cobas®

*Life needs answers*

# cobas Integra 400 plus Analyzer

Qualification Service

**Installation Qualification / Operation Qualification (v.1.0)**

Roche

# cobas Integra 400 *plus*

## General Information

| | |
|---|---|
| Country: | India |
| Customer Name: | Care Diagnostics |
| Customer Address: | 3rd Cross,oppo. ICICI Bank,Neeladri Nagar,Electronic city,Phase-1 Bengaluru-100 |
| Person Responsible for Quality Assurance: | Dr. Meenu.EV |

## System Information

| | S/N |
|---|---|
| cobas Integra 400+: | 420027 |
| Host provider: | NA |
| Software Version: | 3.6 |

## Installation Information

| | | | | |
|---|---|---|---|---|
| Installation Start Date: | 18.02.2020 | | | |
| First Installation: | yes | | | |
| Reconfiguration: | From: | specify | To: | specify |
| Relocation: | From: | | To: | |

Roche Responsible Representative : Mr. Sumith

# Installation Qualification:

This document forms the basis of the Qualification Services Certificate. It certifies that the instrument is installed according to the manufacturer's specifications. The report presents and documents the test procedures, the documentation, reference and acceptance criteria used to verify that the system is installed according specifications. The report demonstrated that all installation qualification criteria have been met satisfactorily.

***Notice:*** The following tests are to be carried out by trained Roche personnel only.

***Purpose:*** The purpose of this test is to confirm that the instrument was delivered undamaged and installed correctly.

| Test # | Test | Pass Fail | Signature Date |
|---|---|---|---|
| IQ.1.1 | Operator's Manual available | Pass | 20.02.2020 |
| IQ 1.2 | Environmental parameters met | Pass | 20.02.2020 |
| IQ 1.3 | Instrument delivered undamaged and complete | Pass | 20.02.2020<br>20.02.2020 |
| IQ 1.4 | Transport locking successfully removed | Pass | 20.02.2020 |
| IQ 1.5 | All connections correctly installed | Pass | 20.02.2020 |
| IQ 1.6 | Instrument positioned according to Installation Manual | Pass | 20.02.2020<br>20.02.2020 |
| IQ 1.7 | Instrument boot process successfully | Pass | 20.02.2020 |
| IQ 1.8 | Checksum according to specification | Pass | 20.02.2020 |
| IQ 1.9 | Mechanical adjustments complete | Pass | 20.02.2020 |
| IQ 1.10 | Auxiliary components positioned | Pass | 20.02.2020 |
| IQ 1.11 | Instrument installation check | Pass | 20.02.2020 |
| IQ 1.12 | Host communication settings checked | yes | 20.02.2020 |

| Test # | Test | Pass Fail | Signature Date |
|---|---|---|---|
| IQ.2 | Installation Qualification for cobas Integra 400+ | yes | 20.02.2020 |

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

| **Deviation #1** | |
|---|---|
| | |
| **Investigation** | |
| | |
| **Action taken** | |
| | |
| **Deviation resolved satisfactorily?** | specify |

| **Deviation #2** | |
|---|---|
| | |
| **Investigation** | |
| | |
| **Action taken** | |
| | |
| **Deviation resolved satisfactorily?** | specify |

| **Deviation #3** | |
|---|---|
| | |
| **Investigation** | |
| | |
| **Action taken** | |
| | |
| **Deviation resolved satisfactorily?** | specify |

# Operational Qualification:

This document is the basis of the Qualification Service Certificate. It certifies that the instrument is operating according to the manufacture's specifications. This report presents and documents the test procedures, documentation, references and acceptance criteria used to verify that the specified system is operating according the specifications. The report demonstrates that all operational qualification criteria have been met satisfactorily.

***Notice:*** The following tests are to be carried out by trained Roche personnel only.

***Purpose:*** The purpose of this test is to check that the modules are operating in accordance with the

| Test # | Test | Pass Fail | Signature Date |
|---|---|---|---|
| OQ.1 | Calibration successfully | Pass | |
| OQ.2 | Quality Control successfully | Pass | |
| OQ.3 | Accuracy check successfully | Pass | |

21/02/2020

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

| **Deviation #1** | |
|---|---|
| | |
| **Investigation** | |
| | |
| **Action taken** | |
| | |
| **Deviation resolved satisfactorily?** | specify |

| **Deviation #2** | |
|---|---|
| | |
| **Investigation** | |
| | |
| **Action taken** | |
| | |
| **Deviation resolved satisfactorily?** | specify |

# Conclusion

| | |
|---|---|
| All test results are acceptable. | yes |
| Any deviation or non-conformances observed have been recorded as a deviation and the relevant forms completed. | yes |
| All acceptance criteria have been met. This equipment is deemed acceptable and the unit is approved for its intended use. | yes |

