

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.

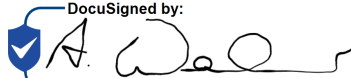
- [1] ISO 15189:2012/ ISO 15189:2014 Medical laboratories — Requirements for quality and competence
- [2] A. Directive 98/79/EC of the European Parliament and of the Council of the 27 October 1998 on vitro diagnostics medical devices;
B. IVD Regulation 2017/746/EU of the European Parliament and of the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

A7F0BA9FE91A46A...

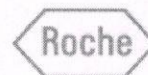
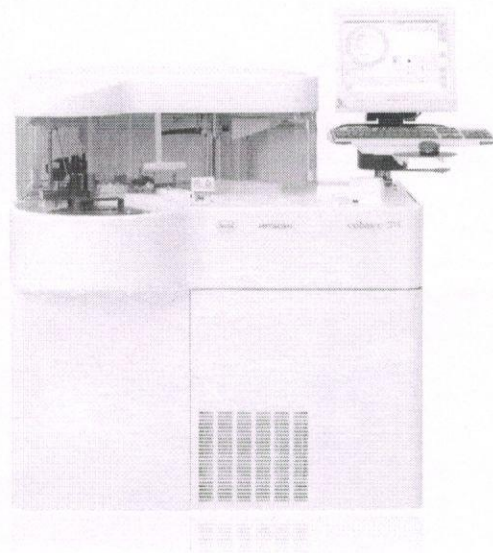
Ralf Zielenski
Head Q&R Compliance, PRRC RDG
Centralised and Point of Care Solutions

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim

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cobas[®] c311 instrument

Qualification Service
Installation Qualification / Operation Qualification (v.1.0)





cobas[®] c311 instrument



General Information

Country: INDIA

Customer Name: REDCLIFFE LABS

Customer Address: Kasthuribai Peta, Near Pushpa Hotel Centre, Mogalrajapuram, Vijaywada-520010

Person Responsible for Quality Assurance: Mr. Siva Kumar

System Information

cobas c311

Serial number	S/N	IP Address
	22E5-02	172.18.38. 230

cobas link: SCL SCL229694

Host provider: NA

User Software Version: V 01-10

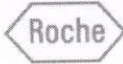
Installation Information

Installation Start Date: 2/1/2023

First Installation:

Relocation: From: To:

Roche Responsible Representative : Mr. Ramesh Bandi, Technical Service Specialist



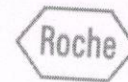
Installation Qualification:

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	Operator's Manual 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	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

NA

Investigation

Action taken

Deviation resolved satisfactorily? Specify

Deviation #2

NA

Investigation

Action taken

Deviation resolved satisfactorily? Specify

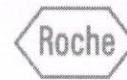
Deviation #3

NA

Investigation

Action taken

Deviation resolved satisfactorily? Specify



Operational Qualification:

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

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

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

Test #	Test	Pass Fail	Signature Date
OQ.1	Calibration successfully	Pass	} <i>RL</i> 15/10/2023
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

NA

Investigation

Action taken

Deviation resolved satisfactorily? Specify

Deviation #2

NA

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

All parameters calibrations were passed. The obtained IQC results are within acceptable range.

Completed by Roche Representative Date 10/01/2023

Print Name Mr. V. Bhavani Prasad Signature

Reviewed by Customer Contact Date 10/01/2023

Print Name Mr. Siva Kumar Signature

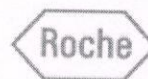
Reviewed by Customer Quality Assurance Date 10/01/2023

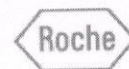
Print Name Mr. Siva Kumar Signature



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cobas[®] c311 instrument
Installation Qualification





Installation Qualification for cobas[®] c311

Description

IQ.1.1	Operator's Manual available	
	Check that a copy of the latest version of the Operator's Manual is available.	Pass
IQ 1.2	Environmental parameters	
	Ambient temperature in the lab is between 15° and 32 °C	Pass
	Ambient humidity at the lab is between 30 and 85% RH and non-condensing	Pass
	Bacteria free, deionized water < 10 cfu/ml	Pass
	Water conductivity 1.0 µS/cm or less	Pass
	Water pressure between 50 and 340 kPa	Pass
	Instrument is not exposed to direct sunlight	Pass
	Floor is level and grade is less than 1/200	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	
	All securing tapes, cushions and securing bracket removed	Pass
IQ 1.5	All connections correctly installed	
	Power distribution board and water supply or drainage facilities provided according manual	Pass
	Power supply voltage at the customer facility:	Pass
	Voltage fluctuation less than ±10V	Pass
	UPS system available	Yes
	Grounding terminal of 10Ω or less available	Pass



