

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
- 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

) ~

Andrea Weber

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ppa/on behalf of the company

Docusigned by:

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A7FORA9FF91A46A

Ralf Zielenski

Head Q&R Compliance, PRRC RDG Centralised and Point of Care Solutions



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Installation Qualification Procedure (IQ)

COBAS INTEGRA® 400 plus Instrument

Version 1.3 placeV

COBAS INTEGRA 400 plus Instrument and and 004 AROUT



Installation Qualification Procedure

Installation Qualification Procedure

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Installation Qualification Procedure

Preface

Revision History

Version	Revision Date	Revision Information		
	April 2016	First release of this document		
1.0	The second secon	Disclaimer removed		
1.1	Mai 2016	Update in "About this Document"		
1.2	October 2018	Updated information about availability of Operators		
1.3	March 2020	Manual from chapter 1		

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Questions or comments regarding the content of this document can be directed to your Roche

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About this Document

This document is to be used to perform an Installation Qualification on a COBAS INTEGRA® 400 plus Instrument. This Qualification covers the COBAS INTEGRA® 400 plus 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.

Version 1.3

Roche

Installation Qualification Procedure

COBAS INTEGRA 400 plus Instrument untant auto non ARDSTALZAROS

Installation Qualification Procedure

General Information

Customer Information

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Address:	Mananthavadi Diagnostic cente
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an ellipsic of F. Hoffmann-La Roche	noto Breel Switzerland.
Instrument Location and Department:	Bio chemistry
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	Yousal C.T

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Roche Representative

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		Shirin nativallitance	

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boos No. 48150, Prakasam Street,

T-Nagas, Chenra: - Goodif.

COBAS INTEGRA 400 plus Instrument and auto 004 AFRATIV



Installation Qualification Procedure

Instrument Information

COBAS INTEGRA® 400 plus instrument

Serial Number

H20523

Installation Qualification Procedure

General Information

Who can perform the qualification of ald links are stremgione the stremgion betall aff

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

Used Software

The COBAS INTEGRA® 400 plus Instrument software version 3.5.2, 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.

Installation Qualification Procedure

Document and Equipment Verification

Objective

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

Acceptance Criteria

The listed documents and equipments are available for the customer.

Procedure

Verify that the Acceptance Criteria are met.

Results support at setting to \$2.5.8 ancress substanting the first part of AHDETMI 2AHOD and

Test #	Item2 BED in set to quies name on man bit / #1	Version	Result Pass / Fail
I <mark>Q</mark> 1.1	Provided access to the latest COBAS INTEGRA® 400 plus Operators Manual (Version 2.7 or higher) (electronically or hard copy)	3.4 Electronicals	Pass +
IQ 1.2	COBAS INTEGRA® 400 plus Installation Manual (Version 1.6 or higher)	3.4	Pass
IQ 1.3	COBAS INTEGRA® 400 plus Packing List	n/a	Pass
IQ 1.4	COBAS INTEGRA® 400 plus Installation Report	n/a	Pass

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Installation Qualification Procedure

Environmental Measurements

Installation Qualification Procedure

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_comp	pleted	acification	ga Isolad	the current conditions on site meet the tech	Verify that	
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Conclusion						
Do the results	s meet a	II the spec	ified Acc			
Yes:		No:				
Signature:	n T			Date: 03 69 201°		
210		nollanta				
				Condition and Specification		
					(2 D)	
			6.			
1		Z14 5		Power Line Frequency Main (50 / 60 Hz, ±8%)		

COBAS INTEGRA 400 plus Instrument and and ODA AND STATE



Comments

Installation Qualification Procedure

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 INTEGRA® 400 plus 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 to 32°C)	23.9°C	Pass
IQ 2.3	Relative Humidity (30 to 80% RH)	58%	Pass
IQ 2.4	Power Line Voltage Main (100-125 V / 200-240 V; -15% +10%)	230 V	Pass
IQ 2.5	Power Line Frequency Main (50 / 60 Hz; ±5%)	50HZ	Pous

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Installation Qualification Procedure

Comments			
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		Objectiv	
Conclusion	2018 por mos supriment oria la resinsifateri memeo e	erit vimey	
	clusion e results meet all the specified Acceptance Criteria defined in this chapter? No: Date: 03/09/2019 and hemoured and this benevitable and or publication and the morphisms of the publication and		
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Yes:	AD A TOTAL CONTRACTOR OF THE PROPERTY OF THE P	Procedi	
Signature:	Date: 03/09/2019	9	
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	Check		
206			
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Installation Qualification Procedure

