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
Sandhofer Straße 116
D-68305 Mannheim

i.V. Andrea Weber
Project Manager Regulatory Affairs

ppa. Dr. Beate Bonefeld
Head of Quality Assurance Mannheim, CPS Quality

[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

c111 V4.3.0.1835 13082
admin 24.05.2022 2:17 PM

Calibrations:

Test	Use	Type	Status
A1W3D	Current	Lot	17.05.2022 12:36
ALB2	Standby	Lot	10.05.2022 10:41
ALP2S	Standby	Lot	23.05.2022 2:39
ALTL	Current	Lot	10.05.2022 10:43
AMYL2	Standby	Lot	02.10.2021 5:03
ASTL	Current	Lot	27.04.2022 3:20
BILD2	Current	Lot	18.05.2022 1:21
BILD2	Standby	Lot	25.04.2022 11:32
BILT3	Current	Set	19.05.2022 11:37
CA2	Standby	Set	09.04.2022 4:35
CHECK	Current	Set	11.02.2022 4:17
CHO2I	Current	Lot	09.05.2022 1:06
CHO2I	Standby	Lot	11.04.2022 11:19
CK2	Standby	Set	15.09.2021 4:57
CREJ2	Current	Set	24.05.2022 11:58
CREJ2	Standby	Set	05.04.2022 12:29
CRP4	Current	Set	24.05.2022 12:11
GGTI2	Standby	Lot	03.04.2022 1:07
GLU2	Current	Lot	24.05.2022 1:48
GLU2	Standby	Set	24.05.2022 11:56
HDLC4	Current	Lot	14.05.2022 11:06
LDHI2	Standby	Lot	13.04.2022 11:41
LIP	Standby	Set	03.02.2022 1:37
PHOS2	Standby	Lot	10.05.2022 11:17
TP2M	Current	Lot	23.05.2022 11:35
TP2M	Standby	Set	18.05.2022 12:20
TRIGL	Current	Lot	17.05.2022 12:33
UA2	Current	Lot	03.05.2022 12:24
UREL	Current	Lot	18.05.2022 12:17
UREL	Standby	Set	16.05.2022 11:28

c111 V4.3.0.1835 13082
admin 24.05.2022 2:17 PM

Calibration Details:

Test	CREJ2
Use	Current
Type	Set
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 24.05.2022 11:58
Creation time	24.05.2022 11:43 AM
Flags	
R0	0.000123315
F	31393.9

c111 V4.3.0.1835 13082
admin 24.05.2022 2:17 PM

Calibration Details:

Test	CREJ2
Use	Standby
Type	Set
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 05.04.2022 12:29
Creation time	05.04.2022 12:15 PM
Flags	Cal Exp
R0	7.61853E-5
F	30413.5

c111 V4.3.0.1835 13082
admin 24.05.2022 2:17 PM

Calibration Details:

Test	TP2M
Use	Current
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 23.05.2022 11:35
Creation time	23.05.2022 11:35 AM
Flags	
R0	0.0280184
F	620.27

c111 V4.3.0.1835 13082
admin 24.05.2022 2:17 PM

Calibration Details:

Test	TP2M
Use	Standby
Type	Set
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	admin, 18.05.2022 12:20
Creation time	18.05.2022 12:20 PM
Flags	
R0	0.0238289
F	719.722

c111 V4.3.0.1835 13082
admin 24.05.2022 2:16 PM

Calibration Details:

Test	CHO2I
Use	Current
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 09.05.2022 1:06 P
Creation time	09.05.2022 12:21 PM
Flags	
R0	-0.000273239
F	23.0422

c111 V4.3.0.1835 13082
admin 24.05.2022 2:16 PM

Calibration Details:

Test	CHO2I
Use	Standby
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 11.04.2022 11:19
Creation time	11.04.2022 11:19 AM
Flags	
R0	-0.000772189
F	23.5517

c111 V4.3.0.1835 13082
admin 24.05.2022 2:17 PM

Calibration Details:

Test	GLU2
Use	Current
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 24.05.2022 1:48 P
Creation time	24.05.2022 1:20 PM
Flags	
R0	6.68317E-5
F	30.3922

c111 V4.3.0.1835 13082
admin 24.05.2022 2:17 PM

Calibration Details:

Test	GLU2
Use	Standby
Type	Set
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 24.05.2022 11:56
Creation time	24.05.2022 11:43 AM
Flags	
R0	0.000268323
F	32.2915

c111 V4.3.0.1835 13082
admin 24.05.2022 2:15 PM

Calibration Details:

Test	ASTL
Use	Current
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 27.04.2022 3:20 P
Creation time	27.04.2022 3:20 PM
Flags	
R0	-0.000245737
F	4992.1

c111	V4.3.0.1835	13082
admin		24.05.2022 2:17 PM

Calibration Details:

Test	TRIGL
Use	Current
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 17.05.2022 12:33
Creation time	17.05.2022 12:33 PM
Flags	
R0	0.00037
F	15.5076

c111 V4.3.0.1835 13082
admin 24.05.2022 2:15 PM

Calibration Details:

Test	A1W3D
Use	Current
Type	Lot
Status	Accepted
Calibrator name	hba1c
Lot ID	468538
Expiration date	31.03.2022
Accepted by	admin, 17.05.2022 12:36
Creation time	17.05.2022 12:36 PM
Flags	
R0	0.00149429
F	1.15522

c111	V4.3.0.1835	13082
admin		24.05.2022 2:15 PM

Calibration Details:

Test	BILD2
Use	Standby
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	admin, 25.04.2022 11:32
Creation time	25.04.2022 11:32 AM
Flags	
R0	5.19631E-5
F	1482.44

c111	V4.3.0.1835	13082
admin		24.05.2022 2:17 PM

Calibration Details:

Test	GGTI2
Use	Standby
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 03.04.2022 1:07 P
Creation time	03.04.2022 1:07 PM
Flags	
R0	0.0006
F	13069.8

c111 V4.3.0.1835 13082
admin 24.05.2022 2:17 PM

Calibration Details:

Test	LDHI2
Use	Standby
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 13.04.2022 11:41
Creation time	13.04.2022 11:41 AM
Flags	
R0	0.000224109
F	13632.9

c111 V4.3.0.1835 13082
admin 24.05.2022 2:17 PM

Calibration Details:

Test	HDLC4
Use	Current
Type	Lot
Status	Accepted
Calibrator name	CF LIP
Lot ID	46928000
Expiration date	30.09.2021
Accepted by	SYS, 14.05.2022 11:06
Creation time	14.05.2022 11:06 AM
Flags	
R0	0.000500591
F	17.2343

c111	V4.3.0.1835	13082
admin		24.05.2022 2:16 PM

Calibration Details:

Test	CA2
Use	Standby
Type	Set
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	admin, 09.04.2022 4:35 P
Creation time	09.04.2022 4:35 PM
Flags	Out of Rng, ? Cal
R0	0.0107352
F	18.2549

c111	V4.3.0.1835	13082
admin		24.05.2022 2:15 PM

Calibration Details:

Test	BILD2
Use	Current
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 18.05.2022 1:21 P
Creation time	18.05.2022 1:21 PM
Flags	
R0	0.000172548
F	1413.02

c111	V4.3.0.1835	13082
admin		24.05.2022 2:15 PM

Calibration Details:

Test	ALB2
Use	Standby
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 10.05.2022 10:41
Creation time	10.05.2022 10:41 AM
Flags	
R0	-0.0738572
F	444.311

c111	V4.3.0.1835	13082
admin		24.05.2022 2:16 PM

Calibration Details:

Test	BILT3
Use	Current
Type	Set
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 19.05.2022 11:37
Creation time	19.05.2022 11:27 AM
Flags	
R0	0.000700001
F	4330.53

c111	V4.3.0.1835	13082
admin		24.05.2022 2:17 PM

Calibration Details:

Test	PHOS2
Use	Standby
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 10.05.2022 11:17
Creation time	10.05.2022 11:17 AM
Flags	Cal Exp
R0	0.105872
F	8.53997

c111 V4.3.0.1835 13082
admin 24.05.2022 2:17 PM

Calibration Details:

Test	CRP4
Use	Current
Type	Set
Status	Accepted
Calibrator name	CF P
Lot ID	47149200
Expiration date	31.10.2022
Accepted by	SYS, 24.05.2022 12:11
Creation time	24.05.2022 11:44 AM
Flags	

c111 V4.3.0.1835 13082
admin 24.05.2022 2:17 PM

Calibration Details:

Test	UA2
Use	Current
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 03.05.2022 12:24
Creation time	03.05.2022 12:24 PM
Flags	
R0	0.000406716
F	6425.52

c111	V4.3.0.1835	13082
admin		24.05.2022 2:15 PM

Calibration Details:

Test	ALP2S
Use	Standby
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	admin, 23.05.2022 2:39 P
Creation time	23.05.2022 2:39 PM
Flags	
R0	0.000566887
F	6000.2

c111 V4.3.0.1835 13082
admin 24.05.2022 2:15 PM

Calibration Details:

Test	ALTL
Use	Current
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 10.05.2022 10:43
Creation time	10.05.2022 10:43 AM
Flags	
R0	-0.000483786
F	4961.19

c111 V4.3.0.1835 13082
admin 24.05.2022 2:18 PM

Calibration Details:

Test	UREL
Use	Current
Type	Lot
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 18.05.2022 12:17
Creation time	18.05.2022 12:06 PM
Flags	
R0	0.00159822
F	129.535

c111 V4.3.0.1835 13082
admin 24.05.2022 2:18 PM

Calibration Details:

Test	UREL
Use	Standby
Type	Set
Status	Accepted
Calibrator name	CFAS
Lot ID	41009300
Expiration date	31.08.2022
Accepted by	SYS, 16.05.2022 11:28
Creation time	16.05.2022 11:15 AM
Flags	
R0	0.000834147
F	157.569

cobas c 111 Installation Qualification Procedure (IQ)

cobas c 111 Instrument

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Preface

Revision History

Version	Revision Date	Revision Information
1.0	April 2016	Initial document
1.1	October 2018	Abbreviation changed to RH Update in "About this Document"

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4070 Basel, Switzerland.
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Copyrights and Trademarks

cobas is a trademark of Roche.

