

## 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.

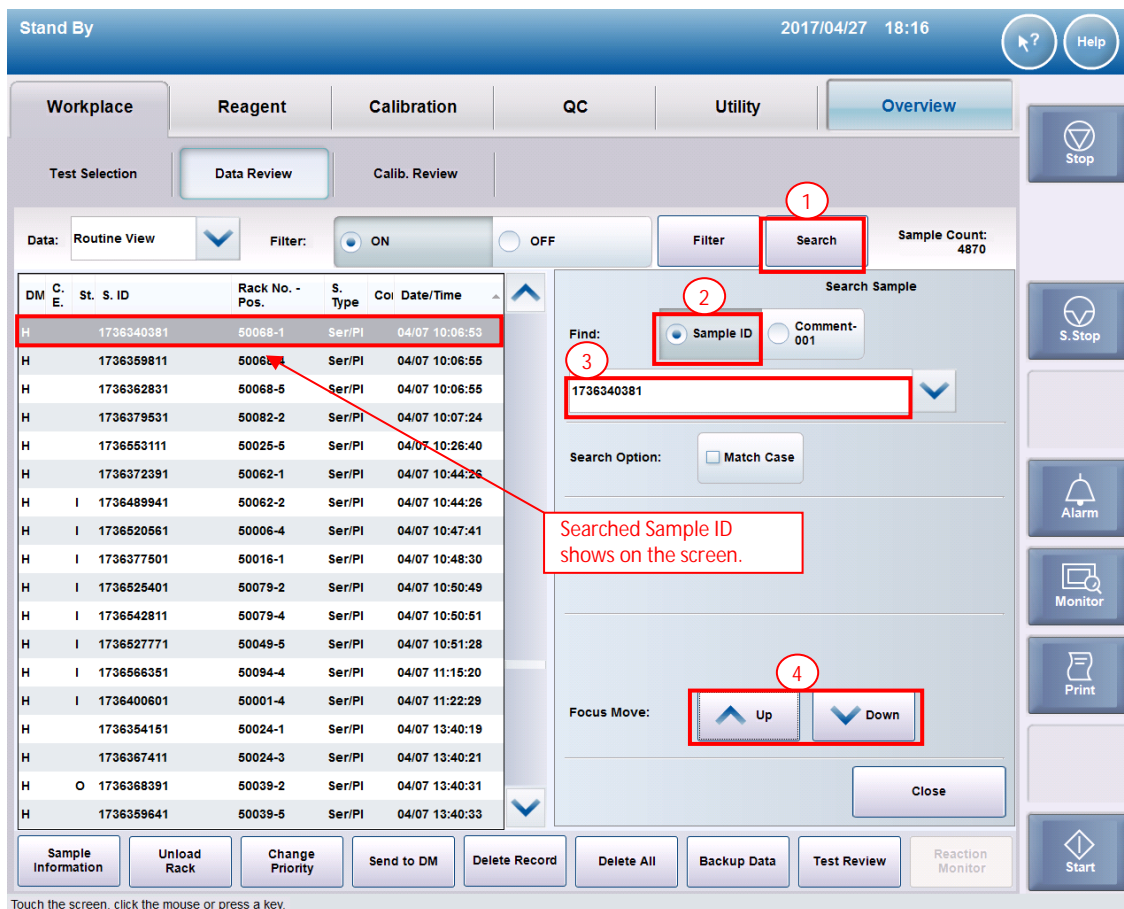


Figure 1. Data Review screen

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

Test Review

Sample : Routine  
S. Type : Ser/PI  
Status : Complete

Sample ID : 1736340381  
Carryover Evasion :

Rack No. - Pos. : 50068-1

Pre-dilution ☐

| Select Result | Test     | Unit | 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  |     |

Verify corresponded e602 module and sampling time.

Sample Information Reagent Detail Original Data All Results Reaction Monitor

Delete Test Update Cancel Previous Next Close

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 status bar with 'Stand By', 'bmserv', and the date/time '2017/06/13 16:47'. Below this is a navigation menu with tabs for 'Workplace', 'Reagent', 'Calibration', 'QC', 'Utility', and 'Overview'. The 'Workplace' tab is active, showing 'Test Selection' with 'Data Review' and 'Calib. Review' options. The 'Data Review' section has a 'Data' dropdown set to 'Routine View', a 'Filter' section with 'ON' and 'OFF' radio buttons, and 'Filter' and 'Search' buttons. A 'Sample Count: 60' is displayed. The main area contains a table of test results. A red box highlights the 'Rack No. - Pos.' column. The table lists various test results for TSH, with results ranging from 0.275 IU/mL to 0.275 IU/mL. The screen also includes a right sidebar with buttons for 'Stop', 'Logoff', 'S. Stop', 'Alarm', 'Monitor', 'Print', and 'Start'. At the bottom, there is a bar with buttons for 'Sample Information', 'Unload Rack', 'Change Priority', 'Send to DM', 'Delete Record', 'Delete All', 'Backup Data', 'Test Review', and 'Reaction Monitor'.

| Div | C. E. | 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 |

Figure 3. Data Review screen

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

Stand By bmserv 2017/06/13 16:50

Workplace Reagent Calibration QC Utility Overview

Test Selection Data Review Calib. Review

Test Review

Sample : Routine Sequence No. : 000211 Rack No. - Pos. : 50037-1

S. Type : Ser/PI Sample ID :

Status : Complete Carryover Evasion :

Pre-dilution

| Select Result | Test | Unit  | Result | Alarm | R. M. | Dil. | A. U. | Time     | C. E. | DM | St. | Rerun | Result | Alarm | R. M. | Dil. | A. U. | Time | C. E. | DM | St. |
|---------------|------|-------|--------|-------|-------|------|-------|----------|-------|----|-----|-------|--------|-------|-------|------|-------|------|-------|----|-----|
| 1st           | TSH  | IU/mL | 0.275  |       |       |      | A1-1  | 16:18:12 |       | H  |     |       |        |       |       |      |       |      |       |    |     |

Verify corresponded e602 module and sampling time.

Sample Information Reagent Detail Original Data All Results Reaction Monitor

Delete Test Update Cancel Previous Next Close

Select a test from the list.

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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