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 INTEGRA® 400 plus instrument is positioned to the minimum space (according iSDoc).	Pass
IQ 3.3	The COBAS INTEGRA® 400 plus instrument is connected to its auxiliary components according to the Installation Manual.	Pass
IQ 3.4	On power-up the instrument initializes successfully and reaches the "Standby" status.	Pass

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Installation Qualification Procedure

Completes	,				evirae	(dO
Conclusion	t all the enceif	ind Appenta	nco Critoria		3 soneigs:	nev
Do the results mee Yes:	No:	led Accepta	nce Criteria	defined in this c	mapter?	
Signature:	Asi	(prinav	Date:	03/09	12019	
				WS attempt		



Installation Qualification Procedure

4 Software Version Verification

Objective

Verify the instrument software and firmware version.

Acceptance Criteria

The software and firmware versions are not outdated.

Procedure

- · Switch on the instrument (if not yet running)
- Log on as "COBASOPERATOR"
- Enter Diagnostic SW
- Choose the tab "System Data" and open "System Version" to display the Software and Firmware Version
- Verify that the Acceptance Criteria are met

Results

Test #	Check	Version	Result Pass / Fail
IQ 4.1	Common User Interface (Version 3.5 or higher)	Z.G.2	Pass
IQ 4.2	Realtime CPU Software (Version 3.4 or higher)	3.G.2	Pass

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COBAS INTEGRA 400 plus Instrument and DOM AND STATE 2A



Installation Qualification Procedure

comments	6 Conclusion
	Conclusion A:
alon Qualification of Jan.	All Acceptance Cotons have been met. The lostello
	the respective equipment was performed succession
Conclusion	
	ceptance Criteria defined in this chapter?
	evad beviesda sedimotorco-pod no enodsiveb IIA
(Peverior Separa	
Signature:	Date: 03[09[2019]
- Old Marine	Spalification of the respective equipment was next
5 Notes	Consments;
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A Market Sacra Vila	
TANKER SAME NASA INS	Signature . LAST
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COBAS INTEGRA 400 plus Instrument and 004 ARESTAL 2A



Installation Qualification Procedure

Installation Qualification Procedure

6 Conclusion		
Conclusion A:		
All Acceptance Criteria have been met. The Installation Qualification of the respective equipment was performed successfully.	of Ves	□ No
If No → continue with conclusion B		
Conclusion B:	dusion results meet	
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 Installatio Qualification of the respective equipment was performed successfully	Yes	asY
Comments:	Notes	
Performed by Roche representative: Anjali Ramch	anda <n.< td=""><td></td></n.<>	

COBAS INTEGRA 400 plus Instrument and ODA ARCHIMICA



Installation Qualification Procedure

Appendix

A Abbreviations

°C	Degrees Celsius	
VA	Volt Ampere	
V	Volt	
A	Ampere	
Hz	Hertz	
%	Percentage	
iSDoc	Service Manual	
n/a	Not applicable	
RH	Relative Humidity	34.0
HT	High Throughput	

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COBAS INTEGRA 400 plus Instrument and ODA ARDETMI ZA



Installation Qualification Procedure

Installation Qualification Procedure

B Deviation Log

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

Number	Description	Reference Page No.
1.		
2.		
3.		
ા.	Service Manual	anula j
4.	Relative Humidity	
5.	Avariginari mgili [
6.		
7.		
8.		
9.		
10.		

Performed by Roche representative:	li Ramachandran
Signature:	Date: 03(09/2019
Reviewed and approved by customer:	mat- Cit
Signature:	Date: 03/09/2019



Operational Qualification Procedure

COBAS INTEGRA 400 plus Operational Qualification Procedure (OQ)

COBAS INTEGRA® 400 plus Instrument

Version 1.7

Roche

COBAS INTEGRA 400 plus Instrument and DOM ARRESTM 2A

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Revision History

Version	Revision Date	Revision Information
1.0	August 2015	First release of this document
1.1	April 2016	Wording adjustment in chapter 3, 4
1.2	May 2016	Wording adjustment in Appendix B
1.3	May 2017	Chapter 4 procedure adjusted
1.4	January 2018	Criteria "ISE Module used" added Chapter 2: Procedure and criteria for Pipetting accuracy added Chapter 4: Chloride added
1.5	October 2018	Update in "About this Document"
1.6	March 2020	Corrected material number for Check Solution
1.7	July 2020	Procedure 3 acceptance criteria and procedure description updated

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COBAS INTEGRA 400 plus Instrument and 004 AFFECTIVITY 2A



Operational Qualification Procedure

About this Document

This document is to be used to perform an Operational Qualification on a COBAS INTEGRA 400 plus instrument. This qualification covers the COBAS INTEGRA 400 plus Instrument as defined in instrument information.