Disclaimer

The **cobas c** 111 instrument is a continuous random-access analyzer intended for the in vitro determination of clinical chemistry and electrolyte parameters in serum, plasma, urine or whole blood (HbA1c). Not to use in life science research.

About this Document

This document is to be used to perform an Installation Qualification on a **cobas c** 111 instrument. This qualification covers the **cobas c** 111 instrument as defined under system information only and does not cover the complete automation environment.

The IQ procedure is recommended but not mandatory.

Documentation of Deviations

All deviations occurring during this qualification procedure must be logged in the Deviation Log and finally commented in the Deviation Report.

General Information

Customer Information

Company: MINU CLINICAL LABORATORY.

Address: 7/8, Sunflower, Royal Complex, Eksar Road, Borivali (W), Mumbai - 91.

Instrument Location and Department:

Contact Person: Dr. Chirag Shah.

Roche Representative

Installation Qualification performed by:

Job Title: Service Engineer.

Company: Mediquip Diagnostics.

Address: 216, Gemstar Commercial Complex, Ramchandra Lane Extn., Malad (W), Mumbai - 64.

General Information

Who can perform the qualification

The Installation Qualification must be performed by Roche trained service personnel/distributors only.

Used Software

The **cobas c** 111 instrument software version V3.0.3.1146 or higher is required for the Installation Qualification and Operational Qualification procedures, which are separate documents and available from GRIPS.

Instrument Information

cobas c 111 Instrument	Serial Number: 13082.
Ion Selective Electrodes (ISE Module)	Serial Number: —

Installation Qualification Procedure

1 Document and Equipment Verification

Objective

Verify that the documents and equipment listed below are available to the customer.

Acceptance Criteria

The listed documents and equipment are available for the customer.

Procedure

- Verify that the acceptance criteria are met.

Results

Test #	Item	Version	Result Pass / Fail
IQ 1.1	**cobas c** 111 Operators Manual (Version 3.0 or higher) (Printed or electronic version)	4.3.	Pass
IQ 1.2	**cobas c** 111 Installation Manual (Version 4.1 or higher)	4.5.	Pass.
IQ 1.3	**cobas c** 111 USB Stick	n/a	
IQ 1.4	**cobas c** 111 Packing List	n/a	
IQ 1.5	**cobas c** 111 Installation Report	n/a	

Comments

Instrument Re-installation

Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☑ No: ☐

Signature: [signature] Date: 11/02/2022

2 Environmental Measurements

Objective

Verify that the current conditions on site meet the technical specifications.

Acceptance Criteria

The current conditions on site meet the technical specifications of the **cobas c** 111 instrument.

Procedure

- Verify that the acceptance criteria are met.

Results

Test #	Condition	Specification	Result Pass / Fail
IQ 2.1	All used measurement equipment is controlled and calibrated	Fulfills conditions	Pass.

Test #	Condition and Specification	Measured Value (with Unit)	Result Pass / Fail
IQ 2.2	Environmental Temperature (15 – 32°C)	25 °C.	Pass.
IQ 2.3	Relative Humidity (30 to 80% RH)	57 % RH	Pass.
IQ 2.4	Power Line Voltage (Main) (100–125 V / 200–240 V (-15%, +10%))	230V	Pass.
IQ 2.5	Power Line Voltage (ISE) (100 – 240 VAC (±10%))	NA.	
IQ 2.6	ISE Supply Voltage (19 – 24 VDC)	NA.	

Comments

N/A.

Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☑ No: ☐

Signature: Sig. Date: 11/02/2022

3 Hardware Installation

Objective

Verify the correct installation of the hardware components.

Acceptance Criteria

The hardware installation is completed without any deviation or non-conformance.

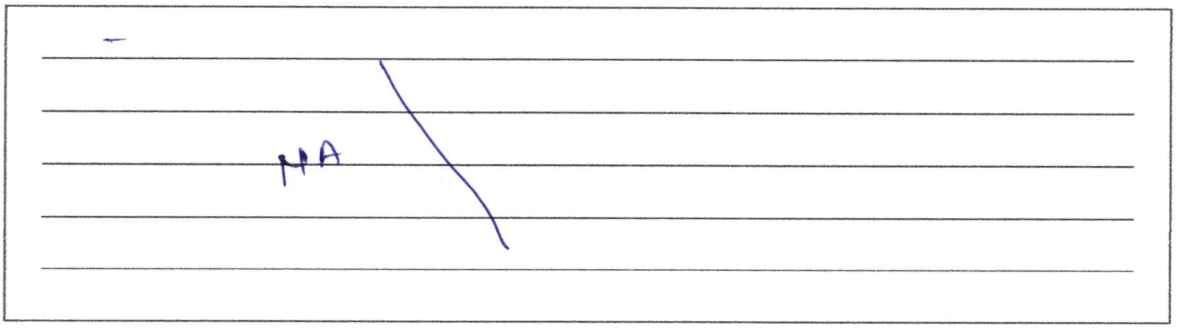
Procedure

- Verify that the acceptance criteria are met.

Results

Test #	Check	Result Pass/ Fail
IQ 3.1	According to the packing list delivered with the instrument the content of the shipment is complete.	Pass.
IQ 3.2	The **cobas c** 111 instrument is positioned according to the minimum space (according iSDoc)	Pass
IQ 3.3	The **cobas c** 111 instrument is connected to its auxiliary components according to the Installation Manual.	Pass
IQ 3.4	ISE auxiliary components are placed and connected according to the Installation Manual.	NA.
IQ 3.5	On power-up the instrument initializes successfully and reaches the status "Standby".	Pass.
IQ 3.6	Air/Water Calibration is performed successfully	Pass.

Comments



Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☑ No: ☐

Signature: [signature] Date: 11/02/2022

4 Software Versions Verification

Objective

Verify the instrument software and firmware versions.

Acceptance Criteria

The software and firmware versions are not outdated.

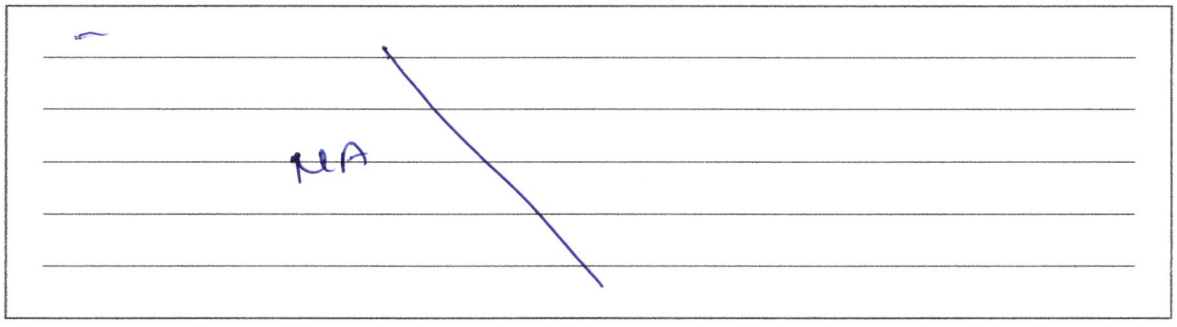
Procedure

- Switch on the instrument (if not yet running).
- Click the "System Status" icon and scroll down until the software and firmware versions are visible.
- Verify that the acceptance criteria are met.

Results

Test #	Check	Version	Result Pass / Fail
IQ 4.1	Instrument Software Version 3.0.3.1146 or higher	4.3.0.1835	Pass
IQ 4.2	Data Management Software DM: 3.0.3.1146 or higher	4.3.0.1834	Pass
IQ 4.3	Instrument Control Software IC: 3.0.1.1001 or higher	4.0.4.1798	Pass
IQ 4.4	DC Slave Control Firmware Version DC Slave: 1.00.00.0712 or higher	1.00.00.0712	Pass
IQ 4.5	ISE Control Firmware Version ISE: 2.03.01.1043 or higher	NA.	
IQ 4.6	Multislave Control Firmware Version Multislave: 1.02.07.0811 or higher	1.02.07.0811	Pass
IQ 4.7	ABS Photometer Control Firmware Version Photometer: 3.02.00.1042 or higher	3.02.00.1042	Pass
IQ 4.8	Operating System Software Version OS: 3.0.0.0903 or higher	4.3.0.1806.	Pass.

