

CALIBRATION CERTIFICATE

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

The calibration includes:

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

Incubation Disk: Range: 36.8°C to 37.2°C

Adjusted: 37°C

<u>Detection Unit:</u> Target: 28.0°C

Adjusted: 28.0°C

PC/CC: Target: 28°C

Adjusted: 28°C

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

Next calibration due on 10/07/2024.

For Roche Diagnostics India Pvt Ltd.,

T R Siddardha,

Aildan des.

Sr.Technical Service Specialist,

Hyderabad.



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

Page 3 of 6

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 satisfactority.

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	1
IQ 1.2	Environmental parameters met	Pass	7
IQ 1.3	Instrument delivered undamaged and complete	Pass	
IQ 1.4	Transport locking successfully removed	Pass	一般 新加工市的的东西
IQ 1.5	All connections correctly installed	Pass	DALA
IQ 1.0	Instrument positioned according to Installation Manual	Pass	1 (April
IQ 1.7	Instrument boot process successfully	Pass	1
IQ 1.8	Checksum according to specification	Pass	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
IQ 1.9	Mechanical adjustments complete	Pass	
IQ 1.10	Auxiliary components positioned	Pass	
IQ 1.11	Instrument installation check	Pass	
IQ 1.12	Host communication settings checked	Pass	J. Branch

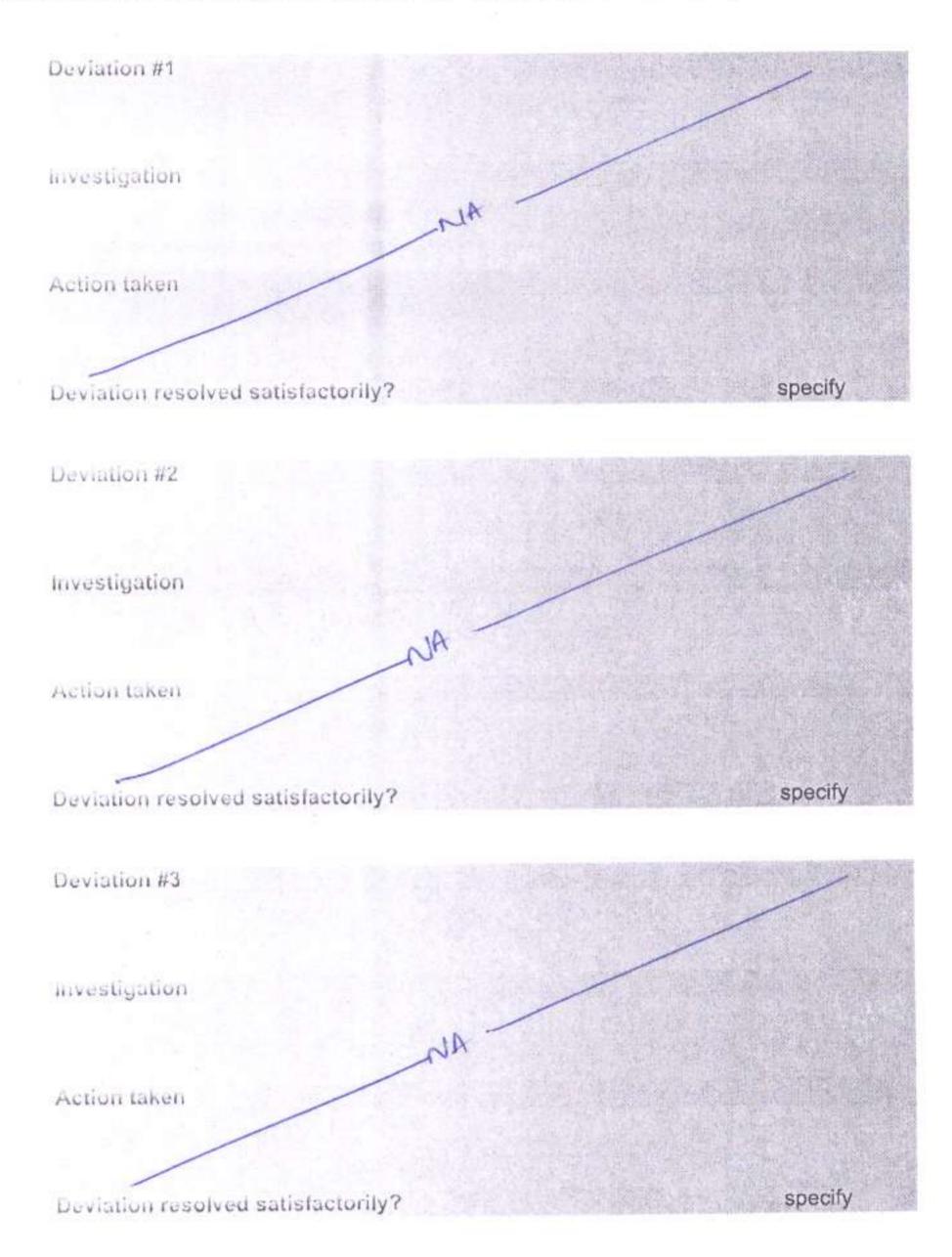
Test#	Test	Pass Fail	Signature Date
IQ.2	Installation Qualification for cobas <ise></ise>	Pass	1) 0
IQ.3	Installation Qualification for cobas <c 303=""></c>	Pass	7 14002
IQ.4	Installation Qualification for cobas <e 402=""></e>	Pass	1 10
RQ.5	Installation Qualification for cobas link	Pass	7





Page 4 of 6

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.







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

Page 5 of 6

Operational Qualification:

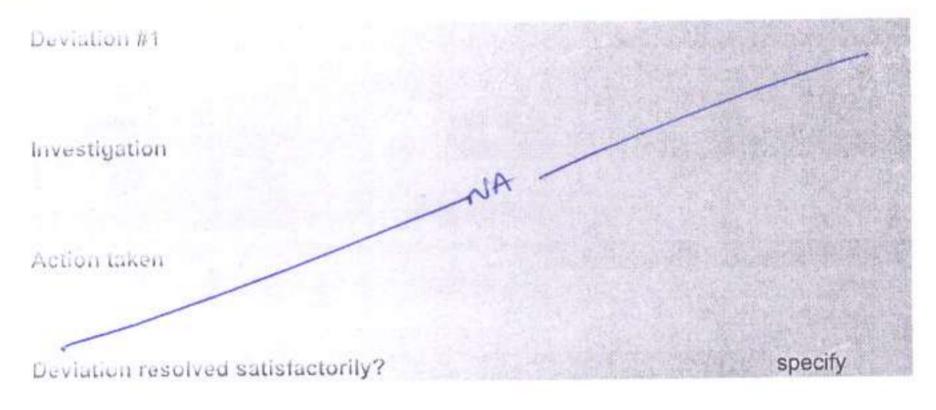
This document is the basis of the Qualification Service Certificate. It certifies that the instrument is operating according to the manufacture's specifications. This report presents and documents the test procedures, documentation, references and acceptance criteria used to verify that the specified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

