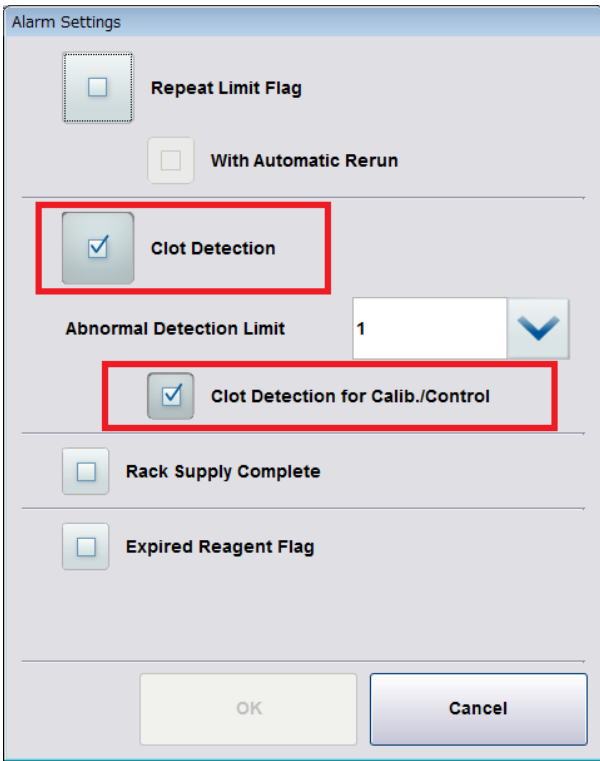
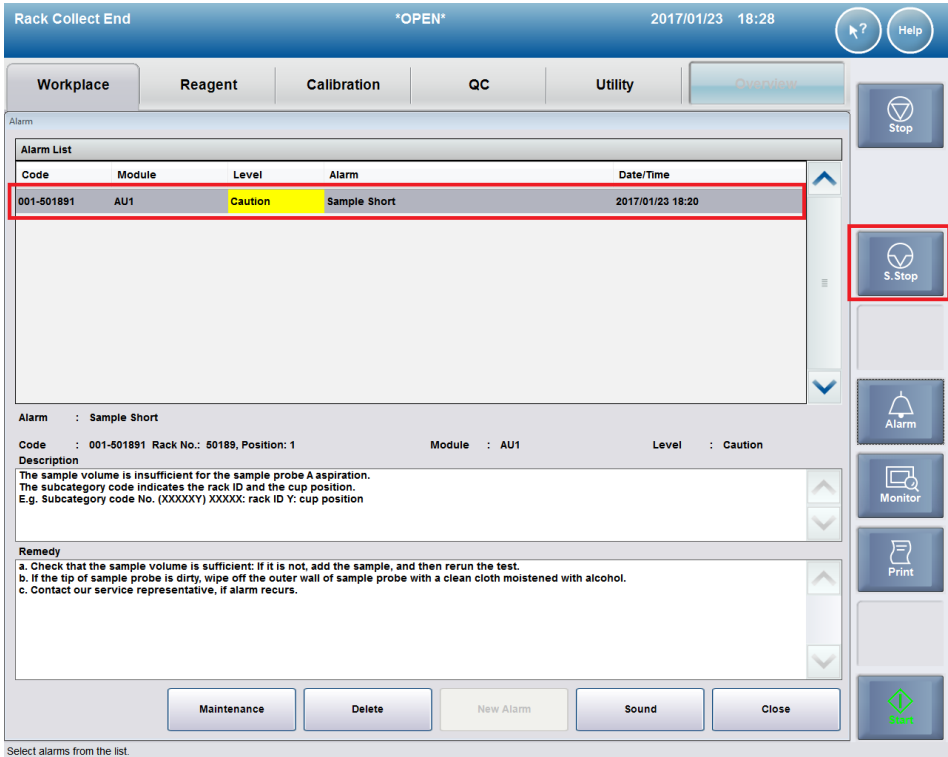


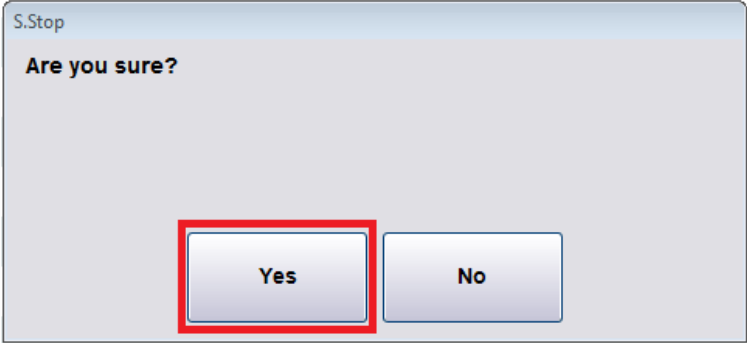
Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® 8000

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 inside and outside of the sample probe. This is described in the Operator’s Manual Version 5.1 and in the manual “cobas 8000 modular analyzer series Interlock Manual c 502 module –Version 2.1 Software version 06-02”. The inside cleaning maintenance actions of the cobas c502 module series can only be performed by specially trained operators. Please refer to the coinciding procedures “Eliminating clogging of the sample probe” and “Cleaning all pipetter probes and rinse nozzles”.

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

	Step	Action																														
<p>Check the Sample Short and Sample Clot alarm</p>	<p>2</p>	<p>The table below shows the system alarm list of Sample Short and Sample Clot.</p> <table border="1" data-bbox="537 342 1511 968"> <thead> <tr> <th>Alarm</th> <th>Module</th> <th>Alarm Code</th> <th>Alarm Sub Category</th> </tr> </thead> <tbody> <tr> <td rowspan="3">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>c502</td> <td>401 – 440 (The cup position is indicated by alarm code)</td> <td>0XXXXX XXXXX: rack No.</td> </tr> <tr> <td rowspan="5">Abnormal Aspiration (The alarm of Sample Clot is issued as "Abnormal Aspiration")</td> <td>ISE</td> <td>441</td> <td>000001</td> </tr> <tr> <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>c502</td> <td>451 – 490 (The cup position is indicated by alarm code)</td> <td>0XXXXX XXXXX: rack No.</td> </tr> <tr> <td>c502</td> <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.	Abnormal Aspiration (The alarm of Sample Clot is issued as "Abnormal Aspiration")	ISE	441	000001	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.	c502	491	000001
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	c502	491	000001																													
<p>Sampling Stop</p>	<p>3</p>	<p>a) When the alarm is issued, select the <i>S. Stop</i> button.</p>  <p>The screenshot shows the 'Rack Collect End' screen with the 'Alarm' section active. The 'Alarm List' table has the following data:</p> <table border="1" data-bbox="542 1178 1333 1419"> <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> <p>The 'S.Stop' button is highlighted with a red box. Below the alarm list, the details for the 'Sample Short' alarm are shown, including the code, module, level, and description. The 'Remedy' section provides instructions for resolving the issue.</p>	Code	Module	Level	Alarm	Date/Time	001-501891	AU1	Caution	Sample Short	2017/01/23 18:20																				
Code	Module	Level	Alarm	Date/Time																												
001-501891	AU1	Caution	Sample Short	2017/01/23 18:20																												

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

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 screenshot displays the 'Alarm List' window with the following data:

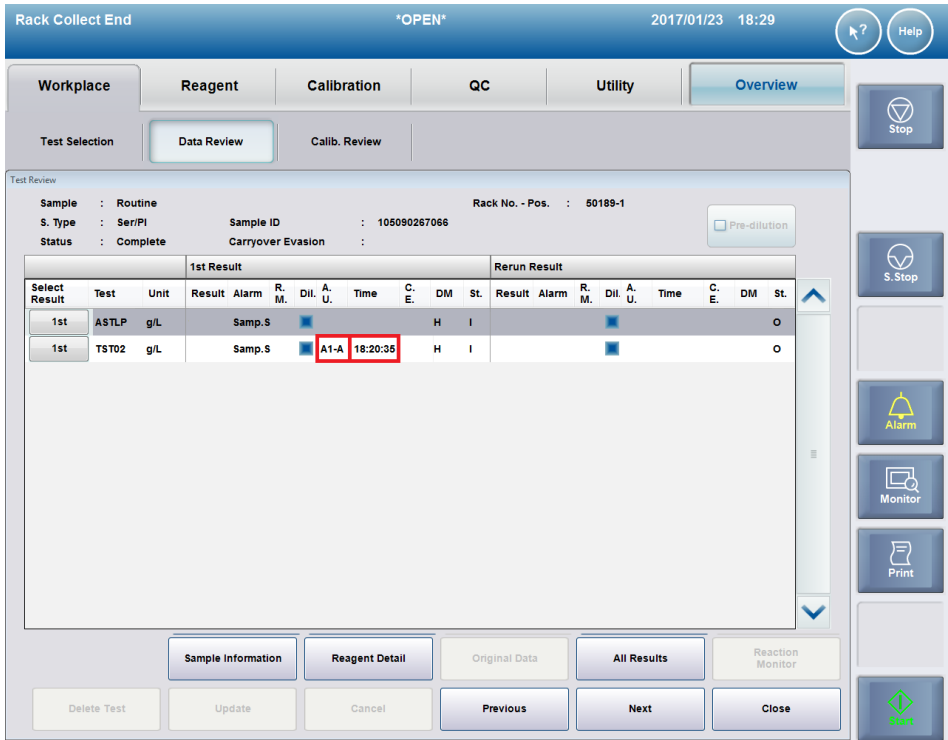
Code	Module	Level	Alarm	Date/Time
001-501891	AU1	Caution	Sample Short	2017/01/23 18:20

Below the alarm list, the 'Description' and 'Remedy' sections are visible. The 'Remedy' section includes instructions such as: '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.', and 'c. Contact our service representative, if alarm recurs.'

The 'Sample List' window shows a table of samples with the following columns: DM, C, E, St, S, ID, Rack No., S. Type, Name, Date/Time, C, E, Dil, Unit, Result, Unit, Alarm, A. U., Rg, St, Strd. The sample '50189-1' is highlighted in red, corresponding to the alarm code.

A callout box points to the alarm code with the text: '001-501891: Sample Short -> Routine Rack No.: 50189 Position: 1'

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

<p>Check sample volume</p>	<p>6</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, replace the sample probe and move on to step 7.</p>
<p>Module and sampling time in Test Review</p>	<p>7</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> 

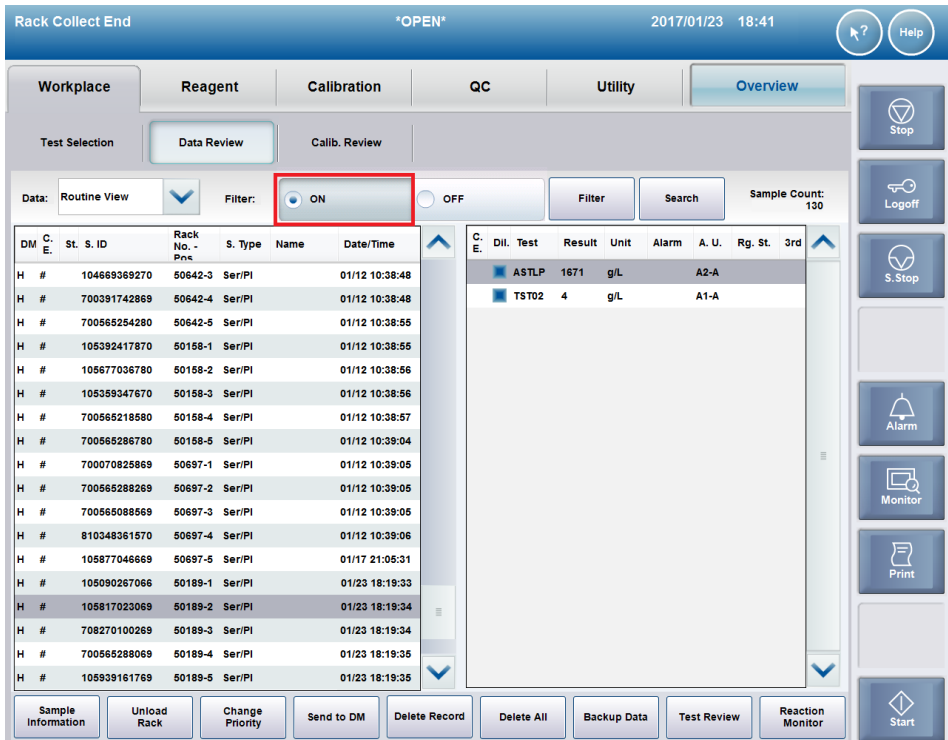
Set filter for the specific module

8

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 shows the 'Workplace' tab of the cobas 8000 software. The 'Data Review' section is active, and the 'Filter' button is highlighted with a red box. The interface includes a top navigation bar with 'Rack Collect End', 'OPEN', and the date/time '2017/01/23 18:29'. Below the navigation bar are tabs for 'Workplace', 'Reagent', 'Calibration', 'QC', 'Utility', and 'Overview'. The 'Data Review' section has a 'Data' dropdown set to 'Routine View', a 'Filter' dropdown set to 'ON', and a 'Filter' button highlighted in red. A table of sample data is visible below the filter controls, with columns for 'DM', 'C.E.', 'St. S. ID', 'Rack No. - Pos.', 'S. Type', 'Name', and 'Date/Time'. A 'Sample Count: 130' is displayed on the right. On the far right, there is a vertical toolbar with buttons for 'Stop', 'Logoff', 'S. Stop', 'Alarm', 'Monitor', 'Print', and 'Start'.

The screenshot shows the 'Filter' dialog box. It has several sections for filtering samples: 'Sample' (Routine, Stat, Control), 'Sample Status' (Ordered, Processing, Complete, Incomplete), 'S. Type' (Ser/PI, Urine, CSF, Suprnt, Others, WhiBld, OraFlu, Hemoly, AmniF, Stool), 'DM Status' (DM Sent), 'Analyzed Unit' (set to 'A1-A' and highlighted in red), 'Analyzed Test', and 'Results with Rerun Only'. There are also fields for 'Arrived Date' and 'Arrived Time'. The 'OK' button is highlighted in red at the bottom.

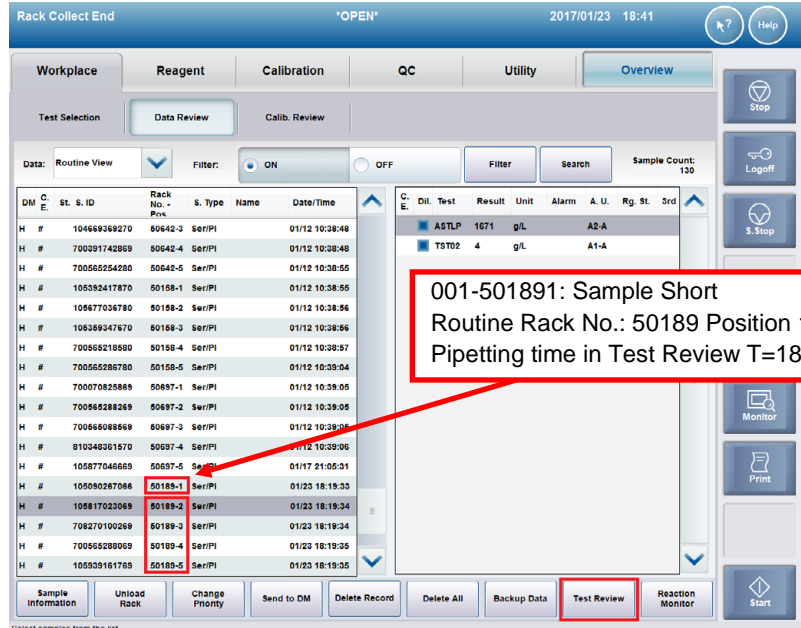
<p>Filter for the specific module</p>	<p>9</p>	<p>Select the [ON] radio button for Filter on Data Review screen.</p>  <p>The screenshot shows the 'Data Review' screen with the 'Filter' radio button selected. The table below lists the sample data shown on the screen.</p> <table border="1"> <thead> <tr> <th>DM</th> <th>C. E.</th> <th>St. S. ID</th> <th>Rack No. - Pnc</th> <th>S. Type</th> <th>Name</th> <th>Date/Time</th> </tr> </thead> <tbody> <tr><td>H</td><td>#</td><td>104669369270</td><td>50642-3</td><td>Ser/PI</td><td></td><td>01/12 10:38:48</td></tr> <tr><td>H</td><td>#</td><td>700391742869</td><td>50642-4</td><td>Ser/PI</td><td></td><td>01/12 10:38:48</td></tr> <tr><td>H</td><td>#</td><td>700565254280</td><td>50642-5</td><td>Ser/PI</td><td></td><td>01/12 10:38:55</td></tr> <tr><td>H</td><td>#</td><td>105392417870</td><td>50158-1</td><td>Ser/PI</td><td></td><td>01/12 10:38:55</td></tr> <tr><td>H</td><td>#</td><td>105677036780</td><td>50158-2</td><td>Ser/PI</td><td></td><td>01/12 10:38:56</td></tr> <tr><td>H</td><td>#</td><td>10539347670</td><td>50158-3</td><td>Ser/PI</td><td></td><td>01/12 10:38:56</td></tr> <tr><td>H</td><td>#</td><td>700565218580</td><td>50158-4</td><td>Ser/PI</td><td></td><td>01/12 10:38:57</td></tr> <tr><td>H</td><td>#</td><td>700565286780</td><td>50158-5</td><td>Ser/PI</td><td></td><td>01/12 10:39:04</td></tr> <tr><td>H</td><td>#</td><td>700070825869</td><td>50697-1</td><td>Ser/PI</td><td></td><td>01/12 10:39:05</td></tr> <tr><td>H</td><td>#</td><td>700565288269</td><td>50697-2</td><td>Ser/PI</td><td></td><td>01/12 10:39:05</td></tr> <tr><td>H</td><td>#</td><td>700565088569</td><td>50697-3</td><td>Ser/PI</td><td></td><td>01/12 10:39:05</td></tr> <tr><td>H</td><td>#</td><td>810348361570</td><td>50697-4</td><td>Ser/PI</td><td></td><td>01/12 10:39:06</td></tr> <tr><td>H</td><td>#</td><td>105877046669</td><td>50697-5</td><td>Ser/PI</td><td></td><td>01/17 21:05:31</td></tr> <tr><td>H</td><td>#</td><td>105090267066</td><td>50189-1</td><td>Ser/PI</td><td></td><td>01/23 18:19:33</td></tr> <tr><td>H</td><td>#</td><td>105817023069</td><td>50189-2</td><td>Ser/PI</td><td></td><td>01/23 18:19:34</td></tr> <tr><td>H</td><td>#</td><td>708270100269</td><td>50189-3</td><td>Ser/PI</td><td></td><td>01/23 18:19:34</td></tr> <tr><td>H</td><td>#</td><td>700565288069</td><td>50189-4</td><td>Ser/PI</td><td></td><td>01/23 18:19:35</td></tr> <tr><td>H</td><td>#</td><td>105939161769</td><td>50189-5</td><td>Ser/PI</td><td></td><td>01/23 18:19:35</td></tr> </tbody> </table>	DM	C. E.	St. S. ID	Rack No. - Pnc	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	#	10539347670	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	#	105877046669	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
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<p>Verify the results or discard the samples</p>	<p>10</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>All affected samples have to be verified/ discarded according to the local rules.</p> <p>An example of tests to be verified is described on the next page.</p>																																																																																																																																					

Example

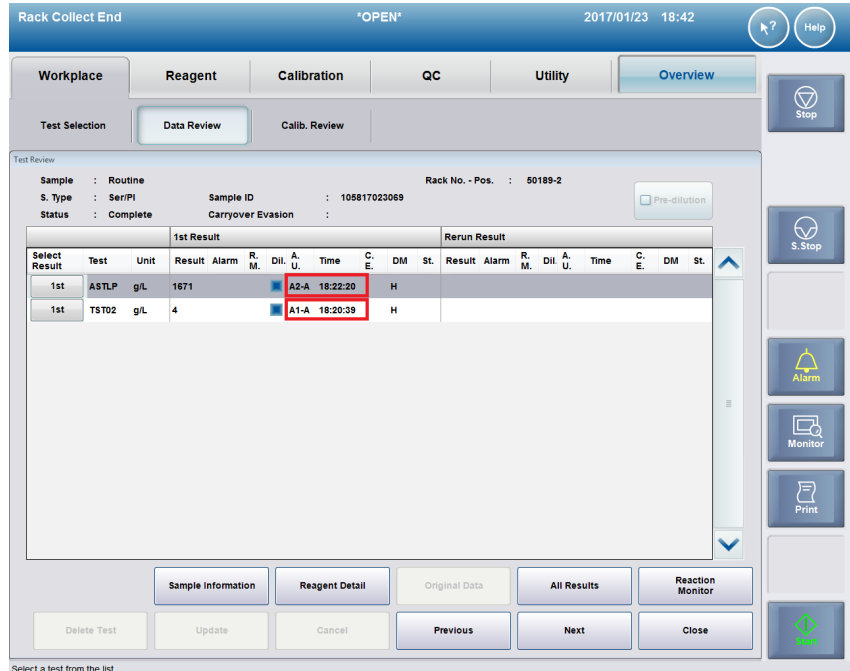
11

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.



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	Samp.S	A1-A	01/23 18:20:35		Target for verification (Sample for which the sample short alarm was issued) Time T=18:20:35, Module A1-A
	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)