Comments



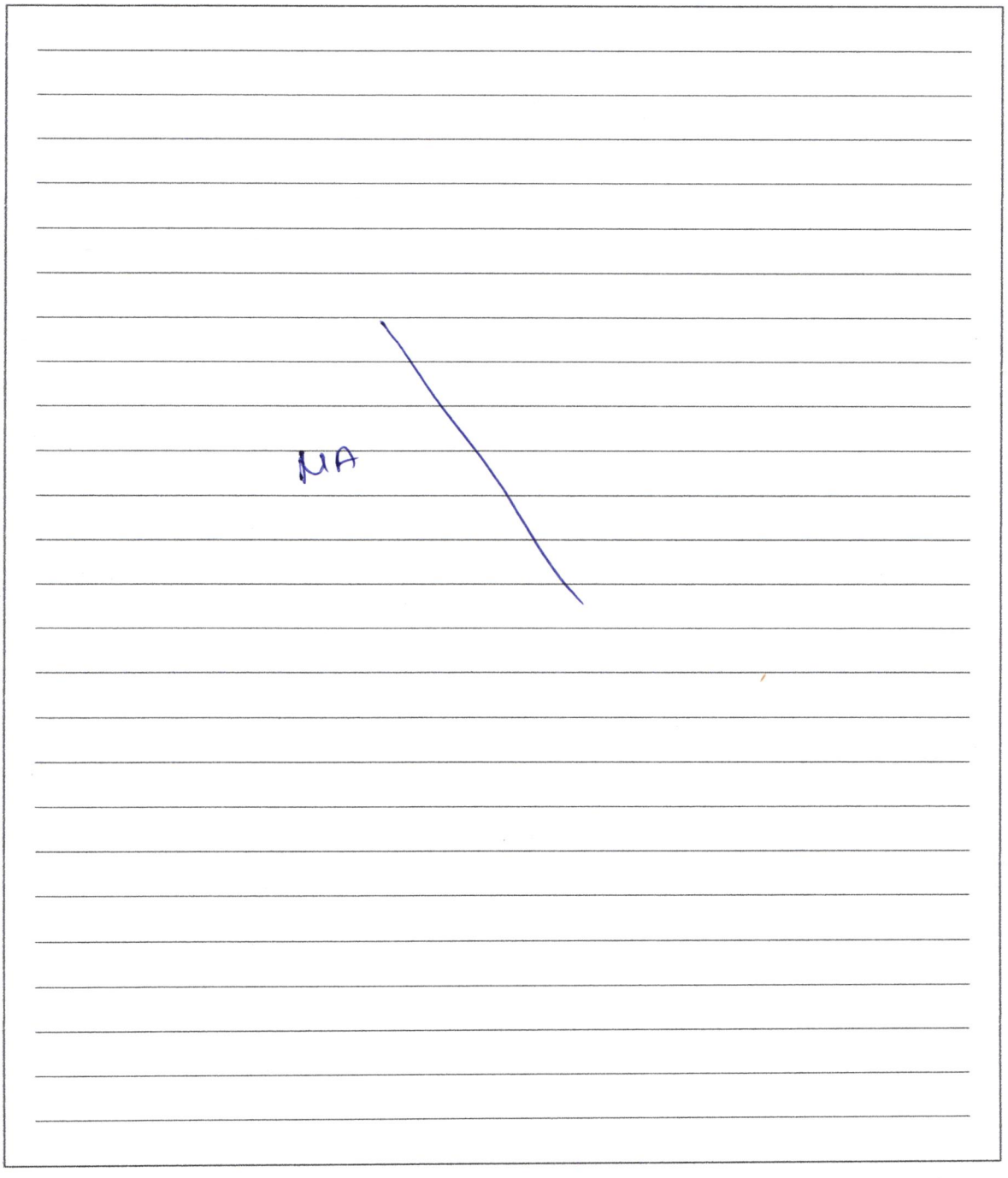
Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☑ No: ☐

Signature: Date: 11/01/2022

5 Notes



Signature: _____ Date: _____

6 Conclusion

Conclusion A:

All acceptance criteria have been met. The Installation Qualification of the respective equipment was performed successfully.	☑ Yes	☒ No
If No ➔ Continue with conclusion B		

Conclusion B:

All deviations or non-conformities observed have been recorded on the Deviation Log (see Appendix) and a corresponding Deviation Report (separate document) has been filled out. The deviations or non-conformities were resolved satisfactorily. Consequently the Installation Qualification of the respective equipment was performed successfully.	☐ Yes NA.	☒ No

Comments:

Installation Qualification performed successfully.

Performed by Roche representative: Dhanraj Dhangar.

Signature: Dhg. Date: 11/02/2022

Appendix

A Abbreviations

°C	Degrees Celsius
VAC	Volts Alternating Current
VDC	Volts Direct Current
Hz	Hertz
A	Ampere
%	Percentage
iSDoc	Service Manual
N/A	Not applicable
RH	Relative Humidity

B Deviation Log

Record all deviations noticed during the Installation Qualification in the list below:

Number	Description	Reference Page No.
1.		
2.		
3.		
4.		
5.		
6.	NA.	
7.		
8.		
9.		
10.		

Performed by Roche representative: Dhanraj Dhongar.

Signature: Date: 11/02/2022

Reviewed and approved by customer: Dr. Chirag. B. Shah

Signature: Date: 11/02/2022

Only for use in the IVD environment.

cobas c 111 Operational Qualification Procedure (OQ)

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Preface

Revision History

Version	Revision Date	Revision Information
1.0	August 2015	First release of this document
1.1	April 2016	Wording adjustment in Chapter 4
1.2	May 2016	Wording adjustment in Appendix B
1.3	April 2017	Chapter 2 added: Tool Filter Segment Information Chapter 4: adjusted QC setting
1.4	January 2018	Criteria "ISE Module used" added Chapter 2: Check tool filter segment acceptance criteria and procedure adjusted Chapter 3: Procedure and criteria for Pipetting accuracy added Chapter 5: Chloride electrode added
1.5	August 2018	Update on "About this Document"
1.6	September 2019	Removed chapter 2: Check Tool Filter Segment Refer to SN-CPS-2019-142: cobas c 111 - Operational Qualification (OQ) – "Check Tool Filter Segment" removed
1.7	July 2020	Corrected material number for Check Solution Sample Corrected paragraph numbering of procedures Procedure 3 acceptance criteria and procedure description updated

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About this Document

This document is to be used to perform an Operational Qualification on a cobas c 111 instrument. This qualification covers the cobas c 111 Instrument as defined in instrument information.

The OQ procedure is recommended but not mandatory.

Documentation of Deviations

All deviations occurring during this qualification procedure must be logged in the Deviation Log and finally commented in the Deviation Report.

General Information

Customer Information

Company: MINU CLINICAL LABORATORY.

Address: 7/8, Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai - 91.

Instrument Location and Department:

Contact Person: Dr. Chirag Shah.

Roche Representative

Operational Qualification performed by:

Job Title: Service Engineer.

Company: Mediquip Diagnostics.

Address: 216, Gemstar commercial complex, Ramchandra Lane Extn. Malad (w), Mumbai - 64.

Instrument Information

cobas c 111 instrument	Serial Number: 13082.
Ion Selective Electrodes (ISE Module)	Serial Number: NA.
ISE Module used:	☐ Yes ☑ No * * If "NO" is selected the ISE Module is not used, and Chapter 5 is not applicable for the OQ procedure. Proceed to Chapter 6. In addition, OQ 1.2 is not applicable.

General Information

Who can perform the tests

The Operational Qualification must be performed only by Roche trained service personnel/distributors.

Used software

The cobas c 111 instrument software version 3.0 or higher, is required to perform the Installation Qualification and Operational Qualification. These procedures are described in separate documents and can be downloaded from GRIPS.

Operational Qualification Procedure

1 Correct Initialization

ISE Module used:	☐ Yes ☑ No* * If "NO" is selected, the ISE Module is not used, and OQ 1.2 is not applicable.

Objective

Verify the correct initialization of the instrument.

Acceptance criteria

The hardware and software systems must initialize without error message. The instrument must change to "Standby" in the following.

Procedure

- Switch on the instrument and observe the initialization of the hardware and software systems.
- The instrument must reach the "Standby" status without error messages.