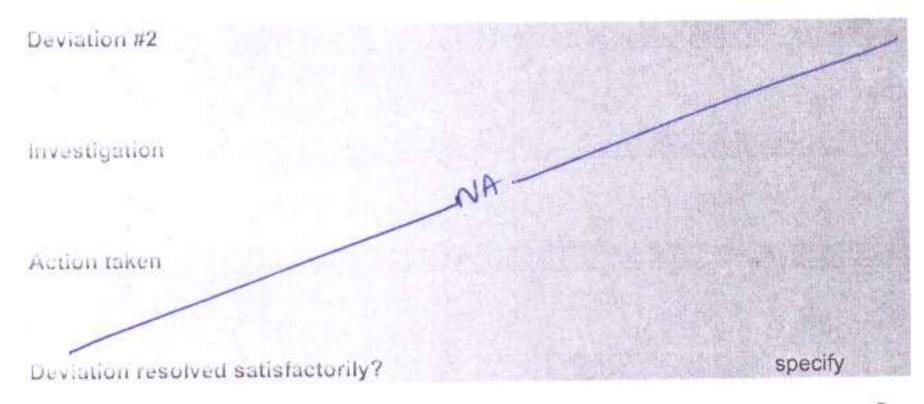
Notice: The following tests are to be carried out by trained Roche personnel only.

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

Test #	Test	Pass Signature Fail Date	
00.1	Calibration successfully	Pass) 10 N	
00.2	Quality Control successfully	Pass Die	7
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.







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

Page 6 of 6

Conclusion

	Ail test results are acceptable.		yes	
	Any deviation or non-conformances observed as a deviation and the relevant forms comple		ded	
	All acceptance criteria have been met. This e acceptable and the unit is approved for its int	equipment is deem ended use.	yes	
Comments	All calibrations passed. Q	C Values a	re with in acceptable	yang
Completed	by Roche Representative	Date -	27/07/2021	
Print Name	Bhavani Prasad.V	Signature	Bri	
Reviewed	by Customer Contact	Date .	27/07/202	
Print Name	MOHO AZHERUDDIM	Signature	Africa	ii.
	by Customer Quality Assurance	Date	27 07/2021	
Print Nam	MOHD AZTERUDDIN	Signature		74
	WETECH PUT			
	September 1 State Complete 1 State Compl		cobas	-



Page 1 of 3

cobas® pure integrated solutions

Description	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
	Vvater 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
IO 1.5	All connections correctly installed	
	Power distribution board and water supply/drainage facilities located within 5m from the instrument.	Pass
	Power supply voltage at the customer facility:	Pass
	UPS system available:	Pass
	Voltage fluctuation less than ±20V	Pass
	Grounding terminal of 10Ω or less available	Pass
		cobas





Qualification Service Installation Qualification (v.2.0)

Page 2 of 3

IQ 1.6	Instrument positioned according to Installation Manual	
	System layout is according to the description in the	Pass
	Modules are installed according to the installation manual with official tools	Pass
IQ 1.7	Instrument boot process successful	
	IP address configuration correct	Pass
	First system boot-up	Pass
	Change cobas link IP Internet NIC (162.132.241.10)	Pass
IQ 1.8	Checksum according to specification	
	Version of installed cobas pure user software	
	Installation of country language successful	Pass
	Checksum of installed software is correct according to Installation Guide	Pass
IQ 1.9	Mechanical adjustments complete	
	All mechanical adjustments for the Sample Line and Rotor are carried out	Pass
	Rack transport during mechanical check function	Pass
	Mechanical adjustments backed up	Pass
IQ 1.10	Auxiliary components positioned	
	Rack trays are installed	Pass
10 1.11	Instrument installation check	
	Print function	Pass
	Download parameters from CL to CU PC	Pass
	Download applications	Pass
	Registered electrodes for ISE	Pass
	Rack/Sample barcode read check (attached printout)	cobas*



Qualification Service Installation Qualification (v.2.0)

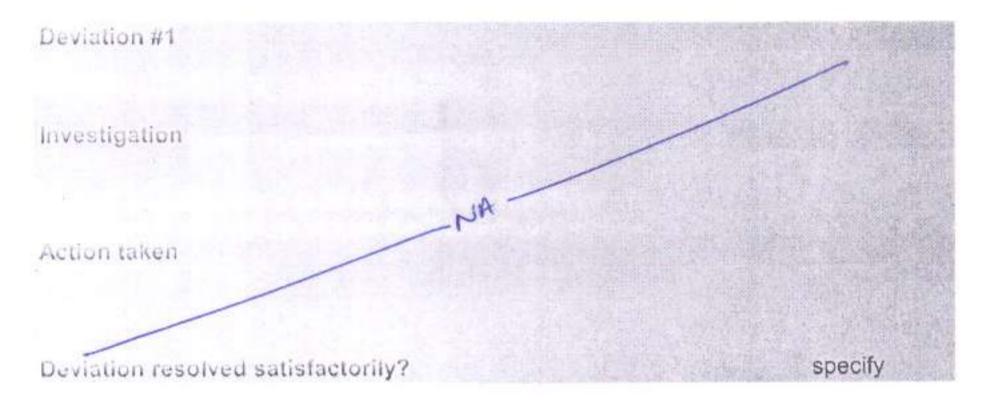
Page 3 of 3

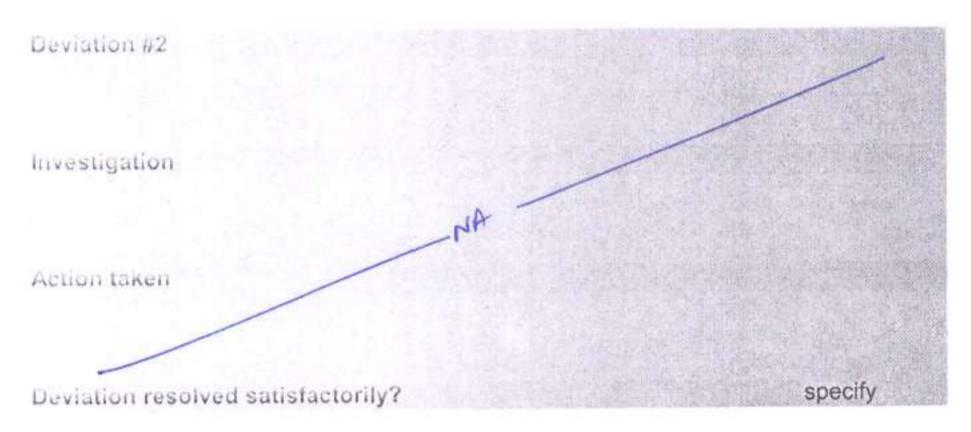
IQ 1,12 Host communication settings checked

