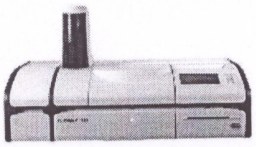
cobas® c111



General Information

Country:	INDIA
Customer Name:	Dr. Potdar Laboratories
Customer Address:	First Floor, Shashwat Heights, 519, Shukrawar Peth, Solapur
Person Responsible for Quality Assurance:	Dr. Potdar

System Information

	S/N
cobas C111 :	15260
Host provider:	
Software Version:	3.0.185

Installation Information

Installation Start Date:	26/9/2019		
First Installation:	yes		
Reconfiguration: From:		To:	
Relocation: From:		To:	

Roche Responsible Representative : Pravin Kankure

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	26/9/2019
IQ 1.2	Environmental parameters met	Pass	26/9/2019
IQ 1.3	Instrument delivered undamaged and complete	Pass	26/9/2019
		Pass	26/9/2019
IQ 1.4	Transport locking successfully removed	Pass	26/9/2019
IQ 1.5	All connections correctly installed	Pass	26/9/2019
IQ 1.6	Instrument positioned according to Installation Manual	Pass	26/9/2019
		Pass	26/9/2019
IQ 1.7	Instrument boot process successfully	Pass	26/9/2019
IQ 1.8	Checksum according to specification	Pass	26/9/2019
IQ 1.9	Mechanical adjustments complete	Pass	26/9/2019
IQ 1.10	Auxiliary components positioned	Pass	26/9/2019
IQ 1.11	Instrument installation check	Pass	26/9/2019
IQ 1.12	Host communication settings checked	Pass	26/9/2019

Test #	Test	Pass Fail	Signature Date
IQ.2	Installation Qualification for cobas c111	Pass	26/9/2019

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	9/10/2019
OQ.2	Quality Control successfully	Pass	9/10/2019
OQ.3	Accuracy check successfully	Pass	9/10/2019

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.	yes
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 RANGES

Completed by Roche Representative — Date 9/10/2019

Print Name Shivajirao Mohite — Signature Mohite

Reviewed by Customer Contact — Date

Print Name Dr. Potdar — 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:	YES
	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	4.3.0.1835
	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

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

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: yes

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

OQ.2 Quality Control

Specify the type of control used:

BIORAD CHEMISTRY ASSAYED CONTROL

QC of all photometric parameters within acceptable range: 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	10
Rate A Assay	10

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