Results

Test #	Module	State Display	Result: Pass / Fail	Verified by & Date
OQ 1.1	Instrument Hardware	No hardware error messages during initialization	PASS.	[illegible] 11/02/2022
OQ 1.2	ISE	LED on the ISE front cover lights green	NA.	
OQ 1.3	Instrument Software	The SW is in "Standby" status without error message	PASS.	[illegible] 11/02/2022

Comments

1

NA

Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☑ No ☐

Signature: [illegible] Date: 11/02/2022

2 Check Pipetting Accuracy (CHECK Test)

Objective

This check is intended to verify the precision of the pipetting system. The test results deliver information if a pipetting problem might have contributed to an application problem.

Acceptance criteria

The CHECK Test results must be within the specified range defined in the iSDoc service manual, as follows:

Coefficient of Variation (% CV)

< 1.5 %

Mean Value

The mean values must be within the range printed on the bottle Check Solution Sample.

Material Required

- Sample: Check Solution Sample (cat. no. 20757144322)

This material is not a spare part and must be ordered as chemistry.

Procedure

Important:
For the complete workflow description for "Check Pipetting Accuracy" refer to iSDoc:
"Description > Diagnostic Software > Fluid > Check Pipetting Accuracy"

Procedure short description:

Prepare:

- The BTS (barcode transfer sheet) of the latest 'CHECK' version is available and can be downloaded on GRIPS.
  Path: "GRIPS" > "cobas c 111" > "Document Type 'BTS on Request'" > "CHECK / ACN 399 / cobas c 111".
- Ensure that the 'CHECK' application is installed and set to ON.
- Ensure that at least 2 free cuvette segments are available. If necessary unload used cuvette segments and load new ones.
- Fill 10 drops of CHECK Solution Sample into the Hitachi cup.

Perform the tests:

- Select <Utilities> <Diagnostics>. In the Diagnostics tree expand the folder <Fluid> and select <Check Pipetting Accuracy>.
- Follow the instructions provided in the software.
- After completion of the run, the 'Mean' / 'SD' and 'CV' are automatically calculated and displayed.

Validate results:

- Compare the value of Mean and % CV with the values described in "Acceptance Criteria "at the beginning of this Chapter 3.

Reagents & Specification

Reagent	Lot & Exp. Date	Low Δ abs	Target Δ abs	High Δ abs
Check Solution Sample	55981601/Feb-2023	1·32	1·39	1·46.

Results

Test #	Test	Result:	Result: pass / fail	Verified by & Date
OQ 2.1	Mean	1.38592Abs	Pass	Alg&. 11/02/2022
OQ 2.2	CV %	0.499534%	Pass.	Alg&. 11/02/2022

Test #	Test	Result: pass / fail	Verified by & Date
OQ 2.3	"Pipetting Accuracy" passed according to specifications	Pass.	Alg&. 11/02/2022

Comments

NA

Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☑ No ☐

Signature: Alg&. Date: 11/02/2022

3 Aspartate Aminotransferase (ASTL)

Objective

The ASTL test is sensitive to temperature variations, and therefore an indicator of a stable temperature system.

Acceptance criteria

Calibration and quality control without flags, and quality control within specified range.

The manufacturer recommends setting Rule 1 to "3s" (standard deviation) for quality control measurements.

Procedure

- Configure the ASTL test (Import and Install ASTL; ACN: 687).
- Configure the system to run the calibration (Calibrator for automated systems = Cfas, Cat. No. 10759350 190).
  - ➔ Enter manually or scan the barcode for the correct **lot-specific value** for ASTL, which can be found in the lot-specific value sheet for Cfas.
- Configure the system to run one normal control and one pathologic control (e.g. PreciControl ClinChem Multi 1 or 2).
  - ➔ Enter the correct lot-specific value for ASTL, which can be found in the lot-specific value sheets of the particular quality control.
    - By hand held barcode scanner:
      - Read the barcode from the lot specific value sheet of the QC material.
    - Manually:
      - Enter the "value" for the "Mean Concentration".
      - Enter the "1 s" value for "Standard Deviation".
  - ➔ Configure the system to run the controls using Rule 1 set to "3 s" (standard deviation) for this procedure.

  Note:
  The system software will calculate the acceptance range according to the criteria defined for Rule 1. Thus, the lot-specific 1 s value entered in the software will be multiplied by 3, and 3 s will be applied as the acceptance range.
- Load ASTL reagent set (Cat. No. 04657543 190).
- Order calibration and QC and place the prepared Cfas and controls on the mentioned position on the sample area.
- Run calibration and Quality Controls.

Reagents & Specification

Reagent	Lot & Exp. Date	
ASTL reagent set	(10) 57222301	30/11/2022.

Calibrator	Lot & Exp. Date	Lot – Specific Value	Unit
C Fas.	410093 / Aug - 2022.	106 U/L.	U/L.

QC Material	Lot & Exp. Date	Lot–specific value	Lot-specific 1s* value	Unit
PCC1	46149006, 28/2/2023.	45.6	2.7.	U/L.

* The acceptance range will be automatically calculated as 3 s by the system software.

Measurements

QC	Result	Unit	Date and Time
PCC1	45.8.	U/L	11/2/2022, 10:35 AM.
2			

Results

Test #	Test	Result: pass / fail	Verified by & Date
OQ 3.1	ASTL calibration performed using correct lot-specific value and without flag	PASS	11/02/2022 Dlg&.
OQ 3.2	ASTL quality controls without flag and within specified range	PASS.	11/02/2022 Dlg&.

Comments

NA

Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☑ No ☐

Signature: Dlg&. Date: 11/02/2022

4 Run Sodium, Potassium and Chloride Calibration

ISE Module used:	☐ Yes ☐ No * * If "NO" is selected the ISE Module is not used, and Chapter 5 is not applicable for the OQ procedure. Proceed to Chapter 6.
Electrodes used:	Sodium: ☐ Yes ☐ No * NA Potassium: ☐ Yes ☐ No * NA Chloride: ☐ Yes ☐ No * NA * If "NO" is selected the particular electrode is not used, and therefore the electrode specific calibration is not applicable for the OQ procedure.

Objective

The sodium, potassium and chloride calibration is an indicator of a stable ISE system.

Acceptance criteria

Calibration results without flags.

Preparation

- Prepare ISE Activator, Deproteinizer and Etcher.
- Start Service Action Condition ISE tubing twice.
- Start Service Action Electrode Service once.

Procedure

- Configure sodium, potassium and chloride test (Import and Install ISE indirect).
- Configure the system to run the calibrations (Enter Lot No. and Expiration of solution 1 and solution 2 of the ISE calibrator set, place Reference solution and Calibrator indirect/urine on the ISE module).
- Order calibration for sodium-indirect, potassium-indirect and chloride-indirect and place the cups on the mentioned positions.
- Run calibration for sodium-indirect, potassium-indirect and chloride-indirect.

Results

Test #	Test	Result: pass / fail	Verified by & Date	n/a if electrode not used
OQ 4.1	Sodium-indirect calibration without flag	-	-	-
OQ 4.2	Potassium-indirect calibration without flag	-	-	-
OQ 4.3	Chloride-indirect calibration without flag	NA	NA	NA

Comments

ISE not in use.

Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☒ No ☐

Signature: - Date: -

5 Notes

NA

Signature: _____ Date: _____

6 Conclusion

Conclusion A:

All acceptance criteria have been met. The Operational Qualification of the respective equipment was performed successfully.	☑ Yes	☐ No
If No ➔ continue with conclusion B		

Conclusion B:

All deviations or non-conformities observed have been recorded on the Deviation Log (see Appendix) and a corresponding Deviation Report (separate document) has been filled out. The deviations or non-conformities were resolved satisfactorily. Consequently the Operational Qualification of the respective equipment was performed successfully.	☐ Yes	☐ No NA.

Comments:

Operational Qualification successfully completed.

Performed by Roche representative: Dhanraj Dhangar.

Signature: D.D.

Date: 11/02/2022

Appendix

A Abbreviations

°C	Degrees Celsius
VA	Volt Ampere
V	Volt
A	Ampere
Hz	Hertz
%	Percentage
iSDoc	Service Manual
n/a	Not applicable
Δ abs	Delta Absorbance
HT	High Throughput
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
STDDev	Standard Deviation
SD	Standard Deviation
CV	Coefficient of variation

B Deviation Log

Record all deviations noticed during the Operational Qualification in the list below:

Number	Description	Reference Page No.
1.		
2.		
3.		
4.		
5.	NA.	
6.		
7.		
8.		
9.		
10.		

Performed by Roche representative: Dhanraj Dhangar.

