



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.

Mannheim, 18 December 2017

Roche Diagnostics GmbH

Roche Diagnostics GmbH

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i.V. Andrea Weber
Project Manager Regulatory Affairs

ppa. Dr. Beate Bonefeld
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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



HITACHI

Sample Results Report

User ID: REDCLIFFE

02/11/2022 16:45

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot	User ID	Registered
Q001023	Q30001-1	Name / Lot: PCCC1 / 525027	REDCLIFFE	02/11/2022 08:44:44

Test	Unit	Sample Type	Result	Data	Alarm	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
ALB2-G	g/dL	Ser/PI	3.36			CC	Current	R1-R3 608713	0003128	
ALP2	U/L	Ser/PI	99.2			CC	Current	R1-R3 638132	0006144	
ALTP	U/L	Ser/PI	47.2			CC	Current	R1-R3 645075 R2 654893	0010272 0002698	
ALTP	U/L	Ser/PI	46.9			CC	SB1	R1-R3 645075 R2 654893	0010291 0002698	
AMYL2	U/L	Ser/PI	104	QCErr		CC	Current	R1-R3 606164	0000131	

Handwritten signatures

System: cobas pure

Serial No.: 2148-03

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Sample Results Report

User ID: REDCLIFFE

02/11/2022 16:45

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot	Registered
Q001023	Q30001-1	Name / Lot: PCCC1 / S25027	User ID: REDCLIFFE 02/11/2022 08:44:44

Test	Unit	Sample Type	Result	Data	Alarm	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message										
ASTP	U/L	Ser/PI	46.6			CC	Current	R1-R3 R2	644916 654893	0012464 0002698
BILD2-J	mg/dL	Ser/PI	0.883			CC	Current	R1-R2	638375	0001745
BILT3	mg/dL	Ser/PI	0.896			CC	Current	R1-R3	600237	0005507
BILT3	mg/dL	Ser/PI	0.832			CC	S81	R1-R3	600237	0003379
CA2	mg/dL	Ser/PI	9.06			CC	Current	R1-R3	622620	0001788
CHOL2-A	mg/dL	Ser/PI	106			CC	Current	R1	616068	0001279
CREJ2	mg/dL	Ser/PI	1.04			CC	Current	R1-R3	627775	0003636

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System: cobas pure

Serial No.: 2148-03

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Sample Results Report

User ID: REDCLIFFE

02/11/2022 16:45

Result Type: First Sorted by: Date

Sequence No. Rack ID - Pos. Sample ID / QC Lot

Comment

User ID

Registered

Q001023 Q30001-1 Name / Lot: PCCC1 / 525027 02/11/2022 08:44:44

REDCLIFFE

Test	Unit	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message								

CRP4	mg/L	Ser/Pl		9.46	CC	Current	R1-R3	610880	0002827
CRP-HS	mg/L	Ser/Pl		10.3	CC	Current	R1-R3	597985	0000476
GGT2-I	U/L	Ser/Pl		62.3	CC	Current	R1-R3	653840	0000164
GLUC3	mg/dL	Ser/Pl		110	CC	Current	R1-R3	629487	0002779
GLUC3	mg/dL	Ser/Pl		110	CC	S81	R1-R3	629487	0004279
HDLc4	mg/dL	Ser/Pl		44.0	CC	Current	R1-R3	626113	0007914
IRON2	µg/dL	Ser/Pl		155	CC	Current	R1-R3	623943	0002052

System: cobas pure

Serial No.: 2148-03

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Adrian
02/11

Sample Results Report

User ID: REDCLIFFE

02/11/2022 16:45

Result Type: First Sorted by: Date

Sequence No. Rack ID - Pos. Sample ID / QC Lot

Comment Q001023 Q30001-1 Name / Lot: PCCCT1 / 525027 User ID

Registered 02/11/2022 08:44:44

REDCLIFFE

Result Data Alarm

Test	Unit	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
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ISE CL	mmol/L	Ser/Pl		ISE	Current	624120	0008125	Q9124 T9294
						612530	0011652	
						638437	0011224	

ISE CL-P	mmol/L	Plasma		ISE	Current	624120	0008125	Q9124 T9294
						612530	0011652	
						638437	0011224	

ISE CL-S	mmol/L	Serum		ISE	Current	624120	0008125	Q9124 T9294
						612530	0011652	
						638437	0011224	

ISE K	mmol/L	Ser/Pl		ISE	Current	624120	0008125	G1642 T9294
						612530	0011652	
						638437	0011224	

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System: cobas pure

Serial No.: 2148-03

Sample Results Report

User ID: REDCLIFFE

02/11/2022 16:45

Result Type: First Sorted by: Date

Sequence No. Rack ID - Pos. Sample ID / QC Lot

Comment Q001023 Q30001-1 Name / Lot PCC1 / 525027 User ID Registered

02/11/2022 08:44:44

Test	Unit	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
ISE K-P	mmol/L	Plasma		ISE	Current	624120	0008125	G1642 T9294
						612530	0011652	
						638437	0011224	
ISE K-S	mmol/L	Serum		ISE	Current	624120	0008125	G1642 T9294
						612530	0011652	
						638437	0011224	
ISE NA	mmol/L	Ser/Pl		ISE	Current	624120	0008125	W7468 T9294
						612530	0011652	
						638437	0011224	
ISE NA-P	mmol/L	Plasma		ISE	Current	624120	0008125	W7468 T9294
						612530	0011652	
						638437	0011224	

System: cobas pure Serial No.: 2148-03

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Handwritten signatures and initials

Sample Results Report

User ID: REDCLIFFE

02/11/2022 16:45

Result Type: First Sorted by: Date

Sequence No. Rack ID - Pos. Sample ID / QC Lot

Registered

Comment Q001023 Q30001-1 Name / Lot PCCC1 / 525027 User ID REDCLIFFE

02/11/2022 08:44:44

Test	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
ISE NA-S	Serum	115.2	ISE	Current	IS		
					DIL		
					REF		
							W7468 T9294

LDHI2	U/L	Ser/Pl	193	CC	Current	R1-R3	589772	0000754
LDLC3	mg/dL	Ser/Pl	75.8 QCErr	CC	Current	R1-R3	572897	0001078
PHOS2	mg/dL	Ser/Pl	4.06	CC	Current	R1-R3	653804	0008005
TP2	g/dL	Ser/Pl	4.99	CC	Current	R1-R3	635652	0004369
TRIGL	mg/dL	Ser/Pl	152 QCErr	CC	Current	R1	643364	0001502

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System: cobas pure

Serial No.: 2148-03

Sample Results Report

User ID: REDCLIFFE

02/11/2022 16:45

Result Type: First Sorted by: Date

Sequence No. Rack ID - Pos. Sample ID / QC Lot

Comment: Q001023 Q30001-1 Name / Lot: PCCCI / 525027 User ID: REDCLIFFE Registered

02/11/2022 08:44:44

Test	Unit	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
UA2	mg/dL	Ser/Pl		CC	Current	R1-R3	627564	0001578
UIBC-1	µg/dL	Ser/Pl		CC	Current	R1-R3	637859	0000407
UIBC-1	µg/dL	Ser/Pl		CC	SB1	R1-R3	637859	0016349
UREAL	mg/dL	Ser/Pl		CC	Current	R1-R3	651528	0010756

System: cobas pure

Serial No.: 2148-03

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Sample Results Report

User ID: REDCLIFFE

02/11/2022 16:45

Result Type: First Sorted by: Date

Sequence No. Rack ID - Pos. Sample ID / QC Lot

Comment

Q002023 Q30001-3 Name / Lot: PCCC2 / 461603 User ID Registered 02/11/2022 08:44:44

REDCLIFFE

Result Data Alarm

Test	Unit	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
ALB2-G	g/dL	Ser/Pl		CC	Current	R1-R3	608713	0003128
			5.23					
ALP2	U/L	Ser/Pl		CC	Current	R1-R3	638132	0006144
			232					
ALTP	U/L	Ser/Pl		CC	Current	R1-R3	645075	0010272
			113			R2	654893	0002698
ALTP	U/L	Ser/Pl		CC	SB1	R1-R3	645075	0010291
			114			R2	654893	0002698
AMYL2	U/L	Ser/Pl		CC	Current	R1-R3	606164	0000131
			188					
ASTP	U/L	Ser/Pl		CC	Current	R1-R3	644916	0012464
			143			R2	654893	0002698

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System: cobas pure

Serial No.: 2148-03

Sample Results Report

User ID: REDCLIFFE

02/11/2022 16:45

Result Type: First Sorted by: Date

Sequence No. Rack ID - Pos. Sample ID / QC Lot

Comment Q002023 Q30001-3 Name / Lot: PCCC2 / 461603 User ID

Registered 02/11/2022 08:44:44

REDCLIFFE

Test	Result Data Alarm	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
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BILD2-J	2.82	CC	Current	R1-R2	638375	0001745
mg/dL						
Ser/Pl						
BILT3	3.44	CC	Current	R1-R3	600237	0005507
mg/dL						
Ser/Pl						
BILT3	3.15	CC	S81	R1-R3	600237	0003379
mg/dL						
Ser/Pl						
CA2	13.0	CC	Current	R1-R3	622620	0001788
mg/dL						
Ser/Pl						
CHOL2-A	178	CC	Current	R1	616068	0001279
mg/dL						
Ser/Pl						
CREJ2	3.51	CC	Current	R1-R3	627775	0003636
mg/dL						
Ser/Pl						
CRP4	53.5	CC	Current	R1-R3	610880	0002827
mg/L						
Ser/Pl						

System: cobas pure

Serial No.: 2148-03

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Sample Results Report

User ID: REDCLIFFE

02/11/2022 16:45

Result Type: First Sorted by: Date

Sequence No. Rack ID - Pos. Sample ID / QC Lot

Q002023 Q30001-3 Name / Lot PCCC2 / 461603 User ID Registered

Comment REDCLIFFE 02/11/2022 08:44:44

Test	Unit	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Data Alarm								
Result Message								

GGT2-I	U/L	Ser/Pl		275	CC	Current	R1-R3	653840	0000164
GLUC3	mg/dL	Ser/Pl		241	CC	Current	R1-R3	629487	0002779
GLUC3	mg/dL	Ser/Pl		242	CC	SB1	R1-R3	629487	0004279
HDLC4	mg/dL	Ser/Pl		58.0	CC	Current	R1-R3	626113	0007914
IRON2	µg/dL	Ser/Pl		247	CC	Current	R1-R3	623943	0002052
ISE CL	mmol/L	Ser/Pl		102.1	ISE	Current	IS	624120	0008125
							DIL	612530	0011652
							REF	638437	0011224

Q9124 T9294

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System: cobas pure

Serial No.: 2148-03

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Sample Results Report

User ID: REDCLIFFE

02/11/2022 16:45

Result Type: First Sorted by: Date

Sequence No. Rack ID - Pos. Sample ID / QC Lot

Comment: Q002023 Q30001-3 Name / Lot: PCCC2 / 461603 User ID: REDCLIFFE Registered

02/11/2022 08:44:44

Test	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
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ISE CL-P	Plasma		102.0	ISE	Current	IS DIL REF	624120 612530 638437	0008125 0011652 0011224	Q9124 T9294
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ISE CL-S	Serum		101.9	ISE	Current	IS DIL REF	624120 612530 638437	0008125 0011652 0011224	Q9124 T9294
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ISE K	Ser/Pl		6.96	ISE	Current	IS DIL REF	624120 612530 638437	0008125 0011652 0011224	G1642 T9294
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ISE K-P	Plasma		6.99	ISE	Current	IS DIL REF	624120 612530 638437	0008125 0011652 0011224	G1642 T9294
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System: cobas pure

Serial No.: 2148-03

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Sample Results Report

User ID: REDCLIFFE

02/11/2022 16:45

Result Type: First Sorted by: Date

Sequence No. Rack ID - Pos. Sample ID / QC Lot

Comment: Q002023 Q30001-3 Name / Lot: PCCC2 / 461603 User ID: REDCLIFFE

Registered

02/11/2022 08:44:44

Test	Sample Type	Dilution	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
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ISE K-S	Serum	7.01	ISE	Current	624120	0008125	G1642 T9294
					612530	0011652	
					638437	0011224	

ISE NA	Ser/Pl	133.6	ISE	Current	624120	0008125	W7468 T9294
					612530	0011652	
					638437	0011224	

ISE NA-P	Plasma	133.3	ISE	Current	624120	0008125	W7468 T9294
					612530	0011652	
					638437	0011224	

ISE NA-S	Serum	133.6	ISE	Current	624120	0008125	W7468 T9294
					612530	0011652	
					638437	0011224	

Handwritten signatures and initials

System: cobas pure

Serial No.: 2148-03

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Sample Results Report

User ID: REDCLIFFE

02/11/2022 16:45

Result Type: First Sorted by: Date

Sequence No.	Rack ID - Pos.	Sample ID / QC Lot	Registered
Q002023	Q30001-3	Name / Lot: PCCC2 / 461603	02/11/2022 08:44:44
			User ID: REDCLIFFE

Test	Unit	Sample Type	Result	Data	Alarm	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
Result Message										
LDHI2	U/L	Ser/PI	297			CC	Current	R1-R3	589772	0000754
LDLC3	mg/dL	Ser/PI	94.8			CC	Current	R1-R3	572897	0001078
PHOS2	mg/dL	Ser/PI	8.07			CC	Current	R1-R3	653804	0008005
TP2	g/dL	Ser/PI	8.04			CC	Current	R1-R3	635652	0004369
TRIGL	mg/dL	Ser/PI	205			CC	Current	R1	643364	0001502
UA2	mg/dL	Ser/PI	9.25			CC	Current	R1-R3	627564	0001578
UIBC-1	µg/dL	Ser/PI	242			CC	Current	R1-R3	637859	0000407

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System: cobas pure

Serial No.: 2148-03

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Sample Results Report

User ID: REDCLIFFE

02/11/2022 16:45

Result Type: First Sorted by: Date

Sequence No. Rack ID - Pos. Sample ID / QC Lot

Comment Q002023 Q30001-3 Name / Lot: PCCC2 / 461603 User ID

Registered

02/11/2022 08:44:44

REDCLIFFE

Test	Result Data Alarm	A. U.	Priority	R. P. Lot	R. P. Serial No.	ProCell Lot / Electrode
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UIBC-I	228	CC	SB1	R1-R3	637859	0016349
µg/dL	Ser/Pl					
UREAL	118	CC	Current	R1-R3	651528	0010756
mg/dL	Ser/Pl					

Symbols attached to "Test"

*: Rerun test

*: eFlow subresult, supplemented test for formula calculated test and Hb/HbA1c test

System: cobas pure

Serial No.: 2148-03