Host settings customised to local site and tested

Pass

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





Deviation #3	
Investigation	
Action taken	Professional Control of the Control
Deviation resolved satisfactorily?	specify





Installation Qualification for cobas® pure <ISE>

Description

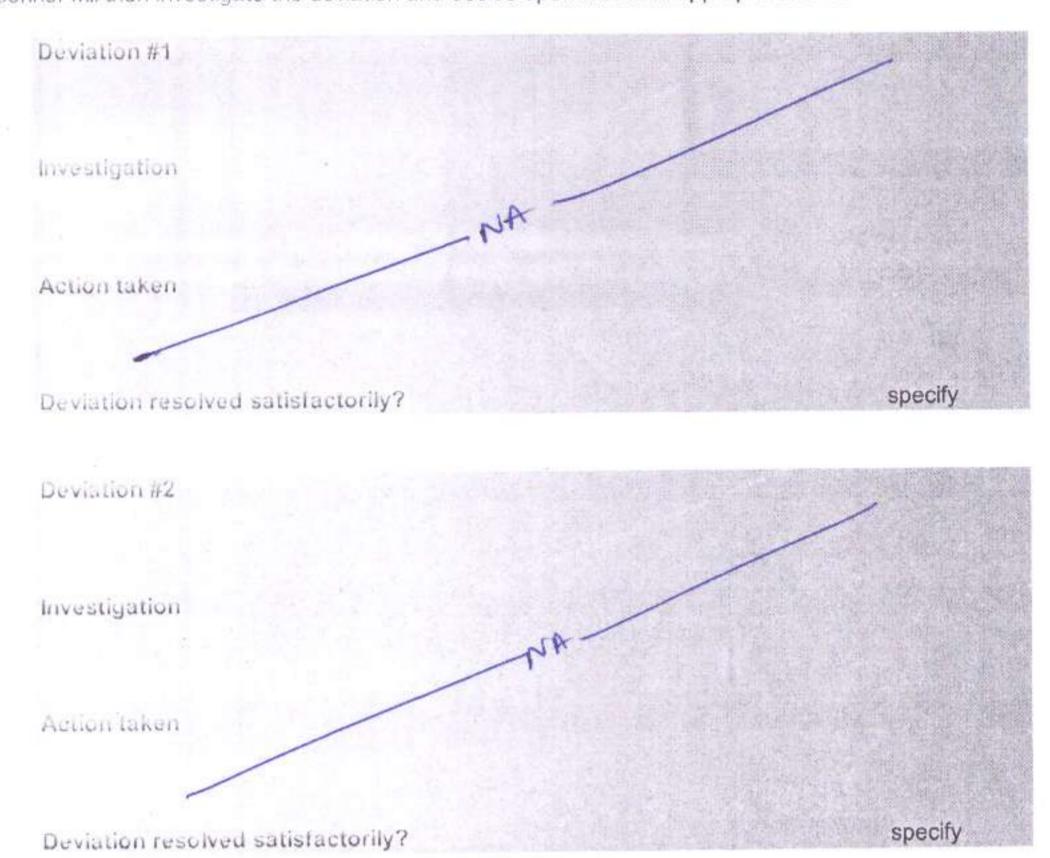
(Q.2.2	Mechanical adjustments complete	
	All mechanical adjustments for ISE mechanical parts are carried out	Pass
	Adjustment check during mechanical check function	Pass
IQ.2.3	Auxiliary components positioned	
	ISE Reagents are loaded	Pass
IQ 2.4	Gear pump adjustment	
	Gear pump adjustment executed (attached printout)	Pass
IQ 2.5	Instrument installation check	
	ISE Check 20 times (attached printout)	Pass
IQ 2.6	ISE Check 20 times (attached printout) Application installation	Pass





Page 2 of 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.



Installation Qualification for cobas® pure <c 303>:

Description	1922-00-10		
	10.3.1	Function check of c 303 module according to specifications	enschapelin := wholein
		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
	Q.3.3	Probes and consumables installation	
		Sample Probe and Reagent probe are installed	Pass
		Reaction cells are installed	Pass
	Q 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-Dic pack green	Pass
		Exchange incubation bath water	Pass
		Water flow of rinse stations as well as consumption of the detergents were adjusted	Pass
		Air surge 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





Qualification Service Installation Qualification (v.2.0)

Page 2 of 2

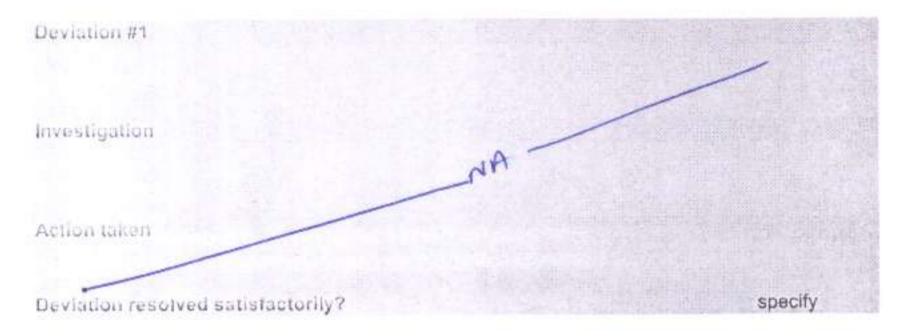
	Adjustment check during mechanical check function	Pass
IQ 3.5	Gear pump adjustment	
	Gear pump adjustment (attached printout)	Pass
IQ 3.6	Application installation	
	Download Special Wash (all)	Pass
	Download of Auxiliary Reagents from cobas link ECO-D, NAOHD, SMS and PYP (PYP if ASTP2 is not available)	Pass
	Menu>System>Auxiliary Reagent Packs>Download	
	Download of applications from cobas link ASTP (20220) (if ASTP2 (20230) is not available), CHGL2 (20411) CREUZ (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	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	Adjustments data backed up	Pass

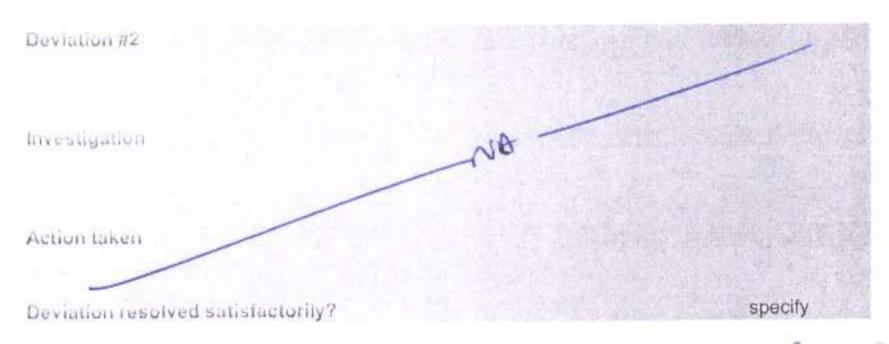




Page 2 of 2

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.