Signature: Date: 11/02/2022

Reviewed and approved by customer: Dr. Chirag. B. Shah

Signature: Date: 11/02/2022

cobas c111

Fully Automated Clinical Chemistry Analyzer

Installation Qualification

Operation Qualification

Performance Qualification

For

Minu Clinical Lab,

Mumbai

(PQ) Performance Qualification

1.1. Performance assay run

PQ Instructions

PQ is performed as below:

1. Precision Study

    a. Inter Assay: QC run performed for days

Date: 8th April 2022

Signature: 

Comments

Results: Instrument ID: _____ Sr. No # 13082

Chart 1: Data Record – Precision- InterAssay / Between Run

Test	ALT	AST	BILD2	BILT3	CA	CHOL
Sample	PCCC1	PCCC1	PCCC1	PCCC1	PCCC1	PCCC1
Rep 1	46.5	48.2	0.9	1.1	9.04	102.04
Rep 2	45	47.3	0.9	1.1	8.84	101.36
Rep 3	43.1	47.1	0.9	1	8.81	102.22
Rep 4	44.3	48.3	0.9	1.1	9.1	102.04
Rep 5	44.8	47.3	0.9	1.1	9.46	102.17
Rep 6	44.1	47.7	0.9	1	8.87	101.38
Rep 7	43.3	48.3	0.9	1	9.11	100.08
Rep 8	44.3	47.3	0.9	1	9.04	103.2
Rep 9	44.6	47.2	0.9	0.9	8.99	103.74
Rep 10	44.8	47.5	0.9	0.9	9.1	101.99
Rep 11	43.4	47.5	0.9	0.9	9.06	101.14
Rep 12	44.7	47.1	0.9	1.1	8.93	102.38
Rep 13	44.2	46.6	0.9	0.9	8.83	104.22
Rep 14	44	46.8	0.9	0.9	9.06	102.72
Rep 15	43	47.8	0.9	1.1	8.87	102.41
Rep 16	43.6	46.8	0.9	1	8.73	101.27
Rep 17	47	48.1	1	1	9.09	101.51
Rep 18	46.4	48	0.9	1	9.16	104.91
Rep 19	45.2	47.3	0.9	1	9.14	101.19
Rep 20	46.5	47.8	1	1	9.48	104.49
Mean	44.64	47.50	0.91	1.01	9.04	102.32
SD	1.19	0.51	0.03	0.08	0.19	1.25
CV %	2.65	1.08	3.38	7.55	2.15	1.22

Results: Instrument ID: _____ Sr. No # 13082

Chart 1: Data Record – Precision- Inter Assay / Between Run

Test	CREJ2	CRP	GLU	HDL	TRIG	UA
Sample	PCCC1	PCCC1	PCCC1	PCCC1	PCCC1	PCCC1
Rep 1	1	8.78	108.7	32.51	115.94	5
Rep 2	1	8.6	109.25	32.44	115.89	5
Rep 3	1	8.68	108.75	32.59	116.57	5
Rep 4	0.9	8.72	108.21	31.89	114.66	4.9
Rep 5	1	9.24	108.08	31.84	116.2	4.8
Rep 6	0.9	8.56	105.36	32.79	114.89	5
Rep 7	0.9	8.51	106.52	32.77	113.57	4.9
Rep 8	0.9	8.44	109.16	32.98	116.69	4.9
Rep 9	1	8.39	110.02	33.31	115.89	4.9
Rep 10	0.9	8.6	108.48	32.6	115.72	5
Rep 11	1	8.44	107	31.92	116.49	5.1
Rep 12	0.9	8.33	108.79	33.57	117.69	4.9
Rep 13	1	8.36	107.92	33.38	117.6	4.9
Rep 14	1	8.19	107.65	33.04	116.17	4.8
Rep 15	1	9.43	103.79	32.89	114.69	4.8
Rep 16	1	8.9	107.53	31.97	115.43	4.9
Rep 17	0.9	8.66	107.23	32.32	115.11	4.8
Rep 18	1	8.83	105.43	31.72	113.14	4.8
Rep 19	1	9.64	107.25	32.84	115.4	4.9
Rep 20	1	9.46	111.9	33.91	116.04	4.7
Mean	0.97	8.74	107.85	32.66	115.69	4.90
SD	0.05	0.41	1.77	0.61	1.15	0.10
CV %	5.07	4.65	1.64	1.87	0.99	1.99

Results: Instrument ID: _____ Sr. No # 13082

Chart 1: Data Record – Precision- Inter Assay / Between Run

Test	UREA					
Sample	PCCC1					
Rep 1	35.6					
Rep 2	39.05					
Rep 3	37.47					
Rep 4	38.09					
Rep 5	37.64					
Rep 6	37.27					
Rep 7	36.61					
Rep 8	38.85					
Rep 9	37.94					
Rep 10	36.98					
Rep 11	38.49					
Rep 12	37.15					
Rep 13	37.11					
Rep 14	37.11					
Rep 15	37.11					
Rep 16	37.01					
Rep 17	36.14					
Rep 18	36..01					
Rep 19	35.8					
Rep 20	36.25					
Mean	37.25					
SD	0.95					
CV %	2.56					

1.2. Approval Certification

According to the assay results that are comprised in this document the system can be approved for routine operation.

System Released for Routine Operation N/A ☐ Complete ☐

Application Specialist

Date: 8th April 2022

Signature:_____

Name: Mehul Rana

Customer : Minu Clinical Lab, Mumbai

Date: _____

Signature:_____

Name: _____

Comments

Notes:

cobas c 111 Installation Qualification Procedure (IQ)

cobas c 111 Instrument

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Preface

Revision History

Version	Revision Date	Revision Information
1.0	April 2016	Initial document
1.1	October 2018	Abbreviation changed to RH Update in "About this Document"

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4070 Basel, Switzerland.
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Every effort has been made to ensure that all the information contained in this document is correct at the time of printing.
However, Roche Diagnostics Ltd reserves the right to make any changes necessary without notice as part of ongoing product development.

Copyrights and Trademarks

cobas is a trademark of Roche.

Disclaimer

The **cobas c** 111 instrument is a continuous random-access analyzer intended for the in vitro determination of clinical chemistry and electrolyte parameters in serum, plasma, urine or whole blood (HbA1c). Not to use in life science research.

About this Document

This document is to be used to perform an Installation Qualification on a **cobas c** 111 instrument. This qualification covers the **cobas c** 111 instrument as defined under system information only and does not cover the complete automation environment.

The IQ procedure is recommended but not mandatory.

Documentation of Deviations

All deviations occurring during this qualification procedure must be logged in the Deviation Log and finally commented in the Deviation Report.

General Information

Customer Information

Company: MINU CLINICAL LABORATORY.

Address: 7/8, Sunflower, Royal Complex, Eksar Road, Borivali (W), Mumbai - 91.

Instrument Location and Department:

Contact Person: Dr. Chirag Shah.

Roche Representative

Installation Qualification performed by:

Job Title: Service Engineer.

Company: Mediquip Diagnostics.

Address: 216, Gemstar Commercial Complex, Ramchandra Lane Extn., Malad (W), Mumbai - 64.

General Information

Who can perform the qualification

The Installation Qualification must be performed by Roche trained service personnel/distributors only.

Used Software

The **cobas c** 111 instrument software version V3.0.3.1146 or higher is required for the Installation Qualification and Operational Qualification procedures, which are separate documents and available from GRIPS.

Instrument Information

cobas c 111 Instrument	Serial Number: 13082.
Ion Selective Electrodes (ISE Module)	Serial Number: —

Installation Qualification Procedure

1 Document and Equipment Verification

Objective

Verify that the documents and equipment listed below are available to the customer.

Acceptance Criteria

The listed documents and equipment are available for the customer.

Procedure

- Verify that the acceptance criteria are met.

Results

Test #	Item	Version	Result Pass / Fail
IQ 1.1	**cobas c** 111 Operators Manual (Version 3.0 or higher) (Printed or electronic version)	4.3.	Pass
IQ 1.2	**cobas c** 111 Installation Manual (Version 4.1 or higher)	4.5.	Pass.
IQ 1.3	**cobas c** 111 USB Stick	n/a	
IQ 1.4	**cobas c** 111 Packing List	n/a	
IQ 1.5	**cobas c** 111 Installation Report	n/a	

Comments

Instrument Re-installation

Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☑ No: ☐

Signature: [signature] Date: 11/02/2022

2 Environmental Measurements

Objective

Verify that the current conditions on site meet the technical specifications.

Acceptance Criteria

The current conditions on site meet the technical specifications of the **cobas c** 111 instrument.

Procedure

- Verify that the acceptance criteria are met.

Results

Test #	Condition	Specification	Result Pass / Fail
IQ 2.1	All used measurement equipment is controlled and calibrated	Fulfills conditions	Pass.

Test #	Condition and Specification	Measured Value (with Unit)	Result Pass / Fail
IQ 2.2	Environmental Temperature (15 – 32°C)	25 °C.	Pass.
IQ 2.3	Relative Humidity (30 to 80% RH)	57 % RH	Pass.
IQ 2.4	Power Line Voltage (Main) (100–125 V / 200–240 V (-15%, +10%))	230V	Pass.
IQ 2.5	Power Line Voltage (ISE) (100 – 240 VAC (±10%))	NA.	
IQ 2.6	ISE Supply Voltage (19 – 24 VDC)	NA.	

Comments

N/A.

Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☑ No: ☐

Signature: Sig. Date: 11/02/2022

3 Hardware Installation

Objective

Verify the correct installation of the hardware components.

Acceptance Criteria

The hardware installation is completed without any deviation or non-conformance.

