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 *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)
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.

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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.

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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 moodule
- 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 e**602"
b) **See Attachment 2** "How to identify and deal with potential mixed sample results on **cobas e**601"
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.

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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,

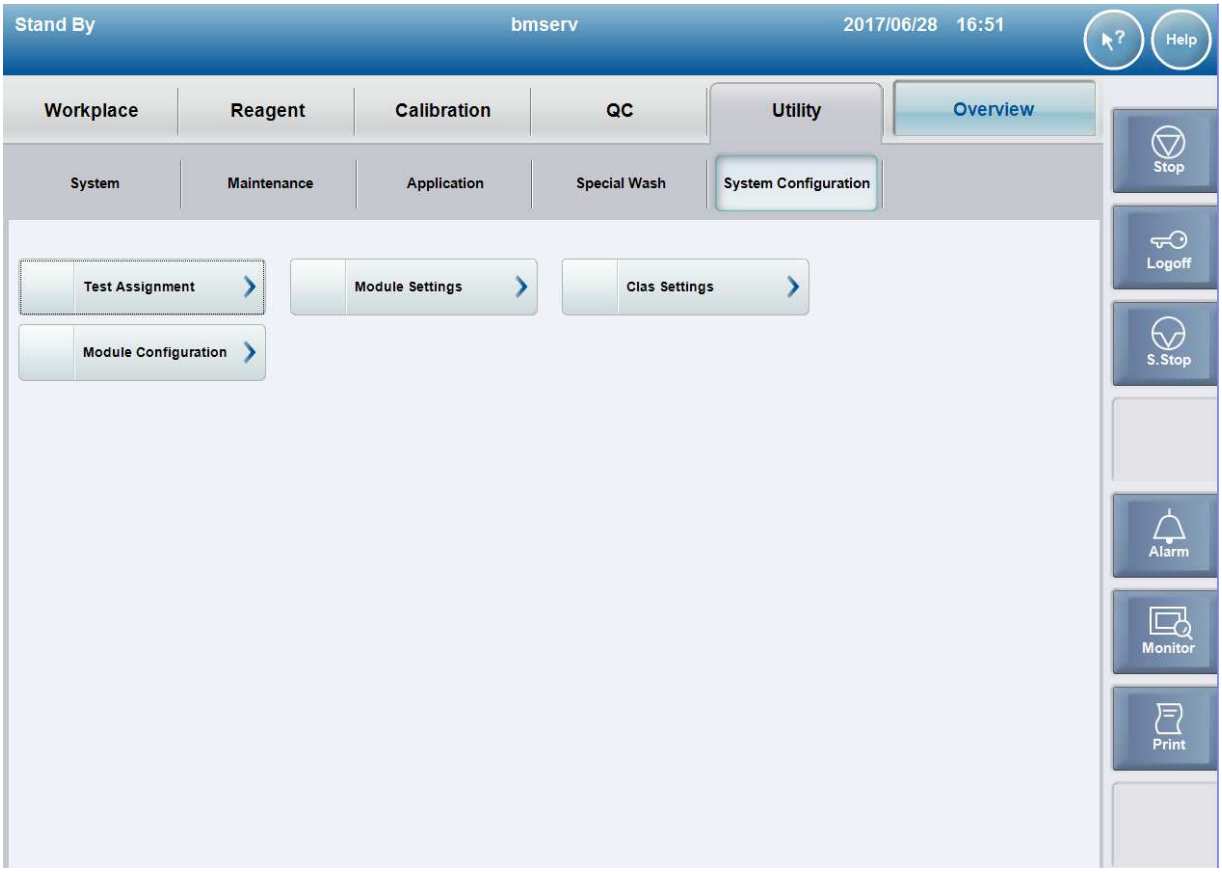
Roche Diagnostics Asia Pacific Pte Ltd
Email: sg.regulatory@roche.com

ATTACHMENT A

e602 Module Rack Buffer Setting

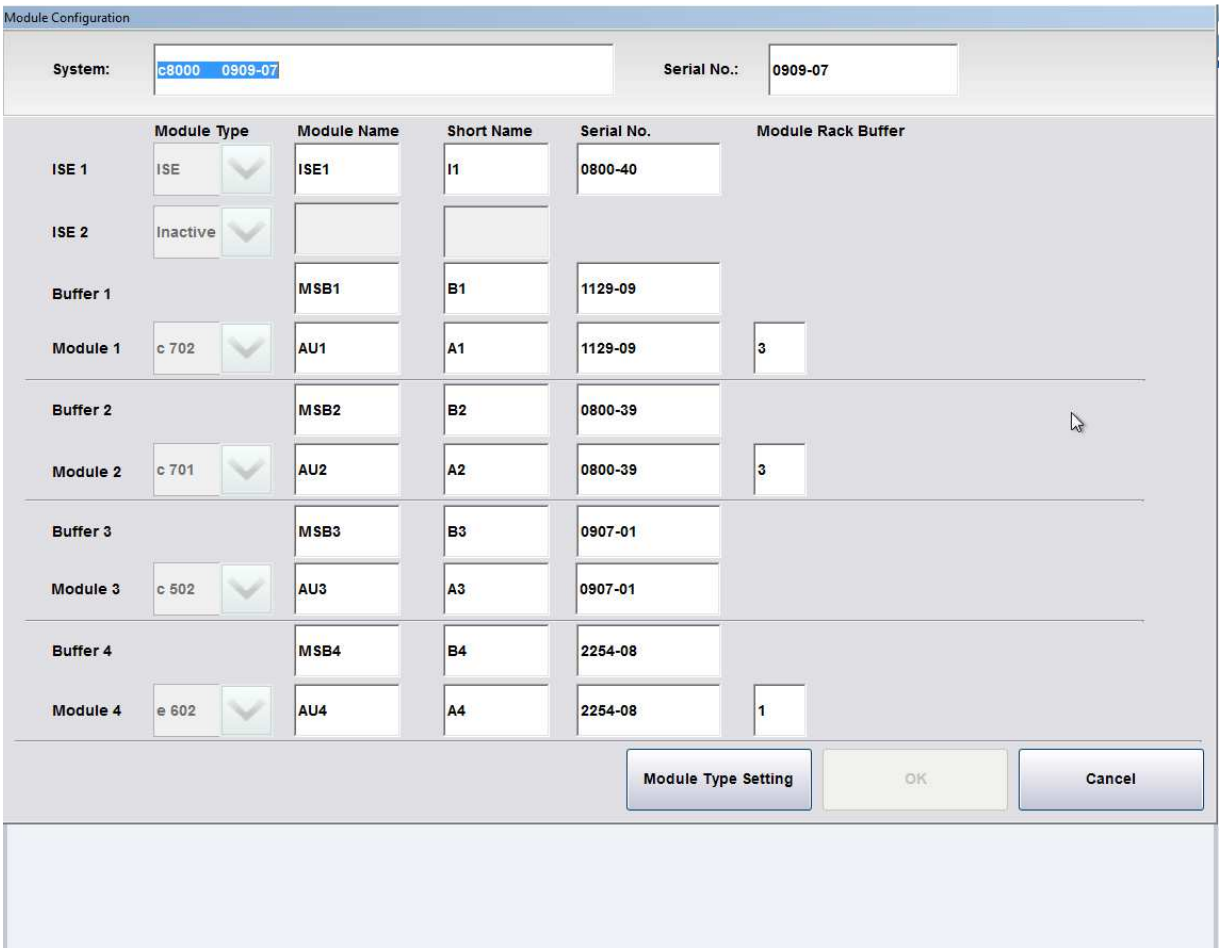
This screen can be accessed by an operator with administrator level password only.

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.

