Roche Diagnostics India Pvt. Ltd.

Field Service Report

Case number: CAS-0016347020 **Order Number: WO-01148431 | Visit Date: 21/10/2022**

Instrument Details

Instrument/Module: ISE 9180
Serial Number: 28874

Additional Details

PO:

Customer details

Customer Number: 0052617645
Customer Name: Prakash Diagnostic Laboratory
Street Address: Magadi Main Road
Zip: 560091 - Bangalore
Contact Name: Gulshan
Contact Phone: +919854366780

Service Activity Code: **PM Visit**

Purpose of Visit

PM Visit

Performed Activities

PM was done as per procedure.
Replaced harness main tubing & Na+ electrode from customer stock.
Calibrated the analyzer found to be in ready mode.
Note : kindly enter in to Amc . Please purchase & replace k+ & cl- electrodes since both electrodes are weak.

Time Report

Category	Start	End	Hours	Invoice Type
05913616001-Service labour time	21/10/2022 3:52 pm	21/10/2022 5:11 pm	1.32	Free of Charge
09396896001-Service travel time	21/10/2022 3:18 pm	21/10/2022 3:52 pm	0.55	Free of Charge

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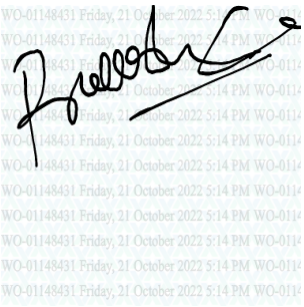
Customer Parts Used

Part Number	Description	Quantity
03074064001-HARNESS, MAIN TUBING, 918X	HARNESS, MAIN TUBING, 918X	1

Signature

Customer Signature
Gulshan



Roche support
Kumar Ramegowda

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.

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*

DocuSigned by:
ECA5294AC4E94AF...

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

ppa/*on behalf of the company*

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

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