

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 of 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.



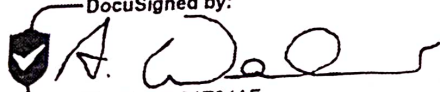
- [1] ISO 15189:2012/ ISO 15189:2014 Medical laboratories — Requirements for quality and competence
- [2] A. Directive 98/79/EC of the European Parliament and of the Council of the 27 October 1998 on vitro diagnostics medical devices;
B. IVD Regulation 2017/746/EU of the European Parliament and of the 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, 4. August 2021

Sincerely,

Roche Diagnostics GmbH

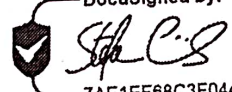
i.V./on behalf of the company

DocuSigned by:

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Andrea Weber
Manager Global Regulatory Affairs

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim

i.V./on behalf of the company

DocuSigned by:

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Stefan Grigarczik
Manager Global Regulatory Affairs



Roche Professional Services Engineering Installation Report

Name of Institution: Redcliffe Lifetech Pvt Ltd
 Complete Address : Plot No 402, Paneer Nagar, Mogappair
 City : Chennai Pin Code : 600037 Telephone No : +91 8438142608
 Person In-Charge. : Mr. Joseph Victor Email ID : joseph.victor@redcliffelabs.com
 Instrument Model : Cobas e 303 Serial No : 2257-04
 Software Ver : 01-02 Cobas Link Serial No : SCL227042
 Department (kindly \checkmark) : Pathology Blood Bank Other (mention) Department of Clinical Biochemistry
 Installation Commencement Date : 30 July 2022 Date of Installation : 03 August 2022
 Travel Hours _____ Work Hours _____ REXIS ORD No WO-01115750

◆ **Transportation Damage & Discrepancy Report: (please update after inspection)**

A. List of Missing items : None
 B. Notes on any damages : -
 C. General Remark : None

◆ **Installation checks & Summary: (please indicate status)**

A. Power Supply:	229V, AC
B. Software Installation & Boot-up:	Done
C. Mechanical Adjustments & Setup:	Done
D. Fluidic Adjustment & Setup:	Done
E. System Checks & Status Print Outs:	Done

Installation Feedback:
 (Please rate your Satisfaction Level as per the Scale)

1 2 3 4 5 6 7 8 9 10
 ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓
 Unsatisfactory Fair Good V. Good Excellent

Pre-Installation Information 10
 Service Personnel's response in general 10
 Product installation & its timely Completion 10
 Overall Installation Satisfaction 10

For REDCLIFFE LIFETECH PVT. LTD.

Authorised Signatory

Signature of Engineer *Ramesh.R* Signature & Seal of Customer *[Signature]* Date 03 August 2022

Name of Engineer Ramesh.R Engineer's Comment Instrument installed successfully



Roche Professional Services Engineering Installation Report

Name of Institution: Redcliffe Lifetech Pvt Ltd

Complete Address : Plot No402, Paneer Nagar, Mogappair

City : Chennai Pin Code : 600037 Telephone No : +91 8438142608

Person In-Charge. : Mr. Joseph Victor Email ID : joseph.victor@redcliffelabs.com

Instrument Model : Cobas e 402 Serial No : 2255-01

Software Ver : 01-02 Cobas Link Serial No : SCL227042

Department (kindly Pathology Blood Bank Other (mention) Department of Clinical Biochemistry

Installation Commencement Date : 30 July 2022 Date of Installation : 03 August 2022

Travel Hours _____ Work Hours _____ REXIS ORD No WO-01115748

◆ Transportation Damage & Discrepancy Report: {please update after inspection}

A. List of Missing items : None

B. Notes on any damages : NA

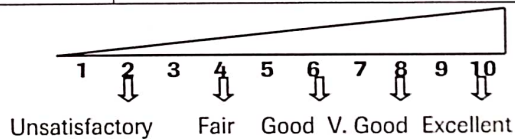
C. General Remark : None

◆ Installation checks & Summary: {please indicate status}

A. Power Supply:	230V, AC
B. Software Installation & Boot-up:	Done
C. Mechanical Adjustments & Setup:	Done
D. Fluidic Adjustment & Setup:	Done
E. System Checks & Status Print Outs:	Done

Installation Feedback:

(Please rate your Satisfaction Level as per the Scale)



Pre-Installation Information 10

Service Personnel's response in general 10

Product installation & its timely Completion 10

Overall Installation Satisfaction 10

Comments
FOR REDCLIFFE LIFETECH PVT. LTD.

