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

Roche Professional Services

ISO 9001:2015 certified

Roche

Rexis case id : _____

Report No.	Instrument Model	Instrument Serial No.	Visit Date	Call Type
C 59647	c111	15260	5/07/2021	☑ Engineering ☐ Application ☐ Other (pls specify):

Charge Type:				
☐ Service Contract	☑ Warranty	☐ Ad-hoc	☐ Placement / Rental	☐ Other (pls specify) :

Lab / Inst./Hosp. Name:	Contact / User Name :
Dr. Potdar laboratories. Solapur.	Dr - Potdar

Call Received Date :		Call Attended Dates :	5/07/2021	Travel Hours:	Work Hours :	☐ In Station
Time:		Time:	10:00	30 min	2 Hrs.	☑ Out-Station

Problem Description : PM

Action Summary : PM call done.
Replaced PM kit.
calibration & QC done.
machine working ok.

Spare / Parts Reagent Consumables Used (as Applicable) :

GMMI No.	Item	Qty.	Batch No.	Total Value (Est.)	Notes :
	PM kit	01			

Service Engineer / Application Specialist Remarks : MC ok.

Customer Remarks :

Problem Resolved Yes / No

Service Feedback : ☐ 1. Poor ☐ 2. Fair ☐ 3. Good ☐ 4. V.Good ☐ 5.Excellent

Service Engineer / Application Specialist Name :	3 SP Address Seal	Customer's / User's Name :
Pravin. K.		Dr. K V Potdar
Service Engineer / Application Specialist Signature :		**Customer's / User's Signature :**

For Internal / Office Use Only (as Applicable)

SA Code :	Function:	Cause :	Remedy :	Cause :	Code :	Fix :

Please Specify with Code (for any 'XD' reasons):

DR. POTDAR LABORATORIES 519, Shashwat Heights, Shukrawar Peth, Mantri Chowk SOLAPUR.

Regional Diagnostics India Pvt. Ltd. : 501 B & 601 B, Silver Utopia, Cardinal Gracious Road, Chakala Road, Andheri (East), Mumbai - 400 069

Regional Office North: 3rd Floor, MGF Corporate Park, Plot No. A2, District Centre, Saket, New Delhi - 110017 I Ph.: +91-11-4603 4500 I Fax: +91-11-4603 4528

Regional Office South: Shreyas, Chamiers Towers, 8th Floor, West Wing, New No. 37, Old No. 23 & 24, Chamiers Road, Teynam pet, Chennai - 600 018. I Ph.: +91-44-4390 0300 I Fax: +91-44-430 0325

Regional Office East: 4C, Akash Tower, 781 Anandpur, Near Ruby Hospital, Kolkata-700107.I Ph.: +91-33-4015 3700 I Fax: +91-33-4015 3701

REGIONAL COPY

RPS On-Line Toll Free No: 18001237599 / Toll No: +91-44-30413900

Version - 04 RPS | FSR | F

c111 V4.3.0.1835 15260
lab 07.07.2021 11:35

QC Status:

S	Test	ID	Flag	Result
	ALB2	BIORAD1		4.46g/dL
	ALP2S	BIORAD1		97.0U/L
	ALTL	BIORAD1		24.7U/L
	ASTL	BIORAD1		38.9U/L
	BILT3	BIORAD1		0.8mg/dL
	CHO2I	BIORAD1		244.29mg/dL
	CREJ2	BIORAD1		2.1mg/dL
	GLU2	BIORAD1	<R2(2s)	78.30mg/dL Lmin
	HDLC4	BIORAD1		63.31mg/dL
	TP2M	BIORAD1		6.1g/dL
	TRIGL	BIORAD1		187.01mg/dL
	UA2	BIORAD1		4.7mg/dL
	UREL	BIORAD1		32.21mg/dL
	ALB2	BIORAD2		3.05g/dL
	ALP2S	BIORAD2		410.4U/L
	ALTL	BIORAD2		93.3U/L
	ASTL	BIORAD2		201.8U/L
	BILT3	BIORAD2		4.0mg/dL
	CHO2I	BIORAD2		99.80mg/dL
	CREJ2	BIORAD2		5.2mg/dL
	GLU2	BIORAD2		285.85mg/dL
	HDLC4	BIORAD2	>R2(2s)	27.20mg/dL Lmin
	TP2M	BIORAD2		3.9g/dL
	TRIGL	BIORAD2		100.16mg/dL
	UA2	BIORAD2		9.3mg/dL
	UREL	BIORAD2		96.00mg/dL

