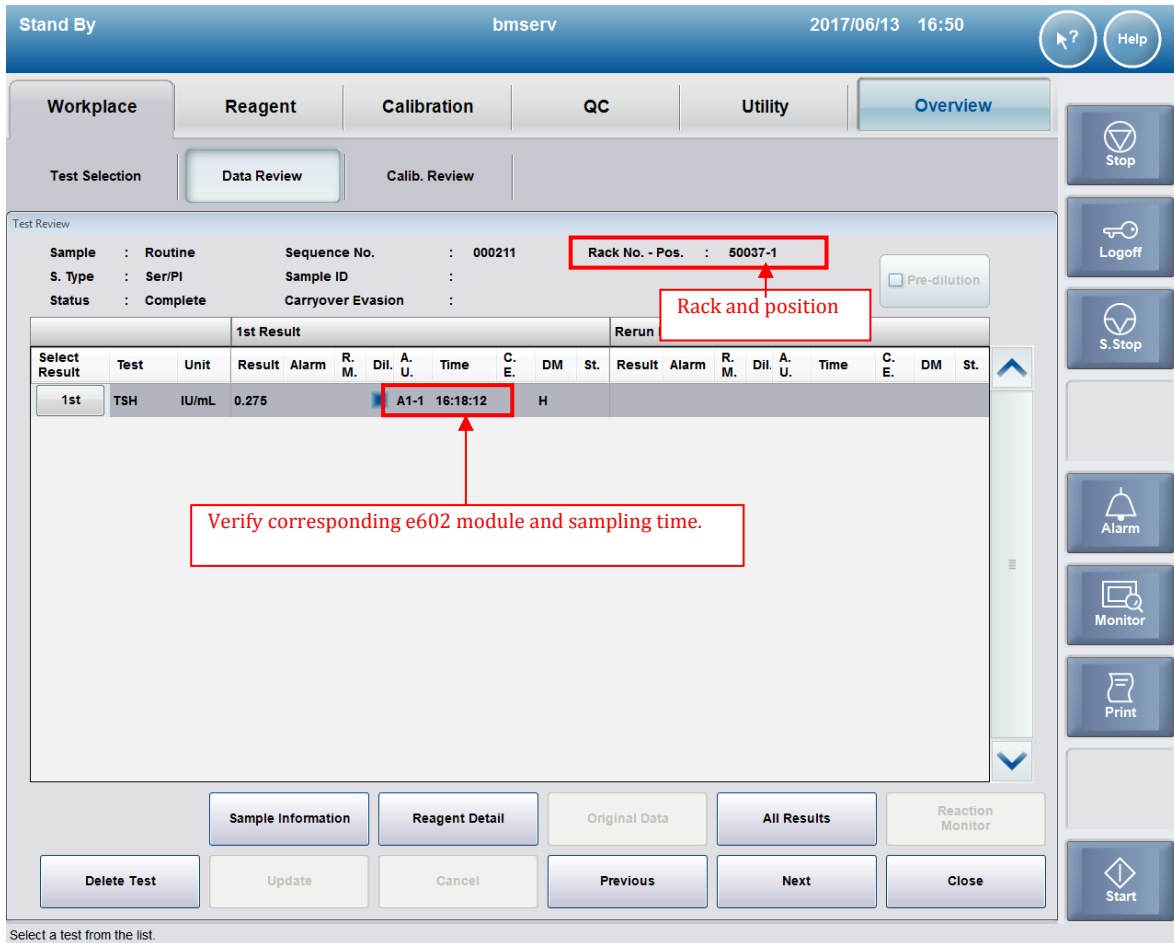


Figure 4. Test Review screen

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.

## 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 301-00015 (Caution Level) is also issued earlier on the Alarm screen.

