



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

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

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

Photometer Check

31/05/24

17:

-----PREVIOUS DATA-----

DATE 31/05/24 17:01

340 nm	65535
376 nm	65535
415 nm	65535
450 nm	65535
480 nm	65535
505 nm	65535
546 nm	65535
570 nm	65535
600 nm	65535
660 nm	65535
700 nm	65535
800 nm	65535

-----CURRENT DATA-----

DATE 31/05/24 17:14

340 nm	11406
376 nm	9454
415 nm	9747
450 nm	8959
480 nm	8728
505 nm	8692
546 nm	8635
570 nm	8766
600 nm	8781
660 nm	8771
700 nm	8770
800 nm	9116

----- ABNORMAL CELL LIST -----

31/05/24 17:18		----- WAVELENGTH (nm) -----										
CELL NO.	340	376	415	450	480	505	546	570	600	660	700	800
001	11408	9453	9749	8961	8729	8693	8635	8767	8781	8769	8768	9113
002	11406	9450	9746	8960	8729	8693	8635	8766	8780	8769	8767	9105
003	11420	9461	9754	8963	8727	8688	8627	8757	8771	8764	8766	9108
004	11414	9460	9753	8966	8737	8701	8648	8783	8801	8791	8792	9125
005	11410	9457	9752	8964	8733	8698	8644	8777	8795	8786	8787	9123
006	11413	9454	9750	8962	8730	8693	8634	8766	8781	8772	8773	9112
007	11418	9461	9757	8969	8738	8702	8648	8781	8798	8789	8789	9126
008	11416	9458	9751	8964	8731	8695	8636	8767	8781	8771	8771	9108
009	11421	9466	9755	8969	8739	8702	8645	8774	8784	8772	8769	9101
010	11412	9457	9753	8966	8735	8698	8642	8772	8785	8774	8772	9109
011	11412	9467	9757	8968	8737	8701	8648	8782	8800	8790	8791	9125
012	11411	9455	9752	8964	8731	8696	8639	8770	8783	8772	8771	9109
013	11407	9448	9746	8960	8729	8693	8635	8767	8781	8770	8767	9106
014	11417	9458	9750	8960	8725	8686	8627	8756	8771	8764	8765	9108
015	11414	9460	9753	8965	8735	8699	8647	8782	8800	8791	8792	9126
016	11414	9457	9754	8966	8734	8699	8645	8778	8796	8787	8789	9124
017	11410	9450	9746	8960	8727	8692	8633	8765	8781	8772	8772	9112
018	11417	9460	9755	8967	8737	8701	8647	8780	8798	8789	8790	9126
019	11419	9458	9752	8965	8732	8695	8637	8769	8783	8773	8774	9111
020	11421	9464	9754	8969	8739	8704	8647	8777	8789	8775	8772	9105
021	11415	9456	9753	8966	8736	8699	8643	8774	8788	8777	8775	9114
022	11413	9464	9757	8967	8737	8701	8647	8782	8800	8791	8791	9126
023	11410	9455	9751	8963	8731	8696	8639	8769	8783	8772	8771	9110
024	11407	9448	9746	8961	8729	8694	8637	8768	8783	8772	8772	9112
025	11415	9457	9752	8962	8727	8689	8630	8761	8776	8769	8769	9113
026	11415	9462	9754	8967	8738	8703	8649	8784	8802	8793	8794	9130
027	11410	9456	9753	8964	8732	8698	8644	8777	8796	8788	8789	9125
028	11409	9451	9747	8961	8729	8693	8634	8766	8782	8774	8774	9115
029	11411	9456	9753	8964	8734	8699	8644	8778	8796	8788	8789	9127
030	11416	9457	9752	8965	8733	8696	8637	8769	8782	8774	8774	9113
031	11420	9464	9754	8969	8739	8703	8647	8777	8789	8775	8773	9107
032	11412	9453	9751	8964	8733	8697	8641	8772	8786	8774	8774	9113
033	11414	9466	9759	8970	8739	8703	8649	8784	8802	8793	8794	9129
034	11413	9458	9754	8966	8735	8698	8640	8771	8784	8773	8772	9113
035	11406	9449	9746	8960	8728	8693	8635	8766	8780	8769	8766	9108
036	11416	9459	9752	8961	8725	8686	8627	8757	8771	8765	8765	9112
037	11418	9465	9758	8969	8740	8704	8651	8785	8804	8794	8796	9133
038	11410	9456	9752	8964	8732	8697	8643	8777	8795	8787	8788	9127
039	11410	9451	9747	8959	8727	8690	8632	8764	8779	8771	8771	9112
040	11410	9456	9753	8964	8734	8698	8645	8779	8796	8788	8789	9128
041	11415	9459	9752	8965	8731	8695	8636	8768	8781	8771	8771	9111
042	11433	9478	9767	8979	8748	8712	8655	8784	8798	8782	8779	9115
043	11413	9456	9752	8965	8734	8698	8642	8773	8787	8775	8773	9114
044	11417	9471	9764	8973	8742	8706	8653	8787	8804	8796	8797	9134
045	11431	9475	9767	8977	8746	8708	8650	8782	8796	8782	8780	9122
046	11410	9454	9748	8961	8729	8693	8636	8767	8782	8771	8769	9110
047	11415	9457	9751	8959	8724	8686	8625	8756	8771	8764	8765	9112
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064	11416	9461	9751	8966	8736	8701	8644	8775	8787	8773	8772	9108
065	11410	9453	9749	8963	8731	8695	8640	8771	8785	8774	8773	9115

