

Urgent Field Safety Notice

SBN-CPS-2017-012

CPS / Serum Work Area
Version 1
21-June-2017

Mixed sample results in immunochemistry modules

Product Name	MODULAR ANALYTICS <E170> (GMMI 03617505001) MODULAR ANALYTICS EVO <E170> (GMMI 04998642001) cobas e 601 module (GMMI 04745922001) cobas e 602 module (GMMI 05990378001)
Product Description	MODULAR ANALYTICS <E170> (GMMI 03617505001) MODULAR ANALYTICS EVO <E170> (GMMI 04998642001) cobas e 601 module (GMMI 04745922001) cobas e 602 module (GMMI 05990378001)
GMMI / Part No Device Identifier	MODULAR ANALYTICS <E170> (GMMI 03617505001) MODULAR ANALYTICS EVO <E170> (GMMI 04998642001) cobas e 601 module (GMMI 04745922001) cobas e 602 module (GMMI 05990378001)
Instrument/System Affected	MODULAR ANALYTICS MODULAR ANALYTICS EVO cobas 6000 analyzer series cobas 8000 modular analyzer series
SW Version	All of the software versions
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

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

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

- Immunochemistry module (**cobas e** 602, **cobas e** 601 and E170 modules) is included in its respective system (cobas 8000 modular analyzer series, cobas 6000 analyzer series, MODULAR ANALYTICS, MODULAR ANALYTICS EVO).
- The “**Module Rack Buffer setting**” ≠ “1” à Two or more sample racks stay in the idling/processing line (L-Line) consecutively during operation.

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- One rack (Rack A) is undergoing sampling and the following rack (Rack B) is waiting for measurement.
- The Gripper (T/V Carrier) fails to pick up the last vessel (cup) on Rack A. As a consequence, the measurement for the sample in the last vessel which failed to be picked up is canceled and the warning **"Tip/Cup pick up error"** (Caution Level) is issued.
- Sample position 1 of the following rack (Rack B) is empty or has no test order for the immunochemistry module.

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

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

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

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

The two alarms below must occur within a few minutes time difference in between both alarms

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

Actions taken by Roche Diagnostics

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

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

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

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Note:

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

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

Actions to be taken by the customer/user

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

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

1) Collect the remaining racks in the system.

Standalone systems:

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

Lab automation connected systems:

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

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

Att 1 “How to identify and deal with potential mixed sample results on **cobas e602**”

Att 2 “How to identify and deal with potential mixed sample results on **cobas e601**”

Att 3 “How to identify and deal with potential mixed sample results on E170”

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

4) Run measurements for the identified samples again.

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Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied.

Please transfer this notice to other organizations/individuals on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

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

Best regards,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com

Target

How to identify and deal with potential mixed sample results on **cobas** e602 if the two alarms below occur within a short time.

- | Tip/Cup pick up error (Caution Level) Alarm 301-000002 or 301-000015
- | Abnormal L2-line Movement (S.Stop Level) Alarm 104-000005

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 issued in advance shortly, by the Alarm screen and Daily Alarm Trace.

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 components:

- Alarm List Table:**

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 Details:**

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.
- Buttons:** Maintenance, Delete, New Alarm, Sound, Close

2. Collect the remained racks in the corresponded **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.

- I CLAS connected system:
 - 2-1) Stop sending racks from CLAS, then wait until all results for measuring samples output.
 - 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. Printout "Daily Alarm Trace" and check the alarm "301-000002 Tip/Cup pick up error" or "301-000015 Tip/Cup pick up error" occurs in short time from the occurrence time of "104-000005 Abnormal L2-line Movement".

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

If two alarms below occur in a short time, the failure could happen.

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

If you identified that the software failed follow the next procedure!

2. Handling of potential 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 by performing "Reset or Rack Reset" to Unloader.

Follow 1 through 4 in the Figure 1 below.

