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 [2A.] which is currently switching to IVD Regulation 2017/746/EU (final timeline: May 26, 2022) [2B.] requires for all CE marked products that the manufacturer assures compliance of the products with the requirements of the mentioned directive or regulation. 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 13485:2016 [3] 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.

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890
Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

[1] ISO 15189:2012/ ISO 15189:2014 Medical laboratories — Requirements for quality and competence

[2] A. Directive 98/79/EC of the European Parliament and of the Council of the 27 October 1998 on vitro diagnostics medical devices;
B. IVD Regulation 2017/746/EU of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

[3] EN ISO 13485:2016 Medical devices — Quality management systems-Requirements for regulatory purposes

[4] CFR Part 820, Quality System regulations 21 Regulations on medical devices

Mannheim, 4. August 2021

Sincerely,

Roche Diagnostics GmbH

i.V./*on behalf of the company*

DocuSigned by:
ECA5294AC4E94AF...

Andrea Weber
Manager Global Regulatory Affairs

i.V./*on behalf of the company*

DocuSigned by:
7AE1EF68C3F0440...

Stefan Grigarczik
Manager Global Regulatory Affairs

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim

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

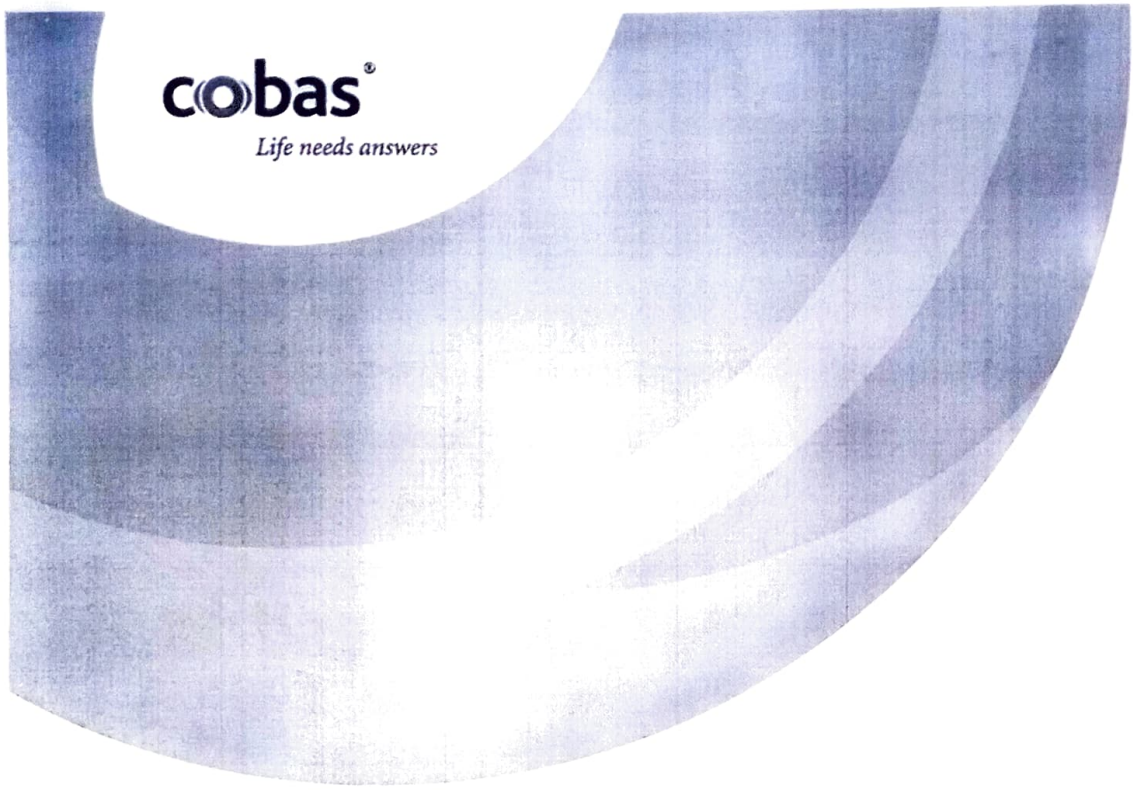
Time Report	
Effective Visit Date : 13.08.2021	Complete Date : 13.08.2021