***Comments***

Instrument working satisfactorily

Completed by Roche Representative — Date 21/02/2020

Print Name Loy Mascrarenhas
Application Specialist — Signature

Reviewed by Customer Contact — Date 22/02/2020

Print Name Dr. Meenu. E. V — Signature

Reviewed by Customer Quality Assurance — Date

Print Name — Signature

# Installation Qualification for cobas® Integra 400 plus

***Description***

| | | |
|---|---|---|
| IQ.1.1 | Operator's Manual available | |
| | Check that a copy of the latest version of the Operator's Manual is available. | Pass |
| IQ 1.2 | Environmental parameters | |
| | Ambient temperature in the lab is between 15° and 32 °C | Pass |
| | Relative Humidity maximum of 50% at 32 °C and non-condensing | Pass |
| | Bacteria free, deionized water < 10 cfu/ml | Pass |
| | Water conductivity 1.0 µS/cm or less | Pass |
| | Dust and Vibration free | Pass |
| | Instrument is not exposed to direct sunlight | Pass |
| IQ 1.3 | Instrument delivered undamaged and | |
| | All covers are undamaged | Pass |
| | All accessory boxes are delivered | Pass |
| | Instrument does not show any external damage | Pass |
| IQ 1.4 | Transport locking successfully removed | |
| | Unpacking of the different modules and accessories without damage to units | Pass |
| IQ 1.5 | All connections correctly installed | |
| | Power supply voltage at the customer facility: | 230V ±2V |
| | UPS system available: | yes |
| | Voltage fluctuation less than 230 ±5V | Pass |
| | Grounding less than 1.0 V | Pass |

| | | |
|---|---|---|
| IQ 1.6 | Instrument positioned according to Installation Manual | |
| | System layout is according to the description in the | Pass |
| IQ 1.7 | Instrument boot process successful | |
| | IP address configuration successful | Pass |
| | System Configuration successful | Pass |
| | First system boot-up | Pass |
| IQ 1.8 | Checksum according to specification | |
| | Version of installed cobas Integra 400+ software | 3.5.2 |
| | Installation of country language successful | yes |
| IQ 1.9 | Mechanical adjustments complete | |
| | All mechanical adjustments are carried out | Pass |
| IQ 1.10 | Auxiliary components positioned | |
| | | Pass |
| IQ 1.11 | Instrument installation check | |
| | Print function | yes |
| | Rack/Sample barcode read check | Pass |

| | | |
|---|---|---|
| IQ 1.12 | Host communication settings checked | |
| | Check Host settings according to Host manual | yes |
| | Check Host communication | yes |

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

| **Deviation #1** | |
|---|---|
| | |
| **Investigation** | |
| | |
| **Action taken** | |
| | |
| **Deviation resolved satisfactorily?** | specify |

| **Deviation #2** | |
|---|---|
| | |
| **Investigation** | |
| | |
| **Action taken** | |
| | |
| **Deviation resolved satisfactorily?** | specify |

| **Deviation #3** | |
|---|---|
| | |
| **Investigation** | |
| | |
| **Action taken** | |
| | |
| **Deviation resolved satisfactorily?** | specify |

# Installation Qualification for cobas® Integra 400 plus:

***Description***

| | | |
|---|---|---|
| IQ.2.1 | Function check of Integra400+ module according to specifications | |
| | System layout is according to the description in the manual | Pass |
| | Integra 400+ is installed according to the installation manual and using official tools | Pass |
| IQ.2.2 | Mechanical adjustments complete | |
| | All mechanical adjustments for the different Integra 400+ mechanical parts are carried out | Pass |
| IQ.2.3 | Auxiliary components positioned | |
| | Wash solutions are installed at the Integra 400+ | Pass |
| | ISE electrodes are installed | not applicable |
| | ISE solutions are installed | not applicable |
| | Probe B & Probe C (Reagent & Sample) pipetters installed | Pass |
| IQ 2.4 | Instrument installation check | |
| | Air water Calibration | Pass |
| | Prime Fluid System | Pass |
| | Analyzer Rotor (Reaction) temperature 37°C ± 0.5°C | Pass |

| | | |
|---|---|---|
| | Carry out Instrument Check according to Method Sheet of the cobas c pack INSTC (Art. No. 04851013 190) (attached printout) | Pass |
| | ISE Check 20 times (attached printout) | not applicable |
| IQ 2.5 | Assay installation | |
| | Download of applications from TAS (attached list of applications) | Pass |
| | Load corresponding reagent c-packs | Pass |

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

| | |
|---|---|
| **Deviation #1** | |
| | |
| **Investigation** | |
| | |
| **Action taken** | |
| | |
| **Deviation resolved satisfactorily?** | specify |

| | |
|---|---|
| **Deviation #2** | |
| | |
| **Investigation** | |
| | |
| **Action taken** | |
| | |
| **Deviation resolved satisfactorily?** | specify |

# Operational Qualification:

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

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

***Description***

## OQ 1 Calibration

Calibration of all photometric parameters successful (attached printout) — yes

Calibration of all ISE parameters successful (attached printout) — not applicable

## OQ.2 Quality Control

Specify the type of control used:

Preci control (Roche)

QC of all photometric parameters within acceptable range (attached printout) — yes

QC of ISE parameters within acceptable range (attached printout) — not applicable

## OQ.3.1 Accuracy check for ISE

Perform test with analytical reagents

| | Number of det. |
|---|---|
| Na | 21 |
| K | 21 |
| Cl | 21 |

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

Accuracy check for ISE was within acceptable range not applicable

### OQ.3.2 Accuracy check for Photometric Assays

Perform test with analytical reagents

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

Sample solution: Precicontrol (Roche Control)
Fill cobas cups with Precicontrol & perform 21 determinations of each parameter.

Accuracy check for Photometric Assays was within acceptable range: yes

### OQ.3.2 Precision check for Photometric Assays

Perform test with analytical reagents

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

Sample solution: Precicontrol ( Roche Control )
Fill cobas cups with Precicontrol & perform 21 determinations of each parameter.

