To Whom It May Concern

ISO 15189:2012 Requirements reg. "Calibration & Verification Procedures"[1]

All Roche Diagnostics products which are distributed and for which a Free-Sales-Certificate is issued, are CE-marked. The In-Vitro-Diagnostics Directive of the European Union[2] requires for all CE marked products that the manufacturer assures compliance of the products with the requirements of the In-Vitro-Diagnostics Directive. This means that all processes in the development and manufacturing of Roche Diagnostics products are guided by a Quality Management System. Our Quality Management System is in compliance with the requirements from ISO 9001:2008[3], ISO 13485:2003 + AC: 2007[4], and QSReg[5].

The mentioned regulations require that the production systems and measuring devices used are qualified and the manufacturing and test procedures are validated[6]. This status has to be assured by scheduled maintenance and by regular qualification resp. validation reviews and updates.

All physical quantities, calibrators and controls used in Roche Diagnostics systems are fully traceable to certified standards or reference materials. The performance of all Roche Diagnostics systems at the customer site is assured if regular QC measurements, cleaning and maintenance procedures as described in the instructions for use or service documentation are performed. By having controlled internal procedures and by running the tasks required in the respective user documentation, all Roche Diagnostics systems will perform as specified during their defined lifetime.

Additional calibration or verification procedures are NOT required of the user in order to assure the specified performances of every Roche Diagnostics system. Only if a user deviates from these manufacturer's recommendations does he have to establish site-specific calibration and verification procedures as part of his accreditation process.

Graz, 26-Feb-2013

Dr. Johann Harer
Head of Quality Management & Regulatory Affairs

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1 ISO 15189:2012, Medical laboratories - Requirements for quality and competence

2 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

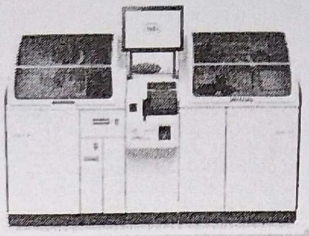
3 ISO 9001:2008, Quality Management Systems - Requirements

4 ISO 13485:2003 + Cor.1:2009, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes)

5 Quality System Regulations, 21 CFR Part 820, requirements on medical devices

6 21 CFR Part 809, 21 CFR Part 210, 21 CFR Part 11; GAMP 5 guideline; Annex 15 to the EU Guide to cGMP

cobas® pure integrated solutions



General Information

Country:	INDIA
Customer Name:	REDCLIFFE LIFE TECH Pvt Ltd.
Customer Address:	H.No -59,South opposite of Block -1,Madhuban Apartment,Kailashpuri, Malahi Pakri,Kankarbagh,Behind Raymond Showroom,Patna ,Bihar-800020
Person Responsible for Quality Assurance:	Mr.Ravishankar Dubey

System Information

cobas pure <c 303><e 402>

	S/N	IP Address	
cobas pure Control unit		172.18.38.	230
SU	2275-02	172.18.38.	245
303	(21)2261-07	172.18.38.	231
402	(21)2261-08	172.18.38.	232

Host provider:
cobas IT firewall:
Control Unit Software Version: 8366030 -01-02

Installation Information

Installation Start Date: 17/11/2022

First Installation: yes

Reconfiguration: From: To:

Relocation: From: To:

Roche Responsible Representative :

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	
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	not applicable	

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

21/12/22

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? specify

Deviation #2
Investigation
Action taken
Deviation resolved satisfactorily? specify

Deviation #3
Investigation
Action taken
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 specifications

Test #	Test	Pass Fail	Signature Date
OQ 1	Calibration successfully	Pass	
OQ 2	Quality Control successfully	Pass	
OQ 3	Accuracy check successfully	Pass	2/12/22

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? specify

Deviation #2

Investigation

Action taken

Deviation resolved satisfactorily? specify

cobas® pure integrated solutions

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:	yes
	UPS system available:	yes
	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	8366030-01-02
	Installation of country language successful	yes
	Checksum of installed software is correct according to Installation Guide	yes
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	yes
	Download parameters from CL to CU PC	Pass
	Download applications	Pass
	Registered electrodes for ISE	Pass
	Rack/Sample barcode read check (attached printout)	Pass

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

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?	specify

Deviation #2	
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #3	
Investigation	
Action taken	
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

Completed by Roche Representative — Date 2.12.22

Print Name SUDIP KUMAR SAHU/SIDHARTH MURAMULLA — Signature

Reviewed by Customer Contact — Date

Print Name RAVISHANKAR DUBEY — Signature 2/12/22

Reviewed by Customer Quality Assurance — Date

Print Name MR.BANTU YADAV — Signature

Radcliffe Lifetech Pvt. Ltd. Patna

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	yes
IQ 2.4	Gear pump adjustment	
	Gear pump adjustment executed (attached printout)	yes
IQ 2.5	Instrument installation check	
	ISE Check 20 times (attached printout)	yes
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
Action taken
Deviation resolved satisfactorily? specify

Deviation #2
Investigation
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
	Cell Blank Measurement (attached printout)	Pass
	Incubation water bath temperature 37 °C ± 0.1 °C	Pass

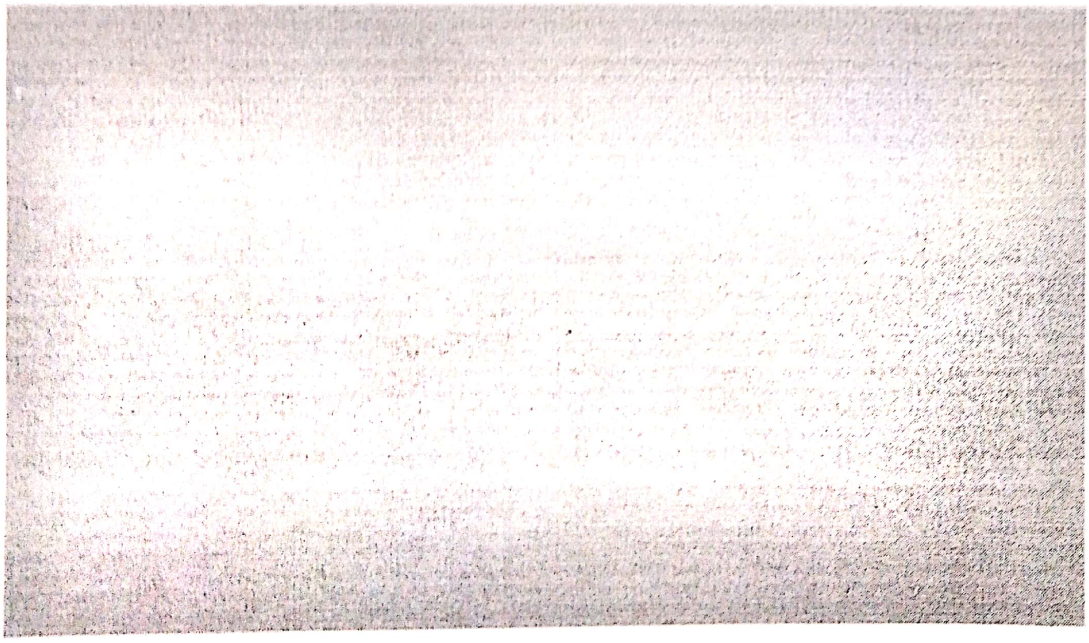
	Adjustment check during mechanical check function	Pass
IQ 3.5	Gear pump adjustment	
	Gear pump adjustment (attached printout)	yes
IQ 3.6	Application installation	
	Download Special Wash (all)	Pass
	Download of Auxiliary Reagents from cobas link ECO-D, NAOHD, SMS and PYP (PYP if ASTP2 is not available) 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
Action taken
Deviation resolved satisfactorily? specify

Deviation #2
Investigation
Action taken
Deviation resolved satisfactorily? specify

cobas®



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	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	yes
	Waste liner, CC/PC cups, CleanCell, ProCell, PreClean and Assay Cup&Tip trays loaded	yes
	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? specify

Deviation #2

Investigation

Action taken

Deviation resolved satisfactorily? specify

Deviation #3

Investigation

Action taken

Deviation resolved satisfactorily? specify

Installation Qualification for cobasLink

Description

IQ.5.1 cobasLink connectivity test

cobasLink is installed according to the cobas Link cobas pure manual	YES
Internet connection is available	YES

IQ.5.2 cobasLink configuration

cobas link Configurator/System Check Latest patches installed	OK
General settings are entered according to cobasLink Manual (Laboratory/cobasLink/Utilities incl. certificate)	OK
cobas link Configurator/System Check (green traffic light)	OK
The CU - configuration was sent to CL and is visible @ cobas Link configurator/Query Tool/ RSi2 > Execute	YES

IQ.5.3 cobasLink Initiate Upload/ Download

The configuration was sent to the TSN server with "Initiate Upload"	YES
The application files arrive after "Initiate Download"	YES
Perform Sync with cobas link Maintenance>Service>Sync with cobas link Wait 30min	YES

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? specify

Deviation #2

Investigation

Action taken

Deviation resolved satisfactorily? specify

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 : 564943

TSH CalSet lot : 614854

OQ.2 Quality Control

Specify the type of control used:

PCCC1 lot : 525027

PCCC2 lot : 535719

PCU1 lot : 556403

PCU2 lot : 556405

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%	0.27%
K	21	1.20%	0.47%
Cl	21	1.70%	0.23%

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%	1.62%
GLUC3	21	1.00%	0.21%
CREJ2	21	2.50%	1.97%
TP2	21	1.00%	0.43%
CHOL2	21	1.00%	0.45%

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%	0.61%

Precision: yes

OQ 3.4 Trace Doc

Calibration: yes

QC results: yes

Sample: yes

Deviation #1

Investigation

Action taken

Deviation resolved satisfactorily? specify

Attachments

cobas®

Sample Results Report

User ID: RCL

11/03/2023 10:04

Sequence No.	Rack ID	Pos.	Sample ID / QC Lot		User ID	Registered	
Q012078	Q30007-3		Name / Lot:	PC VITDT1 / 612474	RCL	11/03/2023	09:25:12

Test	Result	Data Alarm					
Unit	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message							
VITDT 3	21.4						
ng/mL	Ser/Pl		IC	Current	662815	0006331	668920

Sequence No.	Rack ID	Pos.	Sample ID / QC Lot		User ID	Registered	
Comment							
Q012078	Q30007-4		Name / Lot:	PC VITDT2 / 612475	RCL	11/03/2023	09:25:12

Test	Result	Data Alarm					
Unit	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message							
VITDT 3	36.2						
ng/mL	Ser/Pl		IC	Current	662815	0006331	668920

B. Bhushan

Pooja singh
11/03/23

System [illegible] Serial No. 2275-02

Result Message								
ALB2-G		3.31						
g/dL	Ser/Pl			CC	Current	R1-R3	663677	0001684
ALP2		109						
U/L	Ser/Pl			CC	Current	R1-R3	654864	0000413
ALTP		48.5						
U/L	Ser/Pl			CC	Current	R1-R3	674483	0005876
						R2	674481	0011433
AMYL2		81.8						
U/L	Ser/Pl			CC	Current	R1-R3	630349	0002964
APOAT		101						
mg/dL	Ser/Pl		NACL	CC	Current	R1-R3	588324	0000380
APOBT		41.6						
mg/dL	Ser/Pl		NACL	CC	Current	R1-R3	631378	0000940

Result Message							
ASTP		47.2					
U/L	Ser/Pl		CC	Current	R1-R3	663695	0016869
					R2	674481	0011433
BILD2-D		0.717					
mg/dL	Ser/Pl		CC	Current	R1-R2	670789	0003841
BILT3		0.856					
mg/dL	Ser/Pl		CC	Current	R1-R3	622281	0006338
CA2		8.38					
mg/dL	Ser/Pl		CC	Current	R1-R3	661077	0000822
CHOL2-A		95.5					
mg/dL	Ser/Pl		CC	Current	R1	658312	0003540
CREJ2		1.03					
mg/dL	Ser/Pl		CC	Current	R1-R3	627775	0002684
CRP4		5.47					
mg/L	Ser/Pl		CC	Current	R1-R3	645296	0004009

Name / Lot PCCC1 / 525205 11/03/2023

Result Message								
CRP-HS mg/L	Ser/Pl	6.95	CC	Current	R1-R3	626644	0001139	
GGT2-I U/L	Ser/Pl	53.0	CC	Current	R1-R3	663681	0015045	
GLUC3 mg/dL	Ser/Pl	101	CC	Current	R1-R3	672328	0002479	
HDLC4 mg/dL	Ser/Pl	28.4	CC	Current	R1-R3	626113	0007929	
IRON2 µg/dL	Ser/Pl	108	CC	Current	R1-R3	652627	0004394	
ISE CL mmol/L	Ser/Pl	81.5	ISE	Current	IS DIL REF	661339 644059 539523	0013775 0002699 0007940	W1160 X6581

B. Bhushan

Test / Unit	Sample Type	Result Data Alarm / Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message								
ISE K		3.57						
mmol/L	Ser/Pl		ISE	Current	IS	661339	0013775	L3903 X6581
					DIL	644059	0002699	
					REF	539523	0007940	
ISE NA		113.6						
mmol/L	Ser/Pl		ISE	Current	IS	661339	0013775	C5871 X6581
					DIL	644059	0002699	
					REF	539523	0007940	
LIP		44.3 OBS.RR						
U/L	Ser/Pl		CC	Current	R1-R3	647416	0002871	
PHOS2		3.66						
mg/dL	Ser/Pl		CC	Current	R1-R3	653804	0006833	
TP2		4.90						
g/dL	Ser/Pl		CC	Current	R1-R3	693361	0006895	
TRIGL		125						
mg/dL	Ser/Pl		CC	Current	R1	661743	0005476	

B. Brusham

Unit	Sample Type	Dilution	A.Ur.	Priority	R1 R3 Lot	R1 R3 Serial No.	ProCell Lot / Electrode
Result Message							
UA2		4.80					
mg/dL	Ser/Pl		CC	Current	R1-R3	664685	0004464
UA2		4.84					
mg/dL	Ser/Pl		CC	SB1	R1-R3	664685	0002503
UIBC-I		196					
µg/dL	Ser/Pl		CC	Current	R1-R3	637859	0014907
UREAL		41.2					
mg/dL	Ser/Pl		CC	Current	R1-R3	663424	0002257
UREAL		41.0					
mg/dL	Ser/Pl		CC	SB1	R1-R3	674482	0007492

Test	Unit	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode	Result Message
ALB2-G	g/dL	Ser/Pl	4.95	CC	Current	R1-R3	663677	0001684	
ALP2	U/L	Ser/Pl	280	CC	Current	R1-R3	654864	0000413	
ALTP	U/L	Ser/Pl	129	CC	Current	R1-R3 R2	674483 674481	0005876 0011433	
ASTP	U/L	Ser/Pl	145	CC	Current	R1-R3 R2	663695 674481	0016869 0011433	
BILD2-D	mg/dL	Ser/Pl	2.14	CC	Current	R1-R2	670789	0003841	
BILT3	mg/dL	Ser/Pl	3.24	CC	Current	R1-R3	622281	0006338	

B. Bhushan

Operator Date

Q002078 Q30001-2 Name / Lot: PCCC2 / 535719 11/03/2023 09:25:33

Test / Unit	Sample Type	Result / Dilution	Alarm / A.U.	Prot./U.		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message								
CA2 mg/dL	Ser/Pl	13.6	CC	Current	R1-R3	661077	0000822	
CHOL2-A mg/dL	Ser/Pl	174	CC	Current	R1	658312	0003540	
CREJ2 mg/dL	Ser/Pl	3.85	CC	Current	R1-R3	627775	0002684	
GGT2-I U/L	Ser/Pl	236	CC	Current	R1-R3	663681	0015045	
GLUC3 mg/dL	Ser/Pl	233	CC	Current	R1-R3	672328	0002479	
HDLC4 mg/dL	Ser/Pl	59.5	CC	Current	R1-R3	626113	0007929	
IRON2 µg/dL	Ser/Pl	245	CC	Current	R1-R3	652627	0004394	

B. Bhuvana

System cobas pure Serial No.: 2275-02

Result type First Sorted by Date

Q002078 Q30001-2 Name / Lot: PCCC2 / 535719 11/03/2023 09:25:33

RCL

Test / Unit / Result Message	Sample Type	Result / Date Alarm / Dilution	A U	Priority	R P Lot	R R Serial No.	ProCell Lot / Electrode
ISE CL		101.9					
mmol/L	Ser/Pl		ISE	Current	IS 661339	0013775	W1160 X6581
					DIL 644059	0002699	
					REF 539523	0007940	
ISE K		7.28					
mmol/L	Ser/Pl		ISE	Current	IS 661339	0013775	L3903 X6581
					DIL 644059	0002699	
					REF 539523	0007940	
ISE NA		136.9					
mmol/L	Ser/Pl		ISE	Current	IS 661339	0013775	C5871 X6581
					DIL 644059	0002699	
					REF 539523	0007940	
LDHI2		295					
U/L	Ser/Pl		CC	Current	R1-R3 628352	0002360	
PHOS2		8.36					
mg/dL	Ser/Pl		CC	Current	R1-R3 653804	0006833	

System: cobas pure Serial No: 2275-02

Unit	Sample Type	Dilution	Mode	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message							
TP2		7.69					
g/dL	Ser/Pl		CC	Current	R1-R3	693361	0006895
TRIGL		220					
mg/dL	Ser/Pl		CC	Current	R1	661743	0005476
UA2		10.1					
mg/dL	Ser/Pl		CC	Current	R1-R3	664685	0004464
UA2		10.2					
mg/dL	Ser/Pl		CC	SB1	R1-R3	664685	0002503
UIBC-I		244					
µg/dL	Ser/Pl		CC	Current	R1-R3	637859	0014907
UREAL		118					
mg/dL	Ser/Pl		CC	Current	R1-R3	663424	0002257
UREAL		122					
mg/dL	Ser/Pl		CC	SB1	R1-R3	674482	0007492

Result Type: First Sorted by: Date

Sequence No.	Rack ID	Pos.	Sample ID / Control Lot	Registered
Q010078	Q30001-4	Name / Lot:	RFCO2 / 626900	11/03/2023 09:25:33

RCL

Test	Result	Unit	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode	Result Message
RF-II	52.3	IU/mL	Ser/Pl		CC	Current	R1-R3	634798	0001645	
RF-II	53.2	IU/mL	Ser/Pl		CC	SB1	R1-R3	634798	0001653	

System: cobas pure Serial No.: 2275-02

Unit	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode	Result Message
B12 2 pg/mL	Ser/Pl	568	IC	Current	584567	0192565	668920	
FERR ng/mL	Ser/Pl	85.3	IC	Current	602731	0091950	668920	
HCG-BETA mIU/mL	Ser/Pl	15.7	IC	Current	584575	0014368	668920	
IGE 2 IU/mL	Ser/Pl	148	IC	SB1	619045	0057498	668920	
PRL 2 ng/mL	Ser/Pl	27.8	IC	Current	580119	0062791	668920	
T3 ng/dL	Ser/Pl	244	IC	Current	622585	0058817	668920	
T4 µg/dL	Ser/Pl	8.33	IC	Current	653184	0005265	668920	

Q006078	Q30006-2	Name / Lot:	RANDOX L2 / 2107EC	11/03/2023	09:25:53

RCL

Test	Result	Unit	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode	Result Message
TSH	2.15	µIU/mL	Ser/Pl		IC	Current	653314	0077445	668920	

Result type: First Sorted by: Date

Sequence No	Rack ID	Pos.	Sample ID / Barcode	Operator
Q016078	Q30006-3	Name / Lot:	RANDOX L 3 / 2110EC	11/03/2023 09:25:53

RCL

Unit Result Message	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
B12 2 pg/mL	Ser/Pl	858	IC	Current	584567	0192565	668920
FSH mIU/mL	Ser/Pl	56.2	IC	Current	625761	0016808	668920
FT3 3 pg/mL	Ser/Pl	15.6	IC	Current	611920	0008056	668920
FT4 3 ng/dL	Ser/Pl	5.65	IC	Current	630888	0057701	668920
IGE 2 IU/mL	Ser/Pl	683	IC	Current	619045	0057502	668920
IGE 2 IU/mL	Ser/Pl	669	IC	SB1	619045	0057498	668920
LH mIU/mL	Ser/Pl	55.7	IC	Current	570728	0034466	668920

Result type: First Sorted by: Date:

Sequence No.	Rack ID	Position	Sample ID	Operator	Registered
Q016078	Q30006-3	Name / Lot:	RANDOX L 3 / 2110EC	RCL	11/03/2023 09:25:53

Test	Result	Unit	Sample Type	Dilution	A. U.	Priority	R-P Lot	R-P Serial No.	ProCell Lot / Electrode	Result Message
PROG 3	27.4	ng/mL	Ser/Pl		IC	Current	617608	0057653	668920	
T3	380	ng/dL	Ser/Pl		IC	Current	622585	0058817	668920	
T4	13.4	µg/dL	Ser/Pl		IC	Current	653184	0005265	668920	
TPSA	20.7	ng/mL	Ser/Pl		IC	Current	620922	0053448	668920	
TSH	20.2	µIU/mL	Ser/Pl		IC	Current	653314	0077445	668920	

Symbols attached to "Test"
"+": Rerun test
"*": eFlow subresult, supplemented test for formula calculated test and Hb/HbA1c test

System: cobas pure Serial No.: 3375-02