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.



cobas Integra 400 plus Analyzer

Qualification Service

Installation Qualification / Operation Qualification (v.1.0)

Roche

cobas®

Life needs answers

cobas Integra 400 plus Analyzer

Installation Qualification

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Operational Qualification

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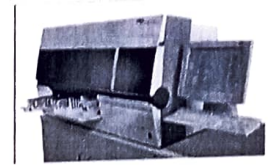
Attachments

Roche

cobas Integra 400 *plus*



General Information

Country:	India
Customer Name:	Abirami Kidney Care (P) Ltd
Customer Address:	No:581, 582, Brough Road, Erode-638011
Person Responsible for Quality Assurance:	Mrs. Raji

System Information

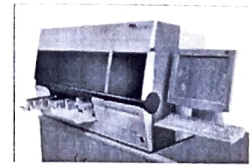
	S/N
cobas Integra 400+:	402158
Host provider:	
Software Version:	3.6.2.1904

Installation Information

Installation Start Date:				
First Installation:	yes			
Reconfiguration:	From:	specify	To:	specify
Relocation:	From:		To:	

Roche Responsible Representative : Mr. Tamaraiselvan

cobas Integra 400 *plus*



General Information

Country:	India
Customer Name:	Abirami Kidney Care (P) Ltd
Customer Address:	No:581, 582, Brough Road, Erode-638011
Person Responsible for Quality Assurance:	Mrs. Raji

System Information

cobas Integra 400+:	S/N 402158
Host provider:	
Software Version:	3.6.2.1904

Installation Information

Installation Start Date:				
First Installation:	yes			
Reconfiguration:	From: specify		To:	specify
Relocation:	From:		To:	

Roche Responsible Representative : Mr. Tamaraiselvan

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	10/22/2021
IQ 1.2	Environmental parameters met	Pass	10/22/2021
IQ 1.3	Instrument delivered undamaged and complete	Pass	10/22/2021
IQ 1.4	Transport locking successfully removed	Pass	10/22/2021
IQ 1.5	All connections correctly installed	Pass	10/22/2021
IQ 1.6	Instrument positioned according to Installation Manual	Pass	10/22/2021
IQ 1.7	Instrument boot process successfully	Pass	10/22/2021
IQ 1.8	Checksum according to specification	Pass	10/22/2021
IQ 1.9	Mechanical adjustments complete	Pass	10/22/2021
IQ 1.10	Auxiliary components positioned	Pass	10/22/2021
IQ 1.11	Instrument installation check	Pass	10/22/2021
IQ 1.12	Host communication settings checked	yes	10/22/2021

Test #	Test	Pass Fail	Signature Date
IQ.2	Installation Qualification for cobas Integra 400+	specify	10/22/2021

NA

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

Investigation

Action taken

Deviation resolved satisfactorily? specify

Deviation #2

Investigation

Action taken

Deviation resolved satisfactorily? specify

Deviation #3

Investigation

Action taken

Deviation resolved satisfactorily? specify

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.

Notice: The following tests are to be carried out by trained Roche personnel only.

Purpose: The purpose of this test is to check that the modules are operating in accordance with the specifications.

Test #	Test	Pass Fail	Signature Date
OQ.1	Calibration successfully	Pass	10/25/2021
OQ.2	Quality Control successfully	Pass	10/25/2021
OQ.3	Precision check successfully	Pass	10/25/2021

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

Investigation

Action taken

Deviation resolved satisfactorily?	specify

Deviation #2	
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

Instrument is ready for operation

Completed by Roche Representative Date 10/28/2021

Print Name Dr. Raju - Application specialist

Signature Raju

Reviewed by Customer Contact

Date 26.10.2021

Print Name V. RAJESHWARI

Signature V. Rajeshwari

Reviewed by Customer Quality Assurance

Date 26.10.2021

Print Name

Dr. T. Saravanan, M.D., D.M., (Nephrology)
Consultant Nephrologist & Transplant Physician
Reg. No.:76095
Medical Director
Abirami Kidney Care, Erode - 638 011.