7-7-2021

c111 V4.3.0.1835 15260
lab 07.07.2021 12:15

Calibration Details:

Test	GLU2
Use	Current
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009100
Expiration date	31.08.2022
Accepted by	SYS, 07.07.2021 12:13
Creation time	07.07.2021 12:00
Flags	
R0	0.000553466
F	35.0299

c111 V4.3.0.1835 15260
lab 05.07.2021 11:33

QC Status:

S	Test	ID	Flag	Result
	ALB2	BIORAD1		4.43g/dL
	ALP2S	BIORAD1		96.9U/L
	ALTL	BIORAD1		24.9U/L
	ASTL	BIORAD1		38.9U/L
	BILT3	BIORAD1		0.8mg/dL
	CHO2I	BIORAD1		242.57mg/dL
	CREJ2	BIORAD1		2.0mg/dL
	GLU2	BIORAD1		79.75mg/dL
	HDLC4	BIORAD1		61.63mg/dL
	TP2M	BIORAD1		6.3g/dL
	TRIGL	BIORAD1		185.52mg/dL
	UA2	BIORAD1		4.6mg/dL
	UREL	BIORAD1		31.76mg/dL
	ALB2	BIORAD2		2.96g/dL
	ALP2S	BIORAD2		411.9U/L
	ALTL	BIORAD2		92.3U/L
	ASTL	BIORAD2		197.2U/L
	BILT3	BIORAD2		3.9mg/dL
	CHO2I	BIORAD2		97.72mg/dL
	CREJ2	BIORAD2		4.8mg/dL
	GLU2	BIORAD2		280.45mg/dL
	HDLC4	BIORAD2	>R2(2s)	26.49mg/dL Lmin
	TP2M	BIORAD2		4.0g/dL
	TRIGL	BIORAD2		98.80mg/dL
	UA2	BIORAD2		9.2mg/dL

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admin 26.09.2019 14:33

Abs. Air/Water Calibration:

Abs. Air/Water Calibration.
Cuvette segment is moved to handling position 1.
Insert an empty cuvette segment, then press <OK>.
Cuvette segment is moved to handling position 2.
Insert an empty cuvette segment, close the cover, then press <OK>.
Starting the calibration.

Waiting for completion.
Maintenance action complete.

Wavelength	H2O	H2O cuvette
340	-0.0057	0.0777
378	-0.0041	0.0749
409	-0.0034	0.0731
449	-0.0002	0.075
480	0.0009	0.0748
512	0.0025	0.076
520	0.0026	0.0759
552	0.0037	0.0767
583	0.0048	0.0775
629	0.006	0.0783
652	0.0066	0.0789
659	0.0064	0.0786

Outlier statistics:
Air : 0
Water : 0
Diff : 0
Total : 0

Press <OK> to use these values.
Then press <Cuvettes> and exchange the two segments.

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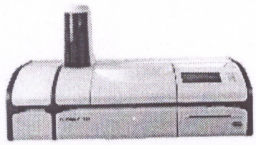
admin 26.09.2019 14:51

Check Pipetting Accuracy:

Place sample '@CHK' on the instrument.
Created 16 CHECK test orders in sample order '@CHK'.
Cuvette segment is moved to handling position 1.
Insert first cuvette segment, then click OK.
Cuvette segment is moved to handling position 2.
Insert second cuvette segment and close the main cover, then click OK.
System changes to operating and runs CHECK tests. Wait for completion.
# of results = 16, Mean = 1.27131Abs
SD = 0.00893266, CV = 0.702636%
Diagnostic action completed.

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

	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	27.9	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	26.856	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

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

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