



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 [2] requires for all CE marked products that the manufacturer assures compliance of the products with the requirements of the In-Vitro-Diagnostics Directive. 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 13485:2012 [3] + AC:2012 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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- [1] ISO 15189:2012/ ISO 15189:2014 Medical laboratories – Requirements for quality and competence
- [2] Directive 98/79/EC of the European Parliament and of the Council of the 27 October 1998 on vitro diagnostics medical devices
- [3] EN ISO 13485:2012 + AC:2012 Medical devices – Quality management systems-Requirements for regulatory purposes
- [4] CFR Part 820, Quality System regulations 21 Requirements on medical devices

Check Pipetting Accuracy:

Place sample '@CHK' on the instrument.
Created 16 CHECK test orders in sample order '@CHK'.

Cuvette segment is moved to handling position 1.

Insert first cuvette segment, then click OK.

Cuvette segment is moved to handling position 2.

Insert second cuvette segment and close the main cover, then click OK.

System changes to operating and runs CHECK tests. Wait for completion.

of results = 16, Mean = 1.31547Abs

SD = 0.0082379, CV = 0.626231%

Diagnostic action completed.

Order Details:

Sample ID	@CHK
Order ID	@CHK
Order state	All processed
Sample state	Done

S	Test	Flag	Result
!	CHECK		1.3425Abs
!	CHECK		1.3108Abs
!	CHECK		1.3126Abs
!	CHECK		1.3108Abs
!	CHECK		1.3175Abs
!	CHECK		1.3151Abs
!	CHECK		1.3139Abs
!	CHECK		1.3089Abs
!	CHECK		1.3053Abs
!	CHECK		1.3103Abs
!	CHECK		1.3160Abs
!	CHECK		1.3172Abs
!	CHECK		1.3184Abs
!	CHECK		1.3147Abs
!	CHECK		1.3122Abs
!	CHECK		1.3212Abs

c111
admin

V4.3.0.1835

20421

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Abs. Air/Water Calibration:

Abs. Air/Water Calibration.

Cuvette segment is moved to handling position 1.

Insert an empty cuvette segment, then press <OK>.

Cuvette segment is moved to handling position 2.

Insert an empty cuvette segment, close the cover, then press <OK>.

Starting the calibration.

Waiting for completion.

Maintenance action complete.

Wavelength	H2O	H2O cuvette
340	-0.0003	0.0835
378	-0.0003	0.0778
409	0.0006	0.0759
449	0.0026	0.0764
480	0.0044	0.0772
512	0.0059	0.0782
520	0.0062	0.0783
552	0.0075	0.0792
583	0.0084	0.0802
629	0.0095	0.0812
652	0.0099	0.0817
659	0.0101	0.0819

Outlier statistics:

Air : 0

Water : 0

Diff : 0

Total : 0

Press <OK> to use these values.

Then press <Cuvettes> and exchange the two segments.

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Calibration Details:

Test UREL
Use Current
Type Lot
Status Accepted
Calibrator name CFAS
Lot ID 56494200
Expiration date 31.12.2023
Accepted by \$SYS\$, 04.02.2024 6:18 A
Creation time 04.02.2024 6:18 AM
Flags
RO 0.00110315
F 117.101

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Calibration Details:

Test TRIGL
Use Current
Type Lot
Status Accepted
Calibrator name CFAS
Lot ID 56494200
Expiration date 31.12.2023
Accepted by \$SYS\$, 10.02.2024 9:06 A
Creation time 10.02.2024 9:06 AM
Flags
RO -3.00044E-5
F 16.116

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admin 10.02.2024 6:32 PM

Calibration Details:

Test TP2H
Use Standby
Type Set
Status Accepted
Calibrator name CFAS
Lot ID 56494200
Expiration date 31.12.2023
Accepted by \$SYS\$, 06.02.2024 6:58 A
Creation time 06.02.2024 6:46 AM
Flags
RO 0.0231553
F 664.727

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Calibration Details:

Test CH02I
Use Current
Type Lot
Status Accepted
Calibrator name CFAS
Lot ID 56494200
Expiration date 31.12.2023
Accepted by \$SYS\$, 07.02.2024 10:39
Creation time 07.02.2024 10:39 AM
Flags
RO -0.000710215
F 22.4979

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admin 10.02.2024 6:26 PM

Calibration Details:

Test CREJ2
Use Standby
Type Lot
Status Accepted
Calibrator name CFAS
Lot ID 56494200
Expiration date 31.12.2023
Accepted by \$SYS\$, 19.01.2024 6:51 A
Creation time 19.01.2024 6:51 AM
Flags
RO -0.000109172
F 26748.8

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Calibration Details:

Test GLU2
Use Current
Type Lot
Status Accepted
Calibrator name CFAS
Lot ID 56494200
Expiration date 31.12.2023
Accepted by \$SYS\$, 09.02.2024 10:09
Creation time 09.02.2024 10:09 AM
Flags
RO 0.00121881
F 33.0047

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Calibration Details:

Test ALB2
Use Standby
Type Lot
Status Accepted
Calibrator name CFAS
Lot ID 56494200
Expiration date 31.12.2023
Accepted by \$SYS\$, 03.02.2024 12:03
Creation time 03.02.2024 12:03 PM
Flags
RO -0.0907178
F 405.233

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admin 10.02.2024 6:24 PM

Calibration Details:

Test BILT3
Use Standby
Type Lot
Status Accepted
Calibrator name CFAS
Lot ID 56494200
Expiration date 31.12.2023
Accepted by \$SYS\$, 18.11.2023 10:22
Creation time 18.11.2023 10:22 AM
Flags
RO 0.000400005
F 4144.58

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Calibration Details:

Test UA2
Use Current
Type Lot
Status Accepted
Calibrator name CFAS
Lot ID 56494200
Expiration date 31.12.2023
Accepted by \$SYS\$, 04.02.2024 6:17 A
Creation time 04.02.2024 6:17 AM
Flags
RO 0.000311939
F 6189.69

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admin 16.02.2024 7:02 AM

Get Measure Diagnostics Values:

Sending command to get measure diagnostics values.
Waiting for completion.

100% Air Pos. 1:
1: 4248 2: 5121 3: 5819
4: 5397 5: 5852 6: 5383
7: 5394 8: 5977 9: 5620
10: 5610 11: 5010 12: 4677

100% Air Pos. 2:
1: 4247 2: 5120 3: 5819
4: 5398 5: 5853 6: 5382
7: 5394 8: 5978 9: 5620
10: 5611 11: 5009 12: 4677

100% Air Pos. Dark:
1: 253 2: 251 3: 252
4: 252 5: 252 6: 250
7: 251 8: 250 9: 252
10: 253 11: 253 12: 252

Stability: 32768
Variance: 0.589744

Diagnostic action completed.

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Check Abs Measurement:

Cuvette segment is moved to handling position 1.
Insert a cuvette segment, then click OK.
Measuring cuvette ...

1: 83 mAbs
2: 78 mAbs
3: 75 mAbs
4: 74 mAbs
5: 73 mAbs
6: 72 mAbs
7: 72 mAbs
8: 72 mAbs
9: 72 mAbs
10: 72 mAbs
11: 72 mAbs
12: 72 mAbs

Diagnostic action completed.
Remove first segment!