cobas® c311 instrument

General Information

Country:	INDIA
Customer Name:	ESIC Medical College & Hospital
Customer Address:	Ashok Pillar Main Rd, K. K. Nagar, Chennai, Tamil Nadu 600078
Person Responsible for Quality Assurance:	Dr.Madhubala

System Information

cobas c311

	S/N		IP Address	
Serial number	22A8-01		172.18.38.	231

cobas link: SCL

Host provider: N/A

User Software Version: 01-13

Installation Information

Installation Start Date: 21-Jul-22

First Installation: Yes

Relocation: From: To:

Roche Responsible Representative : Mr.Vivek Kumar

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	22-Jul-22
IQ 1.2	Environmental parameters met	Pass	22-Jul-22
IQ 1.3	Instrument delivered undamaged and complete	Pass	22-Jul-22
			22-Jul-22
IQ 1.4	Transport locking successfully removed	Pass	22-Jul-22
IQ 1.5	All connections correctly installed	Pass	22-Jul-22
IQ 1.6	Instrument positioned according to Installation Manual	Pass	22-Jul-22
			22-Jul-22
IQ 1.7	Instrument boot process successfully	Pass	22-Jul-22
IQ 1.8	Checksum according to specification	Pass	22-Jul-22
IQ 1.9	Mechanical adjustments complete	Pass	22-Jul-22
IQ 1.10	Auxiliary components positioned	Pass	22-Jul-22
IQ 1.11	Instrument installation check	Pass	22-Jul-22
IQ 1.12	Host communication settings checked	Pass	22-Jul-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	
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #2	
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #3	
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	22-Jul-22
OQ.2	Quality Control successfully	Pass	22-Jul-22
OQ.3	Accuracy check successfully	Pass	22-Jul-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	
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #2	
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

Completed by Roche Representative — Date 7/22/2022

Print Name M.Vijayaarasan — Signature

Reviewed by Customer Contact — Date 22/07/2022

Print Name Dr.Madhubala — Signature

डॉ. वि. मधुबाला / Dr. V. MADHUBALA, M.D.
प्रोफेसर एंड एचओडी / Professor & HOD
जीव रसायन विभाग / Department of Biochemistr
क.रा.बी.नि. चिकित्सा महाविद्यालय एवं पी.जी.आई.एम.एस.अ
E.S.I.C. Medical College & PGIMSR
के.के. नगर, चेन्नई-78.

Reviewed by Customer Quality Assurance — Date 22/07/2022

Print Name Dr.Madhubala — Signature

डॉ. वि. मधुबाला / Dr. V. MADHUBALA, M.D.,
प्रोफेसर एंड एचओडी / Professor & HOD
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E.S.I.C. Medical College & PGIMSR
के.के. नगर, चेन्नई-78 / K.K. Nagar, Chennai-78.

Roche Diagnostics India Pvt. Ltd.

Field Service Report

Case number: CAS-0017504389

Order Number: WO-11057346 | Ser. Report Created Date: 21/07/2023

Instrument Details

Instrument/Module: cobas c 311

Serial Number: 22A8-01

Internal Instrument Name:

Additional Details

:

Customer details

Customer Number: 0052012436

Customer Name: E.S.I.C.HOSPITAL The Medical Superintendent

Street Address: Dept of Biochemistry

Zip: 600078 - CHENNAI

Contact Name: Dr.Madhubala

Contact Phone:

Service Activity Code: PM Visit

Purpose of Visit

PM cobas c 311 Major

Performed Activities

Check the instrument clean the modules and replace pm kit and perform the maintenance and cellblank measurements and photometer check and perform the qc good and instrument is working fine

Time Report

Category	Start	End	Hours	Invoice Type
05913616001-Service labour time	21/07/2023 4:00 pm	21/07/2023 7:49 pm	3.82	Free of Charge

Travel

Value	Hours
Travel	0.5

Spare Parts

Part Number	Description	Quantity	Invoice Type
05182522001-KIT MAINTENANCE 6 MONTHS COBAS C311	KIT MAINTENANCE 6 MONTHS COBAS C311	1	Customer Invoice
05182549001-KIT MAINTENANCE 1 YEAR COBAS C311	KIT MAINTENANCE 1 YEAR COBAS C311	1	Customer Invoice

Roche Diagnostics India Pvt. Ltd.

Field Service Report

Case number: CAS-0017504389

Order Number: WO-11057346 | Ser. Report Created Date: 21/07/2023

Signature

Customer Signature
Dr.Madhubala

Roche support
Vasanth Kumar

Sign Here

24/07/2023.
डॉ. वि. मधुबाला / Dr. V. MADHUBALA, M.D.,
प्रोफेसर एंड एचओडी / Professor & HOD
जैव रसायन विभाग / Department of Biochemistry
E.S.I.C. Medical College & PGIMSR,
K.K. Nagar, Chennai-78.

Customer Signature

P. Vasanth

Roche Signature

The customer acknowledges the service intervention as performed in accordance with Roche recommendations:
- This Service report has been signed by the authorized representative of your organization.
- Discreparcies if any must be intimated within a period of seven (7) days of the receipt of the email, in the absence of which the report will be final and conclusive.
- This report shall be governed by the laws of India and the courts at Mumbai shall have the exclusive jurisdiction to deal with the disputes arising hereunder.

Customer Support Center No:
Toll Free No: 1800-123-7599 || Phone No: 044-43900345 ||
(Mon to Sat 8 AM to 8 PM)
e-mail: customersupportcenterIndia@roche.com ||||||||||||||||
Roche DiaLog: https://dialog.roche.com
Service Report Version Number: 1

Thank You

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 [2] requires for all CE marked products that the manufacturer assures compliance of the products with the requirements of the In-Vitro-Diagnostics Directive. 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 13485:2012 [3] + AC:2012 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.

Mannheim,

Roche Diagnostics GmbH

Roche Diagnostics GmbH
Sandhofer Strafje 116
D-68305 Mannheim

i.V. Andrea Weber
Project Manager **Regulatory** Affairs

ppa. Dr. Beate Bonefeld
Head of Quality Assurance Mannheim, CPS Quality

[i] ISO 15189:2012/ ISO 15189:2014 Medical laboratories — Requirements for quality and competence
[2] Directive 98/79/EC of the European Parliament and of the Council of the 27 October 1998 on vitro diagnostics medical devices
[3] EN ISO 13485:2012 + AC:2012 Medical devices — Quality management systems-Requirements for regulatory purposes
[4] CFR Part 820, Quality System regulations 21 Requirements on medical devices