

# Field Safety Notice

## SBN-CPS-2017-005

CPS / SWA High/Mid Volume Solutions  
Version 1  
10-Mar-2017

### Fretting corrosion on Sample Probe connector may cause sporadic Liquid Level Detection (LLD) failure

<b>Product Name /</b>	PROBE SAMPLE (GMMI 04547241001)
<b>GMMI</b>	PROBE SAMPLE S (GMMI 05899427001)
<b>(Part No. Device Identifier)p</b>	SAMPLE PROBE (GMMI 04945794001)
<b>Instrument/System Affected</b>	<b>cobas c</b> 311 analyzer (cat. no. 04826876001) <b>cobas c</b> 501 module (cat. no. 04745914001) <b>cobas c</b> 502 module (cat. no. 05964067001) <b>cobas c</b> 701 module (cat. no. 05641489001) <b>cobas c</b> 702 module (cat. no. 06473245001) <b>cobas</b> 8000 ISE module 900 (cat. no. 05641497001) <b>cobas</b> 8000 ISE module 1800 (cat. no. 05964075001)
<b>SW Version</b>	Not applicable
<b>Type of Action</b>	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

### Description of Situation

Due to a change in the sample probe connector production, high connector movement during operation may lead to fretting corrosion on the sample probe connector. In very rare cases, a disturbance of the sample liquid level detection (LLD) may happen. In those instances, the malfunction of the sample probe liquid level detection (LLD) may result in the sample probe dipping deeper than intended, leading to inadequate washing of sample probe. The carry over of subsequent sample(s) may occur. Alarms/flags (e.g. "Clot Detection", "Clot Detection for Calib./Control", "Sample Short", "Abnormal Aspiration") will be triggered. The laboratory will be alerted. Guide on next steps when such alarms are encountered is also available as attached (Document titled: *"How to proceed whenever the system alarm "Sample Short" or "Abnormal Aspiration"*). Results should be interpreted in conjunction with patient's clinical status, medical history and other appropriate parameters.

# Fretting corrosion on Sample Probe connector may cause sporadic Liquid Level Detection (LLD) failure

Sample probes with the new connector types have been produced since the beginning of 2017. With this, the sample liquid level detection (LLD) is ensured to fully function as specified.

## Actions taken by Roche Diagnostics

The manufacturer Hitachi High Technologies Corporation has clearly identified the root cause and since the beginning of 2017, the affected sample probe connector has been changed to a new connector type. With that new connector type the sample liquid level detection (LLD) is ensured to fully function as specified.

Our Field Service Representatives will contact the laboratories for the change of potentially affected sample probes.

## Actions to be taken by the customer/user

When alarms/flags (e.g. “Clot Detection”, “Clot Detection for Calib./Control”, “Sample Short”, “Abnormal Aspiration”) are encountered, please refer to the relevant instrument document titled *“How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” (as attached).*

In the event of suspicious/abnormal results, review the sample/results according to the laboratory’s procedures.

# **Fretting corrosion on Sample Probe connector may cause sporadic Liquid Level Detection (LLD) failure**

## **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)

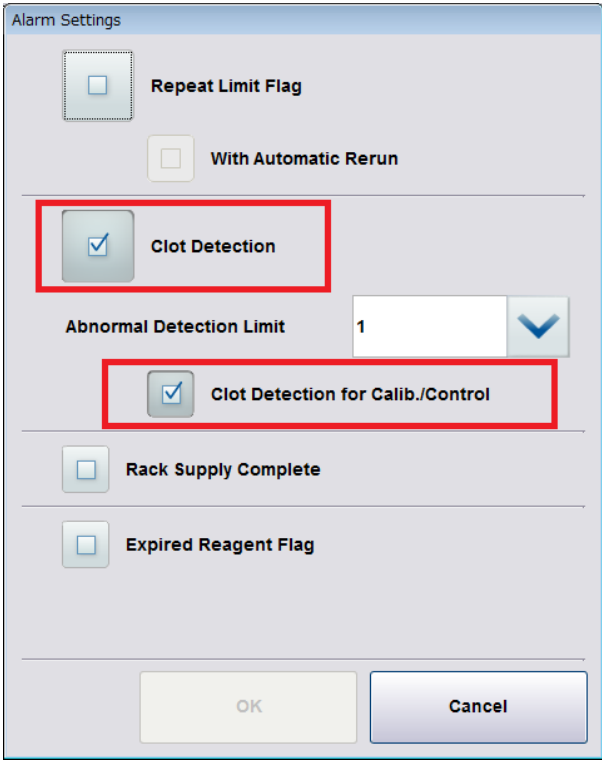
## Attachment 1:

### FSN-CPS-2017-005: “How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” for cobas® 8000

#### For cobas® 8000:

When the system alarm *Sample Short* or *Abnormal Aspiration* is issued while there is still sufficient amount of sample volume, it is necessary to replace the sample probe. A verification of the measurement results is required.

When there is no replacement sample probe available, clean the outside and inside of the sample probe. This is described in 2 manuals: Operator’s Manual (under section “*Cleaning all pipetter probes and rinse nozzles*”) and “cobas 8000 modular analyzer series Interlock Manual c 502 module” manual (under section “*Eliminating clogging of the sample probe*”). The inside cleaning maintenance actions of the cobas c502 module series can only be performed by specially trained operators. “” and “”.

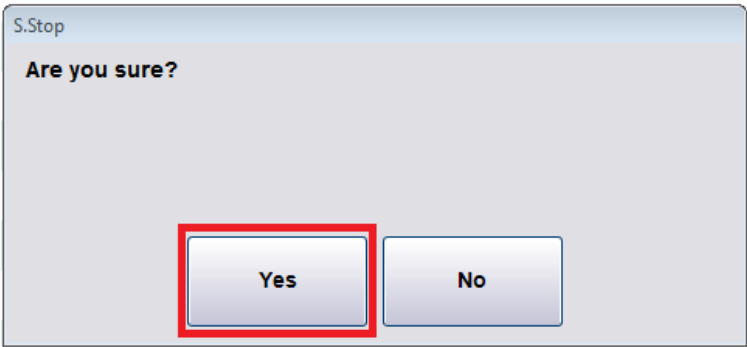
	Step	Action
<b>Clot Detection ON</b>	<b>1</b>	<p>Verify the Clot Detection and Clot Detection for Calib./Control settings in <i>Utility-System-Alarm Settings</i>.</p> 

**Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® 8000**

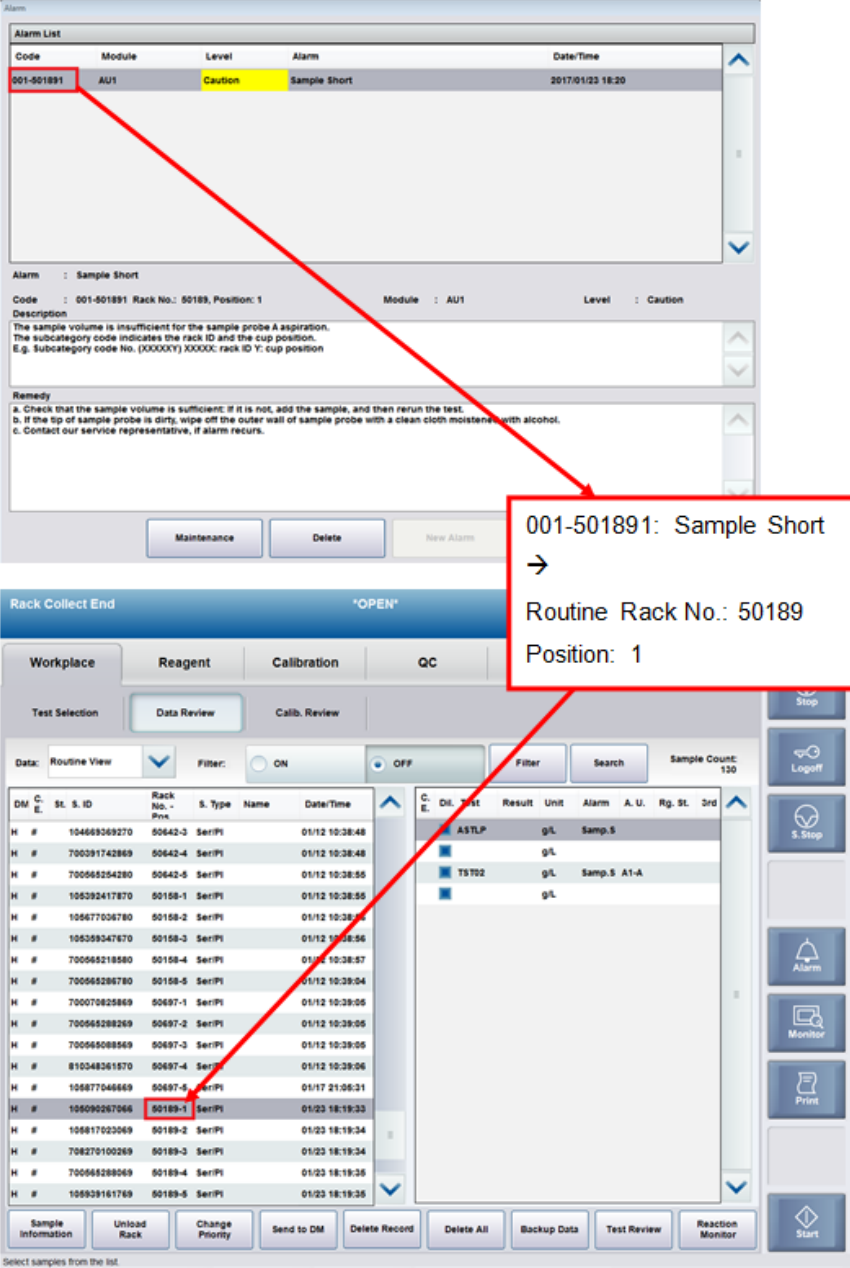
	Step	Action																												
Check the Sample Short and Sample Clot alarm	2	<p>The table below shows the system alarm list of Sample Short and Sample Clot.</p> <table><thead><tr><th>Alarm</th><th>Module</th><th>Alarm Code</th><th>Alarm Sub Category</th></tr></thead><tbody><tr><td rowspan="4">Sample Short</td><td>ISE</td><td>010</td><td>XXXXXY XXXXX: rack No. Y: cup position</td></tr><tr><td>c701/c702</td><td>001 - 002</td><td>XXXXXY XXXXX: rack No. Y: cup position</td></tr><tr><td rowspan="2">c502</td><td>401 – 440 (The cup position is indicated by alarm code)</td><td>0XXXXX XXXXX: rack No.</td></tr><tr><td>441</td><td>000001</td></tr><tr><td rowspan="5">Abnormal Aspiration  (The alarm of Sample Clot is issued as "Abnormal Aspiration")</td><td>ISE</td><td>007</td><td>XXXXXY XXXXX: rack No. Y: cup position</td></tr><tr><td>c701/c702</td><td>004 - 005</td><td>XXXXXY XXXXX: rack No. Y: cup position</td></tr><tr><td rowspan="3">c502</td><td>451 – 490 (The cup position is indicated by alarm code)</td><td>0XXXXX XXXXX: rack No.</td></tr><tr><td>491</td><td>000001</td></tr></tbody></table>	Alarm	Module	Alarm Code	Alarm Sub Category	Sample Short	ISE	010	XXXXXY XXXXX: rack No. Y: cup position	c701/c702	001 - 002	XXXXXY XXXXX: rack No. Y: cup position	c502	401 – 440 (The cup position is indicated by alarm code)	0XXXXX XXXXX: rack No.	441	000001	Abnormal Aspiration  (The alarm of Sample Clot is issued as "Abnormal Aspiration")	ISE	007	XXXXXY XXXXX: rack No. Y: cup position	c701/c702	004 - 005	XXXXXY XXXXX: rack No. Y: cup position	c502	451 – 490 (The cup position is indicated by alarm code)	0XXXXX XXXXX: rack No.	491	000001
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		491	000001																											
		Sampling Stop	3	<p>a) When the alarm is issued, select the <i>S. Stop</i> button.</p> <div><div><div><div>Rack Collect End</div><div>*OPEN*</div><div>2017/01/23 18:28</div><div><div>?</div>Help</div></div><div><div>Workplace</div><div>Reagent</div><div>Calibration</div><div>QC</div><div>Utility</div><div>Overview</div></div><div><div>Alarm</div><div><div>Alarm List</div><table><thead><tr><th>Code</th><th>Module</th><th>Level</th><th>Alarm</th><th>Date/Time</th></tr></thead><tbody><tr><td>001-501891</td><td>AU1</td><td>Caution</td><td>Sample Short</td><td>2017/01/23 18:20</td></tr></tbody></table></div><div><div>Alarm : Sample Short</div><div>Code : 001-501891 Rack No.: 50189, Position: 1Module : AU1Level : Caution</div><div>Description</div><div>The sample volume is insufficient for the sample probe A aspiration. The subcategory code indicates the rack ID and the cup position. E.g. Subcategory code No. (XXXXXY) XXXXX: rack ID Y: cup position</div><div>Remedy</div><div>a. Check that the sample volume is sufficient: If it is not, add the sample, and then rerun the test. b. If the tip of sample probe is dirty, wipe off the outer wall of sample probe with a clean cloth moistened with alcohol. c. Contact our service representative, if alarm recurs.</div></div><div><div>Maintenance</div><div>Delete</div><div>New Alarm</div><div>Sound</div><div>Close</div></div><div>Select alarms from the list.</div></div><div><div>Stop</div><div>S.Stop</div><div>Alarm</div><div>Monitor</div><div>Print</div><div>Start</div></div></div></div>	Code	Module	Level	Alarm	Date/Time	001-501891	AU1	Caution	Sample Short	2017/01/23 18:20																
Code	Module	Level	Alarm	Date/Time																										
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**Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® 8000**

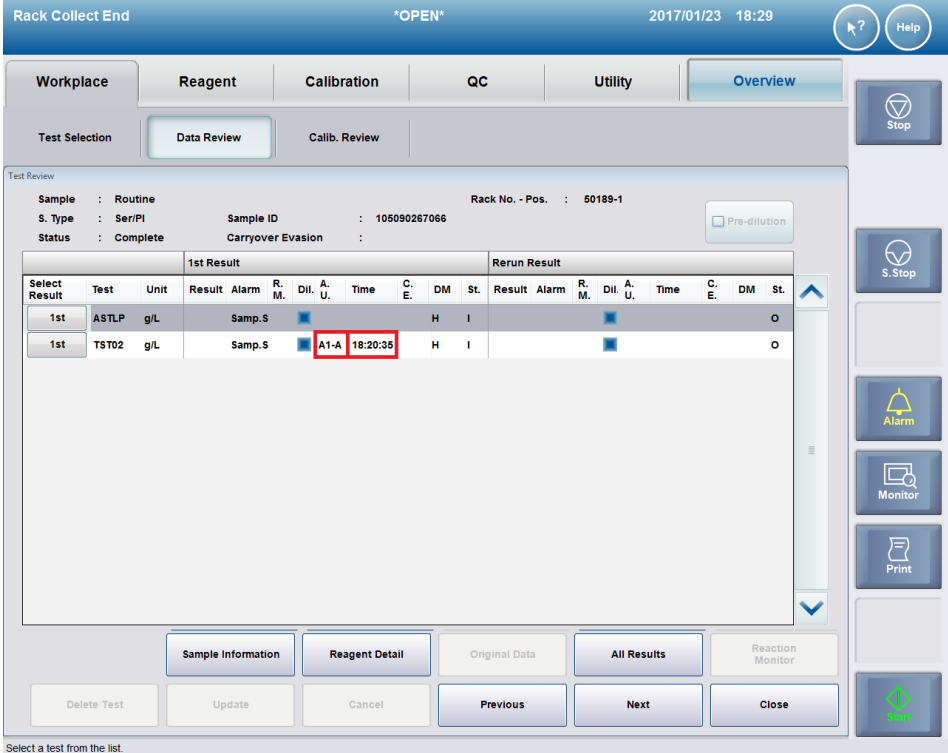
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	Step	Action
	<b>3b</b>	b) When the [S. Stop] window appears, choose <i>[Yes]</i> . 
<b>Wait until racks are unloaded</b>	<b>4</b>	Wait until all of racks are collected in the unloading area. (Waiting time may vary depending on the condition of the ordered analysis)

# Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® 8000

<p><b>Identify sample for which alarm was issued</b></p>	<p><b>5</b></p>	<p>Identify the sample for which the system alarm was issued according to the code of the system alarm (refer to the following figure).</p>  <p>Example of a sample with Sample Short alarm on a routine rack.</p>
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**Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® 8000**

<p><b>Check sample volume</b></p>	<p><b>6</b></p>	<p>Check</p> <p>a) the sample volume in the sample container, and</p> <p>b) whether there is any substance adhered to the sample probe.</p> <p>No action is required when the sample volume is insufficient, and the sample probe is clean.</p> <p>When there is sufficient sample volume and the probe is not clean, replace the sample probe and move on to step 7.</p>
<p><b>Module and sampling time in Test Review</b></p>	<p><b>7</b></p>	<p>Check the module and the sampling time for which the alarm was issued in the <i>Test Review</i> screen (<i>Workplace-Data Review-patient sample (in sample list)-Test Review</i>).</p> 

**Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® 8000**

**Set filter for the specific module**

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Set an “*Analyzed Unit*” filter for samples for which sampling was performed on the specific module from step 7 (in *Workplace-Data Review-Filter*).

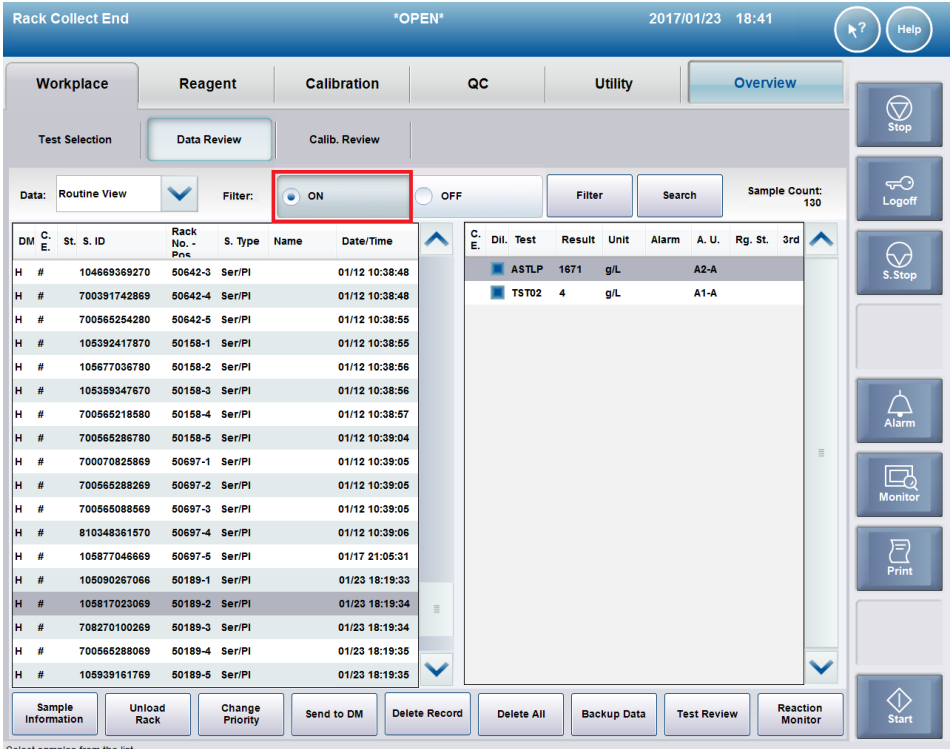
The screenshot displays the 'Workplace-Data Review-Filter' interface. The top navigation bar includes 'Rack Collect End', 'OPEN', and the date/time '2017/01/23 18:29'. Below this, there are tabs for 'Workplace', 'Reagent', 'Calibration', 'QC', 'Utility', and 'Overview'. The 'Workplace' tab is active, showing a 'Data Review' section with a 'Filter' button highlighted in red. The 'Filter' dialog box is open, showing various filter options. The 'Sample' section has 'Routine' selected. The 'S. Type' section has 'Ser/PI' selected. The 'DM Status' section has 'Analyzed Unit' selected, with 'A1-A' in the dropdown menu. The 'OK' button is highlighted in red.

DM	C. E.	St.	S. ID	Rack No. - Pos.	S. Type	Name	Date/Time
H	#		104669369270	50642-3	Ser/PI		01/12 10:38:48
H	#		700391742869	50642-4	Ser/PI		01/12 10:38:48
H	#		700565254280	50642-5	Ser/PI		01/12 10:38:55
H	#		105392417870	50158-1	Ser/PI		01/12 10:38:55
H	#		105677036780	50158-2	Ser/PI		01/12 10:38:56
H	#		105359347670	50158-3	Ser/PI		01/12 10:38:56
H	#		700565218580	50158-4	Ser/PI		01/12 10:38:57
H	#		700565286780	50158-5	Ser/PI		01/12 10:39:04
H	#		700070825869	50697-1	Ser/PI		01/12 10:39:05
H	#		700565288269	50697-2	Ser/PI		01/12 10:39:05
H	#		700565088569	50697-3	Ser/PI		01/12 10:39:05
H	#		810348361570	50697-4	Ser/PI		01/12 10:39:06
H	#		105677046669	50697-5	Ser/PI		01/17 21:05:31
H	#		105090267066	50189-1	Ser/PI		01/23 18:19:33
H	#		105817023069	50189-2	Ser/PI		01/23 18:19:34
H	#		708270100269	50189-3	Ser/PI		01/23 18:19:34
H	#		700565288069	50189-4	Ser/PI		01/23 18:19:35
H	#		105939161769	50189-5	Ser/PI		01/23 18:19:35

Filter dialog box details:

- Sample: ☐ Routine ☐ Stat ☐ Control
- S. Type: ☐ Ser/PI ☐ Urine ☐ CSF ☐ Suprnt ☐ Others ☐ WHiBld ☐ OraFlu ☐ Hemoly ☐ AmniP ☐ Stool
- DM Status: ☐ DM Sent ☒ Analyzed Unit (A1-A) ☐ Analyzed Test ☐ Results with Rerun Only
- Arrived Date:  /  /  -  /  /  Arrived Time:  :  -  :
- Buttons: OK, Cancel

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<p><b>Filter for the specific module</b></p>	<p><b>9</b></p>	<p>Select the <i>[ON]</i> radio button for Filter on Data Review screen.</p> 
<p><b>Verify the results or discard samples</b></p>	<p><b>10</b></p>	<p>Check the test results which were measured after the sampling time in step 7 on the <i>Data Review</i> screen in step 9.</p> <p>Verification of affected samples will be based on laboratory procedures/protocols. An example of tests to be verified is described on the next page.</p>

# Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® 8000

## Example

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On the *Data Review* screen, select all samples that were sampled on the analyzer unit after the sample with the sample short alarm, including the sample concerned. Then display the Test Review window.

