Roche

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.

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, 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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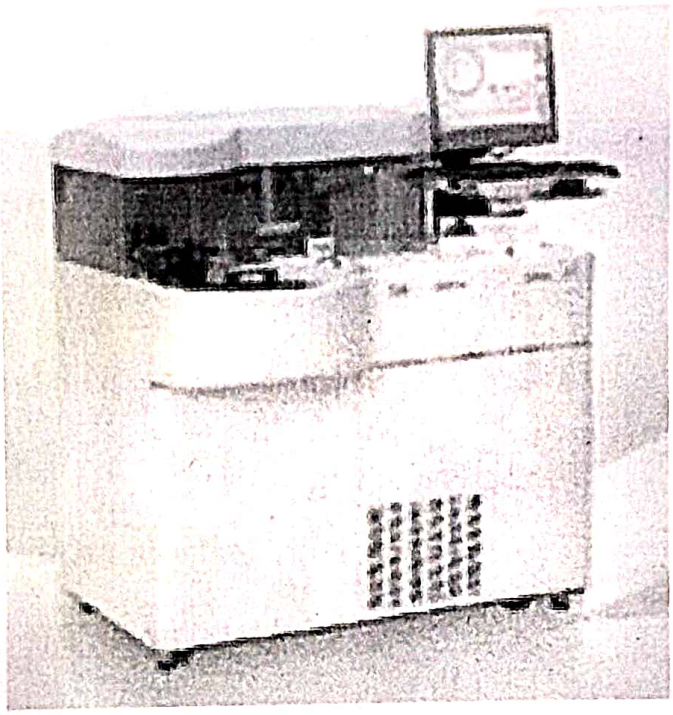
Stefan Grigarczik
Manager Global Regulatory Affairs

Roche



INSTALLATION QUALIFICATION

OPERATION QUALIFICATION

&

OPERATIONAL QUALIFICATION

VALIDATION REPORT

Equipment Name: Cobas c311

Equipment Make: Roche/Hitachi

Equipment Model No.: Cobas c311

Equipment Serial No.: 18L9-09

Supplier: Roche Diagnostics India Pvt. Ltd.

- **APPROVAL OF THE IQ\OQ\PQ PROCEDURE:**

Both Clinical Laboratory and Roche Diagnostics India Pvt. Ltd. are jointly responsible for the installation of (Cobas c-311) S. No.: 18L9-09 in the Clinical Laboratory.

Validation Team from (Vendor):

Name: 1. Mr. Hari Singh
2. Mr. Deepak Patidar

Signature:

Date: 07/10/2023

Company: Roche Diagnostics India Pvt. Ltd.

Validation Team from Clinical Lab:

Name: Mr. Pavan Kushwah

Signature:

Date: 7/10/2023

Department: Lab. Supervisor

Site: Redcliffe Lifetech Pvt. Ltd. Shanti Madhuvan Plaza, Delhi Gate Agra, U.P

II. INSTRUCTIONS:

1. This document is to be completed at the time the system is shifted to its current location (Clinical Laboratory) and setup for operation.

2. An authorized (Company) representative will check the system and enter the specific data related to installation, operational and performance qualification.

3. Employees of (customer) Clinical Laboratory will verify each result and sign the results. The members of the validation will carry this out.

4. All deviation from the normal specification to include any problems with installation will be noted under COMMENTS.

II. SCOPE

This installation Qualification protocol is performed on the (Instrument Name).**Cobas c-311 S. No. 18L9-09,** located at **Redcliffe Lifetech Pvt. Ltd. Shanti Madhuvan Plaza, Delhi Gate Agra, U.P** This protocol defines the documentation that is used to evaluate the Instrument Installation in accordance with the manufacturer's specifications and Intended use. Successful completion of this protocol verifies that this instrument has been Installed, operated in accordance with the intended usage.

Installation checks are performed to verify that the instrument has been installed with proper connections and utilities.

Operational qualification will evaluate that the instrument have operational features available for the successful operation of instrument in accordance with the manufacturer's specifications.

Performance qualification will verify the actual functioning or performance of instrument.

IV. Certificate of Purchase Order compliance

I certify to the best of my knowledge, the instrument – **Cobas c-311**
S. No. 18L9-09 installed on..... **28/09/2023** ..., has been placed under agreement and is in compliance with the specifications of the agreement.

V. Equipment Description

	Instrument Identification	Verified by	Date
1	Equipment name: Cobas c-311	Mr. Deepak Patidar	28/09/2023
2	Model: Cobas c-311	Mr. Deepak Patidar	28/09/2023
3	Marketed By:	Roche Diagnostics India Private Limited	28/09/2023
4	Serial No:18L9-09	Mr. Deepak Patidar	28/09/2023
5	Size:66cm(w);135cm(l);75cm(h)	Mr. Deepak Patidar	28/09/2023
6	Power:AC 224 V+/-10%;60Hz Single Phase; Earthing 2V	Mr. Deepak Patidar	28/09/2023

VI. Utilities

S. No.	Utility	Verified by	Date
1	**Environmental conditions as required.** (Free from dust, electrical and magnetic interference), Yes **Yes/No** **Temperature:** 25 degree Celsius **Humidity:** 45-85%	Mr. Deepak Patidar	28/09/2023
2	**Adequate space for installation: Yes / No** Yes	Mr. Deepak Patidar	28/09/2023
3	**Electrical Outlets:** Actual voltage on site (230V) **Yes / No**	Mr. Deepak Patidar	28/09/2023
4	**Grounded** Yes **Yes / No**	Mr. Deepak Patidar	28/09/2023

5	Connected through UPS	Yes	Yes / No	Mr. Deepak Patidar	28/09/2023
6	Stabilizer	Yes	Yes / No	Mr. Deepak Patidar	28/09/2023

VII. The instrument has been checked for the following:

S. No.	Verification		Verified by	Date
1	Instrument is identified Yes	Yes / No	Mr. Deepak Patidar	28/09/2023
2	Manufacturer's specification are included Yes	Yes / No	Mr. Deepak Patidar	28/09/2023
3	Accessories /consumables are listed Yes	Yes / No	Mr. Deepak Patidar	28/09/2023
4	Equipment manual from the manufacturer Yes	Yes / No	Mr. Deepak Patidar	28/09/2023
5	Manufacturer certificate of compliance is attached Yes	Yes / No	Mr. Deepak Patidar	01/13/2021

VIII. Accessories / Consumables

The following accessories were supplied with the instrument. Check 'verified by" in case they are found to be in order. **Separate list included**.

SNo.	Description	Quantity	Verified by	Date
01	As per the List	As per The List	Mr. Deepak Patidar	28/09/2023

IX. List of Manuals and Certificates

Supplier provides the following with the instrument:

1	Operating Manual	Available - Yes / No
2	Purchase order	Available - Yes / No
3	Calibration certificate	Available - Yes / No
4	Software validation certificate	Available - Yes / No
5	Instrument / kit approval certificate	Available - Yes / No
6	Safety Instructions	Available - Yes / No
7	Training Records	Available - Yes / No
8	Certificate of Authorization/Training of the engineer	Available - Yes / No
9	If any other	Available - Yes / No

X. Maintenance:

The instrument listed within this document will be placed under the control of purchasing institution with respect to proper maintenance procedures as detailed in the operator's manual. The maintenance procedures will be filed separately.

A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period vendor will offer several level of maintenance agreements and performance testing services to assist you in maintaining GLP/GMP compliance.

Contacting your local representative and requesting the additional service agreement can supply additional information.

XI. INSTALLATION PROCEDURE

A - Installation of Hardware and software

Follow the instructions mentioned in the Installation guide.

B- Installation of Printer

Follow the instructions mentioned in the Installation guide.

XII. OPERATIONAL QUALIFICATION

a) Following features/ functions are available in the instrument as per manufacturer's specification and verified e.g. self-test, washer assays, quality control, test assay, maintenance checks.

Test No.	Test Name	Test Purpose	Verified	Date
1.	Quality Control	To check the accuracy of results	**Mr. Hari Singh**	**05/09/2023**
2.	Maintainance	To maintain the system	**Mr. Hari Singh**	**05/09/2023**
3.	Calibration feature	Auto Calibration	**Mr. Hari Singh**	**05/09/2023**
4.	Test Assay	Routine Biochemistry	**Mr. Hari Singh**	**05/09/2023**

Certificate of Training:

Technician Training

This certifies that the Following Staff listed below have received basic user training for the system described.

S. No.	Training Program	Initials	Date
1	Instrument Setup	All technicians are present.	**05/09/2023**
2	System Operation	All technicians are present	**05/09/2023**
3	Basic Troubleshooting	All technicians are present	**05/09/2023**

Training given by: Mr. Hari Singh

XII. PERFORMANCE QUALIFICATION

Performance qualification validates the test procedure performed on the new instrument. Performance qualification not only validates instrument performance but also test procedure. Following are the steps required to validate your instrument and method.

1- Run all levels of QC sample and verify the values with acceptable range given in the insert of quality control samples.
2- Run the precision for all the parameters 10 times.

QC Results - Pass/ Fail: PASS

PRECISION- Pass/ Fail:PASS

Validation procedures performed by

Name: Mr. Hari Singh

Designation: Application Specialist

Signature:

Date: 07/10/2023

Company: Roche Diagnostics India Pvt. Ltd.

Validation procedures performed by Clinical Lab:

Name: Mr. Pavan Kushwah

Signature:

Department: Biomedical Engineer.

Site: Redcliffe Lifetech Pvt. Ltd. Shanti Madhuvan Plaza, Delhi Gate Agra, U.P

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

NAME PCCC1 DATE 25/05/24 09:43:03
S.NO. C003083 073 OPERATOR ID bmserv
LOT 56497800

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
CREJ2	1.0	mg/dL	(0.92- 1.16)	
TP2	5.1	g/dL	(4.54- 5.34)	
ALB2	3.4	g/dL	(2.91- 3.71)	
ALTL	46	U/L	(45.3- 57.7)	
LDLC3	62	mg/dL	(53.6- 74.0)	
GLUC3	102	mg/dL	(92- 112)	
ASTL	44	U/L	(39.3- 50.1)	
HDLC4	30	mg/dL	(25.6- 35.2)	
CHO2I	103	mg/dL	(94- 114)	
IRON2	110.74	ug/dL	(96- 120)	
BILD2	0.858	mg/dL	(0.796- 1.100)	
CRP4	5.59	mg/L	(5.36- 7.00)	
UREAL	39.8	mg/dL	(36.2- 44.2)	
GGTI2	54	U/L	(47.6- 60.4)	
ALP2L	98	U/L	(95- 119)	
UA2	4.5	mg/dL	(4.21- 5.13)	
CA2	8.6	mg/dL	(7.94- 9.30)	
UIBCI	219	ug/dL	(184- 244)	
TRIGL	113	mg/dL	(103- 127)	
BILT3	0.855	mg/dL	(0.834- 1.062)	
PHOS2	3.62	mg/dL	(3.20- 3.92)	
CRPHS	7.92	mg/L	(7.2- 8.4)	

25/05/24

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* HITACHI AUTOMATIC ANALYZER *
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NAME PCCC1 DATE 25/05/24 09:43:03
S.NO. C003083 073 OPERATOR ID bmserv
LOT 56497800

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
Na	112	mmol/L	(105- 117)	
K	3.50	mmol/L	(3.28- 3.68)	
Cl	84.0	mmol/L	(80.0- 90.4)	

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* HITACHI AUTOMATIC ANALYZER *
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NAME PCCC2 DATE 25/05/24 09:43:03
S.NO. C004083 074 OPERATOR ID bmserv
LOT 59539300

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
CREJ2	3.8	mg/dL	(3.24- 4.12)	
TP2	8.5	g/dL	(7.66- 8.98)	
ALB2	5.3	g/dL	(4.68- 5.96)	
ALTL	119	U/L	(114- 146)	
LDLC3	100	mg/dL	(88- 120)	
GLUC3	243	mg/dL	(221- 269)	
ASTL	139	U/L	(124- 160)	
HDLC4	52	mg/dL	(43.8- 60.6)	
CHO2I	168	mg/dL	(153- 185)	
IRON2	248.07	ug/dL	(214- 274)	
BILD2	2.454	mg/dL	(2.28- 3.16)	
CRP4	50.37	mg/L	(44.7- 58.3)	
UREAL	121.9	mg/dL	(112- 136)	
GGTI2	230	U/L	(199- 255)	
ALP2L	236	U/L	(228- 292)	
UA2	9.4	mg/dL	(8.83- 10.79)	
CA2	13.3	mg/dL	(12.3- 14.3)	
UIBCI	246	ug/dL	(228- 304)	
TRIGL	211	mg/dL	(192- 236)	
BILT3	3.398	mg/dL	(3.26- 4.14)	
PHOS2	8.21	mg/dL	(7.33- 8.97)	

25/05/24

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* HITACHI AUTOMATIC ANALYZER *
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NAME PCCC2 DATE 25/05/24 09:43:03
S.NO. C004083 074 OPERATOR ID bmserv
LOT 59539300

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
Na	136	mmol/L	(128- 144)	
K	7.01	mmol/L	(6.63- 7.47)	
Cl	102.4	mmol/L	(97- 109)	

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* HITACHI AUTOMATIC ANALYZER *
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NAME PCA1N
S.NO. C011083 075
LOT 71835800

DATE 25/05/24 09:43:03
OPERATOR ID bmserv

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
HB-W3	10.045 H	mmol/L	(0- 0)	
A1-W3	0.361 H	mmol/L	(0- 0)	
HbA1c	5.44	%	(4.98- 6.34)	

25/05/24

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* HITACHI AUTOMATIC ANALYZER *
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NAME PCA1P
S.NO. C012083 076
LOT 71835900

DATE 25/05/24 09:43:03
OPERATOR ID bmserv

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
HB-W3	10.207 H	mmol/L	(0- 0)	
A1-W3	0.900 H	mmol/L	(0- 0)	
HbA1c	10.22	%	(9.1- 11.5)	

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* HITACHI AUTOMATIC ANALYZER *
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NAME RFCO2
S.NO. C013083 078
LOT 73131500

DATE 25/05/24 09:43:03
OPERATOR ID bmserv

TEST	RESULT	UNIT	EXPECTED VALUE	ALARM
RF-II	55	IU/mL	(46.2- 56.6)	