Roche Diagnostics India Pvt. Ltd.
Field Service Report



Case number CAS-0019594500

Order Number WO-26808390 | Ser. Report Created Date 31/05/2024

Instrument Details	Customer details
Instrument/Module cobas e 411	Customer Number 0052072954
Serial Number 1432-11	Customer Name Tirupati Diagnostic Center
Internal Instrument Name	Street Address R.B.Ghosh Road
	Zip 713101 - BURDWAN
Additional Details	Contact Name Pallavi Maji
	Contact Phone +919434019277

Service Activity Code PM Visit (Interim)

Purpose of Visit

Interim PM visit of Cobas e411

Performed Activities

Interim PM done as per procedure.

PM kit replaced.

Dusting done. Lubricated all the mechanical units.

Wash stations, pump filter cleaned.

Maintenance performed.

Run QC.

QC values are within range.

Working satisfactorily.

Time Report

Category	Start	End	Hours	Invoice Type
05913616001-Service labour time	31/05/2024 11:34	31/05/2024 13:33	1.98	Free of Charge

Travel

Category	Hours
Travel	4.32

Spare Parts

Part Number	Description	Quantity	Invoice Type
07938071001-KIT MAINTENANCE E2010 / E411 6 MONTHS	KIT MAINTENANCE E2010 / E411 6 MONTHS	1	Free of Charge

Signature

Customer Signature
Pallavi Maji

Roche support
Abhijit Guria - Reactive

Sign Here



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

Roche Diagnostics India Pvt. Ltd.
Field Service Report



Case number CAS-0019594500

Order Number WO-26808390 | Ser. Report Created Date 31/05/2024

Instrument Details

Instrument/Module cobas e 411

Serial Number 1432-11

Internal Instrument Name

Additional Details

Customer details

Customer Number 0052072954

Customer Name Tirupati Diagnostic Center

Street Address R.B.Ghosh Road

Zip 713101 - BURDWAN

Contact Name Pallavi Maji

Contact Phone +919434019277

Service Activity Code PM Visit (Interim)

Purpose of Visit

Interim PM visit of Cobas e411

Performed Activities

Interim PM done as per procedure.

PM kit replaced.

Dusting done. Lubricated all the mechanical units.

Wash stations, pump filter cleaned.

Maintenance performed.

Run QC.

QC values are within range.

Working satisfactorily.

