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.

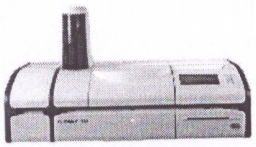
Additional calibration or verification procedures are NOT required of the user in order to assure the specified performance of every system of Roche Diagnostics GmbH. Only if a user deviates from these manufacturer's recommendations, the user have to establish site-specific calibration and verification procedures as part of his accreditation process.

Mannheim, 18 December 2017

Roche Diagnostics GmbH

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim

# 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

cobas C111 : S/N 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 |

# 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

| Carry over | | | | |
|---|---|---|---|---|
| | Nacl | Sample | Nacl | % carryover |
| Albumin | 0.1 | 2.83 | 0.12 | 0.0088 |
| Alk.phosphatase | -0.7 | 357.9 | -0.4 | 0.014 |
| ALTL | -0.7 | 83.2 | -1 | 0.02 |
| ASTL | 0.7 | 173.9 | 0.7 | 0.003 |
| Bili Direct | 0 | 1.5 | 0 | 0 |
| Bili Total | 0 | 3.6 | 0 | 0 |
| Cholesterol | 0.29 | 90.8 | -0.16 | 0.0116 |
| Creat | -0.1 | 4.6 | -0.2 | 0.012 |
| Glucose | -0.21 | 274.6 | -0.26 | 0.0126 |
| HDL | 0.06 | 22.5 | -0.14 | 0.0114 |
| T.Protein | -0.1 | 3.9 | -0.1 | 0.011 |
| Triglyceride | 0.18 | 91.9 | 0.32 | 0.0068 |
| Uric Acid | 0 | 9.5 | 0 | 0 |
| Urea | -0.27 | 92.04 | -0.32 | 0.0132 |

| Assay | ALB | ALP | ALTL | AST | BIL - D | BIL- T | CHOL | CREAT | GLUCOSE | HDL | TP | TGL | UA | UREA |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 4.27 | 100.1 | 26 | 40 | 0.4 | 0.8 | 236 | 2 | 81 | 59 | 6.5 | 190 | 4.8 | 32 |
| 2 | 4.38 | 104 | 26 | 41 | 0.4 | 0.8 | 241 | 2 | 81 | 60 | 6.7 | 191 | 4.9 | 32 |
| 3 | 4.38 | 103 | 26 | 40 | 0.4 | 0.8 | 239 | 2 | 81 | 59 | 6.6 | 193 | 4.9 | 32.7 |
| 4 | 4.38 | 103 | 26 | 40 | 0.4 | 0.8 | 239 | 1.9 | 81 | 59 | 6.6 | 192 | 4.9 | 32 |
| 5 | 4.38 | 104 | 26 | 40 | 0.4 | 0.9 | 237 | 2 | 81 | 60 | 6.6 | 193 | 4.9 | 32 |
| 6 | 4.25 | 97 | 26 | 40 | 0.4 | 0.8 | 232 | 2 | 78 | 58 | 6.4 | 184 | 4.7 | 32 |
| 7 | 4.33 | 101 | 25 | 41 | 0.4 | 0.8 | 236 | 1.9 | 80.8 | 60 | 6.6 | 190 | 4.8 | 33 |
| 8 | 4.38 | 101 | 27 | 41 | 0.4 | 0.8 | 240 | 1.9 | 81 | 59 | 6.7 | 193 | 4.9 | 33 |
| 9 | 4.37 | 105 | 26 | 40 | 0.4 | 0.8 | 239 | 2 | 81 | 59 | 6.7 | 194 | 4.9 | 33 |
| 10 | 4.38 | 105 | 26 | 41 | 0.4 | 0.8 | 239 | 1.9 | 80 | 59 | 6.6 | 191 | 4.9 | 33 |
| Mean | 4.35 | 102.31 | 26 | 40.4 | 0.4 | 0.81 | 237.8 | 1.96 | 80.58 | 59.2 | 6.6 | 191.1 | 4.86 | 32.47 |
| SD | 0.05011 | 2.5309 | 0.4714 | 0.5164 | 6E-17 | 0.03162 | 2.61619 | 0.05164 | 0.95893 | 0.63246 | 0.09428 | 2.84605 | 0.06992 | 0.50343 |
| CV | 1.15198 | 2.47375 | 1.81309 | 1.27821 | 1E-14 | 3.90405 | 1.10016 | 2.63468 | 1.19004 | 1.06834 | 1.4285 | 1.4893 | 1.4387 | 1.55045 |

| | ALB | ALP | ALTL | AST | BIL D | BIL T | CHOL | CREAT | GLUC | HDL | TP | TGL | UA | UREA |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| RUN 1 | 4.29 | 103.4 | 25.3 | 39.1 | 0.4 | 0.9 | 236.3 | 2 | 81.35 | 58.39 | 6.5 | 190.73 | 4.9 | 32.6 |
| | 4.13 | 98.4 | 24.4 | 39.1 | 0.4 | 0.7 | 226.4 | 1.9 | 78 | 55.9 | 6.3 | 183.1 | 4.7 | 31.5 |
| | 4.17 | 98.2 | 25.6 | 39.1 | 0.4 | 0.8 | 232.8 | 1.9 | 82.4 | 57.5 | 6.4 | 191.8 | 4.7 | 31.4 |
| | 4.3 | 104.9 | 25.7 | 39.1 | 0.4 | 0.8 | 236.1 | 2 | 81.2 | 58.3 | 6.4 | 191.2 | 4.8 | 31.4 |
| | 4.3 | 102.1 | 24.1 | 39 | 0.4 | 0.9 | 237.8 | 2 | 80.9 | 58.5 | 6.4 | 191.8 | 4.8 | 32.9 |
| RUN 2 | 4,24 | 105.5 | 25 | 38.7 | 0.4 | 0.8 | 234.9 | 2.1 | 81.5 | 58.2 | 6.4 | 191.7 | 4.8 | 31.9 |
| | 4.4 | 106 | 25.6 | 38.9 | 0.4 | 0.8 | 243.2 | 2.2 | 82.7 | 60 | 6.6 | 193.2 | 4.9 | 32.2 |
| | 4.4 | 103.8 | 26.8 | 42.1 | 0.4 | 0.8 | 245.7 | 2.2 | 84.9 | 61.8 | 6.6 | 193.7 | 5 | 32 |
| | 4.5 | 104.2 | 26.6 | 42.1 | 0.5 | 0.8 | 251.9 | 2.2 | 84.2 | 53.6 | 6.6 | 200.1 | 5 | 32.9 |
| | 4.36 | 100.2 | 26.8 | 39.7 | 0.5 | 0.8 | 241.5 | 2.2 | 84.3 | 62.6 | 6.5 | 194 | 4.9 | 32 |
| RUN 3 | 4.33 | 89.1 | 28.2 | 41.7 | 0.4 | 0.8 | 238.6 | 2 | 80.9 | 60.8 | 6.3 | 185 | 4.7 | 31.6 |
| | 4.26 | 88.7 | 27.4 | 41.3 | 0.4 | 0.8 | 237.8 | 2 | 79.9 | 60.6 | 6.4 | 185.3 | 4.7 | 30.1 |
| | 4.4 | 91.8 | 27.4 | 41.1 | 0.4 | 0.8 | 241.6 | 2 | 81.9 | 61.1 | 6.4 | 188.3 | 4.8 | 30.7 |
| | 4.4 | 93.2 | 28.6 | 42.2 | 0.5 | 0.8 | 243.5 | 2.1 | 82.3 | 61.1 | 6.4 | 191.6 | 4.8 | 31 |
| | 4.4 | 93.7 | 28.2 | 42.5 | 0.5 | 0.9 | 246.6 | 2.1 | 82 | 62.1 | 6.5 | 190 | 4.8 | 31.4 |
| RUN 4 | 4.2 | 83.8 | 27.2 | 40.6 | 0.4 | 0.8 | 229.7 | 2 | 78.8 | 58.7 | 5.9 | 180.4 | 4.6 | 30.4 |
| | 4.2 | 86.5 | 27.5 | 41.4 | 0.4 | 0.8 | 235.9 | 2 | 89.7 | 60.2 | 6.2 | 180.6 | 4.7 | 30.8 |
| | 4.1 | 86.1 | 28.4 | 42.2 | 0.4 | 0.8 | 239.2 | 2.1 | 80.4 | 60.8 | 6.1 | 181.2 | 4.7 | 31.4 |
| | 4.3 | 89 | 27.8 | 42.1 | 0.4 | 0.8 | 238.5 | 2.1 | 79.7 | 62.4 | 6.4 | 183.3 | 4.9 | 31.2 |
| | 4.2 | 86 | 27.9 | 42.3 | 0.5 | 0.9 | 239.5 | 2.1 | 80.4 | 60.7 | 6.2 | 188.9 | 4.8 | 30.4 |
| RUN 5 | 4.2 | 85.5 | 27.4 | 41 | 0.4 | 0.8 | 237.3 | 2 | 80.1 | 60.2 | 6.3 | 183 | 4.7 | 31.7 |
| | 4.3 | 85.6 | 26.2 | 40.8 | 0.4 | 0.8 | 239.2 | 2.1 | 81 | 60.7 | 6.3 | 185.2 | 4.7 | 29.8 |
| | 4.3 | 86.3 | 26.6 | 42.1 | 0.4 | 0.9 | 242.3 | 2.1 | 80.5 | 60.8 | 6.2 | 187.4 | 4.8 | 30.4 |
| | 4.1 | 83.2 | 26 | 41.1 | 0.4 | 0.7 | 232.1 | 1.9 | 78.9 | 59 | 5.9 | 180.1 | 4.6 | 29.3 |
| | 4.3 | 86.6 | 25.7 | 40.8 | 0.4 | 0.7 | 236.8 | 1.9 | 80.3 | 59.1 | 6 | 182.3 | 4.7 | 30.6 |
| MEAN | 4.284 | 93.672 | 26.656 | 40.804 | 0.42 | 0.8083 | 238.61 | 2.048 | 81.53 | 59.724 | 6.328 | 187.76 | 4.78 | 31.264 |
| SD | 0.108 | 8.074 | 1.259 | 1.315 | 0.041 | 0.058 | 5.446 | 0.096 | 2.391 | 2.067 | 0.197 | 5.275 | 0.108 | 0.926 |
| CV | 2.520 | 8.620 | 4.724 | 3.224 | 9.720 | 7.220 | 2.282 | 4.700 | 2.933 | 3.460 | 3.111 | 2.810 | 2.260 | 2.962 |