The OQ procedure is recommended but not mandatory.

Documentation of Deviations

Version 1.7

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

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COBAS INTEGRA 400 plus Instrument and DOA AND THE CALL



Operational Qualification Procedure

General Information

Customer Information

Santar Nontees	
Company:	MDC Laboratory
	15E Module used:
Address:	Mananthavadi Diagnostic Centa
	Health clas Suilding
	cluskunny Road Mananthavadi
	Wayaned - 670645
	The Operational Qualification must be perform
Instrument Location and Department:	Biochemistzy
	USED SOTWARD AND AND AND THE COMMENTS
	Shygno K.S
	Yoursaf E. T
Roche Representative	
Operational Qualification performed by:	Abisli Ramachandtan
Job Title:	Application Specialist
	Roche-
Address:	Poche Disampetice lodis Put. H

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Down NO. 46 & 50, Prakasan Staret





Operational Qualification Procedure

Instrument Information

COBAS INTEGRA 400 plus instrument	Serial Number: H20523
ISE Module used:	Yes * If "NO" is selected the ISE Module is not used, Chapter 4 is not applicable for the OQ procedure. Proceed to Chapter 5.

General Information

Who can perform the tests

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

Used software

The COBAS INTEGRA 400 plus instrument software version 3.5.2 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.

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Operational Qualification Procedure

Operational Qualification Procedure

1 Correct Initialization

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.

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COBAS INTEGRA 400 plus Instrument and the AMOST MICE.



Operational Qualification Procedure

Results

Test #	Module	State Display	Result: Pass / Fail	Verified by & Date
OQ 1.1	Instrument Hardware	No hardware error messages during initialization	Pass	Anjeli"
OQ 1.2	Controller Rack	All watchdog LED's on the PCB's in the controller rack light green	Pass	Anjah' autonali
OQ 1.3	Instrument Software	The SW is in "Standby" status without error message	Pass	Anjah.

Operational Qualification Procedure

completed.	

Conclusion	1					
Do the result	s meet al	I the specif	fied accepta	ınce criteri	a defined in this chapter?	
Yes:	Ø	No				
Signature:	-			Date:	03/09/2019	

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Operational Qualification Procedure

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 on agua-andos 2 ablod holds Maceptance criteria

The CHECK Test results must be within the specified range defined in the iSDoc service manual.

The Coefficient of Variation (%CV) and the Mean Value must be within the following specifications:

Coefficient of Variation (%CV)

Mean Value

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

Material Required

- Cassette: CHECK (cat. no. 20757136322)
- Sample: Check Solution Sample (cat. no. 20757144322)

These two materials are not spare parts and must be ordered as chemistry.

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COBAS INTEGRA 400 plus Instrument and 004 AREATM



Operational Qualification Procedure

Procedure

Important:

For the complete workflow description for "Check Pipetting Accuracy" refer to iSDoc: Description > Fluid/ Pipetting > Check Pipetting Accuracy.

Procedure short description:

Prepare

- Load (Multi) test CHECKB and CHECKC (Configuration > Tests > Load).
- Prepare a Sample Rack which holds 2 cobas-cups on cup-adaptors.
- Fill the 2 cobas-cups with Check Solution Sample (approximately 5 drops of liquid).
- Place the Check Cassette on a cassette rack.

Ordering the Test

- Create an order for fluid system B:
 Sample ID: e.g. CheckB
 Create multiple test (n=16) for each test: CHKCR, CHKCS, CHKCSR.
- Create an order for fluid system C:
 Sample ID: e.g. CheckC
 Create multiple test (n=16) for each test: CHKCR, CHKCS, CHKCSR.

Important:

✓ Since this test is a multi-test, always perform all 3 tests in a single order from a single cup.

Running the Tests

Important:

✓ Always wait until all tests are performed before continuing with validating results!

Prepare validation of Results

- Click on the Results button to access the results window.
- Click on the Sample tab. The calculated results are listed.
- Click with the right mouse button on the test to be validated. A pop-up window appears.
- Select "Statistics". The statistics for all calculated tests are shown.
 2 results are relevant: The Mean and the Coefficient of Variation (%CV).
 Each test can be selected in the drop-down-menu (reagent, sample, and start Reagent).



