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

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Project Manager Regulatory Affairs

ppa. Dr. Beate Bonefeld
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[1] ISO 15189:2012/ ISO 15189:2014 Medical laboratories – Requirements for quality and competence
[2] Directive 98/79/EC of the European Parliament and of the Council of the 27 October 1998 on vitro diagnostics medical devices
[3] EN ISO 13485:2012 + AC:2012 Medical devices – Quality management systems-Requirements for regulatory purposes
[4] CFR Part 820, Quality System regulations 21 Requirements on medical devices

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

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

Case No.	CAS-0011032862	Instrument Model	cobas Integra 400 plus
Order No.	ORD-0014300467	Instrument Serial No.	402158
Contract Type	IN-COMPREHENSIVE	Finance Status	RENT
Lab/Inst./hosp.Name		Abirami Kidney Care	
Customer No.		0052606946	
Contact Name :		SHANTHI SOCIAL SERVICES	
Contact Number :		04222575528	
Address :		No.582, Brough Road,	
City :		Erode	

Call Received Date/Time:	27.01.2020 17:45	Call Attended Date/Time:	13.08.2021 11:30

Job Type	PM Visit
Job Description	
Action Summary	Problem Description : Preventive Maintenance for cobas integra 400 plus. Action Summary : Performed the preventive maintenance as per the check list, Cleaned the lamp housing,photometer lens, waste Reservoir, internal and external water reservoir, reagent and sample Compartment,probes,Cleaned and lubricated the analyzer unit , Cleaned and lubricated the syringe modules, Replaced the KitMaintenance I 400 plus, Performed the workstations and Rotor adjustments, Checked and adjusted the robotictransfer belt tensions, Performed the diagnostic checks, Found Diagnostics are OK, Performed the pipettingaccuracy check and QC, Found checks and QC values are within range. Remarks : Instrument is working fine. Customer Satisfaction Rating (1-5): 5

Spare Part Replaced					
Part No	Parts Description	Batch No	Batch Expiry Date	Qty	Invoice Type
08425094001(1)	KIT MAINTENANCE W/O ISE TUBING I400PLUS (1)			1	Free of charge

(1): Customer owned

Time Report	
Effective Visit Date : 13.08.2021	Complete Date : 13.08.2021

Date	Type	Time
2021.08.13	Quality Control--Standard	0.5
2021.08.13	Travel Time--Standard	2.5
2021.08.13	Working Time--Standard	4
	Total:	7

Customer's Signature Name : Dr.Saravanan	Service Engineer/Application Specialist Name : Thamaraiselvan Subramani

	
Date: 13.08.2021	Date: 13.08.2021

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.