001-501891: Sample Short  
Routine Rack No.: 50189 Position 1  
Pipetting time in Test Review T=18:20:35

Confirm the module and the time on which the sampling was performed.

The example *Test Review* window of samples on *Data Review* screen is described in the table below.

**Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® 8000**

Rack	Test	Alarm	A.U.	Time	St.	Judgment of measurement result
50189-1	TST02	<b>Samp.S</b>	<b>A1-A</b>	<b>01/23 18:20:35</b>		Target for verification (Sample for which the sample short alarm was issued) <b>Time T=18:20:35、 Module A1-A</b>
	ASTLP				M	
50189-2	TST02		A1-A	01/23 18:20:39		Target for verification (pipetted on module A1-A after 18:20:35)
	ASTLP		A2-A	01/23 18:22:20		Target for verification (sample pipetted on module A1-A after time 18:20:35)
50189-3	TST02		A1-A	01/23 18:20:42		Target for verification (pipetted on module A1-A after time 18:20:35)
	ASTLP		A2-A	01/23 18:22:26		Target for verification (sample pipetted on module A1-A after time 18:20:35)
50189-4	TST02		A1-A	01/23 18:20:46		Target for verification (pipetted on module A1-A after time 18:20:35)
	ASTLP		A2-A	01/23 18:22:32		Target for verification (sample pipetted on module A1-A after time 18:20:35)
50189-5	TST02		A1-A	01/23 18:20:49		Target for verification (pipetted on module A1-A after time 18:20:35)
	ASTLP		A2-A	01/23 18:22:38		Target for verification (sample pipetted on module A1-A after time 18:20:35)

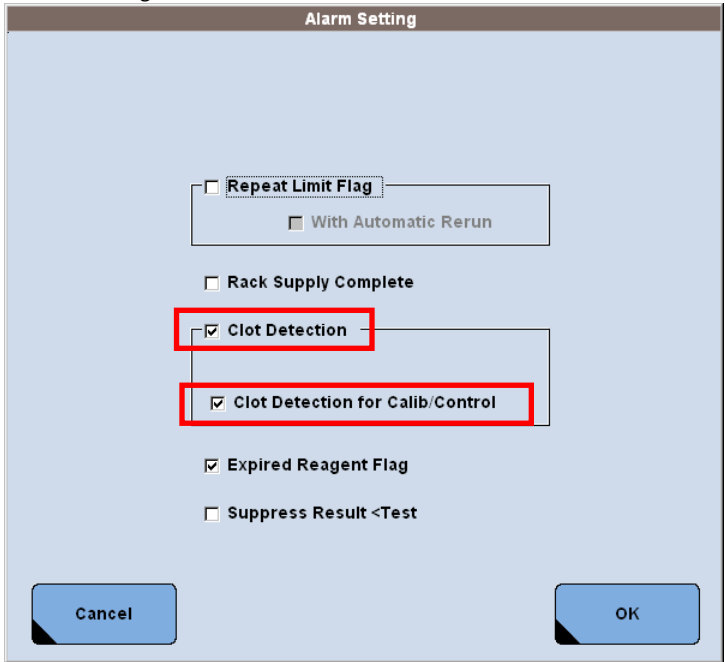
## Attachment 2:

### FSN-CPS-2017-005: “How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” for cobas® 6000

#### For cobas® 6000:

When the system alarm *Sample Short* or *Abnormal Probe Sucking* is issued while there is still sufficient amount of sample volume, it is necessary to replace the sample probe. A verification of the measurement results is required.



When there is no replacement sample probe available, clean the outside and inside of the sample probe. This is described in 2 manuals: Operator’s Manual (under section “*Cleaning sample probe, reagent probes, ISE probe and ISE sipper nozzle*”) and “Interlock function cobas c 501 with ISE” manual (under section “*Replacing sample, ISE and reagent probes – elimination of blockages*”). The inside cleaning maintenance actions of the cobas® 6000 analyzer series can only be performed by specially trained operators.

	Step	Action
<b>Clot Detection ON</b>	<b>1</b>	<p>Verify the Clot Detection and Clot Detection for Calib/Control settings in <i>Utility-System-Alarm Settings</i>.</p> 

**Att FSN-CPS-2017-005 How to proceed whenever the system alarm "Sample Short" or "Abnormal Aspiration" is issued on cobas® 6000**

	Step	Action																																																	
Check the Sample Short and Sample Clot alarm	2	<p>The table below shows the system alarm list of Sample Short and Sample Clot.</p> <table><thead><tr><th>Alarm</th><th>Alarm Code</th><th>Alarm Sub-Code</th></tr></thead><tbody><tr><td rowspan="9">Sample Short</td><td>431--435</td><td>0001-9999</td></tr><tr><td>436--440</td><td>0001-9999</td></tr><tr><td>401--405</td><td>0001-9999</td></tr><tr><td>406--410</td><td>0001-9999</td></tr><tr><td>411--415</td><td>0001-9999</td></tr><tr><td>416--420</td><td>0001-9999</td></tr><tr><td>421--425</td><td>0001-9999</td></tr><tr><td>426--430</td><td>0001-9999</td></tr><tr><td>441</td><td>0001</td></tr><tr><td rowspan="8">Abnormal Probe-sucking (The alarm of Sample Clot is issued as "Abnormal Probe-sucking")</td><td>481--485</td><td>0001--9999</td></tr><tr><td>486--490</td><td>0001--9999</td></tr><tr><td>451--455</td><td>0001--9999</td></tr><tr><td>456--460</td><td>0001--9999</td></tr><tr><td>461--465</td><td>0001--9999</td></tr><tr><td>466--470</td><td>0001--9999</td></tr><tr><td>471--475</td><td>0001--9999</td></tr><tr><td>476--480</td><td>0001--9999</td></tr></tbody></table>	Alarm	Alarm Code	Alarm Sub-Code	Sample Short	431--435	0001-9999	436--440	0001-9999	401--405	0001-9999	406--410	0001-9999	411--415	0001-9999	416--420	0001-9999	421--425	0001-9999	426--430	0001-9999	441	0001	Abnormal Probe-sucking (The alarm of Sample Clot is issued as "Abnormal Probe-sucking")	481--485	0001--9999	486--490	0001--9999	451--455	0001--9999	456--460	0001--9999	461--465	0001--9999	466--470	0001--9999	471--475	0001--9999	476--480	0001--9999										
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	426--430	0001-9999																																																	
	441	0001																																																	
Abnormal Probe-sucking (The alarm of Sample Clot is issued as "Abnormal Probe-sucking")	481--485	0001--9999																																																	
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	476--480	0001--9999																																																	
3	<p>a) When the alarm is issued, select the <i>S. Stop</i> button.</p> <div><div><div><div>Alarm</div><table><thead><tr><th>Code</th><th>Module</th><th>Level</th><th>Alarm</th><th>Date/Time</th></tr></thead><tbody><tr><td>403-0401</td><td>c501</td><td>Caution</td><td>Sample Short</td><td>24/01/17 09:42</td></tr><tr><td>028-0002</td><td>c501</td><td>Caution</td><td>Inc. Water Temperature Error</td><td>24/01/17 09:41</td></tr><tr><td>029-0001</td><td>c501</td><td>Caution</td><td>Inc. Water Level Too Low</td><td>24/01/17 09:41</td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></tbody></table><div><div>Description and Remedy</div><div><div>Code :403-0401</div><div>Level :Caution</div><div>Description:There is insufficient sample volume in the specified sample container in the Pos.3 on a Routine rack.Subcode indicates Rack No.</div><div>Remedy : (1) Check to see whether the volume of sample is sufficient: If it is not, add volume, and then rerun the test. (2) If the tip of sample probe is dirty, use alcohol to clean the outer wall of sample probe. Please contact service representative, if the alarm recurs.</div></div></div><div><div>Delete</div><div>New Alarm</div><div>Sound</div><div>Maint.</div><div>Close</div></div></div></div><div><div>Stop</div><div>Shut Down</div><div>S. Stop</div><div>Alarm</div><div>Print</div><div>Start</div></div></div> <p>b) When the [S. Stop] window appears, choose <i>/Yes/</i>.</p>	Code	Module	Level	Alarm	Date/Time	403-0401	c501	Caution	Sample Short	24/01/17 09:42	028-0002	c501	Caution	Inc. Water Temperature Error	24/01/17 09:41	029-0001	c501	Caution	Inc. Water Level Too Low	24/01/17 09:41																														
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028-0002	c501	Caution	Inc. Water Temperature Error	24/01/17 09:41																																															
029-0001	c501	Caution	Inc. Water Level Too Low	24/01/17 09:41																																															