Authorised Signatory

Signature of Engineer *Ramesh.R* Signature & Seal of Customer _____ Date 03 August 2022

Name of Engineer Ramesh.R Engineer's Comment Instrument installed successfully

"In case of Complaints/Inquiries please reach our Customer Support Centre at 1800-123-7599/044-30413900"



Roche Professional Services

Engineering Installation Report

Name of Institution: Redcliffe Lifetech Pvt Ltd

Complete Address : Plot No 402, Paneer Nagar, Mogappair

City : Chennai Pin Code : 600037 Telephone No : +91 8438142608

Person In-Charge. : Mr. Joseph Victor Email ID : joseph.victor@redcliffelabs.com

Instrument Model : Cobas SSU Serial No : 2266-02

Software Ver : 01-02 Cobas Link Serial No : SCL227042

Department (kindly √) : Pathology Blood Bank Other (mention) Department of Clinical Biochemistry

Installation Commencement Date : 30 July 2022 Date of Installation : 03 August 2022

Travel Hours _____ Work Hours _____ REXIS ORD No WO-01116225

◆ **Transportation Damage & Discrepancy Report: {please update after inspection}**

A. List of Missing items : None

B. Notes on any damages : -

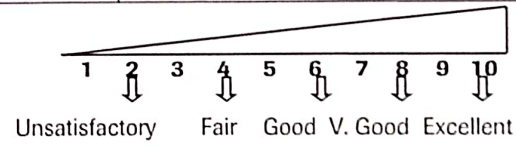
C. General Remark : None

◆ **Installation checks & Summary: {please indicate status}**

A. Power Supply:	229V, AC
B. Software Installation & Boot-up:	Done
C. Mechanical Adjustments & Setup:	Done
D. Fluidic Adjustment & Setup:	Done
E. System Checks & Status Print Outs:	Done

Installation Feedback:

(Please rate your Satisfaction Level as per the Scale)



Pre-Installation Information

Service Personnel's response in general

Product installation & its timely Completion

Overall Installation Satisfaction

For **REDCLIFFE LIFETECH PVT. LTD.**

Authorised Signatory

Signature of Engineer *Ramesh.R* Signature & Seal of Customer *[Signature]* Date 03 August 2022

Name of Engineer Ramesh.R Engineer's Comment Instrument installed successfully

Roche Professional Services Engineering Installation Report



Name of Institution: Redcliffe Lifetech Pvt Ltd

Complete Address : Plot No 402, Paneer Nagar, Mogappair

City : Chennai Pin Code : 600037 Telephone No : +91 8438142608

Person In-Charge. : Mr. Joseph Victor Email ID : joseph.victor@redcliffelabs.com

Instrument Model : Fortigate 50E Serial No : FGT50E5620022084

Software Ver : 6.0.12 Cobas Link Serial No : SCL227042

Department (kindly √) : Pathology Blood Bank Other (mention) Department of Clinical Biochemistry

Installation Commencement Date : 30 July 2022 Date of Installation : 03 August 2022

Travel Hours _____ Work Hours _____ REXIS ORD No WO-01115747

◆ **Transportation Damage & Discrepancy Report: {please update after inspection}**

A. List of Missing items : None

B. Notes on any damages : -

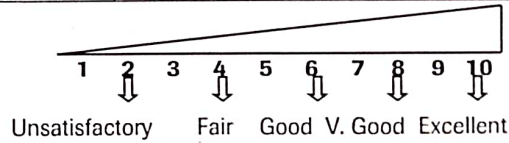
C. General Remark : None

◆ **Installation checks & Summary: {please indicate status}**

A. Power Supply:	229V, AC
B. Software Installation & Boot-up:	Done
C. Mechanical Adjustments & Setup:	Done
D. Fluidic Adjustment & Setup:	Done
E. System Checks & Status Print Outs:	Done

Installation Feedback:

(Please rate your Satisfaction Level as per the Scale)



Pre-Installation Information 10

Service Personnel's response in general 10

Product installation & its timely Completion 10

Overall Installation Satisfaction 10

For REDCLIFFE LIFETECH PVT. LTD.
Comments _____

Authorised Signatory

Signature of Engineer [Signature] Signature & Seal of Customer [Signature] Date 03 August 2022

Name of Engineer Ramesh.R Engineer's Comment Instrument installed successfully

Sample Results Report

Sample Results Report

User ID: admin

Date: 26/01/2023 10:26

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot	Registered
Q001032	Q30001-1	Name / Lot: PCCC1 / 515304	26/01/2023 09:15:24
			User ID: 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	41.6			U/L	Ser/PI		CC	SB1	R1-R3	663695	0002063
									R2	674481	0021476
BILD2-J	0.900			mg/dL	Ser/PI		CC	Current	R1-R2	652625	0000885
BILT3	0.889			mg/dL	Ser/PI		CC	Current	R1-R3	622281	0008148
CA2	9.34			mg/dL	Ser/PI		CC	Current	R1-R3	645917	0001198
CHOL2-I	91.5			mg/dL	Ser/PI		CC	Current	R1	658312	0002325
CREJ2	0.960			mg/dL	Ser/PI		CC	Current	R1-R3	657564	0000047
CRP4	9.44			mg/L	Ser/PI		CC	Current	R1-R3	645296	0004076

Handwritten signature

System: cobas pure

Serial No.: 2266-02

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2 of 5

Sample Results Report

Sample Results Report

User ID: admin

26/01/2023 10:26

Result Type: First

Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot	Registered
Q001032	Q30001-1	Name / Lot: PCCC1 / 515304	26/01/2023 09:15:24
			User ID: admin

Test	Result	Data Alarm	Unit	Sample Type	Dilution	A.U.	Priority	R.P. Lot	R.P. Serial No.	ProCell Lot / Electrode
CRP-HS	10.6		mg/L	Ser/Pl		CC	Current	R1-R3	597985	0000260
GGT2-I	56.7		U/L	Ser/Pl		CC	Current	R1-R3	663681	0005299
GLUC3	107		mg/dL	Ser/Pl		CC	Current	R1-R3	643503	0005876
HDLC4	27.9		mg/dL	Ser/Pl		CC	Current	R1-R3	626113	0000592
IRON2	108		µg/dL	Ser/Pl		CC	Current	R1-R3	623943	0002066
ISE CL	87.3		mmol/L	Ser/Pl		ISE	Current	IS	644054	0003964
								DIL	612531	0011556
								REF	668697	0012647

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System cobas pure

Serial No.: 2266-02

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Sample Results Report

Sample Results Report

User ID: admin

26/01/2023 10:26

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot	Registered
Q001032	Q30001-1	Name / Lot: PCCC1 / 515304	26/01/2023 09:15:24
			User ID: admin

Test	Unit	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode	
ISE K	mmol/L	Ser/Pl	3.91	ISE	Current	IS DIL REF	644054 612531 668697	0003964 0011556 0012647	12852 V9558
ISE NA	mmol/L	Ser/Pl	117.8	ISE	Current	IS DIL REF	644054 612531 668697	0003964 0011556 0012647	Y8596 V9558
LDLC3	mg/dL	Ser/Pl	57.3	CC	Current	R1-R3	590647	0003570	
PHOS2	mg/dL	Ser/Pl	4.47	CC	Current	R1-R3	653804	0006602	
TP2	g/dL	Ser/Pl	4.65	CC	Current	R1-R3	653836	0007282	
TRIGL	mg/dL	Ser/Pl	121	CC	Current	R1	661743	0005484	

System: cobas pure

Serial No.: 2266-02

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Sample Results Report

User ID: admin

26/01/2023 10:26

Result Type: First Sorted by: Date

Sequence No	Rack ID - Pos	Sample ID / QC Lot	Registered
Q001032	Q30001-1	Name / Lot: PCCC1 / 515304	26/01/2023 09:15:24
			User ID: admin

