CALIBRATION CERTIFICATE

This is to certify that the cobas pure is a fully automated analyzer bearing the serial numbers **SSU: 2265-09, Cobas c 303:2256-10, e 402: 2254-09,** at **REDCLIFFE LIFE TECH PVT LTD, Hyderabad** has been calibrated on **11/07/2023.**

The calibration includes:

Adjustments: Checked and adjusted sample/Reagent Rotor, Incubator, Sample/Reagent probe, Bead Mixer and their respective home positions.

Incubation Disk:	Range: 36.8°C to 37.2°C Adjusted: 37°C
Detection Unit:	Target: 28.0°C Adjusted: 28.0°C
PC/CC:	Target: 28°C Adjusted: 28°C

Adding to this all the temperatures, Blank Cell Calibration and volumes drawn by all pumps were checked and found they are OK.

Next calibration due on 10/07/2024.

For Roche Diagnostics India Pvt Ltd.,

T R Siddardha,
Sr.Technical Service Specialist,
Hyderabad.

Installation Qualification:

This document forms the basis of the Qualification Services Certificate. It certifies that the instrument is installed according to the manufacturer's specifications. The report presents and documents the test procedures, the documentation, reference and acceptance criteria used to verify that the system is installed according specifications. The report demonstrated that all installation qualification criteria have been met satisfactorily.

Notice: The following tests are to be carried out by trained Roche personnel only.

Purpose: The purpose of this test is to confirm that the instrument was delivered undamaged and installed correctly.

Test #	Test	Pass Fail	Signature Date
IQ.1.1	User assistance available	Pass	
IQ 1.2	Environmental parameters met	Pass	
IQ 1.3	Instrument delivered undamaged and complete	Pass	
IQ 1.4	Transport locking successfully removed	Pass	
IQ 1.5	All connections correctly installed	Pass	
IQ 1.6	Instrument positioned according to Installation Manual	Pass	27/07/2022
IQ 1.7	Instrument boot process successfully	Pass	
IQ 1.8	Checksum according to specification	Pass	
IQ 1.9	Mechanical adjustments complete	Pass	
IQ 1.10	Auxiliary components positioned	Pass	
IQ 1.11	Instrument installation check	Pass	
IQ 1.12	Host communication settings checked	Pass	

Test #	Test	Pass Fail	Signature Date
IQ.2	Installation Qualification for cobas <ISE>	Pass	27/07/2022
IQ.3	Installation Qualification for cobas <c 303>	Pass	
IQ.4	Installation Qualification for cobas <e 402>	Pass	
IQ.5	Installation Qualification for cobas link	Pass	

Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

Deviation #1

Investigation

Action taken

NA

Deviation resolved satisfactorily? specify

Deviation #2

Investigation

NA

Action taken

Deviation resolved satisfactorily? specify

Deviation #3

Investigation

Action taken

NA

Deviation resolved satisfactorily? specify

Operational Qualification:

This document is the basis of the Qualification Service Certificate. It certifies that the instrument is operating according to the manufacture's specifications. This report presents and documents the test procedures, documentation, references and acceptance criteria used to verify that the specified system is operating according the specifications. The report demonstrates that all operational qualification criteria have been met satisfactorily.

Notice: The following tests are to be carried out by trained Roche personnel only.

Purpose: The purpose of this test is to check that the modules are operating in accordance with the

Test #	Test	Pass Fail	Signature Date
OQ.1	Calibration successfully	Pass	} 27/07/2022
OQ.2	Quality Control successfully	Pass	
OQ.3	Accuracy check successfully	Pass	

Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

Deviation #1

Investigation

Action taken NA

Deviation resolved satisfactorily? specify

Deviation #2

Investigation

Action taken NA

Deviation resolved satisfactorily? specify

Conclusion

All test results are acceptable.	yes
Any deviation or non-conformances observed have been recorded as a deviation and the relevant forms completed.	yes
All acceptance criteria have been met. This equipment is deemed acceptable and the unit is approved for its intended use.	yes

Comments: All calibrations passed. QC values are within acceptable range.

Completed by Roche Representative

Print Name: Bhavani Prasad.V

Date: 27/07/2022

Signature:

Reviewed by Customer Contact

Print Name: MOHD AZHERUDDIN

Date: 27/07/2022

Signature:

Reviewed by Customer Quality Assurance

Print Name: MOHD AZHERUDDIN

Date: 27/07/2022

Signature:

REDCLIFFE LIFETECH PVT. LTD
2nd Floor
1-4-168/4/4/NR,
Satya Complex,
Old Alwal,
Secunderabad,
Telangana
500010
9700431921, 9140-46043002

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Description		
IQ 1.1	User assistance available	
	Check that a User Assistance opens and has content.	Pass
IQ 1.2	Environmental parameters	
	Ambient temperature in the lab is between 18° and 32 °C	Pass
	Ambient humidity at the lab is between 30 and 85% RH and non-condensing	Pass
	Bacteria free, deionized water < 10 cfu/ml	Pass
	Water conductivity 1.0 µS/cm or less	Pass
	Water pressure between 50 kPa and 340 kPa	Pass
	Instrument is not exposed to direct sunlight	Pass
	Floor is level and grade is ≤ 1/200 (≤0.5%)	Pass
IQ 1.3	Instrument delivered undamaged and complete	
	All covers are undamaged	Pass
	All accessory boxes are delivered	Pass
	Instrument does not show any external damage	Pass
IQ 1.4	Transport locking successfully removed	
	Unpacking of the different modules and accessories without damage to units	Pass
IQ 1.5	All connections correctly installed	
	Power distribution board and water supply/drainage facilities located within 5m from the instrument.	Pass
	Power supply voltage at the customer facility:	Pass
	UPS system available:	Pass
	Voltage fluctuation less than ±20V	Pass
	Grounding terminal of 10Ω or less available	Pass

IQ 1.6	Instrument positioned according to Installation Manual	
	System layout is according to the description in the manual	Pass
	Modules are installed according to the installation manual with official tools	Pass
IQ 1.7	Instrument boot process successful	
	IP address configuration correct	Pass
	First system boot-up	Pass
	Change cobas link IP Internet NIC (162.132.241.10)	Pass
IQ 1.8	Checksum according to specification	
	Version of installed cobas pure user software	
	Installation of country language successful	Pass
	Checksum of installed software is correct according to Installation Guide	Pass
IQ 1.9	Mechanical adjustments complete	
	All mechanical adjustments for the Sample Line and Rotor are carried out	Pass
	Rack transport during mechanical check function	Pass
	Mechanical adjustments backed up	Pass
IQ 1.10	Auxiliary components positioned	
	Rack trays are installed	Pass
IQ 1.11	Instrument installation check	
	Print function	Pass
	Download parameters from CL to CU PC	Pass
	Download applications	Pass
	Registered electrodes for ISE	Pass
	Rack/Sample barcode read check (attached printout)	Pass

IQ 1.12	Host communication settings checked	
	Host settings customised to local site and tested	Pass

Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

Deviation #1	
Investigation	
Action taken	NA
Deviation resolved satisfactorily?	specify

Deviation #2	
Investigation	
Action taken	NA
Deviation resolved satisfactorily?	specify

Deviation #3	
Investigation	
Action taken	NA
Deviation resolved satisfactorily?	specify

Installation Qualification for cobas® pure <ISE>

	Description	
IQ 2.2	Mechanical adjustments complete	
	All mechanical adjustments for ISE mechanical parts are carried out	Pass
	Adjustment check during mechanical check function	Pass
IQ 2.3	Auxiliary components positioned	
	ISE Reagents are loaded	Pass
IQ 2.4	Gear pump adjustment	
	Gear pump adjustment executed (attached printout)	Pass
IQ 2.5	Instrument installation check	
	ISE Check 20 times (attached printout)	Pass
IQ 2.6	Application installation	
	Download of applications from cobas link: Na (29070) K (29080) Cl (29090)	Pass

Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

Deviation #1	
Investigation	NA
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #2	
Investigation	NA
Action taken	
Deviation resolved satisfactorily?	specify

Installation Qualification for cobas® pure <c 303>:

	Description	
IQ.3.1	Function check of c 303 module according to specifications	
	System layout is according to the description in the manual	Pass
	c 303 AU is installed according to the installation manual with official tools	Pass
IQ.3.2	Mechanical adjustments complete	
	All mechanical adjustments for the different c 303 mechanical parts are carried out	Pass
IQ.3.3	Probes and consumables installation	
	Sample Probe and Reagent probe are installed	Pass
	Reaction cells are installed	Pass
IQ 3.4	Instrument installation check	
	Basic and Acid wash bottles are loaded	Pass
	Water pressure: Main pump 50.0--60.0 kPa, Gear Pump 320 kpa	Pass
	Load ECO-D c pack green	Pass
	Exchange incubation bath water	Pass
	Water flow of rinse stations as well as consumption of the detergents were adjusted	Pass
	Air purge for syringes and reagents	Pass
	Photometer check (attached printout)	Pass
	Coil Blank Measurement (attached printout)	Pass
	Incubation water bath temperature 37 °C ± 0.1 °C	Pass