Operational Qualification Procedure

Validation

- Compare the values of the mean against the values printed on the CHECK cassette or on the bottle of the CHECK Solution Sample.
- Example:
 CHKBR (Check B Reagent): Mean: 0.381
 (on cassette: Δ Abs R1: 0.374 0.385 0) The result is within the range. Test O.K.
- Compare the value of Mean and %CV with the values described in "Acceptance Criteria" at the beginning of this Chapter 2.

Reagents & Specification

Reagent	Lot & Exp. Date	Low A abs	Target Δ abs	High Δ abs
Check Sample	C10)60820501	1.26	1.33	1.40
Check Cassette R1	56878501	0.385	0.397	0.409
Check Cassette SR	56878501	0.381	0.393	0.405

Version 1.7



Operational Qualification Procedure

Results

Test #	Test	Result: CV %	Result: Mean	Result: pass / fail	Verified by & Date
OQ 2.1	CHKBR	0.40	0.395	Pass	Am'ali'
OQ 2.2	CHKBS	0.34	1. 335	Pass	Amjali
OQ 2.3	CHKBSR	0.92	0.393	Pass	Angiah'
OQ 2.4	CHKCR	0.24	0.3944	Pass	Anjali.
OQ 2.5	CHKCS	0.30	1.319	Pass	Anjahi
OQ 2.6	CHKCSR	0.28	0.392	Pass	Anjah!

Test #	Test	Result: pass / fail	Verified by & Date
OQ 2.7	"Pipetting Accuracy" passed according to specifications	Pass	Anjah.

Comments

completed.	
J.	Y ₄
***************************************	10-00-00-00-00-00-00-00-00-00-00-00-00-0

Conclusion

Do the resu	ults meet a	all the spec	ied acceptance criteria defined	in this chapter?
Van				

Signature:



Date:

03/09/2019

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 using "Accuracy" and the lot-specific 3 s (3 x SD) as the "Permissible Dev."

Procedure

- Configure the ASTL test (Load ASTL, test ID 0-494).
- 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 and 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 all barcodes from the lot specific value sheet of the QC material.
 - Manually:
 - Ensure that only the "Accuracy Mode" is selected; unselect all other options.
 - Enter the value in the "Assigned Value" field.
 - Enter the 3 x 1 s (SD) in the "Permissible Dev." field.
- Place Cfas (Std1), water (Std2) and control materials on a prepared sample rack (QC/CAL) and load the rack to the sample area.
- Load ASTL c-pack reagent cassette (Cat. No. 20764949 322).
- Run calibration.
- Run quality controls.



Operational Qualification Procedure

Reagents & Specification

Reagent	Lot & Exp. Date			
ASTL Cassette	60286301	. 29/10/202	2 William & 2017	
Calibrator	Lot & Exp. Date	Lot - specific val	ue	Unit
Calibrator: c.f.a.s	53994101	101.0		UIL
QC Material	Lot & Exp. Date	3 x 1s (lot-specific) "Permissible Dev."	Lot-specific "Assigned Value"	Unit
BIORAD	26491	1.0	1.0	ULL

Measurement

	Re	sult	Unit	Date and Time
BIORAD 34.4 UL 14/08/202	RAD	34· H	UIL	14/08/2022

-> Enter manually or scan the beroods for the correct lot-specific value for ASTL which

Load ASTL c-pack reagent cassette (Cut. No. 20784949 322).

COBAS INTEGRA 400 plus Instrument at a sign 004 ASPETMENT



Operational Qualification Procedure

Results

Test #	Test	Result: pass / fail	Verified by & Date
OQ 3.1	ASTL calibration without flag	Pass	Agair boundouse
OQ 3.2	ASTL quality controls without flag and within specified range	Pass	Anjali'

Comments		
Committee		

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	In answertent on at notification epinol	ids has multivered muchos ad T

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Do the res	sults meet all	l the spec	ified accepta	ance criteria defined in this chapter?	sič. «
		02000			1612 =

Yes:

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- 1	~	

No

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ш			1	

Signature:



Date:

14/08/2022

* Load ISE ! (ISE indirect) from the TAS file:

. Load ISE-D (ISE direct) from the TAS file.

Enter manually the lot number and expiry date for the ISE calibrators Sol-1 and Sol-2.

Place the Sol-1 and Sol-2 bottles on the ISE rack.