**Att FSN-CPS-2017-005 How to proceed whenever the system alarm "Sample Short" or "Abnormal Aspiration" is issued on cobas® 6000**

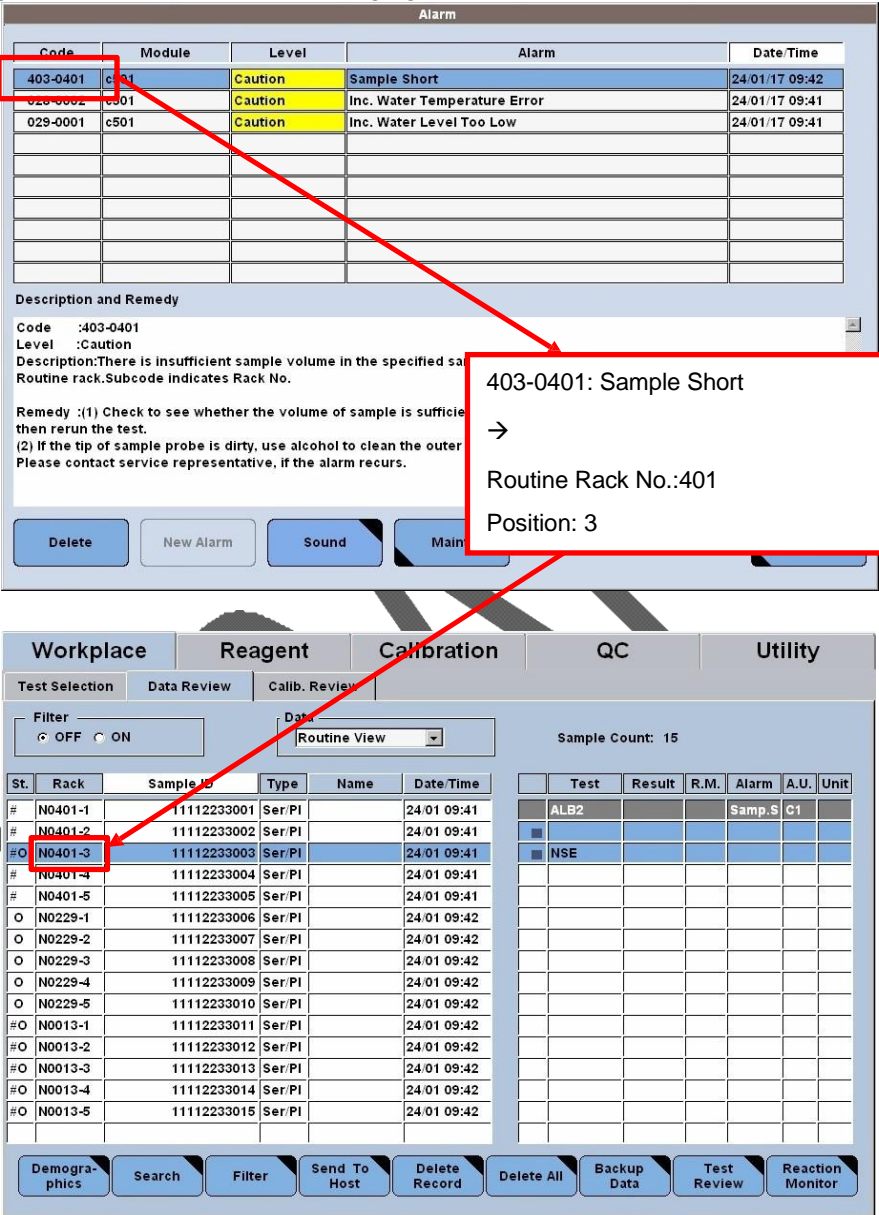
		 <p>c) Confirm the confirmation window with [Yes]</p> 
<b>Wait until racks are unloaded</b>	<b>4</b>	Wait until all racks are transferred to the unloader. (Waiting time may vary depending on the condition of the ordered analysis)

**Att FSN-CPS-2017-005 How to proceed whenever the system alarm "Sample Short" or "Abnormal Aspiration" is issued on cobas® 6000**

**Identify sample for which alarm was issued**

**5**

Identify the sample for which the system alarm was issued according to the code of the system alarm (refer to the following figure).



The Alarm screen displays the following data:

Code	Module	Level	Alarm	Date/Time
403-0401	c501	Caution	Sample Short	24/01/17 09:42
028-0002	c501	Caution	Inc. Water Temperature Error	24/01/17 09:41
029-0001	c501	Caution	Inc. Water Level Too Low	24/01/17 09:41

Description and Remedy:

Code :403-0401  
Level :Caution  
Description:There is insufficient sample volume in the specified sample rack.Subcode indicates Rack No.  
Remedy : (1) Check to see whether the volume of sample is sufficient then rerun the test.  
(2) If the tip of sample probe is dirty, use alcohol to clean the outer tip.  
Please contact service representative, if the alarm recurs.

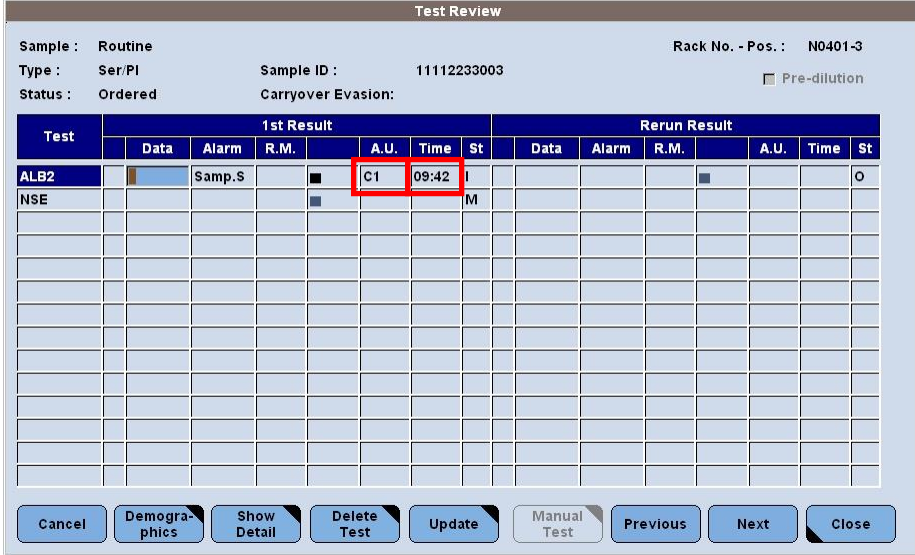
Buttons: Delete, New Alarm, Sound, Main

The Workplace screen displays the following sample list:

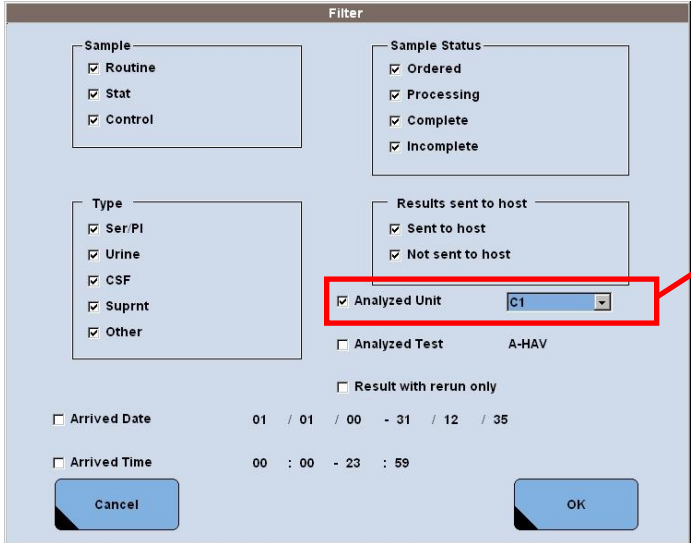
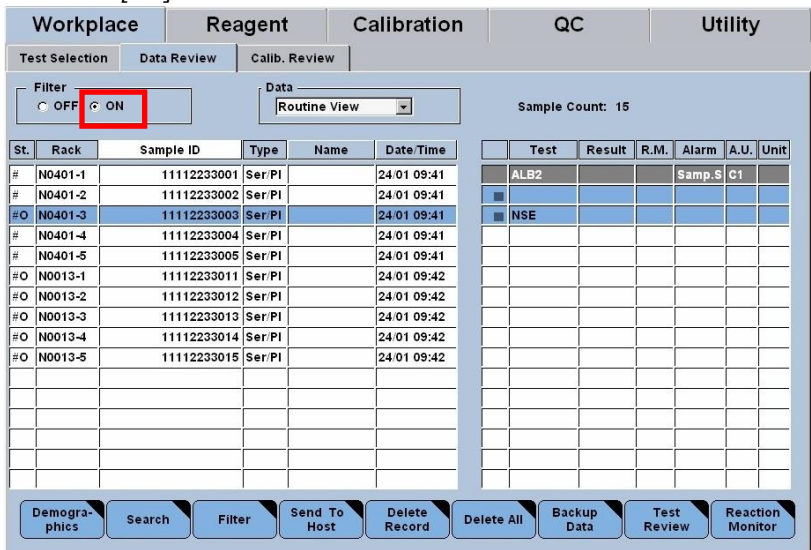
St.	Rack	Sample ID	Type	Name	Date/Time
#	N0401-1	11112233001	Ser/Pl		24/01 09:41
#	N0401-2	11112233002	Ser/Pl		24/01 09:41
#	N0401-3	11112233003	Ser/Pl		24/01 09:41
#	N0401-4	11112233004	Ser/Pl		24/01 09:41
#	N0401-5	11112233005	Ser/Pl		24/01 09:41
O	N0229-1	11112233006	Ser/Pl		24/01 09:42
O	N0229-2	11112233007	Ser/Pl		24/01 09:42
O	N0229-3	11112233008	Ser/Pl		24/01 09:42
O	N0229-4	11112233009	Ser/Pl		24/01 09:42
O	N0229-5	11112233010	Ser/Pl		24/01 09:42
#O	N0013-1	11112233011	Ser/Pl		24/01 09:42
#O	N0013-2	11112233012	Ser/Pl		24/01 09:42
#O	N0013-3	11112233013	Ser/Pl		24/01 09:42
#O	N0013-4	11112233014	Ser/Pl		24/01 09:42
#O	N0013-5	11112233015	Ser/Pl		24/01 09:42

Example of a sample with Sample Short alarm on a routine rack.

**Att FSN-CPS-2017-005 How to proceed whenever the system alarm "Sample Short" or "Abnormal Aspiration" is issued on cobas® 6000**

<p><b>Check sample volume</b></p>	<p><b>6</b></p>	<p>Check</p> <p>a) the sample volume in the sample container, and</p> <p>b) whether there is any substance adhered to the sample probe.</p> <p>No action is required when the sample volume is insufficient, and the sample probe is clean.</p> <p>When there is sufficient sample volume and the probe is not clean, replace the sample probe and move on to step 7.</p>
<p><b>Module and sampling time in Test Review</b></p>	<p><b>7</b></p>	<p>Check the module and the sampling time for which the alarm was issued in the <i>Test Review</i> screen (<i>Workplace-Data Review-patient sample (in sample list)-Test Review</i>).</p>  <p>The screenshot shows the 'Test Review' interface. At the top, it displays 'Sample : Routine', 'Type : Ser/PI', 'Status : Ordered', 'Sample ID : 11112233003', and 'Rack No. - Pos. : N0401-3'. Below this is a table with two main sections: '1st Result' and 'Rerun Result'. The '1st Result' section has columns for 'Test', 'Data', 'Alarm', 'R.M.', 'A.U.', 'Time', and 'St'. The 'Rerun Result' section has the same columns. The first row in the '1st Result' section is for 'ALB2', with 'Data' as 'Samp.S', 'Alarm' as 'C1', and 'Time' as '09:42'. The 'Rerun Result' section is empty. At the bottom of the screen are several buttons: 'Cancel', 'Demographics', 'Show Detail', 'Delete Test', 'Update', 'Manual Test', 'Previous', 'Next', and 'Close'.</p>

**Att FSN-CPS-2017-005 How to proceed whenever the system alarm "Sample Short" or "Abnormal Aspiration" is issued on cobas® 6000**

<p><b>Set filter for the specific module</b></p>	<p><b>8</b></p>	<p>Set an "Analyzed Unit" filter for samples for which sampling was performed on the specific module from step 7 (in <i>Workplace-Data Review-Filter</i>).</p> 
<p><b>Filter for the specific module</b></p>	<p><b>9</b></p>	<p>Select the <i>[ON]</i> radio button for Filter on <i>Data Review</i> screen.</p> 
<p><b>Verify the results or discard the samples</b></p>	<p><b>10</b></p>	<p>Check the test results which measured after the sampling time in step 7 on the data review screen in step 9.</p> <p>Verification of affected samples will be based on laboratory procedures/protocols.</p> <p>An example of tests to be verified is described on the next page.</p>

**Att FSN-CPS-2017-005 How to proceed whenever the system alarm "Sample Short" or "Abnormal Aspiration" is issued on cobas® 6000**

**Example**

**11**

On the *Data Review* screen, select all samples that were sampled on the analyzer unit after the sample with the sample short alarm, including the sample concerned. Then display the *Test Review* window.

**Workplace**   **Reagent**   **Calibration**   **QC**   **Utility**

Test Selection   Data Review   Calib. Review

Filter: ☐ OFF ☐ ON   Data: Routine View

403-0401: Sample Short  
Routine Rack No.:401 Position: 3

St.	Rack	Sample ID	Type	Name	Date/Time
#	N0401-1	11112233001	Ser/PI		24/01 09:41
#	N0401-2	11112233002	Ser/PI		24/01 09:41
#	N0401-3	11112233003	Ser/PI		24/01 09:41
#	N0401-4	11112233004	Ser/PI		24/01 09:41
#	N0401-5	11112233005	Ser/PI		24/01 09:41
O	N0229-1	11112233006	Ser/PI		24/01 09:42
O	N0229-2	11112233007	Ser/PI		24/01 09:42
O	N0229-3	11112233008	Ser/PI		24/01 09:42
O	N0229-4	11112233009	Ser/PI		24/01 09:42
O	N0229-5	11112233010	Ser/PI		24/01 09:42
#	N0013-1	11112233011	Ser/PI		24/01 09:42
#	N0013-2	11112233012	Ser/PI		24/01 09:42
#	N0013-3	11112233013	Ser/PI		24/01 09:42
#	N0013-4	11112233014	Ser/PI		24/01 09:42
#	N0013-5	11112233015	Ser/PI		24/01 09:42

Demographics   Search   Filter   Send To Host   Delete Record   Delete All   Backup Data   Test Review   Reaction Monitor

Confirm the module and the time on which the sampling was performed.