	Adjustment check during mechanical check function	Pass
IQ 3.5	Gear pump adjustment	
	Gear pump adjustment (attached printout)	Pass
IQ 3.6	Application installation	
	Download Special Wash (all)	Pass
	Download of Auxiliary Reagents from cobas link ECO-D, NAOHD, SMS and PYP (PYP if ASTP2 is not available) Menu>System>Auxiliary Reagent Packs>Download	Pass
	Download of applications from cobas link ASTP (20220) (if ASTP2 (20230) is not availble), CHOL2 (20411) CREJ2 (20470) GLUC3 (20630) TP2 (21110) CONA-P2 (20993) CONA-R1 (21280) INST-S1 (21290) INST-R1 (21291) Menu>Application>Download	Pass
IQ 3.7	Instrument check	
	Instrument Check (attached printout)	Pass
IQ 3.8	Backup of adjustment data	
	Adjustments data backed up	Pass

Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

Deviation #1

Investigation

NA

Action taken

Deviation resolved satisfactorily? specify

Deviation #2

Investigation

NA

Action taken

Deviation resolved satisfactorily? specify

Installation Qualification for cobas® pure <e 402>:

	Description	
IQ.4.1	Function check of e 402 module according to specifications	
	e 402 AU is installed according to the installation manual with official tools	Pass
IQ.4.2	Mechanical adjustments complete	
	All mechanical adjustments for the different e 402 mechanical parts are carried out	Pass
	Adjustment check during mechanical check function	Pass
	Water pressure: Gear pump 320 kPa. Main pump 50.0–60.0 kPa	Pass
	Water flow of all rinse stations and wash station was adjusted and validated	Pass
IQ.4.3	Auxiliary components installed	
	Sample probe, reagent probe, microbeads mixer, measuring cell, sipper probe and pre-wash sipper probe installed	Pass
	Waste liner, CC/PC cups, CleanCell, ProCell, PreClean and Assay Cup&Tip trays loaded	Pass
	System prime and system air purge for syringes and reagents	Pass
IQ.4.4	Instrument installation check	
	Temperatures within specifications	Pass
	No alarms during check	Pass
	Air Aspiration Calibration	Pass
	PMT Setting	Pass
	Blank Cell calibration (attached printout)	Pass
	Instrument Check (attached printout)	Pass
IQ.4.5	Application installation	
	"Elecsys TSH for Instrument Check" * e-pack does not need TSH application to be downloaded. * GMMI : 0702 8091 200	Pass
	- For Precision Check (OQ.3.3) you need a New TSH e-pack and download TSH (10172) application from cobas link. IC TSH can not be used for Precision Check.	
IQ.4.6	Backup of adjustment data	
	Adjustments data backed up	Pass

Deviation Report: Any discrepancies found during the installation must be documented in the space below.

Deviation #1

Investigation

Action taken

Deviation resolved satisfactorily?

NA

specify

Deviation #2

Investigation

Action taken

Deviation resolved satisfactorily?

NA

specify

Deviation #3

Investigation

Action taken

Deviation resolved satisfactorily?

NA

specify

Installation Qualification for cobasLink

Description

IQ.5.1	cobasLink connectivity test	
	cobasLink is installed according to the cobas Link cobas pure manual	Pass
	Internet connection is available	Pass
IQ.5.2	cobasLink configuration	
	cobas link Configurator/System Check Latest patches installed	Pass
	General settings are entered according to cobasLink Manual (Laboratory/cobasLink/Utilities incl. certificate)	Pass
	cobas link Configurator/System Check (green traffic light)	Pass
	The CU - configuration was sent to CL and is visible @ cobas Link configurator/Query Tool/ RSi2 > Execute	Pass
IQ.5.3	cobasLink Initiate Upload/ Download	
	The configuration was sent to the TSN server with "Initiate Upload"	Pass
	The application files arrive after "Initiate Download"	Pass
	Perform Sync with cobas link Maintenance>Service>Sync with cobas link Wait 30min	Pass

Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

Deviation #1

Investigation

Action taken

Deviation resolved satisfactorily? NA specify

Deviation #2

Investigation

Action taken

Deviation resolved satisfactorily? NA specify

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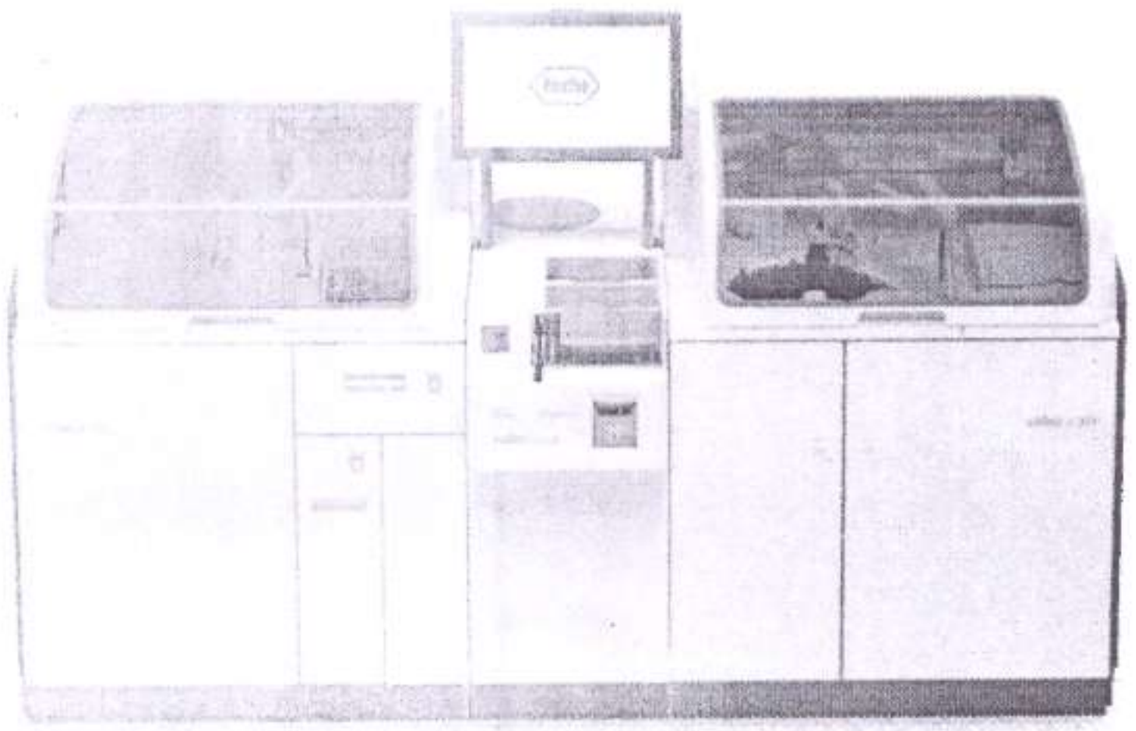
Operational Qualification



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Operational Qualification:

Notice:

The steps described in OQ.1 have to be carried out after a new system installation and after any repair action which requires additional calibration.

If the service action does not affect the measurement performance, only apply steps OQ.2 and OQ.3 of the Operation Qualification.

Description

OQ 1 Calibration

Calibration of all photometric parameters successful (attached printout)	yes
Calibration of ISE parameters successful (attached printout)	yes
Calibration of all Immuno parameters successful (attached printout)	yes

Specify the type of calibrator used:

C.F.A.S. lot :	539837
TSH CalSet lot :	575647

OQ 2 Quality Control

Specify the type of control used:

PCCC1 lot :	525027
PCCC2 lot :	519198
PCU1 lot :	558012
PCU2 lot :	558014

QC of all photometric parameters within acceptable range (attached printout)	yes
QC of ISE parameters within acceptable range (attached printout)	yes
QC of Immuno parameters within acceptable range (attached printout)	yes

OQ 3.1 Precision check for ISE

Perform precision check using PCCC1 n=21

	Number of det.	Expected < CV	Actual CV	
Na	21	1.00%	-	} Refer PQ data
K	21	1.20%	-	
Cl	21	1.70%	-	

Expected precision CV values are only to judge performance of newly installed analyzer, for official specification please refer to assay specific Method sheet.

Precision check for ISE was within acceptable range yes

OQ 3.2 Precision check for Photometric Assays

Perform precision check using PCCC1 n=21

	Number of det.	Exspected < CV	Actual CV	
ASTP/ASTP2	21	2.00%	-	Refer PQ data
GLUC3	21	1.00%	-	
CREJ2	21	2.50%	-	
TP2	21	1.00%	-	
CHOL2	21	1.00%	-	

Expected precision CV values are only to judge performance of newly installed analyzer, for official specification please refer to assay specific Method sheet.

Precision check for Photometric Assays was within acceptable range: yes

OQ 3.3 Precision check for Immunology Assays

Perform precision check using PCU1 n=21 per Channel

New TSH (10172) Reagent

	Number of det.	Exspected < CV	Actual CV	
TSH Ch.1	21	5.00%	-	Refer PQ data

check for: yes

OQ 3.4 software

results for

yes

for

yes

results for

yes

Deviation #1	
Investigation	
Action taken	NA
Deviation resolved satisfactorily?	specify

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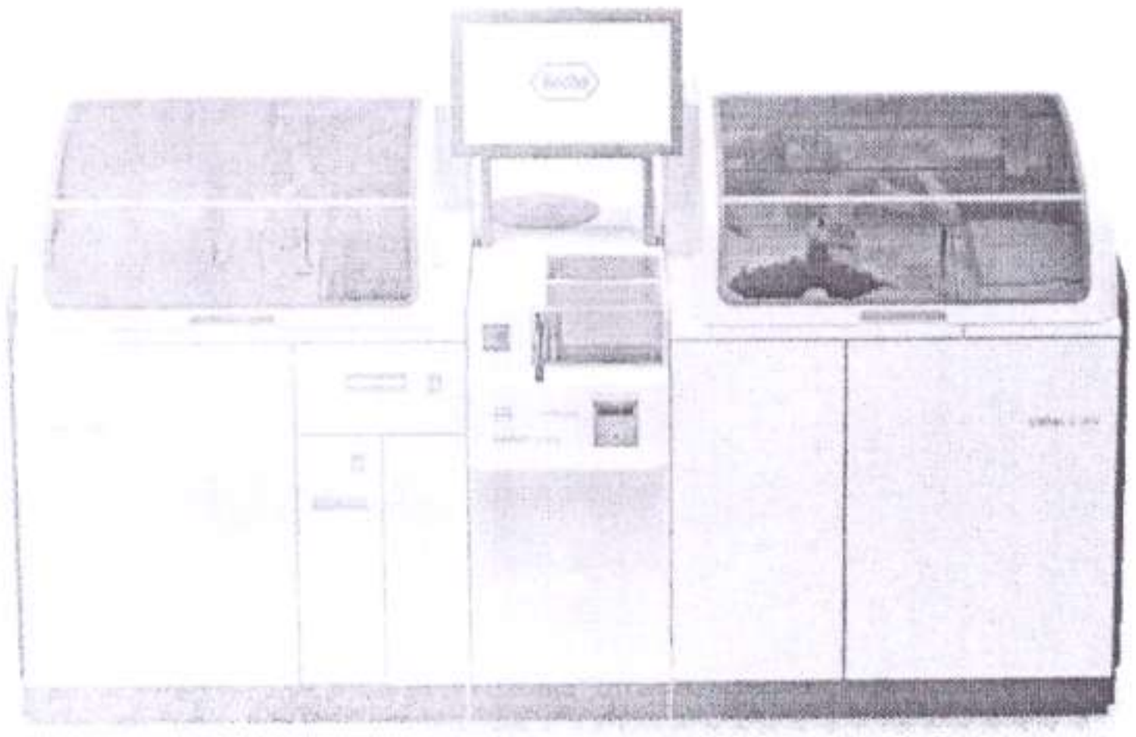
Attachments



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Attachments

1. Calibration Result

2. Controls data

3. Precision data (Refer PQ data)

Revision History

Version					
v.1.0	Date	24-Nov-20	Author	mooniyer
	Initial release			
v.2.0	Date	20-Apr-21	Author	mooniyer

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Calibration Monitor

User ID: REDCLIFFE

13/07/2022 17:20

Calibration Data

13/07/2022 17:20

13/07/2022 17:20:27 (IC)

REDCLIFFE

TSH Unit: µIU/mL Calib. Lot: 575647 Calibration ID: 0000000001 ASSAY R.P.: 622589/0066887 ProCell: 620137

Result Message: Lot calibration was successfully generated.

Timeout Message:

	---Cal 1----	---Cal 2----
Target Value	0.000000	1.76
Signal 1	562	25527
Signal 2	569	25723
Diff	--	
Dup	--	--
System Error	--	--
Calculation Result	--	
Calibration Factor	1.00	

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HITACHI

Calibration Monitor

User ID:

13/07/2022 17:10

Calibration Data

13/07/2022 17:10

13/07/2022 17:10:26 (CC)

CREJ2 Calibration ID: 0000000014 R1 606453/0000623 R2 ------/------- R3 606453/0000623

STD Name	Lot	First Abs.	Second Abs.	First Initial Abs.	Second Initial Abs.	Data Alarm
--S1---	999999	0.0000	0.0001	0.0376	0.0377	
--S2---	539837	0.0263	0.0259	0.2045	0.2046	

-Intercept-	- K -
0.0001	14230.8

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Calibration Monitor

User ID:

13/07/2022 17:10

Calibration Data 13/07/2022 17:10

13/07/2022 17:10:42 (CC)

GLUC3 Calibration ID: 0000000015 R1 629487/0003430 R2 ------/------- R3 629487/0003430

STD Name	Lot	First Abs.	Second Abs.	First Initial Abs.	Second Initial Abs.	Data Alarm
--S1---	999999	0.0037	0.0035	0.0873	0.0867	
--S2---	539837	0.6512	0.6522	0.7719	0.7718	

-Intercept-	- K -
0.0036	16.8184

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Sample Results Report

User ID: REDCLIFFE

27/07/2022 14:48

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot			Registered	
Comment				User ID		
Q001002	Q30001-1	Name / Lot:	PCCC1 / 525027		15/07/2022	10:54:59
				REDCLIFFE		

Test		Result	Data Alarm					
Unit	Sample Type	Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message								
ALB2-G		3.11						
g/dL	Ser/Pl		CC	Current	R1-R3	619902	0003076	
AMYL2		84.0						
U/L	Ser/Pl		CC	Current	R1-R3	618366	0001399	
CA2		8.12						
mg/dL	Ser/Pl		CC	Current	R1-R3	622620	0000354	
CHOL2-I		94.2						
mg/dL	Ser/Pl		CC	Current	R1	640736	0002898	
CREJ2		1.02						
mg/dL	Ser/Pl		CC	Current	R1-R3	606453	0000623	
CRP4		9.58						
mg/L	Ser/Pl		CC	Current	R1-R3	618926	0008618	

System: cobas pure Serial No.: 2265-09

Sample Results Report

User ID: REDCLIFFE

27/07/2022 14:48

Result Type: First

Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot			Registered	
Comment				User ID		
Q001002	Q30001-1	Name / Lot:	PCCC1 / 525027		15/07/2022	10:54:59
				REDCLIFFE		

Test		Result	Data Alarm					
Unit	Sample Type	Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message								
GGT2-I		55.1						
U/L	Ser/Pl		CC	Current	R1-R3	622199	0003410	
GLUC3		103						
mg/dL	Ser/Pl		CC	Current	R1-R3	629487	0003430	
HDLC4		31.0						
mg/dL	Ser/Pl		CC	Current	R1-R3	590715	0001401	
IRON2		107						
µg/dL	Ser/Pl		CC	Current	R1-R3	623943	0002726	
LDLC3		57.6						
mg/dL	Ser/Pl		CC	Current	R1-R3	572897	0001196	
TRIGL		44.2 QCErr						
mg/dL	Ser/Pl		CC	Current	R1	618847	0001482	
UA2		4.66						
mg/dL	Ser/Pl		CC	Current	R1-R3	627564	0003683	

System: cobas pure

Serial No.: 2265-09

Sample Results Report

User ID: REDCLIFFE

27/07/2022 14:49

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot			Registered	
Comment				User ID		
Q002002	Q30001-2	Name / Lot:	PCCC2 / 519198		15/07/2022	10:54:59
				REDCLIFFE		

Test		Result	Data Alarm					
Unit	Sample Type	Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message								
GGT2-I		228						
U/L	Ser/Pl		CC	Current	R1-R3	622199	0003410	
GLUC3		243						
mg/dL	Ser/Pl		CC	Current	R1-R3	629487	0003430	
HDLC4		60.5						
mg/dL	Ser/Pl		CC	Current	R1-R3	590715	0001401	
IRON2		235						
µg/dL	Ser/Pl		CC	Current	R1-R3	623943	0002726	
LDLC3		105						
mg/dL	Ser/Pl		CC	Current	R1-R3	572897	0001196	
TRIGL		142 QCErr						
mg/dL	Ser/Pl		CC	Current	R1	618847	0001482	
UA2		9.58						
mg/dL	Ser/Pl		CC	Current	R1-R3	627564	0003683	

System: cobas pure Serial No.: 2265-09

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HITACHI

Sample Results Report

User ID: REDCLIFFE

27/07/2022 14:49

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot			Registered	
Comment				User ID		
Q002002	Q30001-2	Name / Lot:	PCCC2 / 519198		15/07/2022	10:54:59
				REDCLIFFE		

Test		Result	Data	Alarm				
Unit	Sample Type	Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message								
ALB2-G		5.01						
g/dL	Ser/Pl		CC	Current	R1-R3	619902	0003076	
AMYL2		183						
U/L	Ser/Pl		CC	Current	R1-R3	618366	0001399	
CA2		12.6						
mg/dL	Ser/Pl		CC	Current	R1-R3	622620	0000354	
CHOL2-I		171						
mg/dL	Ser/Pl		CC	Current	R1	640736	0002898	
CREJ2		4.07						
mg/dL	Ser/Pl		CC	Current	R1-R3	606453	0000623	
CRP4		55.6						
mg/L	Ser/Pl		CC	Current	R1-R3	618926	0008618	

System: cobas pure Serial No.: 2265-09

Sample Results Report

User ID: REDCLIFFE 13/07/2023 10:30

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot		Registered	
Comment				User ID	
Q001083	Q30001-1	Name / Lot:	PCCC1 / 564978	13/07/2023	09:47:18
				REDCLIFFE	

Test		Result	Data Alarm						
Unit	Sample Type	Dilution		A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message									
ALB2-G		3.35							
g/dL	Ser/Pl			CC	Current	R1-R3	689517	0000405	
ALP2		111							
U/L	Ser/Pl			CC	Current	R1-R3	710401	0006409	
ALTP		53.8							
U/L	Ser/Pl			CC	Current	R1-R3	704668	0017833	
						R2	703735	0005892	
APOAT		95.0							
mg/dL	Ser/Pl		NACL	CC	Current	R1-R3	695028	0000089	
APOBT		48.4							
mg/dL	Ser/Pl		NACL	CC	Current	R1-R3	631378	0000950	
ASTP		45.1							
U/L	Ser/Pl			CC	Current	R1-R3	700988	0001063	
						R2	703735	0005892	

Sample Results Report

User ID: REDCLIFFE 13/07/2023 10:30

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot		Registered	
Comment				User ID	
Q001083	Q30001-1	Name / Lot:	PCCC1 / 564978	13/07/2023	09:47:18
				REDCLIFFE	

Test		Result	Data Alarm					
Unit	Sample Type	Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message								
BILD2-D		0.720						
mg/dL	Ser/Pl		CC	Current	R1-R2	700536	0000883	
BILT3		0.903						
mg/dL	Ser/Pl		CC	Current	R1-R3	647036	0008342	
CA2		8.86						
mg/dL	Ser/Pl		CC	Current	R1-R3	690455	0006521	
CHOL2-I		107						
mg/dL	Ser/Pl		CC	Current	R1	702347	0002265	
CREJ2		1.00						
mg/dL	Ser/Pl		CC	Current	R1-R3	711464	0004019	
CRP4		6.05						
mg/L	Ser/Pl		CC	Current	R1-R3	699752	0003169	
CRP-HS		7.47						
mg/L	Ser/Pl		CC	Current	R1-R3	626644	0000861	

Sample Results Report

User ID: REDCLIFFE 13/07/2023 10:30

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot		Registered	
Comment				User ID	
Q001083	Q30001-1	Name / Lot:	PCCC1 / 564978	13/07/2023	09:47:18
				REDCLIFFE	

Test		Result	Data Alarm						
Unit	Sample Type	Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode	
Result Message									
GGT2-I		52.7							
U/L	Ser/Pl		CC	Current	R1-R3	711304	0017237		
GLUC3		105							
mg/dL	Ser/Pl		CC	Current	R1-R3	702348	0005174		
HDLC4		31.4							
mg/dL	Ser/Pl		CC	Current	R1-R3	704173	0000729		
IRON2		109							
µg/dL	Ser/Pl		CC	Current	R1-R3	711465	0002092		
ISE CL		83.1OBS.EL							
mmol/L	Ser/Pl		ISE	Current	IS	669181	0004406	Y9695 A1058	
					DIL	709792	0013894		
					REF	668700	0011367		
ISE K		3.49OBS.EL							
mmol/L	Ser/Pl		ISE	Current	IS	669181	0004406	P8015 A1058	
					DIL	709792	0013894		
					REF	668700	0011367		

Sample Results Report

User ID: REDCLIFFE 13/07/2023 10:30

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot		Registered	
Comment				User ID	
Q001083	Q30001-1	Name / Lot:	PCCC1 / 564978	13/07/2023	09:47:18
				REDCLIFFE	

Test Unit	Sample Type	Result Data Alarm Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message								
ISE NA		112.6 OBS.EL						
mmol/L	Ser/Pl		ISE	Current	IS	669181	0004406	G2899 A1058
					DIL	709792	0013894	
					REF	668700	0011367	
LDHI2		169 ReagEx OBS.RR						
U/L	Ser/Pl		CC	Current	R1-R3	618368	0001335	
LDLC3		59.6						
mg/dL	Ser/Pl		CC	Current	R1-R3	619975	0003614	
PHOS2		3.58						
mg/dL	Ser/Pl		CC	Current	R1-R3	703308	0006906	
TP2		5.03						
g/dL	Ser/Pl		CC	Current	R1-R3	713203	0008892	
TRIGL		114						
mg/dL	Ser/Pl		CC	Current	R1	703177	0000243	

Sample Results Report

User ID: REDCLIFFE 13/07/2023 10:30

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot			Registered	
Comment				User ID		
Q001083	Q30001-1	Name / Lot:	PCCC1 / 564978		13/07/2023	09:47:18
				REDCLIFFE		