Page 1 of 2

Installation Qualification for cobas® pure <e 402>:

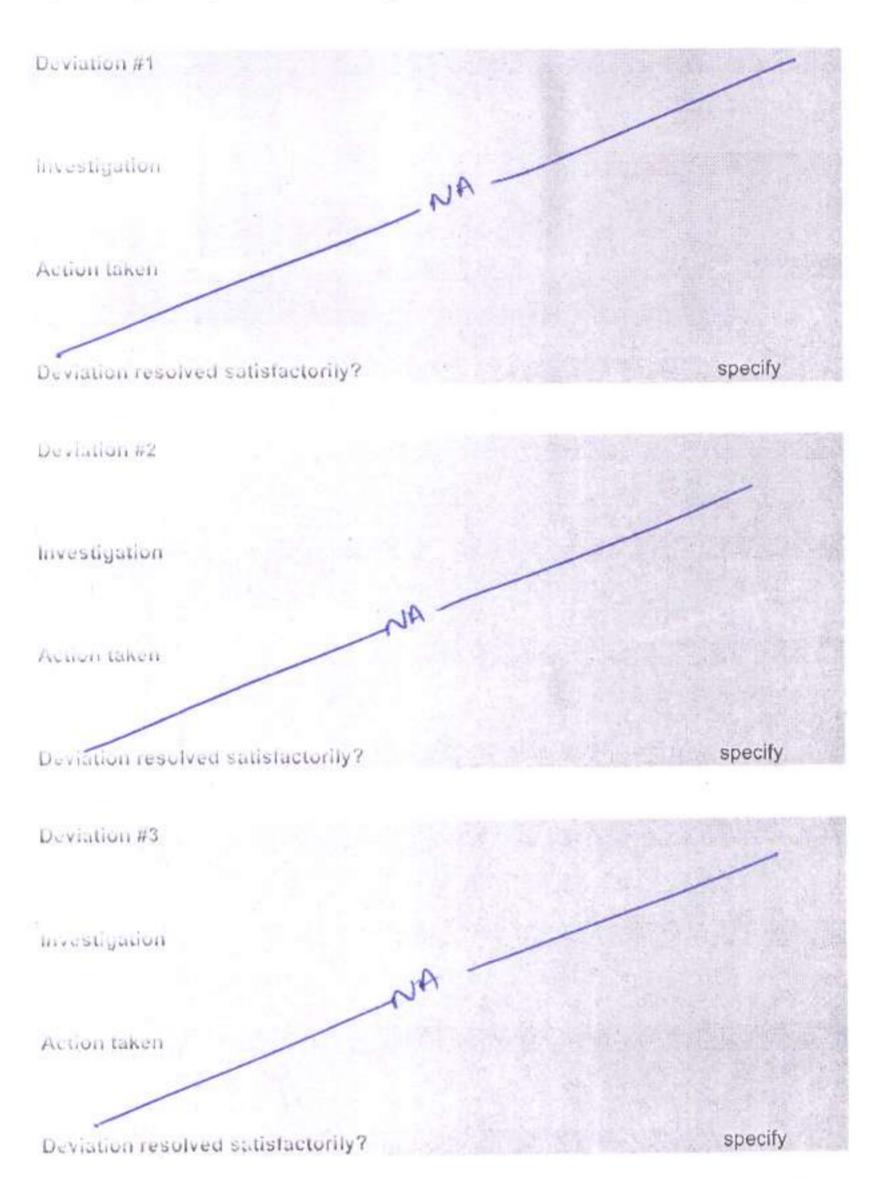
Description		
10.4.1	Function check of e 402 module according to specifications	
	e 402 AU is installed according to the installation manual with official tools	Pass
IQ.4.2	Mechanical adjustments complete	
	All mechanical adjustments for the different e 402 mechanical parts are carried out	Pass
	Adjustment 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
10.4.3	Auxiliary components installed	
	Sample probe, reagent probe, microbeads mixer, measuring cell, sipper probe and pre-wash sipper probe installed	Pass
	Waste liner, CC/PC cups, CleanCell, ProCell, PreClean and Assay Cup&Tip trays loaded	Pass
	System prime and system air purge for syringes and reagents	Pass
10.4.4	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
10.4.5	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 dewnload TSH (10172) application from cobas link. IC TSH can not be used for Precision Check. 	
IQ.4.0	Buckup of adjustment data	
	Adjustments data backed up	Pass





Page 2 of 2

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





Page 1 of 2

Installation Qualification for cobasLink

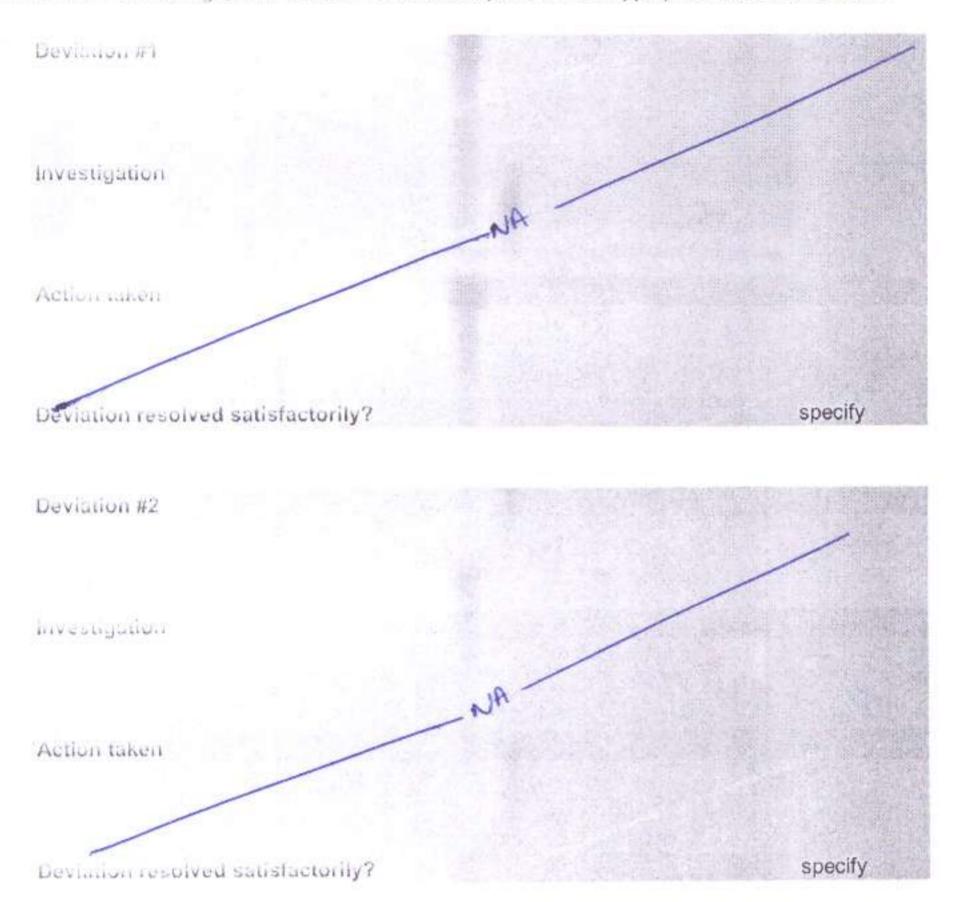
Description	IQ.5.1	cobasLink connectivity test	
		cobasLink is installed according to the cobas Link cobas pure manual	Pass
		Internet connection is available	Pass
	IQ.5.2	cobast.ink configuration	
		cobas link Configurator/System Check Latest patches installed	Pass
		Ceneral settings are entered according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