Precision check for Photometric Assays was within acceptable range: yes

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

| |
|---|
| **Deviation #1** |
| |
| **Investigation** |
| |
| **Action taken** |
| |
| **Deviation resolved satisfactorily?** specify |

# Attachments

1. Precision - Intra & Inter assay

2. Accuracy Check

## Roche Professional Services

**(ISO 9001:2015 Certified)**

# Instrument Commissioning Report

Name of Institution: Care Diagnostics

Complete Address: 3rd Cross,oppo. ICICI Bank,Neeladri Nagar,Electronic city,Phase-1.

City: Bengaluru Pin Code: 560100

Person Incharge : Dr.Meenu EV REXIS ORD : ORD-0014381412

Instrument Model: cobas Integra 400Plus Serial No.: 4220027

SW Version : 3.6 Training Completed On : 21-02-2020

Call Received Date: 19-02-2020 Call Attended Date: 20-02-2020

Travel Hours : 9+2+2+9 Work Hours: 9+9

## System Configuration & Preliminary application work:

**(Please check in the Box)**

| | | | |
|---|---|---|---|
| A. System configuration & programming | ☑ | E. Assay Calibration | ☑ |
| B. Hardware Overview | ☑ | F. QC Run | ☑ |
| C. Software Overview | ☑ | G. User Maintenance | ☑ |
| D. Sample & QC Processing | ☑ | H. Precision Check & Evaluation | ☑ |
| I. Basics of Telephone Trouble Shooting | ☑ | | |

## Training Feedback:

**(Please rate as per the Scale)**

1 2 3 4 5 6 7 8 9 10

Unsatisfactory Fair Good V. Good Excellent

| | |
|---|---|
| Structure | 10 |
| Objective Reached | 10 |
| Ratio of Lecture to Practical time | 10 |
| Quality of Lecture | 10 |
| Completeness of Information | 10 |
| Knowledge | 10 |
| Openness to Questions | 10 |
| **Overall Training Satisfaction** | 10 |

Comments

CARE - DIAGNOSTICS BANGALORE Electronic City 560100

**Signature of Trainer** **Signature & Seal of Customer** **Date** 22/2/2020

**Name of Trainer** Loy Mascarenhas **Trainer's Comment:** Instrument Working Satisfactory

*"In case of Complaints/Inquiries please reach our Customer Support Centre at 1800-123-7599/044-30413900"*



**Roche Diagnostics India Private Limited** 501-B & 601-B, Silver Utopia, Cardinal Gracious Road, Chakala Road, Andheri (East), Mumbai- 400069
Tel.: +91 22 66974900 Fax : +91 22 66974909

## Roche Professional Services

# Engineering Installation Report

Name of Institution: CARE DIAGNOSTICS

Complete Address : 3RD CROSS, NEELADRI NAGAR, ELECTRONIC CITY PHASE 1

City : BENGALURU Pin Code : 560100 Telephone No : 8610702227

Person In-Charge. : SUDHARSAN. M Email ID : care2lab@gmail.com.

Instrument Model : COBAS INTEGRA 400 PLUS Serial No : 420027

Software Ver : VER: 3.6.2 Cobas Link Serial No : NA

Department ( kindly √ ) : ☐ Pathology ☐ Blood Bank ☐ Other (mention) _____

Installation Commencement Date : _____ Date of Installation : _____

Travel Hours_____ Work Hours _____ REXIS ORD No ORD-0014381410

**♦ Transportation Damage & Discrepancy Report: {please update after inspection}**

A. List of Missing items : — NIL —

B. Notes on any damages : — NIL —

C. General Remark : — NIL —

**♦ Installation checks & Summary: {please indicate status}**

| | |
|---|---|
| A. Power Supply: | OK P-N: 230.2V, P-E: 230.6V, N-E: 0.4V |
| B. Software Installation & Boot-up: | OK |
| C. Mechanical Adjustments & Setup: | OK |
| D. Fluidic Adjustment & Setup: | OK |
| E. System Checks & Status Print Outs: | OK |

## Installation Feedback:

**(Please rate your Satisfaction Level as per the Scale)**

1 2 3 4 5 6 7 8 9 10

Unsatisfactory Fair Good V. Good Excellent

| | | Comments |
|---|---|---|
| Pre-Installation Information | ☐ | |
| Service Personnel's response in general | ☐ | |
| Product installation & its timely Completion | ☐ | |
| **Overall Installation Satisfaction** | ☐ | |

CARE DIAGNOSTICS BANGALORE Electronic City 9538009359

**Signature of Engineer**_____ **Signature & Seal of Customer**_____ **Date** 20/2/2020

**Name of Engineer** SUMITH. P **Engineer's Comment** INSTALLATION COMPLETED SUCCESSFU

*"In case of Complaints/Inquiries please reach our Customer Support Centre at 1800-123-7599/044-30413900"*