Test	Unit	Sample Type	Result	Data	Alarm	A-U	Priority	R-P Lot	R-P Serial No	ProCell Lot / Electrode
UA2	mg/dL	Ser/Pl	4.68			CC	Current	R1-R3	664685	0004476
UIBC-I	µg/dL	Ser/Pl	228			CC	Current	R1-R3	637859	0015211
UIBC-I	µg/dL	Ser/Pl	227			CC	SB1	R1-R3	637859	0015248
UREAL	mg/dL	Ser/Pl	39.3			CC	Current	R1-R3	663424	0003266

Symbols attached to "Test"

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

System: cobas pure Serial No.: 2266-02

Sample Results Report

Sample Results Report

User ID: admin

26/01/2023 10:28

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot	Registered
Q002032	Q30001-2	Name / Lot: PCCC2 / 525131	26/01/2023 09:15:24
			User ID: admin

Test	Unit	Sample Type	Result	Data	Alarm	A/U	Priority	Repl. Lot	R.F. Serial No.	Repl. Lot / Electrode
ALB2-G	g/dL	Ser/Pl	4.94			CC	Current	R1-R3	663677	0001683
ALB2-G	g/dL	Ser/Pl	4.84			CC	SB1	R1-R3	663677	0000387
ALP2	U/L	Ser/Pl	231			CC	Current	R1-R3	654864	0003414
ALTP	U/L	Ser/Pl	130			CC	Current	R1-R3 R2	661052 674481	0014491 0021476
ASTP	U/L	Ser/Pl	132			CC	Current	R1-R3 R2	663695 674481	0002024 0021476

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Sample Results Report

Sample Results Report

User ID: admin

Date: 26/01/2023 10:28

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot	Registered
Q002032	Q30001-2	Name / Lot: PCCC2 / 525131	26/01/2023 09:15:24
			User ID: admin

Test	Result	Data	Alarm	Unit	Sample Type	Dilution	A.U.	Priority	R.P. Lot	R.P. Serial No.	ProCell Lot / Electrode
ASTP	130			U/L	Ser/Pl		CC	SB1	R1-R3 663695 674481	0002063 0021476	
BILD2-J	2.57			mg/dL	Ser/Pl		CC	Current	R1-R2 652625	0000885	
BILT3	3.10			mg/dL	Ser/Pl		CC	Current	R1-R3 622281	0008148	
CA2	13.6			mg/dL	Ser/Pl		CC	Current	R1-R3 645917	0001198	
CHOL2-I	165			mg/dL	Ser/Pl		CC	Current	R1 658312	0002325	
CREJ2	4.12			mg/dL	Ser/Pl		CC	Current	R1-R3 657564	0000047	
CRP4	54.3			mg/L	Ser/Pl		CC	Current	R1-R3 645296	0004076	

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Sample Results Report

Sample Results Report

User ID: admin

26/01/2023 10:28

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos	Sample ID / QC Lot	Registered
Q002032	Q30001-2	Name / Lot: PCCC2 / 525131	26/01/2023 09:15:24
			User ID: admin

Test	Result	Data	Alarm	Unit	Sample Type	Dilution	A.U	Priority	R.P. Lot	R.P. Serial No.	ProCell Lot / Electrode	
GGT2-I	237			U/L	Ser/Pl		CC	Current	R1-R3	663681	0005299	
GLUC3	244			mg/dL	Ser/Pl		CC	Current	R1-R3	643503	0005876	
HDLC4	55.2			mg/dL	Ser/Pl		CC	Current	R1-R3	626113	0000592	
IRON2	240			µg/dL	Ser/Pl		CC	Current	R1-R3	623943	0002066	
ISE CL	103.2			mmol/L	Ser/Pl		ISE	Current	IS	644054	0003964	S8151 V9558
									DIL	612531	0011556	
									REF	668697	0012647	
ISE K	7.36			mmol/L	Ser/Pl		ISE	Current	IS	644054	0003964	I2852 V9558
									DIL	612531	0011556	
									REF	668697	0012647	