IQ 1.6	Instrument positioned according to Installation Manual	
	System layout is according to the service manual	Pass
	was installed according to the installation manual and official jigs and tools were used	Pass
IQ 1.7	Instrument boot process successful	
	IP address configuration successful	Pass
	System Configuration successful	Pass
	First system boot-up	Pass
	Instrument communication check	Pass
IQ 1.8	Checksum according to specification	
	Version no. of installed cobas® c311 user software	V.01-10
	Installation of country language successful	Yes
	Checksum of installed software is correct according to software information	Yes
IQ 1.9	Mechanical adjustments complete	
	Mechanism check performed	Pass
	Necessary corrections of adjustment performed	Pass
	Mechanical adjustments backed up	Yes
IQ 1.10	Auxiliary components positioned	
	Piercer installed	Pass
	Sample, Reagent pipetter and sipper nozzle installed	Yes
	Wash solutions are installed at the c311	Pass
	ISE electrodes are installed	Yes
	ISE solutions are installed	Yes
	Reaction cuvettes are placed	Pass



IQ 1.11 Instrument installation check

Incubation water bath exchange	Pass
Photometer check (result printout attached)	Pass
Air purge for syringes and reagents	Pass
Incubation water bath temperature $37^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$	Pass
Cell blank measurement (result printout attached)	Pass
Print functionality tested	Pass
Communication with cobas link	Pass
Activate RD mode cassette volume check	Pass
Set compensated limit of ISE	Yes
Enter calibrator codes for ISE	Yes
Sample barcode read check	Pass
Customize software	not applicable

IQ 1.12 Host communication settings checked

Check Host settings according to Host manual	not applicable
Check Host communication	not applicable



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

NA

Investigation

Action taken

Deviation resolved satisfactorily? Specify

Deviation #2

NA

Investigation

Action taken

Deviation resolved satisfactorily? Specify

Deviation #3

NA

Investigation

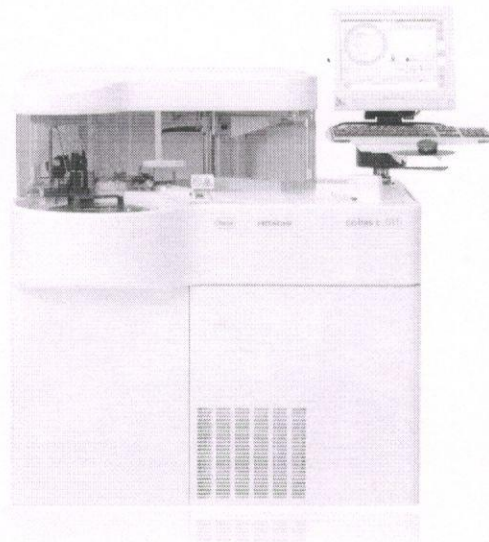
Action taken

Deviation resolved satisfactorily? Specify

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cobas[®] c311 instrument

Operational Qualification





Operational Qualification for cobas® c311

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, perform only steps OQ.2 and OQ.3 of the Operation Qualification.

Description

OQ.1 Calibration

Calibration of all photometric parameters successful (attached printout)

Calibration of all ISE parameters successful (attached printout)

OQ.2 Quality Control

Specify the type of control used:

Preci control clinchem 1 & 2

QC of all photometric parameters within acceptable range (see attached results)

QC of ISE parameters within acceptable range (see attached results)

OQ.3.1 Accuracy check for ISE

Perform test with analytical reagents

			Number of det.
Na	ACN	989	21
K	ACN	990	21
Cl	ACN	991	21

Sample solution: NA

Accuracy check for ISE was within acceptable range



OQ.3.2 Accuracy check for Photometric Assays

Perform test with analytical reagents

	Number of det.
2-point/end-point Assay	21
Rate A Assay	21

Sample solution:

Fill 21 Hitachi cups with pooled serum and perform 21 determinations of Glucose parameter and ALT parameter.