Time Report

Category	Start	End	Hours	Invoice Type
05913616001-Service labour time	08/06/2024 14:05	08/06/2024 14:21	0.27	Free of Charge

Customer Parts Used

Part Number	Description	Quantity
07938071001-KIT MAINTENANCE E2010 / E411 6 MONTHS	KIT MAINTENANCE E2010 / E411 6 MONTHS	1

Signature

Customer Signature
Pallavi Maji

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Service Report Version Number: 1

Thank You



Case number: CAS-0019595357

Order Number: WO-26809984 | Ser. Report Created Date: 31/05/2024

Instrument Details

Instrument/Module: cobas c 311
Serial Number: 16F3-03

Customer details

Customer Number: 0052072954
Customer Name: Tirupati Diagnostic Center
Street Address: R.B.Ghosh Road
Zip: 713101 - BURDWAN

Checklist Details

CHECKLIST RESULT FOR cobas c 311 PM Checklist

Section - Warning

QUESTION	ANSWER
Warning: Incorrect results or damage to the instrument due to non-compliance of maintenance intervals. Always follow the recommended procedures and service intervals	Please confirm that you have read the warning note.

Section - Sample pipetting mechanism

QUESTION	ANSWER
Dirt on nozzle, clogging, amount of discharged rinse water	Yes
Dirt on nozzle rinse and drying cylinder, amount of discharged rinse water	Yes
Dirt on PI	Yes
Dirt on tube, deterioration, looseness of nipple	Yes
Stop-descent positions on cell, sampling, detergent bottle sides	Yes
Abnormal descent sensing operation	Yes
Greasing on shaft	Yes
Pressure sensor for clogging detection	Yes
Action status during operation	Yes

Section - Reagent pipetting mechanism

QUESTION	ANSWER
Dirt on nozzle, clogging, amount of discharged rinse water	Yes
Dirt on nozzle rinse and drying cylinder, amount of discharged rinse water	Yes
Dirt on PI	Yes
Dirt on tube, deterioration, looseness of nipple	Yes
Stop-descent positions on cell, reagent, ISE bottle sides	Yes
Dirt on PI for HP, upper dead point	Yes
Abnormal descent sensing operation	Yes
Greasing on shaft: linear bearing in X, Z directions	Yes
Check of pressure sensor for blank aspiration	Yes
Action status during operation	Yes

Section - Piercer mechanism

QUESTION	ANSWER
Dirt on piercer, deterioration	Yes
Piercer operation (c-pack loading oper)	Yes

Section - Reagent disk

QUESTION	ANSWER
Dirt on PI	Yes
Dirt on cassette sensor	Yes
Shutter opening/closing, solenoid operation	Yes
BCR reading operation	Yes

Section - Reaction disk

QUESTION	ANSWER
Dirt on incubator drain filter, clogging	Clean (once per month)
Dirt on reaction cell, scratches, crack	Replace (every three months)
Dirt on transmission window of incubator bath	Clean (once per month)
Water level and circulation of incubator bath	Yes
Measuring incubator bath water temperature	Yes
Cleaning of waste solution filter of incubator bath	Clean (once per month)
Dirt on PI for HP, cell counter and ADC	Yes
Dirt on liquid level sensor	Yes

Section - Sample disk

QUESTION	ANSWER
Dirt on PI	Yes
Dirt on CUP sensor	Yes
BCR reading operation, scratches	Yes

Section - Ultrasonic mixing mechanism

QUESTION	ANSWER
Dirt on ultrasonic mixing mechanism	Clean at least once per year
Checking ultrasonic output	Yes
Cell stop positions	Yes

Section - Rinse mechanism

QUESTION	ANSWER
Dirt on vacuum bin	Yes
Nozzle descent position	Yes
Amount of rinse water and detergent discharged into cell	Yes
Wear of the tubes and cracks in the rinse arm	Yes
Dirt on nozzle tube, chapped	Replace every two months
Dirt on nozzle, damaged	Yes
Dirt on vacuum tank	Yes
Aspiration status of overflowed water	Yes
Dirt on PI	Yes
Leak from detergent check valve, filter clogged	Clean (once per month), Check

