Roche

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.

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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, 4. August 2021

Sincerely,

Roche Diagnostics GmbH

i.V./*on behalf of the company*

DocuSigned by:
ECA5294AC4E94AF...

Andrea Weber
Manager Global Regulatory Affairs

i.V./*on behalf of the company*

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Stefan Grigarczik
Manager Global Regulatory Affairs

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim

C001018 089 LOT 26491 BIORAD 1

05/09/22 09:19:41 ADMIN	ALB	ASTL	GLUC3	TRIGL	TP2
	4.46	30.0	78.3	212.4	6.66
	CA2	AMYL2	PHOS2	HDLC4	CHO2I
	9.2	83	3.88	50.5	267.9
	GGTI2	UIBCI	UREAL	LDLC3	UA2
	64.4	59.3	33.9	135.3	4.7
	BILT3	BILD2	CREJ2	ALTL	ALP2L
	0.714	0.354	1.68	21.0L	97
	IRON2				
	254.37				

05/09/22

Data Monitor 05/09/22 17:51

C001018 089 LOT 26491 BIORAD 1

	Na	K	Cl
05/09/22 09:19:41 ADMIN	146	4.01	104.5

05/09/22

	C0C2018 090	LOT 26492	BIORAD 2		
05/09/22	ALB	ASTL	GLUC3	TR.GL	TP2
09:19:41	2.72	171.8	272.4	109.4	4.31
ADMIN					
	CA2	PHOS2	HDLC4	CHO2I	GGT2
	12.0	7.87	17.0	112.7	169.5
	UIBCI	UREAL	LDLC3	UA2	BILT3
	128.3	100.1	64.0	9.3	3.505
	BILD2	CREJ2	ALTL	ALPTL	IRON2
	1.441	4.75	87.9	393	65.16

05/9/22

Data Monitor 05/09/22 17:51

C002018 C90 LOT 26492 BIORAD 2

	Na	K	Cl
05/09/22 09:19:41 ADMIN	124	6.14	82.4

05/09/22