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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	-0.0005	0.0829
378	0.0006	0.0788
409	0.0033	0.0791
449	0.0067	0.0811
480	0.0085	0.0816
512	0.0102	0.0833
520	0.0105	0.0834
552	0.0110	0.0834
583	0.0116	0.0838
629	0.0120	0.0839
652	0.0120	0.0841
659	0.0118	0.0840

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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Initialize Degasser Fluid Sensor:

Insert the tubing adapter, then press <OK>
to prime fluid system.
Priming water system.

Waiting on.
Air: 51 Fluid: 150 Level: 3 State: 0
Maintenance action complete.

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System Status:

Analyzer: OK
Fluid System: Ready
Temperature: Heating OK, Cooling OK
Fan: OK
Degasser Fluid Sensor: OK
Bottles: OK
Maintenance: OK
Printer: OK
Number of DC Applications: 0
Version: 3.0.1.1001
DM: 3.0.1.1001
IC: 3.0.1.1001
DC Slave: 1.00.00.0712
ISE: unknown
Multislave: 1.02.07.0811
Photometer: 3.02.00.1042
Language: 3.0.0.0901
OS: 3.0.0.0903

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Init Photometer:

Sending command to initialize the
photometer.
Waiting for completion.

Cygnal Gain:

1: 4	2: 4	3: 2
4: 2	5: 2	6: 2
7: 2	8: 2	9: 2
10: 2	11: 2	12: 2

Stability:

1: 1	2: 0	3: 1
4: 0	5: 0	6: 0
7: 1	8: 1	9: 2
10: 1	11: 1	12: 1

100% ADC:

1: 1323	2: 1738	3: 1758
4: 1915	5: 2203	6: 2047
7: 2094	8: 2370	9: 2163
10: 2264	11: 1960	12: 1891

Dark ADC Gain 1:

1: 248	2: 252	3: 249
4: 251	5: 253	6: 250
7: 248	8: 253	9: 254
10: 246	11: 247	12: 252

Dark ADC Gain 2:

1: 248	2: 245	3: 252
4: 252	5: 252	6: 249
7: 251	8: 248	9: 252
10: 252	11: 248	12: 249

Dark ADC Gain 4:

1: 251	2: 249	3: 248
4: 252	5: 251	6: 251
7: 251	8: 251	9: 250
10: 252	11: 250	12: 253

Dark ADC Gain 8:

1: 249	2: 251	3: 247
4: 248	5: 250	6: 251
7: 250	8: 249	9: 251
10: 251	11: 251	12: 251

Dark ADC Gain 16:

1: 249	2: 251	3: 251
4: 251	5: 252	6: 253
7: 248	8: 250	9: 250
10: 252	11: 250	12: 251

Dark ADC Gain 32:

1: 251	2: 252	3: 251
4: 251	5: 252	6: 253
7: 249	8: 250	9: 252
10: 246	11: 250	12: 250

Dark ADC Gain 64:

1: 251	2: 252	3: 255
4: 254	5: 252	6: 252
7: 252	8: 254	9: 249
10: 250	11: 249	12: 250

Voltage 15V: 14.866497
Voltage 12V: 11.963465
100% Dynamic: 1245
Dark Dynamic: 248

Diagnostic action completed.

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Check Sensitivity 100% and 0%:

Sending command for measurements.
Waiting for completion.

100% Signal:
1: 1323 2: 1738 3: 1 4: 1915 5: 2
203 6: 2047
7: 2094 8: 2370 9: 2163
10: 2263 11: 1960 12: 1891
Dark ADC Gain 1:
1: 248 2: 252 3: 252
4: 252 5: 252 6: 253
7: 250 8: 250 9: 250
10: 251 11: 251 12: 252
Dark ADC Gain 2:
1: 250 2: 255 3: 252
4: 249 5: 251 6: 249
7: 249 8: 250 9: 250
10: 252 11: 250 12: 252
Dark ADC Gain 4:
1: 249 2: 247 3: 252
4: 250 5: 251 6: 250
7: 252 8: 251 9: 252
10: 252 11: 250 12: 253
Dark ADC Gain 8:
1: 253 2: 248 3: 248
4: 253 5: 251 6: 248
7: 251 8: 250 9: 251
10: 250 11: 251 12: 248
Dark ADC Gain 16:
1: 254 2: 252 3: 252
4: 249 5: 250 6: 248
7: 251 8: 253 9: 251
10: 252 11: 255 12: 249
Dark ADC Gain 32:
1: 252 2: 247 3: 248
4: 250 5: 250 6: 251
7: 252 8: 248 9: 251
10: 251 11: 253 12: 250
Dark ADC Gain 64:
1: 250 2: 253 3: 252
4: 250 5: 247 6: 251
7: 249 8: 248 9: 252
10: 251 11: 250 12: 251

Diagnostic action completed.

To Whom It May Concern

For ISO 15189:2012, ISO 15189:2014 and ISO 15189:2022 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.

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[1] ISO 15189:2012/ ISO 15189:2014/ ISO 15189:2022 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, 7. August 2023

Sincerely,

Roche Diagnostics GmbH

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