Section - Pipetter mechanism (S, R, SIP)

QUESTION	ANSWER
Pipetter seal piece	Replace every two months
Mixing of air, water leak (looseness of nipple)	Yes
Dirt on PI	Yes
Bearing operation status	Yes

Section - Cooling unit

QUESTION	ANSWER
Cooling status	Yes
Circulating pump status	Yes

Dirt on connecting tube, deterioration	Yes
Condensed water receptacle status	Yes
Cooling air leaked status (duct, reagent disk cover, shutter)	Yes

Section - Photometer

QUESTION	ANSWER
Deterioration of photometer lamp	Yes
Dirt on sensor side window	Yes
Dirt on heat ray cut filter lens	Replace every two months
Dirt on lens	Yes
Circulation of photometer lamp cooling water	Yes
Cell blank value	Yes
Photometer check	Yes

Section - Vacuum system

QUESTION	ANSWER
Vacuum pump (looseness of valve, etc.)	Yes
Vacuum tube status	Yes
Vacuum switch operation status	Yes
Dirt on vacuum tank, deterioration	Yes
Dirt on paper filter	Replace every two months

Section - Water supply/ drainage system

QUESTION	ANSWER
Water supply pressure: 80-100kPa	Yes
Applied water pressure: Max. 300kPa	Yes
Dirt on drain tube, deterioration	Yes
Water supply pump status	Yes

Section - Electrical system

QUESTION	ANSWER
Connection of PCB connectors	Yes
Fan operation status (dirt)	Yes
Thermal sensor status	Yes
AC/DC voltage check	Yes

Section - Miscellaneous

QUESTION	ANSWER
Coating each mechanism with grease	Yes
Cleaning of cell rinse container, tube	Yes

Section - ISE Unit - Sipper Nozzle Mechanism

QUESTION	ANSWER
Dirt, clogging, deterioration of nozzle and flow path	No
Dirt on PI	No
Mixing of air into flow path	No
Descent position into cell	No
Thermostatic bath temperature/incubator bath water circulation status (mixing of air)	No
Action status during operation	No
Deterioration of electrode Na or 9000 samples	
Deterioration of electrode K or 9000 samples	
Deterioration of electrode Cl(Green) or 9000 samples	
Deterioration of electrode Ref 6 month	No
Electrode lead status	No

Leak from solenoid valves	No
Deterioration of aspiration tube	
Deterioration of sipper tube	
Solenoid valve operation	No

Signature

Customer Signature
Pallavi Maji

Roche support
Abhijit Guria - Reactive




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Service Report Version Number: 1

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Field Service Report



Case number CAS-0019595357

Order Number WO-26809984 | Ser. Report Created Date 31/05/2024

Instrument Details	Customer details
Instrument/Module cobas c 311	Customer Number 0052072954
Serial Number 16F3-03	Customer Name Tirupati Diagnostic Center
Internal Instrument Name	Street Address R.B.Ghosh Road
	Zip 713101 - BURDWAN
Additional Details	Contact Name Pallavi Maji
	Contact Phone +919434019277

Service Activity Code PM Visit

Purpose of Visit

PM visit of Cobas c311

Performed Activities

PM done as per procedure.

PM kits replaced.

Performed Incubator water exchange, cell blank measurement, photometer check and found ok.

Run QC.

QC values are within range.

Time Report

Category	Start	End	Hours	Invoice Type
05913616001-Service labour time	31/05/2024 14:00	31/05/2024 18:30	4.50	Free of Charge

Travel

Category	Hours
Travel	0.25

Customer Parts Used

Part Number	Description	Quantity
05182522001-KIT MAINTENANCE 6 MONTHS COBAS C311	KIT MAINTENANCE 6 MONTHS COBAS C311	1
05182549001-KIT MAINTENANCE 1 YEAR COBAS C311	KIT MAINTENANCE 1 YEAR COBAS C311	1

Signature

Customer Signature
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