Page 2 of 2

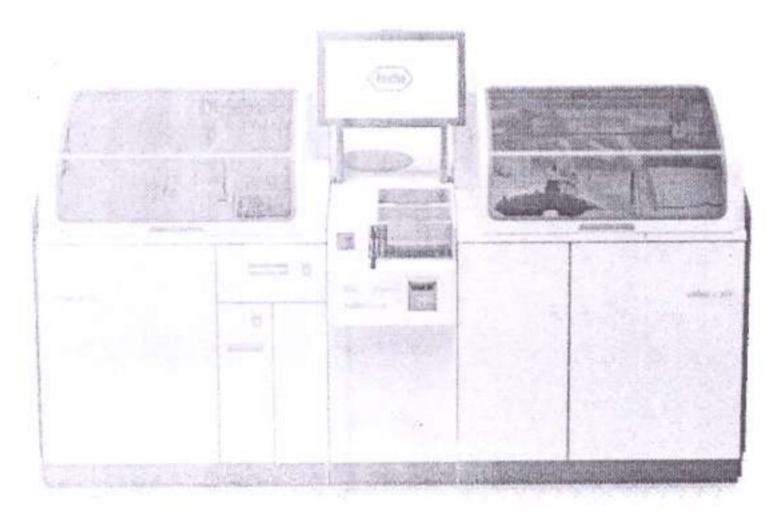
Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.





cobas® pure integrated solutions

Operational Qualification





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

Page 1 of 3

Operational Qualification:

Notice:

The sleps described in OQ.1 have to be carried out after a new system 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

OUT	Cambration			100000
	Calibration of all photor successful (attached pr		yes	
	Calibration of ISE paral (allached printody)	neters successful	yes	
	Calibration of all Immur (attached printout)	no parameters successful	yes	
	Specify the type of calit	orator used:		
	C.F.A.S. lot:	537837		
	TSH CalSet lot	575647		
04.2	Country Control			
	Specify the type of conf	rol used:		
	PCCC1 lot :	525027		
	PCCC2 lot:	519198		
	PCU1 lot :	558012		
	PCU2 lot	558014		
	QU of all photometric p acceptable range (attac		yes	
	QC of ISE parameters (attached printout)	within acceptable range	yes	
	QC of Immuno parametrange (attached printou		yes	
Ou 3.1	Precision check for ISE			
	Perform precision oned	k using PCCC1 n=21		

Number Expected Actual CV of det. < CV Actual CV

No. 21 1.00% Refer PQ date

K 21 1.20% Refer PQ date

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

Processor check for ISL was within acceptable range

CI

yes



Page 2 ut 3

OU.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%)	
GLUC3	21	1.00%		06.	PQ data
CREJZ	21	2.50%		> Kefer	pa and
TP2	21	1.00%			
CHOL2	21	1.00%)	

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

Precision check for Photometric Assays was within acceptable range yes

OC.3.3 Precision check for Immunology Assays

Perform precision check using PCU1 n=21 per Channel

New TSH (10172) Reagent

Number Exspected Actual CV

of det. < CV

TSH Ch.1 21 5.00% - Refer PQ data

check for yes

QQ 3.4 software

results for

yes

tor

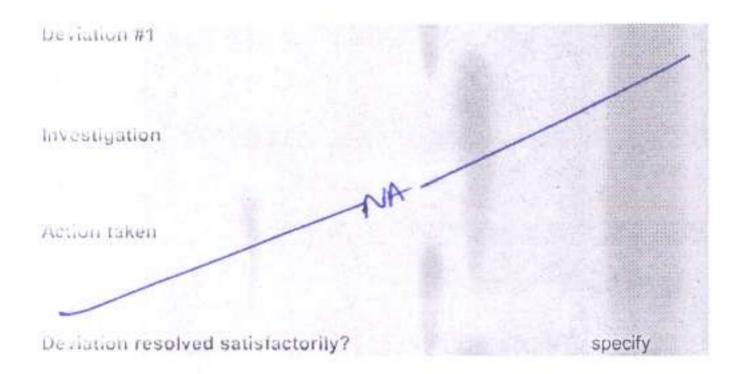
yes

results for

yes

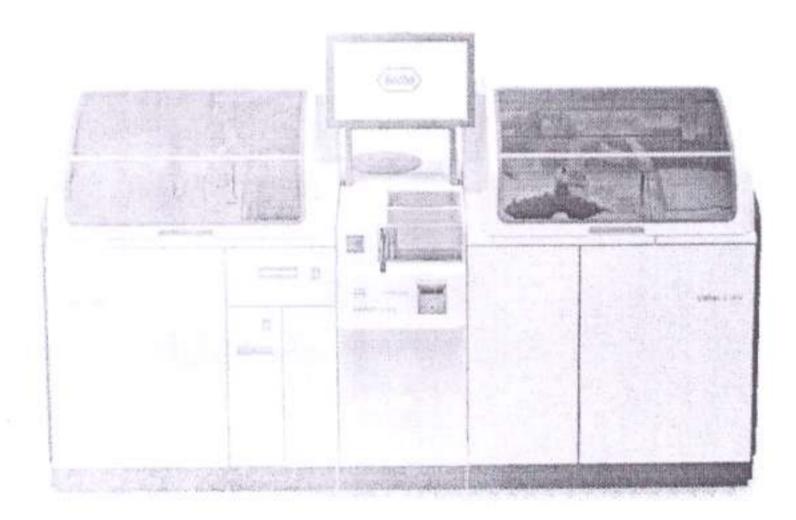


Page 3 of 3





cobas® pure integrated solutions Attachments





Page Let

Attachments

- 1. Calibration Results 2. Controls data
- 3. Precision data (Refer PQ data)

Qualification Service Operation Qualification (v.2.0)



Page 1 of 1

Revision History

Version	v.1.0	Date	24-Nov-20		Author	mooniyer	
		Initial relea	ise				
	v.2.0	Date	20-Apr-21	Merchania.	Author	mooniyer	