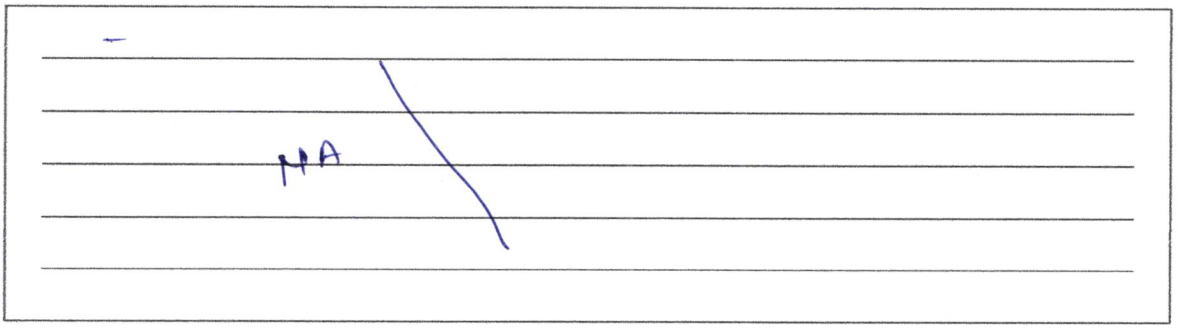
Procedure

- Verify that the acceptance criteria are met.

Results

Test #	Check	Result Pass/ Fail
IQ 3.1	According to the packing list delivered with the instrument the content of the shipment is complete.	Pass.
IQ 3.2	The **cobas c** 111 instrument is positioned according to the minimum space (according iSDoc)	Pass
IQ 3.3	The **cobas c** 111 instrument is connected to its auxiliary components according to the Installation Manual.	Pass
IQ 3.4	ISE auxiliary components are placed and connected according to the Installation Manual.	NA.
IQ 3.5	On power-up the instrument initializes successfully and reaches the status "Standby".	Pass.
IQ 3.6	Air/Water Calibration is performed successfully	Pass.

Comments



Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☑ No: ☐

Signature: [signature] Date: 11/02/2022

4 Software Versions Verification

Objective

Verify the instrument software and firmware versions.

Acceptance Criteria

The software and firmware versions are not outdated.

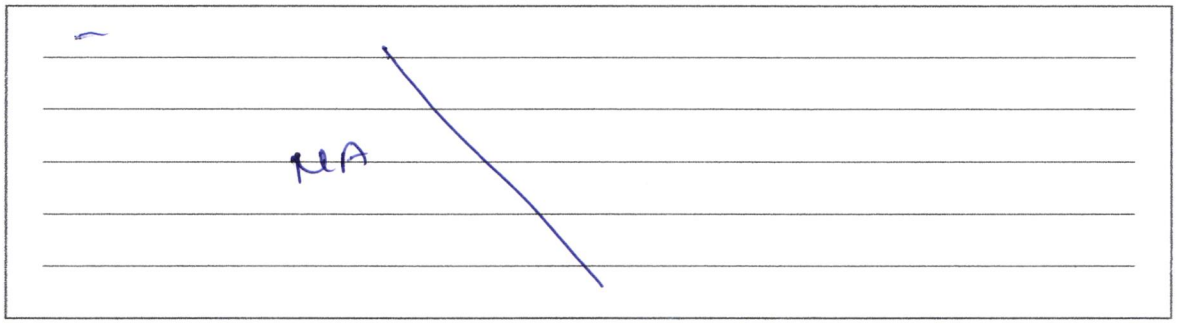
Procedure

- Switch on the instrument (if not yet running).
- Click the "System Status" icon and scroll down until the software and firmware versions are visible.
- Verify that the acceptance criteria are met.

Results

Test #	Check	Version	Result Pass / Fail
IQ 4.1	Instrument Software Version 3.0.3.1146 or higher	4.3.0.1835	Pass
IQ 4.2	Data Management Software DM: 3.0.3.1146 or higher	4.3.0.1834	Pass
IQ 4.3	Instrument Control Software IC: 3.0.1.1001 or higher	4.0.4.1798	Pass
IQ 4.4	DC Slave Control Firmware Version DC Slave: 1.00.00.0712 or higher	1.00.00.0712	Pass
IQ 4.5	ISE Control Firmware Version ISE: 2.03.01.1043 or higher	NA.	
IQ 4.6	Multislave Control Firmware Version Multislave: 1.02.07.0811 or higher	1.02.07.0811	Pass
IQ 4.7	ABS Photometer Control Firmware Version Photometer: 3.02.00.1042 or higher	3.02.00.1042	Pass
IQ 4.8	Operating System Software Version OS: 3.0.0.0903 or higher	4.3.0.1806.	Pass.

Comments



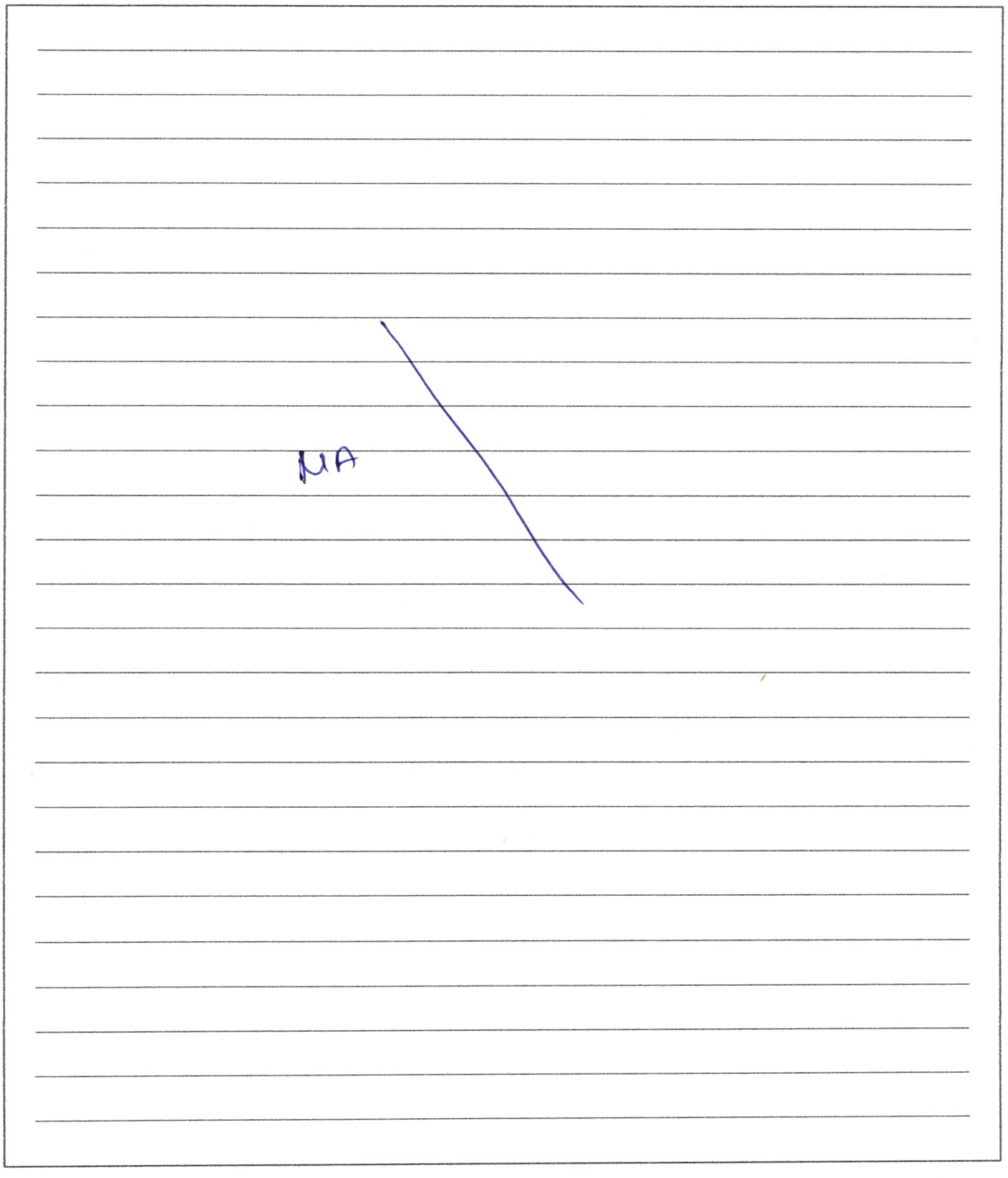
Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☑ No: ☐

Signature: Date: 11/01/2022

5 Notes



Signature: _____ Date: _____

6 Conclusion

Conclusion A:

All acceptance criteria have been met. The Installation Qualification of the respective equipment was performed successfully.	☑ Yes	☒ No
If No ➔ Continue with conclusion B		

Conclusion B:

All deviations or non-conformities observed have been recorded on the Deviation Log (see Appendix) and a corresponding Deviation Report (separate document) has been filled out. The deviations or non-conformities were resolved satisfactorily. Consequently the Installation Qualification of the respective equipment was performed successfully.	☐ Yes NA.	☒ No

Comments:

Installation Qualification performed successfully.