Accuracy check for Photometric Assays was within acceptable range

Yes

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

Deviation #1	NA
Investigation	
Action taken	
Deviation resolved satisfactorily?	Specify

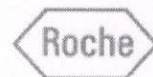


Attachments

1. Calibration Reports
2. QC Reports
3. Precision Check Report

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Attachments



Calibration Monitor

09/01/23

16:12

09/01/23	bmserv							
15:56:19	99999900	56499500						
	ALP2L	----S1----	----S2----					
		1 347	229 1683	S1ABS	K	LOT	SERIAL	
		1 344	229 1685	1	11886	00664840	066243	
09/01/23	bmserv							
15:56:19	99999900	56499500						
	ALTL	----S1----	----S2----					
		3 21388	-386 23239	S1ABS	K	LOT	SERIAL	
		2 21434	-389 23222	3	-2425	00644462	035484	
09/01/23	bmserv							
15:56:19	99999900	56499500						
	ASTL	----S1----	----S2----					
		-1 21703	-392 23339	S1ABS	K	LOT	SERIAL	
		0 21688	-390 23320	-1	-2521	00660224	014600	
09/01/23	bmserv							
15:56:19	99999900	56499500						
	BILD2	----S1----	----S2----					
		1 -5	694 893	S1ABS	K	LOT	SERIAL	
		-1 3	696 895	0	370	00653822	004988	
09/01/23	bmserv							
15:56:19	99999900	56499500						
	GLUC3	----S1----	----S2----					
		29 901	6402 7635	S1ABS	K	LOT	SERIAL	
		29 898	6482 7718	29	301	00652817	065785	
09/01/23	bmserv							
15:56:19	99999900	56499500						
	CHO2I	----S1----	----S2----					
		1387 1397	5075 5143	S1ABS	K	LOT	SERIAL	
		1389 1401	5034 5105	1388	431	00664782	009224	
09/01/23	bmserv							
15:56:19	99999900	56499500						
	GGTI2	----S1----	----S2----					
		2 2282	150 3581	S1ABS	K	LOT	SERIAL	
		2 2288	149 3565	2	7500	00657581	013552	
09/01/23	bmserv							
15:56:19	99999900	56499500						
	UREAL	----S1----	----S2----					
		1 19912	-1914 19226	S1ABS	K	LOT	SERIAL	
		1 19891	-1902 19203	1	-5291	00648255	037826	
09/01/23	bmserv							
15:56:19	99999900	53215800						
	HDLC4	----S1----	----S2----					
		7 17	1749 2147	S1ABS	K	LOT	SERIAL	
		8 15	1764 2162	8	354	00608226	041635	
09/01/23	bmserv							
15:56:19	99999900	56499500						
	BILT3	----S1----	----S2----					
		20 65	444 543	S1ABS	K	LOT	SERIAL	
		20 58	440 541	20	941	00627767	015503	

Calibration Monitor

09/01/23 16:20

09/01/23	bmserv							
15:56:19	99999900	56499500						
	PHOS2	----S1----	----S2----					
	1989	1997	5895	6403	S1ABS	K	LOT	SERIAL
	1988	1991	5947	6463	1989	133	00652800	044909
09/01/23	bmserv							
15:56:19	99999900	53215800						
	LDLC3	----S1----	----S2----					
	61	122	2079	2386	S1ABS	K	LOT	SERIAL
	63	123	2080	2400	62	6591	00638787	037390
09/01/23	bmserv							
15:56:19	99999900	56499500						
	UA2	----S1----	----S2----					
	70	130	1039	1170	S1ABS	K	LOT	SERIAL
	72	127	1034	1162	71	534	00648524	006601
09/01/23	bmserv							
15:56:19	99999900	56499500						
	TRIGL	----S1----	----S2----					
	1107	1124	2976	3030	S1ABS	K	LOT	SERIAL
	1105	1120	2963	3013	1106	751	00648443	065615
09/01/23	bmserv							
15:56:19	99999900	56499500						
	IRON2	----S1----	----S2----					
	60	138	710	903	S1ABS	K	LOT	SERIAL
	51	130	712	901	56	30840	00657869	077501

