Installation Qualification Procedure (IQ)

COBAS INTEGRA® 400 plus Instrument

Table of Contents

Preface

Revision History

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

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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.

General Information

Customer Information

Company: MDC

Address: Manandhavadi Diagnostic centre
Healthclub Building
Cleskunnu Road, Manandhavadi
Wayanad - 670645

Instrument Location and Department: Biochemistry

Contact Person: Shyam K.S
Yousaf C.T

Roche Representative

Installation Qualification performed by: Anjali

Job Title: Application Specialist

Company: Roche.

Address: Roche Diagnostic India Pvt. Ltd
4th floor, SKCL Harmony Square
Door No. 48 & 50, Prakasam Street,
T-Nagar, Chennai - 600017

Instrument Information

COBAS INTEGRA® 400 plus instrument Serial Number: 420523

General Information

Who can perform the qualification

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

1 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

Test #	Item	Version	Result Pass / Fail
IQ 1.1	Provided access to the latest COBAS INTEGRA® 400 plus Operators Manual (Version 2.7 or higher) (electronically or hard copy)	3.4 Electronicaly	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

Comments

completed.

Conclusion

Do the results meet all the specified Acceptance Criteria defined in this chapter?

Yes: ☑ No: ☐

Signature:  Date: 03/09/2019

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%)	50 HZ	Pass

Comments

Completed

Conclusion

Do the results meet all the specified Acceptance Criteria defined in this chapter?

Yes: ☑ No: ☐

Signature: 

Date: 03/09/2019

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

Comments

Completed.

Conclusion

Do the results meet all the specified Acceptance Criteria defined in this chapter?

Yes: ☑ No: ☐

Signature: Date: 03/09/2019

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)	3.6.2	Pass
IQ 4.2	Realtime CPU Software (Version 3.4 or higher)	3.6.2	Pass

Comments

Conclusion

Do the results meet all the specified Acceptance Criteria defined in this chapter?

Yes: ☑ No: ☐

Signature: Date: 03/09/2019

5 Notes

Signature: Date: 03/09/2019

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	☐ No

Comments:

Performed by Roche representative: Anjali Ramachandran.

Signature: _____ Date: 03/09/2019

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
HT	High Throughput

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.		
7.		
8.		
9.		
10.		

Performed by Roche representative: Anjali Ramachandran

Signature: _____ Date: 03/09/2019

Reviewed and approved by customer: Yousaf. CT

Signature: _____ Date: 03/09/2019

COBAS INTEGRA 400 plus Operational Qualification Procedure (OQ)

COBAS INTEGRA® 400 plus Instrument

Table of Contents

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 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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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

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: MDC Laboratory

Address: Manandhavadi Diagnostic Centre
Health club Building
Cluskunnu Road, Manandhavadi
Wayanad - 670645

Instrument Location and Department: Biochemistry

Contact Person: Shyam K.S
Yousaf E.T

Roche Representative

Operational Qualification performed by: Anjali Ramachandran

Job Title: Application Specialist

Company: Roche.

Address: Roche Diagnostics India Pvt. Ltd.
4th floor, Skel Harmony Square
Door NO. 48 & 50, Prakasam Street
T. Nagar, Chennai - 600 017

Instrument Information

COBAS INTEGRA 400 plus instrument	Serial Number: HR0523
ISE Module used:	☐ Yes ☑ No * * 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.

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.

Results

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

Comments

completed.

Conclusion

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

Yes: ☑ No ☐

Signature: Date: 03/09/2019

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

Coefficient of Variation (%CV)	
CHKBR / CHKCR (R1)	< 0.5%
CHKBS / CHKCS	< 1.5%
CHKBSR /CHKCSR (R2)	< 1.5%

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.

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).

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 Δ abs	Target Δ abs	High Δ abs
Check Sample	(10)60820501	1.26	1.33	1.40
Check Cassette R1	5C8785O1	0.385	0.397	0.409
Check Cassette SR	5C8785O1	0.381	0.393	0.405

Results

Test #	Test	Result: CV %	Result: Mean	Result: pass / fail	Verified by & Date
OQ 2.1	CHKBR	0.40	0.395	Pass	Anjali
OQ 2.2	CHKBS	0.34	1.335	Pass	Anjali
OQ 2.3	CHKBSR	0.92	0.393	Pass	Anjali
OQ 2.4	CHKCR	0.24	0.3944	Pass	Anjali
OQ 2.5	CHKCS	0.30	1.319	Pass	Anjali
OQ 2.6	CHKCSR	0.28	0.392	Pass	Anjali

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

Comments

Completed.

Conclusion

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

Yes: ☑ No ☐

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.