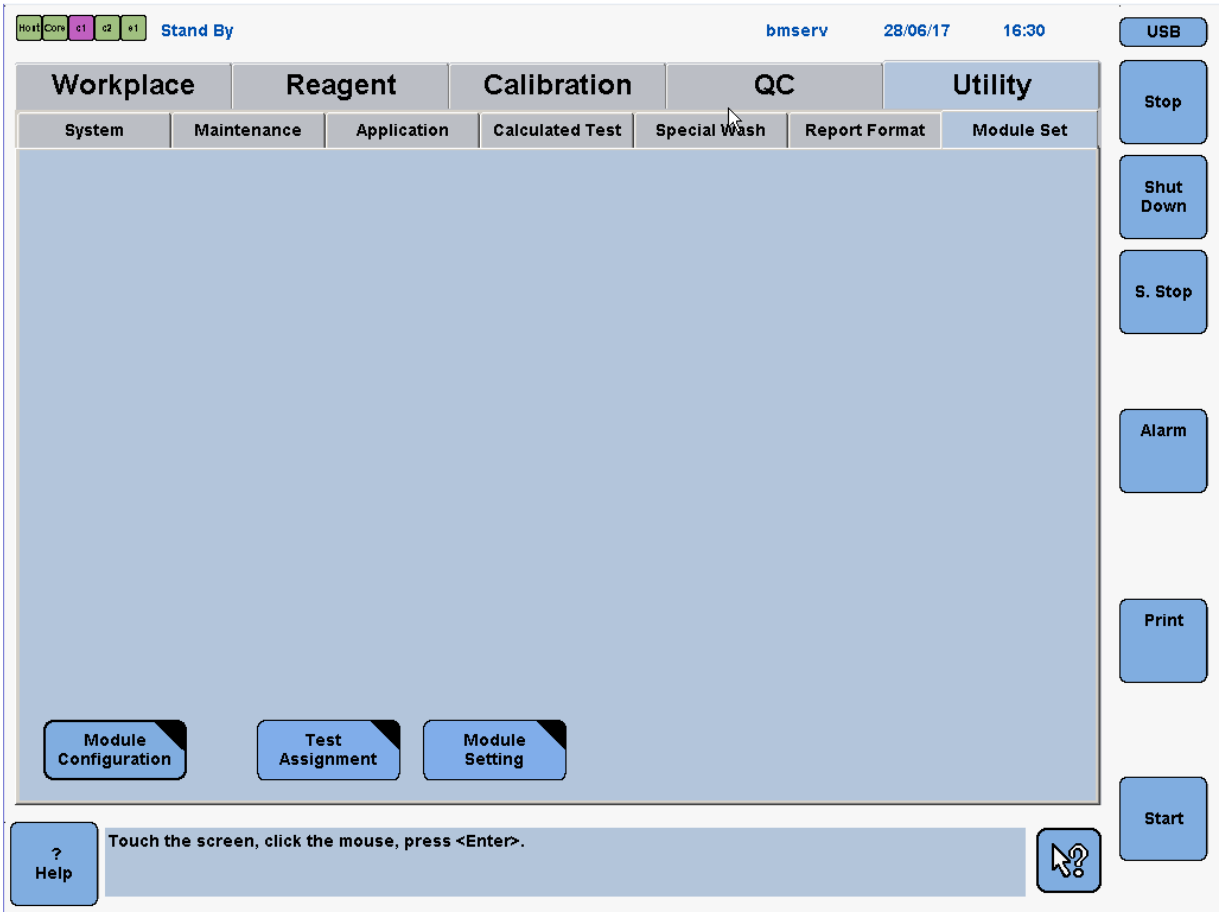


ATTACHMENT B

e601 Module Rack Buffer Setting

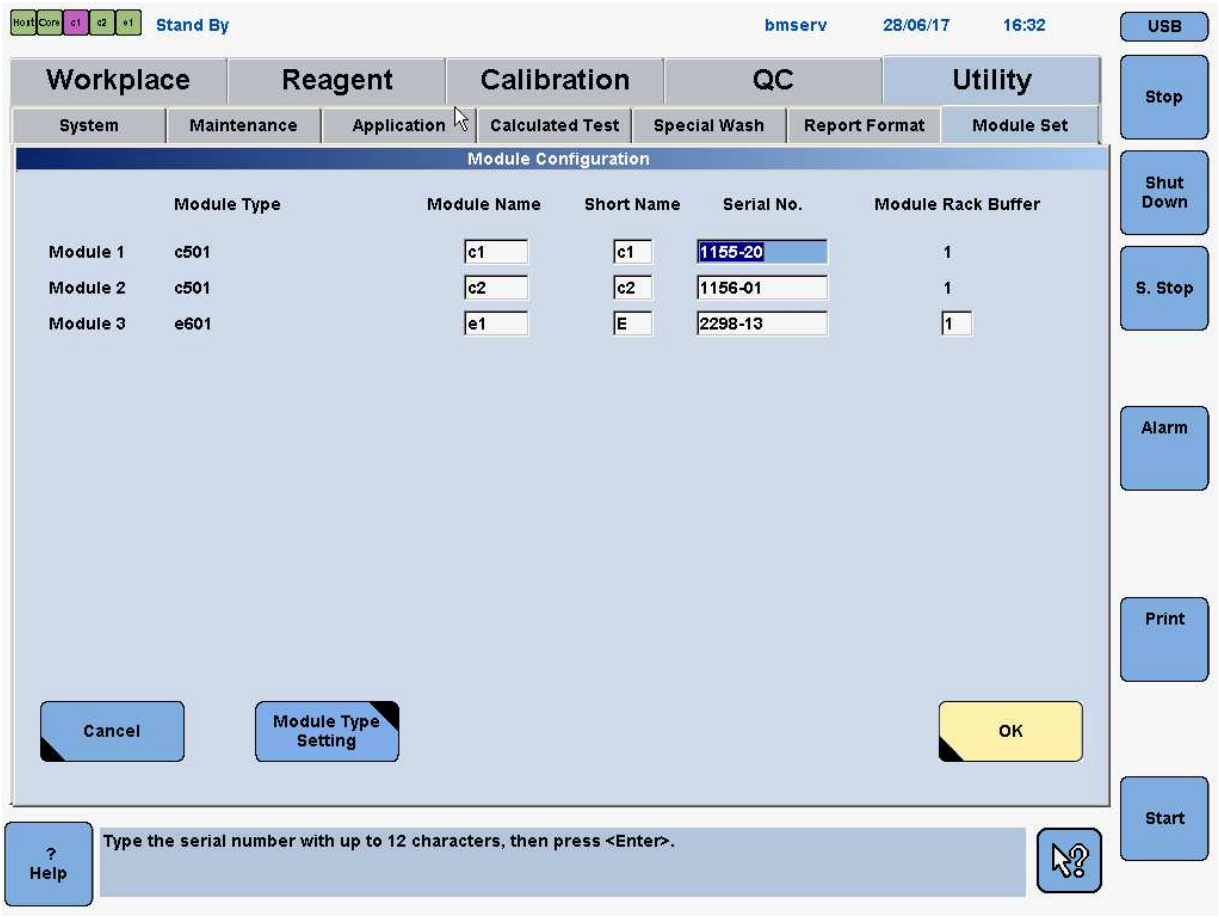
This screen can be accessed by an operator with administrator level password only.

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.