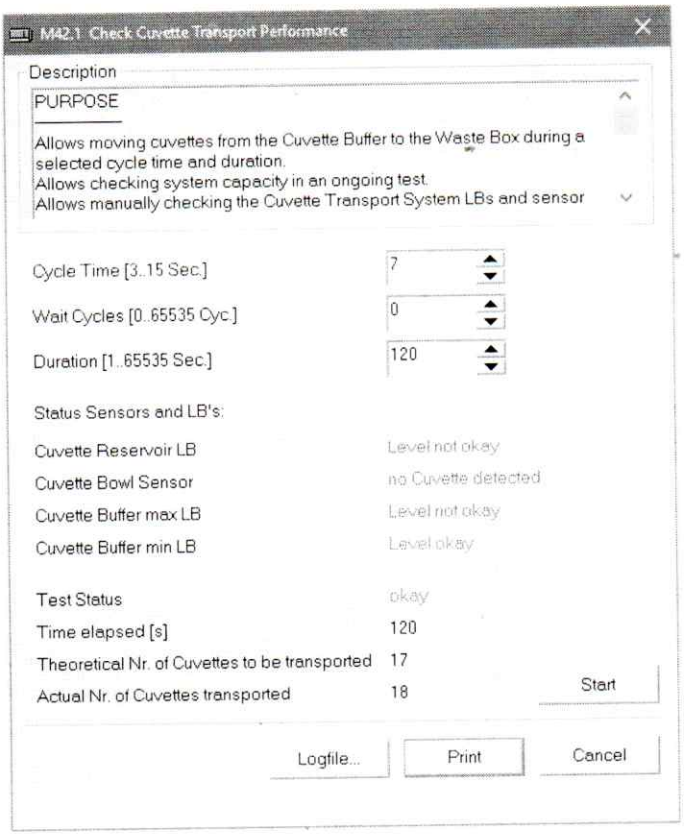


Roche Diagnostics India Private Limited
501-B & 601-B, Silver Utopia, Cardinal Gracious Road, Chakala Road, Andheri (East),Mumbai- 400069
Tel.: +91 22 66974900 Fax : +91 22 66974909

# INTEGRA 400 plus

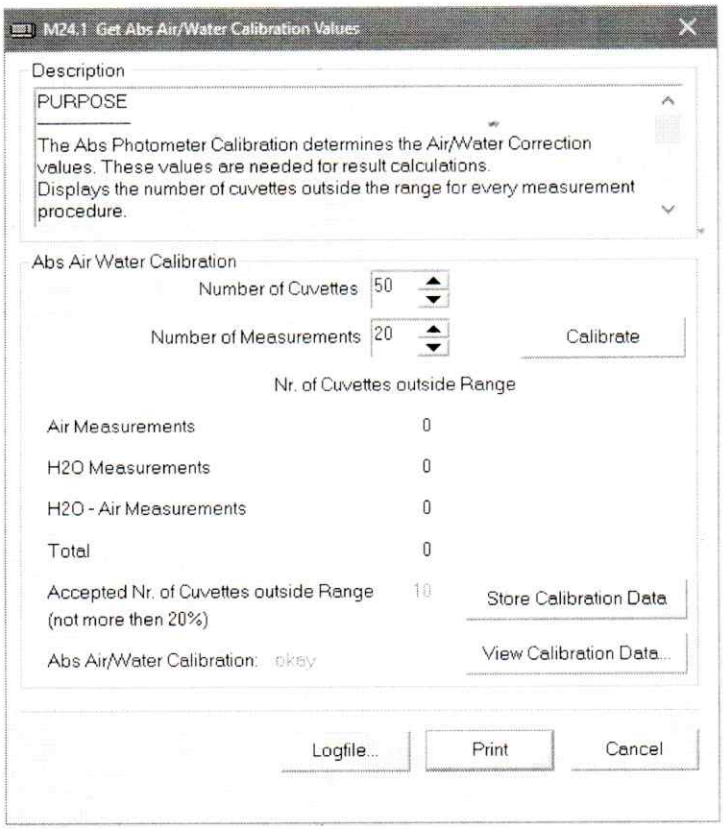
**System Version:** 3.6.2.1904 **Cui Version:** 3.6.2 **Cui Build:** 1904

**System Serial Number:** 420027 Wednesday, February 19, 2020 / 11:06



# INTEGRA 400 plus

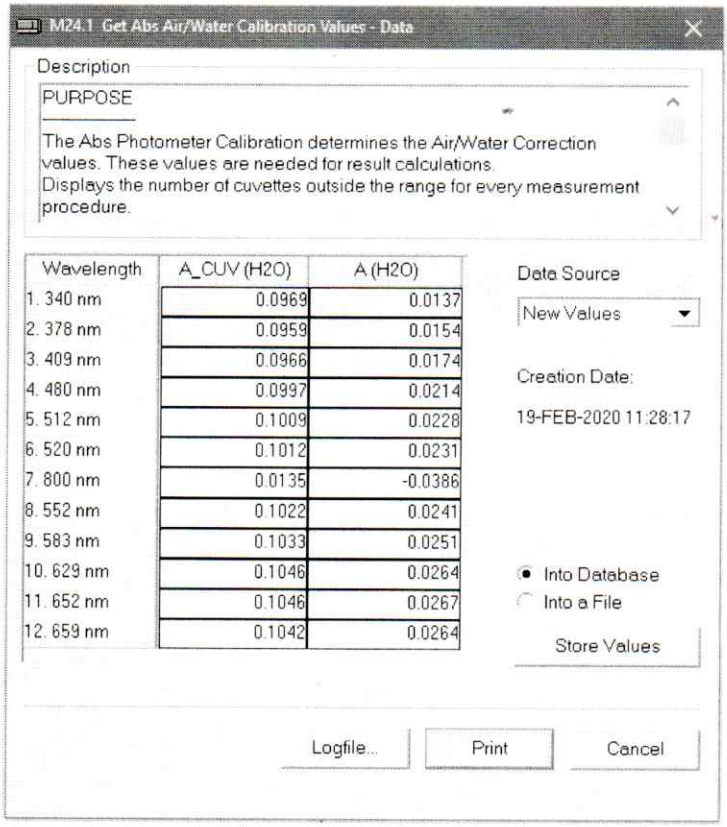
| | | | | | |
|---|---|---|---|---|---|
| **System Version:** | 3.6.2.1904 | **Cui Version:** | 3.6.2 | **Cui Build:** | 1904 |
| **System Serial Number:** | 420027 | | | Wednesday, February 19, 2020 / 11:27 | |