Run the sodium-direct, potassium-direct and chloride-direct calibration

Run the sodium-indirect, potassium-indirect and chloride-indirect calibration.

COBAS INTEGRA 400 plus Instrument all all g 004 ARDSTAL



Operational Qualification Procedure

4 Run Sodium, Potassium and Chloride Calibration

ISE Module used:	Yes No * * If "NO" is selected the ISE Module is not used, and Chapter 4 is not applicable for the OQ procedure. Proceed to Chapter 5.
Electrodes used:	Sodium: Yes No * Potassium: Yes No * Chloride: Yes: note electrode color:
Objective	
The sodium, potassium and chlori	de calibration is an indicator of a stable ISE system.
Acceptance criteria	
Calibration results without flags.	

Preparation

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

Procedure

- Prepare the system to run the calibrations.
- Load ISE-D (ISE direct) from the TAS file.
- · Load ISE-I (ISE indirect) from the TAS file.
- Enter manually the lot number and expiry date for the ISE calibrators Sol-1 and Sol-2.
- Place the Sol-1 and Sol-2 bottles on the ISE rack.
- Run the sodium-direct, potassium-direct and chloride-direct calibration.
- · Run the sodium-indirect, potassium-indirect and chloride-indirect calibration.

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Operational Qualification Procedure

R	00	••	Ite
п	65	u	

Test #	Test	Result: pass / fail	Verified by & Date	n/a if electrode not used
OQ 4.1	Sodium-direct calibration without flag			
OQ 4.2	Potassium-direct calibration without flag			
OQ 4.3	Sodium-indirect calibration without flag			
OQ 4.4	Potassium-indirect calibration without flag			
OQ 4.5	Chloride-direct calibration without flag			
OQ 4.6	Chloride-indirect calibration without flag			

|--|

To the results meet all the spec	ified acceptance criteria	defined in this chapter?
----------------------------------	---------------------------	--------------------------

Yes:

Signature:



No

Date:

03/09/2019



Operational Qualification Procedure

To Mi	. A yd bating V 12	listed and the last	11-123
		t in the second	
		Reduction Control Reduction	100
• —		57900 30000000	
		Potassium-direct calibration	142
=		- golf roorlity	26.00
		Softuns-Indirect celibration	
-		without the damp and the without the damp and the damp an	CAL
4			
-		Potasarum-inclined culibration	7.00
<u> </u>		Without Hag	
		politos (Gless reporte addicated)	
		pall toothiw	8,510
		Chlonus Homes Celiptation	0.4.6
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	8	2100	Comm
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		gnisi	Conclu
	Mene agintee in this chapter	esulis meet all the specifica disceptance	Paris DU
	ature:	Date: 03/09/20	

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Operational Qualification Procedure

6 Conclusion	xib	Appen
Conclusion A:		A 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	107	
	Amp Hert Perc	
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 CI
Comments: noticities to indicate the indicat		
completed.		
		•
Performed by Roche representative:	andako	
Signature: Date	03	,

COBAS INTEGRA 400 plus Instrument and auto 00% ASTORT



Operational Qualification Procedure

Operational Qualification Procedure

Appendix

A Abbreviations

°C	Degrees Celsius a linteresson transported year memoripa evitageest er
VA	Volt Ampere
٧	Volt a northern with continues of the
Α	Ampere
Hz	Hertz
%	Percentage
iSDoc	Service Manual
n/a	Not applicable
Δ abs	Delta Absorbance
HT	High Throughput
IQ	Installation Qualification
0Q	Operational Qualification
PQ	Performance Qualification
CV	Coefficient of variation

Performed by Roche representative:

Signature:

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Operational Qualification Procedure

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.		
6.		
7.		
8.		
9.		
10.		

Performed by Ro	che representative:	Anjali Ramac	bendara.
Signature:		Date	03/09/2019
Reviewed and ap	oproved by customer:	Lonsof Cit	
Signature:		Date	03/09/2019

Cobas Integra 400 plus Serial No. 42052Qq

MDC, MANANTHAVADI Serial No. 420523

1. Precision Study
Run two level of QC both normal accommod Study

1. Precision Study

Performance Qualification

Comments

MDC, MANANTHAVADI Serial No. 420523

Performance assay run

PQ Instructions

PQ is performed as needed. Please complete each PQ section and attach any documents that are requested to be completed.

1. Precision Study

Run two level of QC both normal and abnormal 5 times for tests and calculate Mean, SD and CV%.