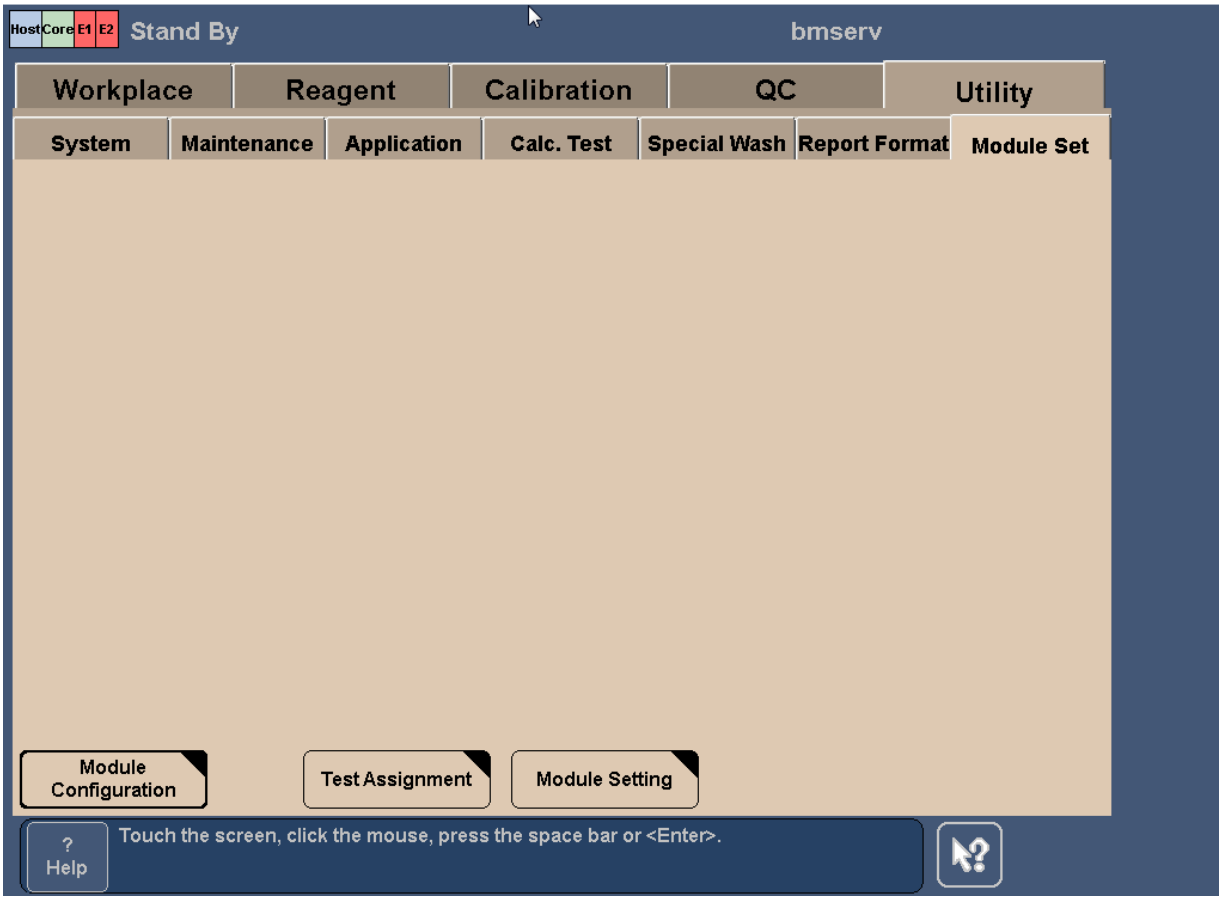


ATTACHMENT C

E170 Module Rack Buffer Setting

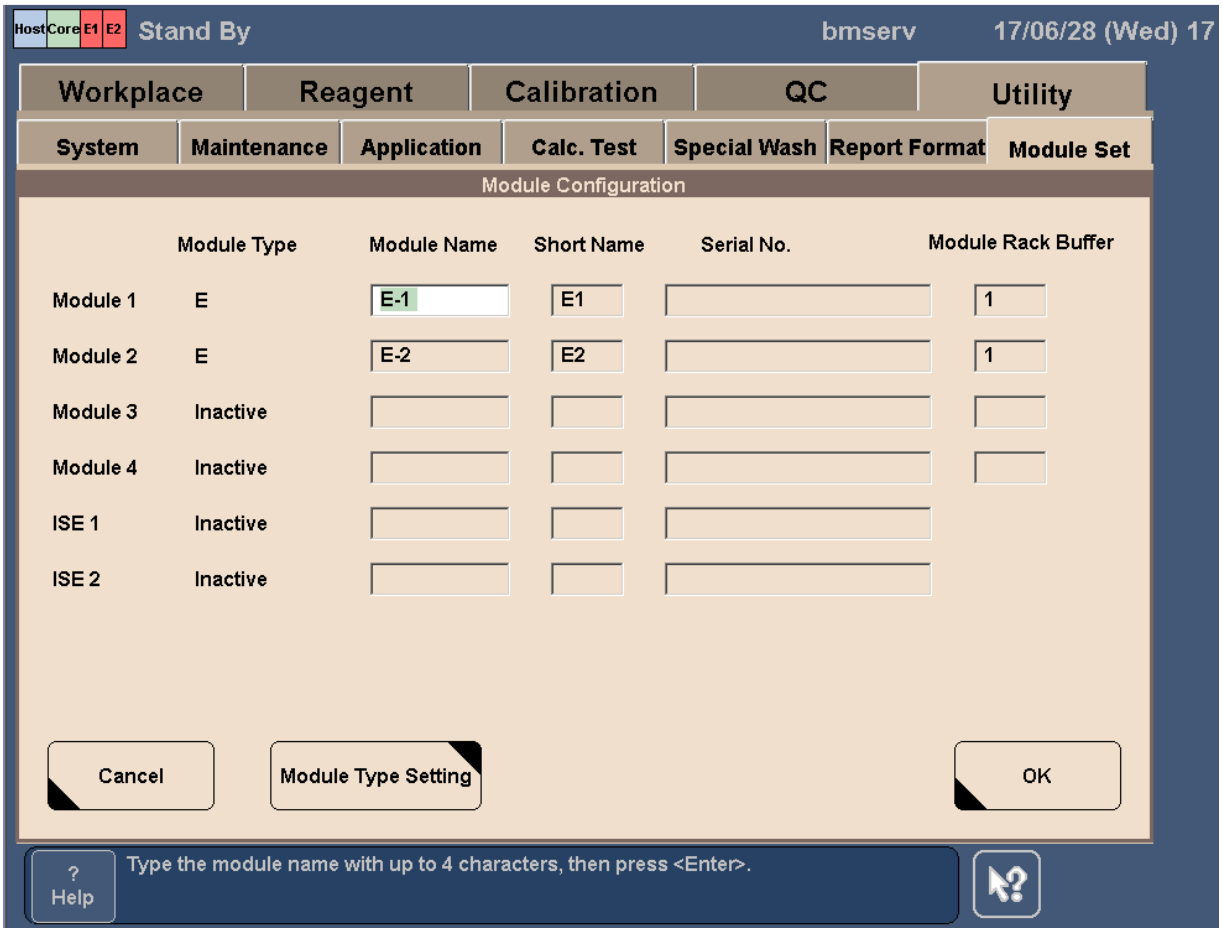
This screen can be accessed by an operator with administrator level password only.

Step 1: Select Utility > Module Set > Module Configuration



ATTACHMENT C

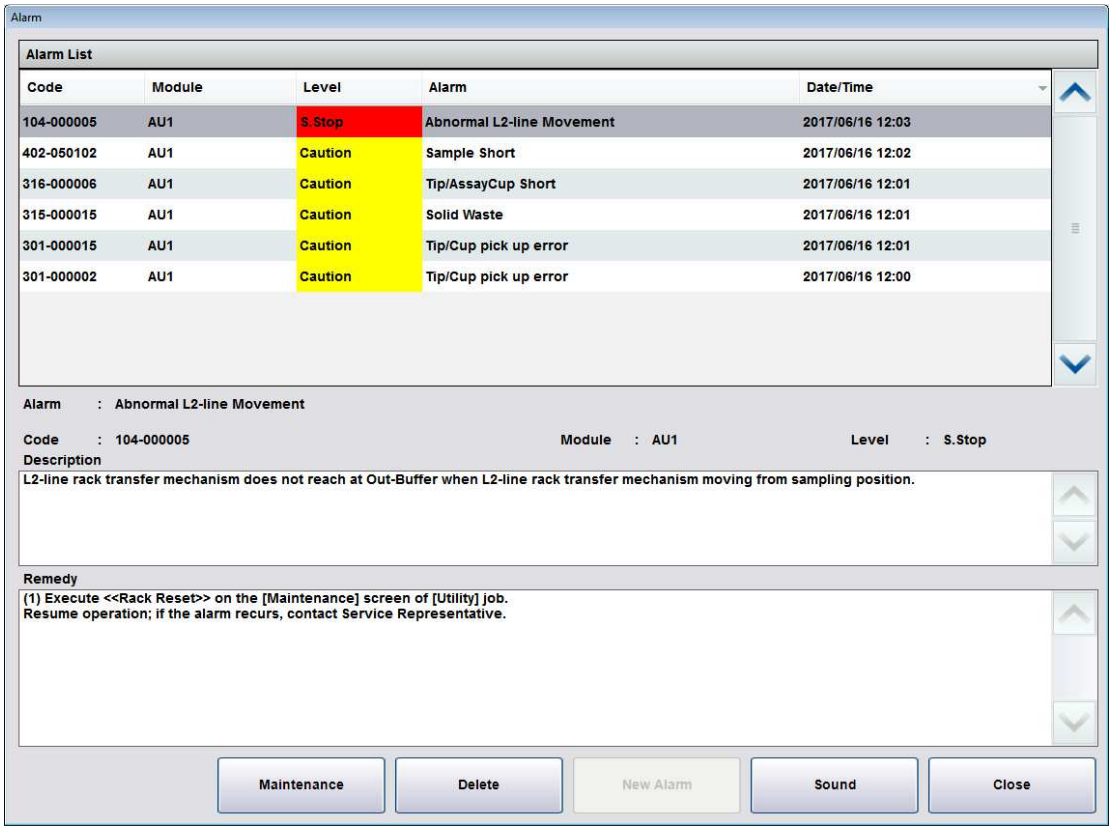
Step 2: For Module Type E only, change the number under "Module Rack Buffer" to 1 and click OK.



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.



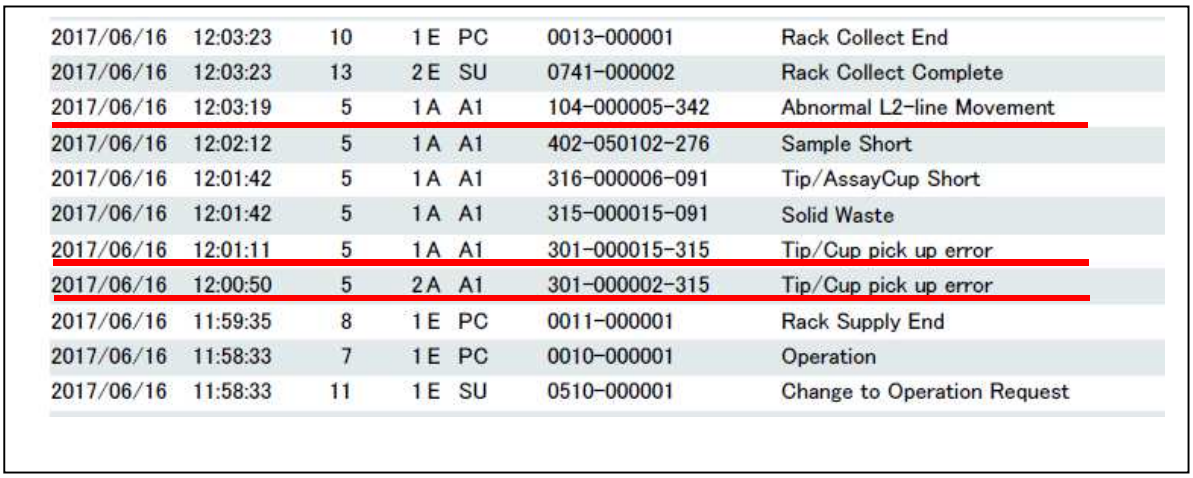
2. Collect the remained racks in the **cobas** e602 module.
   - Standalone system:

   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.

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.

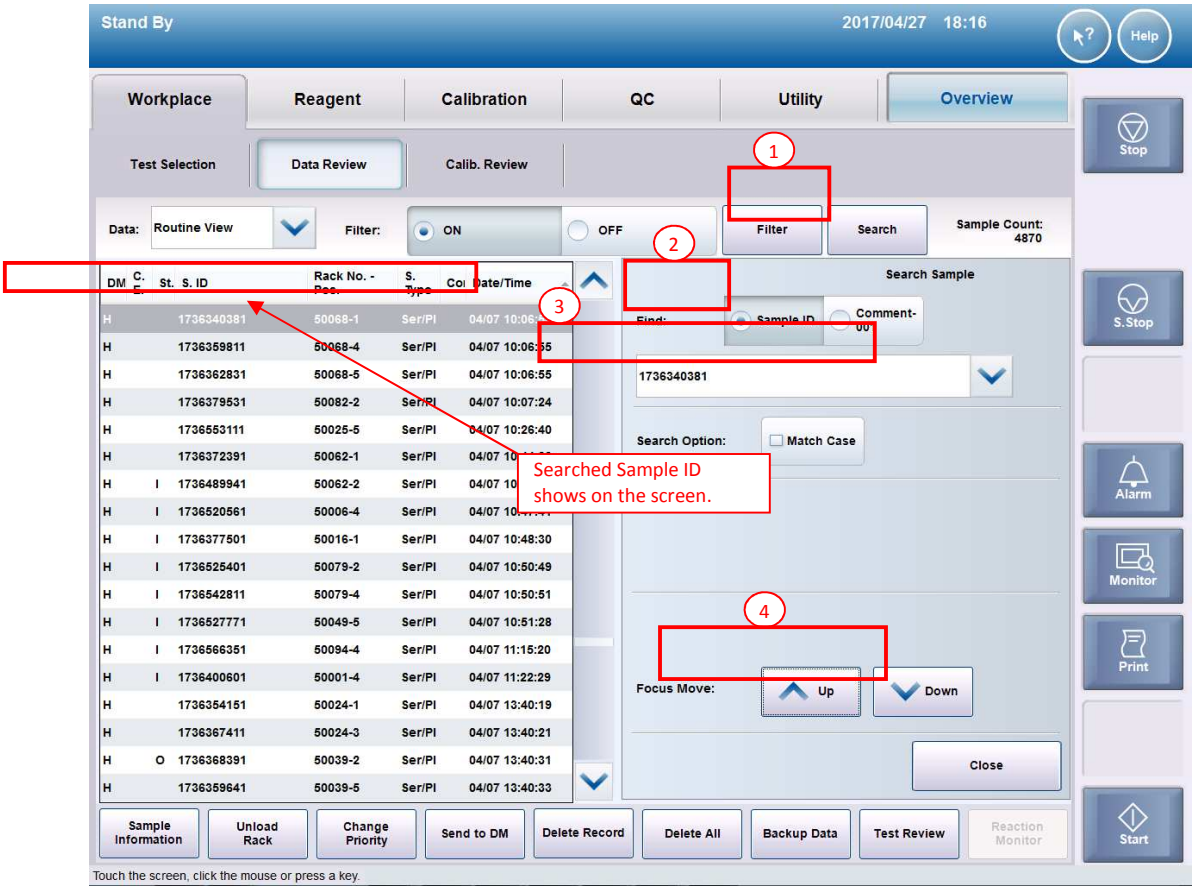


Figure 1. Data Review screen

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

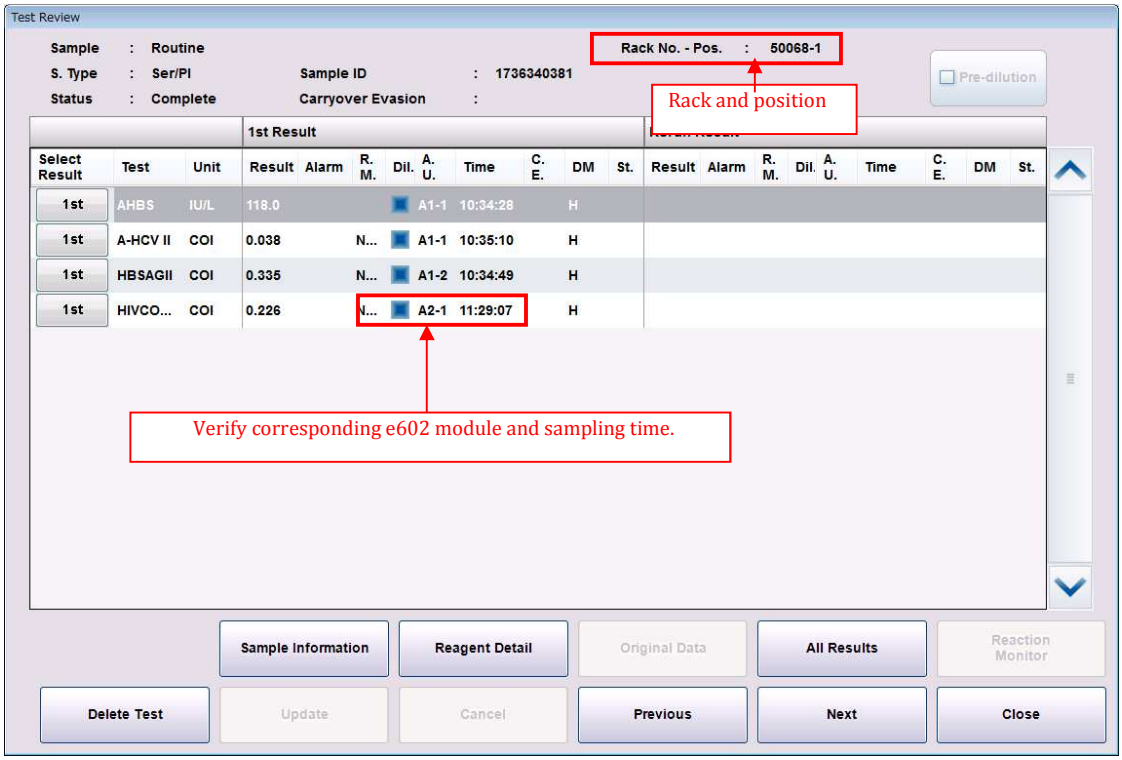


Figure 2. Test Review screen

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".