**Test Review**

Sample : Routine   Rack No. - Pos. : N0401-3  
Type : Ser/PI   Sample ID : 11112233003   Pre-dilution ☐  
Status : Ordered   Carryover Evasion:

Test	1st Result						Rerun Result					
	Data	Alarm	R.M.	A.U.	Time	St	Data	Alarm	R.M.	A.U.	Time	St
ALB2		Samp.S		C1	09:42	I						O
NSE						M						

403-0401: Sample Short  
Routine Rack No.:401 Position: 3  
Pipetting time in Test Review T = 9:42

Cancel   Demographics   Show Detail   Delete Test   Update   Manual Test   Previous   Next   Close

The example *Test Review* window of samples on *Data Review* screen is described in the table below.

**Att FSN-CPS-2017-005 How to proceed whenever the system alarm "Sample Short" or "Abnormal Aspiration" is issued on cobas® 6000**

Rack	Test	Alarm	A.U.	Time	St.	Judgment of measurement result
N0401-1	ALB2		C1	09:42		OK
	NSE		E1-2	09:47		OK
N0401-2	ALB2		C1	09:42		OK
	NSE		E1-2	09:48		OK
N0401-3	ALB2	<b>Samp.S</b>	<b>C1</b>	<b>09:42</b>		Target for verification (Sample for which the sample short alarm was issued) <b>Time T=09:42, Module C1</b>
	NSE				M	
N0401-4	ALB2		C1	09:42		Target for verification (pipetted on module C1 after 9:42)
	NSE		E1-2	09:48		Target for verification (sample pipetted on module c1 after 9:42)
N0401-5	ALB2		C1	09:42		Target for verification (pipetted on module C1 after 9:42)
	NSE		E1-2	09:49		Target for verification (sample pipetted on module c1 after 9:42)
N0013-1	ALB2				M	
	NSE		E1-2	09:44		OK
N0013-2	ALB2				M	
	NSE		E1-2	09:44		OK
N0013-3	ALB2				M	
	NSE		E1-2	09:45		OK
N0013-4	ALB2				M	
	NSE		E1-2	09:46		OK
N0013-5	ALB2				M	
	NSE		E1-2	09:46		OK
N0229-1	ALB2		C1	09:42		Target for verification (pipetted on module C1 after 9:42)
	NSE				M	
N0229-2	ALB2		C1	09:43		Target for verification (pipetted on module C1 after 9:42)
	NSE				M	
N0229-3	ALB2		C1	09:43		Target for verification (pipetted on module C1 after 9:42)
	NSE				M	
N0229-4	ALB2		C1	09:43		Target for verification (pipetted on module C1 after 9:42)
	NSE				M	
N0229-5	ALB2		C1	09:43		Target for verification (pipetted on module C1 after 9:42)
	NSE				M	

No target for verification,  
since not pipetted on c1  
module

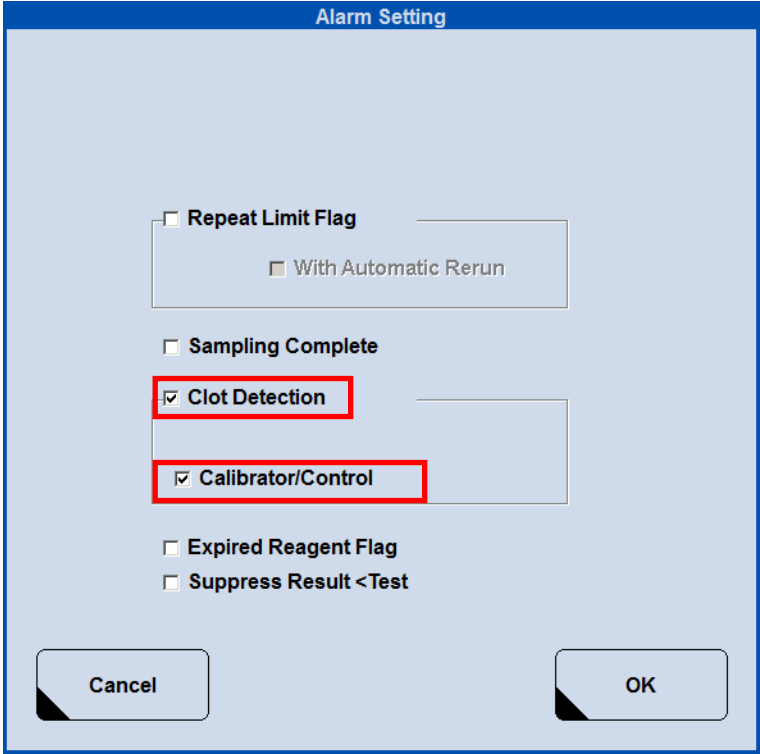
## Attachment 3:

### FSN-CPS-2017-005: “How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” for cobas® c311

#### For cobas® c311:

When the system alarm *Sample Short* or *Abnormal Probe sucking* is issued while there is still sufficient amount of sample volume, it is necessary to replace the sample probe. A verification of the measurement results is required.

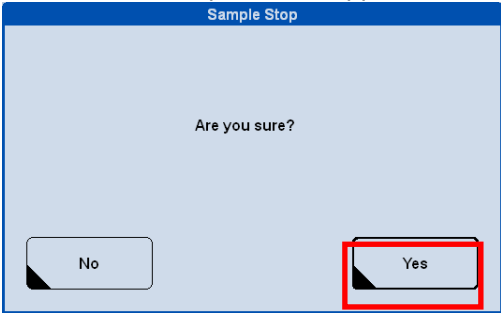
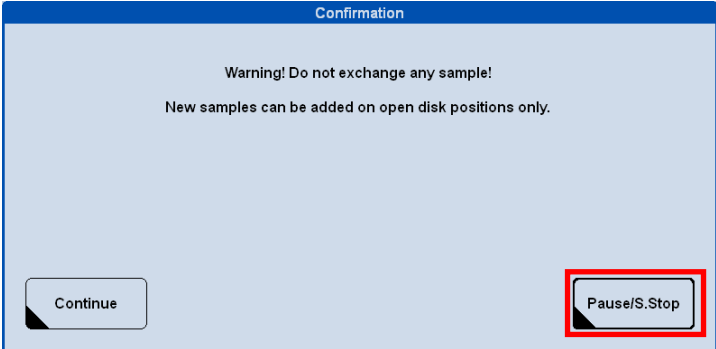
When there is no replacement sample probe available, clean the inside and the outside of the sample probe. This is described in the Operator’s Manual (under sections “*Eliminating clogging of the pipetter probes*” and “*Cleaning probes and nozzles*”).

