



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 of 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, 4. August 2021

Sincerely,

Roche Diagnostics GmbH

i.V. /on behalf of the company

DocuSigned by:

ECAS294AC4E94AF...

Andrea Weber
Manager Global Regulatory Affairs

i.V. /on behalf of the company

DocuSigned by:

7AE1EF68C3F0440...

Stefan Grigarczik
Manager Global Regulatory Affairs

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim

QC Data Monitor

User ID: admin

21/12/2022 09:58

Control Data

21/12/2022 09:58

Q001148 Q30001-1 Lot 515304
21/12/2022 09:43:45 PCCCI

-----Final Data-----

ALB2-G(CC)

ALP2(CC)

ALTp(CC)

Ser/Pl	Current	Ser/Pl	Current	Ser/Pl	Current
2.94	R1 645910/0002881	89.3	R1 654864/0003338	46.3	R1 661052/0016233
	R2 -----/-----		R2 -----/-----		R2 654893/0001699
	R3 645910/0002881		R3 654864/0003338		R3 661052/0016233

ASTP(CC)

BIID2-J(CC)

BIIN3(CC)

Ser/Pl	Current	Ser/Pl	Current	Ser/Pl	Current
44.6	R1 644916/0007033	0.925	R1 652625/0003205	0.903	R1 622281/0003572
	R2 654893/0001699		R2 652625/0003205		R2 -----/-----
	R3 644916/0007033		R3 -----/-----		R3 622281/0003572

CA2(CC)

CHOL2-I(CC)

CREJ2(CC)

Ser/Pl	Current	Ser/Pl	Current	Ser/Pl	Current
8.96	R1 645917/0001207	90.3	R1 658312/0004409	0.906	R1 627775/0000533
	R2 -----/-----		R2 -----/-----		R2 -----/-----
	R3 645917/0001207		R3 -----/-----		R3 627775/0000533

CRP4(CC)

CRP-HS(CC)

GST2-I(CC)

System: cobas pure

Serial No.:

2266-02

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Ser/Pl	Current	Ser/Pl	Current	Ser/Pl	Current
8.54	mg/L	R1 618926/0001933	9.91	mg/L	R1 597985/0000260
		R2 -----/-----			R2 -----/-----
		R3 618926/0001933			R3 597985/0000260

Ser/Pl	Current	Ser/Pl	Current	Ser/Pl	Current
GGT2-I (CC)		GLUC3 (CC)		HDLc4 (CC)	
Ser/Pl	SBI	Ser/Pl	Current	Ser/Pl	Current
53.9	U/L	R1 653840/0006265	104	mg/dL	R1 629487/0003088
		R2 -----/-----			R2 -----/-----
		R3 653840/0006265			R3 629487/0003088

Ser/Pl	Current	Ser/Pl	Current	Ser/Pl	Current
IRON2 (CC)		ISE CL (ISE)		ISE R (ISE)	
Ser/Pl	Current	Ser/Pl	Current	Ser/Pl	Current
101	µg/dL	R1 641946/0000645	83.8	mmol/L	IS 644054/0003950
		R2 -----/-----			DIL 612531/0011551
		R3 641946/0000645			REF 661046/0005061
					E1e S8151: V9558

Ser/Pl	Current	Ser/Pl	Current	Ser/Pl	Current
ISE NA (ISE)		LDLC3 (CC)		PHOS2 (CC)	
Ser/Pl	Current	Ser/Pl	Current	Ser/Pl	Current
113.1	mmol/L	IS 644054/0003950	56.1	mg/dL	R1 590647/0003554
		DIL 612531/0011551			R2 -----/-----
		REF 661046/0005061			R3 590647/0003554
		E1e Y8596: V9558			R3 653804/0005055

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PHOS2 (CC)			TP2 (CC)			TRIGL (CC)		
Ser/Pl	mg/dL	SBI	Ser/Pl	g/dL	Current	Ser/Pl	mg/dL	Current
4.29		R1 653804/0005041	4.48		R1 653836/0008868	116		R1 661743/0005556
		R2 -----/-----			R2 -----/-----			R2 -----/-----
		R3 653804/0005041			R3 653836/0008868			R3 -----/-----

UA2 (CC)			UIBC-I (CC)			UIBC-I (CC)		
Ser/Pl	mg/dL	Current	Ser/Pl	µg/dL	Current	Ser/Pl	µg/dL	SBI
4.58		R1 641760/0002386	221		R1 637859/0015129	221		R1 637859/0015114
		R2 -----/-----			R2 -----/-----			R2 -----/-----
		R3 641760/0002386			R3 637859/0015129			R3 637859/0015114

UREAL (CC)		
Ser/Pl	mg/dL	Current
38.6		R1 651528/0007553
		R2 -----/-----
		R3 651528/0007553

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21/12/2022 10:03

Ser./Pl	Current	Ser./Pl	SBI	Ser./Pl	Current
244	R1 653840/0005104	246	R1 653840/0006265	246	R1 629487/0003088
	R2 -----/-----		R2 -----/-----		R2 -----/-----
	R3 653840/0005104		R3 653840/0006265		R3 629487/0003088

HDLC4 (CC)		IRON2 (CC)		ISE CL (ISE)	
Ser./Pl	Current	Ser./Pl	Current	Ser./Pl	Current
55.1	R1 626113/0006754	233	R1 641946/0000645	102.6	R1 644054/0003950
	R2 -----/-----		R2 -----/-----		R2 DIL 612531/0011551
	R3 626113/0006754		R3 641946/0000645		R3 REF 661046/0005061
					Ele S8151: V9558

ISE K (ISE)		ISE NA (ISE)		IDL C3 (CC)	
Ser./Pl	Current	Ser./Pl	Current	Ser./Pl	Current
7.27	IS 644054/0003950	136.2	IS 644054/0003950	99.4	R1 590647/0003554
	DIL 612531/0011551		DIL 612531/0011551		R2 -----/-----
	REF 661046/0005061		REF 661046/0005061		R3 590647/0003554
	Ele I2852: V9558		Ele Y8596: V9558		

PHOS2 (CC)		PHOS2 (CC)		TP2 (CC)	
Ser./Pl	Current	Ser./Pl	SBI	Ser./Pl	Current
8.29	R1 653804/0005055	8.27	R1 653804/0005041	7.65	R1 653836/0008868
	R2 -----/-----		R2 -----/-----		R2 -----/-----
	R3 653804/0005055		R3 653804/0005041		R3 653836/0008868

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St. John

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21/12/2022 10:03

TRIGL (CC)		Current		UA2 (CC)		Current		UIBC-I (CC)		Current	
Ser/Pl	mg/dL	R1	R2	Ser/Pl	mg/dL	R1	R2	Ser/Pl	µg/dL	R1	R2
212		661743/0005556	-----/-----	9.63		641760/0002386	-----/-----	282		637859/0015129	-----/-----
		R3	-----/-----			R3	641760/0002386			R3	637859/0015129

UIBC-I (CC)		SBI		UREAL (CC)		Current	
Ser/Pl	µg/dL	R1	R2	Ser/Pl	mg/dL	R1	R2
282		637859/0015114	-----/-----	114		651528/0007553	-----/-----
		R2	-----/-----			R2	-----/-----
		R3	637859/0015114			R3	651528/0007553

J. J. J.

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2266-02