



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.



- [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*

*ppa/on behalf of the company*

DocuSigned by:  
  
ECA5294AC4E94AF...

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

DocuSigned by:  
  
A7F0BA9FE91A46A...

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

**Roche Diagnostics GmbH**  
Sandhofer Straße 116  
D-68305 Mannheim

# Roche Professional Services Engineering Installation Report



Name of Institution: SRL LIMITED  
 Complete Address : CA 11 , Urvashi Phase II, Ambedkar Sarani, City Centre, Durgapur-7132216  
 City : Durgapur Pin Code : 7132216 Telephone No : 8918125173  
 Person In-Charge. : Dr. Deborshi Saha Email ID : dipankar.karmakar@srl.in  
 Instrument Model : COBAS INTEGRA 400 plus Serial No : 422101  
 Software Ver : 3.06.02 Cobas Link Serial No : N/A  
 Department ( kindly  $\sqrt{\quad}$  ) :  Pathology  Blood Bank  Other (mention) \_\_\_\_\_  
 Installation Commencement Date : 23.07.2022 Date of Installation : 29.07.2022  
 Travel Hours 4 Work Hours 10 REXIS ORD No WO-01101989

◆ **Transportation Damage & Discrepancy Report: {please update after inspection}**

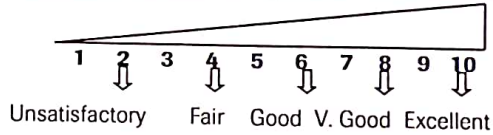
A. List of Missing items : Nill  
 B. Notes on any damages : Nill  
 C. General Remark : Checked Ok

◆ **Installation checks & Summary: {please indicate status}**

A. Power Supply:	230 VAC, 50Hz Single Phase with 1.1V Neutral vs Earthing
B. Software Installation & Boot-up:	Checked Ok
C. Mechanical Adjustments & Setup:	Checked Ok
D. Fluidic Adjustment & Setup:	Checked Ok
E. System Checks & Status Print Outs:	Attached

## Installation Feedback:

(Please rate your Satisfaction Level as per the Scale)



Pre-Installation Information   
 Service Personnel's response in general   
 Product installation & its timely Completion   
 Overall Installation Satisfaction

Comments

Signature of Engineer Sachin Mal Signature & Seal of Customer [Signature]  
 Name of Engineer Sachin Mal/Debasis Porel Engineer's Comment Instrument installed successfully

**SRL LIMITED**  
 Durgapur Lab  
 No. CA11  
 Ambedkar Sarani  
 City Centre, Durgapur-713216

"In case of Complaints/Inquiries please reach our Customer Support Centre at 1800-123-7599/044-30413900"

Date	Time	Order ID/Cal/QC	Test	Result Unit	Flag
1/20/2023	09:24	2 PCC2	ALB2	5.21 g/dL	
1/20/2023	09:24	1 PCC1	ALB2	3.19 g/dL	
1/20/2023	09:24	3 PCC2	ALP2L	233 U/L	
1/20/2023	09:25	3 PCC2	ALTL	114 U/L	
1/20/2023	09:25	4 PCC1	ALTL	44 U/L	
1/20/2023	09:25	3 PCC2	ASTL	142 U/L	
1/20/2023	09:25	4 PCC1	ASTL	43 U/L	
1/20/2023	09:25	3 PCC2	BILD2	2.39 mg/dl	
1/20/2023	09:25	4 PCC1	BILD2	0.89 mg/dl	
1/20/2023	09:26	3 PCC2	BILT3	3.32 mg/dl	
1/20/2023	09:26	4 PCC1	BILT3	0.93 mg/dl	
1/20/2023	09:26	4 PCC1	CA2	8.96 mg/dl	
1/20/2023	09:26	3 PCC2	CHOL2	172 mg/dl	
1/20/2023	09:26	4 PCC1	CHOL2	91 mg/dl	
1/20/2023	09:27	3 PCC2	CREJ2	3.66 mg/dl	
1/20/2023	09:27	4 PCC1	CREJ2	0.92 mg/dl	
1/20/2023	09:27	3 PCC2	CRP4	54.11 mg/L	
1/20/2023	09:27	4 PCC1	CRP4	9.16 mg/L	
1/20/2023	09:28	4 PCC1	GGTI2	54 U/L	
1/20/2023	09:28	3 PCC2	GLUC3	250 mg/dl	
1/20/2023	09:28	4 PCC1	GLUC3	106 mg/dl	
1/20/2023	09:28	3 PCC2	HDLC4	54 mg/dl	
1/20/2023	09:28	4 PCC1	HDLC4	27 mg/dl	
1/20/2023	09:29	3 PCC2	LDHI2	301 U/L	
1/20/2023	09:29	4 PCC1	LDHI2	177 U/L	
1/20/2023	09:30	3 PCC2	LDLC3	102 mg/dl	c
1/20/2023	09:30	4 PCC1	LDLC3	57 mg/dl	c
1/20/2023	09:33	3 PCC2	TP2	7.73 g/dl	
1/20/2023	09:33	4 PCC1	TP2	4.45 g/dl	
1/20/2023	09:33	3 PCC2	TRIGL	214 mg/dl	
1/20/2023	09:33	4 PCC1	TRIGL	116 mg/dl	
1/20/2023	09:33	3 PCC2	UA2	10.13 mg/dl	
1/20/2023	09:33	4 PCC1	UA2	4.94 mg/dl	
1/20/2023	09:34	3 PCC2	UREL	118 mg/dl	
1/20/2023	09:34	4 PCC1	UREL	38 mg/dl	
1/20/2023	09:35	4 PCC1	ALP2L	93 U/L	
1/20/2023	09:35	3 PCC2	CA2	13.71 mg/dl	
1/20/2023	09:35	3 PCC2	GGTI2	220 U/L	

All QC are acceptable

D. Solan.  
20.01.23

Dr. Umeshi Saini, MD (Path)  
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Uruchi Phase-II, Ambikapur Sarani  
City Centre, Durgapur-713213