Date: 26/08/2022

Signature:

Comments:

completed

Roche

MDC, MANANTHAVADI Serial No. 420523

\sim		Α.	DT	4		-:		Data
ι,	П	H		100	rec	ISI	\mathbf{o}	Dala

TEST	SAN	MPI	- Tasker	RUN 1	RUN 2	RUN 3	RUN 4	RUN 5	MEAN	SD	CV%
ALB	1.0	1	16.4	5.26	5.28	5.18	5.15	5.15	5.15	0.02	0.388
ASTL	0.04	1	0,4	29.8	29.8	29.8	29.9	29.9	29.8	0.02	0.067
GLUC3	0.0	1	5.1	101.8	96.9	97.0	96.8	98.4	97.0	1.00	1,030
TRIGL	0.00	1	3.31	261.9	261.9	265.0	261.3	261.7	262.3	0.74	0.282
TP2	0.00	1	3.74	7.7	7.7	7.7	0 7.7 8	07.7	0 7.7	0.0	0.0
CA2	10.11	1	1.04	9.7	9.7	9.8	9.9	10.1	9.8	0.08	0.816

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MDC, MANANTHAVADI Serial No. 420523

TEST	SAMPLE RUN	RUN 1	RUN 2	RUN 3	RUN 4	RUN 5	MEAN	SD	CV%
PHOS 2	1	3.8	3.8	3.8	3.8	3.7	3.8	0.02	0.526
HDLC 4	1 1 F1	42.7	42.7	42.6	42.4	41.4	42.3	0.26	0.613
CHO2	1	205.8	197.2	202.4	201.0	203.7	202.0	1.72	0.851
UREA L	1	26.1	26.1	26.5	26.4	26.9	26.4	0.16	0.606
UA2	20,01	5.0	5.0	4.9	4.8	4.9	4.9	0.04	0.816
BILT3	00.11	1.3	1.2	1.2	1.2	1.1	1.2	0.02	1.666
BILD2	\$7,01 E.S	0.31	0.32	0.31	0.31	0.31	0.31	0.002	0.645
CREJ 2	0.01	0.75	0.75	0.74	0.74	0.72	0.74	0.006	0.810
ALTL	80.01 8	46.3	46.0	46.2	46.2	45.9	46.1	0.08	0.173
ALP2 L	1	144.9	138.9	138.7	140.1	139.6	139.0	1.24	0.883

Roche

MDC, MANANTHADI

MDC, MANANTHAVADI Serial No. 420523

Results:	Instrument ID: MDC/INTGRA	<u>l</u> 01 Sr. N	lo # 420523
Chart 2: Acceptance Cri	teria vs. Performance Test Results.		

TESTS	SAMPLE RUN	RUNS	Acceptance Criteria CV%	Test Results CV%	Pass/Fail
ALB	6.173	5	2	0.388	PASS
ASTL	684.0	5	3	0.067	PASS
GLUC3	1	5	2	1.030	PASS
TRIGL	1	5	3	0.282	PASS
TP2	1	5	2	0.00	PASS
CA2	1	5	2	0.816	PASS
PHOS2	1	5	3	0.526	PASS
HDLC4	1	5	3	0.613	PASS
CHOL2	1	5	3	0.851	PASS
UREAL	1	5	3	0.606	PASS
UA2	1	5	2	0.816	PASS
BILT3	1	5	3	1.666	PASS

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MDC, MANANTHAVADI Serial No. 428523

Cobas Integra 400 plus PQ

MDC, MANANTHADI Serial No. 420523

Cobas Integra 400 plus

TESTS	SAMPLE RUN	RUNS	Acceptance Criteria CV%	Test Results CV%	Pass/Fail
BILD2	1	5	3	0.645	PASS
CREJ2	Results	College CV%	3 444	0.810	PASS
ALTL	881.0	5	3	0.173	PASS
ALP2L	784.0	5	3	0.883	PASS
PASS	1.630	2	8 1	1	DUE
					£AD
PASS		*			HOS2
					HOL2
					IREAL

Roche

Doc no: 20071201/ACC/PQ

Keche

SRL Diagnostics, Raipur Serial No. 422093

3.2. 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



BUISNESS -	- Ap	olication	Specia	list
------------	------	-----------	--------	------

DATE: - 26/08/2022

SIGNATURE:

1

NAME:

ANJALI RAMACHANDRAN

Customer:

Date:-

26 08 2022

Signature:-

Name:-

Jiya. P. Alias

Comments

completed.

Roche