

## **cobas<sup>®</sup> c111 Analyzer**

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



**cobas<sup>®</sup> c111 Analyzer**

**Installation Qualification**





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**cobas<sup>®</sup> c111 Analyzer**

## **Operational Qualification**



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**cobas<sup>®</sup> c111 Analyzer**

## **Attachments**







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

cobas C111 : S/N 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 to 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.

<b>Deviation #1</b>
NA
<b>Investigation</b>
<b>Action taken</b>
<b>Deviation resolved satisfactorily?</b> specify

<b>Deviation #2</b>
NA
<b>Investigation</b>
<b>Action taken</b>
<b>Deviation resolved satisfactorily?</b> specify

<b>Deviation #3</b>
NA
<b>Investigation</b>
<b>Action taken</b>
<b>Deviation resolved satisfactorily?</b> 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 to 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
OO.1	Calibration successfully	Pass	Jan 08. 2021
OO.2	Quality Control successfully	Pass	Jan 08. 2021
OO.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.

<b>Deviation #1</b>
NA
<b>Investigation</b>
<b>Action taken</b>
<b>Deviation resolved satisfactorily?</b> specify

<b>Deviation #2</b>
NA
<b>Investigation</b>
<b>Action taken</b>
<b>Deviation resolved satisfactorily?</b> 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

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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<sup>®</sup> 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	
	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) pipettors 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



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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

2-point/end-point Assay (GLUC2)	Number of det.	Lot
Mean <input type="text"/>		Expiry
SD		
CV		

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

Sample solution: Human serum

Accuracy check for Photometric Assays was within acceptable range

**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.

<b>Deviation #1</b>
NA
<b>Investigation</b>
<b>Action taken</b>
<b>Deviation resolved satisfactorily?</b> <input type="text" value="specify"/>



## Attachments

1. Precision Check