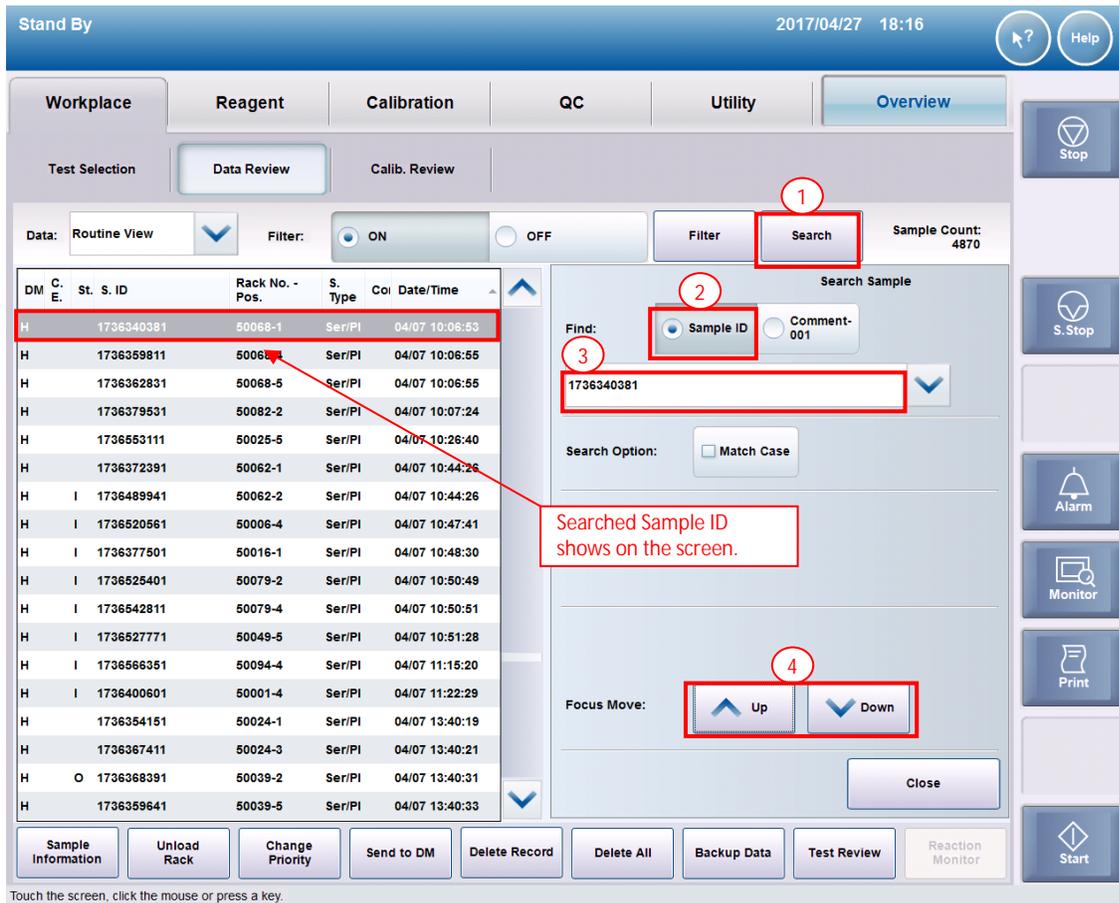


Figure 1. Data Review screen

Attachment 1 FSN-CPS-2017-012 "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 corresponded **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, Status: Complete, Sample ID: 1736340381, and Rack No. - Pos.: 50068-1. A table below shows test results for four samples. The fourth row is highlighted, showing a result of 0.226 for test HIVCO... at rack position A2-1 with a sampling time of 11:29:07. A callout box points to this row with the text 'Verify corresponded e602 module and sampling time.'

Select Result	Test	Unit	Result	Alarm	R. M.	Dil. U.	A. U.	Time	C. E.	DM	St.	Result	Alarm	R. M.	Dil. U.	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				A2-1	11:29:07			H										

Figure 2. Test Review screen

Note:

Corresponded **cobas** e602 means that the module which has alarm "Abnormal L2-line Movement (S.Stop Level)". Please check the alarm from Alarm screen or Daily Alarm Trace.

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

- 2.1.4. The rack concerned sample mismatching can be identified by the sample which sampling time is the latest.

2.2. Rack position number mode

2.2.1. Go to Workplace > Data Review screen, search racks collected by performing "Reset or Rack Reset" to Unloader.

Note: If the same rack is repeatedly using, the newest "Date/Time" is the latest used.

The screenshot displays the 'Data Review' screen in the cobas e602 software. The interface includes a top navigation bar with 'Stand By', 'bmserv', and the date/time '2017/06/13 16:47'. Below this are tabs for 'Workplace', 'Reagent', 'Calibration', 'QC', 'Utility', and 'Overview'. The 'Data Review' tab is active, showing a table of test results. A red box highlights the 'Rack No. - Pos.' column in the table. The table columns are: DV, C. E., S. No., S. ID, Rack No. - Pos., S. Type, Comment, and Date/Time. The table lists various samples with their respective rack positions and dates. A detailed view of a sample is shown on the right, displaying 'TSH' with a result of '0.275 IU/mL' and 'A1-1'. The bottom of the screen features a toolbar with 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 visible on the right side of the screen.

DV	C. E.	S. 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

Figure 3. Data Review screen

Attachment 1 FSN-CPS-2017-012 "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 corresponded **cobas** e602 module and sampling time.