	Step	Action
<b>Clot Detection ON</b>	<b>1</b>	<p>Verify the Clot Detection and Clot Detection for Calib/Control settings in <i>Utility-System-Alarm Settings</i>.</p> 

**Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® c311**

	Step	Action									
Check the Sample Short and Sample Clot alarm	2	<p>The table below shows the system alarm list of Sample Short and Sample Clot.</p> <table><thead><tr><th>Alarm</th><th>Alarm-Code</th><th>Alarm-Sub-Code</th></tr></thead><tbody><tr><td>Sample-Short</td><td>010</td><td>0001~0110</td></tr><tr><td>Abnormal-Probe-sucking</td><td>012</td><td>0001~0110</td></tr></tbody></table>	Alarm	Alarm-Code	Alarm-Sub-Code	Sample-Short	010	0001~0110	Abnormal-Probe-sucking	012	0001~0110
Alarm	Alarm-Code	Alarm-Sub-Code									
Sample-Short	010	0001~0110									
Abnormal-Probe-sucking	012	0001~0110									
Sampling Stop	3	<p>a) When the alarm is issued, select the S. Stop button.</p>									

**Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® c311**

	<b>3b</b>	<p>b) When the [S. Stop] window appears, choose [Yes].</p>  <p>c) Confirm the confirmation window with <i>[Pause/S.Stop]</i></p> 
<b>Wait until status Sampling Stop</b>	<b>4</b>	Wait until the system status switches to Sampling Stop.

Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® c311

Identify sample for alarm which was issued

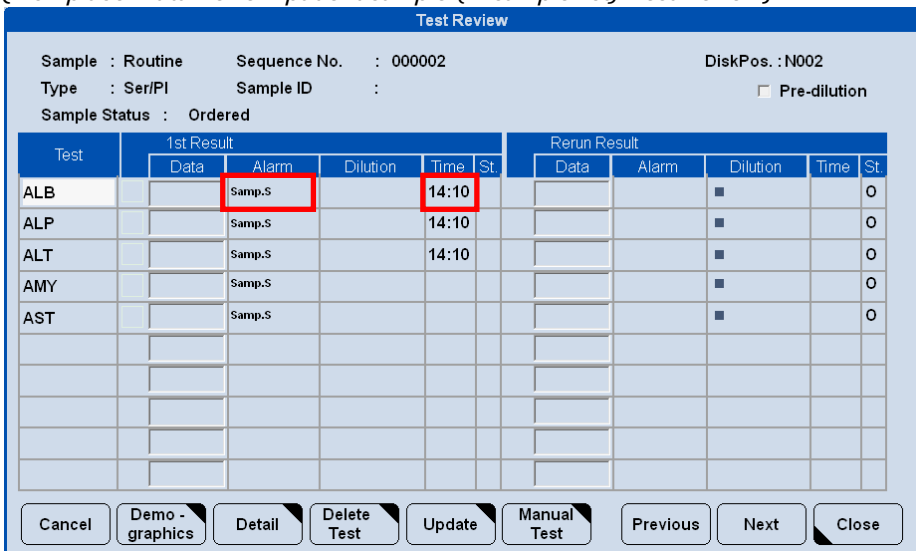
5

Identify the sample for which the system alarm was issued according to the code of the system alarm (refer to the following figure).

010-0002: Sample Short  
→Position: 2

Example of a sample with Sample Short alarm.

**Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® c311**

<b>Check sample volume</b>	<b>6</b>	<p>Check</p> <p>a) the sample volume in the sample container, and</p> <p>b) whether there is any substance adhered to the sample probe.</p> <p>No action is required when the sample volume is insufficient, and the sample probe is clean.</p> <p>When there is sufficient sample volume and probe is not clean, replace the sample probe and move on to step 7.</p>
<b>Sampling time in Test Review</b>	<b>7</b>	<p>Check the sampling time for which the alarm was issued in the <i>Test Review</i> screen (<i>Workplace-Data Review-patient sample (in sample list)-Test Review</i>).</p> 
<b>Verify the results or discard the samples</b>	<b>8</b>	<p>Check the test results which were measured after the sampling time in step 7 on the data review screen.</p> <p>Verification of affected samples will be based on laboratory procedures/protocols.</p> <p>An example of tests to be verified is described below</p>

Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® c311

Example

9

On the *Data Review* screen, select all samples that were sampled on the analyzer unit after the sample with the sample short alarm, including the sample concerned. Then display the Test Review window.

Core AU

Sampling Stop

bmserv

01/24/17 (Tue) 14:22

Workplace

Reagent

Calibration

QC

Utility

Test Selection

Data Review

Filter

OFF

ON

Routine View

Sample Count: 5

St.	S. No.	Disk	Sar	Type	NAME	Arrived Date/Time
O	N000001	N001		Ser/PI		01/24 14:08
O	N000002	N002		Ser/PI		01/24 14:08
O	N000003	N003		Ser/PI		01/24 14:08
O	N000004	N004		Ser/PI		01/24 14:09
O	N000005	N005		Ser/PI		01/24 14:09

Test	Result	Alarm	Unit
ALB	Samp.S		
ALP	Samp.S		
ALT	Samp.S		
AMY	Samp.S		
AST	Samp.S		

Demo-graphics

Search

Filter

Send To Host

Delete Record

Delete All

Backup Data

Test Review

Reaction Monitor

?

Help

Select the sample from the list box.

Stop

Shut down

S. Stop

Alarm

Media Eject

Print

Pause/Scan

Start

CAP NUM

Test Review

Sample : Routine    Sequence No. : 000002    DiskPos. : N002

Type : Ser/PI    Sample ID :    ☐ Pre-dilution

Sample Status : Ordered

Test	1st Result					Rerun Result				
	Data	Alarm	Dilution	Time	St.	Data	Alarm	Dilution	Time	St.
ALB		Samp.S		14:10						O
ALP		Samp.S		14:10						O
ALT		Samp.S		14:10						O
AMY		Samp.S								O
AST		Samp.S								O

Cancel

Demo-graphics

Detail

Delete Test

Update

Manual Test

Previous

Next

Close

The example *Test Review* window of samples on *Data Review* screen is described in the table below.

**Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® c311**

S.No	Disk Pos.	Test	Alarm	Time	Judgment of measurement result
N000001	N001	ALB	-	14:09	OK
	N001	ALP	-	14:09	OK
	N001	ALT	-	14:09	OK
	N001	AMY	-	14:10	OK
	N001	AST	-	14:10	OK
N000002	N002	ALB	Samp.S	14:10	Target for verification (sample for which the sample short alarm was issued)
	N002	ALP	Samp.S	14:10	Target for verification (sample for which the sample short alarm was issued)
	N002	ALT	Samp.S	14:10	Target for verification (sample for which the sample short alarm was issued)
	N002	AMY	Samp.S	-	-
	N002	AST	Samp.S	-	-
N000003	N003	ALB	-	14:11	Target for verification (sample pipetted after 14:10)
	N003	ALP	-	14:11	Target for verification (sample pipetted after 14:10)
	N003	ALT	-	14:11	Target for verification (sample pipetted after 14:10)
	N003	AMY	-	14:11	Target for verification (sample pipetted after 14:10)
	N003	AST	-	14:11	Target for verification (sample pipetted after 14:10)
N000004	N004	ALB	-	14:12	Target for verification (sample pipetted after 14:10)
	N004	ALP	-	14:12	Target for verification (sample pipetted after 14:10)
	N004	ALT	-	14:12	Target for verification (sample pipetted after 14:10)
	N004	AMY	-	14:12	Target for verification (sample pipetted after 14:10)
	N004	AST	-	14:12	Target for verification (sample pipetted after 14:10)
N000005	N005	ALB	-	14:13	Target for verification (sample pipetted after 14:10)
	N005	ALP	-	14:13	Target for verification (sample pipetted after 14:10)
	N005	ALT	-	14:13	Target for verification (sample pipetted after 14:10)
	N005	AMY	-	14:13	Target for verification (sample pipetted after 14:10)
	N005	AST	-	14:13	Target for verification (sample pipetted after 14:10)