0		
	U	7
	M	3
-	C)
	Ĉ	Ì
	C)

Calibration Monitor

User ID: REDCLIFFE

HITACHI

(Roche)

13/07/2022 17:20

			60										
0													
7:2		7											
Н		13											
		620137											
023	FE												
13/07/2022	REDCLIFFE	ProCell:											
107	DCI	OCe											
13	RE	Pr											
		37											
		89											
		900											
		6											
		258											
		622											
		Pi.											
		R											
		SA											
		AS											
		Calibration ID: 00000000001	successfully generated.										
		000											
		000											
at		00											
Calibration Data													
10		E	ed										
rat		on	rat		63								
ib		ti	ne		-								
Cal		bra	ge		2	94	27	23		1	1		
1000		11	1.y		Cal 2	1.76	25527	25723					
		Ca	fu]		-		~	64					
			SS		i.								
			cce										
		47	sa										
		575647	was										
					1								
		Calib. Lot:	calibration		-	5							
		ŭ	ati		H	00	562	569	1	1	ł	1	1.00
		,q	br		Cal	0.00000	വ	S					H
		ali	ali		Ĭ	0.							
		O			T.	0							
			Lot										
				d)								ע	ы
		н	age	age								ul.	to
	=	1/m	80	S								Res	Fac
)I)	hIt	Me	M		ue					OL	r r	r r
	12	Unit: pIU/mL	Result Message:	Timeout Message:		Val	_	N			System Error	Calculation Resu	Calibration Factor
	0:5	nit	esi	ше		t	1	+			m I	119	ra
	7:2	D	K	Ţ		rge	Signal	Signal 2	EE	0.	ste	lcu	111
	-	Volume.				Target Value	Sic	Si	Diff	dng	SY	Ca	Ca
)22	TSH											
	120	-											
	10/												
	13/07/2022 17:20:27 (IC)												
	1316-2												

System:

95		
	U	7
	(ď
1980	C	2
	Ć	Ò
	C	1

Calibration Monitor

User ID:

HITACHI

13/07/2022 17:10

Roche

13/07/2022 17:10:26 (CC) CREJ2 STD Name S1 S2 -Thtercept- -Thtercept- -Thtercept- -Thtercept- - K -	Calibration ID: 0000000014	R1 606453/0000623 Second Abs. First			1	17:10
999999 539837	ion ID: 0000000014	606453/00006 econd Abs.				
			23 R2/	R3 606453/0000623		
	First Abs.		First Initial Abs.	Second Initial Abs.	Data Alarm	
	0.0000	0.0001	0.0376	0.0377		
-Intercent K -	0.0263	0.0259	0.2045	0.2046		
-Intercent K -						
0.0001 14230.8						

2265-09

Calibration Monitor

User ID:

13/07/2022 17:10

	TAPL	
	_	•
/	(Roche)	

System:



HITACHI

27/07/2022 14:48

Sample Results Report

User ID: REDCLIFFE

	Registered	User ID	15/07/2022 10:54:59			DroCell Lot / Flactrode	(302 1000 1												
		n		RI		R. P. Serial No.			920000		0001399		0000354		0002898		0000623		0008618
						R. P. Lot			619902		618366		622620		640736		606453		618926
			/ 525027						R1-R3		R1-R3		R1-R3		R1		R1-R3		R1-R3
Date			PCCC1			J. Priority			Current		Current		Current		Current		Current		Current
Sorted by:	Sample ID / QC Lot		Name / Lot:		Result Data Alarm	Dilution A. U.			2		8		20		20		S		8
	Rack ID - Pos.		Q30001-1		Result D	Sample Type D		3.11		84.0		8.12		94.2		1.02		9.58	
			0300			Samp	essage		Ser/PI		Ser/PI		Ser/PI		Ser/PI		Ser/PI		Ser/PI
Result Type:	Sequence No.	Comment	Q001002		Test	Unit	Result Message	ALB2-G	g/dL	AMYL2	J/N	CA2	mg/dL	CH0L2-I	mg/dL	CREJ2	mg/dL	CRP4	mg/L

of

User ID: REDCLIFFE 27/07/2022 14:48 orted by:	nple ID / QC Lot	PCCC1 / 525027	larm	A. U. Priority R. P. Lot R. P. Serial No. ProCell Lot / Flectrode		CC Current R1-R3 622199 0003410	CC Current R1-R3 629487 0003430		CC Current R1-R3 590715 0001401	CC Current R1-R3 623943 0002726	CC Current R1-R3 572897 0001196	CC Current R1 618847 0001482	
Sorted by:	Sample ID / QC Lot	Name / Lot: PCCC	ta Alarm	Ü.								8	
Sample Results Report Result Type: First	Rack ID - Pos.	Q30001-1	Result Data Alarm	Sample Type Dil	age	55.1 Ser/PI	Ser/Pl	310	Ser/PI	Ser/PI	57.6 Ser/PI	Ser/Pl	4.66
Sample Re Result Type:	Sequence No. Comment	Q001002	Test	Unit	Result Message	GGT2-I U/L	GLUC3 mg/dL	HDI C4	mg/dL	IRON2 µg/dL	LDLC3 mg/dL	TRIGL mg/dL	UA2

27/07/2022 14:49	Registered	15/07/2022 10:54:59		Profell 1 of / Flortrodo								
	I lear ID	OI Jaco	KEDCLIFFE	R P Serial No		0003410	0003430	0001401	0002726	0001196	0001482	0003683
User ID: REDCLIFFE				R. P. Lot		622199	629487	590715	623943	572897	618847	627564
NS		PCCC2 / 519198				R1-R3	R1-R3	R1-R3	R1-R3	R1-R3	R1	R1-R3
Date	-	DCCC		U. Priority		Current	Current	Current	Current	Current	Current	Current
Sorted by:	Sample ID / QC Lot	Name / Lot:	Result Data Alarm	Dilution A.		228 CC	243 CC	60.5 CC	235 CC	105 CC	142 QCErr	9.58 CC
Sample Results Report Result Type: First	Rack ID - Pos.	Q30001-2		Sample Type	age	Ser/PI	Ser/PI	Ser/PI	Ser/PI	Ser/PI	Ser/PI	Ser/PI
Sample Re Result Type:	Sequence No.	Q002002	Test	Unit	Result Message	GGT2-I U/L	GLUC3 mg/dL	HDLC4 mg/dL	IRON2 µg/dL	LDLC3 mg/dL	TRIGL mg/dL	UA2 mg/dL

3



HITACHI

27/07/2022 14:49

User ID: REDCLIFFE

Roche

Sample Results Report

Result Type: First Sorted by:

