Roche

To Whom It May Concern

ISO 15189:2012 Requirements reg. "Calibration & Verification Procedures"[1]

All Roche Diagnostics products which are distributed 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 the development and manufacturing of Roche Diagnostics products are guided by a Quality Management System. Our Quality Management System is in compliance with the requirements from ISO 9001:2008[3], ISO 13485:2003 + AC: 2007[4], and QSReg[5].

The mentioned regulations require that the production systems and measuring devices used are qualified and the manufacturing and test procedures are validated[6]. 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 Diagnostics systems are fully traceable to certified standards or reference materials. The performance of all Roche Diagnostics systems at the customer site is assured if regular QC 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 Roche Diagnostics systems will perform as specified during their defined lifetime.

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

Graz, 26-Feb-2015

Dr. Johann Hare
Head of Quality Management & Regulatory Affairs

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1 ISO 15189:2012, Medical laboratories - Requirements for quality and competence
2 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
3 ISO 9001:2008, Quality Management Systems - Requirements
4 ISO 13485:2003 + Cor.1:2009, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
5 Quality System Regulations, 21 CFR Part 820, requirements on medical devices
6 21 CFR Part 809, 21 CFR Part 210, 21 CFR Part 11; GAMP 5 guideline; Annex 15 to the EU Guide to cGMP

Roche Professional Services *(ISO 9001:2015 certified)*

Customer Support Center No: 1800-123-7599 /Toll No: +91-44-30413900

Case No.	CAS-0011155348	**Instrument Model**	Cobas 4000 c311 stand alone system
Order No.	ORD-0014447253	**Instrument Serial No.**	18M5-05
Contract Type	IN-COMPREHENSIVE	**Finance Status**	RENT
Lab/Inst./hosp.Name		Standard Healthcare	
Customer No.		0052613706	
Contact Name:		Standard Healthcare	
Contact Number:		919315958990	
Address:		SK-174, Sector 116,	
City:		Noida	

Call Received Date/Time:	20.02.2020 17:30	**Call Attended Date/Time:**	04.05.2021 02:00

Job Type	PM Visit
Job Description	
Action Summary	Cause:PM Visit Workdone:Done surface and modules cleaning of the analyzer, Check/done alignment of sample probe/reagent probe at all position. >Both maintenance kits has changed & system hardware checked has perforemd as per pm checklist and ok. >All onboard qc has checked & ok Verification:PM completed & system is working fine. Customer Satisfaction Rating (1-5):

Spare Part Replaced

Part No	Parts Description	Batch No	Batch Expiry Date	Qty	Invoice Type
05182522001(1)	KIT MAINTENANCE 6 MONTHS COBAS C311(1)			1	Free of charge
05182549001(1)	KIT MAINTENANCE 1 YEAR COBAS C311(1)			1	Free of charge

(1): Customer owned

Time Report

Effective Visit Date: 04.05.2021 **Complete Date:** 04.05.2021

Date	Type	Time
2021.05.04	Travel Time--Standard	2
2021.05.04	Working Time--Standard	5
	Total:	7

Customer's Signature Name : Mr Kuldeep	**Service Engineer/Application Specialist** Name : Irfan Majeed
4/5/21	04/05/21

COBAS® c311 Preventive Maintenance Checklist

Customer Name: Standard Healthcare Pvt ltd

Type: Yearly

Instrument S/N: 18M5-05

Date: 05-04-21

Case ID: ORD-0014447253

PM Communication: Yes

ISE Active: No

		Remarks (if any)	Recommended	FSE Action
Cover / Housing			Clean	CL
Vaccum Dust from analyzer			Clean	CL
Replace Seals in Syringe Assembly			Replace	R
Heat Cut Filter			Clean/Replace	R
Replace Halogen Lamp,if necessary			Check/Replace	CK
Replace Nozzle Tips			Replace	R
Replace Sipper Tube			Replace	R
Replace PV Tube			Replace	R
USM Cell Cover			Clean/Replace	CL
Sample Probe			Clean	CL
Reagent Probe (R1 and R2)			Clean	CL
ISE probe			Clean	CL
Reagent Piercer and Gripper			Clean	CL
Wash Stations(Sample/ R1/ R2/ ISE)			Clean	CL
Incubator			Clean	CL
USM			Clean	CL
Incubator Filter			Clean	CL
Incubator Water level Sensor			Clean	CL
ISE Electrodes			Check/Repalce	Not Done
Reaction Cells			Clean/Replace	Not Done
Rinse Water Check(For Water Blank)			Check	CL
ISE Sipper Waste Pipe			Clean	CL
Sensors			Clean	CL
Hepa Filter			Check/Replace	R
Vacuum bottle Drain			Inspect/Replace	CL
Barcode Reader Window			Clean	CL
Rinse Mechanism Tubing			Inspect/Replace	CK
Lubricate each Mechanism			Lubricate	CK
Mechanics				
Incubator Filling			Check	CK
Mechanism Check			Check	CK
Final Check				
Photometer Check	Attach Printout		Perform	Performed
Cell blank Measurement	Attach Printout		Perform	Performed
Pipetting Accuracy Check	Attach Printout		Perform	Performed
QC Check (Few Parameters)	Attach Printout		Perform	Performed

CL= Clean, L= Lubricate, R= Replace, I/R= Inspect/Replace, CK= Check, PRT= Print, TD= To Do

FSE Name	Irfan majeed	Customer Name	Mr Kuldeep
FSE Signature	Majeed	Seal & Signature	STANDARD DIAGNOSTICS PVT. LTD. Noida

Cell Blank Measurement 04/05/21 18:48

04/05/21 18:33	WAVELENGTH (nm)											
CELL NO.	340	376	415	450	480	505	546	570	600	660	700	800
001	12835	9600	9421	8842	8709	8596	8364	8331	8239	8143	7916	7542

Photometer Check 04/05/21 18:30

PREVIOUS DATA		CURRENT DATA	
DATE	04/05/21 18:26	DATE	04/05/21 18:30
340 nm	12852	340 nm	12835
376 nm	9618	376 nm	9599
415 nm	9442	415 nm	9421
450 nm	8863	450 nm	8842
480 nm	8730	480 nm	8708
505 nm	8617	505 nm	8596
546 nm	8386	546 nm	8364
570 nm	8352	570 nm	8331
600 nm	8261	600 nm	8239
660 nm	8163	660 nm	8142
700 nm	7936	700 nm	7916
800 nm	7565	800 nm	7545

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* HITACHI AUTOMATIC ANALYZER *
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NAME PCCC2
S.NO. C007055 078
LOT 41010500

DATE 04/05/21 18:58:40
OPERATOR ID bmserv

TEST	RESULT		UNIT	EXPECTED VALUE		ALARM
Test03	8.05		g/dL	(7.16-	8.40)	
Test08	9.7		mg/dL	(8.58-	10.50)	
Test09	7.52		mg/dL	(6.80-	8.32)	
Test11	235.39		ug/dL	(212-	268)	
UIBCI	266.1		ug/dL	(235-	311)	
Test15	210.2		mg/dL	(190-	234)	
Test17	120.1		mg/dL	(109-	133)	
Test21	60.8		mg/dL	(51.9-	71.9)	
MG	2.9	L	mg/dL	(2.92-	3.44)	ReagEX
LDH	322		U/L	(258-	330)	