



To Whom It May Concern

For ISO 15189:2012 and ISO 15189:2014 accredited Laboratories — requirements regarding "Calibration & Verification Procedures" [1]

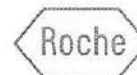
All In vitro Diagnostics Products which are manufactured and distributed by Roche Diagnostics GmbH and for which a Free-Sales-Certificate is issued, are CE-marked.

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:

ECA5294AC4E94AF

Andrea Weber
Manager Global Regulatory Affairs

i.V. /on behalf of the company

DocuSigned by:

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Stefan Grigarczik
Manager Global Regulatory Affairs

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Sandhofer Straße 116
D-68305 Mannheim

Data Monitor

05/09/22 17:49

05/09/22	CO01018 089	LOT 26491	BIORAD 1		
09:19:41	ALB	ASTL	GLUC3	TRIGL	TP2
ADMIN	4.46	30.0	70.3	212.4	6.66
	CA2	AMYL2	PHOS2	HDLCA	CHO21
	9.2	83	3.88	50.5	267.9
	GGT12	GIBCI	UREAL	LDLC3	UA2
	64.4	59.3	33.9	135.3	4.7
	BILT3	BILD2	CREJ2	ALPL	ALP2L
	0.714	0.354	1.88	21.0L	97
	IRON2				
	254.37				

05/09/22
[Signature]

Data Monitor

05/09/22 17:51

C001018 089
05/09/22 Na
09:19:41 146
ADMIN

LOT 26491 BIORAD 1
K C1
4.01 104.5

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Data Monitor

05/09/22 17:49

C062018 090	LOT 26492	BIORAD 2		
05/09/22	ASTL	GLUC3	TRIGL	TP2
09:19:41	171.8	272.4	109.4	4.31
ADMIN				
CA2	PHOS2	HDLG4	CHO2I	GGT12
12.0	7.87	17.0	112.7	169.5
UIBC1	UREAL	LDL3	UA2	BILTB
128.3	100.1	64.0	9.3	3.505
BILD2	CREJ2	ALTL	ALP1L	IRON2
1.441	4.75	87.9	275	65.16

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Date Monitor

05/09/22 17:51

C002018 C90
05/09/22 Na
09:19:41 124
ADMIN

LOT 26492
K
6.14

BIORAD 2
C1
82.4

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