Roche Diagnostics India Pvt. Ltd.

Field Service Report

Case number: CAS-0016843895

Order Number: WO-03362122 | Ser. Report Created Date: 26/03/2023

Instrument Details

Instrument/Module: COBAS INTEGRA 400 plus

Serial Number: 420471

Internal Instrument Name:

Additional Details

:

Customer details

Customer Number: 0052614393

Customer Name: M/s Pathkind Diagnostics Pvt Ltd

Street Address: Near HDFC Bank ,Shadatpura

Zip: 275101 - Mau

Contact Name: Rajesh

Contact Phone: +919547874563

Service Activity Code: PM Visit

Purpose of Visit

PM COBAS INTEGRA 400 plus Major

Performed Activities

Check and clean all PCB's,Clean ROTOR,Incubation area,washing stations,Clean probes and robotic transfer head and lubricated properly
Clean Analyzer,air filter and internal reservoir
Check and replace new KIT MAINTENANCE I400/400plus GMMI-05670713001, replace PM kit is provided by Roche under FOC
Restart system along with all required consumable
Perform all due maintenance and priming
Perform air/water calibration,data found ok
Perform all parameters calibration and QC
Results found ok
Per samples results found ok
M/C Status ok working satisfactory
PM Major done successfully

Time Report

Category	Start	End	Hours	Invoice Type
05913616001-Service labour time	26/03/2023 2:45 pm	26/03/2023 6:30 pm	3.75	Contract

Travel

Value	Hours
Travel	3.9

Spare Parts

Roche Diagnostics India Pvt. Ltd.

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Part Number	Description	Quantity	Invoice Type
05670713001-KIT MAINTENANCE I400/400PLUS	KIT MAINTENANCE I400/400PLUS	1	Contract

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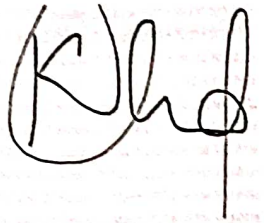
Signature

Customer Signature
Rajesh



Customer Signature

Roche support
Rajnish Dwivedi

Roche Signature

The customer acknowledges the service intervention as performed in accordance with Roche recommendations:
- This Service report has been signed by the authorized representative of your organization.
- 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.
- 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.

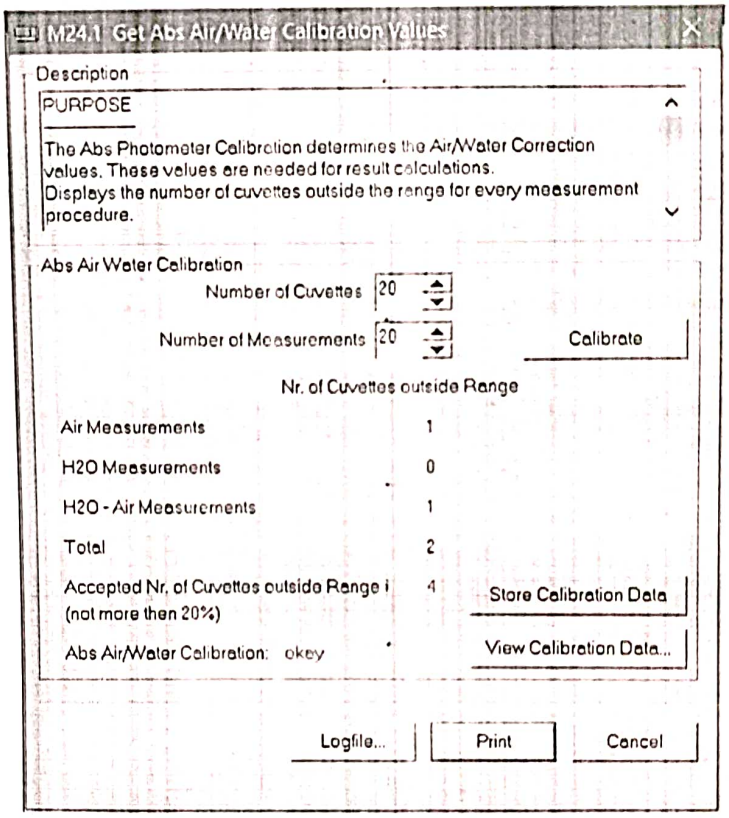
Customer Support Center No:
Toll Free No: 1800-123-7599 || Phone No: 044-43900345 ||
(Mon to Sat 8 AM to 8 PM)
e-mail: customersupportcenterIndia@roche.com ||||||||||||||||||
Roche DiaLog: https://dialog.roche.com
Service Report Version Number: 1

Thank You

INTEGRA 400 plus

System Version: 3.6.2.1904 **CuI Version:** 3.6.2 **CuI Build:** 1904

System Serial Number: 420471 Mar 26, 2023 / 16:33



INTEGRA 400 plus

System Version: 3.6.2.1904 CuI Version: 3.6.2 CuI Build: 1904

System Serial Number: 420471 Mar 26, 2023 / 16:35

M24.1 Get Abs Air/Water Calibration Values - Data

Description

PURPOSE

The Abs Photometer Calibration determines the Air/Water Correction values. These values are needed for result calculations.
Displays the number of cuvettes outside the range for every measurement procedure.

Wavelength	A_CUV (H2O)	A (H2O)
1. 340 nm	0.0834	-0.0008
2. 378 nm	0.0806	0.0025
3. 409 nm	0.0834	0.0054
4. 480 nm	0.0875	0.0107
5. 512 nm	0.0894	0.0124
6. 520 nm	0.0896	0.0128
7. 800 nm	0.0132	-0.0413
8. 552 nm	0.0911	0.0142
9. 583 nm	0.0923	0.0154
10. 629 nm	0.0940	0.0171
11. 652 nm	0.0950	0.0179
12. 659 nm	0.0955	0.0183

Data Source: New Values

Creation Date: 26-MAR-2023 16:34:51

(•) Into Database
( ) Into a File

Store Values

The Abs Photometer Calibration determines the Air/Water Correction

Logfile... Print Cancel

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 by 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, 10. August 2021

Sincerely,

Roche Diagnostics GmbH

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

Andrea Weber
Manager Global Regulatory Affairs
Centralised and Point of Care Solutions

ppa/*on behalf of the company*

Ralf Zielenski
Head Q&R Compliance, PRRC RDG
Centralised and Point of Care Solutions