Date

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

e e						
ProCell Lot / Electrode						
R. P. Serial No.	9208000	0001399	0000354	0002898	0000623	0008618
R. P. Lot	619902	618366	622620	640736	606453	618926
	R1-R3	R1-R3	R1-R3	R1	R1-R3	R1-R3
Priority	Current	Current	Current	Current	Current	Current
A. U.	20	8	8	S	9	8
Result Data Alarm Dilution	5.01	183	12.6	171	4.07	55.6
Sample Type	Ser/PI	Ser/Pl	Ser/PI	Ser/PI	Ser/PI	Ser/PI
Test Unit Result Message	ALB2-G g/dL	AMYL2 U/L	CA2 mg/dL	CHOL2-I mg/dL	CREJ2 mg/dL	CRP4 mg/L

 $^{\circ}$

of



16

of

00

cobas pure

13/07/2023 10:30		Registered		13/07/2023 09:47:18 REDCLIFFE		o. ProCell Lot / Electrode																
			-	~		R. P. Lot R. P. Serial No.			0000883		0008342			0006521		0002265		0004019		0003169		0000861
User ID: REDCLIFFE						R. P. Lot			700536		647036			690455		702347		711464		699752		626644
Us				/ 564978					R1-R2		R1-R3			R1-R3		R1		R1-R3		R1-R3		R1-R3
	Date			PCCC1/		Priority			Current		Current			Current		Current		Current		Current		Current
	1	Sample ID / QC Lot		Name / Lot;	ata Alarm	Dilution A. U.			CC		20))		CC		CC		9		CC
ort		Pos.		-	Result Data Alarm			0.720		0.903			8.86		107		1.00		6.05		7.47	
sults Rep	First	Rack ID - Pos.		Q30001-1		Sample Type	age		Ser/PI		Car/DI	11/120		Ser/PI		Ser/PI		Ser/PI		Ser/PI		Ser/PI
Sample Results Report	Result Type:	Sequence No.	Comment	Q001083	Test	Unit	Result Message	BILD2-D	mg/dL	CTIIO	ma/dl	Jp /611	CA2	mg/dL	CH0L2-I	mg/dl	CREJ2	mg/dL	CRP4	mg/L	CRP-HS	mg/L

16

4

13/07/2023 10:30		13/07/2023 09:47:18 REDCLIFFE	ProCell Lot / Flectrode						Y9695 A1058	P8015 A1058
	asn	RED	p D Carial Mo		0017237	0005174	0000729	0002002	0004406 0013894 0011367	0004406 0013894 0011367
User ID: REDCLIFFE			2 0		711304	702348	704173	711465	669181 709792 668700	669181 709792 668700
User		564978			R1-R3	R1-R3	R1-R3	R1-R3	IS DIL REF	IS DIL REF
Date		PCCC1/		A. U. Priority	Current	Current	Current	Current	Current	Current
	QC Lot	ot		A. U.	SS	22	S	S	ISE	ISE
Sorted by		Name / Lot:	Result	Dilution	52.7	105	31.4	109	83.10BS.EL	3.49 OBS.EL
Sample Results Report	Rack ID - Pos.	Q30001-1		Sample Type	Ser/PI	Ser/PI	Ser/PI	Ser/PI	Ser/PI	Ser/PI
Sample Re	Sequence No.	Q001083	Test	Unit Recult Message	GGT2-1 U/L	GLUC3 mg/dL	HDLC4 mg/dL	IRON2 µg/dL	ISE CL mmol/L	ISE K mmol/L

13/07/2023 10:30		Registered	13/07/2023 09:47:18			ProCell Lot / Electrode			G2899 A1058													
		User ID	DEDYCHEE	NEW TOTAL		R. P. Serial No.			0004406	0013894	0011367		0001335		0003614		9069000		0008892			0000243
User ID: REDCLIFFE						R. P. Lot			669181	709792	002899		618368		619975		703308	**	713203			703177
USE			1 / 564978						IS	DIL	REF		R1-R3		R1-R3		R1-R3		R1-R3			R1
	Date		PCCC1 /			A. U. Priority			Current				Current		Current		Current		Current			Current
		Sample ID / QC Lot	Name / Lot:	- 1	Result Data Alarm	Dilution A. U.		112.6 OBS.EL	ISE			169 ReagEx OBS.RR	O)	9.69	20	3.58	2	5.03	22		114	22
Sample Results Report	First	Rack ID - Pos.	Q30001-1			Sample Type	age		Ser/PI	88			Ser/PI		Ser/PI		Ser/PI		Ser/PI			Ser/PI
Sample Re	Result Type:	Sequence No.	Q001083		Test	Unit	Result Message	ISE NA	mmol/L			LDH12	N/L	IDIG	mg/dL	PHOS2	mg/dL	COT	211 0/dl	72/2	TRIGL	mg/dL

cobas pure

16

Sample Results Report

Result Type:	First	Sorted by:	Date	te					
Sequence No.	Rack ID - Pos.	Sample ID / Q	CLot					Registered	
Comment							User ID		
Q001083	Q30001-1	Name / Lot:		PCCC1 / 5	564978		REDCLIFFE	13/07/2023 FFE	09:47:18
Test		Result Data Alarm							
Unit	Sample Type	Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode	
Result Message	age.								
UA2		4.56							
mg/dL	Ser/PI		y	Current	R1-R3	695529	0002745		
UIBC-I		224							
hg/dL	Ser/PI		20	Current	R1-R3	694806	0001260		
UREAL		37.6							

0022867

712545

R1-R3

Current

2

Ser/Pl

mg/dL



cobas pure

System:

10001	_			1
	4			
	6(
9000 0000	0	2000 2000		
		ode		
		~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~		
		5		
Second Street	3	100000 DEC51		

