

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 Union² 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 9001:2008³, ISO 13485:2003 + AC: 2007⁴, and QSReg⁵.

The mentioned regulations 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 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

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

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

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

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

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

Qualification Service Installation Qualification / Operation Qualification (v.2.0)

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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=""></e></c>			
	S/N	IP Address		
cobas pure Control	unit	172.18.38.	230	
CII				
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:
8386030 -01-02

Qualification Service

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Installation Information

Installation Start Date: 17/11/2022

First Installation:

Reconfiguration: From: To:

Relocation: From: To:

Roche Responsible Representative

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Qualification Service Installation Qualification / Operation Qualification (v.2.0)

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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	0.800 Buch 115	ature ate
IQ.1.1	User assistance available	Pass	7	
IQ 1.2	Environmental parameters met	Pass	16 34	
IQ 1.3	Instrument delivered undamaged and complete	Pass	/17	14
IQ 1.4	Transport locking successfully removed	Pass		Av.
IQ 1.5	All connections correctly installed	Pass	BA	Marillia.
IQ 1.6	Instrument positioned according to Installation Manual	Pass	To	1.12
IQ 1.7	Instrument boot process successfully	Pass	4 6	XYI
IQ 1.8	Checksum according to specification	Pass	16 25	
ĪQ 1.9	Mechanical adjustments complete	Pass	The Oliver	
IQ 1.10	Auxiliary components positioned	Pass ///	26 66	
IQ 1.11	Instrument installation check	Pass	876. W	
IQ 1.12	Host communication settings checked	not applicable	1000 100	

Test#	Test	Pass Fail	Signature Date
IQ.2	Installation Qualification for cobas <ise></ise>	yes ///	2
IQ.3	Installation Qualification for cobas <c 303=""></c>	yes	MICALLI
IQ.4	Installation Qualification for cobas <e 402=""></e>	yes	
IQ.5	Installation Qualification for cobas link	yes	J. C. Yilliam M. C.
		/	9/12/





Qualification Service Installation Qualification / Operation Qualification (v.2.0)

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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	englishmen in terminal desired Alver Region of the Region
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 specifications

Test#	Test	Pass Fall	Signature
OQ.1	Calibration successfully	Pass	The state of the s
00.2	Quality Control successfully	Pass	16 thatter
00.3	Accuracy check successfully	Pass	1
Control of the last of the las	in seemal y sheets adoptionally	Pass	1 2 2

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					20 12 13 20 10 10 12		
Investigation							
Action taken							
Deviation resolved	l satisfacto	orlly?				spec	ify
Participated and the second se	EW.						

Deviation #2		
Investigation		
Action taken		
Deviation resolved satisfa	ctorily?	specify

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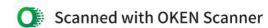
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cobas® pure integrated solutions

