

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

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

Roche Diagnostics Asia Pacific Pte Ltd

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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

Attachment 1:

FSN-CPS-2017-005: "How to proceed whenever the system alarm "Sample Short" or "Abnormal Aspiration" for cobas[®] 8000

For cobas[®] 8000:

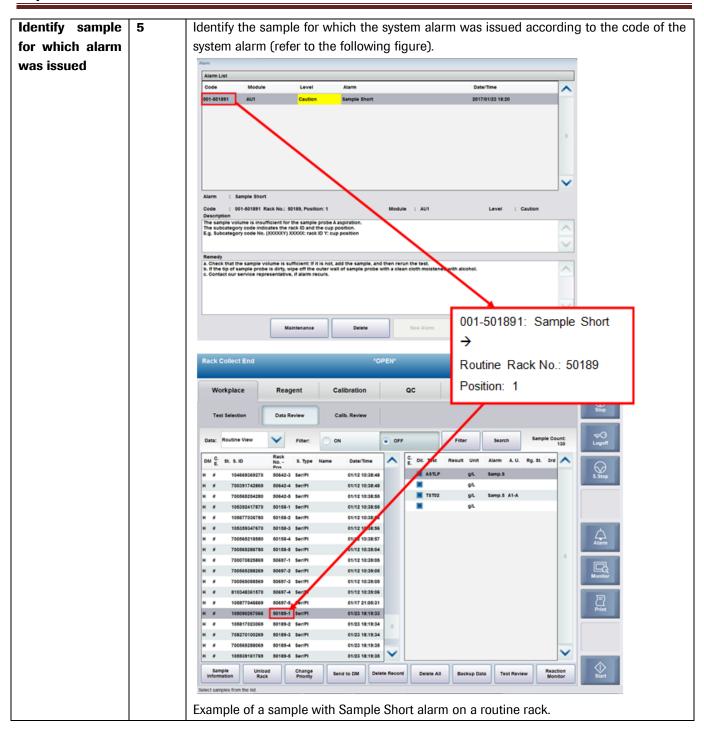
When the system alarm *Sample Short* or *Abnormal Aspiration* is issued while there is still sufficient amount of sample volume, it is necessary to replace the sample probe. A verification of the measurement results is required.

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
Clot Detection	1	Verify the Clot Detection and Clot Detection for Calib/Control settings in Utility-System-
ON		Alarm Settings.
		Alarm Settings
		Repeat Limit Flag
		With Automatic Rerun
		Clot Detection
		Abnormal Detection Limit 1
		Clot Detection for Calib./Control
		Rack Supply Complete
		Expired Reagent Flag
		ОК Cancel
		OK Cancel

	Step	Action			
Check the	2	The table below shows the	system alarn	n list of Sample Short and	d Sample Clot.
Sample Short and Sample Clot		Alarm	Module	Alarm Code	Alarm Sub Category
alarm		Sample Short	ISE	010	XXXXXY XXXXX: rack No.
			c701/c702	001 - 002	Y: cup position XXXXXY XXXXX: rack No.
			c502	401 – 440 (The cup position is	Y: cup position 0XXXXX XXXXX: rack No.
				indicated by alarm code) 441	000001
		Abnormal Aspiration	ISE	007	XXXXXY XXXXX: rack No.
		(The alarm of Sample Clot is issued as "Abnormal Aspiration")	c701/c702	004 - 005	Y: cup position XXXXXY XXXXX: rack No.
			c502	451 – 490 (The cup position is indicated by alarm code)	Y: cup position 0XXXXX XXXXX: rack No.
				491	000001
Sampling Stop	3	a) When the alarm is Rack Collect End Workplace Reagent	Calibration	ct the <i>S. Stop</i> button. 2017/01/23 ac utility	18:28 R? Help
		Code Module Level 001-501891 AU1 Caution	Alarm Sample Short	Date/Time 2017/01/23 18:20	
					E S.Stop
		Alarm : Sample Short Code : 001-501891 Rack No.: 50189, Position: 1 Description The sample volume is insufficient for the sample prob	e A aspiration.	odule : AU1 Level :	Caution
		The subcategory code indicates the rack ID and the cc E.g. Subcategory code No. (XXXXXY) XXXXX: rack ID Y: Remedy a. Check that the sample volume is sufficient: If it is no b. If the ip of sample probe is dirty, wipe off the outer	cup position	rerun the test.	Monitor Print
		b. If the up of sample probe is unity, while on the outer c. Contact our service representative, if alarm recurs.	or sample prope with a		
		Maintenance Select alarms from the list.	Delete	New Alarm Sound	Close
		School diditis from the list.			

	Step	Acti	on							
	3b	b)	When	the	[S.	Stop]	window	appears,	choose	[Yes].
		S.Sto	р							
		Ar	e you sure:	?						
			-							
					Yes		No			
					res		NO			
Wait until racks	4	Wait	until all o	of racks	are co	llected in	the unloadir	ng area. (Wa	iting time m	iay vary
are unloaded		depe	ending on t	he condi	tion of t	the ordered	d analysis)			



Check sample	6	Check
volume		a) the sample volume in the sample container, and
		b) whether there is any substance adhered to the sample probe.
		No action is required when the sample volume is insufficient, and the sample probe is
		clean.
		When there is sufficient sample volume and the probe is not clean, replace the sample
		probe and move on to step 7.
Module and	7	Check the module and the sampling time for which the alarm was issued in the Test
sampling time in		Review screen (Workplace-Data Review-patient sample (in sample list)-Test Review).
Test Review		Rack Collect End *OPEN* 2017/01/23 18:29
		Workplace Reagent Calibration QC Utility Overview
		Test Selection Data Review Calib. Review
		Test Review
		Sample : Routine Rack No Pos. : 50189-1 S. Type : Ser/PI Sample ID : 105090267066
		Status : Complete Carryover Evasion 1st Result Rerun Result
		Select Test Unit Result Alarm M. Dil. A. Time C. DM St. Result Alarm M. Dil. A. Time C. DM St.
		1st ASTLP g/L Samp.S H I O 1st TST02 g/L Samp.S A1-A 18:20:35 H I O
		Monitor
		Print
		Sample Information Reagent Detail Original Data All Results Reaction Monitor
		Delete Test Update Cancel Previous Next Close Start
		Select a test from the list.

Set filter for the	8		-	' filter for sa				as perfori	med on the
specific module		SPECIFIC MO		ep 7 (in <i>Work</i>	(place-Data DPEN*		Iter). 2017/01/23 1:	8:29	() (Help
		Workplace	Reagent	Calibration	QC	Utility	0	verview	
		Test Selection	Data Review	Calib. Review					Stop
		Data: Routine View	Filter:	ON	• OFF	Filter	Search	Sample Count: 130	्रू⊖ Logoff
		DM E. St. S. ID H # 10466936	No S. Type Pos 270 50642-3 Ser/Pl	01/12 10:38:48			Alarm A. U. R <u>c</u> Samp.S	g. St. 3rd 🔨	S.Stop
		H # 70039174 H # 70056525 H # 10539241	280 50642-5 Ser/Pl	01/12 10:38:48 01/12 10:38:58 01/12 10:38:58	5 🔳 TSTO	-	Samp.S A1-A		
		H # 105677034 H # 10535934 H # 700565211	670 50158-3 Ser/Pl	01/12 10:38:56 01/12 10:38:56 01/12 10:38:57	5				Alarm
		H # 700565280 H # 70007082	780 50158-5 Ser/Pl 869 50697-1 Ser/Pl	01/12 10:39:04 01/12 10:39:05	5			Ξ	Alarm
		H # 70056528 H # 70056508 H # 81034836	569 50697-3 Ser/Pl	01/12 10:39:08 01/12 10:39:08 01/12 10:39:08	5				Monitor
		H # 10587704 H # 10509026 H # 10581702	066 50189-1 Ser/Pl	01/17 21:05:31 01/23 18:19:33 01/23 18:19:34	3				Print
		H # 70827010 H # 70056528	269 50189-3 Ser/Pl 2069 50189-4 Ser/Pl	01/23 18:19:34 01/23 18:19:35	4 5			~	
		H # 10593916 Sample Information	769 50189-5 Ser/Pl Unload Rack Priority	01/23 18:19:35	lete Record Delete A	II Backup Data	Test Review	Reaction Monitor	Start
		Select samples from the list Filter Sample:	t	Sample Status:					
		Routine Stat		Ordered Processing					
		Control		Complete					
		S. Type:	WhiBid	DM Status:					
		Urine CSF	OraFlu Hemoly	Analyzed Unit	A1-A]			
		Suprnt Others	AmniF Stool	Analyzed Test Results with Reru	n Only				
		Arrived Date			1	-			
				ок	Cancel	Ĵ			

Filter for the	9	Select the [ON] radio button for Filter on Data Review screen.
specific module		Rack Collect End *OPEN* 2017/01/23 18:41
		Workplace Reagent Calibration QC Utility Overview
		Test Selection Data Review Calib. Review
		Data: Routine View V Filter: ON OFF Filter Search Sample Count: 130
		DM C. St. S. ID No S. Type Name Date/Time C. Dill. Test Result Unit Alarm A. U. Rg. St. 3rd A Proc
		H # 1046693693270 50642-3 SeriPi 01/12 10:38:48 ASTLP 1671 g/L A2-A H # 700391742869 50642-4 SeriPi 01/12 10:38:48 TST02 4 g/L A1-A
		H # 700565254280 50642-5 Ser/PI 01/12 10:38:55 H # 105392417870 50158-1 Ser/PI 01/12 10:38:55
		H # 105677035780 50158-2 Ser/PI 01/12 10:38:56
		H # 105359347670 50158-3 SeriPI 01/1210:38:56 H # 700565218580 50158-4 SeriPI 01/1210:38:57
		H # 700565218580 50158-4 Ser/PI 01/12 10:38:57 H # 700565286780 50158-5 Ser/PI 01/12 10:39:04
		H # 700070825859 50697-1 Ser/PI 01/1210:39:05
		H # 700565288289 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 01/1210:39:06 H # 105877046669 50697-5 Ser/PI 01/17 21:05:31
		Print
		H # 105090267066 50189-1 Ser/PI 01/2318:19:33
		H # 708270100269 50189-3 Ser/PI 01/23 18:19:34
		H # 700555288059 50189-4 Ser/PI 01/23 18:19:35
		H # 105939161769 50189-5 Ser/PI 01/23 18:19:35 💟
		Sample Information Unload Rack Change Priority Send to DM Delete Record Delete All Backup Data Test Review Reaction Monitor
		Select samples from the list
lerify the	e 10	Check the test results which were measured after the sampling time in step 7 on th
results o	r	Data Review screen in step 9.
liscard the	•	
samples		Verification of affected samples will be based on laboratory procedures/protocols.
		An example of tests to be verified is described on the next page.

Example	11	On the Date Device encorport all complex that were compled on the applyzer unit
Example		On the <i>Data Review</i> 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. Rack Collect End *OPEN* 2017/01/23 18:41
		Workplace Reagent Calibration QC Utility Overview
		Test Selection Data Review Calib. Review
		Data: Routine View V Filter: ON OFF Filter Search Sample Count: 130
		DM C. St. S. ID Rack No S. Type Name DaterTime A C. Dil. Test Result Unit Alarm A. U. Rg. St. 3rd
		H # 10468369270 5042-3 5er/FI 01/1210:3848 E 5370 9L A3-A 53.50p
		H # 700555254280 50642-5 5er/FI 01/12 10:38:55 H # 105352417870 50158-1 5er/FI 01/12 10:38:55 0011-501891: Sample Short
		H # 10557703780 50158-2 Ser/FPI 01/12 10:38:56 H # 105359547870 50158-3 Ser/FPI 01/12 10:38:56 Routine Rack No.: 50189 Position 1
		H # 700555218580 50158-4 Ser/PI 01/12 10:38:67 H # 700555287780 50158-5 Ser/PI 01/12 10:38:67 Pipetting time in Test Review T=18:20:35
		H # 700070825859 50657-1 Ser/FH 01/12 10:38:05 H # 700555282239 50657-2 Ser/FH 01/12 10:38:05
		H # 7005505555 50657-3 Ser/FI 01/12 103505 H # S10045051570 50657-4 Ser/FI 01/12 103505
		H # 105877046669 50697-5 59-20 01/17 21:05:31
		H # 10581702069 50183-2 Ser/PI 01/23 18:19:34
		H # 708270100289 \$018-3 \$er/FI 01/23 18:19-34 H # 700565280069 \$018-4 \$er/FI 01/23 18:19-34
		H # 109333161769 5019-5 Ser/PI 01/23 16:15.25 Sample Unload Change Send to DM Delete All Backup Data Test Review Monitor Start
		Information Rack Priority and to UM Overla Accord Delete All Backup Udd Instruction Monitor Start Select samples from the list.
		Confirm the module and the time on which the sampling was performed.
		Rack Collect End *OPEN* 2017/01/23 18:42
		Workplace Reagent Calibration QC Utility Overview
		Test Selection Data Review Calib. Review
		Test Review Sample : Routine Rack No Pos. : 50199-2
		S. Type : Ser/PI Sample ID : 105617023059 Status : Complete Carryover Evasion :
		Ist Result Rerun Result Select Test Unit A: Time C: Dil A: Time C: Stop Result Test Unit Result A: Time C: DM St. Stop
		1st ASTLP g/L 1871 X A2-A 18:22:20 H
		1st T\$T02 g/L 4 A1-A 18:20:39 H
		Monitor
		E Prim
		Sample Information Reagent Detail Original Data All Results Reaction Monitor
		Delete Test Update Cancel Previous Next Close Select a lest from the list.
		The example Test Review window of samples on Data Review screen is described in the
		table below.

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				Μ	
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
Clot Detection ON	Step 1	Action Verify the Clot Detection and Clot Detection for Calib/Control settings in Utility-System- Alarm Settings.

	Step	Action							
Check the	2	The table below shows the syste	em alarm list of Sam	ple Short and Sample	Clot.				
Sample Short		Alarm¶	Alarm · Code¶	Alarm · Sub · Code¶	α				
and Sample Clot		α	Ω	Ω					
alarm		Sample Short¤	431·-·435¤	0001-9999¤	σ				
			436·-·440¤	0001-9999¤	σ				
			401 ·- ·405¤	0001-9999¤	n				
			406·-·410¤	0001-9999¤	σ				
			411 - ∙415¤	0001-9999¤	n				
			416·-·420¤	0001-9999¤	σ				
			421 ·-·425¤	0001-9999¤	σ				
			426 ∙430¤	0001-9999¤	σ				
			441¤	0001¤	σ				
		Abnormal Probe sucking	481·-·485¤	0001·-·9999¤	σ				
		¶	486·-·490¤	00019999¤	σ				
		(The alarm of Sample Clot	451·-·455¤	00019999¤	σ				
		is issued as "Abnormal	456·-·460¤	00019999¤	σ				
		Probe sucking")∝	461 465¤	0001·-·9999¤	σ				
			466·-·470¤	00019999¤	σ				
			471·-·475¤	0001·-·9999¤	σ				
			476 480¤	00019999¤	n				
		028-0002 c501 Caution Inc	nple is sufficient: If it is not, add volu lean the outer wall of sample probe.		Shut Down S. Stop Alarm Print				

		S. Stop Are you sure? No C) Confirm the confirmation window with [Yes]
		Confirmation
		Are you sure?
Wait until racks are unloaded	4	Wait until all racks are transferred to the unloader. (Waiting time may vary depending on the condition of the ordered analysis)

r which alarm	5					the system		n was issu	ed acco	ording	to the	e co
		system al	arm (re	efer to t	he follo	wing figure	e).					
as issued						Alar	m					
		Code	Mod	lule	Level			Alarm		Dat	e/Time	
		403-0401	c 91		aution	Sample Short					7 09:42	
		029-0001	c501		aution aution	Inc. Water Tem Inc. Water Lev					7 09:41	-
			_									_
												-
												-
		Description	and Remed	dy								
			03-0401									-
		Description				e in the specified	sa					
		Routine rac	sk.Subcode	indicates Ra	ack No.		40)3-0401: S	ample S	Short		
		Remedy :(1 then rerun		see whether	the volume	of sample is suffi	cie →					
		(2) If the tip	of sample p			ol to clean the out	er 7					
		Please com	tact service	representa	tive, if the a	larm recurs.	R	outine Rac	k No.:40	01		
					-			aitian. 2				
		Delete		New Alarm	Sou	ind Mi		osition: 3				
		L									d	
		Work	nlace	Re	agent	Calibr	ation				tility	
		Work		1	agent	Calibra	ation	Q	c	Ut	tility	
		Test Select		Re ta Review	Calib. Re		ation	Q	c	Ui	tility	
			tion Dat	1	Calib. Re		ation		C	U	tility	
		Filter -	tion Dat	ta Review	Calib. Re Data - Rour	view tine View		Sample C	count: 15			
		Filter	tion Dat	ta Review	Calib. Re Data - Rour	view tine View 💌 Name Date	Time	Sample C	count: 15	R.M. Alarm	A.U. U	Init
		Test Select Filter © OFF St. Rack # N0401-1 # N0401-2	tion Dat	mple 10 1111223300	Calib. Re Data - Rout Type 1 Ser/PI 2 Ser/PI	view tine View	Time 09:41	Sample C	count: 15		A.U. U	init
		Test Select Filter	C ON	ta Review mple 19 1111223300 1111223300 1111223300	Calib. Re Data Rour Type 1 Ser/PI 2 Ser/PI 3 Ser/PI	view iine View Name Date 24/01 24/01 24/01	Time 09:41 09:41 09:41	Sample C	count: 15	R.M. Alarm	A.U. U	Init
		Test Select Filter	C ON	ta Review mple 19 1111223300 1111223300 1111223300 1111223300	Calib. Re Data Rour Type 1 Ser/PI 2 Ser/PI 3 Ser/PI 4 Ser/PI	view Name Date 24/01 24/01 24/01 24/01	Time 09:41 09:41 09:41 09:41	Sample C Test ALB2	count: 15	R.M. Alarm	A.U. U	init
		Test Select Filter	C ON	ta Review mple 19 1111223300 1111223300 1111223300	Calib. Re Data Rout Ser/PI Ser/PI Ser/PI Ser/PI Ser/PI	view iine View Name Date 24/01 24/01 24/01	Time 39:41 39:41 39:41 39:41 39:41 39:41	Sample C Test ALB2	count: 15	R.M. Alarm	A.U. U	init
		Test Select Filter ∽ OFF St. Rack # N0401-1 # N0401-3 # N0401-3 # N0401-5 Ø N0401-5 Ø N0401-5 Ø N0401-5 Ø N0401-5 Ø N0401-5 Ø N0229-1 Ø N0229-2	C ON Sar	ta Review mple b 1111223300 1111223300 1111223300 1111223300 1111223300 1111223300	Calib. Re Data Rout 1 Ser/PI 2 Ser/PI 3 Ser/PI 4 Ser/PI 5 Ser/PI 6 Ser/PI 7 Ser/PI	View Name Date 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01	Time 39:41 39:41 39:41 39:41 39:41 39:41 39:42 39:42	Sample C Test ALB2	count: 15	R.M. Alarm	A.U. U	
		Test Select Filter © OFF St. Rack # N0401-1 # N0401-3 # N0401-3	C ON Sar	ta Review mple 10 1111223300 1111223300 1111223300 1111223300 1111223300 1111223300 1111223300	Calib. Re Data Rour Type 1 Ser/PI 2 Ser/PI 3 Ser/PI 5 Ser/PI 6 Ser/PI 7 Ser/PI 8 Ser/PI	View Time View Take 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01	Time 39:41 39:41 39:41 39:41 39:41 39:42 39:42 39:42 39:42	Sample C Test ALB2	count: 15	R.M. Alarm	A.U. U	
		Test Select Filter © OFF St. Rack # N0401-1 # N0401-2 # N0401-3 # N0401-3 # N0401-3 Ø N0229-1 O N0229-2 O N0229-3 Ø N0229-4	C ON	ta Review mple to 111223300 1111223300 1111223300 1111223300 1111223300 1111223300 1111223300 1111223300	Calib. Re Data Rout Type 1 SerPI 2 SerPI 3 SerPI 4 SerPI 5 SerPI 6 SerPI 6 SerPI 8 SerPI 9 SerPI	Name Date 2401 2401 2401 2401 2401 2401 2401 2401	Time 19:41 19:41 19:41 19:41 19:42 19:42 19:42 19:42 19:42	Sample C Test ALB2	count: 15	R.M. Alarm	A.U. U	
		Test Select Filter © OFF St. Rack # N0401-1 # N0401-2 # N0401-3 # N0401-3 # N0401-3 0 N0229-1 0 N0229-2 0 N0229-3 0 N0229-3	C ON Sar	ta Review mple 10 1111223300 1111223300 1111223300 1111223300 1111223300 1111223300 1111223300	Calib. Re Rout Type 1 SerPl 2 SerPl 3 SerPl 5 SerPl 6 SerPl 8 SerPl 8 SerPl 9 SerPl 9 SerPl 0 SerPl	View Time View Take 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01	Time)9:41)9:41)9:41)9:42)9:42)9:42)9:42)9:42)9:42	Sample C Test ALB2	count: 15	R.M. Alarm	A.U. U	
		Test Select Filter © OFF St. Rack # N0401-1 # N0401-3 # N0401-3 # N0401-5 N0401-5 N0401-6 N0401-7 # N0401-7 0 N0229-1 0 N0229-2 0 N0229-3 0 N0229-4 0 N0229-5 0 N0229-5 0 N0229-4 0 N0229-5 0 N0229-5 0 N0229-5 # 0 N0013-1 # 0 N0013-2	C ON Sar	ta Review ta Review till ta Review ti ta Review till ta Review till ta Review till ta Review til	Calib. Re Calib. Re Rout Type 1 SerPl 2 SerPl 3 SerPl 4 SerPl 6 SerPl 6 SerPl 7 SerPl 8 SerPl 9 SerPl 9 SerPl 9 SerPl 2 SerPl 2 SerPl 2 SerPl 2 SerPl 2 SerPl 2 SerPl 3 SerPl 4 SerPl 4 SerPl 5 Ser	View Ine View Name Date 24/01	Time 09:41 09:41 09:41 09:41 09:42 09:42 09:42 09:42 09:42 09:42 09:42	Sample C Test ALB2	count: 15	R.M. Alarm	A.U. U	
		Test Select Filter © OFF St. Rack # N0401-1 # N0401-2 # N0401-3 # N0401-3 # N0401-3 # N0401-3 # N0401-3 # N0401-5 O N0229-1 O N0229-2 O N0229-3 O N0229-4 O N0229-4 O N0013-1 #O N0013-2 #O N0013-3	C ON Sar	ta Review ta Review ta Review tilleasa	Calib. Re Rout Type 1 Ser.PI 2 Ser.PI 3 Ser.PI 5 Ser.PI 6 Ser.PI 9 Ser.PI 9 Ser.PI 9 Ser.PI 1 Ser.PI 2 Ser.PI 3 Ser.PI 3 Ser.PI 3 Ser.PI 3 Ser.PI	View Time View Table Tab	Time 39:41 39:41 39:41 39:42 39:	Sample C Test ALB2	count: 15	R.M. Alarm	A.U. U	
		Test Select Filter © OFF St. Rack # N0401-1 # N0401-3 # N0401-3 # N0401-5 N0401-5 N0401-6 N0401-7 # N0401-7 0 N0229-1 0 N0229-2 0 N0229-3 0 N0229-4 0 N0229-5 0 N0229-5 0 N0229-4 0 N0229-5 0 N0229-5 0 N0229-5 # 0 N0013-1 # 0 N0013-2	C ON Sar	ta Review ta Review till ta Review ti ta Review till ta Review till ta Review till ta Review til	Calib. Re Rour Type 1 SerPl 2 SerPl 3 SerPl 6 SerPl 6 SerPl 9 SerPl 9 SerPl 9 SerPl 1 SerPl 2 SerPl 3 SerPl 4 SerPl 4 SerPl	View Ine View Name Date 24/01	Time 39:41 39:41 39:41 39:42 39:	Sample C Test ALB2	count: 15	R.M. Alarm	A.U. U	
		Test Select Filter © OFF St. Rack # N0401-1 # N0401-2 # N0401-3 # N0401-4 # N0401-4 # N0401-5 © N0229-1 © N0229-2 # N0401-3 # 0 N0013-1 # 0 N0013-3 # 0 N0013-4	C ON Sar	ta Review mplate 1111223300 1111223300 1111223300 1111223300 1111223300 1111223300 1111223300 1111223300 1111223301 1111223301 1111223301 1111223301 1111223301 1111223301	Calib. Re Rour Type 1 SerPl 2 SerPl 3 SerPl 6 SerPl 6 SerPl 9 SerPl 9 SerPl 9 SerPl 1 SerPl 2 SerPl 3 SerPl 4 SerPl 4 SerPl	Name Date 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01	Time 39:41 39:41 39:41 39:42 39:	Sample C Test ALB2	count: 15	R.M. Alarm	A.U. U	
		Test Select Filter © OFF St. Rack # N0401-1 # N0401-2 #0 N0401-3 # N0401-3 # N0401-3 # N0401-3 # N0429-2 0 N0229-2 0 N0229-3 0 N0229-4 0 N0229-5 0 N0023-5 #0 N0013-1 #0 N0013-2 #0 N0013-3 #0 N0013-4 #0 N0013-5 #0 N0013-6 #0 N0013-7 #0 N0013-8 #0 N0013-8 #0 N0013-7	C ON	ta Review ta Review till ta Review till till till till till till till til	Calib. Re Calib. Re Rout Type 1 SerPl 2 SerPl 3 SerPl 4 SerPl 5 SerPl 9 SerPl 9 SerPl 1 SerPl 1 SerPl 2 SerPl 3 SerPl 3 SerPl 3 SerPl 3 SerPl 5 SerPl 7 SerPl 8 SerPl 9 SerPl 1 SerPl 9 SerPl 1 Ser	Name Date 24/01 24/01	Time 29:41 39:41 39:41 39:41 39:42 39:	Sample C	count: 15	R.M. Alarm	A.U. U	
		Test Select Filter © OFF St. Rack # N0401-1 # N0401-2 # N0401-3 # N0401-3 # N0401-3 # N0401-3 © N0229-1 © N0229-2 © N0229-3 © N0229-5 © N0013-2 #© N0013-4 #© N0013-5	C ON Sar	ta Review ta Review till ta Review till till till till till till till til	Calib. Re Rout Type 1 SerPl 2 SerPl 3 SerPl 6 SerPl 6 SerPl 9 SerPl 9 SerPl 9 SerPl 1 SerPl 2 SerPl 3 SerPl 4 SerPl 5 SerPl 5 SerPl 5 SerPl 5 SerPl 5 SerPl 6 SerPl 9 SerPl	Name Date 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01 24/01	Time 29:41 39:41 39:41 39:41 39:42 39:	Sample C	count: 15	R.M. Alarm	A.U. U S C1 	

Check sample volume	6	Check a) the sat b) wheth No action clean. When the probe an Check th	er there n is requ ere is su d move	is any uired w ifficient on to s	substar hen the sample step 7.	ice ac samp volu	dhere ble vo me a	ed to olume nd th	the sa e is ins ne pro	suffici be is i	ent, and not clea	ın, repla	ace the	sample
sampling time in		Review s				•	-							
Test Review				2 SHIPIG	.co Ball	27107	Test R		.e ourn		. samp	ie noty i		
		Type :	Routine Ser/Pl Ordered		Sample ID : Carryover E∖	/asion:	111122	233003			Rack N		N0401-3 e-dilution	
		Test	Data	10	1st Result		Time	C t	Data		Rerun Resu		Time	
		ALB2	Data	Alarm Samp.S	R.M.	A.U.	Time 09:42	St	Data	Alarm	R.M.	A.U.	Time St	
		NSE						M						
				- <u> </u>		_								
						-	-							
						1								
						-								
						1								
		Cancel	Demogr phics	a- Sho Det		elete est	Upda	ate	Manua Test	l Pr	evious	Next	Close	

Set filter for the	8	Set an "Analyzed Unit" filter for samples for which sampling was performed on the
	0	specific module from step 7 (in <i>Workplace-Data Review-Filter</i>).
specific module		specific module from step 7 (in <i>Workplace-Data Review-Filter</i>).
		Sample Status
		□ Stat □ □ Processing
		다 Control 다 Complete
		□ Incomplete
		Type Results sent to host Module C1
		↓ ↓ </th
		I Suprat I Analyzed Unit C1 ▼
		Cother
		□ Arrived Time 00 : 00 - 23 : 59
		Cancel OK
Filter for the	9	Select the [ON] radio button for Filter on Data Review screen.
specific module		Workplace Reagent Calibration QC Utility
		Test Selection Data Review Calib. Review
		Filter Data
		C OFF C ON Routine View V Sample Count: 15
		St. Rack Sample ID Type Name Date/Time Test Result R.M. Alarm A.U. Unit
		# N0401-1 11112233001 Ser/PI 24:01:09:41 ALB2 Samp.S C1
		# N0401-2 11112233002 Ser PI 24/01 09:41 ■ #0 N0401-3 11112233003 Ser PI 24/01 09:41 ■ NSE ■
		# N0401-4 11112233004 Ser.PI 24:01 09:41
		# N0401-5 11112233005 Ser/PI 24/01 09:41 #0 N0013-1 11112233011 Ser/PI 24/01 09:42
		#0 N0013-2 11112233012 Ser/PI 24:01 09:42
		#0 N0013-3 11112233013 SerPI 24/01 09:42 #0 N0013-4 11112233014 SerPI 24/01 09:42
		#0 N0013-4 11112233013 Ser/PI 24/01/95-42 #0 N0013-5 11112233015 Ser/PI 24/01/95-42
		Demogra- Search Filter Send To Delete All Backup Test Reaction
		phics Search Host Record Delete An Data Review Monitor
Verify the	10	Check the test results which measured after the sampling time in step 7 on the data
results or		review screen in step 9.
discard the		
samples		Verification of affected samples will be based on laboratory procedures/protocols.
		An example of tests to be verified is described on the next page.

Example	11	On the D				•			-		-	
		after the	•		•		alarm	inclu	ding t	the sam	iple cor	ncern
		Then disp			100			_		1	10-12-0-00-	
		Workp		Reage		Calibratio	n	Q	2	U	Itility	ł.
		Test Selecti	on Data Re	eview C	alib. Review	r						۰.
		Filter OFF (ON		Data Routine View		403-	0401: S	ample	Short		
							Rout	ine Rac	k No.:	401 Posi	ition: 3	
		St. Rack # N0401-1	Sample	12233001 Se	pe Name	Date/Time		ALB2		Samp.	5 C1	
		# N0401-2		12232002 Se		24/01 09:41		ALU2		ownp.		
		#O N0401-3		12233003 Se	ACCOUNT OF	24/01 09:41		NSE				
		# N0401-4	1000000	12233004 Se	1200000	24/01 09:41					_	
		# N0401-5 O N0229-1		12233005 Se 12233006 Se		24/01 09:41						
		O N0229-2		12233007 Se		24/01 09:42					_	
		O N0229-3		12233008 Se		24/01 09:42						
		O N0229-4		12233009 Se		24/01 09:42						
		O N0229-5	la la la la	12233010 Se		24/01 09:42					_	6
		#O N0013-1 #O N0013-2	2112-112-112-1	12233011 Se 12233012 Se	2010/02/14	24/01 09:42					- <u> </u>	
		#O N0013-3		12233013 Se		24/01 09:42	- /					
		#O N0013-4		12233014 Se		24/01 09:42						
		#O N0013-5	111	12233015 Se	r/PI	24/01 09:42						
				J					ļ.			4
		Demogra-	Search	Filter	Send To	Delete	Delete		kup	Test	Reaction	
		phics			Host	Record			ata	Review	Monitor	
			ne mouui	e and tr	ie time on	which th	e sam	pling v	/as pe	rformed.		_
		Sample: F Type: S	Routine ier/Pl	Samp	le ID :	which the Test Review	e sam	pling v		lo Pos. :		
		Sample: F Type: S	Routine	Samp Carry	ie ID : over Evasion:	Test Review	e sam		Rack N	No Pos. : Pre-	N0401-3	
		Sample: F Type: S	Routine Ser/Pl Ordered	Samp Carry 1st R	ile ID : over Evasion: esult	Test Review		R	Rack N	lo Pos. : I Pre-	N0401-3 -dilution	
		Sample : F Type : S Status : C Test	Routine ier/PI Drdered Data A	Samp Carry 1st R Alarm R.M.	ie ID : over Evasion: esuit A.U.	Test Review 11112233003 Time St	e sam		Rack N	lo Pos. : I Pre-	N0401-3 -dilution Time St	
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		Sample : F Type : S Status : C Test ALB2	Routine ier/PI Drdered Data A	Samp Carry 1st R Alarm R.M.	ie ID : over Evasion: esuit A.U. C1	Test Review 11112233003 Time St 09:42 I		R	Rack N	lo Pos. : I Pre-	N0401-3 -dilution Time St	
		Sample : F Type : S Status : C Test ALB2	Routine ier/PI Drdered Data A	Samp Carry 1st R Alarm R.M.	ie ID : over Evasion: esuit A.U. C1	Test Review 11112233003 Time St 09:42 I		R	Rack N	lo Pos. : I Pre-	N0401-3 -dilution Time St	
		Sample : F Type : S Status : C Test ALB2	Routine ier/PI Drdered Data A	Samp Carry 1st R Alarm R.M.	ie ID : over Evasion: esuit A.U. C1	Test Review 11112233003 Time St 09:42 I		R	Rack N	lo Pos. : I Pre-	N0401-3 -dilution Time St	
		Sample : F Type : S Status : C Test ALB2	Routine ier/PI Drdered Data A	Samp Carry 1st R Alarm R.M.	ie ID : over Evasion: esuit A.U. C1	Test Review 11112233003 Time St 09:42 I		R	Rack N	lo Pos. : I Pre-	N0401-3 -dilution Time St	
		Sample : F Type : S Status : C Test ALB2	Routine ier/PI Drdered Data A	Samp Carry 1st R Alarm R.M.	ie ID : over Evasion: esuit A.U. C1	Test Review 11112233003 Time St 09:42 1 M M	Data	R	Rack M	No Pos. : Pre- ult A.U. 1 	N0401-3 -dilution Time St	
		Sample : F Type : S Status : C Test ALB2	Routine ier/PI Drdered Data A	Samp Carry 1st R Alarm R.M.	ie ID : over Evasion: esuit A.U. C1	Test Review 11112233003 Time St 09:42 1 M M	Data	R	Rack M	No Pos. : Pre- ult A.U. 1 	N0401-3 -dilution Time St	
		Sample : F Type : S Status : C Test ALB2	Routine ier/PI Drdered Data A	Samp Carry 1st R Alarm R.M.	ie ID : over Evasion: esuit A.U. C1	Test Review 11112233003 Time St 09:42 I M I I I I I I I I I I I I I I I I I	Data	R Alarm International Alarm	Rack N	No Pos. : Pre- ult A.U. 1 	N0401-3 -dilution Time St 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	
		Sample : F Type : S Status : C Test ALB2	Routine ier/PI Drdered Data A	Samp Carry 1st R Alarm R.M.	ie ID : over Evasion: esuit A.U. C1	Test Review 11112233003	Data Data 103-04 Routin	Alarm Alarm IO1: Sar e Rack	Rack N erun Rest R.M.	III Pos. : Pre- UIT A.U. 1 A.U.	N0401-3 -dilution Time St 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	
		Sample : F Type : S Status : C Test ALB2	Routine ier/PI Drdered Data A	Samp Carry 1st R Alarm R.M.	ie ID : over Evasion: esuit A.U. C1	Test Review 11112233003	Data Data 103-04 Routin	Alarm Alarm IO1: Sar e Rack	Rack N erun Rest R.M.	No Pos. : Pre- Ult A.U. 1 A.U. 1 A	N0401-3 -dilution Time St 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2
		Sample : F Type : S Status : C Test ALB2	Routine ier/PI Drdered Data A	Samp Carry 1st R Alarm R.M.	ie ID : over Evasion: esuit A.U. C1	Test Review 11112233003	Data Data 103-04 Routin	Alarm Alarm Ho1: Sar e Rack	Rack N erun Rest R.M.	III Pos. : Pre- UIT A.U. 1 A.U.	N0401-3 -dilution Time St 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2
		Sample : F Type : S Status : C Test ALB2	Routine ier/PI ordered	Samp Carry 1st R Alarm R.M. amp.S	le ID : over Evasion: esuit C1 C1 C1 C1 C1 C1 C1 C1 C1 C1 C1 C1 C1	Test Review 11112233003	Data Data 103-04 Routin Pipetti	R Alarm H01: Sar Rack ng time	Rack N erun Rest R.M.	III Pos. : Pre- UIT A.U. 1 A.U.	N0401-3 -dilution Time St 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2
		Sample : F Type : S Status : C Test ALB2	Routine ier/PI Drdered Data A	Samp Carry 1st R Alarm R.M.	ie ID : over Evasion: esuit A.U. C1	Test Review 11112233003	Data Data 103-04 Routin	R Alarm 101: Sar e Rack ng time	Rack N erun Rest R.M.	III Pos. : Pre- UIT A.U. 1 A.U.	N0401-3 -dilution Time St 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2
		Sample : Fr Type : S Status : C ALB2 NSE	toutine ier/PI Data / Sc Sc Sc Sc Sc Sc Sc Sc Sc Sc Sc Sc Sc	Samp Carry 1st R Alarm R.M. amp.S 	le ID : esuit A.U. C1	Test Review 11112233003 Time St 09:42 I M I I I I I I I I I I I I I I I I I	Data Data 103-04 Routin Pipetti	R Alarm 101: Sar e Rack ng time	Rack N erun Resu R.M.	No Pos. : Pre- III A.U. 1 A.U.	N0401-3 -dilution Time St 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2
		Sample : Fr Type : S Status : C ALB2 NSE	Routine ier/PI ordered	Samp Carry 1st R Alarm R.M. amp.S 	le ID : over Evasion: esuit A.U. C1 C1 C1 C1 C1 C1 C1 C1 C1 C1 C1 C1 C1	Test Review 11112233003 Time St 09:42 I M M	Data Data 103-04 Routin Pipetti Manu Test	R Alarm 01: Sar e Rack ng time	Rack N erun Rest R.M.	No Pos. : Pre- Ult A.U. 1 A.U.	N0401-3 -dilution $Time St = 0$ 0 0 0 $T = 9:4$	
		Sample : Fr Type : S Status : C ALB2 NSE	Routine ier/PI Data / Sa Sa Sa Sa Sa Sa Sa Sa Sa Sa Sa Sa Sa	Samp Carry 1st R Alarm R.M. amp.S 	le ID : over Evasion: esuit A.U. C1 C1 C1 C1 C1 C1 C1 C1 C1 C1 C1 C1 C1	Test Review 11112233003 Time St 09:42 I M M	Data Data 103-04 Routin Pipetti Manu Test	R Alarm 01: Sar e Rack ng time	Rack N erun Rest R.M.	No Pos. : Pre- Ult A.U. 1 A.U.	N0401-3 -dilution $Time St = 0$ 0 0 0 $T = 9:4$	

Rack	Test	Alarm	A.U.	Time	St.	Judo	gment 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	Samp.S	C1	09:42		Targ	et for verification
						(San	nple for which the sample short
							m was issued)
				<u> </u>		Time	e T=09:42, Module C1
	NSE				М		
N0401-4	ALB2		C1	09:42			et for verification
			+				etted on module C1 after 9:42)
	NSE		E1-2	09:48			et for verification
							ple pipetted on module c1 after
N0401-5	ALB2		C1	09:42		9:42) et for verification
100401-5	ALBZ			09.42		-	etted on module C1 after 9:42)
	NSE	+	E1-2	09:49			et for verification
	NOL		L 1-2	05.45		-	nple pipetted on module c1 after
						9:42	
N0013-1	ALB2				м	0.42	
10013-1	NSE	+	E1-2	09:44		ок	No target for verification,
N0013-2	ALB2			00.44	М		since not pipetted on c1
	NSE	+	E1-2	09:44		OK	
N0013-3	ALB2				М		module
	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		Targ	et for verification
							etted on module C1 after 9:42)
	NSE		Τ	1	М		
N0229-2	ALB2		C1	09:43			et for verification
				<u> </u>		(pipe	etted on module C1 after 9:42)
	NSE				М		
N0229-3	ALB2		C1	09:43			et for verification
				_		(pipe	etted on module C1 after 9:42)
	NSE				М	<u> </u>	
N0229-4	ALB2		C1	09:43			et for verification
			+	+		(pipe	etted on module C1 after 9:42)
NIGODO E	NSE		01	00.10	М	+	
N0229-5	ALB2		C1	09:43			et for verification
	NCE		+	+			etted on module C1 after 9:42)
	NSE				M		

Attachment 3:

FSN-CPS-2017-005: "How to proceed whenever the system alarm "Sample Short" or "Abnormal Aspiration" for $cobas^{\mbox{\tiny B}}$ 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
Clot Detection ON	Step 1	Action Verify the Clot Detection and Clot Detection for Calib/Control settings in Utility-System- Alarm Settings. Repeat Limit Flag With Automatic Rerun Sampling Complete
		☑ Clot Detection ☑ Calibrator/Control □ Expired Reagent Flag □ Suppress Result <test< p=""> Cancel OK</test<>

	Step	Action							
Check the	2	The table below shows the syst	tem alarm list of Sample	Short and Sample Clot.					
Sample Short		Alarm	Alarm Code	Alarm Sub Code					
and Sample		α	Ø	Ø	£				
Clot alarm		Sample-Short¤	010¤	0001~0110¤	Τ,				
		Abnormal Probe-sucking¤	012¤	0001~0110¤					
Sampling Stop	3	a) When the alarm is issued, se	elect the S. Stop button.						
		Core AU Sampling Stop		bmserv 01/24/17 (Tu	e) 14:11				
			Alarm						
		Code Module Level	Alarm	Date/Time	Stop				
		010-0002 AU Caution	Sample Short	01/24/17 14:10					
					Shut down				
					S. Stop				
		Description And Remedy			S. Stop				
		Description And Remedy Code :010-0002							
					Alarm				
		Code :010-0002 Level :Caution Description		, E	Alarm				
		Code :010-0002 Level :Caution		A	Alarm				
		Code :010-0002 Level :Caution Description Sample to be aspirated was insufficient.	ole is sufficient: If it is not, add volum	e, and then rerun the test.	Alarm Media Eject				
		Code :010-0002 Level :Caution Description Sample to be aspirated was insufficient. Remedy	ole is sufficient: If it is not, add volume Sound Maint.	e, and then rerun the test.	Alarm Media Eject				
		Code :010-0002 Level :Caution Description Sample to be aspirated was insufficient. Remedy (1) Check to see whether the volume of samp	Sound Maint.		Alarm Media Eject Print Pause/				
		Code :010-0002 Level :Caution Description Sample to be aspirated was insufficient. Remedy (1) Check to see whether the volume of sample Delete New Alarm Touch the screen click the mouse	Sound Maint.		Alarm Media Eject Print Pause/ Scan				

	3b	b) When the [S. Stop] window appears, choose [Yes].
		Are you sure? No Yes Confirm the confirmation window with [Pause/S.Stop] Confirmation Warning! Do not exchange any sample! New samples can be added on open disk positions only. Pause/S.Stop
		Wait until the system status switches to Compling Stap
Wait until	4	Wait until the system status switches to Sampling Stop.
status Sampling Stop		
Samping Stop		

Identify sample	5 Identify the sample for which the system alarm was issued according to the code of the
for which	system alarm (refer to the following figure).
alarm was issued	Sampling Stop bmserv 01/24/17 (Tue) 14:11
135000	Code Module Level Alarm Date/Time Stop
	010-0002 AU Caution Sample Short 01/24/17 14:10 Shut
	S. Stop
	Alarm
	Code :010-0002 010-0002: Sample
	Description Short
	Sample to be aspirated was insufficient. Remedy → Position: 2
	(i) Check to see whether the volume of sample is sufficient: If it is not, add volume, a
	Delete New Alarm Sound Maint. Close Scan
	Touch the screen, click the mouse, press the space bar or Enter>. Start
	Image: Sampling Stop bmserv 01/24/17 (Tue) 14:13
	Workplace Reagent Calibration QC Utility
	Test Selection Data Review Filter Data
	OFF ⊂ ON Foutine View Sample Count: 5
	St. S. No. Disk Sar Type NAME Arrived Date/Time Test Result Alarm Unit P N000001 Not Ser/PI 01/24 14:08 ALB Samp.5 S. Stop
	O N000002 Ser/Pl 01/24 14:08 O N000003 Hees Ser/Pl 01/24 14:08
	O N000004 N004 Ser/PI 01/24 14:09 Image: Constraint of the series of the
	AMY Samp.S Alarm
	AST Samp.S Media
	Eject
	Print
	Demo- Search Send To Delete Backup Test Reaction Scan
	graphics Search Filter Host Record All Data Review Monitor
	Example of a sample with Sample Short alarm.

Check sample	6	Check										
volume		a) the sample volu	me in the sample	e container,	and							
		b) whether there is	s any substance a	adhered to t	the sample pr	obe.						
		No action is requir	red when the sam	nple volume	is insufficien	t, and the sar	nple probe is					
		clean.										
		When there is sufficient sample volume and probe is not clean, replace the sample										
		probe and move of	•	unio una pi			lo oumpio					
Sampling time	7	Check the sampli		h the alar	m was issued	in the Test	Review screen					
in Test Review	/		0				Neview Scieei					
in rest Review		(Workplace-Data F	Review-patient sa	Test Review	mple listj-tes	i Keviewj.						
				Test Review								
		Sample : Routine	•	000002		DiskPos. : N00	2					
		Type : Ser/Pl	Sample ID :			□ Pre-	dilution					
		Sample Status : Or			Rerun Result							
		Test Data		n Time St.	Data Alarr	n Dilution	Time St.					
		ALB	Samp.S	14:10		-	0					
		ALP	Samp.S	14:10		-	0					
		ALT	Samp.S	14:10		•	0					
		AMY	Samp.S			•	0					
		AST	Samp.S			•	0					
					Manual							
		Cancel Cancel Graphics	Detail Delete Test	Update	Manual Test Previ	ous Next	Close					
Verify the	8	Check the test res	sulte which word	moneurod	after the cor	nling time i	n stop 7 op th					
•	0	data review screen		measureu		iping time i						
results or			1.									
discard the												
samples		Verification of affe				procedures/	protocols.					
		An example of test	ts to be verified is	s described	below							

Example	9	On the Data Revi	ew screen sele	rt all samples	that were sampled	on the analyzer up
латріс	3			•	rm, including the	
		Then display the			init, including the	sample concerne
		Sampling Sto		1000.	bmserv 0	1/24/17 (Tue) 14:22
		Workplace Test Selection Data	Reagent Review	Calibration	QC Ut	Stop
		Filter • OFF • ON	Data Routine View	•	Sample Count: 5	Shut down
		St. S. No. Disk O N000001 N001		Arrived Date/Time	Test Result Alarm ALB Samp.S	Unit S. Stop
		O N000002 N002 O N000003 N003	Ser/PI 01/	24 14:08 24 14:08	ALP Samp.S	
		O N000004 N004 O N000005 N005		24 14:09 24 14:09	ALT Samp.S	
					AMY Samp.S	Alarm
					AST Samp.S	
						Media Eject
						Print
		Demo- strables Search	Filter Send To	Delete Delete	Backup	Reaction Pause/
		(graphics)	ble from the list box.	Record	I Data Review	Monitor
				Test Review		
		Sample : Routine Type : Ser/Pl Sample Status : C		000002	DiskP	os. : N002 □ Pre-dilution
		1st F	Result		Rerun Result	
		Test Dat				ution Time St.
		ALB	Samp.S Samp.S	14:10 14:10		0
		ALT	Samp.S	14:10		0
		AMY	Samp.S		•	0
		AST	Samp.S			0
		Cancel Demo - graphics	Detail Delete Test	Update	rest Previous N	lext
		The example Test	Review window	of samples or	Data Review scree	en is described in t
		table below.	ACTION WITHOUT	or sumples of		

			_			
	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
				Second prior		(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
	11000001		-		44.40	(sample pipetted after 14:10)
	N000004	N004	ALB	-	14:12	Target for verification
		N004	ALP		44.40	(sample pipetted after 14:10)
		N004	ALP	-	14:12	Target for verification (sample pipetted after 14:10)
		N004	ALT	-	14:12	Target for verification
		N004	ALI	-	14.1Z	(sample pipetted after 14:10)
		N004	AMY	-	14:12	Target for verification
		11004	AW	-	14.12	(sample pipetted after 14:10)
		N004	AST	-	14:12	Target for verification
		14004	101	_	14.12	(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
					1	(sample pipetted after 14:10)