Performed by Roche representative: Dhanraj Dhangar.

Signature: Dhg. Date: 11/02/2022

Appendix

A Abbreviations

°C	Degrees Celsius
VAC	Volts Alternating Current
VDC	Volts Direct Current
Hz	Hertz
A	Ampere
%	Percentage
iSDoc	Service Manual
N/A	Not applicable
RH	Relative Humidity

B Deviation Log

Record all deviations noticed during the Installation Qualification in the list below:

Number	Description	Reference Page No.
1.		
2.		
3.		
4.		
5.		
6.	NA.	
7.		
8.		
9.		
10.		

Performed by Roche representative: Dhanraj Dhongar.

Signature: Date: 11/02/2022

Reviewed and approved by customer: Dr. Chirag. B. Shah

Signature: Date: 11/02/2022

Only for use in the IVD environment.

cobas c 111 Operational Qualification Procedure (OQ)

cobas c 111 Instrument

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Preface

Revision History

Version	Revision Date	Revision Information
1.0	August 2015	First release of this document
1.1	April 2016	Wording adjustment in Chapter 4
1.2	May 2016	Wording adjustment in Appendix B
1.3	April 2017	Chapter 2 added: Tool Filter Segment Information Chapter 4: adjusted QC setting
1.4	January 2018	Criteria "ISE Module used" added Chapter 2: Check tool filter segment acceptance criteria and procedure adjusted Chapter 3: Procedure and criteria for Pipetting accuracy added Chapter 5: Chloride electrode added
1.5	August 2018	Update on "About this Document"
1.6	September 2019	Removed chapter 2: Check Tool Filter Segment Refer to SN-CPS-2019-142: cobas c 111 - Operational Qualification (OQ) – "Check Tool Filter Segment" removed
1.7	July 2020	Corrected material number for Check Solution Sample Corrected paragraph numbering of procedures Procedure 3 acceptance criteria and procedure description updated

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About this Document

This document is to be used to perform an Operational Qualification on a cobas c 111 instrument. This qualification covers the cobas c 111 Instrument as defined in instrument information.

The OQ procedure is recommended but not mandatory.

Documentation of Deviations

All deviations occurring during this qualification procedure must be logged in the Deviation Log and finally commented in the Deviation Report.

General Information

Customer Information

Company: MINU CLINICAL LABORATORY.

Address: 7/8, Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai - 91.

Instrument Location and Department:

Contact Person: Dr. Chirag Shah.

Roche Representative

Operational Qualification performed by:

Job Title: Service Engineer.

Company: Mediquip Diagnostics.

Address: 216, Gemstar commercial complex, Ramchandra Lane Extn. Malad (w), Mumbai - 64.

Instrument Information

cobas c 111 instrument	Serial Number: 13082.
Ion Selective Electrodes (ISE Module)	Serial Number: NA.
ISE Module used:	☐ Yes ☑ No * * If "NO" is selected the ISE Module is not used, and Chapter 5 is not applicable for the OQ procedure. Proceed to Chapter 6. In addition, OQ 1.2 is not applicable.

General Information

Who can perform the tests

The Operational Qualification must be performed only by Roche trained service personnel/distributors.

Used software

The cobas c 111 instrument software version 3.0 or higher, is required to perform the Installation Qualification and Operational Qualification. These procedures are described in separate documents and can be downloaded from GRIPS.

Operational Qualification Procedure

1 Correct Initialization

ISE Module used:	☐ Yes ☑ No* * If "NO" is selected, the ISE Module is not used, and OQ 1.2 is not applicable.

Objective

Verify the correct initialization of the instrument.

Acceptance criteria

The hardware and software systems must initialize without error message. The instrument must change to "Standby" in the following.

Procedure

- Switch on the instrument and observe the initialization of the hardware and software systems.
- The instrument must reach the "Standby" status without error messages.

Results

Test #	Module	State Display	Result: Pass / Fail	Verified by & Date
OQ 1.1	Instrument Hardware	No hardware error messages during initialization	PASS.	[illegible] 11/02/2022
OQ 1.2	ISE	LED on the ISE front cover lights green	NA.	
OQ 1.3	Instrument Software	The SW is in "Standby" status without error message	PASS.	[illegible] 11/02/2022

Comments

1

NA

Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☑ No ☐

Signature: [illegible] Date: 11/02/2022

2 Check Pipetting Accuracy (CHECK Test)

Objective

This check is intended to verify the precision of the pipetting system. The test results deliver information if a pipetting problem might have contributed to an application problem.

Acceptance criteria

The CHECK Test results must be within the specified range defined in the iSDoc service manual, as follows:

Coefficient of Variation (% CV)

< 1.5 %

Mean Value

The mean values must be within the range printed on the bottle Check Solution Sample.

Material Required

- Sample: Check Solution Sample (cat. no. 20757144322)

This material is not a spare part and must be ordered as chemistry.

Procedure

Important:
For the complete workflow description for "Check Pipetting Accuracy" refer to iSDoc:
"Description > Diagnostic Software > Fluid > Check Pipetting Accuracy"

Procedure short description:

Prepare:

- The BTS (barcode transfer sheet) of the latest 'CHECK' version is available and can be downloaded on GRIPS.
  Path: "GRIPS" > "cobas c 111" > "Document Type 'BTS on Request'" > "CHECK / ACN 399 / cobas c 111".
- Ensure that the 'CHECK' application is installed and set to ON.
- Ensure that at least 2 free cuvette segments are available. If necessary unload used cuvette segments and load new ones.
- Fill 10 drops of CHECK Solution Sample into the Hitachi cup.

Perform the tests:

- Select <Utilities> <Diagnostics>. In the Diagnostics tree expand the folder <Fluid> and select <Check Pipetting Accuracy>.
- Follow the instructions provided in the software.
- After completion of the run, the 'Mean' / 'SD' and 'CV' are automatically calculated and displayed.

Validate results:

- Compare the value of Mean and % CV with the values described in "Acceptance Criteria "at the beginning of this Chapter 3.

Reagents & Specification

Reagent	Lot & Exp. Date	Low Δ abs	Target Δ abs	High Δ abs
Check Solution Sample	55981601/Feb-2023	1·32	1·39	1·46.

Results

Test #	Test	Result:	Result: pass / fail	Verified by & Date
OQ 2.1	Mean	1.38592Abs	Pass	Alg&. 11/02/2022
OQ 2.2	CV %	0.499534%	Pass.	Alg&. 11/02/2022

Test #	Test	Result: pass / fail	Verified by & Date
OQ 2.3	"Pipetting Accuracy" passed according to specifications	Pass.	Alg&. 11/02/2022

Comments

NA

Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☑ No ☐

Signature: Alg&. Date: 11/02/2022

3 Aspartate Aminotransferase (ASTL)

Objective

The ASTL test is sensitive to temperature variations, and therefore an indicator of a stable temperature system.

Acceptance criteria

Calibration and quality control without flags, and quality control within specified range.

The manufacturer recommends setting Rule 1 to "3s" (standard deviation) for quality control measurements.

Procedure

- Configure the ASTL test (Import and Install ASTL; ACN: 687).
- Configure the system to run the calibration (Calibrator for automated systems = Cfas, Cat. No. 10759350 190).
  - ➔ Enter manually or scan the barcode for the correct **lot-specific value** for ASTL, which can be found in the lot-specific value sheet for Cfas.
- Configure the system to run one normal control and one pathologic control (e.g. PreciControl ClinChem Multi 1 or 2).
  - ➔ Enter the correct lot-specific value for ASTL, which can be found in the lot-specific value sheets of the particular quality control.
    - By hand held barcode scanner:
      - Read the barcode from the lot specific value sheet of the QC material.
    - Manually:
      - Enter the "value" for the "Mean Concentration".
      - Enter the "1 s" value for "Standard Deviation".
  - ➔ Configure the system to run the controls using Rule 1 set to "3 s" (standard deviation) for this procedure.

  Note:
  The system software will calculate the acceptance range according to the criteria defined for Rule 1. Thus, the lot-specific 1 s value entered in the software will be multiplied by 3, and 3 s will be applied as the acceptance range.
- Load ASTL reagent set (Cat. No. 04657543 190).
- Order calibration and QC and place the prepared Cfas and controls on the mentioned position on the sample area.
- Run calibration and Quality Controls.

Reagents & Specification

Reagent	Lot & Exp. Date	
ASTL reagent set	(10) 57222301	30/11/2022.

Calibrator	Lot & Exp. Date	Lot – Specific Value	Unit
C Fas.	410093 / Aug - 2022.	106 U/L.	U/L.

QC Material	Lot & Exp. Date	Lot–specific value	Lot-specific 1s* value	Unit
PCC1	46149006, 28/2/2023.	45.6	2.7.	U/L.

* The acceptance range will be automatically calculated as 3 s by the system software.