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 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 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	Description	User assistance available	
Ambient temperature in the lab is between 18° and 32 °C Ambient humidity at the lab is between 30 and 85% RH and non-condensing Bacteria free, deionized water < 10 cfu/ml Pass Water conductivity 1.0 µS/cm or less Water pressure between 50 kPa and 340 kPa 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 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			Pass
32 °C Ambient humidity at the lab is between 30 and 85% RH and non-condensing Bacteria free, deionized water < 10 cfu/ml Pass Water conductivity 1.0 μS/cm or less Water pressure between 50 kPa and 340 kPa 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 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	JQ 1,2	Environmental parameters	
RH and non-condensing Bacteria free, deionized water < 10 cfu/ml Pass Water conductivity 1.0 µS/cm or less Water pressure between 50 kPa and 340 kPa 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 All accessory boxes are delivered 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			Pass
Water conductivity 1.0 μS/cm or less Water pressure between 50 kPa and 340 kPa 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 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			Pass
Water pressure between 50 kPa and 340 kPa Instrument is not exposed to direct sunlight Floor is level and grade is ≤ 1/200 (≤0.5%) Pass IQ 1.3 Instrument delivered undamaged and complete All covers are undamaged 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 IQ 1.5 All connections correctly installed Power distribution board and water supply/drainage		Bacteria free, deionized water < 10 cfu/ml	Pass
Instrument is not exposed to direct sunlight Floor is level and grade is ≤ 1/200 (≤0.5%) Pass IQ 1.3 Instrument delivered undamaged and complete All covers are undamaged All accessory boxes are delivered 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 IQ 1.5 All connections correctly installed Power distribution board and water supply/drainage		Water conductivity 1.0 μS/cm or less	Pass
Floor is level and grade is ≤ 1/200 (≤0.5%) IQ 1.3 Instrument delivered undamaged and complete All covers are undamaged All accessory boxes are delivered 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		Water pressure between 50 kPa and 340 kPa	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		Instrument is not exposed to direct sunlight	Pass
All covers are undamaged All accessory boxes are delivered 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		Floor is level and grade is ≤ 1/200 (≤0.5%)	Pass
All accessory boxes are delivered 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	IQ 1.3	Instrument delivered undamaged and complete	
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		All covers are undamaged	Pass
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		All accessory boxes are delivered	Pass
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		Instrument does not show any external damage	Pass
without damage to units Pass All connections correctly installed Power distribution board and water supply/drainage	IQ 1.4	Transport locking successfully removed	
Power distribution board and water supply/drainage			Pass
	IQ 1.5	All connections correctly installed	
facilities located within 5m from the instrument.		Power distribution board and water supply/drainage facilities located within 5m from the instrument.	Pass
Power supply voltage at the customer facility:		Power supply voltage at the customer facility:	yes
UPS system available:		UPS system available:	yes
Voltage fluctuation less than ±20V		Voltage fluctuation less than ±20V	Pass
Grounding terminal of 10Ω or less available		Grounding terminal of 10Ω or less available	Pass



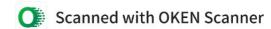




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IQ 1.6 Instrument positioned according to Installation Manual	
System layout is according to the description in the manual	Pass
Modules are installed according to the installation rnanual with official tools	Pass
IQ 1.7 Instrument boot process successful	
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) H	CObas [®]



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IQ 1.12 Host communication settings checked

Host settings customised to local site and tested

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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	
nvestigation	
Action taken	
Deviation resolved satisfactorily?	specify







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Conclusion

All test results are acceptable.		yes //////		
Any deviation or non-conformances observe as a deviation and the relevant forms comple		d yes		
All acceptance criteria have been met. This e acceptable and the unit is approved for its in		yes and the		
Comments				
		01010-		
Completed by Roche Representative	Date	2.12.12		
SUDIP KUMAR SAHU/SIDHARTH MURAM	ULLA Signature	Waly		
	-	P.		
			110	tech
Reviewed by Customer Contact	Date	0		CA
Print Name RAVISHANKAR DUBEY	Signature	1. ans	Pat	na)≦)
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Reviewed by Customer Quality Assurance	Date			i o to
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Qualification Service Installation Qualification (v.2.0)

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Installation Qualification for cobas® pure <ISE>

Description

10.2.2	Mechanical adjustments complete	and the second of the second o
	All mechanical adjustments for ISE mechanical parts are carried out	Pass
	Adjustment check during mechanical check function	Pass
IQ.2,3	Auxillary components positioned	
	ISE Reagents are loaded	yes alla della
IQ 2.4	Gear pump adjustment	hill masin di disa kadalik kanda kan kini birin birin
	Gear pump adjustment executed (attached printout)	yes
IQ 2.5	Instrument installation check	
	ISE Check 20 times (attached printout)	yes www.
IQ 2.6	Application installation	
	Download of applications from cobas link: Na (29070) K (29080) CI (29090)	Pass





Qualification Service
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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





Installation Qualification for cobas® pure <c 303>:

Description IQ.3.1 Function check of c 303 module according to specifications Pass System layout is according to the description in the manual c 303 AU is installed according to the installation manual with official tools Pass 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 Pass detergents were adjusted 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-P1 (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

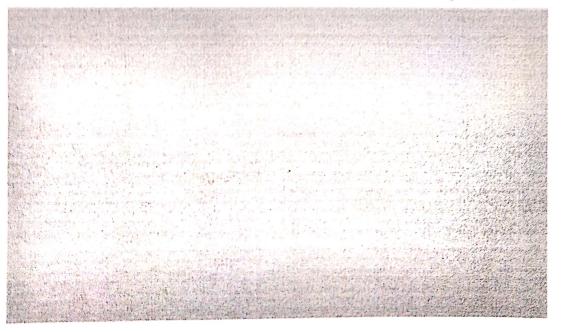


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Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

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>:

	pare v	6 4027.
IQ.4,1	Function check of a 402 module according to specification	Contract the second second
	e 402 AU is installed according to the installation	
	manual with official tools	Paes
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	Paos
	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 System prime and system air purge for syringes	yes
	and reagents	Paes
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. 	
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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
The second secon	STATE OF THE PARTY
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

n	IQ.5_1	cobasLink connectivity test	on an arms
		cobasLink is installed according to the cobas Link cobas pure manual	YES
		Internet connection is available	YES
	IQ.5.2	cobasLink configuration	palalalah kalendari sarah salah sa
		cobas link Configurator/System Check Latest patches installed	ÖK
		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	cobast ink 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				100
Investigation				
Action taken				
Deviation resolved	l satisfactorily	17		specify
Deviation #2				
Investigation				
Action taken				
Deviation resolved	l satisfactorily	7		specify

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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

mm .	SOFTER AN ARCHAEL STORY WAS ARREST OF	
OQ 1	Calibration	i

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)

QC of Immuno parameters within acceptable

range (attached printout)

OQ.3.1 Precision check for ISE

Perform precision check using PCCC1 n=21

		pected CV Actual CV	v
Na	21 1.	.00% 0.27%	
K	21 1.	.20% 0.47%	
CI	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

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OQ.3.2 Precision check for Photometric Assays

Perform precision check using PCCC1 n=
--

ASTP/ASTP2 21 2.00% 1.62% GLUC3 21 1.00% 0.21% CREJ2 21 2.50% 1.97% TP2 21 1.00% 0.45% CHOI 2 21 1.00% 0.45%		Number of det.	Exspected < CV	Actual CV
21 1.00% 0.45%	GLUC3	21	1.00%	0.21%
	CREJ2	21	2.50%	1.97%

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 Exspected
of det. < 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

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Qualification Service Installation Qualification / Operation Qualification (v.2.0)

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Deviation #1	M. Contraction of the Contractio		
Deviation #1	Professional Control		CONTRACTOR
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Qualification Service Installation Qualification / Operation Qualification (v.2.0)

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Attachments



Sample Ro	sults Report			1.1	ser ID: RCL		
Pacielt Turas		Sorted has	Оат				U ₂ 0372023 10:04
0011070		Provide and the second second					
@ Q011078	Q30007-3	Name / Lot:		PC VITDT1 / 612474			11/03/2023 09:25.12
ाल्नु ।		câulcidateValaire				RCL	
- Uhi(c) +6. Testhi Mas		0)110(2(3))	A Co	Briong	18. 19. 2010	र हि उद्यान ए ।	Proteil log of Barroge
VITDT 3		21.4					
ng/mL	Ser/Pl		IC	Current	662815	0006331	668920
Sequence (No.	Region Pos	Şəmple ID / Qo	(Jol)				
Q012078	Q30007-4	Name / Lot:	1.1.1.1	PC VITDT2 / 612475		ildearl)	Callena Co
4.16		, 250		10 11012 / 6124/5		RCL	11/03/2023 09:25:12
Test.		esult Data Alarm					
Result Mess	Sample Type age	Plution	AUL	Princip	R. P. Lart	R. P. Senal No.	ProCell Loff (declare
VITDT 3		36.2	terra in militari an Tanathina di an			A STATE OF THE STA	Secretary of the second
ng/mL	Ser/Pl		IC	Current	662815	0006331	668920

