To Whom It May Concern

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

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

The In-Vitro-Diagnostics Directive of the European Union [2A.] which is currently switching to IVD Regulation 2017/746/EU (final timeline: May 26, 2022) [2B.] requires for all CE marked products that the manufacturer assures compliance of the products with the requirements of the mentioned directive or regulation. This means that all processes in development and manufacturing of Roche Diagnostics GmbH products are guided by a Quality Management System. Our Quality Management System is in compliance with the requirements from ISO 13485:2016 [3] and 21 CFR Part 820 [4].
The mentioned regulations and standards require that the production systems and measuring devices used are qualified and the manufacturing and test procedures are validated. This status has to be assured by scheduled maintenance and by regular qualification resp. validation reviews and updates.

All physical quantities, calibrators and controls used in Roche Diagnostic systems are fully traceable to certified standards or reference materials. The performance of all In-vitro diagnostics systems of Roche Diagnostics GmbH at the customer site is assured if regular Quality Control measurements, cleaning and maintenance procedures as described in the instructions for use or service documentation are performed. By having controlled internal procedures and by running the tasks required in the respective user documentation, all In-vitro diagnostics systems of Roche Diagnostics GmbH will be performed as specified during their defined lifetime.

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

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

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

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

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

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

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

Mannheim, 10. August 2021

Sincerely,

Roche Diagnostics GmbH

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

DocuSigned by:
ECA5294AC4E94AF...

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

ppa/*on behalf of the company*

DocuSigned by:
Ralf Zielenski
A7F0BA9FE91A46A...

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

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim

cobas®

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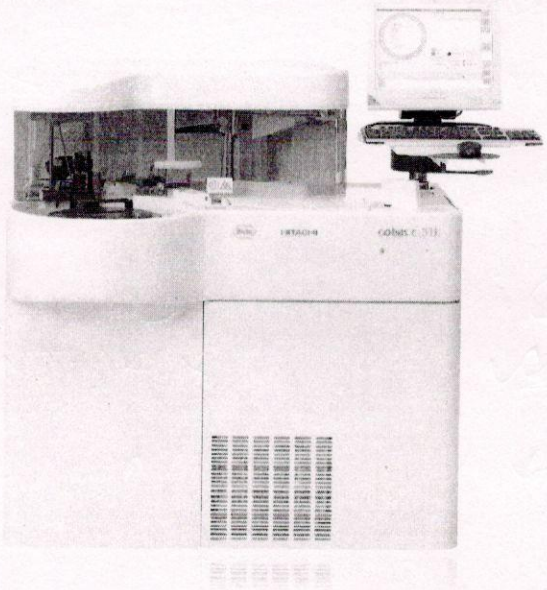
cobas® c311 instrument

Qualification Service

Installation Qualification / Operation Qualification (v.1.0)



Roche

cobas® c311 instrument

General Information

Country:	INDIA
Customer Name:	REDCLIFFE LIFETECH PVT.LTD
Customer Address:	Ground floore E -7/137, HIG, Arera coloney ward - 49 , zone - 9 Bhopal M. P., 462016
Person Responsible for Quality Assurance:	Dr.Sakar Saxena

System Information

cobas c311

	S/N	IP Address
Serial number	22C0-04	172.18.38. 211

cobas link: SCL 224849 Modem/ISDN

Host provider: NA

User Software Version: 01-13

Installation Information

Installation Start Date: 14-Dec-22

First Installation: Yes

Relocation: From: To:

Roche Responsible Representative : MANOJ BAMRELE

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	
		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	
		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	**NONE**
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #2	**NONE**
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #3	**NONE**
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	
OQ.2	Quality Control successfully	Pass	
OQ.3	Accuracy check successfully	Pass	16/12/22

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	NONE
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #2	NONE
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.	No
All acceptance criteria have been met. This equipment is deemed acceptable and the unit is approved for its intended use.	Yes

Comments

ALL RESULTS WITHIN ACCEPTABLE LIMITS

Completed by Roche Representative — Date 17/12/2022

Print Name Kaushik Patel — Signature K Patel

Reviewed by Customer Contact — Date 17-12-22

Print Name Brajesh Raikwar — Signature

Redcliffe Life Tech Pvt. Ltd.
E-7/137, Sagar Tower,
10 1/2 No. Stop Arera Colony,
Bhopal-462016

Reviewed by Customer Quality Assurance — Date

Print Name Dr.Sakar Saxena — Signature

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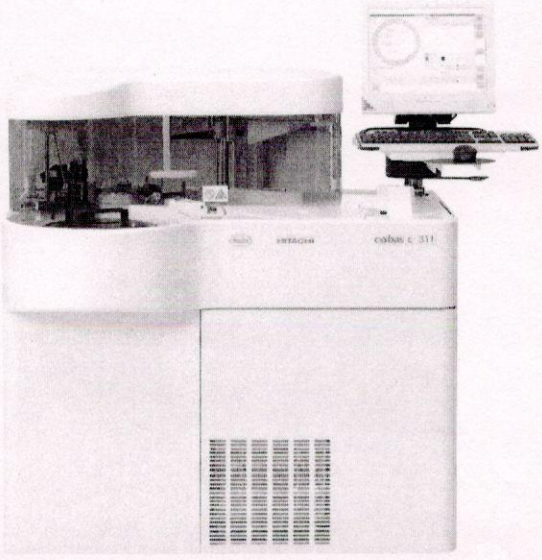
Installation Qualification



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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:	240V
	Voltage fluctuation less than ±10V	Pass
	UPS system available	Pass
	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	1-13
	Installation of country language successful	Pass
	Checksum of installed software is correct according to software information	Pass
IQ 1.9	Mechanical adjustments complete	
	Mechanism check performed	Pass
	Necessary corrections of adjustment performed	Pass
	Mechanical adjustments backed up	Pass
IQ 1.10	Auxiliary components positioned	
	Piercer installed	Pass
	Sample, Reagent pipetter and sipper nozzle installed	Pass
	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	Pass
	Air purge for syringes and reagents	Pass
	Incubation water bath temperature 37°C ± 0.1°C	Pass
	Cell blank measurement	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	yes

IQ 1.12	Host communication settings checked	
	Check Host settings according to Host manual	yes
	Check Host communication	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	NONE
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #2	NONE
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #3	NONE
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

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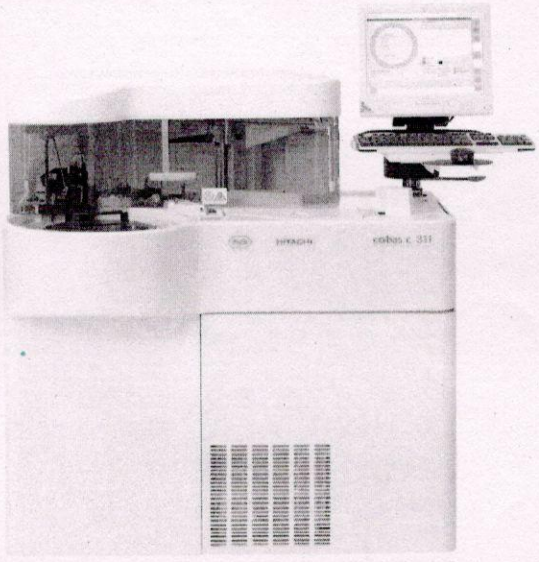
Operational Qualification



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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	Yes
Calibration of all ISE parameters successful (attached printout)	Yes

OQ.2 Quality Control

Specify the type of control used:

Assayed Chemistry Control Bio-Rad Level-1 & 2

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

OQ.3.1 Accuracy check for ISE

Perform test with analytical reagents

			Number of det.
Na	ACN	989	5
K	ACN	990	5
Cl	ACN	991	5

Accuracy check for ISE was within acceptable range Yes

OQ.3.2 Accuracy check for Photometric Assays

Perform test with analytical reagents

	Number of det.
2-point/end-point Assay	13
Rate A Assay	5

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

NONE

Investigation

Action taken

Deviation resolved satisfactorily? specify

Attachments

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Attachments

Roche

****
* HITACHI AUTOMATIC ANALYZER *
****

NAME PCCC1 DATE 23/06/23 09:45:55
S.NO. C009097 086 OPERATOR ID ADMIN
LOT 56497800

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
GLUC3	103.3	mg/dL	(92- 112)	
TRIGL	111.4	mg/dL	(103- 127)	
HDLC4	32.3	mg/dL	(25.6- 35.2)	
BILT3	0.9	mg/dL	(0.834- 1.062)	
ASTL	44.8	U/L	(39.3- 50.1)	
BILD2	0.9	mg/dL	(0.796- 1.100)	
ALTL	50.3	U/L	(45.3- 57.7)	
ALP2L	98	U/L	(95- 119)	
TP2	4.8	g/dL	(4.54- 5.34)	
ALB2	3.3	g/dL	(2.91- 3.71)	
GGTI2	55	U/L	(47.6- 60.4)	
CREJ2	1.0	mg/dL	(0.92- 1.16)	
UREAL	42.1	mg/dL	(36.2- 44.2)	
UA2	4.6	mg/dL	(4.21- 5.13)	
PHOS2	3.6	mg/dL	(3.20- 3.92)	
CHO2I	103	mg/dL	(94- 114)	
IRON2	112.4	ug/dL	(96- 120)	
UIBCI	222.6	ug/dL	(184- 244)	
CRP4	5.7	mg/L	(5.36- 7.00)	
CA2	8.8	mg/dL	(7.94- 9.30)	

Vikash

****
* HITACHI AUTOMATIC ANALYZER *
****

NAME PCCC2
S.NO. C010097 087
LOT 59539300

DATE 23/06/23 09:45:55
OPERATOR ID ADMIN

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
GLUC3	243.0	mg/dL	(221- 269)	
TRIGL	204.3	mg/dL	(192- 236)	
HDLC4	54.0	mg/dL	(43.8- 60.6)	
BILT3	3.6	mg/dL	(3.26- 4.14)	
ASTL	140.2	U/L	(124- 160)	
BILD2	2.6	mg/dL	(2.28- 3.16)	
ALTL	127.7	U/L	(114- 146)	
ALP2L	244	U/L	(228- 292)	
TP2	7.9	g/dL	(7.66- 8.98)	
ALB2	5.3	g/dL	(4.68- 5.96)	
GGTI2	232	U/L	(199- 255)	
CREJ2	3.6	mg/dL	(3.24- 4.12)	
UREAL	125.3	mg/dL	(112- 136)	
UA2	9.6	mg/dL	(8.83- 10.79)	
PHOS2	8.2	mg/dL	(7.33- 8.97)	
CHO2I	164	mg/dL	(153- 185)	
CA2	13.4	mg/dL	(12.3- 14.3)	

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* HITACHI AUTOMATIC ANALYZER *
****

NAME PCCC1 DATE 23/06/23 09:45:55
S.NO. C009097 086 OPERATOR ID ADMIN
LOT 56497800

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
Na	111	mmol/L	(105- 117)	
K	3.42	mmol/L	(3.28- 3.68)	
Cl	81.9	mmol/L	(74.9- 85.3)	

Vikash

****
* HITACHI AUTOMATIC ANALYZER *
****

NAME PCCC2 DATE 23/06/23 09:45:55
S.NO. C010097 087 OPERATOR ID ADMIN
LOT 59539300

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
Na	134	mmol/L	(128- 144)	
K	6.95	mmol/L	(6.63- 7.47)	
Cl	99.7	mmol/L	(93- 105)	

Vikash