Reagents & Specification

Reagent	Lot & Exp. Date
ASTL Cassette	60286301 , 29/10/2022

Calibrator	Lot & Exp. Date	Lot – specific value	Unit
Calibrator: c.f.a.s	53994101 31.07.2023	101.0	U/L

QC Material	Lot & Exp. Date	3 x 1s (lot–specific) "Permissible Dev."	Lot–specific "Assigned Value"	Unit
BIORAD	26491	1.0	1.0	U/L

Measurement

QC	Result	Unit	Date and Time
BIORAD	34.4	U/L	14/08/2022

Results

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

Comments

Completed.

Conclusion

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

Yes: ☑ No ☐

Signature: Date: 14/08/2022

4 Run Sodium, Potassium and Chloride Calibration

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

Results

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			

Comments

Conclusion

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

Yes: ☐ No ☐

Signature: Date: 03/09/2019

5 Notes

Signature: _____ Date: 03/09/2019.

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

Comments:

completed.

Performed by Roche representative: Anjali Ramachandran

Signature: _____ Date: 03/09/2019

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
CV	Coefficient of variation

B Deviation Log

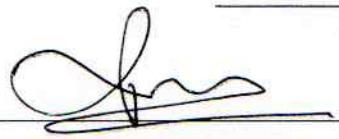
Record all deviations noticed during the Operational Qualification in the list below:

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

Performed by Roche representative: Anjali Ramachandran.

Signature:  Date: 03/09/2019

Reviewed and approved by customer: Tanishq CIT

Signature:  Date: 03/09/2019

Cobas Integra 400 plus
PQ

MDC, MANANTHAVADI
Serial No. 420523

(PQ)
Performance Qualification

Roche
Doc no: 20071201/ACC/PQ

Cobas Integra 400 plus
PQ

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

Cobas Integra 400 plus
PQ

MDC, MANANTHAVADI
Serial No. 420523

CHART 1: Precision Data

TEST	SAMPLE RUN	RUN 1	RUN 2	RUN 3	RUN 4	RUN 5	MEAN	SD	CV%
ALB	1	5.26	5.28	5.18	5.15	5.15	5.15	0.02	0.388
ASTL	1	29.8	29.8	29.8	29.9	29.9	29.8	0.02	0.067
GLUC3	1	101.8	96.9	97.0	96.8	98.4	97.0	1.00	1.030
TRIGL	1	261.9	261.9	265.0	261.3	261.7	262.3	0.74	0.282
TP2	1	7.7	7.7	7.7	7.7	7.7	7.7	0.0	0.0
CA2	1	9.7	9.7	9.8	9.9	10.1	9.8	0.08	0.816

Cobas Integra 400 plus
PQ

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	42.7	42.7	42.6	42.4	41.4	42.3	0.26	0.613
CHO2 I	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	1	5.0	5.0	4.9	4.8	4.9	4.9	0.04	0.816
BILT3	1	1.3	1.2	1.2	1.2	1.1	1.2	0.02	1.666
BILD2	1	0.31	0.32	0.31	0.31	0.31	0.31	0.002	0.645
CREJ 2	1	0.75	0.75	0.74	0.74	0.72	0.74	0.006	0.810
ALTL	1	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

Cobas Integra 400 plus
PQ

MDC, MANANTHAVADI
Serial No. 420523

Results: _____ **Instrument ID:** MDC/INTGRA/01 **Sr. No # 420523**

Chart 2: Acceptance Criteria vs. Performance Test Results.

TESTS	SAMPLE RUN	RUNS	Acceptance Criteria CV%	Test Results CV%	Pass/Fail
ALB	1	5	2	0.388	PASS
ASTL	1	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

Cobas Integra 400 plus
PQ

MDC, MANANTHADI
Serial No. 420523

TESTS	SAMPLE RUN	RUNS	Acceptance Criteria CV%	Test Results CV%	Pass/Fail
BILD2	1	5	3	0.645	PASS
CREJ2	1	5	3	0.810	PASS
ALTL	1	5	3	0.173	PASS
ALP2L	1	5	3	0.883	PASS

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 - Application Specialist

DATE: - 26/08/2022

SIGNATURE :

NAME:
ANJALI RAMACHANDRAN

Customer:

Date:- 26/08/2022

Signature:-

Name:- Jiya. P. Alias

Comments
completed.

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.

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

[1] ISO 15189:2012/ ISO 15189:2014 Medical laboratories — Requirements for quality and competence

[2] A. Directive 98/79/EC of the European Parliament and of the Council of the 27 October 1998 on vitro diagnostics medical devices;
B. IVD Regulation 2017/746/EU of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

[3] EN ISO 13485:2016 Medical devices — Quality management systems-Requirements for regulatory purposes

[4] CFR Part 820, Quality System regulations 21 Regulations on medical devices

Mannheim, 10. August 2021

Sincerely,

Roche Diagnostics GmbH

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

DocuSigned by:
ECA5294AC4E94AF...