# INTEGRA 400 plus

**System Version:** 3.6.2.1904 **Cui Version:** 3.6.2 **Cui Build:** 1904

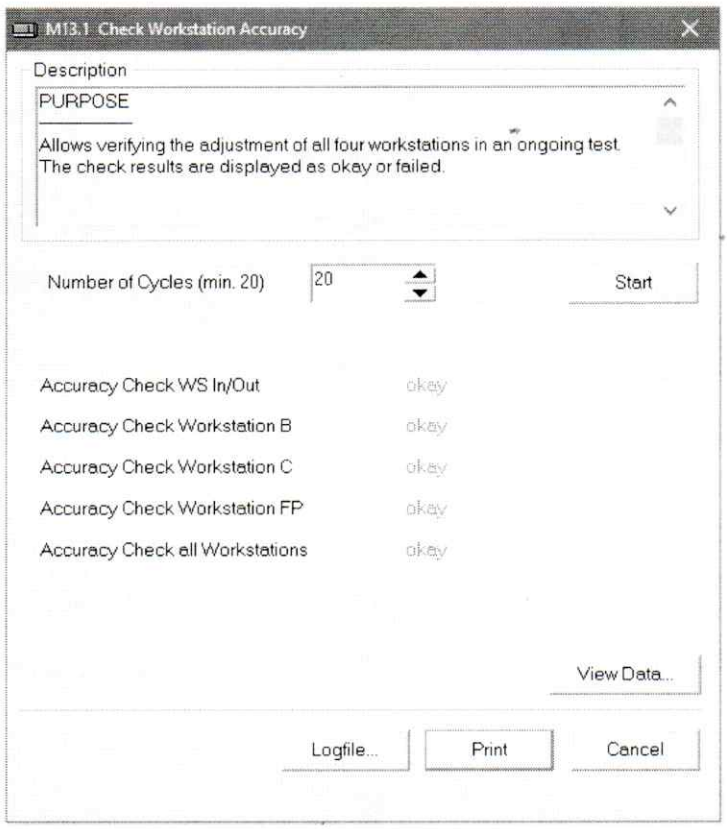
**System Serial Number:** 420027 Wednesday, February 19, 2020 / 11:28



# INTEGRA 400 plus

**System Version:** 3.6.2.1904 **Cui Version:** 3.6.2 **Cui Build:** 1904

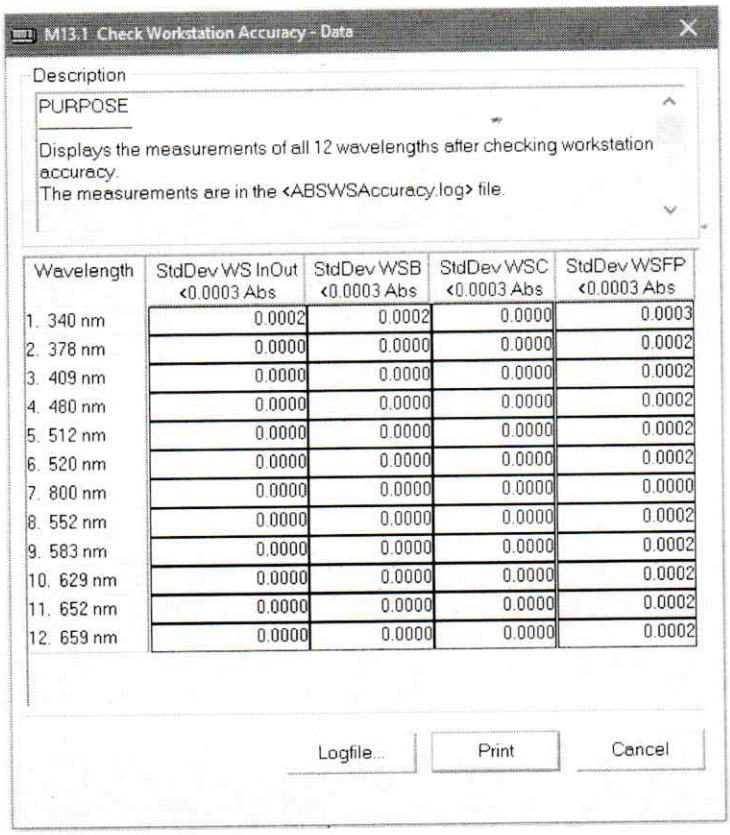
**System Serial Number:** 420027 Wednesday, February 19, 2020 / 11:44