Signature

Dr. T. Saravanan, M.D., D.M., (Nephrology)
Consultant Nephrologist & Transplant Physician
Reg. No.:76095
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cobas

Installation Qualification for cobas® Integra 400 plus

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 complete	
	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 different modules and accessories without damage to units	Pass
IQ 1.5	All connections correctly installed	
	Power supply voltage at the customer facility:	230V ±2V
	UPS system available:	yes

Voltage fluctuation less than 230 ±5V	Pass
Grounding less than 1.0 V	Pass

IQ 1.6	Instrument positioned according to Installation Manual	
	System layout is according to the description in the manual	Pass

IQ 1.7	Instrument boot process successful	
	IP address configuration successful	Pass
	System Configuration successful	Pass
	First system boot-up	Pass

IQ 1.8	Checksum according to specification	
	Version of installed cobas Integra 400+ software	3.6.2
	Installation of country language successful	yes

IQ 1.9	Mechanical adjustments complete	
	All mechanical adjustments are carried out	Pass

IQ 1.10	Auxiliary components positioned	
		Pass

IQ 1.11	Instrument installation check

Print function	yes
Rack/Sample barcode read check	Pass

IQ 1.12	Host communication settings checked	
	Check Host settings according to Host manual	yes
	Check Host communication	yes