Calibration Monitor

09/01/23 16:23

09/01/23 16:16:31 bmserv

TEST	IS.EMF	S1 EMF	S2 EMF	S3 EMF	SLOPE	IS.CONC.	S3 CONC.	C.VALUE
Na-A	-33.1	-37.3	-29.6	-29.5	61.6	140	160	0
K-A	-36.2	-50.0	-27.5	-27.4	61.1	5.04	7.03	-0.03
Cl-A	137.9	142.4	133.1	133.0	-52.8	97.1	120	0

 * REDCLIFFE LABS - VIJAYAWADA *

NAME PCCC1 DATE 10/01/23 12:03:06
 S.NO. C002001 089 OPERATOR ID bmserv
 LOT 51530400

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
ALP2L	98	U/L	(86.8- 110.4)	
ALTL	47	U/L	(39.6- 50.4)	
ASTL	46	U/L	(39.8- 50.6)	
BILD2	1.0	mg/dL	(0.811- 1.119)	
GLUC3	101	mg/dL	(94- 114)	
UA2	4.8	mg/dL	(4.22- 5.18)	
TRIGL	117	mg/dL	(106- 130)	
CHOL	89	mg/dL	(80.7- 98.7)	
GGT	55	U/L	(48.4- 61.6)	
UREAL	41.4	mg/dL	(35.9- 43.9)	
HDLC4	28	mg/dL	(22.3- 30.7)	
BILT3	0.9	mg/dL	(0.849- 1.081)	
IRON2	109.9	ug/dL	(95- 119)	
PHOS2	4.3	mg/dL	(3.87- 4.75)	
LDLC3	53.6	mg/dL	(46.1- 63.7)	

* REDCLIFFE LABS - VIJAYAWADA *

NAME
S.NO.
LOT

PCCC1
C002001 089
51530400

DATE 10/01/23 12:03:06
OPERATOR ID bmserv

TEST
Na
K
Cl

RESULT	UNIT	EXPECTED VALUE	ALARM
112	mmol/L	(108- 120)	
3.76	mmol/L	(3.60- 4.04)	
86.8	mmol/L	(83.4- 94.2)	

 * REDCLIFFE LABS - VIJAYAWADA *

NAME PCCC2 DATE 10/01/23 12:03:06
 S.NO. C001001 090 OPERATOR ID bmserv
 LOT 52513100

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
ALP2L	241	U/L	(219- 279)	
ALTL	130	U/L	(113- 145)	
ASTL	148	U/L	(126- 162)	
BILD2	2.7	mg/dL	(2.17- 3.01)	
GLUC3	240	mg/dL	(223- 271)	
UA2	10.1	mg/dL	(8.80- 10.76)	
TRIGL	218	mg/dL	(193- 237)	
CHOL	167	mg/dL	(151- 183)	
GGT	236	U/L	(211- 267)	
UREAL	124.5	mg/dL	(112- 136)	
HDLC4	55	mg/dL	(45.7- 63.3)	
BILT3	3.5	mg/dL	(3.15- 4.03)	
IRON2	246.9	ug/dL	(218- 278)	
PHOS2	8.3	mg/dL	(7.53- 9.21)	
LDLC3	98.7	mg/dL	(83.4- 115.4)	

* REDCLIFFE LABS - VIJAYAWADA *

NAME PCCC2 DATE 10/01/23 12:03:06
S.NO. C001001 090 OPERATOR ID bmserv
LOT 52513100

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
Na	135	mmol/L	(128- 144)	
K	7.24	mmol/L	(6.83- 7.71)	
Cl	105.1	mmol/L	(99- 111)	