# INTEGRA 400 plus

**System Version:** 3.6.2.1904 **Cui Version:** 3.6.2 **Cui Build:** 1904

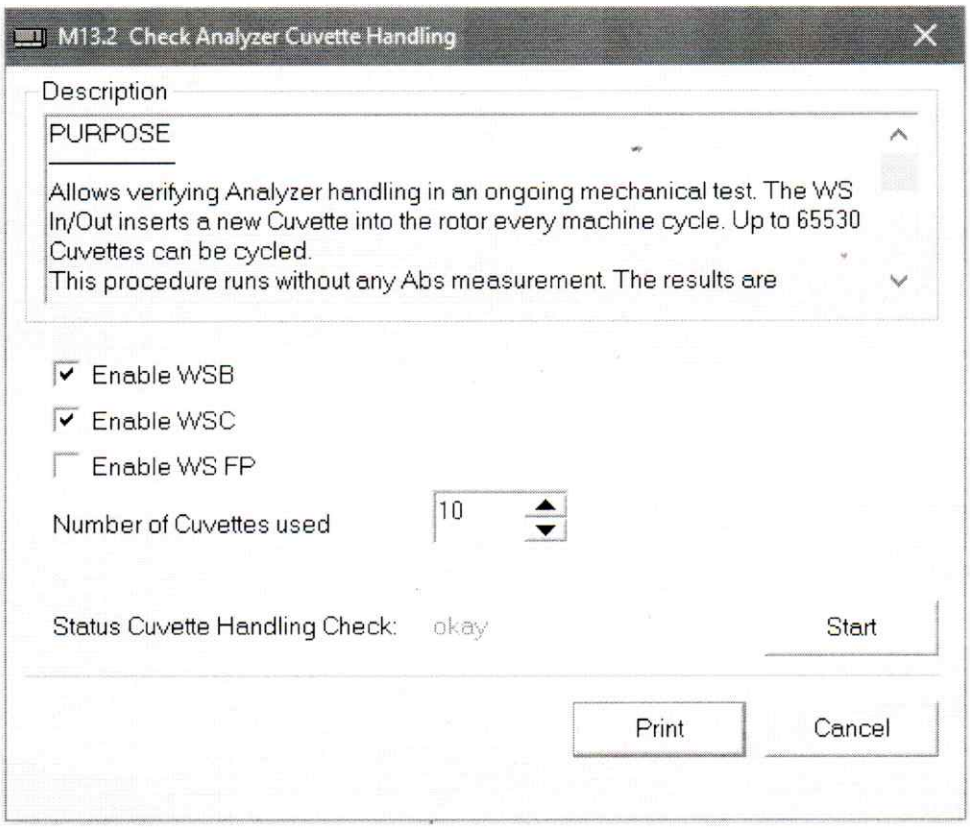
**System Serial Number:** 420027 Wednesday, February 19, 2020 / 11:44




| Wavelength | StdDev WS InOut <0.0003 Abs | StdDev WSB <0.0003 Abs | StdDev WSC <0.0003 Abs | StdDev WSFP <0.0003 Abs |
|---|---|---|---|---|
| 1. 340 nm | 0.0002 | 0.0002 | 0.0000 | 0.0003 |
| 2. 378 nm | 0.0000 | 0.0000 | 0.0000 | 0.0002 |
| 3. 409 nm | 0.0000 | 0.0000 | 0.0000 | 0.0002 |
| 4. 480 nm | 0.0000 | 0.0000 | 0.0000 | 0.0002 |
| 5. 512 nm | 0.0000 | 0.0000 | 0.0000 | 0.0002 |
| 6. 520 nm | 0.0000 | 0.0000 | 0.0000 | 0.0002 |
| 7. 800 nm | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 8. 552 nm | 0.0000 | 0.0000 | 0.0000 | 0.0002 |
| 9. 583 nm | 0.0000 | 0.0000 | 0.0000 | 0.0002 |
| 10. 629 nm | 0.0000 | 0.0000 | 0.0000 | 0.0002 |
| 11. 652 nm | 0.0000 | 0.0000 | 0.0000 | 0.0002 |
| 12. 659 nm | 0.0000 | 0.0000 | 0.0000 | 0.0002 |

# INTEGRA 400 plus

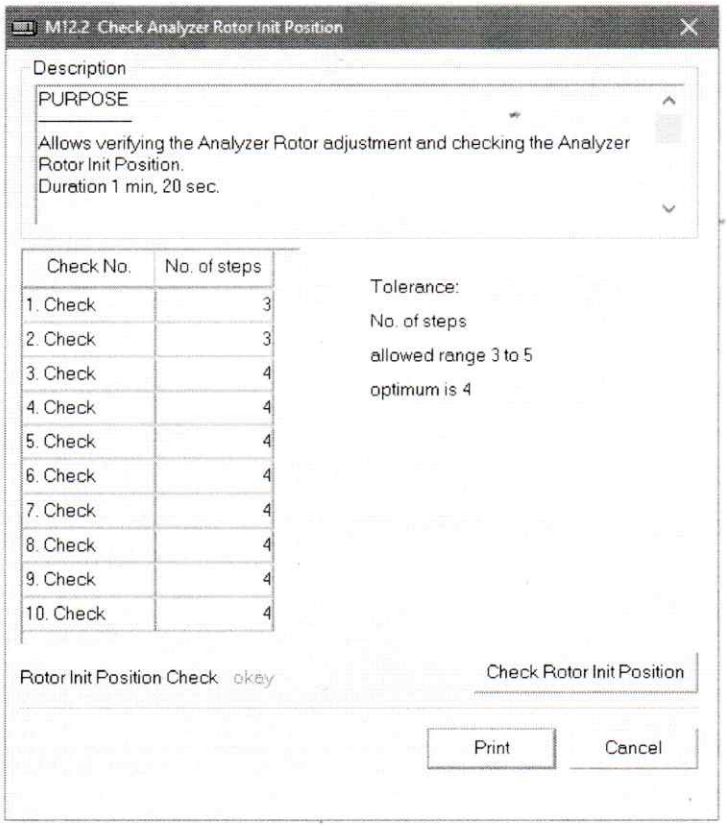
| | | | | | |
|---|---|---|---|---|---|
| **System Version:** | 3.6.2.1904 | **Cui Version:** | 3.6.2 | **Cui Build:** | 1904 |
| **System Serial Number:** | 420027 | | | Wednesday, February 19, 2020 / 11:51 | |



