DocuSign Envelope ID: CF271677-8BAA-4056-8E6A-10A5B6C5E2C8

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

DocuSign Envelope ID: CF271677-8BAA-4056-8E6A-10A5B6C5E2C8

[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...

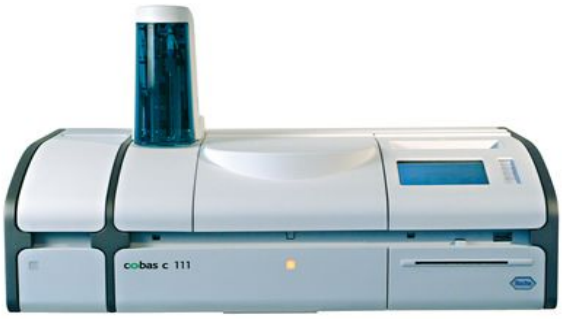
Ralf Zielenski
Head Q&R Compliance, PRRC RDG
Centralised and Point of Care Solutions

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim

cobas®
Life needs answers

cobas® c111 Analyzer

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



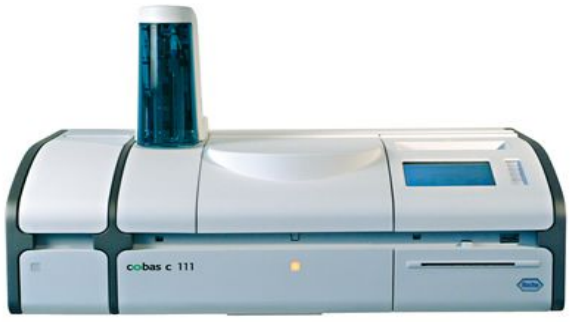
Roche

cobas®

Life needs answers

cobas® c111 Analyzer

Installation Qualification



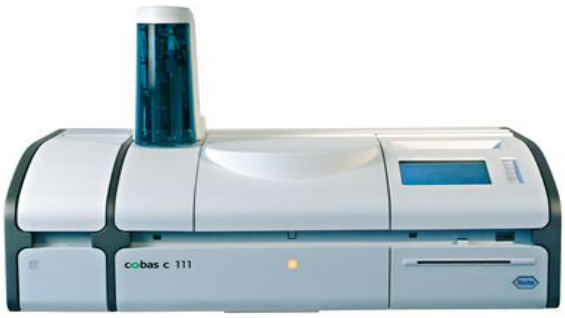
Roche

cobas®

Life needs answers

cobas® c111 Analyzer

Operational Qualification



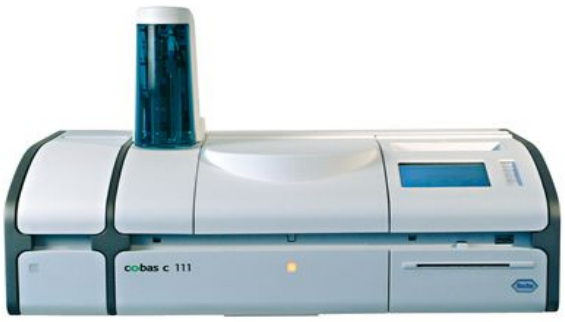
Roche

cobas®

Life needs answers

cobas® c111 Analyzer

Attachments




Roche

cobas® c111

General Information

Country:	India
Customer Name:	A3 Hormone Lab
Customer Address:	261, Krishnammal Nagar, Fairlands, Salem-636016
Person Responsible for Quality Assurance:	Dr. Gandhi

System Information

	S/N
cobas C111 :	15595
Host provider:	NA
Software Version:	

Installation Information

Installation Start Date:	Jan 08. 2021			
First Installation:	yes			
Reconfiguration:	From:		To:	
Relocation:	From:		To:	

Roche Responsible Representative : Mr. Alex

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	not applicable	

Test #	Test	Pass Fail	Signature Date
IQ.2	Installation Qualification for cobas c111	yes	Jan 08 2021

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.

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	Jan 08. 2021
OQ.2	Quality Control successfully	Pass	Jan 08. 2021
OQ.3	Accuracy check successfully	Pass	Jan 08. 2021

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

Completed by Roche Representative Date Jan 08 2021

Print Name Mr. Alex Signature _____

Reviewed by Customer Contact Date Jan 08 2021

Print Name Dr. Gandhi Signature _____

Reviewed by Customer Quality Assurance Date _____

Print Name _____ Signature _____

Installation Qualification for cobas® c111

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
	Relative Humidity maximum of 50% at 32 °C and non-condensing	Pass
	Bacteria free, deionized water < 10 cfu/ml	Pass
	Water conductivity 1.0 µS/cm or less	Pass
	Dust and Vibration free	Pass
	Instrument is not exposed to direct sunlight	Pass
IQ 1.3	Instrument delivered undamaged and	
	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	
	Unpacking of the Analyzer and accessories without damage to units	Pass
IQ 1.5	All connections correctly installed	
	Power supply voltage at the customer facility:	Pass
	UPS system available:	yes
	Voltage fluctuation less than 230 ±5V	Pass
	Grounding less than 1.0 V	Pass

IQ 1.6	Instrument positioned according to Installation Manual	
	System layout is according to the description in the	Pass
IQ 1.7	Instrument boot process successful	
	IP address configuration successful	Pass
	System Configuration successful	Pass
	First system boot-up	Pass
IQ 1.8	Checksum according to specification	
	Version of installed cobas C111 software	Yes
	Installation of country language successful	Yes
IQ 1.9	Mechanical adjustments complete	
	All mechanical adjustments are carried out	Pass
IQ 1.10	Auxiliary components positioned	
	Handheld Barcode Scanner	Pass
IQ 1.11	Instrument installation check	
	Print function	yes
	Sample barcode read check	Pass

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

Installation Qualification for cobas® c111:

Description

IQ.2.1	Function check of C111 according to specifications	
	System layout is according to the description in the manual	Pass
	Cobas c111 is installed according to the installation manual and using official tools	Pass
IQ.2.2	Mechanical adjustments complete	
	All mechanical adjustments for the c111 mechanical parts are carried out	Pass
IQ.2.3	Auxiliary components positioned	
	Wash solutions are installed at c111	Pass
	ISE electrodes are installed	not applicable
	ISE solutions are installed	not applicable
	Probe (Reagent & Sample) pipetters installed	Pass
IQ 2.4	Instrument installation check	
	Air water Calibration	Pass
	Prime Fluid System	Pass
	Analyzer Rotor (Reaction) temperature 37°C ± 0.5°C	Pass

IQ 2.5	Pipetting Accuracy Check			
Check Solution	Gluc3	21	Pass	Jan 08 2021

	Initialize Degasser Fluid Sensor Check	Pass
	ISE Check 20 times (attached printout)	not applicable
IQ 2.6	Assay installation	
	Install Application	Pass
	Load corresponding reagent c-packs	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

Operational Qualification:

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

Description

OQ 1 Calibration

Calibration of all photometric parameters successful (attached printout): yes

Calibration of all ISE parameters successful (attached printout): not applicable

OQ.2 Quality Control

Specify the type of control used:

Bio-Rad

QC of all photometric parameters within acceptable range (attached printout): yes

QC of ISE parameters within acceptable range (attached printout): not applicable

OQ.3.1 Accuracy check for ISE

Perform test with analytical reagents

	Number of det.
Na	21
K	21
Cl	21

Sample solution: PNU (code 300 / Cat. No. 10171735, 10171743, 10651257).
Fill 21 Hitachi cups with PNU (code: 300) and perform Na, K and Cl tests. Calculate the CV.

Accuracy check for ISE was within acceptable range: not applicable

OQ.3.2 Precision check for Photometric Assays

Perform test with analytical reagents

	Number of det.	
2-point/end-point Assay (GLUC2)		Lot
Mean		Expiry
SD		
CV		

	Number of det.	
2-point/end-point Assay (TRIGL)		Lot:
Mean		Expiry
SD		
CV		

Sample solution: Human serum

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. Precision Check

HORMONE LAB
Assured Accurate Affordable

261, Krishnammal Nagar,
Fairlands, Salem 636016
Tamil Nadu, INDIA
Phone : 0427-4042601
Mobile : +91 99945 27758, 96005 13336, 95008 39918
E-mail : a3hormonelab@gmail.com

c111 V4.3.0.1835 15595
admin 22.10.2021 12:13

Calibrations:

Test	Use	Type	Status
A1W3D	Current	Lot	21.10.2021 17:58
ALB2	Current	Lot	08.10.2021 17:11
ALBUR	Current	Set	25.08.2021 13:57
ALP2S	Current	Lot	18.10.2021 18:50
ALP2S	Standby	Lot	17.10.2021 13:14
ALTL	Current	Lot	07.09.2021 12:45
ASTL	Current	Set	18.10.2021 18:56
BILT3	Current	Lot	18.10.2021 15:01
CA2	Current	Lot	13.09.2021 19:49
CHECK	Current	Set	27.12.2019 6:51
CHO2I	Current	Lot	19.10.2021 11:12
CREJ2	Current	Lot	16.10.2021 18:26
CRJ2U	Current	Lot	16.10.2021 18:26
CRP4	Current	Lot	28.09.2021 16:17
GLU2	Current	Lot	21.10.2021 11:01
HDLC4	Current	Set	20.10.2021 14:03
LDH12	Current	Lot	04.09.2021 14:45
LDLC3	Current	Lot	20.09.2021 12:05
PHOS2	Current	Lot	18.10.2021 18:58
TP2M	Standby	Lot	08.10.2021 19:59
TR1GL	Current	Lot	18.10.2021 10:59
UA2	Current	Set	20.10.2021 13:02
UREL	Current	Lot	05.10.2021 12:53

All parameters calibration within acceptable limit.

Dr. M. (GANDHI).

A3 HORMONE LAB
D.No.261, Krishnammal Nagar,
Fairlands, SALEM-636016.
Phone: 0427-4042601