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

The screenshot shows the Alarm screen of a cobas e601 system. The system status is 'Stand By' and the time is 13:55 on 13/06/17. The alarm table is as follows:

Code	Module	Level	Alarm	Date/Time
104-0005	e601	Sample Stop	Abnormal L2-line Movement	13/06/17 13:34
402-0401	e601	Caution	Sample Short	13/06/17 13:33
315-0015	e601	Caution	Solid Waste	13/06/17 13:33
301-0015	e601	Caution	Tip/Cup pick up error	13/06/17 13:32
301-0002	e601	Caution	Tip/Cup pick up error	13/06/17 13:32

The selected alarm (104-0005) has the following details:

**Description and Remedy**

Code :104-0005  
 Level :Sample 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.

Buttons at the bottom of the alarm screen include: Delete, New Alarm, Sound, Maint., and Close. A vertical toolbar on the right contains: USB, Stop, Shut Down, S. Stop, Alarm, Print, and Start.

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 FSN-CPS-2017-12 “How to identify and deal with potential mixed sample results on cobas e601\_V2”**

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 **in combination** within a short time from the time alarm “104-000005 Abnormal L2-line Movement” **within an immunochemistry module**. If yes, go to the next procedure for identifying of rack with potential mixed sample results.

**Note:**

**Time between the two alarms**

The time between the two alarms depends of 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).

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 (1)
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 J
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 (3)
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 (3)
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
13/06 13:31	628	1	E	11-502-0000-000	Restart
13/06 13:31	4	7	A	02-113-0006-001	Abnormal Temp Control
13/06 13:31	2	9	A	01-029-0001-065	Inc. Water Level Too Low
13/06 13:31	2	9	A	01-113-0010-063	Abnormal Temp Control
13/06 13:30	4	1	E	02-001-0000-000	START (2)
13/06 13:30	3	1	E	15-001-0000-000	Start

(1) Find L2 Line alarm and specify occurred module (circled in red)

(2) Find the corresponding module (circled in red) at “start”

(3) Check whether the corresponding module (circled in red) has Tip/Cup pick up error in between (1) and (2).

If two alarms below occur in combination in an immunochemistry module, the failure could happen.

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

Note:

**Same alarms are put together in Daily Alarm Trace**

Daily Alarm Trace shows the first time of occurrence alarm only and the following same alarm are put together into the first alarm as shown in the example of Alarm Trace below.

This showing way could make confusion as if it took longer time from the time of alarm "Tip/Cup pick up error" to the time of alarm "Abnormal L2-Line Movement". However, alarm "Tip/Cup pick up error" actually occurred (not shown i.e. being put together) much shorter from the time of occurrence of "Abnormal L2-Line Movement" alarm.

**[e.g.]**

Alarm "301-0002 Tip/Cup pick up error" firstly occurred at 08:42:05 and then, the same alarm occurred three times within an operation status (4 times occurred totally = **4A**)

Alarm "301-0015 Tip/Cup pick up error" firstly occurred at 08:42:50 and then, the same alarm occurred one time within an operation status (2 times occurred totally = **2A**)

13/06 12:14	2	1A 01-113-0009-063	Abnormal Temp Control
<u>13/06 12:14</u>	<u>62</u>	<u>1A 02-104-0005-342</u>	<u>Abnormal L2-line Movement</u>
13/06 12:13	4	1A 02-402-0401-276	Sample Short
13/06 12:13	4	1A 02-315-0015-091	Solid Waste
.	.	.	.
.	.	.	.
.	.	.	.
<u>13/06 08:43</u>	<u>4</u>	<u>2A 02-301-0015-315</u>	<u>Tip/Cup pick up error</u>
<u>13/06 08:42</u>	<u>4</u>	<u>4A 02-301-0002-315</u>	<u>Tip/Cup pick up error</u>
13/06 08:31	<u>2</u>	<u>30A 01-029-0001-065</u>	Inc. Water Level Too Low
13/06 08:31	2	7A 01-113-0010-063	Abnormal Temp Control
13/06 08:31	<u>4</u>	<u>25A 02-113-0006-141</u>	Abnormal Temp Control
13/06 08:31	628	1E 11-502-0000-000	Restart
13/06 08:31	4	7A 02-113-0006-001	Abnormal Temp Control
13/06 08:31	2	9A 01-029-0001-065	Inc. Water Level Too Low

**Time between the two alarms**

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).

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

## 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.

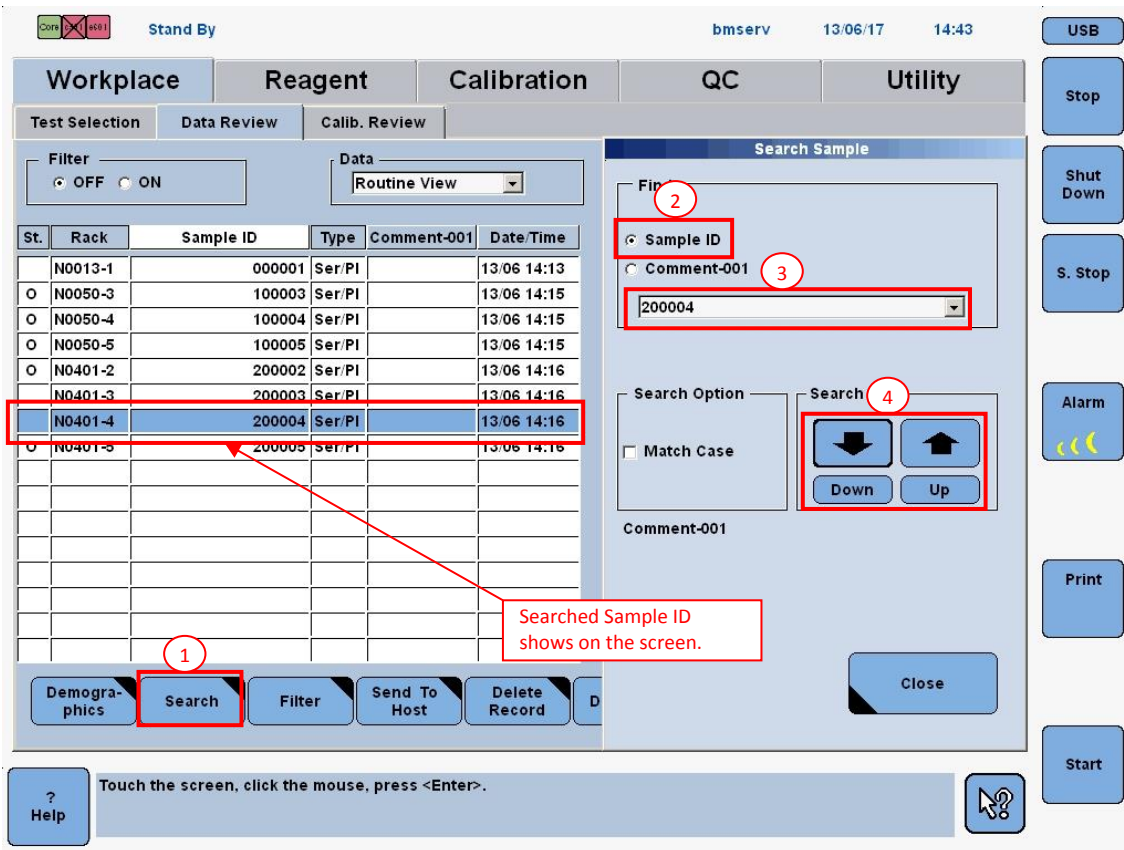


Figure 1. Data Review screen

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

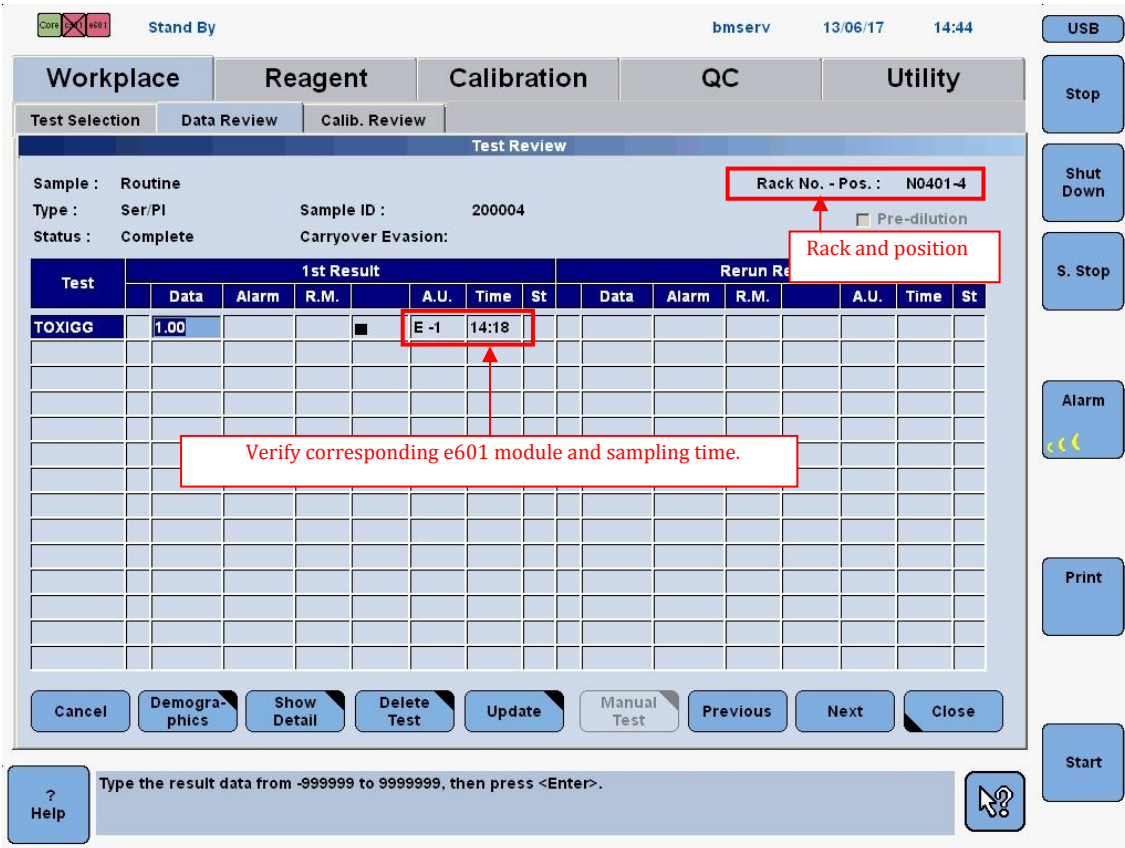


Figure 2. Test Review screen

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' application. The interface includes a top navigation bar with 'Workplace', 'Reagent', 'Calibration', 'QC', and 'Utility' tabs. Below this, there are sub-tabs for 'Test Selection', 'Data Review', and 'Calib. Review'. A 'Filter' section has 'OFF' selected. The 'Data' dropdown is set to 'Routine View', and 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, which contains values such as N0050-5, N0401-1, N0401-2, N0401-3, N0401-4, N0401-5, N, N0050-3, N0050-4, N0050-5, N, N0401-2, N0401-3, N0401-4, and N0401-5. The 'Test' column shows 'TOXIGG' with a 'Result' of '1.00' and 'Unit' of 'IU/mL'. The bottom of the screen features a toolbar with buttons for 'Demographics', 'Search', 'Filter', 'Send To Host', 'Delete Record', 'Delete All', 'Backup Data', 'Test Review', and 'Reaction Monitor'. On the right side, there are additional buttons: 'USB', 'Stop', 'Shut Down', 'S. Stop', 'Alarm', 'Print', and 'Start'. A 'Help' button is located at the bottom left.