# INTEGRA 400 plus

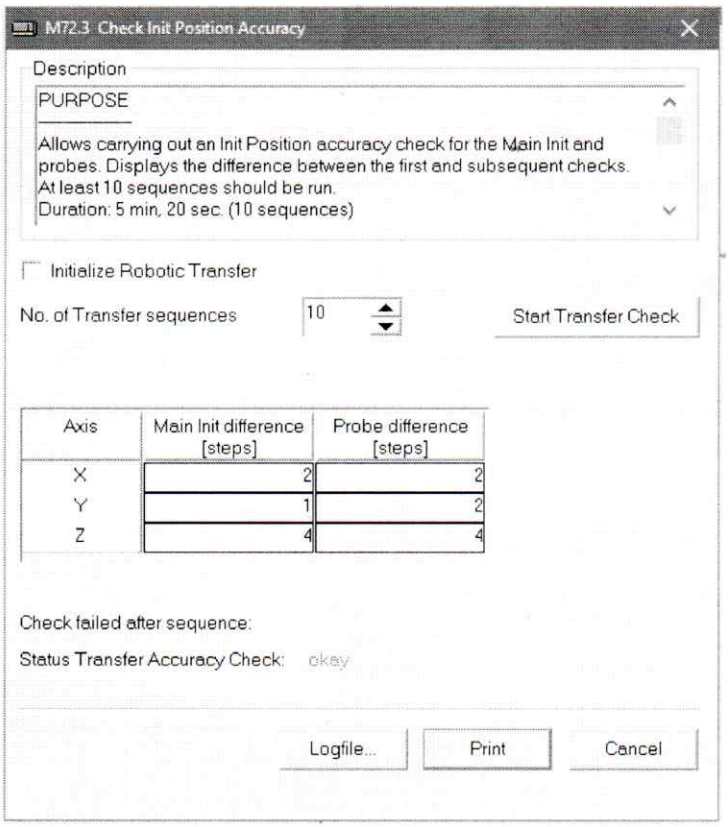
**System Version:** 3.6.2.1904 **Cui Version:** 3.6.2 **Cui Build:** 1904

**System Serial Number:** 420027 Wednesday, February 19, 2020 / 11:53



# INTEGRA 400 plus

| | | | | | |
|---|---|---|---|---|---|
| **System Version:** | 3.6.2.1904 | **Cui Version:** | 3.6.2 | **Cui Build:** | 1904 |
| **System Serial Number:** | 420027 | | | | Wednesday, February 19, 2020 / 12:01 |



## Final Report

Wednesday, February 19, 2020 13:31

Hospital / Lab Name
Address 1
Address 2
City, State, Zip Code
Phone No.

| | | | |
|---|---|---|---|
| Patient ID: | CHECK C | Order ID: | 2 |
| Name: | CHECK C | Created: | Wednesday, February 19, 2020 12:50 |
| Date of Birth: | Sex: Undefined | | |

| Test | Result | Unit | Flag | Reference Range |
|---|---|---|---|---|
| Unassigned | | | | |
| CHECK C Reagenz | 0.40549 | Abs | | |
| CHECK C Reagenz | 0.40608 | Abs | | |
| CHECK C Reagenz | 0.40504 | Abs | | |
| CHECK C Reagenz | 0.40444 | Abs | | |
| CHECK C Reagenz | 0.40620 | Abs | | |
| CHECK C Reagenz | 0.40387 | Abs | | |
| CHECK C Reagenz | 0.40590 | Abs | | |
| CHECK C Reagenz | 0.40474 | Abs | | |
| CHECK C Reagenz | 0.40371 | Abs | | |
| CHECK C Reagenz | 0.40596 | Abs | | |
| CHECK C Reagenz | 0.40471 | Abs | | |
| CHECK C Reagenz | 0.40660 | Abs | | |
| CHECK C Reagenz | 0.40506 | Abs | | |
| CHECK C Reagenz | 0.40577 | Abs | | |
| CHECK C Reagenz | 0.40658 | Abs | | |
| CHECK C Reagenz | 0.40427 | Abs | | |
| CHECK C Sample | 1.25679 | Abs | | |
| CHECK C Sample | 1.23145 | Abs | | |
| CHECK C Sample | 1.24491 | Abs | | |
| CHECK C Sample | 1.22921 | Abs | | |
| CHECK C Sample | 1.24011 | Abs | | |
| CHECK C Sample | 1.23786 | Abs | | |
| CHECK C Sample | 1.23789 | Abs | | |
| CHECK C Sample | 1.23981 | Abs | | |
| CHECK C Sample | 1.24352 | Abs | | |
| CHECK C Sample | 1.25219 | Abs | | |
| CHECK C Sample | 1.23928 | Abs | | |

## Final Report

Wednesday, February 19, 2020 13:31

Hospital / Lab Name
Address 1
Address 2
City, State, Zip Code
Phone No.