Measurements

QC	Result	Unit	Date and Time
PCC1	45.8.	U/L	11/2/2022, 10:35 AM.
2			

Results

Test #	Test	Result: pass / fail	Verified by & Date
OQ 3.1	ASTL calibration performed using correct lot-specific value and without flag	PASS	11/02/2022 Dlg&.
OQ 3.2	ASTL quality controls without flag and within specified range	PASS.	11/02/2022 Dlg&.

Comments

NA

Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☑ No ☐

Signature: Dlg&. Date: 11/02/2022

4 Run Sodium, Potassium and Chloride Calibration

ISE Module used:	☐ Yes ☐ No * * If "NO" is selected the ISE Module is not used, and Chapter 5 is not applicable for the OQ procedure. Proceed to Chapter 6.
Electrodes used:	Sodium: ☐ Yes ☐ No * NA Potassium: ☐ Yes ☐ No * NA Chloride: ☐ Yes ☐ No * NA * If "NO" is selected the particular electrode is not used, and therefore the electrode specific calibration is not applicable for the OQ procedure.

Objective

The sodium, potassium and chloride calibration is an indicator of a stable ISE system.

Acceptance criteria

Calibration results without flags.

Preparation

- Prepare ISE Activator, Deproteinizer and Etcher.
- Start Service Action Condition ISE tubing twice.
- Start Service Action Electrode Service once.

Procedure

- Configure sodium, potassium and chloride test (Import and Install ISE indirect).
- Configure the system to run the calibrations (Enter Lot No. and Expiration of solution 1 and solution 2 of the ISE calibrator set, place Reference solution and Calibrator indirect/urine on the ISE module).
- Order calibration for sodium-indirect, potassium-indirect and chloride-indirect and place the cups on the mentioned positions.
- Run calibration for sodium-indirect, potassium-indirect and chloride-indirect.

Results

Test #	Test	Result: pass / fail	Verified by & Date	n/a if electrode not used
OQ 4.1	Sodium-indirect calibration without flag	-	-	-
OQ 4.2	Potassium-indirect calibration without flag	-	-	-
OQ 4.3	Chloride-indirect calibration without flag	NA	NA	NA

Comments

ISE not in use.

Conclusion

Do the results meet all the specified acceptance criteria defined in this chapter?

Yes: ☒ No ☐

Signature: - Date: -

5 Notes

NA

Signature: _____ Date: _____

6 Conclusion

Conclusion A:

All acceptance criteria have been met. The Operational Qualification of the respective equipment was performed successfully.	☑ Yes	☐ No
If No ➔ continue with conclusion B		

Conclusion B:

All deviations or non-conformities observed have been recorded on the Deviation Log (see Appendix) and a corresponding Deviation Report (separate document) has been filled out. The deviations or non-conformities were resolved satisfactorily. Consequently the Operational Qualification of the respective equipment was performed successfully.	☐ Yes	☐ No NA.

Comments:

Operational Qualification successfully completed.

Performed by Roche representative: Dhanraj Dhangar.

Signature: D.D.

Date: 11/02/2022

Appendix

A Abbreviations

°C	Degrees Celsius
VA	Volt Ampere
V	Volt
A	Ampere
Hz	Hertz
%	Percentage
iSDoc	Service Manual
n/a	Not applicable
Δ abs	Delta Absorbance
HT	High Throughput
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
STDDev	Standard Deviation
SD	Standard Deviation
CV	Coefficient of variation

B Deviation Log

Record all deviations noticed during the Operational Qualification in the list below:

Number	Description	Reference Page No.
1.		
2.		
3.		
4.		
5.	NA.	
6.		
7.		
8.		
9.		
10.		

Performed by Roche representative: Dhanraj Dhangar.

Signature: Date: 11/02/2022

Reviewed and approved by customer: Dr. Chirag. B. Shah

Signature: Date: 11/02/2022

cobas c111

Fully Automated Clinical Chemistry Analyzer

Installation Qualification

Operation Qualification

Performance Qualification

For

Minu Clinical Lab,

Mumbai

(PQ) Performance Qualification

1.1. Performance assay run

PQ Instructions

PQ is performed as below:

1. Precision Study

    a. Inter Assay: QC run performed for days

Date: 8th April 2022

Signature: 

Comments

Results: Instrument ID: _____ Sr. No # 13082

Chart 1: Data Record – Precision- InterAssay / Between Run

Test	ALT	AST	BILD2	BILT3	CA	CHOL
Sample	PCCC1	PCCC1	PCCC1	PCCC1	PCCC1	PCCC1
Rep 1	46.5	48.2	0.9	1.1	9.04	102.04
Rep 2	45	47.3	0.9	1.1	8.84	101.36
Rep 3	43.1	47.1	0.9	1	8.81	102.22
Rep 4	44.3	48.3	0.9	1.1	9.1	102.04
Rep 5	44.8	47.3	0.9	1.1	9.46	102.17
Rep 6	44.1	47.7	0.9	1	8.87	101.38
Rep 7	43.3	48.3	0.9	1	9.11	100.08
Rep 8	44.3	47.3	0.9	1	9.04	103.2
Rep 9	44.6	47.2	0.9	0.9	8.99	103.74
Rep 10	44.8	47.5	0.9	0.9	9.1	101.99
Rep 11	43.4	47.5	0.9	0.9	9.06	101.14
Rep 12	44.7	47.1	0.9	1.1	8.93	102.38
Rep 13	44.2	46.6	0.9	0.9	8.83	104.22
Rep 14	44	46.8	0.9	0.9	9.06	102.72
Rep 15	43	47.8	0.9	1.1	8.87	102.41
Rep 16	43.6	46.8	0.9	1	8.73	101.27
Rep 17	47	48.1	1	1	9.09	101.51
Rep 18	46.4	48	0.9	1	9.16	104.91
Rep 19	45.2	47.3	0.9	1	9.14	101.19
Rep 20	46.5	47.8	1	1	9.48	104.49
Mean	44.64	47.50	0.91	1.01	9.04	102.32
SD	1.19	0.51	0.03	0.08	0.19	1.25
CV %	2.65	1.08	3.38	7.55	2.15	1.22

Results: Instrument ID: _____ Sr. No # 13082

Chart 1: Data Record – Precision- Inter Assay / Between Run

Test	CREJ2	CRP	GLU	HDL	TRIG	UA
Sample	PCCC1	PCCC1	PCCC1	PCCC1	PCCC1	PCCC1
Rep 1	1	8.78	108.7	32.51	115.94	5
Rep 2	1	8.6	109.25	32.44	115.89	5
Rep 3	1	8.68	108.75	32.59	116.57	5
Rep 4	0.9	8.72	108.21	31.89	114.66	4.9
Rep 5	1	9.24	108.08	31.84	116.2	4.8
Rep 6	0.9	8.56	105.36	32.79	114.89	5
Rep 7	0.9	8.51	106.52	32.77	113.57	4.9
Rep 8	0.9	8.44	109.16	32.98	116.69	4.9
Rep 9	1	8.39	110.02	33.31	115.89	4.9
Rep 10	0.9	8.6	108.48	32.6	115.72	5
Rep 11	1	8.44	107	31.92	116.49	5.1
Rep 12	0.9	8.33	108.79	33.57	117.69	4.9
Rep 13	1	8.36	107.92	33.38	117.6	4.9
Rep 14	1	8.19	107.65	33.04	116.17	4.8
Rep 15	1	9.43	103.79	32.89	114.69	4.8
Rep 16	1	8.9	107.53	31.97	115.43	4.9
Rep 17	0.9	8.66	107.23	32.32	115.11	4.8
Rep 18	1	8.83	105.43	31.72	113.14	4.8
Rep 19	1	9.64	107.25	32.84	115.4	4.9
Rep 20	1	9.46	111.9	33.91	116.04	4.7
Mean	0.97	8.74	107.85	32.66	115.69	4.90
SD	0.05	0.41	1.77	0.61	1.15	0.10
CV %	5.07	4.65	1.64	1.87	0.99	1.99

Results: Instrument ID: _____ Sr. No # 13082

Chart 1: Data Record – Precision- Inter Assay / Between Run

Test	UREA					
Sample	PCCC1					
Rep 1	35.6					
Rep 2	39.05					
Rep 3	37.47					
Rep 4	38.09					
Rep 5	37.64					
Rep 6	37.27					
Rep 7	36.61					
Rep 8	38.85					
Rep 9	37.94					
Rep 10	36.98					
Rep 11	38.49					
Rep 12	37.15					
Rep 13	37.11					
Rep 14	37.11					
Rep 15	37.11					
Rep 16	37.01					
Rep 17	36.14					
Rep 18	36..01					
Rep 19	35.8					
Rep 20	36.25					
Mean	37.25					
SD	0.95					
CV %	2.56					

1.2. Approval Certification

According to the assay results that are comprised in this document the system can be approved for routine operation.

System Released for Routine Operation N/A ☐ Complete ☐

Application Specialist

Date: 8th April 2022

Signature:_____

Name: Mehul Rana

Customer : Minu Clinical Lab, Mumbai

Date: _____

Signature:_____

Name: _____

Comments

Notes: