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 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.

[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
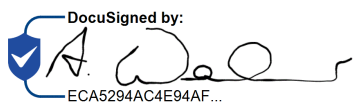
Mannheim, 10. August 2021

Sincerely,

Roche Diagnostics GmbH

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

Andrea Weber   Ralf Zielenski
Manager Global Regulatory Affairs   Head Q&R Compliance, PRRC RDG
Centralised and Point of Care Solutions   Centralised and Point of Care Solutions

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Roche

Operational Qualification for cobas® c311

Notice:

The steps described in OQ.1 have to be carried out after a new system installation and after any repair action which requires additional calibration.

If the service action does not affect the measurement performance, perform only steps OQ.2 and OQ.3 of the Operation Qualification.

Description

OQ.1   Calibration

Calibration of all photometric parameters
successful (attached printout)   yes

Calibration of all ISE parameters successful
(attached printout)   yes

OQ.2   Quality Control

Specify the type of control used:

PCCC1

QC of all photometric parameters within
acceptable range (see attached results)   yes

QC of ISE parameters within acceptable range
(see attached results)   yes

OQ.3.1 Accuracy check for ISE

Perform test with analytical reagents

			Number of det.
Na	ACN	989	15
K	ACN	990	15
Cl	ACN	991	15

Sample solution: PNU (code 300 / Cat. No. 10171735, 10171743, 10651257).
Fill 21 Hitachi cups with PNU (code: 300) and perform Na, K and Cl tests. Calculate the CV.

Accuracy check for ISE was within acceptable range yes

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OQ.3.2 Accuracy check for Photometric Assays

Perform test with analytical reagents

	Number of det.
2-point/end-point Assay	21
Rate A Assay	15

Sample solution: PNU (code 300 / Cat. No. 10171735, 10171743, 10651257).
Fill 21 Hitachi cups with PNU (code: 300) and perform 21 determinations of each parameter.

Accuracy check for Photometric Assays was within
acceptable range   yes

Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

Deviation #1

Investigation

Action taken

Deviation resolved satisfactorily?   specify

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Attachments

TEST	N	MEAN	UNIT	RANGE	MAX.	MIN.	SD	CV(%)
Cl	00015	116.41	mmol/L	1.0	116.9	115.9	0.27	0.23
CREJ2	00015	4.143	mg/dL	0.14	4.23	4.09	0.036	0.88
K	00015	7.721	mmol/L	0.08	7.75	7.67	0.019	0.24
Na	00015	149.3	mmol/L	1	150	149	0.5	0.31

TEST	N	MEAN	UNIT	RANGE	MAX.	MIN.	SD	CV(%)
ASTL	00021	162.24	U/L	2.9	163.8	160.9	0.69	0.43
GLUC3	00021	252.94	mg/dL	2.5	254.1	251.6	0.64	0.25

Ser/Pl   N000014 001   ID Pcheck12
17/12/22   ASTL   GLUC3
17:50:27   162.2   252.3
  bmserv

Ser/Pl   N000015 001   ID Pcheck13
17/12/22   ASTL   GLUC3
17:50:51   163.4   253.2
  bmserv

Ser/Pl   N000016 001   ID Pcheck14
17/12/22   ASTL   GLUC3
17:51:15   162.6   253.3
  bmserv

Ser/Pl   N000017 001   ID Pcheck15
17/12/22   ASTL   GLUC3
17:51:39   162.4   253.6
  bmserv

Ser/Pl   N000018 001   ID Pcheck16
17/12/22   ASTL   GLUC3
17:52:03   162.8   252.9
  bmserv

Ser/Pl   N000019 001   ID Pcheck17
17/12/22   ASTL   GLUC3
17:52:27   163.8   253.2
  bmserv

Ser/Pl   N000020 001   ID Pcheck18
17/12/22   ASTL   GLUC3
17:52:51   162.8   254.1
  bmserv

Ser/Pl   N000021 001   ID Pcheck19
17/12/22   ASTL   GLUC3
17:53:15   162.6   253.7
  bmserv

Ser/Pl   N000022 001   ID Pcheck20
17/12/22   ASTL   GLUC3
17:53:39   162.9   252.6
  bmserv

Ser/Pl   N000023 001   ID Pcheck21
17/12/22   ASTL   GLUC3
17:54:03   162.2   253.4
  bmserv

Ser/Pl   N000003 001   ID Pcheck1
17/12/22   ASTL   GLUC3
17:46:51   160.9   252.8
   bmserv

Ser/Pl   N000004 001   ID Pcheck2
17/12/22   ASTL   GLUC3
17:47:09   161.6   252.3
   bmserv

Ser/Pl   N000005 001   ID Pcheck3
17/12/22   ASTL   GLUC3
17:47:28   161.7   253.1
   bmserv

Ser/Pl   N000006 001   ID Pcheck4
17/12/22   ASTL   GLUC3
17:47:47   161.9   251.6
   bmserv

Ser/Pl   N000007 001   ID Pcheck5
17/12/22   ASTL   GLUC3
17:48:06   161.4   252.1
   bmserv

Ser/Pl   N000008 001   ID Pcheck6
17/12/22   ASTL   GLUC3
17:48:25   161.3   252.6
   bmserv

Ser/Pl   N000009 001   ID Pcheck7
17/12/22   ASTL   GLUC3
17:48:45   162.1   252.4
   bmserv

Ser/Pl   N000010 001   ID Pcheck8
17/12/22   ASTL   GLUC3
17:49:03   162.1   253.3
   bmserv

Ser/Pl   N000011 001   ID Pcheck9
17/12/22   ASTL   GLUC3
17:49:22   161.8   252.2
   bmserv

Ser/Pl   N000012 001   ID Pcheck10
17/12/22   ASTL   GLUC3
17:49:41   162.2   253.6
   bmserv

Ser/Pl   N000013 001   ID Pcheck11
17/12/22   ASTL   GLUC3
17:50:03   162.3   253.5
   bmserv

        C004026 097   LOT 62690000   RFCO2
19/09/23   RF-II
08:35:20   51.4
   bmserv

```
        C009026 094        LOT 52520500        PCCC1
19/09/23      ALB2          ALP2L             AMYL2          ASTL          DBIL2
08:35:20      3.14            89                63           46.0          0.820
  bmserv                                      ReagEX

              BILT3          CA2             CHO21          CREJ2          GGTI2
              1.008          8.81            94.4           0.98            58

              GLUC3          LIP             LDHI2           TP2           TRIGL
              106.6          46.7             172           4.91          117.5

              UA2            UREAL           PHOS2          LDLC3          IRON2
              4.8            41.5            3.65           54.0           110.41

              CRP4           UIBCI           ALTL           HDLC4
              5.93           205.0           47.9           27.0
```

C010026 095	LOT 53571900	PCCC2		
19/09/23 ALB2	ALP2L	AMYL2	ASTL	DBIL2
08:35:20 4.96	259	270	148.3	2.198
bmserv		ReagEX		
BILT3	CA2	CHO2I	CREJ2	GGTI2
3.654	14.17	169.3	3.73	222
GLUC3	LIP	LDHI2	TP2	TRIGL
252.3	101.8	315	7.66	222.6
UA2	UREAL	PHOS2	LDLC3	IRON2
10.1	121.4	8.35	92.4	245.63
CRP4	UIBCI	ALTL	HDLC4	
53.72	254.3	127.6	55.0	

```
        C010027 095      LOT 53571900        PCCC2
19/09/23          Na           K            Cl
09:05:20          143          7.31         106.0
    bmserv
```

```
        C010029 095      LOT 53571900        PCCC2
19/09/23           Na          K             Cl
10:13:28           142         7.44          107.7
  bmserv
```