Andrea Weber
Manager Global Regulatory Affairs
Centralised and Point of Care Solutions

ppa/*on behalf of the company*

DocuSigned by:
Ralf Zielenski
A7F0BA9FE91A46A...

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

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim

Roche Diagnostics India Pvt. Ltd.

Field Service Report

Case number: CAS-0016432102

Order Number: WO-02112314 | Visit Date: 31/01/2023

Instrument Details

Instrument/Module:	COBAS INTEGRA 400 plus
Serial Number:	420523
Internal Instrument Name:	

Additional Details

:

Customer details

Customer Number:	0052612616
Customer Name:	Mananthavady Diagnostic Centre
Street Address:	Club Kunnu Road,
:	670645 - Manathavady
:	Ms Jiya
:	

: PM Visit

Purpose of Visit

PM COBAS INTEGRA 400 plus Major

Performed Activities

Carried put routine pm visit,cleaned the instrument,done instrument checks,done instrument calibration,run qc and samples. Instrument working fine

Time Report

Category	Start	End	Hours	Invoice Type
05913616001-Service labour time	31/01/2023 12:25 pm	31/01/2023 4:00 pm	3.57	Warranty

Travel

Value	Hours
Travel	4.42

Customer Parts Used

Part Number	Description	Quantity
05670713001-KIT MAINTENANCE I400/400PLUS	KIT MAINTENANCE I400/400PLUS	1

Roche Diagnostics India Pvt. Ltd.

Field Service Report

Case number: CAS-0016432102

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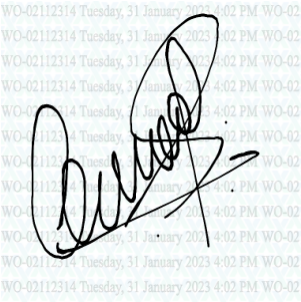
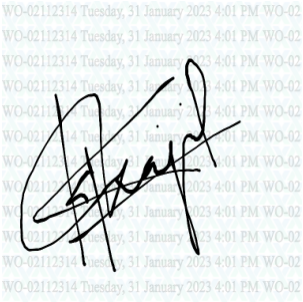
Signature

Customer Signature
Ms Jiya



Customer Signature

Roche support
Prajil CK



Roche Signature

The customer acknowledges the service intervention as performed in accordance with Roche recommendations:
- This Service report has been signed by the authorized representative of your organization.
- Discrepancies if any must be intimated within a period of seven (7) days of the receipt of the email, in the absence of which the report will be final and conclusive.
- This report shall be governed by the laws of India and the courts at Mumbai shall have the exclusive jurisdiction to deal with the disputes arising hereunder.

MDC

EXCELLENCE 26 YEARS IN SERVICE

MANANTHAVADY DIAGNOSTIC CENTRE

HEALTH CLUB BUILDING, CLUB KUNNU ROAD,
MANANTHAVADY, WAYANAD, KERALA – 670645.
MOB : 9288658472

This is to inform that we had informed the company Roche Diagnostics,manufacturer and reagent supplier of our Fully automated Biochemistry analyzer COBAS INTEGRA 400 plus analyzer (Serial No: 420523) installed at our Laboratory to get the calibration certificate for documentation purpose of NABL EL program but the service engineer of Roche Diagnostics supplied a certificate showing the proper functioning of analyzer in their own format (attached along with the IQ, OQ and PQ certificates). The performance of the analyzer is very good (Internal and external QC reports are within range) and the company provides proper maintenance as per scheduled chart.
Hence I request that by considering these facts kindly approve the document attached here for getting the accreditation.

Thanking you,
Yours faithfully
Jiya .P. Alias
Medical Biochemist

Jiya. P. Alias
M.SC Biochemistry

REPORT DISCLAIMER

1. The results reported herein are subject to interpretation by qualified medical professionals only.
2. Customer identities are accepted as provided by the customer or their representatives.
3. Information about the Customer's condition at the time of sample collection such as fasting, food consumption medication, etc are accepted as provided by the customer or representative and shall not be investigated for its truthfulness.
4. If any specimen / sample is received from any other laboratory / Hospital, it is presumed that the sample belongs to the patient identified or named.
5. Test results should be interpreted in context of clinical and other findings if any. In case of any clarification / doubt, the referring doctor/ patient can contact the respective section head of the laboratory.
6. result of the test are influenced by various doctors such as sensitivity, specificity of the procedures of the tests, Quality of the samples and drug interactions etc.,
7. If the test results are found not to be correlating clinically, the clinician can contact the lab in-charge for clarification or retesting where practicable within 24 hours from the time of issue of results.
8. Liability is limited to the extent of amount billed.