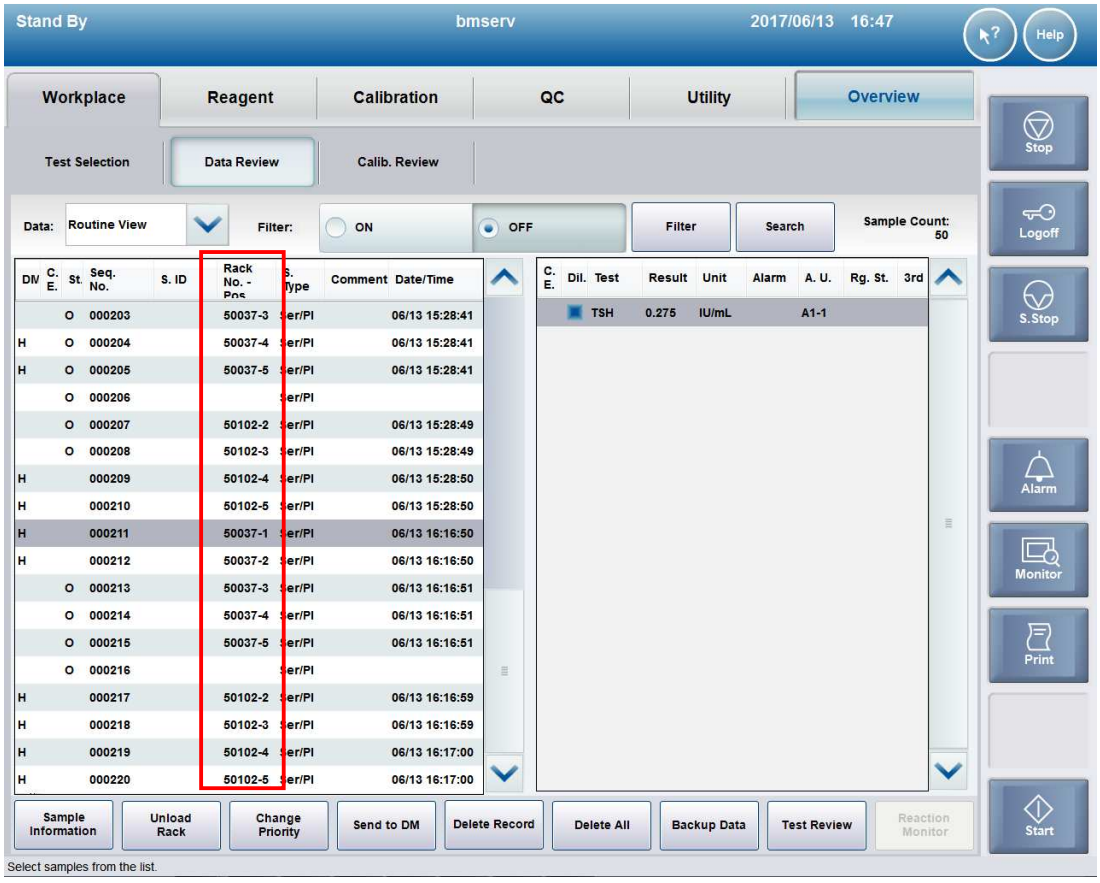


Figure 3. Data Review screen

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

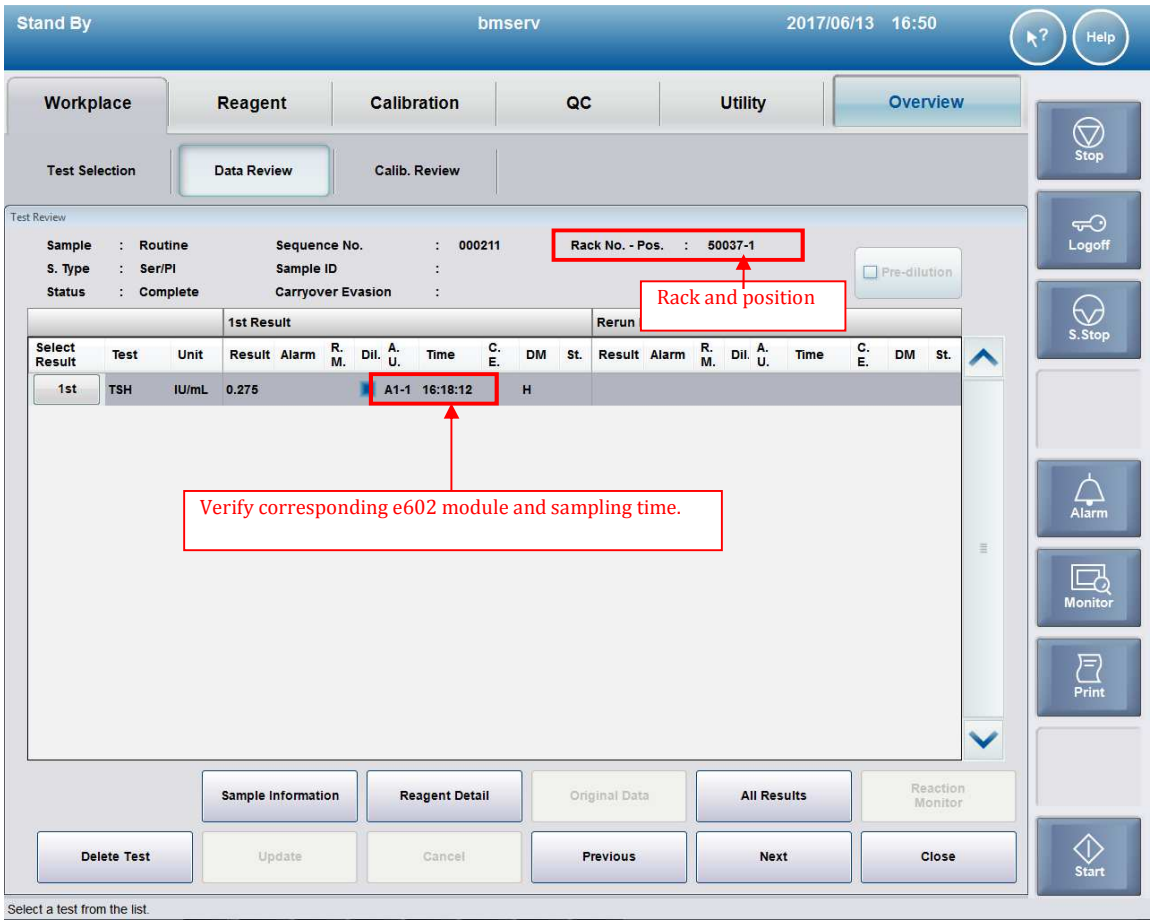


Figure 4. Test Review screen

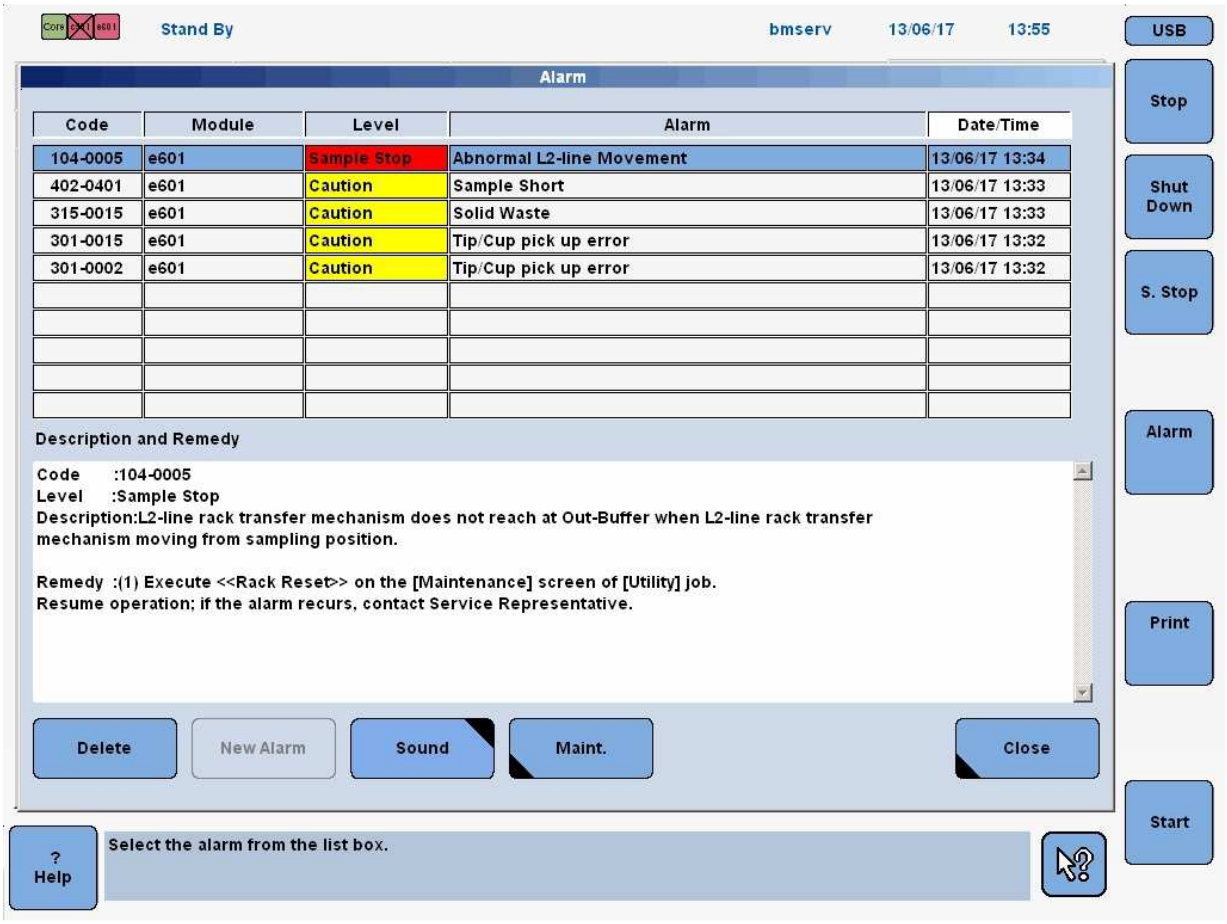
2.2.3. Repeat step 2.2.1. and 2.2.2. for all samples on the collected racks.

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 104-000005 (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.

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.

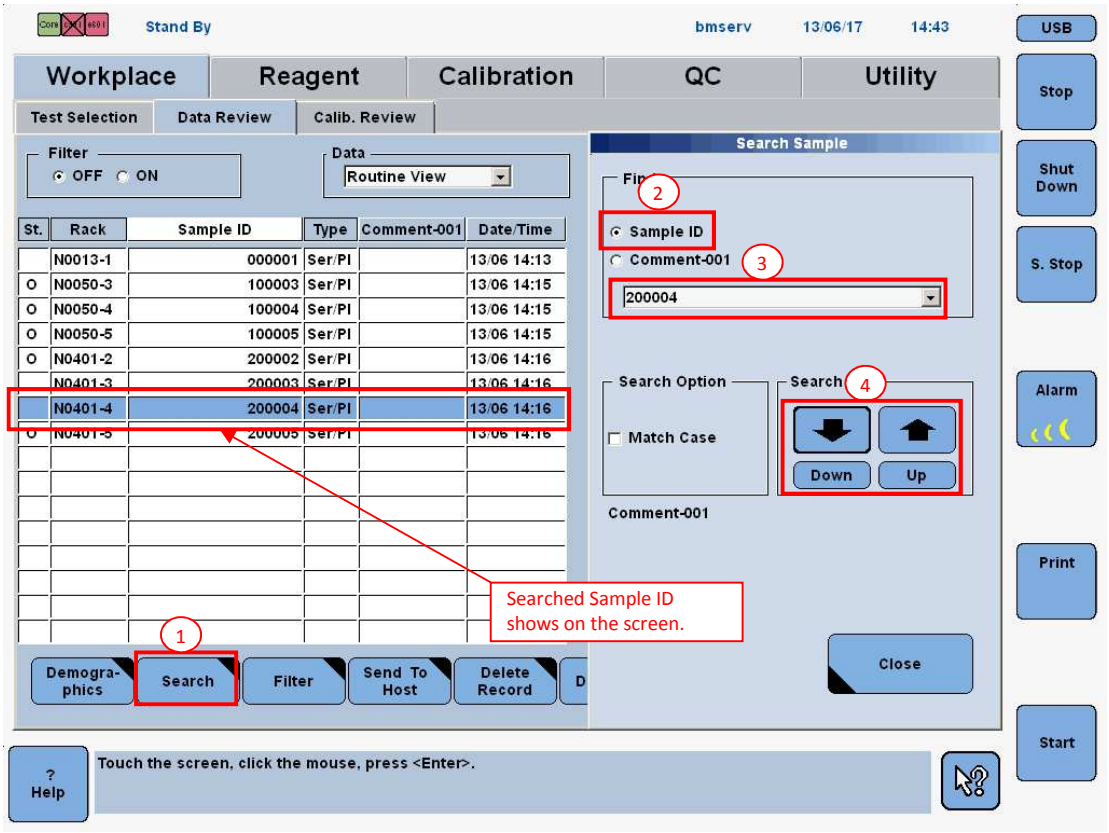
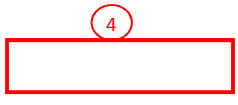


Figure 1. Data Review screen



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

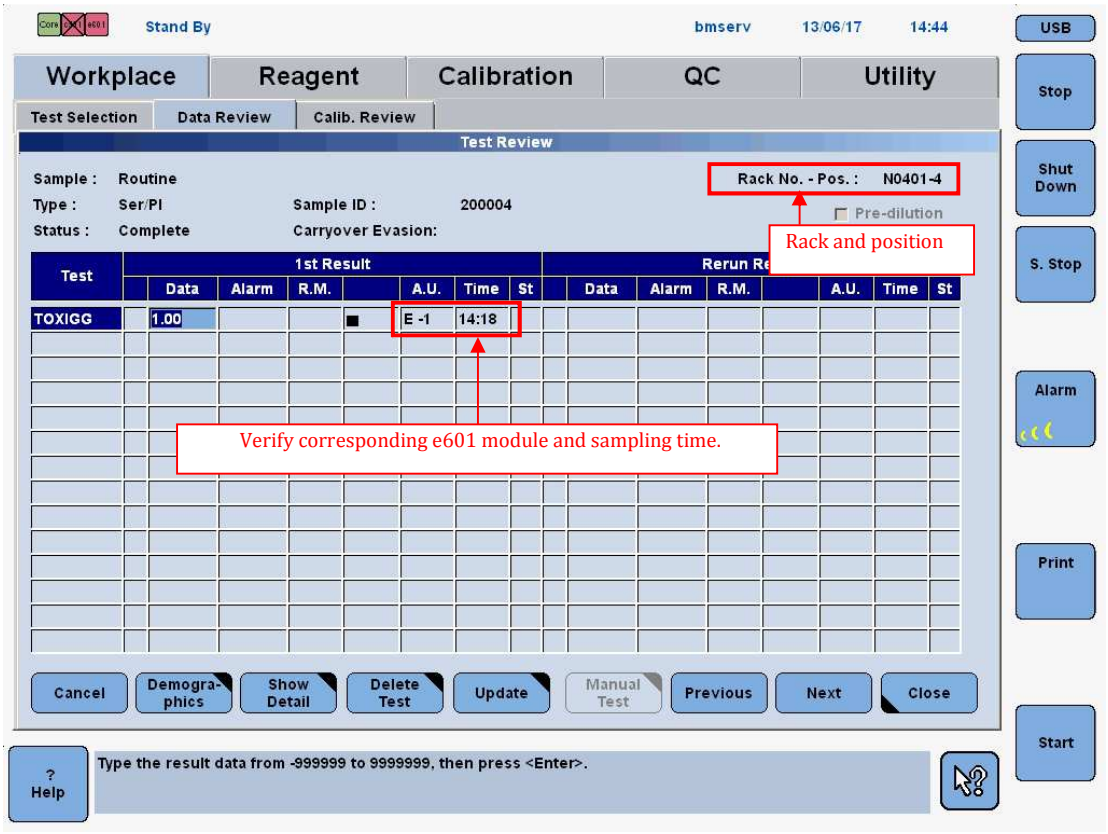


Figure 2. Test Review screen

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".