Precision Check

10/01/23

15:04

TEST	N	MEAN	UNIT	RANGE	MAX.	MIN.	SD	CV(%)
ALTL	00021	40.8	U/L	2	42	40	0.5	1.32
GLUC3	00021	87.3	mg/dL	1	88	87	0.5	0.53

Data Monitor

10/01/23

15:04

Ser/Pl N 10/01/23 13:10:51 bmserv	001 ALTL 41	ID GLUC3 87	1
Ser/Pl N 10/01/23 13:11:03 bmserv	002 ALTL 40	ID GLUC3 87	2
Ser/Pl N 10/01/23 13:11:15 bmserv	003 ALTL 41	ID GLUC3 88	3
Ser/Pl N 10/01/23 13:11:39 bmserv	005 ALTL 40	ID GLUC3 87	5
Ser/Pl N 10/01/23 13:11:27 bmserv	004 ALTL 41	ID GLUC3 87	4
Ser/Pl N 10/01/23 13:12:03 bmserv	006 ALTL 41	ID GLUC3 88	6
Ser/Pl N 10/01/23 13:17:51 bmserv	007 ALTL 41	ID GLUC3 87	7
Ser/Pl N 10/01/23 13:18:03 bmserv	008 ALTL 41	ID GLUC3 87	8
Ser/Pl N 10/01/23 13:18:15 bmserv	009 ALTL 41	ID GLUC3 87	9
Ser/Pl N 10/01/23 13:18:27 bmserv	010 ALTL 40	ID GLUC3 87	10
Ser/Pl N 10/01/23 13:18:39 bmserv	011 ALTL 40	ID GLUC3 87	11

Data Monitor

10/01/23 15:04

Ser/Pl N	012	ID		12
10/01/23	ALTL	GLUC3		
13:18:51	41	88		
bmserv				
Ser/Pl N	013	ID		13
10/01/23	ALTL	GLUC3		
13:24:27	41	87		
bmserv				
Ser/Pl N	014	ID		14
10/01/23	ALTL	GLUC3		
13:24:39	41	87		
bmserv				
Ser/Pl N	015	ID		15
10/01/23	ALTL	GLUC3		
13:24:51	40	88		
bmserv				
Ser/Pl N	016	ID		16
10/01/23	ALTL	GLUC3		
13:25:03	41	88		
bmserv				
Ser/Pl N	018	ID		18
10/01/23	ALTL	GLUC3		
13:25:27	41	88		
bmserv				
Ser/Pl N	019	ID		19
10/01/23	ALTL	GLUC3		
13:30:15	41	87		
bmserv				
Ser/Pl N	020	ID		20
10/01/23	ALTL	GLUC3		
13:30:27	42	87		
bmserv				
Ser/Pl N	021	ID		21
10/01/23	ALTL	GLUC3		
13:30:39	41	87		
bmserv				
Ser/Pl N	022	ID		17
10/01/23	ALTL	GLUC3		
13:30:51	40	87		
bmserv				

Precision Check

10/01/23 15:41

TEST	N	MEAN	UNIT	RANGE	MAX.	MIN.	SD	CV(%)
Cl	00021	113.41	mmol/L	0.7	113.8	113.1	0.17	0.15
K	00021	4.890	mmol/L	0.03	4.90	4.87	0.009	0.19
Na	00021	153.4	mmol/L	1	154	153	0.5	0.32

Data Monitor

10/01/23 15:41

Ser/Pl N000012 001	ID PC12		
10/01/23 Na	K		C1
15:31:54 153	4.87		113.1
bmserv			
Ser/Pl N000013 001	ID PC13		
10/01/23 Na	K		C1
15:32:18 153	4.90		113.4
bmserv			
Ser/Pl N000014 001	ID PC14		
10/01/23 Na	K		C1
15:32:42 153	4.89		113.4
bmserv			
Ser/Pl N000015 001	ID PC15		
10/01/23 Na	K		C1
15:33:06 153	4.90		113.3
bmserv			
Ser/Pl N000016 001	ID PC16		
10/01/23 Na	K		C1
15:33:30 154	4.90		113.5
bmserv			
Ser/Pl N000017 001	ID PC17		
10/01/23 Na	K		C1
15:33:54 154	4.89		113.6
bmserv			
Ser/Pl N000018 001	ID PC18		
10/01/23 Na	K		C1
15:34:18 153	4.90		113.5
bmserv			
Ser/Pl N000019 001	ID PC19		
10/01/23 Na	K		C1
15:34:42 154	4.89		113.4
bmserv			
Ser/Pl N000020 001	ID PC20		
10/01/23 Na	K		C1
15:35:06 153	4.90		113.3
bmserv			
Ser/Pl N000021 001	ID PC21		
10/01/23 Na	K		C1
15:35:30 154	4.90		113.8
bmserv			

Data Monitor

10/01/23 15:41

Ser/Pl	N000001	001	ID PC1		
10/01/23	Na		K		C1
15:28:30	153		4.88		113.1
bmserv					

Ser/Pl	N000002	001	ID PC2		
10/01/23	Na		K		C1
15:28:42	154		4.88		113.4
bmserv					

Ser/Pl	N000003	001	ID PC3		
10/01/23	Na		K		C1
15:28:54	153		4.88		113.3
bmserv					

Ser/Pl	N000004	001	ID PC4		
10/01/23	Na		K		C1
15:29:06	153		4.89		113.4
bmserv					

Ser/Pl	N000005	001	ID PC5		
10/01/23	Na		K		C1
15:29:18	153		4.89		113.3
bmserv					

Ser/Pl	N000006	001	ID PC6		
10/01/23	Na		K		C1
15:29:30	153		4.89		113.5
bmserv					

Ser/Pl	N000007	001	ID PC7		
10/01/23	Na		K		C1
15:29:54	153		4.87		113.3
bmserv					

Ser/Pl	N000008	001	ID PC8		
10/01/23	Na		K		C1
15:30:18	154		4.89		113.6
bmserv					

Ser/Pl	N000009	001	ID PC9		
10/01/23	Na		K		C1
15:30:42	154		4.90		113.7
bmserv					

Ser/Pl	N000010	001	ID PC10		
10/01/23	Na		K		C1
15:31:06	153		4.89		113.3
bmserv					

Ser/Pl	N000011	001	ID PC11		
10/01/23	Na		K		C1
15:31:30	154		4.89		113.5
bmserv					



(ISO 9001:2015 Certified)

Instrument Commissioning Report

Name of Institution: REDCLIFFE LABS
 Complete Address: Kasthuribai Peta, Near Pushpa hotel Centre, Mozabrajapuram
 City: Vijayawada (AP) Pin Code: 520010
 Person Incharge : Mr. Siva Kumar REXIS ORD : _____
 Instrument Model: Cobas c311 Serial No.: 22ES-02
 SW Version : V 01-10 Training Completed On : 10/01/2023
 Call Received Date: 05/01/2023 Call Attended Date: 09/01/2023
 Travel Hours : 4 Hours Work Hours: 12 Hours

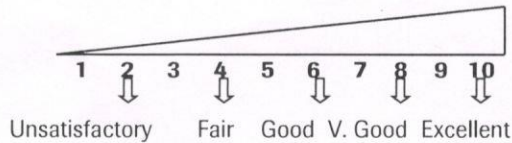
System Configuration & Preliminary application work:

(Please check in the Box)

- A. System configuration & programming E. Assay Calibration
- B. Hardware Overview F. QC Run
- C. Software Overview G. User Maintenance
- D. Sample & QC Processing H. Precision Check & Evaluation
- I. Basics of Telephone Trouble Shooting

Training Feedback:

(Please rate as per the Scale)

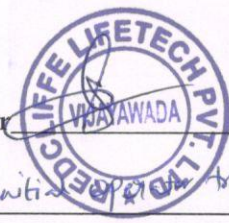


Structure
 Objective Reached
 Ratio of Lecture to Practical time
 Quality of Lecture
 Completeness of Information
 Knowledge
 Openness to Questions

Comments

Overall Training Satisfaction

Signature of Trainer [Signature] Signature & Seal of Customer [Signature] Date 10/01/2023
 Name of Trainer Bharani Prasad Trainer's Comment: Initial approval training Completed.



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



Training Agenda Checklist c311 Analyzer

SW Version: V01-10

Hardware Overview :

(Please check in the Box)

Sample System	<input checked="" type="checkbox"/>	Water & Waste system	<input checked="" type="checkbox"/>
Reagent System	<input checked="" type="checkbox"/>	Control Unit	<input checked="" type="checkbox"/>
Mixing	<input checked="" type="checkbox"/>	Cobas Link Overview	<input checked="" type="checkbox"/>
Photometric System	<input checked="" type="checkbox"/>	Power Switch	<input checked="" type="checkbox"/>
ISE System	<input checked="" type="checkbox"/>	System Reagent	<input checked="" type="checkbox"/>

Software Overview & Routine Operation :

Workplace:

(Please check in the Box)

Workplace	<input checked="" type="checkbox"/>	Barcode Read Error	<input checked="" type="checkbox"/>
Test Selection	<input checked="" type="checkbox"/>	Search	<input checked="" type="checkbox"/>
Data Review	<input checked="" type="checkbox"/>	Data Back Up	<input checked="" type="checkbox"/>

Reagent:

(Please check in the Box)

Red/Yellow/Purple Alarm	<input checked="" type="checkbox"/>	c Pack Loading/Unloading	<input checked="" type="checkbox"/>
Reagent Prime	<input checked="" type="checkbox"/>	Reagent Level Reset	<input checked="" type="checkbox"/>
Inventory Set	<input checked="" type="checkbox"/>		



Roche Professional Services

Calibration:

(Please check in the Box)

Installing Calibrator(Dn. Load)	<input checked="" type="checkbox"/>	Installing Calibrator Manual	<input checked="" type="checkbox"/>
Ordering Calibration	<input checked="" type="checkbox"/>	Loading Calibrators	<input checked="" type="checkbox"/>
Calibration Results	<input checked="" type="checkbox"/>	Calibration Trace	<input checked="" type="checkbox"/>

QC :

(Please check in the Box)

Installing QC	<input checked="" type="checkbox"/>	Ordering QC	<input checked="" type="checkbox"/>
QC Activation	<input checked="" type="checkbox"/>	Loading QC	<input checked="" type="checkbox"/>
QC Accumulation	<input checked="" type="checkbox"/>	Excluding QC	<input checked="" type="checkbox"/>
QC Chart	<input checked="" type="checkbox"/>	QC Table	<input checked="" type="checkbox"/>
Real Time QC	<input checked="" type="checkbox"/>		

System Overview/General :

(Please check in the Box)

Preventive Action	<input checked="" type="checkbox"/>	Workflow Guide	<input checked="" type="checkbox"/>
Overview	<input checked="" type="checkbox"/>	Print View	<input checked="" type="checkbox"/>
Global Buttons	<input checked="" type="checkbox"/>	Intiating Sample Run (Rn.)	<input checked="" type="checkbox"/>
Intiating Sample Run (STAT)	<input checked="" type="checkbox"/>	Logon /Log Off	<input checked="" type="checkbox"/>
Start Conditions	<input checked="" type="checkbox"/>	Automatic Rerun	<input checked="" type="checkbox"/>
Default Profile	<input checked="" type="checkbox"/>	Host (If applicable)	<input checked="" type="checkbox"/>
Data Clear	<input checked="" type="checkbox"/>		



Maintenance:

(Please check in the Box)

- | | | | |
|--------------------------------------|-------------------------------------|---------------------------|-------------------------------------|
| Maintenance Log Sheet
(Handover) | <input checked="" type="checkbox"/> | Daily Maintenance | <input checked="" type="checkbox"/> |
| Weekly Maintenance | <input checked="" type="checkbox"/> | Monthly Maintenance | <input checked="" type="checkbox"/> |
| Pipe Selections | <input checked="" type="checkbox"/> | Cell Blank Interpretation | <input checked="" type="checkbox"/> |
| Photometer Check
(Interpretation) | <input checked="" type="checkbox"/> | | |

Calibration Alarms & Troubleshooting:

(Please check in the Box)

- A. Photometric Calibration Alarms & Troubleshooting Tips
- B. ISE Calibration Alarms & Troubleshooting Tips
- C. Data Alarms & Troubleshooting Tips

Signature of Trainer *Bsu* Signature of Trainee *[Signature]* Date 10/01/2023

Name of Trainer Bhavani Prasad Name(s) of Trainee _____

Trainers Comment: Initial operational training completed.

Trainee 1: U. ACHYUTH

Signature: *[Signature]*

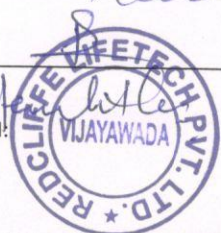
Trainee 2: M. Leelawarao

Signature: *[Signature]*

Trainee 3: T. Sandhya
P. Hemalatha

Signature: _____

Customer Seal: *[Signature]*



 * REDCLIFFE LABS - VIJAYAWADA *

NAME PCCC1 DATE 21/08/23 09:55:24
 S.NO. C005117 089 OPERATOR ID ADMIN
 LOT 52520500

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
ALP2L	89	U/L	(89- 113)	
ALTL	51	U/L	(43.1- 54.7)	
ASTL	45	U/L	(39.3- 50.1)	
CREA	1.0	mg/dL	(0.93- 1.17)	
CA2	8.6	mg/dL	(7.90- 9.26)	
TP2	4.7	g/dL	(4.44- 5.20)	
BILD2	1.0	mg/dL	(0.805- 1.113)	
GLUC3	105	mg/dL	(94- 114)	
UA2	5.0	mg/dL	(4.35- 5.31)	
TRIGL	115	mg/dL	(107- 131)	
CHOL	100	mg/dL	(84.2- 103.0)	
GGT	59	U/L	(51.2- 65.2)	
UREAL	41.1	mg/dL	(36.6- 44.6)	
HDLC4	30	mg/dL	(23.4- 32.2)	
BILT3	1.0	mg/dL	(0.843- 1.075)	
IRON2	111.4	ug/dL	(96- 120)	
UIBCI	205.4	ug/dL	(168- 228)	
PHOS2	3.6	mg/dL	(3.33- 4.05)	
LDLC3	54.8	mg/dL	(48.4- 66.8)	
ALB2	3.19	g/dL	(2.83- 3.59)	

*performed by
T. sandhya*

* REDCLIFFE LABS - VIJAYAWADA *

NAME PCCC1 DATE 21/08/23 09:55:24
S.NO. C005117 089 OPERATOR ID ADMIN
LOT 52520500

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
Na	113	mmol/L	(106- 118)	
K	3.53	mmol/L	(3.29- 3.69)	
Cl	83.4	mmol/L	(78.7- 88.7)	

*performed by
T. sandhya.*

 * REDCLIFFE LABS - VIJAYAWADA *

NAME PCCC2 DATE 21/08/23 09:55:24
 S.NO. C002117 090 OPERATOR ID ADMIN
 LOT 53571900

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
ALP2L	240	U/L	(235- 299)	
ALTL	128	U/L	(111- 143)	
ASTL	142	U/L	(125- 161)	
CREA	3.8	mg/dL	(3.36- 4.28)	
CA2	14.0	mg/dL	(12.7- 15.1)	
TP2	7.4	g/dL	(7.04- 8.28)	
BILD2	2.6	mg/dL	(2.21- 3.05)	
GLUC3	239	mg/dL	(221- 269)	
UA2	10.2	mg/dL	(9.1- 11.1)	
TRIGL	207	mg/dL	(196- 240)	
CHOL	171	mg/dL	(152- 188)	
GGT	234	U/L	(201- 257)	
UREAL	121.2	mg/dL	(112- 136)	
HDLC4	59	mg/dL	(49.4- 68.2)	
BILT3	3.6	mg/dL	(3.20- 4.08)	
IRON2	248.4	ug/dL	(217- 277)	
UIBCI	267.7	ug/dL	(223- 299)	
PHOS2	8.4	mg/dL	(7.70- 9.42)	
LDLC3	89.6	mg/dL	(83.2- 114.8)	
ALB2	4.74	g/dL	(4.30- 5.46)	

performed by
 T Sandhya

* REDCLIFFE LABS - VIJAYAWADA *

NAME PCCC2 DATE 21/08/23 09:55:24
S.NO. C002117 090 OPERATOR ID ADMIN
LOT 53571900

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
Na	136	mmol/L	(127- 143)	
K	7.25	mmol/L	(6.82- 7.70)	
Cl	103.2	mmol/L	(100- 112)	

performed by
T.Sandhya

* REDCLIFFE LABS - VIJAYAWADA *

NAME PCA1N DATE 21/08/23 09:30:00
S.NO. C008116 079 OPERATOR ID ADMIN
LOT 58738300

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
RWD3	5.92	%	(5.01- 6.37)	
A1-W3	0.374 H	mmol/L	(0- 0)	
HB-W3	9.078 H	mmol/L	(0- 0)	

*performed by
T. sundhya*

* REDCLIFFE LABS - VIJAYAWADA *

NAME PCA1P DATE 21/08/23 09:30:00
S.NO. C007116 080 OPERATOR ID ADMIN
LOT 56345100

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
RWD3	11.46	%	(9.4- 11.8)	
A1-W3	0.913 H	mmol/L	(0- 0)	
HB-W3	8.971 H	mmol/L	(0- 0)	

*performed by
T. Sandhya*