**Roche Diagnostics India Pvt. Ltd.**

# Field Service Report

**Case number: CAS-0018357924**

**Order Number: WO-18787598 | Ser. Report Created Date: 23/08/2023**

**Instrument Details**

**Instrument/Module:** ISE 9180
**Serial Number:** 22412
**Internal Instrument Name:**

**Additional Details**

:

**Customer details**

**Customer Number:** 0052317649
**Customer Name:** DDRC SRL Diagnostics Services
**Street Address:** Opposite International Stadium
**Zip:** 682017 - Kochi
**Contact Name:** Selma Selma
**Contact Phone:** +919845251345

**Service Activity Code: PreventiveMaintenance**

**Purpose of Visit**
Preventive Maintenance
Serial/Lot Number 22412

**Performed Activities**
Performed Pm as per the Check list, Cleaned and lubricated all necessary parts. Replaced tube set. Machine ready

**Time Report**

| Category | Start | End | Hours | Invoice Type |
|---|---|---|---|---|
| 05913616001-Service labour time | 23/08/2023 9:09 am | 23/08/2023 11:10 am | 2.02 | Free of Charge |

**Travel**

| Value | Hours |
|---|---|
| Travel | 1 |

## Signature

**Customer Signature**

**Roche support**
Abdul Nahas

**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.

**Thank You**

**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

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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.



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Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

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[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:
A. Weber
ECA5294AC4E94AF...

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

ppa/*on behalf of the company*

DocuSigned by:
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Ralf Zielenski
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