The screenshot displays the 'Test Review' screen with the following details:

- Header: Stand By, bmserv, 2017/06/13 16:50, Help
- Navigation: Workplace, Reagent, Calibration, QC, Utility, Overview
- Test Selection: Data Review, Calib. Review
- Sample Information:
 - Sample: Routine, Sequence No.: 000211, Rack No. - Pos.: 50037-1
 - S. Type: Ser/PI, Sample ID: [blank]
 - Status: Complete, Carryover Evasion: [blank]
- Pre-dilution:
- Results Table:

Select Result	Test	Unit	Result	Alarm	R. M.	Dil. U.	A. U.	Time	C. E.	DM	St.	Result	Alarm	R. M.	Dil. U.	A. U.	Time	C. E.	DM	St.
1st	TSH	IU/mL	0.275				A1-1	16:18:12		H										
- Buttons: Sample Information, Reagent Detail, Original Data, All Results, Reaction Monitor, Delete Test, Update, Cancel, Previous, Next, Close
- Right Panel: Stop, Logoff, S. Stop, Alarm, Monitor, Print, Start

Annotations in the image:

- A red box around 'Rack No. - Pos.: 50037-1' with an arrow pointing to the text 'Rack and position'.
- A red box around 'A1-1' and '16:18:12' in the results table with an arrow pointing to the text 'Verify corresponded e602 module and sampling time.'

Figure 4. Test Review screen

Note:

Corresponded **cobas** e602 means that the module which has alarm "Abnormal L2-line Movement (S.Stop Level)". Please check the alarm from Alarm screen or Daily Alarm Trace.

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

- 2.2.4. The rack concerned sample mismatching can be identified by the sample with the latest sampling time.

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Target

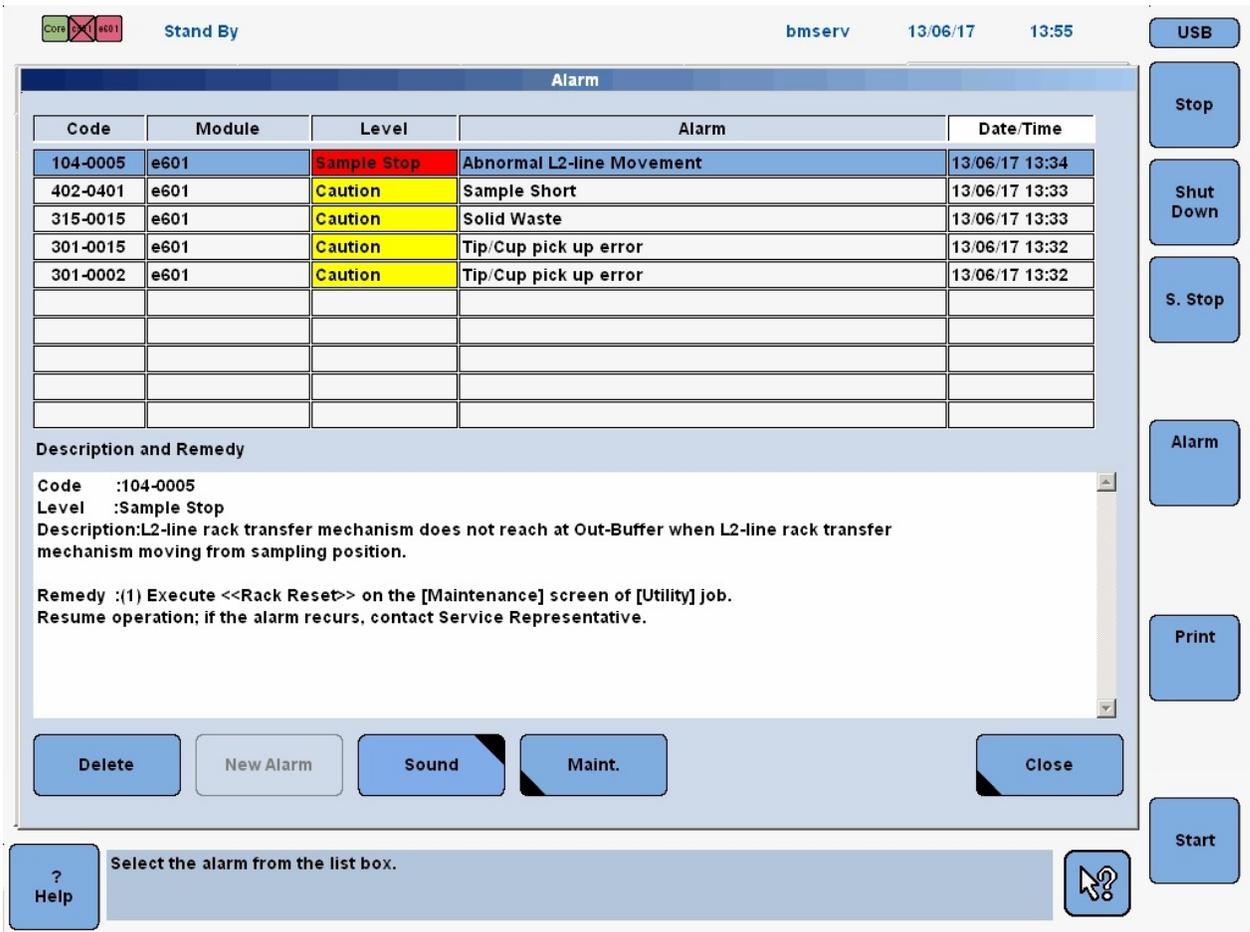
How to identify and deal with potential mixed sample results on **cobas** e601 if the two alarms below occur within a short time.

- | Tip/Cup pick up error (Caution Level) Alarm 301-0002 or 301-0015
- | Abnormal L2-line Movement (S.Stop Level) Alarm 104-0005

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 issued in advance shortly, by the Alarm screen and Daily Alarm Trace.

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 corresponded **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.

I CLAS connected system:

- 2-1) Stop sending racks from CLAS, then wait until all results for measuring samples output.
- 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. Printout "Daily Alarm Trace" and check the alarm "301-000002 Tip/Cup pick up error" or "301-000015 Tip/Cup pick up error" occurs in short time from the occurrence time of "104-000005 Abnormal L2-line Movement".

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

If two alarms below occur in a short time, the failure could happen.

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

If you identified that the software failed follow the next procedure!

2. Handling of potential 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 by performing "Reset or Rack Reset" to Unloader.

Follow 1 through 4 in the Figure 1 below.

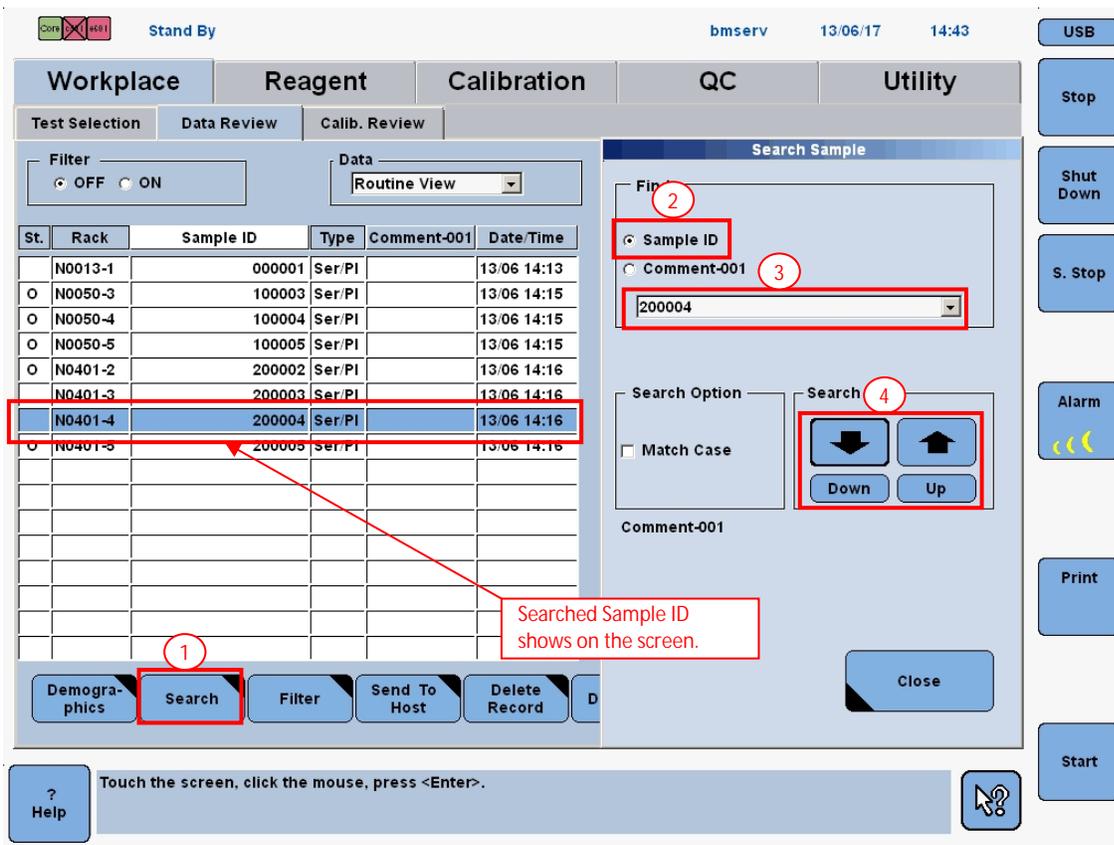


Figure 1. Data Review screen

Attachment 2 FSN-CPS-2017-012 "How to identify and deal with potential mixed sample results on cobas e601"

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

The screenshot displays the 'Test Review' screen with the following details:

- Sample : Routine
- Type : Ser/PI
- Status : Complete
- Sample ID : 200004
- Carryover Evasion:
- Rack No. - Pos. : N0401-4
- Pre-dilution:

Test	1st Result						Rerun Re					
	Data	Alarm	R.M.	A.U.	Time	St	Data	Alarm	R.M.	A.U.	Time	St
TOXIGG	1.00			E -1	14:18							

Buttons at the bottom: Cancel, Demographics, Show Detail, Delete Test, Update, Manual Test, Previous, Next, Close.

Right-side buttons: USB, Stop, Shut Down, S. Stop, Alarm, Print, Start.

Bottom status bar: Type the result data from -999999 to 9999999, then press <Enter>.

Figure 2. Test Review screen

Note:

Corresponded **cobas** e601 means that the module which has alarm "Abnormal L2-line Movement (S.Stop Level)". Please check the alarm from Alarm screen or Daily Alarm Trace.

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

- 2.1.4. The rack concerned sample mismatching can be identified by the sample which sampling time is the latest.

2.2. Rack position number mode

2.2.1. Go to Workplace > Data Review screen, search racks collected by performing "Reset or Rack Reset" to Unloader.

Note: If the same rack is repeatedly using, the newest "Date/Time" is the latest used.

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, there are tabs for 'Test Selection', 'Data Review', and 'Calib. Review'. The 'Data Review' tab is active, showing a 'Filter' section with 'OFF' and 'ON' options, and a 'Data' dropdown set to 'Routine View'. A 'Sample Count: 700' is displayed. The main area contains a table with the following data:

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					

At the bottom of the screen, there are several control buttons: 'Demographics', 'Search', 'Filter', 'Send To Host', 'Delete Record', 'Delete All', 'Backup Data', 'Test Review', and 'Reaction Monitor'. A 'Help' button is located at the bottom left, and a 'Start' button is at the bottom right. On the far right, there are additional buttons: 'USB', 'Stop', 'Shut Down', 'S. Stop', 'Alarm', 'Print', and 'Start'.

Figure 3. Data Review screen

Attachment 2 FSN-CPS-2017-012 "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 corresponded **cobas** e601 module and sampling time.

The screenshot displays the 'Test Review' interface. At the top, it shows 'Stand By' status, 'bmserv', and the date/time '13/06/17 13:55'. The main menu includes 'Workplace', 'Reagent', 'Calibration', 'QC', and 'Utility'. Below this, there are tabs for 'Test Selection', 'Data Review', and 'Calib. Review'. The 'Test Review' section shows sample information: 'Sample: Routine', 'Sequence No.: 001029', 'Type: Ser/PI', 'Sample ID:', 'Status: Complete', and 'Carryover Evasion:'. A red box highlights 'Rack No. - Pos.: N0401-4' with an arrow pointing to a 'Rack and position' label. Below this is a table with columns for 'Test', 'Data', 'Alarm', 'R.M.', 'A.U.', 'Time', and 'St'. The first row shows 'TOXIGG' with a value of '1.00' and an 'E-2' error in the 'A.U.' column. A red box highlights the 'E-2' with an arrow pointing to a 'Verify corresponded e601 module and sampling time.' label. The bottom of the screen features a 'Help' button and a text prompt: 'Type the result data from -999999 to 9999999, then press <Enter>.' On the right side, there are several control buttons: 'USB', 'Stop', 'Shut Down', 'S. Stop', 'Alarm', 'Print', and 'Start'.

Figure 4. Test Review screen

Note:

Corresponded **cobas** e601 means that the module which has alarm "Abnormal L2-line Movement (S.Stop Level)". Please check the alarm from Alarm screen or Daily Alarm Trace.

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

2.2.4. The rack concerned sample mismatching can be identified by the sample with the latest sampling time.

<end of the document>

Target

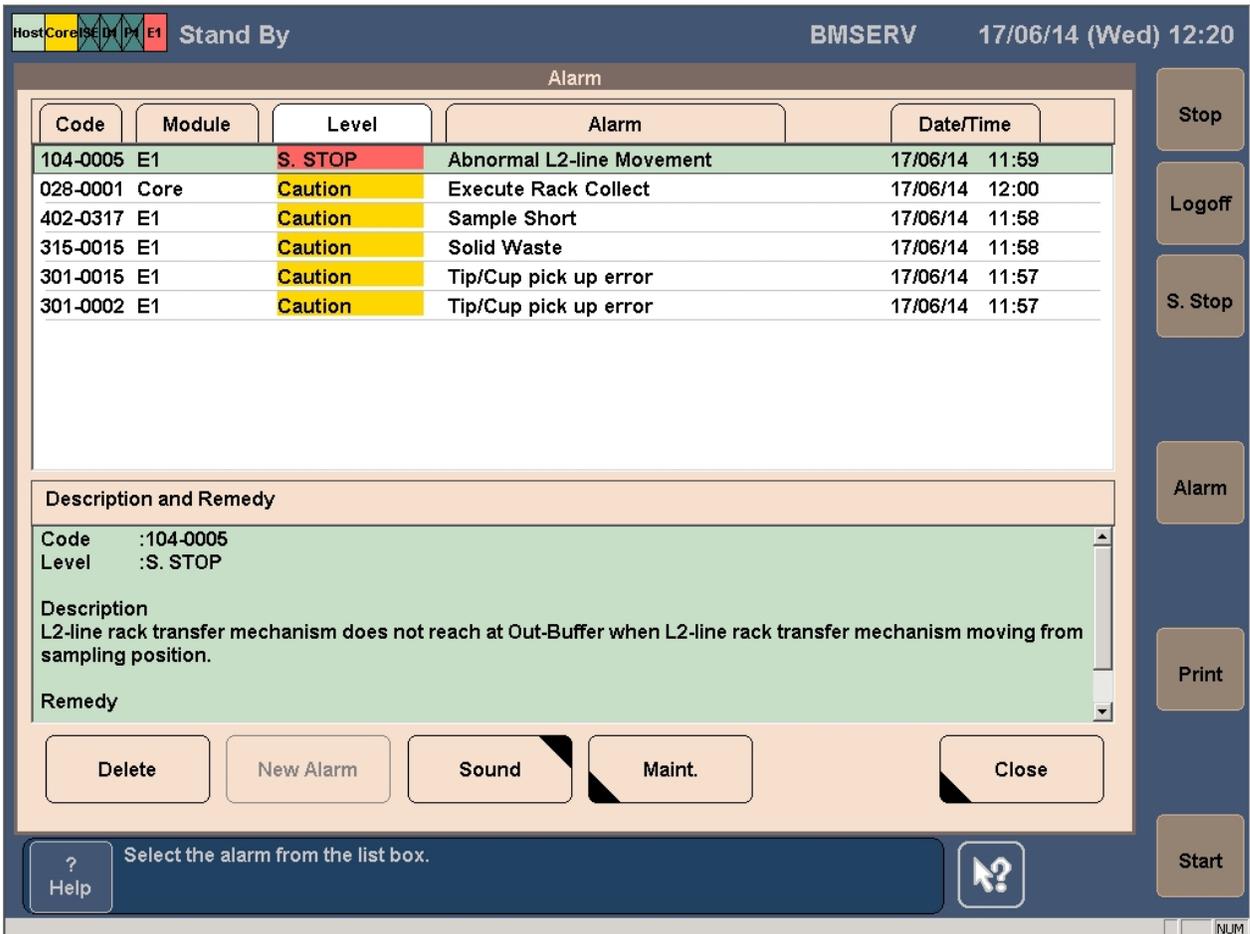
How to identify and deal with potential mixed sample results on cobas e601 if the two alarms below occur within a short time.

- | Tip/Cup pick up error (Caution Level) Alarm 301-0002 or 301-0015
- | Abnormal L2-line Movement (S.Stop Level) Alarm 104-0005

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 issued in advance shortly, by the Alarm screen and Daily Alarm Trace.

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 corresponded 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.

I CLAS connected system:

- 2-1) Stop sending racks from CLAS, then wait until all results for measuring samples output.
- 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. Printout "Daily Alarm Trace" and check the alarm "301-000002 Tip/Cup pick up error" or "301-000015 Tip/Cup pick up error" occurs in short time from the occurrence time of "104-000005 Abnormal L2-line Movement".

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

If two alarms below occur in a short time, the failure could happen.

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

If you identified that the software failed follow the next procedure!

2. Handling of potential 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 by performing "Reset or Rack Reset" to Unloader.

Follow 1 through 4 in the Figure 1 below.

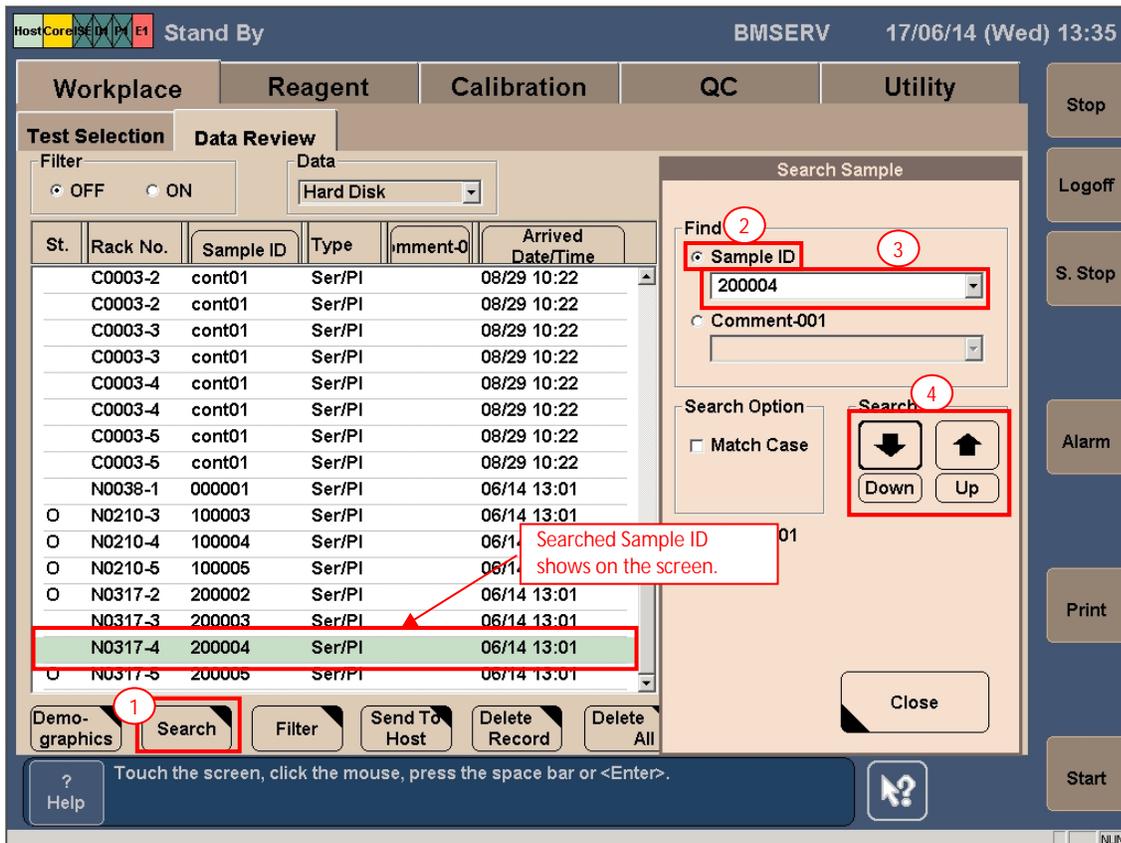


Figure 1. Data Review screen

Attachment 3 FSN-CPS-2017-012 "How to identify and deal with potential mixed sample results on E170"

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

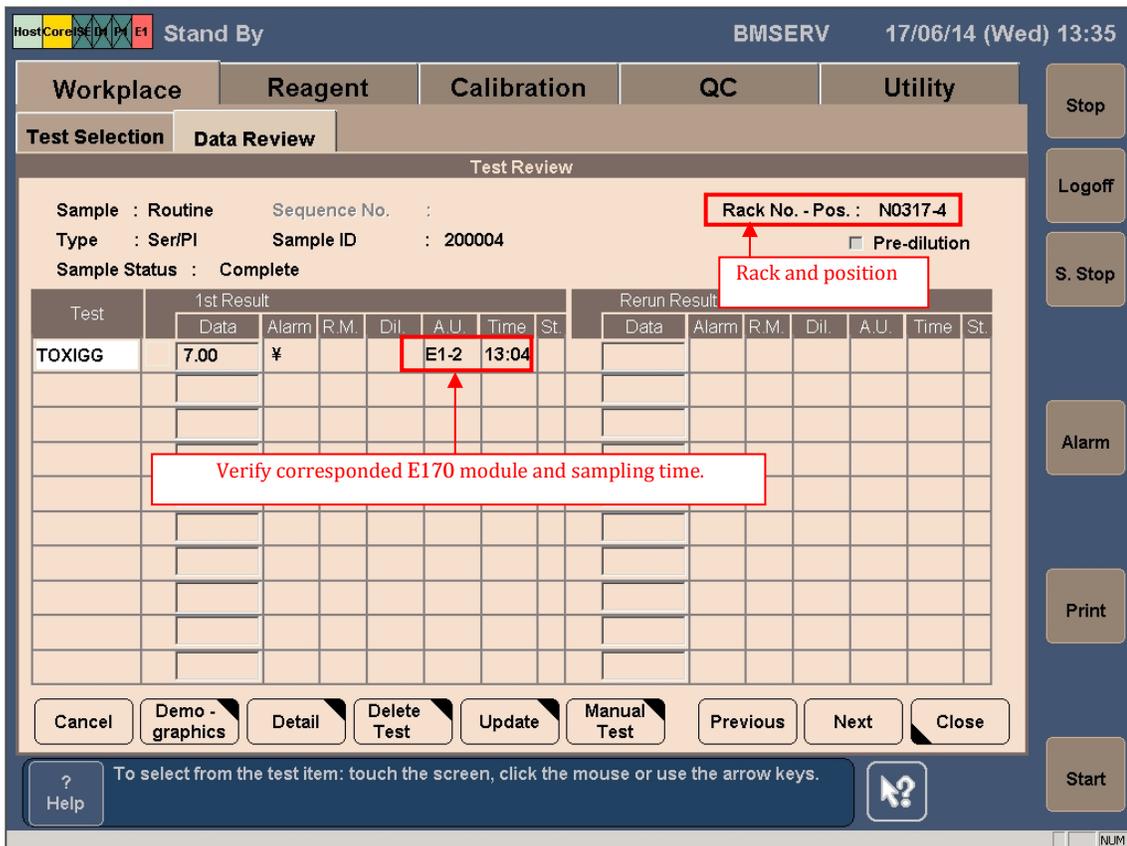


Figure 2. Test Review screen

Note:

Corresponded E170 means that the module which has alarm "Abnormal L2-line Movement (S.Stop Level)". Please check the alarm from Alarm screen or Daily Alarm Trace.

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

- 2.1.4. The rack concerned sample mismatching can be identified by the sample which sampling time is the latest.

2.2. Rack position number mode

2.2.1. Go to Workplace> Data Review screen, search racks collected by performing "Reset or Rack Reset" to Unloader.

Note: If the same rack is repeatedly using, the newest "Date/Time" is the latest used.

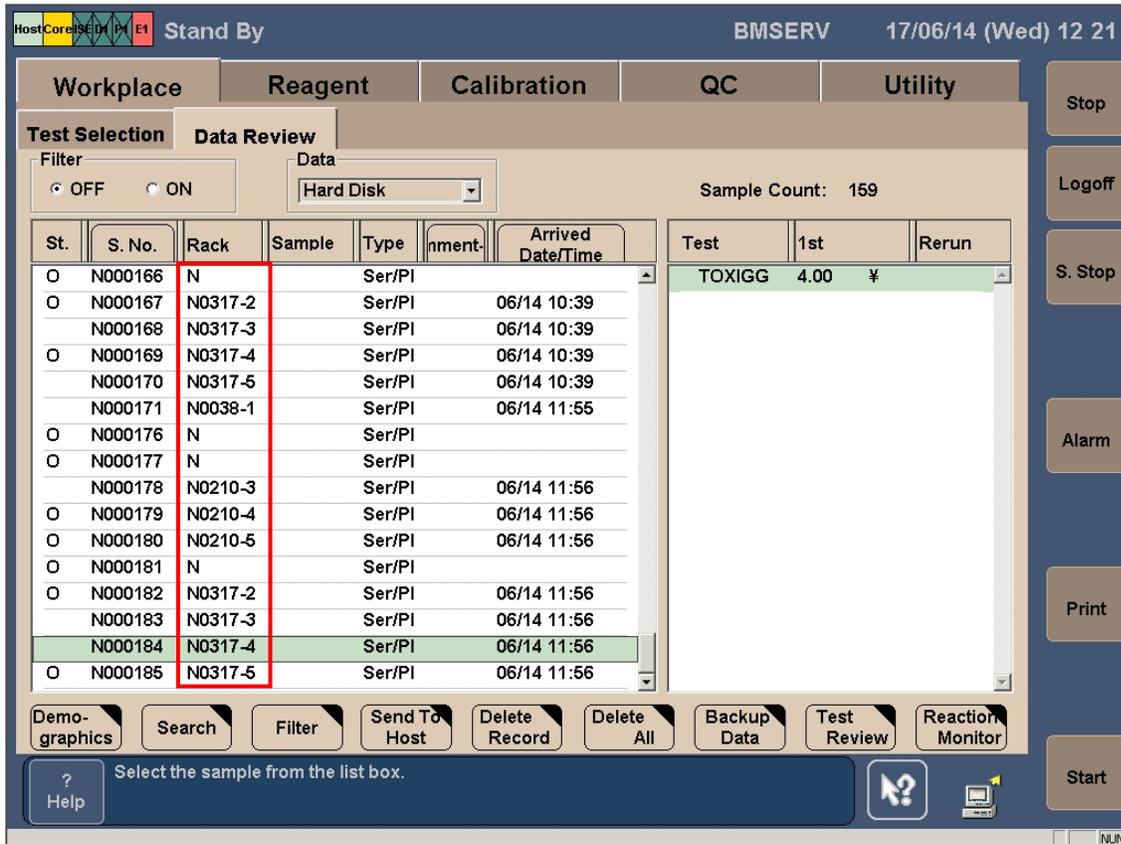


Figure 3. Data Review screen