ssage of the state	Sample Res	Sample Results Report Result Type: First	Sorted by:		Date	User I	User ID; REDCLIFFE	13/07/2023 10:30
Seviple Sevi	ö	Rack ID - Pos.	Sample ID / QC	CLot				Registered ser ID
Sample Type A. U. Priority R. P. Lot R. P. Lot R. P. Lot R. P. Lot Proceil Lot Ser/PI 258 CC Current R1-R3 710401 0000405 Proceil Lot Ser/PI 132 CC Current R1-R3 710401 0006409 Proceil Lot Ser/PI 132 CC Current R1-R3 704668 0017833 P144 P2 703735 0005892 P144 P144<		Q30001-2	Name / Lot.		PCCC2 /	595393		13/07/2023 DCLIFFE
Sample Type Dilution A. U. Priority R. P. Lot R. P. Lot R. P. Serial No. Procell Lot Ser/PI 258 CC Current R1-R3 689517 0000405 Procell Lot Ser/PI 132 CC Current R1-R3 710401 0006409 Procell Lot Ser/PI 132 CC Current R1-R3 704668 0017833 Procell Lot Ser/PI 144 CC Current R1-R3 700988 0001063 Procell Lot Ser/PI CC Current R1-R3 700386 0001063 Procell Lot Ser/PI CC Current R1-R3 700386 0001063 Procell Lot Ser/PI CC Current R1-R3 700586 00006892 Procell Lot Ser/PI CC Current R1-R3 700586 00006893 Procell Lot			Result Data Alarm					
Ser/Pl	Aessa	Sample Type	500	A. U.	Priority		R. P. Lot	No. ProCell Lot,
Ser/Pl CC Current R1-R3 689517 Ser/Pl CC Current R1-R3 710401 Ser/Pl CC Current R1-R3 704668 Ser/Pl CC Current R1-R3 700988 Ser/Pl CC Current R1-R3 700988 Ser/Pl CC Current R1-R3 700536 Ser/Pl CC Current R1-R2 700536 Ser/Pl CC Current R1-R3 647036			5.30					
Ser/PI 132 CC Current R1-R3 710401 Ser/PI 144 CC Current R1-R3 704668 Ser/PI 2.06 CC Current R1-R3 700988 Ser/PI 2.06 CC Current R1-R3 700536 Ser/PI 3.42 CC Current R1-R2 700536		Ser/PI		9	Current	R1-R3	689517	0000405
Ser/PI CC Current R1-R3 710401 Ser/PI CC Current R1-R3 704668 Ser/PI R2 703735 Ser/PI CC Current R1-R3 700988 Ser/PI CC Current R1-R3 700535 Ser/PI CC Current R1-R2 700536 Ser/PI CC Current R1-R3 647036			258					
132 CC Current R1-R3 704668 703735 R2 703735 R2 700988 R2 700988 R2 703735 R2 700988 R2 7003735 R2 700536 R2 700536 R2 700536 R3 R3 R3 R47036 R3 R47036 R4703		Ser/PI		9	Current	R1-R3	710401	0006409
Ser/PI CC Current R1-R3 704668 Ser/PI CC Current R1-R3 700988 Ser/PI 2.06 CC Current R1-R3 700988 Ser/PI CC Current R1-R2 700536 Ser/PI 3.42 CC Current R1-R2 700536			132					
Ser/PI CC Current R1-R3 700988 2.06 Ser/PI CC Current R1-R2 703735 Ser/PI 3.42 CC Current R1-R2 700536 Ser/PI CC Current R1-R3 647036		Ser/PI		S	Current	R1-R3 R2	704668	0005892
Ser/PI CC Current R1-R3 700988 2.06 R2 703735 Ser/PI CC Current R1-R2 700536 33.42 CC Current R1-R3 647036			144					
Ser/Pl CC Current R1-R2 700536 3.42 CC Current R1-R3 647036		Ser/PI		DO	Current	R1-R3 R2	700988	0001063
3.42 CC Current R1-R2 700536 CC Current R1-R3 647036	BILD2-D		2.06					
3.42 CC Current R1-R3 647036		Ser/PI		S	Current	R1-R2	700536	0000883
CC Current R1-R3 647036			3.42					
		Ser/PI		9	Current	R1-R3	647036	0008342

 ∞

13/07/2023 10:30	Registered User ID	13/07/2023 09:47:18 REDCLIFFE		No. ProCell Lot / Electrode														
				R. P. Serial No.	1	0006521		0002265		0004019		0003169		0017237		0005174		0000729
User ID: REDCLIFFE				R. P. Lot		690455		702347		711464		699752		711304		702348		704173
		/ 595393				R1-R3	Č	X		R1-R3		R1-R3		R1-R3		R1-R3		R1-R3
Date		PCCC2 /		Priority		Current		Current		Current		Current		Current		Current		Current
	Sample ID / QC Lot	Lot.		A. U.		CC	(U		S		2)		S		20		CC
t Sorted by:		Name / Lot.	Result Data Alarm	Dilution		13.6	170		3.70		51.7		225		247		52.2	
Sample Results Report	Rack ID - Pos.	Q30001-2		Sample Type	age	Ser/PI		Ser/PI		Ser/PI		Ser/PI		Ser/PI		Ser/PI		Ser/PI
Sample Re	Sequence No. Comment	Q002083	Test	Unit	Result Message	CA2 mg/dL	CHOL2-1	mg/dL	CREJ2	mg/dL	CRP4	mg/L	GGT2-I	U/L	6LUC3	mg/dL	HDLC4	mg/dL

9 of 16

13/07/2023 10:30		Registered		13/07/2023 09:47:18		ProCell Lot / Electrode					Y9695 A1058				P8015 A1058				G2899 A1058				
			User ID	REDCLIFFE		R. P. Serial No. Pro			0002092		0004406	0013894	0011367		0004406 P8C	0013894	0011367		0004406	0013894	0011367		9069000
User ID: REDCLIFFE						R. P. Lot			711465		669181	709792	002899		669181	709792	002899		669181	709792	002899		703308
Use				2 / 595393					R1-R3		SI	DIL	REF		15	DIL	REF		S	DIL	REF		R1-R3
	Date	200000000000000000000000000000000000000		PCCC2 /		J. Priority			Current		Current				Current				Current				Current
	Sorted by:	Sample ID / QC Lot		Name / Lot:	Result Data Alarm	Dilution A. U. Priority		244	22	101.0 OBS.EL	ISE			7.06 OBS.EL	ISE			136.0 OBS.EL	ISE			8.01	22
Sample Results Report	First	Rack ID - Pos.		Q30001-2		Sample Type	ge		Ser/PI		Ser/PI				Ser/PI	6			Ser/PI				Ser/PI
Sample Res	Result Type.	Sequence No.	Comment	Q002083	Test	Unit	Result Message	IRON2	hg/dl	ISE CL	mmol/L			ISE K	mmol/L			ISE NA	mmol/L			PHOS2	mg/dL

Serial No.:

cobas pure

System

Sample Re	Sample Results Report				User	User ID; REDCLIFFE		13/07/2023 10:30	30
Result Type:	First	Sorted by:	ă	Date					
Sequence No.	Rack ID - Pos.	Sample ID / QC Lot	Clot					Registered	
Comment							User ID		
Q002083	Q30001-2	Name / Lot:		PCCC2 / 595393	595393		REDCLIFFE	13/07/2023	09:47:18
Test		Result Data Alarm							
Unit	Sample Type	Dilution	A. U.	Priority		R. P. Lot	R. P. Serial No.	R. P. Serial No. ProCell Lot / Electrode	
Result Message	age								
TP2		8.26							
g/dL	Ser/PI		20	Current	R1-R3	713203	0008892		
TRIGL		212							
mg/dL	Ser/PI		9	Current	R1	703177	0000243		
UA2		9.52							
mg/dL	Ser/PI		00	Current	R1-R3	695529	0002745		
UIBC-I		260							
hg/dL	Ser/PI		CC	Current	R1-R3	694806	0001260		
UREAL		116							
mg/dL	Ser/PI		0	Current	R1-R3	712545	0022867		

cobas pure

System: