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To Whom It May Concern

For ISO 15189:2012 and ISO 15189:2014 accredited Laboratories — requirements regarding "Calibration & Verification Procedures" [1]

All In vitro Diagnostics Products which are manufactured and distributed by Roche Diagnostics GmbH and for which a Free-Sales-Certificate is issued, are CE-marked.

The In-Vitro-Diagnostics Directive of the European Union [2A.] which is currently switching to IVD Regulation 2017/746/EU (final timeline: May 26, 2022) [2B.] requires for all CE marked products that the manufacturer assures compliance of the products with the requirements of the mentioned directive or regulation. This means that all processes in development and manufacturing of Roche Diagnostics GmbH products are guided by a Quality Management System. Our Quality Management System is in compliance with the requirements from ISO 13485:2016 [3] and 21 CFR Part 820 [4].
The mentioned regulations and standards require that the production systems and measuring devices used are qualified and the manufacturing and test procedures are validated. 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 Diagnostic systems are fully traceable to certified standards or reference materials. The performance of all In-vitro diagnostics systems of Roche Diagnostics GmbH at the customer site is assured if regular Quality Control 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 In-vitro diagnostics systems of Roche Diagnostics GmbH will be performed as specified during their defined lifetime.

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

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

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[1] ISO 15189:2012/ ISO 15189:2014 Medical laboratories — Requirements for quality and competence

[2] A. Directive 98/79/EC of the European Parliament and of the Council of the 27 October 1998 on vitro diagnostics medical devices;
B. IVD Regulation 2017/746/EU of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

[3] EN ISO 13485:2016 Medical devices — Quality management systems-Requirements for regulatory purposes

[4] CFR Part 820, Quality System regulations 21 Regulations on medical devices

Mannheim, 10. August 2021

Sincerely,

Roche Diagnostics GmbH

i.V./*on behalf of the company*

DocuSigned by:
ECA5294AC4E94AF...

Andrea Weber
Manager Global Regulatory Affairs
Centralised and Point of Care Solutions

ppa/*on behalf of the company*

DocuSigned by:
Ralf Zielenski
A7F0BA9FE91A46A...

Ralf Zielenski
Head Q&R Compliance, PRRC RDG
Centralised and Point of Care Solutions

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim

cobas® pure integrated solutions

Qualification Service

Installation Qualification / Operation Qualification (v.2.0)

cobas®

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General Information

Country:	INDIA
Customer Name:	Redclieff Lifetech Pvt Ltd
Customer Address:	Saltlake ,Kolkata 700091
Person Responsible for Quality Assurance:	MD KISMAT ANSARI

System Information

cobas pure <c 303><e 402>

cobas pure Control unit	S/N	IP Address
		172.18.38. 230
SU		172.18.38. 245
303	2145-07	172.18.38. 231
402	2143-02	172.18.38. 232

Host provider:	
cobas IT firewall:	
Control Unit Software Version:	01.02

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Qualification Service

Installation Qualification / Operation Qualification (v. 2.0)

Page 1 of 5

Installation Information

Installation Start Date: [redacted]

First installation: yes

Reconfiguration: From: [redacted] To: [redacted]

Relocation: From: [redacted] To: [redacted]

Roche Responsible Representative: [redacted]

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Installation Qualification

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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	yes	

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	

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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

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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	
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	
Deviation resolved satisfactorily?	specify

Deviation #2

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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 13/6/22

Print Name SASWATA DASGUPTA — Signature

Reviewed by Customer Contact — Date 14/06/22

Print Name SUVANKAR BHATTACHARJEE — Signature

REDCLIFFE LIFETECH PRIVATE LIMITED * CG-223 Salt Lake Kol-700091

Reviewed by Customer Quality Assurance — Date 14/06/22

Print Name MD KISMAT ANSARI — Signature

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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

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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

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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

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	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

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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	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 - 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.	Pass
IQ.4.6	**Backup of adjustment data**	
	Adjustments data backed up	Pass

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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

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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

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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

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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 : 539942

TSH CalSet lot : 575647

OQ.2 Quality Control

Specify the type of control used:

PCCC1 lot : 525027

PCCC2 lot : 519198

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%	0.29%
K	21	1.20%	0.30%
Cl	21	1.70%	0.25%

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

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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%	1.99%
GLUC3	21	1.00%	0.49%
CREJ2	21	2.50%	1.64%
TP2	21	1.00%	0.29%
CHOL2	21	1.00%	0.65%

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%	0.92%

Precision: yes

OQ 3.4 Trace Doc

Calibration: yes

QC results: yes

Sample: yes

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Deviation #1
Investigation
Action taken
Deviation resolved satisfactorily? specify

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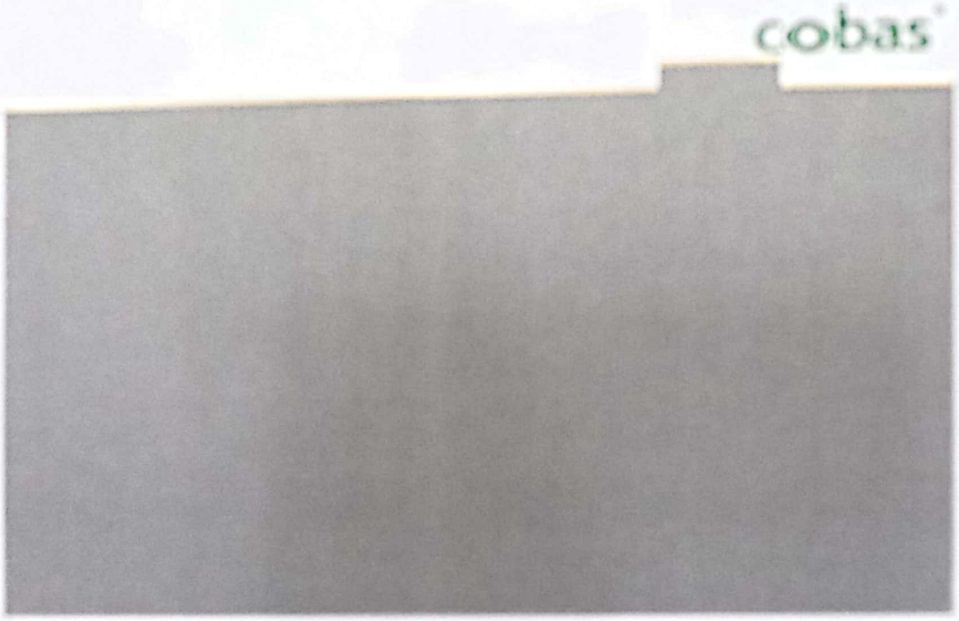
Attachments



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Attachments

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HITACHI

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23/02/2023 15:39

cobas

User ID: ADMIN

Sample Results Report

Result Type: First | Sorted by: Date

Sequence No / Comment	Rack ID - Pos	Sample ID / QC Lot	User ID	Registered
Q002130	Q30001-1	Name / Lot: PCCC1 / 525027	ADMIN	23/02/2023 10:27:32

Test / Unit / Result Message	Sample Type	Result Data Alarm	Dilution	A.U	Priority		R.P. Lot	R.P. Serial No	ProCell Lot / Electrode
ALB2-G g/dL	Ser/Pl	3.28		CC	Current	R1-R3	608713	0000584	
ALP2 U/L	Ser/Pl	90.9		CC	Current	R1-R3	668539	0002241	
ALTP U/L	Ser/Pl	46.3		CC	Current	R1-R3 R2	661052 654893	0014638 0002984	
AMYL2 U/L	Ser/Pl	84.1		CC	Current	R1-R3	630349	0002956	
APOAT mg/dL	Ser/Pl	102 OBS.RR	NACL	CC	Current	R1-R3	588324	0000434	
APOBT mg/dL	Ser/Pl	41.7 OBS.RR	NACL	CC	Current	R1-R3	631378	0000957	

23/02/23.

System: cobas pure   Serial No.: 2154-03

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User ID: ADMIN 23/02/2023 15:39

Sample Results Report

Result Type: First Sorted by: Date

Sequence No.	Rack ID	Pos.	Sample ID / QC Lot	User ID	Registered
Comment					
Q002130	Q30001-1		Name / Lot: PCCC1 / 525027	ADMIN	23/02/2023 10:27:32

Test / Unit / Result Message	Sample Type	Result / Data / Alarm / Dilution	A.U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
ASTP U/L	Ser/Pl	45.9	CC	Current	R1-R3 R2	663695 654893	0015390 0002984
ASTP U/L	Ser/Pl	46.7	CC	SB1	R1-R3 R2	663695 654893	0017958 0002984
BILD2-D mg/dL	Ser/Pl	0.703	CC	Current	R1-R2	652625	0001519
BILT3 mg/dL	Ser/Pl	0.864	CC	Current	R1-R3	622281	0004606
CA2 mg/dL	Ser/Pl	Samp.S	CC	Current			
CHOL2-I mg/dL	Ser/Pl	91.7	CC	Current	R1	640736	0002978

23/02/23

System: cobas pure Serial No.: 2154-03

Sample Results Report

User ID: ADMIN

23/02/2023 15:39

Result Type: First Sorted by: Date

Sequence No.	Rack ID : Pos	Sample ID	QC	Lot	User ID	Registered
Comment						
Q002130	Q30001-1	Name / Lot:		PCCC1 / 525027	ADMIN	23/02/2023 10:27:32

Test / Unit	Sample Type	Result / Dilution	Data Alarm	A..U	Priority	R..P	R..P Lot	R..P Serial No.	ProCal Lot / Electrode
CREJ2 mg/dL	Ser/Pl	1.08		CC	Current	R1-R3	627775	0003592	
CRP4 mg/L	Ser/Pl	9.08		CC	Current	R1-R3	645296	0004112	
CRP-HS mg/L	Ser/Pl	10.4		CC	Current	R1-R3	626644	0000015	
GGT2-I U/L	Ser/Pl	55.2		CC	Current	R1-R3	653840	0006114	
GLUC3 mg/dL	Ser/Pl	101		CC	Current	R1-R3	629487	0003425	
HDLC4 mg/dL	Ser/Pl	29.5		CC	Current	R1-R3	626113	0006797	
IRON2 µg/dL	Ser/Pl	105		CC	Current	R1-R3	641946	0000593	

23/02/23

System: cobas pure Serial No.: 2154-03

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Sample Results Report

Result Type: First Sorted by: Date

Sequence No. / Comment	Rack ID - Pos	Sample ID / QC Lot		User ID	Registered	
Q002130	Q30001-1	Name / Lot:	PCCC1 / 525027	ADMIN	23/02/2023	10:27:32

Test / Unit / Result Message	Sample Type	Result Data Alarm / Dilution	A.U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
ISE NA-S mmol/L	Serum	105.8 QCErr	ISE	Current	IS DIL REF	624115 650042 661046	0000700 0010909 0008910	E2196 X6546
LDHI2 U/L	Ser/Pl	Samp.S	CC	Current				
LDLC3 mg/dL	Ser/Pl	57.0	CC	Current	R1-R3	572897	0001121	
LIP U/L	Ser/Pl	Samp.S	CC	Current	R1-R3	647416	0000052	
PHOS2 mg/dL	Ser/Pl	3.92	CC	Current	R1-R3	653804	0004108	
TP2 g/dL	Ser/Pl	4.68	CC	Current	R1-R3	635652	0005917	

23/02/23

System: cobas pure Serial No.: 2154-03

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Sample Results Report

User ID: ADMIN

23/02/2023 15:39

Result Type: First Sorted by: Date

Sequence No.	Rack ID	Pos.	Sample ID / QC Lot	User ID	Registered
Comment					23/02/2023 10:27:32
Q002130	Q30001-1		Name / Lot: PCCC1 / 525027	ADMIN	

Test / Unit	Sample Type	Result / Data Alarm / Dilution	A U	Priority	R P	R P Lot	R P Serial No.	ProCell Lot / Electrode
TRIGL mg/dL	Ser/Pl	109	CC	Current	R1	643364	0003033	
UA2 mg/dL	Ser/Pl	4.75	CC	Current	R1-R3	627564	0002726	
UIBC-I µg/dL	Ser/Pl	206	CC	Current	R1-R3	637859	0015422	
UIBC-I µg/dL	Ser/Pl	201	CC	SB1	R1-R3	637859	0014774	
UREAL mg/dL	Ser/Pl	37.6	CC	Current	R1-R3	651528	0008399	
UREAL mg/dL	Ser/Pl	39.7	CC	SB1	R1-R3	651528	0008658	

23/02/23.

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

System: cobas pure Serial No.: 2154-03

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Sample Results Report

User ID: ADMIN

23/02/2023 15:38

Result Type: First Sorted by: Date

Sequence No	Rack ID	Pos.	Sample ID / QC Lot	User ID	Registered
Comment					
Q002131	Q30001-1		Name / Lot: PCCC1 / 525027	ADMIN	23/02/2023 13:23:08

Test / Unit / Result Message	Sample Type	Result / Data Alarm / Dilution	A	U	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
ISE CL		89.1						
mmol/L	Ser/Pl		ISE		Current	IS 624115	0000700	X2918 X6546
						DIL 650042	0010909	
						REF 661046	0008910	
ISE K		3.72						
mmol/L	Ser/Pl		ISE		Current	IS 624115	0000700	M6811 X6546
						DIL 650042	0010909	
						REF 661046	0008910	
ISE NA		117.2						
mmol/L	Ser/Pl		ISE		Current	IS 624115	0000700	E2196 X6546
						DIL 650042	0010909	
						REF 661046	0008910	

Symbols attached to "Test"

'+': Rerun test

'*': eFlow subresult, supplemented test for formula calculated test and Hb/HbA1c test

System: cobas pure Serial No.: 2154-03

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23/02/2023 15:37

User ID: ADMIN

Sample Results Report

Result Type: First Sorted by: Date

Sequence No. / Comment	Rack ID - Pos	Sample ID / QC Lot		User ID	Registered
Q002132	Q30001-1	Name / Lot:	PCCC1 / 525027	ADMIN	23/02/2023 13:35:42

Test / Unit / Result Message	Sample Type	Result Data Alarm / Dilution	A.U.	Priority		R.P. Lot	R.P. Serial No.	ProCell Lot / Electrode
CA2 mg/dL	Ser/Pl	9.15	CC	Current	R1-R3	645917	0000592	
LDHI2 U/L	Ser/Pl	180	CC	Current	R1-R3	628352	0002361	
LIP U/L	Ser/Pl	45.3	CC	Current	R1-R3	647416	0000052	

28/02/23

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

System: cobas pure Serial No.: 2154-03

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Sample Results Report

User ID: ADMIN

23/02/2023 15:39

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot	User ID	Registered
Comment				
Q001130	Q30001-2	Name / Lot: PCCC2 / 519198	ADMIN	23/02/2023 10:27:32

Test	Result	Data Alarm							
Unit	Sample Type	Dilution		A. d.	Priority	R. P. Ref.	R. P. Serial No.	Pro. Cal. Lot / Electrode	
Result Message									
ALB2-G		5.10							
g/dL	Ser/Pl			CC	Current	R1-R3	608713	0000584	
ALP2		240							
U/L	Ser/Pl			CC	Current	R1-R3	668539	0002241	
ALTP		123							
U/L	Ser/Pl			CC	Current	R1-R3 R2	661052 654893	0014638 0002984	
AMYL2		186							
U/L	Ser/Pl			CC	Current	R1-R3	630349	0002956	
APOAT		160 OBS.RR							
mg/dL	Ser/Pl		NACL	CC	Current	R1-R3	588324	0000434	
APOBT		74.4 OBS.RR							
mg/dL	Ser/Pl		NACL	CC	Current	R1-R3	631378	0000957	

23/2/23

System: cobas pure Serial No.: 2154-03

Scanned with OKEN Scanner

Sample Results Report

User ID: ADMIN

23/02/2023 15:39

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot		Registered	
Comment			User ID		
Q001130	Q30001-2	Name / Lot:	PCCC2 / 519198	23/02/2023	10:27:32
			ADMIN		

Test	Result	Data Alarm						
Unit	Sample Type	Dilution	A U	Priority		R P Lot	R P Serial No.	ProCell Lot / Electrode
Result Message								
ASTP	149							
U/L	Ser/Pl		CC	Current	R1-R3	663695	0015390	
					R2	654893	0002984	
ASTP	149							
U/L	Ser/Pl		CC	SB1	R1-R3	663695	0017958	
					R2	654893	0002984	
BILD2-D	2.12							
mg/dL	Ser/Pl		CC	Current	R1-R2	652625	0001519	
BILT3	3.46							
mg/dL	Ser/Pl		CC	Current	R1-R3	622281	0004606	
CA2		Samp.S						
mg/dL	Ser/Pl		CC	Current				
CHOL2-I	174							
mg/dL	Ser/Pl		CC	Current	R1	640736	0002978	

23/02/23

System: cobas pure Serial No.: 2154-03

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Sample Results Report

User ID: ADMIN

23/02/2023 15:39

Result Type: First Sorted by: Date

Sequence No.	Rack ID	Pos.	Sample ID / QC Lot		User ID	Registered
Comment						
Q001130	Q30001-2		Name / Lot:	PCCC2 / 519198	ADMIN	23/02/2023 10:27:32

Test / Unit	Sample Type	Result / Dilution	Date Alarm / A U	Priority	R P Lot	R P Serial No.	ProCell Lot / Electrode
CREJ2 mg/dL	Ser/Pl	4.26	CC	Current	R1-R3	627775	0003592
CRP4 mg/L	Ser/Pl	50.4	CC	Current	R1-R3	645296	0004112
GGT2-I U/L	Ser/Pl	226	CC	Current	R1-R3	653840	0006114
GLUC3 mg/dL	Ser/Pl	241	CC	Current	R1-R3	629487	0003425
HDLC4 mg/dL	Ser/Pl	57.3	CC	Current	R1-R3	626113	0006797
IRON2 µg/dL	Ser/Pl	Samp.S	CC	Current			

23/02/23.

System: cobas pure Serial No.: 2154-03

Sample Results Report

User ID: ADMIN

23/02/2023 15:39

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot	User ID	Registered
Comment				
Q001130	Q30001-2	Name / Lot: PCCC2 / 519198	ADMIN	23/02/2023 10:27:32

Test / Unit / Result Message	Sample Type	Result / Data Alarm / Dilution	A U	Priority		R P Lot	R P Serial No.	ProCell Lot / Electrode
ISE CL		98.5						
mmol/L	Ser/Pl		ISE	Current	IS	624115	0000700	X2918 X6546
					DIL	650042	0010909	
					REF	661046	0008910	
ISE CL-P		99.0						
mmol/L	Plasma		ISE	Current	IS	624115	0000700	X2918 X6546
					DIL	650042	0010909	
					REF	661046	0008910	
ISE CL-S		99.0						
mmol/L	Serum		ISE	Current	IS	624115	0000700	X2918 X6546
					DIL	650042	0010909	
					REF	661046	0008910	
ISE K		6.67						
mmol/L	Ser/Pl		ISE	Current	IS	624115	0000700	M6811 X6546
					DIL	650042	0010909	
					REF	661046	0008910	

23/02/23.

System: cobas pure Serial No.: 2154-03

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Sample Results Report

User ID: ADMIN

23/02/2023 15:39

Result Type: First Sorted by: Date

Sequence No	Rack ID - Pos	Sample ID / QC Lot	User ID	Registered
Comment				
Q001130	Q30001-2	Name / Lot: PCCC2 / 519198	ADMIN	23/02/2023 10:27:32

Test Unit Result Message	Sample Type	Result Data Alarm Dilution	A U	Priority		R. P. Lot	R. P. Serial No.	ProCel Lot / Electrode
ISE K-P mmol/L	Plasma	6.68	ISE	Current	IS DIL REF	624115 650042 661046	0000700 0010909 0008910	M6811 X6546
ISE K-S mmol/L	Serum	6.70	ISE	Current	IS DIL REF	624115 650042 661046	0000700 0010909 0008910	M6811 X6546
ISE NA mmol/L	Ser/Pl	128.4	ISE	Current	IS DIL REF	624115 650042 661046	0000700 0010909 0008910	E2196 X6546
ISE NA-P mmol/L	Plasma	128.5	ISE	Current	IS DIL REF	624115 650042 661046	0000700 0010909 0008910	E2196 X6546

28/02/23

System: cobas pure Serial No.: 2154-03

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Sample Results Report

User ID: ADMIN

23/02/2023 15:39

Result Type: First Sorted by: Date

Sequence No.	Rack ID	Pos.	Sample ID / QC Lot	User ID	Registered
Comment					
Q001130	Q30001-2	Name / Lot:	PCCC2 / 519198	ADMIN	23/02/2023 10:27:32

Test	Result	Data Alarm				R/R Lot	R/R Serial No.	ProCell Lot / Electrode
Unit	Sample Type	Dilution	A/U	Priority				
Result Message								
ISE NA-S	129.1							
mmol/L	Serum		ISE	Current	IS	624115	0000700	E2196 X6546
					DIL	650042	0010909	
					REF	661046	0008910	
LDHI2	Samp.S							
U/L	Ser/Pl		CC	Current				
LDLC3	106							
mg/dL	Ser/Pl		CC	Current	R1-R3	572897	0001121	
LIP	Samp.S							
U/L	Ser/Pl		CC	Current				
PHOS2	7.79							
mg/dL	Ser/Pl		CC	Current	R1-R3	653804	0004108	
TP2	7.73							
g/dL	Ser/Pl		CC	Current	R1-R3	635652	0005917	

28/12/23

System: cobas pure Serial No.: 2154-03

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Sample Results Report

User ID: ADMIN

23/02/2023 15:39

Result Type: First Sorted by: Date

Sequence No	Rack ID	Pos.	Sample ID / QC Lot			User ID	Registered
Comment							
Q001130	Q30001-2		Name / Lot:	PCCC2 / 519198		ADMIN	23/02/2023 10:27:32

Test / Unit	Sample Type	Result / Data Alarm / Dilution	A / L	Priority	R P Lot	R P Serial No.	ProCell Lot / Electrode
Result Message							
TRIGL mg/dL	Ser/Pl	207	CC	Current	R1	643364	0003033
UA2 mg/dL	Ser/Pl	9.90	CC	Current	R1-R3	627564	0002726
UIBC-I µg/dL	Ser/Pl	259	CC	Current	R1-R3	637859	0015422
UIBC-I µg/dL	Ser/Pl	Samp.S	CC	SB1	R1-R3	637859	0014774
UREAL mg/dL	Ser/Pl	115	CC	Current	R1-R3	651528	0008399
UREAL mg/dL	Ser/Pl	120	CC	SB1	R1-R3	651528	0008658

23/02/23.

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

System: cobas pure Serial No.: 2154-03

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23/02/2023 15:37

User ID: ADMIN

Sample Results Report

Result Type:	First	Sorted by:	Date		
Sequence No. / **Comment**	**Rack ID . Pos**	**Sample ID / QC Lot**		**User ID**	**Registered**
					23/02/2023 13:35:42
Q001132	Q30001-2	Name / Lot:	PCCC2 / 519198	ADMIN	

Test / Unit / Result Message	Sample Type	Result Data Alarm / Dilution	A.U.	Priority		R.P. Lot	R.P. Serial No.	ProCell Lot / Electrode
CA2 mg/dL	Ser/Pl	13.7	CC	Current	R1-R3	645917	0000592	
IRON2 µg/dL	Ser/Pl	233	CC	Current	R1-R3	641946	0000593	
LDHI2 U/L	Ser/Pl	322	CC	Current	R1-R3	628352	0002361	
LIP U/L	Ser/Pl	101	CC	Current	R1-R3	647416	0000052	

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

System: cobas pure

Serial No.: 2154-03

23/02/23

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User ID: ADMIN

23/02/2023 15:38

Sample Results Report

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot	User ID	Registered
Comment				
Q001131	Q30001-2	Name / Lot: PCCC2 / 519198	ADMIN	23/02/2023 13:23:08

Test / Unit / Result Message	Sample Type	Result, Data Alarm / Dilution	A / U	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
ISE CL		105.6						
mmol/L	Ser/Pl		ISE	Current	IS	624115	0000700	X2918 X6546
					DIL	650042	0010909	
					REF	661046	0008910	
ISE K		7.17						
mmol/L	Ser/Pl		ISE	Current	IS	624115	0000700	M6811 X6546
					DIL	650042	0010909	
					REF	661046	0008910	
ISE NA		138.4						
mmol/L	Ser/Pl		ISE	Current	IS	624115	0000700	E2196 X6546
					DIL	650042	0010909	
					REF	661046	0008910	

28/02/23

Symbols attached to "Test"

'+': Rerun test

'*': eFlow subresult, supplemented test for formula calculated test and Hb/HbA1c test

System: cobas pure Serial No.: 2154-03

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