	icentil Messaci											
-	ALB2-G		3.31	ALL MANAGEMENT				Participate Superince Participation and A	The same of the same			
	g/dL ·	Ser/Pl			CC	Current	R1-R3	663677	0001684			
	ALD2		100									
	ALP2 U/L	Ser/Pl	109		CC	Current	R1-R3	654864	0000413			
	J, L	301/11				current						
	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		•	
									. 7			
	APOAT	C /DI	101	NIACI	CC	Current	D1 D2	500224				
	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			
		m										
	J. Trad		· .									
	2.											
	ystem -	cobas pure	•			Serial No.:	2275-02			2	~_of=+5	
	To the College of the			the state of								

System y' cobas pure	CRP4 mg/L	CREJ2 mg/dL	CHOL2-A mg/dL	CA2 mg/dL	BILT3 mg/dL	BILD2-D mg/dL	ASTP U/L
cobas pure	Ser/Pl	Ser/PI	Ser/Pl	Ser/Pl	Ser/PI	Ser/Pl	Ser/Pl
	5,47	1.03	95.5	8.38	0.856	0.717	47.2
	CC	CC	CC	CC	CC	CC	23
Serial No.	Current	Current	Current	Current	Current	Current	Current
2275-02	R1-R3	R1-R3	R1	R1-R3	R1-R3	R1-R2	R1-R3 R2
	645296	627775	658312	661077	622281	670789	663695
	0004009	0002684	0003540	0000822	0006338	0003841	0016869 0011433
3 of 15					·		

4 of 15			2275-02	Serial No:	S			cobas pure	System cobas p
								A Kerzy	
	0002699	644059 539523	DIL REF				٠.		
W1160 X6581	0013775	661339	IS	Current	ISE		; ;	Ser/Pl	mmol/L
	0004394	652627	₹1-R3	Current	CC		ЭЭ 1 Л	Ser/Pl	hg/dL
	0007929	626113	R1-R3	Current	, (108	Ser/PI	IRON2
) }		28.4		HDLC4
	0002479	672328	R1-R3	Current	CC .		101	Ser/Pl	GLUC3 mg/dL
	0015045	663681	R1-R3	Current	CC		53.0	Ser/Pl	GGT2-I U/L
	0001139	626644	R1-R3	Current	, CC			Ser/Pl	mg/L
A CONTRACTOR OF THE PARTY OF TH							6.95	lessagle	Result N CRP-HS
									E.F
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		The transfer of the State of th	PCCC1 / 525205	المردر ا		Nume / Lot		030001	()013078
		of company of the com			in the state of th	4. km [6.[4]]	9		Section of the sectio

System: cobas pure	TRIGL mg/dL	TP2 g/dL	PHOS2 mg/dL	U/L	ISE NA mmol/L	ISE K	Result Message	Cotsors
	Ser/PI	Ser/PI	Ser/PI	Ser/Pl	Ser/Pl	Ser/Pl	Sample Type	230001 1
S. Brushan	125	4.90	3.66	44.3 OBS.RR	113.6	3.57	Piletion	Name / Lot
5	CC	CC	00	00	ISE	ISE	P.C.	
Serial No.	Current	Current	Current	Current	Current	Current	Pitotity	PCCC1 / 525205
2275-02	R 2	R1-R3	R1-R3	R1-R3	IS DIL	IS DIL REF		525205
	661743	693361	653804	647416	661339 644059 539523	661339 644059 539523	7 7 1-01	
	0005476	0006895	0006833	0002871	0013775 0002699 0007940	0013775 0002699 0007940	R P Serial No	IJd
-5 of 15					C5871 X6581	L3903 X6581	ProCell Lot / Electrode	11/03/2023 09:25

-System:	UREAL mg/dL	UREAL mg/dl	UIBC-I µg/dL	UA2 mg/dL	Resolt Me UA2 mg/dL
cobas pure	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl	sহুটুহ Ser/Pl
5. Shadran	41.0	41.2	196	4.84	4.80
		CC	, ()	6	00
Serial No.:	SB1	Current	Current	SB1	Current
2275-02	R1-R3	R1-R3	R1-R3	R1-R3	R1-R3
	674482	663424	637859	664685	664685
	0007492	0002257	. 0014907	0002503	0004464
ති of 15					
o <u>c</u>					

System	BILT3 mg/dL	BILD2-D mg/dl	ASTP	ALTP U/L	ALP2 U/L	Result Mass ALB2-G 9/dL
cobas pure	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl	Ge Ser/Pl
S. Brussan	3.24	2.14	145	129	280	4.95
	CC	66	CC	CC	6	CC
Serial No.:	Current	Current	Current	Current	Current	Current
2275-02	R1-R3	R1-R2	R1-R3	R1-R3	R1-R3	R1-R3
	622281	670789	663695 674481	674483 674481	654864	663677
	0006338	0003841	0016869 0011433	0005876 0011433	0000413	0001684
7. of 15 :						

System	IRON2 μg/dL	HDLC4 mg/dL	· GLUC3	GGT2-I U/L	CREJ2 mg/dL	CHOL2-A mg/dL	CA2 mg/dL	itesi Unit	Q002078	
cobas pure	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl	i ajdluzs.	Q30001-2	
S. Shrikan	245	59.5	233	236	3.85	174	13.6	(be	2	
	\ -							uilon	Name / Lor	Solved J.
Se	CC	, CC	CC	CC	CC	· CC · ·	CC			Dute
Serial No.:	Current	Current	Current	Current	Current	Current	Current	POOLEN.	PCCC2 / 535719	
2275-02	R1-R3	R1-R3	R1-R3	R1-R3	R1-R3	R1	R1-R3		535719	
	, o	<u></u>	6	66	62	. 65	66	2.2	the state of the s	
	652627	626113	672328	663681	627775	658312	661077			
	0004394	0007929	0002479	0015045	0002684	0003540	0000822	K P SajaJN	ָם װּשְׁרָשְׁיִבְּיִים װְשְׁרָשְׁיִבְּיִים װְשְׁרָשְׁיִבְּיִם װְשְׁרְיִבְּיִים װְשְׁרְיִבְּיִם עִיבְּיִים װְשְׁ	
								Pro		
- 8 O								व्यापका/विवर	11/03/2023	
of 15								rode	3 09:25:33	
									33	

System.	PHOS2 mg/dL	LDHI2	ISE NA mmol/L	ISE K mmol/L	Result Mess ISE CL mmol/L	esult () and ()
cobas pure	Ser/Pl	Ser/Pl	Ser/P)	Ser/Pl	Ser/Pl	First Ognont-2
B. Shusha	8.36	295	136.9	7.28	101.9	- हिल्डाम् । - हिल्हाम्
	CC	CC	JSI	·	ISE	Sorted by: [
Serial No÷	Current	Current	Current	Current	Current	Сэте РСССС2 / 535719
2275-02	R1-R3	R1-R3	IS DIL REF	DIL REF	IS DIL REF	535719
	653804	628352	661339 644059 539523	661339 644059 539523	661339 644059 539523	1% P. 1.(Q)
	0006833	0002360	0013775 0002699 0007940	0013775 0002699	0013775 0002699 0007940	R. P. Serial No.
9-of 15			C5871 X6581	L3903 X6581	W1160 X6581	ಿಸಲಾದ 11/03/2023 ಗೀಂCall (ಸಂಕಿ// ಡೆಜೀನುಕಾಶೆಕ
						09:25:33

System:	UREAL mg/dL	UREAL mg/dL	UIBC-I µg/dL	UA2 mg/dL	UA2 mg/dL	TRIGL mg/dL	Result Vies TP2 g/dL
cobas pure	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl
	122	118	244	10.2	10.1	220	7.69
	CC	00	CC) (C	00	CC	CC
Serial No.	SB1	Current	Current	SB1	Current	Current	Current
2275-02	R1-R3	R1-R3	R1-R3	R1-R3	R1-R3	R1	R1-R3
	674482	663424	637859	664685	664685	661743	693361
	0007492	0002257	0014907	0002503	0004464	0005476	0006895
10 c							
10 of 15							

11 of 15			2275-02	Serial No.:			cobas pure	System
							• .	
	0001653	634798	R1-R3	CC SB1		53.2	Ser/Pl	RF-II IU/mL
	0001645	634798	R1-R3	CC Current		0.30	Ser/Pl	IU/mL
No. Procedition/Affections	N.E. Serial			A. G. Ribiliy	nten	(5)	्टेबलाहोट् ह्या १९४२)	Unit: Result W
11/03/2023 09:25:33 RCL			RFCO2 / 626900	RFC	Name / Lot:	A C 110.112 C 10.000 E E E E E E E E E E E E E E E E E	Q30001-4	Q010078
				Date	First Sorted by: Date			sult Type:

System.	T4 µg/dL	T3 ng/dL	PRL 2 ng/mL	IGE 2 IU/mL	HCG-BETA mIU/mL	FERR ng/mL	Restilt Mess B12 2 pg/mL
့cobas pure	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl	Ser/Pl
	8.33	244	27.8	148	15.7	85.3	568
	īC	i -	ĪĊ	i IC	ī	, 	. IC
Serial No.:	Current	Current	Current	SB1	Current	Current	Current
2275-02							
	653184	622585	580119	619045	584575	602731	584567
	0005265	0058817	0062791	0057498	0014368	0091950	0192565
	668920	668920	668920	668920	668920	668920	668920
12-of 15							

System	µIU/mL	TSH	uni:	Q006078	A light of the state of the sta
cobas pure	Ser/Pl	ssage	Sample Type	Q30006-2	
		2.15	Diluiten	Name / Lot:	
Seria	וכ כר			AND	
Serial No. 2275-02	Current		6.1	RANDOX L2 / 2107EC	
	653314				
	0077445		n e senalivo.	RCL	
13 of	668920		ProCall Lot / Elect	11/03/2023	(1) (1) (1) (1) (1) (1) (1) (1) (1) (1)
of 15			ode	09:25:53	Z

Sorted by: Date

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Uhii Result Mess	Sample Type	Dilegion	<u>au</u>	Pronty		R.P. Lot	R P Serial No.	Procell Let / 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

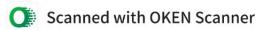
System:

cobas pure

Serial No.:

2275-02

14 of 15



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11/03/2023

RCL

	668920	0077445	653314	Current	Ō	20.2	Ser/Pl	ISH μIU/mL
	668920	0053448	620922	Current	ī	20.7	Ser/Pl	TPSA ng/mL
	668920	0005265	653184	Current	ī	13.4	Ser/Pl	T4 µg/dL
	668920	0058817	622585	Current	Ī	380	Ser/PI	T3 ng/dL
	668920	0057653	617608	Current	Ī	1.	Ser/Pl	ng/mL
sell Low/Heatroce	1910	ত্যান্থিক প্ৰথ	Kiljiga	Hillosty.		Punita:	odingle lype sage	Virit Result Message
11/03/2023 09:25:53				RANDOX L 3 / 2110EC	Name / Lot:	Na	Q016078 Q30006-3	Q016078
				Date	Sorted by:		FIRST	Sequence No.
						**		

SVETOIT

cobas pure

Symbols attached to "Test"

'+': Rerun test

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

Cortal No

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