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-2013

Dr. Johann Harer
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-0013301642	Instrument Model	cobas 6000 c501 module
Order No.	ORD-0017161433	Instrument Serial No.	16Z0-07
Contract Type	IN-COMPREHENSIVE	Finance Status	RENT
Lab/Inst./hosp.Name		Arth Diagnostics Pvt Ltd	
Customer No.		0052070145	
Contact Name :		Kishan Singh	
Contact Number :		+919468703577	
Address :		Plot#4C,Apex Chamber,	
City :		Udaipur	

Call Received Date/Time:	15.04.2021 16:45	Call Attended Date/Time:	27.06.2021 16:30

Job Type	PM Visit
Job Description	
Action Summary	Work done : Preventive Maintenance done, Calibration & Q.C. Done Customer Satisfaction Rating (1-5):5

Spare Part Replaced

Part No	Parts Description	Batch No	Batch Expiry Date	Qty	Invoice Type
07783175001(1)	KIT MAINTENANCE 4 501/502(1)			1	Free of charge
05521521001(1)	KIT MAINTENANCE 1 501/502(1)			1	Free of charge

(1): Customer owned

Time Report

Effective Visit Date : 27.06.2021	Complete Date : 28.06.2021

Date	Type	Time
2021.06.27	Travel Time--Standard	1
2021.06.27	Working Time--Standard	2
2021.06.28	Quality Control--Standard	0.5
2021.06.28	Travel Time--Standard	0.5
2021.06.28	Working Time--Standard	2
	Total:	6

Customer's Signature Name : Singh Kishan	Service Engineer/Application Specialist Name : Manoj Vishwakarma
	

Date: 28.06.2021	Date: 28.06.2021

Disclaimer

1. This Service report has been signed by the authorized representative of your organization.
2. Discrepancies if any must be intimated within a period of seven (7) days of the receipt of the email, in the absence of which the report will be final and conclusive.
3. This report shall be governed by the laws of India and the courts at Mumbai shall have the exclusive jurisdiction to deal with the disputes arising hereunder.

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* HITACHI AUTOMATIC ANALYZER *
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NAME PCCC2 DATE 27/06/21 09:46:17
S.NO. C040053 0001-1 OPERATOR ID bmserv
LOT 46159500

TEST	RATIO COI/MES	RESULT	UNIT	MODULE	ALARM
GLUC3		243.9	mg/dL	C	
ALB2		5.53	g/dL	C	
ALP2L		208	U/L	C	
ALTL		125.2	U/L	C	
ASTL		151.6	U/L	C	
BILD2		2.301	mg/dL	C	
BILT3		3.531	mg/dL	C	
CA2		13.67	mg/dL	C	
CHOL		170.2	mg/dL	C	
CREJ		4.05	mg/dL	C	
TP2		8.08	g/dL	C	
TRIGL		206.9	mg/dL	C	
UA		9.6	mg/dL	C	
UREA		119.7	mg/dL	C	
TEST039		54.5	mg/dL	C	