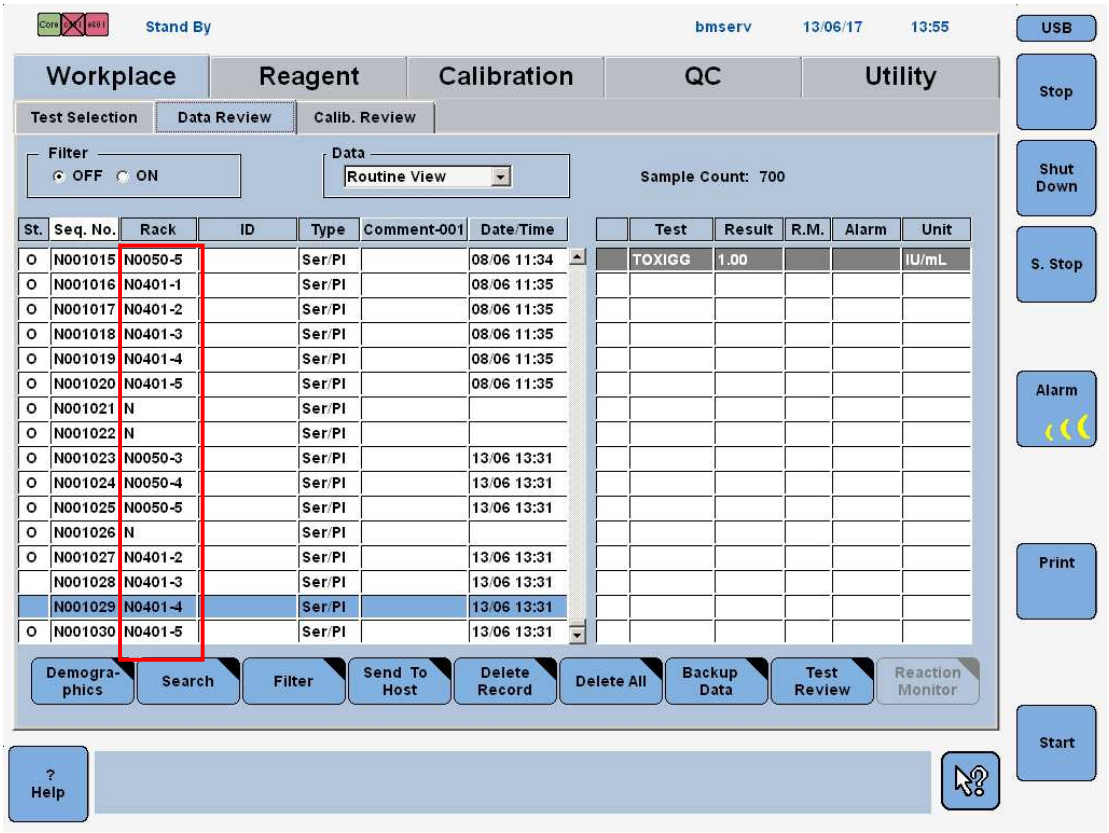


Figure 3. Data Review screen

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

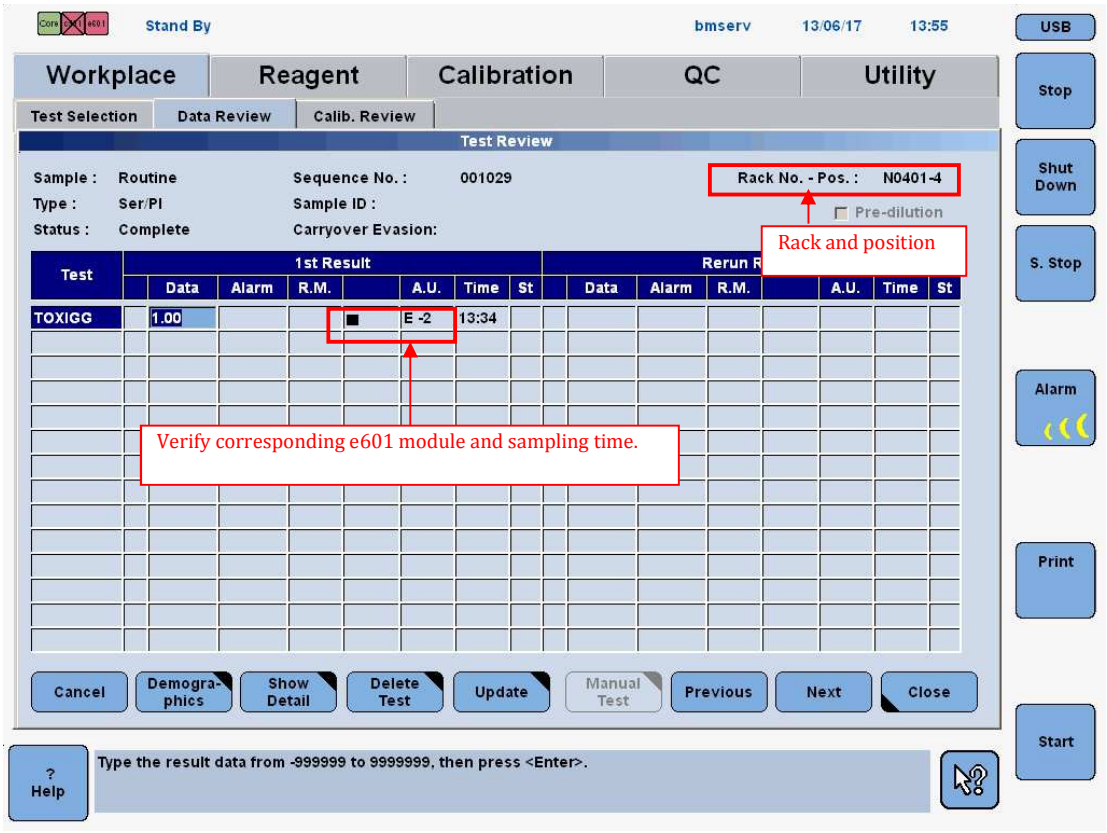


Figure 4. Test Review screen

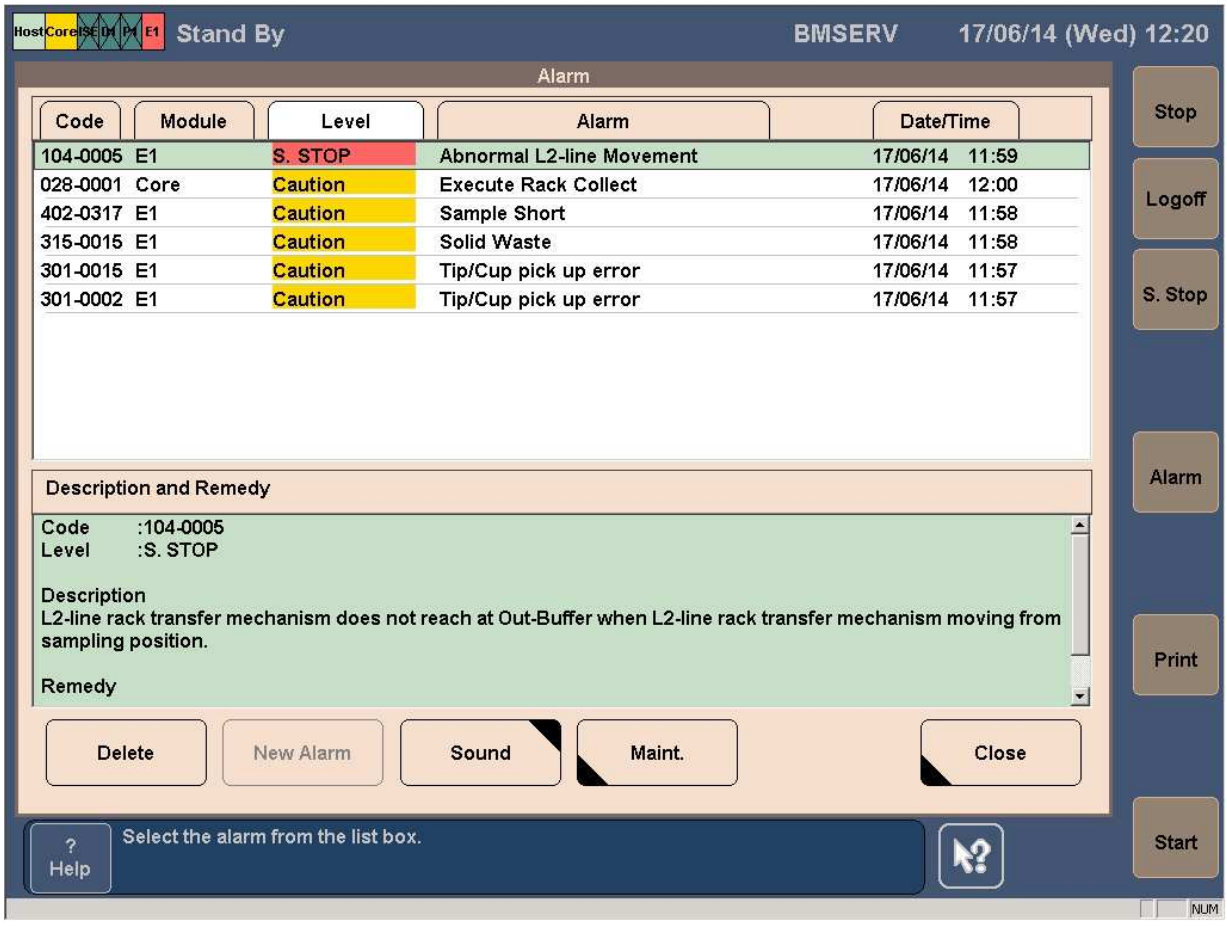
2.2.3. Repeat step 2.2.1. and 2.2.2. for all samples on the collected racks.

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 104-000005 (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 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 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 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.

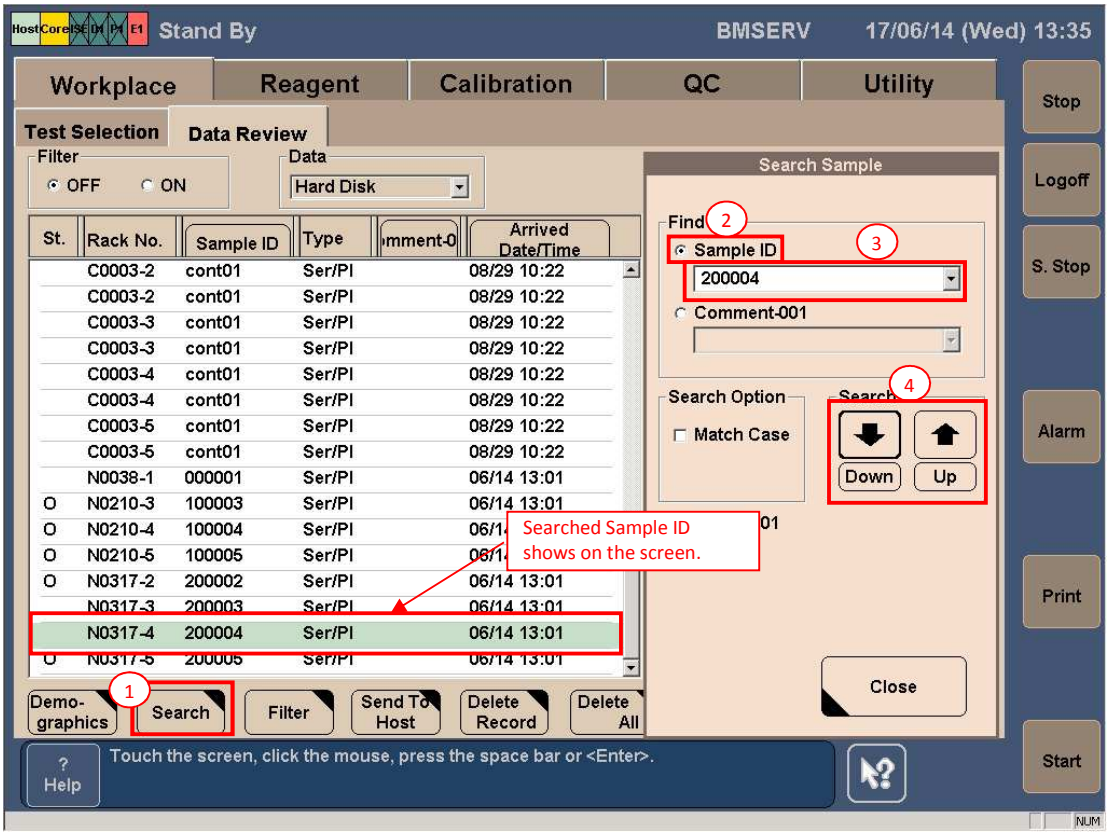


Figure 1. Data Review screen

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

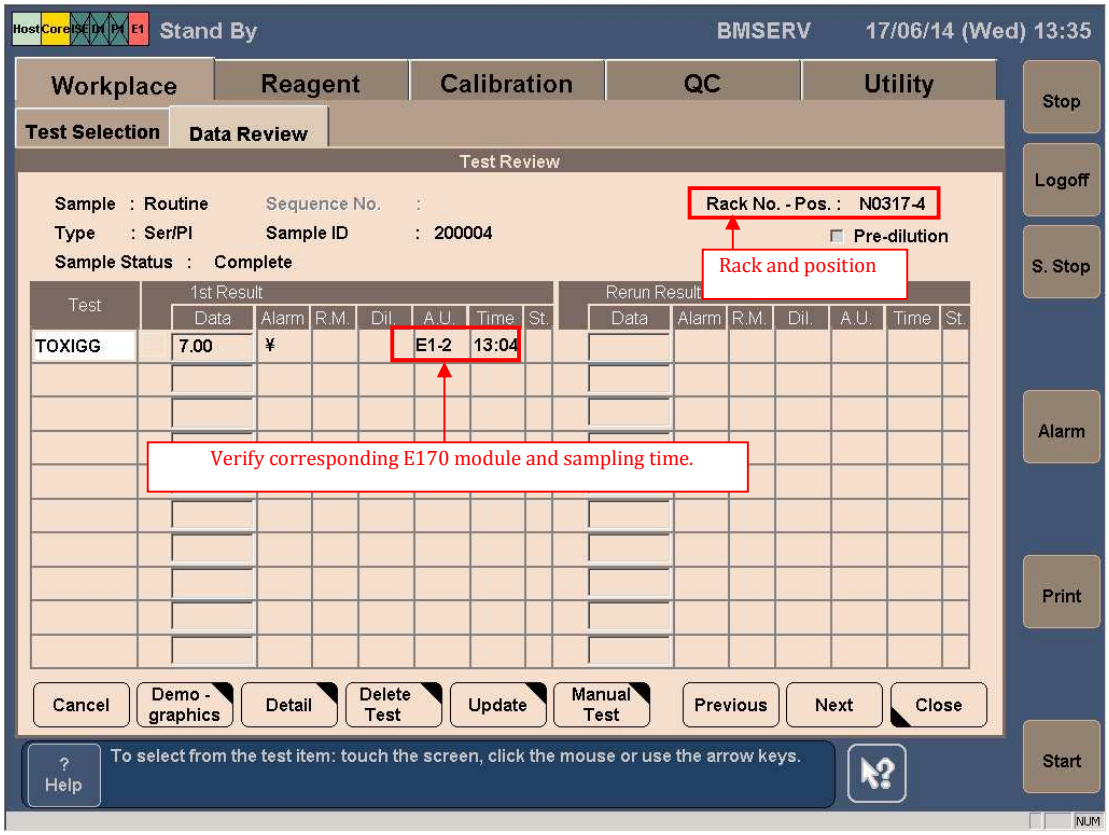


Figure 2. Test Review screen

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".

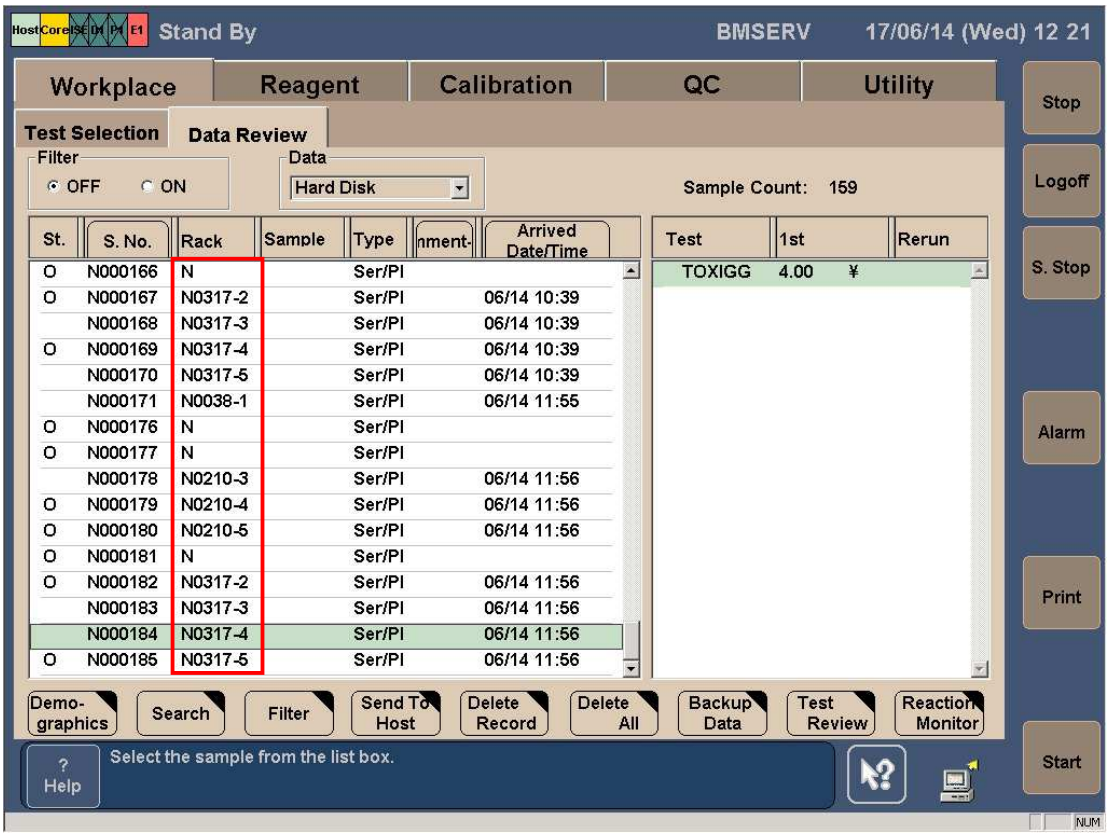


Figure 3. Data Review screen

2.2.2. Select the sample on the searched racks, then open "Test Review" screen. Verify corresponding E170 module and sampling time.

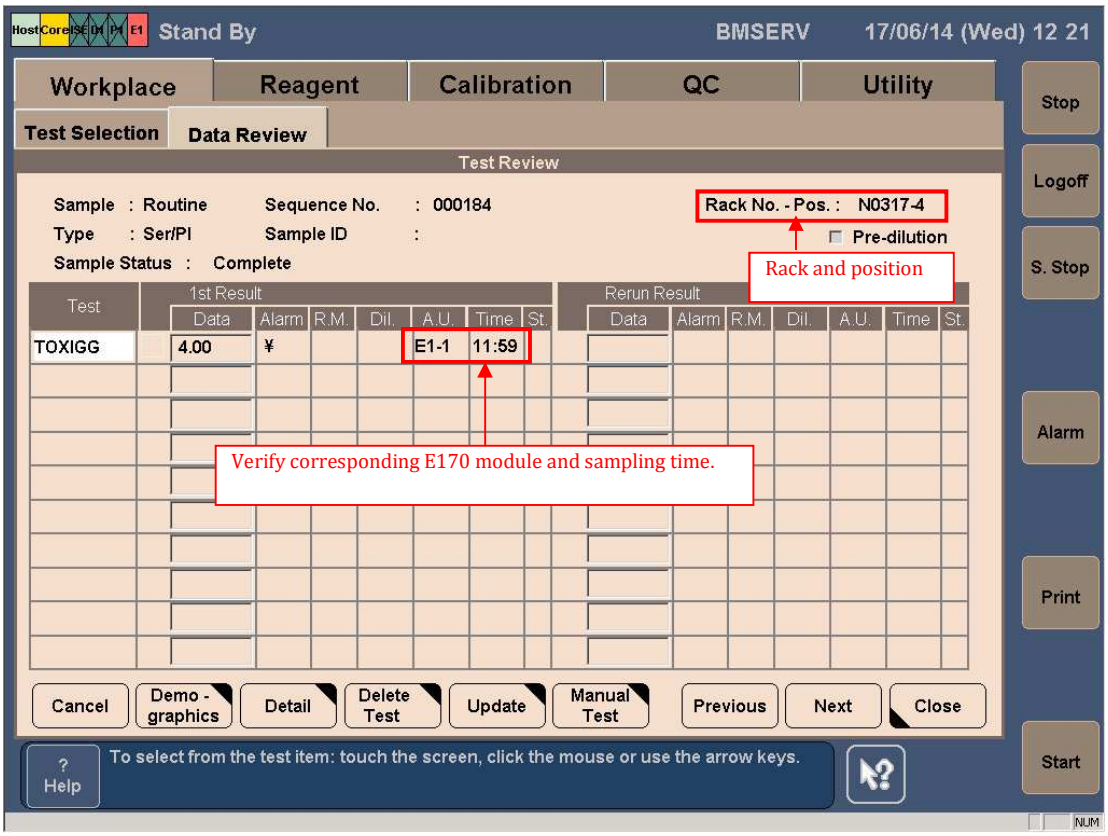


Figure 4. Test Review screen

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.