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	TOXIGG	1.00			IU/mL
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

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

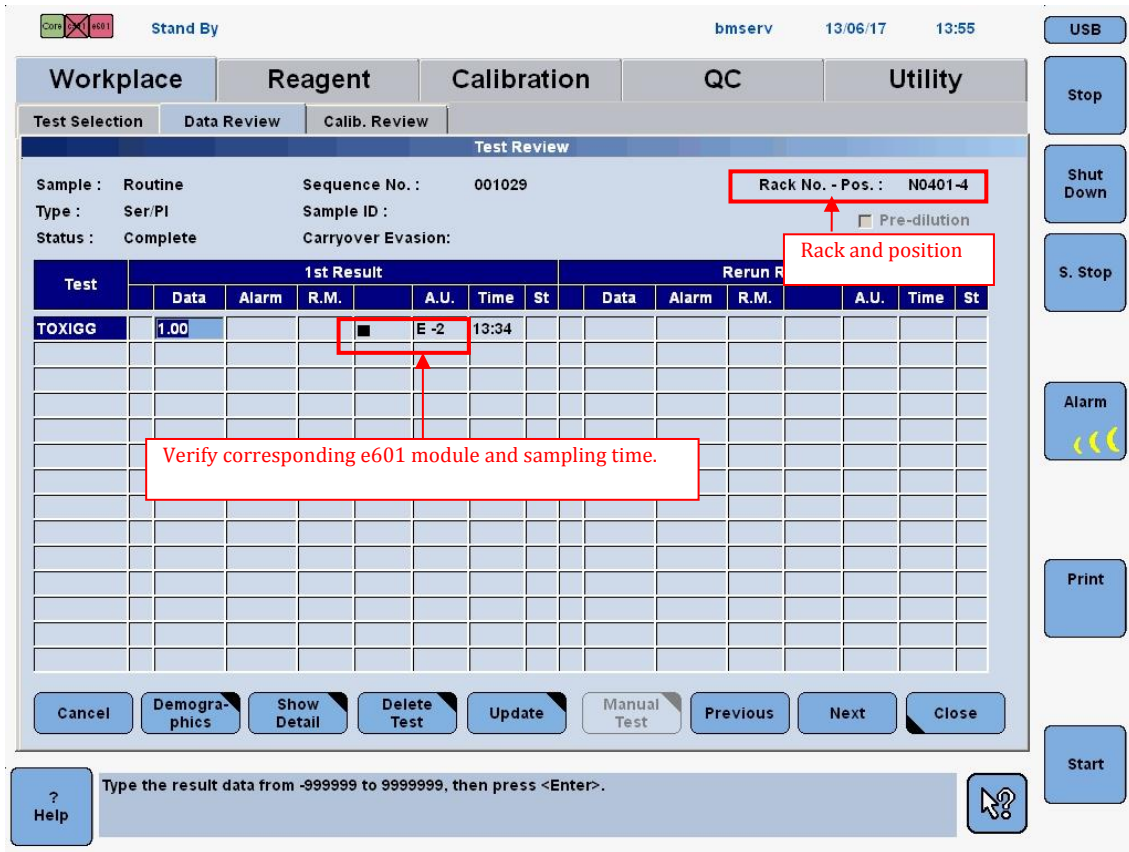


Figure 4. Test Review screen

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.

The screenshot shows the BMSERV Alarm screen. At the top, it displays 'Stand By', 'BMSERV', and the date/time '17/06/14 (Wed) 12:20'. The main area is titled 'Alarm' and contains a table with the following data:

Code	Module	Level	Alarm	Date/Time
104-0005	E1	S. STOP	Abnormal L2-line Movement	17/06/14 11:59
028-0001	Core	Caution	Execute Rack Collect	17/06/14 12:00
402-0317	E1	Caution	Sample Short	17/06/14 11:58
315-0015	E1	Caution	Solid Waste	17/06/14 11:58
301-0015	E1	Caution	Tip/Cup pick up error	17/06/14 11:57
301-0002	E1	Caution	Tip/Cup pick up error	17/06/14 11:57

Below the table is a section titled 'Description and Remedy' for the selected alarm (Code: 104-0005, Level: S. STOP). The description reads: 'L2-line rack transfer mechanism does not reach at Out-Buffer when L2-line rack transfer mechanism moving from sampling position.' The remedy section is currently empty.

At the bottom of the screen, there are several buttons: 'Delete', 'New Alarm', 'Sound', 'Maint.', and 'Close'. A 'Help' button is also present on the left side of the bottom bar.

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.

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 **in combination** within a short time from the time alarm "104-000005 Abnormal L2-line Movement" **within an immunochemistry module**. If yes, go to the next procedure for identifying of rack with potential mixed sample results.

**Note:**

**Time between the two alarms**

The time between the two alarms depends of 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).

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 (1)
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 (3)
06/14 11:57	5	1	A	03-301-0002-315	Tip/Cup pick up error (3)
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 11:55	18	1	E	15-040-0001-000	Ready to Operation
06/14 11:55	18	1	E	15-039-0001-000	Preparation for measurement Complete
06/14 11:55	4	1	E	15-039-0001-000	Preparation for measurement Complete
06/14 11:55	8	1	E	99-033-0001-000	Ready for Operation Complete
06/14 11:53	2	1	E	01-001-0001-000	START
06/14 11:53	2	1	E	02-001-0001-000	START
06/14 11:53	2	1	E	03-001-0001-000	START (2)
06/14 11:53	2	1	E	08-001-0001-000	START
06/14 11:53	2	1	E	07-001-0001-000	START
06/14 11:53	3	1	E	15-001-0001-000	Start 1
06/14 11:53	54	1	E	99-037-0001-000	Parameter Check Complete 1
06/14 11:53	53	1	E	99-042-0001-000	DB Parameter Check OK
06/14 11:53	6	1	E	99-043-0001-000	Reagent Parameter Check Complete
06/14 11:53	4	1	E	99-001-0001-000	Start

(1) Find L2 Line alarm and specify occurred module (circled in red)

(2) Find the corresponding module (circled in red) at "start"

(3) Check whether the corresponding module (circled in red) has Tip/Cup pick up error in between (1) and (2).

If two alarms below occur in combination in an immunochemistry module, the failure could happen.

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

Note:

**Same alarms are put together in Daily Alarm Trace**

Daily Alarm Trace shows the first time of occurrence alarm only and the following same alarm are put together into the first alarm as shown in the example of Alarm Trace below.

This showing way could make confusion as if it took longer time from the time of alarm "Tip/Cup pick up error" to the time of alarm "Abnormal L2-Line Movement". However, alarm "Tip/Cup pick up error" actually occurred (not shown i.e. being put together) much shorter from the time of occurrence of "Abnormal L2-Line Movement" alarm.

**[e.g.]**

Alarm "301-0002 Tip/Cup pick up error" firstly occurred at 08:42:05 and then, the same alarm occurred three times within an operation status (4 times occurred totally = 4A)

Alarm "301-0015 Tip/Cup pick up error" firstly occurred at 08:42:50 and then, the same alarm occurred one time within an operation status (2 times occurred totally = 2A)

06/14 12:14	7	1	E	15-005-0001-000	Rack Supply Complete
06/14 12:14	11	1	E	99-016-0001-000	Restart Disable (All Module)
06/14 12:14	5	1	A	03-104-0005-342	Abnormal L2-line Movement
06/14 12:13	5	1	A	03-402-0317-276	Sample Short
06/14 12:13	5	1	A	03-315-0015-091	Solid Waste
06/14 08:42	5	2A		03-301-0015-315	Tip/Cup pick up error
06/14 08:42	5	4A		03-301-0002-315	Tip/Cup pick up error
06/14 08:42	6	1	E	15-005-0001-000	Rack Supply Complete
06/14 08:42	43	1	E	99-017-0001-000	Barcode Read Complete
06/14 08:41	10	1	E	99-013-0001-000	Rack Supply Complete
06/14 08:40	18	1	E	15-040-0001-000	Ready to Operation

**Time between the two alarms**

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).

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

## 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.

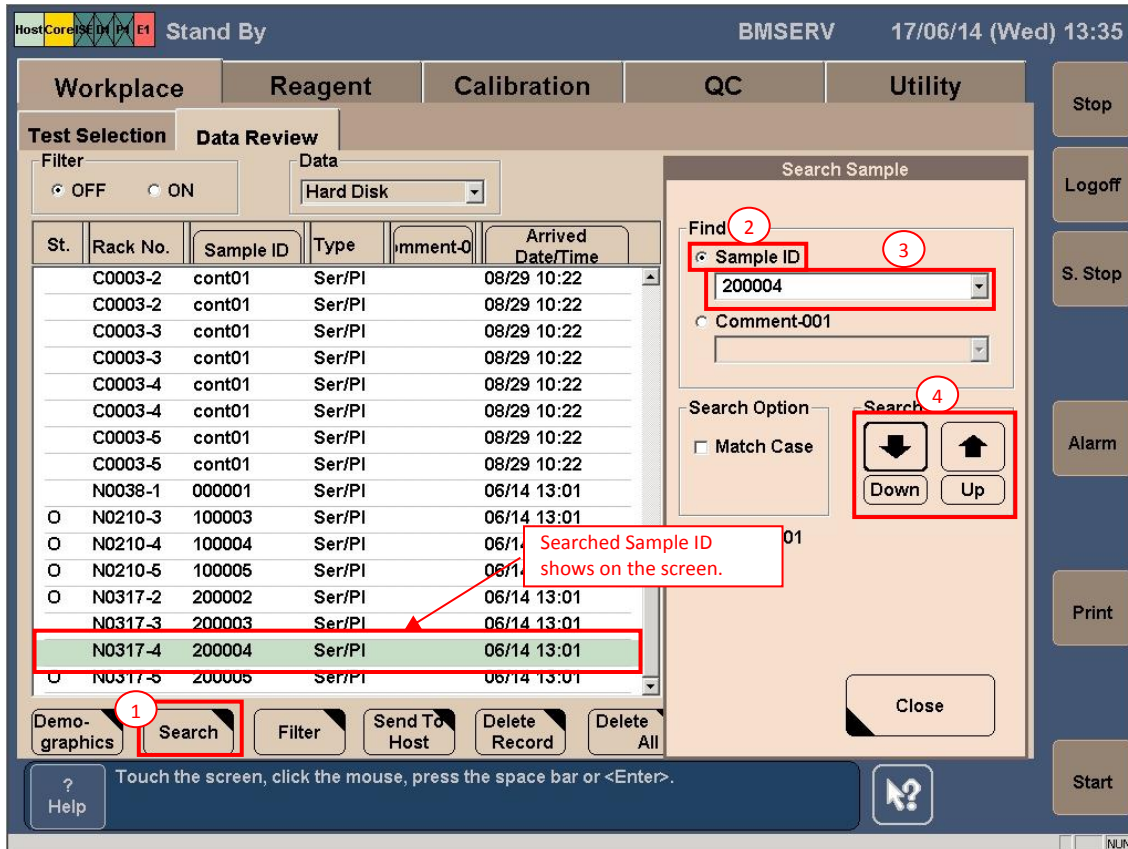


Figure 1. Data Review screen

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

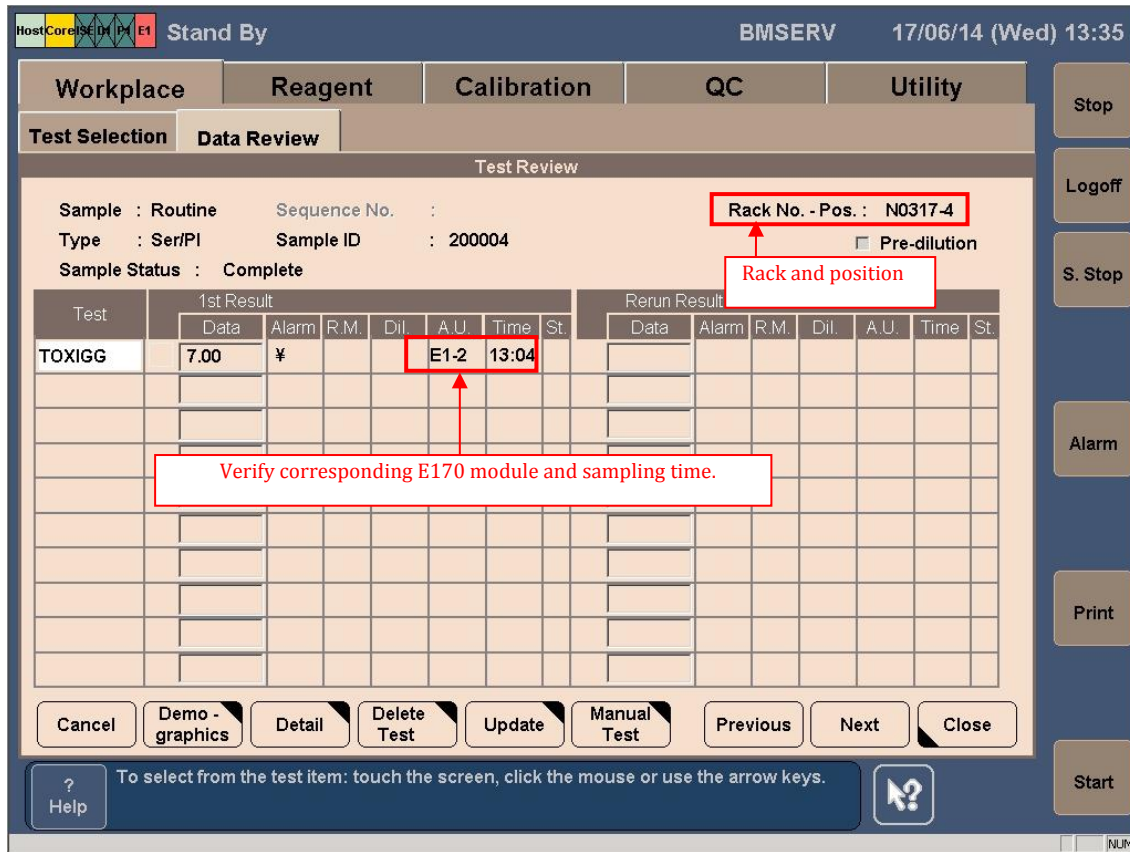


Figure 2. Test Review screen

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".

The screenshot displays the 'Data Review' screen. At the top, it shows 'Host Core SE 01 E1 Stand By', 'BMSERV', and the date/time '17/06/14 (Wed) 12 21'. Below this are tabs for 'Workplace', 'Reagent', 'Calibration', 'QC', and 'Utility'. The 'Data Review' section includes a 'Filter' set to 'OFF' and 'Data' set to 'Hard Disk'. The 'Sample Count' is 159. A table lists samples with columns: St., S. No., Rack, Sample, Type, Comment, Arrived Date/Time, Test, 1st, and Rerun. The 'Rack' column is highlighted in red, and the 'Test' column is highlighted in green. The table shows samples from rack N0317-2 to N0317-5. A 'TOXIGG' test result is visible for sample N000184. At the bottom, there are buttons for 'Demo-graphics', 'Search', 'Filter', 'Send To Host', 'Delete Record', 'Delete All', 'Backup Data', 'Test Review', and 'Reaction Monitor'. A 'Help' button is also present.

St.	S. No.	Rack	Sample	Type	Comment	Arrived Date/Time	Test	1st	Rerun
O	N000166	N		Ser/PI			TOXIGG	4.00	¥
O	N000167	N0317-2		Ser/PI		06/14 10:39			
	N000168	N0317-3		Ser/PI		06/14 10:39			
O	N000169	N0317-4		Ser/PI		06/14 10:39			
	N000170	N0317-5		Ser/PI		06/14 10:39			
	N000171	N0038-1		Ser/PI		06/14 11:55			
O	N000176	N		Ser/PI					
O	N000177	N		Ser/PI					
	N000178	N0210-3		Ser/PI		06/14 11:56			
O	N000179	N0210-4		Ser/PI		06/14 11:56			
O	N000180	N0210-5		Ser/PI		06/14 11:56			
O	N000181	N		Ser/PI					
O	N000182	N0317-2		Ser/PI		06/14 11:56			
	N000183	N0317-3		Ser/PI		06/14 11:56			
	N000184	N0317-4		Ser/PI		06/14 11:56			
O	N000185	N0317-5		Ser/PI		06/14 11:56			

Figure 3. Data Review screen