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
NA

Investigation

Action taken

Deviation resolved satisfactorily? specify

Deviation #2
NA

Investigation

Action taken

Deviation resolved satisfactorily? specify

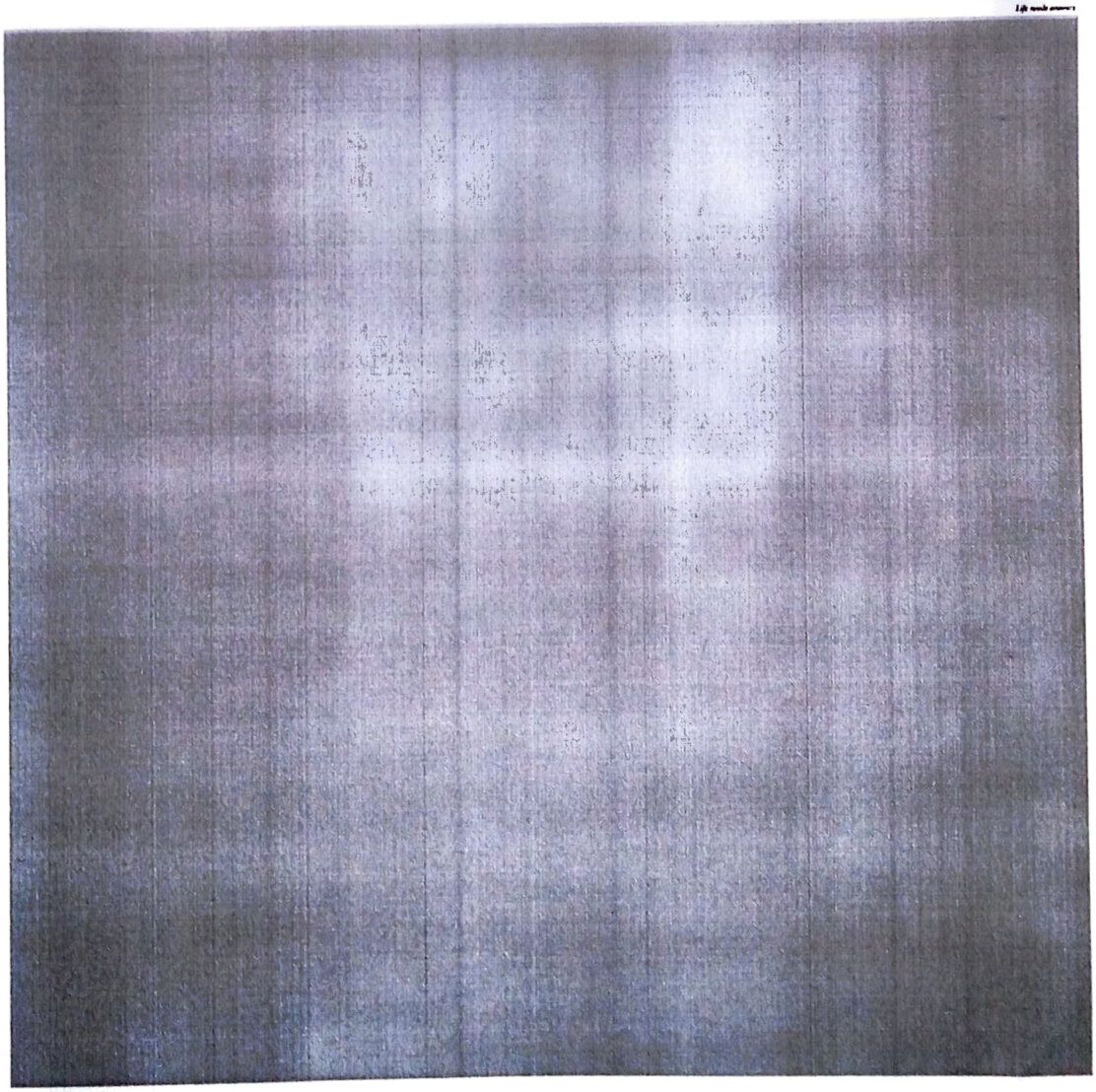
Deviation #3
NA

Investigation

Action taken

Deviation resolved satisfactorily? specify

cobas



Installation Qualification for cobas® Integra 400 plus:

Description

IQ.2.1	Function check of Integra400+ module according to specifications	
	System layout is according to the description in the manual	Pass
	Integra 400+ is installed according to the installation manual and using official tools	Pass
IQ.2.2	Mechanical adjustments complete	
	All mechanical adjustments for the different Integra 400+ mechanical parts are carried out	Pass
IQ.2.3	Auxiliary components positioned	
	Wash solutions are installed at the Integra 400+	Pass
	ISE electrodes are installed	not applicable
	ISE solutions are installed	not applicable
	Probe B & Probe C (Reagent & Sample) pipetters installed	Pass
IQ 2.4	Instrument installation check	
	Air water Calibration	Pass
	Prime Fluid System	Pass
	Analyzer Rotor (Reaction) temperature 37°C ± 0.5°C	Pass

	Carry out Instrument Check according to Method Sheet of the cobas c pack INSTC (Art. No. 04851013 190) (attached printout)	Pass
	ISE Check 20 times (attached printout)	not applicable
IQ 2.5	Assay installation	
	Download of applications from TAS (attached list of applications)	Pass
	Load corresponding reagent c-packs	Pass

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	NA
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #2	NA
Investigation	
Action taken	

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 (attached printout)	yes
Calibration of all ISE parameters successful (attached printout)	not applicable

OQ.2 Quality Control

Specify the type of control used:

Roche

QC of all photometric parameters within acceptable range (attached printout)	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	
K	
Cl	

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

QQ.3.2 Accuracy check for Photometric Assays

Perform test with analytical reagents

GLU,ASTL	Number of det.
2-point/end-point Assay	21
Rate A Assay	

Sample solution: BIORAD

Accuracy check for Photometric Assays was within acceptable range: yes

QQ.3.2 Precision check for Photometric Assays

Perform test with analytical reagents

GLU,ASTL	Number of det.
2-point/end-point Assay	
Rate A Assay	21

Accuracy check for Photometric Assays was within acceptable range: yes

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
NA

Investigation

Action taken	
Deviation resolved satisfactorily?	specify

Attachments

1. Precision - Intra assay