System: cobas pure

Serial No.: 2266-02

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Sample Results Report

User ID: admin

26/01/2023 10:28

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos	Sample ID / QC Lot	Registered
Q002032	Q30001-2	Name / Lot: PCCC2 / 525131	26/01/2023 09:15:24 admin

Test	Result	Data	Alarm	Unit	Sample Type	Dilution	A-U	Priority	R-P Lot	R-P Serial No	ProCell Lot / Electrode
ISE NA	137.7			mmol/L	Ser/Pl						
							ISE	Current	644054	0003064	Y8596 V9558
									612531	0011556	
									668697	0012647	
LDLC3	98.5			mg/dL	Ser/Pl		CC	Current	590647	0003570	
PHOS2	8.35			mg/dL	Ser/Pl		CC	Current	653804	0006602	
TP2	7.64			g/dL	Ser/Pl		CC	Current	653836	0007282	
TRIGL	213			mg/dL	Ser/Pl		CC	Current	661743	0005484	
UA2	9.54			mg/dL	Ser/Pl		CC	Current	664685	0004476	

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Sample Results Report

Result Type: First

Sorted by: Date

User ID: admin

26/01/2023 10:28

Sequence No	Rack ID - Pos	Sample ID / QC Lot	Registered
Q002032	Q30001-2	Name / Lot: PCCC2 / 525131	26/01/2023 09:15:24
			User ID: admin

Test	Unit	Sample Type	Result	Data	Alarm	A.U.	Priority	R.P. Lot	R.P. Serial No	ProCell Lot / Electrode
UIBC-I	µg/dL	Ser/Pl	272			CC	Current	R1-R3	637859	0015211
UIBC-I	µg/dL	Ser/Pl	273			CC	SB1	R1-R3	637859	0015248
UREAL	mg/dL	Ser/Pl	115			CC	Current	R1-R3	663424	0003266

Symbols attached to "Test"

'+' : Rerun test

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

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System: cobas pure

Serial No.: 2266-02

Page No:

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5 of 5

Sample Results Report

Sample Results Report

User ID: admin

26/01/2023 10:25

Result Type: First Sorted by: Date

Sequence No	Rack ID - Pos	Sample ID / OC Lot	Registered
Q017033	Q30004-3	Name / Lot: RFCO1 / 642913	26/01/2023 09:58:31
			User ID: admin

Test	Result Data/Abn							
Unit	Sample type	Dilution	Abn	Priority	Rack	Rack Serial No	Process Lot	Electrode
RF-II	21.4							
IU/mL	Ser/PI		CC	Current	R1-R3	634798	0001648	

Symbols attached to "Test"

+: Rerun test

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

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Sample Results Report



Result Type: First

Sorted by: Date

User ID: admin

Sequence No	Rack ID - Pos	Sample ID / QC Lot	User ID
Q018033	Q30004-4	Name / Lot: RFCO2 / 642914	admin

Test	Result	Data	Alarm	Unit	Priority	R. P. Lot	R. P. Serial No
RF-II	50.6			IU/mL	CC Current	R1-R3	634798 0001648

Sample Results Report



Sample Type: First

Sample Results Report

User ID: admin

Sorted by: Date

Sample No	Rack ID	Pos	Sample ID / QC Lot	User ID
032	Q30001-1		Name / Lot: PCCC1 / 515304	admin

Test	Result	Data	Alarm	A	U	Priority	R	P	Lot	R	P	Serial No	ProcCell
Result Message	Sample Type	Dilution											
ALB2-G		3.23											
/dL	Ser/Pl			CC		Current	R1-R3		663677			0001683	
ALB2-G		3.04											
/dL	Ser/Pl			CC		SB1	R1-R3		663677			0000387	
ALP2		99.0											
/L	Ser/Pl			CC		Current	R1-R3		654864			0003414	
ALTP		48.1											
/L	Ser/Pl			CC		Current	R1-R3 R2		661052 674481			0014491 0021476	
ASTP		43.6											
/L	Ser/Pl			CC		Current	R1-R3 R2		663695 674481			0002024 0021476	