Test		Result	Data Alarm					
Unit	Sample Type	Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message								
UA2		4.56						
mg/dL	Ser/Pl		CC	Current	R1-R3	695529	0002745	
UIBC-I		224						
µg/dL	Ser/Pl		CC	Current	R1-R3	694806	0001260	
UREAL		37.6						
mg/dL	Ser/Pl		CC	Current	R1-R3	712545	0022867	

Sample Results Report

User ID: REDCLIFFE 13/07/2023 10:30

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot		Registered	
Comment				User ID	
Q002083	Q30001-2	Name / Lot:	PCCC2 / 595393	13/07/2023	09:47:18
				REDCLIFFE	

Test		Result	Data Alarm					
Unit	Sample Type	Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message								
ALB2-G		5.30						
g/dL	Ser/Pl		CC	Current	R1-R3	689517	0000405	
ALP2		258						
U/L	Ser/Pl		CC	Current	R1-R3	710401	0006409	
ALTP		132						
U/L	Ser/Pl		CC	Current	R1-R3	704668	0017833	
					R2	703735	0005892	
ASTP		144						
U/L	Ser/Pl		CC	Current	R1-R3	700988	0001063	
					R2	703735	0005892	
BILD2-D		2.06						
mg/dL	Ser/Pl		CC	Current	R1-R2	700536	0000883	
BILT3		3.42						
mg/dL	Ser/Pl		CC	Current	R1-R3	647036	0008342	

Sample Results Report

User ID: REDCLIFFE 13/07/2023 10:30

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot		Registered	
Comment			User ID		
Q002083	Q30001-2	Name / Lot:	PCCC2 / 595393	13/07/2023	09:47:18
			REDCLIFFE		

Test		Result Data Alarm						
Unit	Sample Type	Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message								
CA2		13.6						
mg/dL	Ser/Pl		CC	Current	R1-R3	690455	0006521	
CHOL2-I		170						
mg/dL	Ser/Pl		CC	Current	R1	702347	0002265	
CREJ2		3.70						
mg/dL	Ser/Pl		CC	Current	R1-R3	711464	0004019	
CRP4		51.7						
mg/L	Ser/Pl		CC	Current	R1-R3	699752	0003169	
GGT2-I		225						
U/L	Ser/Pl		CC	Current	R1-R3	711304	0017237	
GLUC3		247						
mg/dL	Ser/Pl		CC	Current	R1-R3	702348	0005174	
HDLC4		52.2						
mg/dL	Ser/Pl		CC	Current	R1-R3	704173	0000729	

Sample Results Report

User ID: REDCLIFFE 13/07/2023 10:30

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot		Registered	
Comment			User ID		
Q002083	Q30001 2	Name / Lot:	PCCC2 / 595393	13/07/2023	09:47:18
			REDCLIFFE		

Test		Result Data Alarm						
Unit	Sample Type	Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message								
IRON2		244						
µg/dL	Ser/Pl		CC	Current	R1 R3	711465	0002092	
ISE CL		101.0 OBS.EL						
mmol/L	Ser/Pl		ISE	Current	IS	669181	0004406	Y9695 A1058
					DIL	709792	0013894	
					REF	668700	0011367	
ISE K		7.06 OBS.EL						
mmol/L	Ser/Pl		ISE	Current	IS	669181	0004406	P8015 A1058
					DIL	709792	0013894	
					REF	668700	0011367	
ISE NA		136.0 OBS.EL						
mmol/L	Ser/Pl		ISE	Current	IS	669181	0004406	G2899 A1058
					DIL	709792	0013894	
					REF	668700	0011367	
PHOS2		8.01						
mg/dL	Ser/Pl		CC	Current	R1-R3	703308	0006906	

Sample Results Report

User ID: REDCLIFFE 13/07/2023 10:30

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot		Registered	
Comment			User ID		
Q002083	Q30001 2	Name / Lot:	PCCC2 / 595393	13/07/2023	09:47:18
			REDCLIFFE		

Test		Result	Data Alarm					
Unit	Sample Type	Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message								
TP2		8.26						
g/dL	Ser/Pl		CC	Current	R1-R3	713203	0008892	
TRIGL		212						
mg/dL	Ser/Pl		CC	Current	R1	703177	0000243	
UA2		9.52						
mg/dL	Ser/Pl		CC	Current	R1-R3	695529	0002745	
UIBC-I		260						
µg/dL	Ser/Pl		CC	Current	R1-R3	694806	0001260	
UREAL		116						
mg/dL	Ser/Pl		CC	Current	R1-R3	712545	0022867	