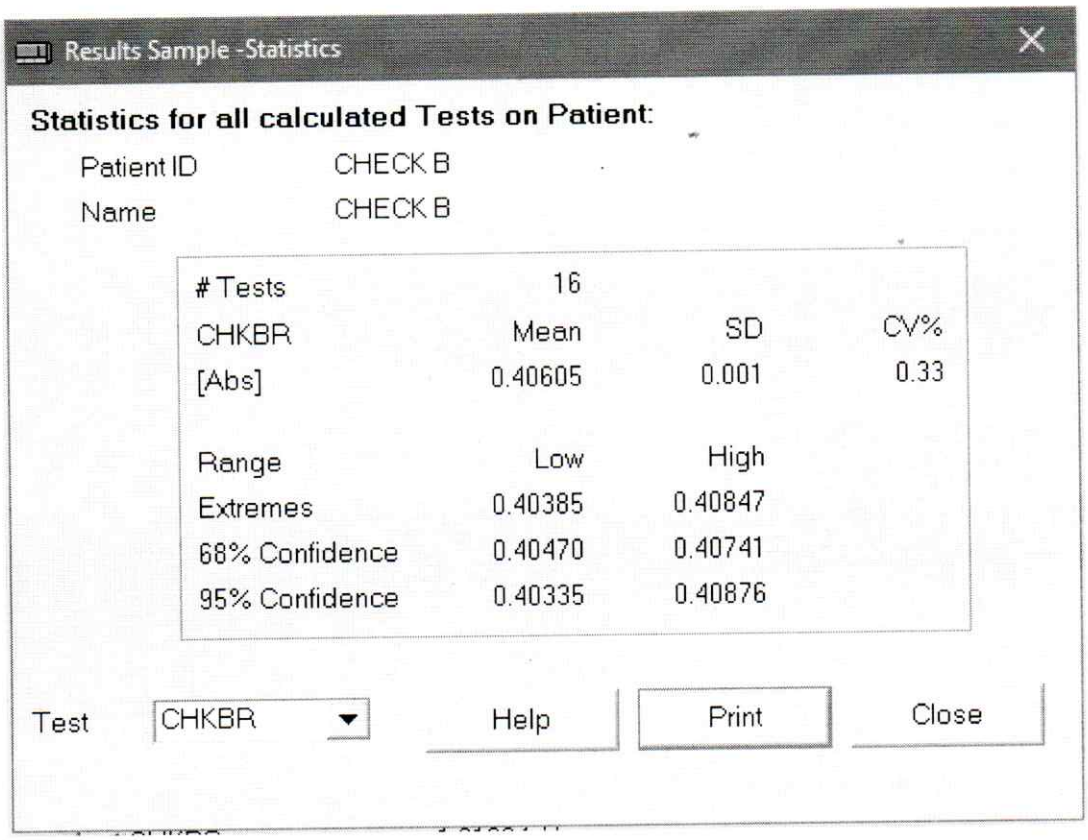
| | | | |
|---|---|---|---|
| Patient ID: | CHECK C | Order ID: | 2 |
| Name: | CHECK C | Created: | Wednesday, February 19, 2020 12:50 |
| Date of Birth: | Sex: Undefined | | |

| Test | Result | Unit | Flag | Reference Range |
|---|---|---|---|---|
| Unassigned | | | | |
| CHECK C Sample | 1.25027 | Abs | | |
| CHECK C Sample | 1.25636 | Abs | | |
| CHECK C Sample | 1.25314 | Abs | | |
| CHECK C Sample | 1.24341 | Abs | | |
| CHECK C Sample | 1.24304 | Abs | | |
| CHECK C Startreagenz | 0.38878 | Abs | | |
| CHECK C Startreagenz | 0.38987 | Abs | | |
| CHECK C Startreagenz | 0.38823 | Abs | | |
| CHECK C Startreagenz | 0.38592 | Abs | | |
| CHECK C Startreagenz | 0.38881 | Abs | | |
| CHECK C Startreagenz | 0.38825 | Abs | | |
| CHECK C Startreagenz | 0.38960 | Abs | | |
| CHECK C Startreagenz | 0.38716 | Abs | | |
| CHECK C Startreagenz | 0.38847 | Abs | | |
| CHECK C Startreagenz | 0.38679 | Abs | | |
| CHECK C Startreagenz | 0.38892 | Abs | | |
| CHECK C Startreagenz | 0.38483 | Abs | | |
| CHECK C Startreagenz | 0.38645 | Abs | | |
| CHECK C Startreagenz | 0.38768 | Abs | | |
| CHECK C Startreagenz | 0.38929 | Abs | | |
| CHECK C Startreagenz | 0.38758 | Abs | | |

# INTEGRA 400 plus

**System Version:** 3.6.2.1904 **Cui Version:** 3.6.2 **Cui Build:** 1904

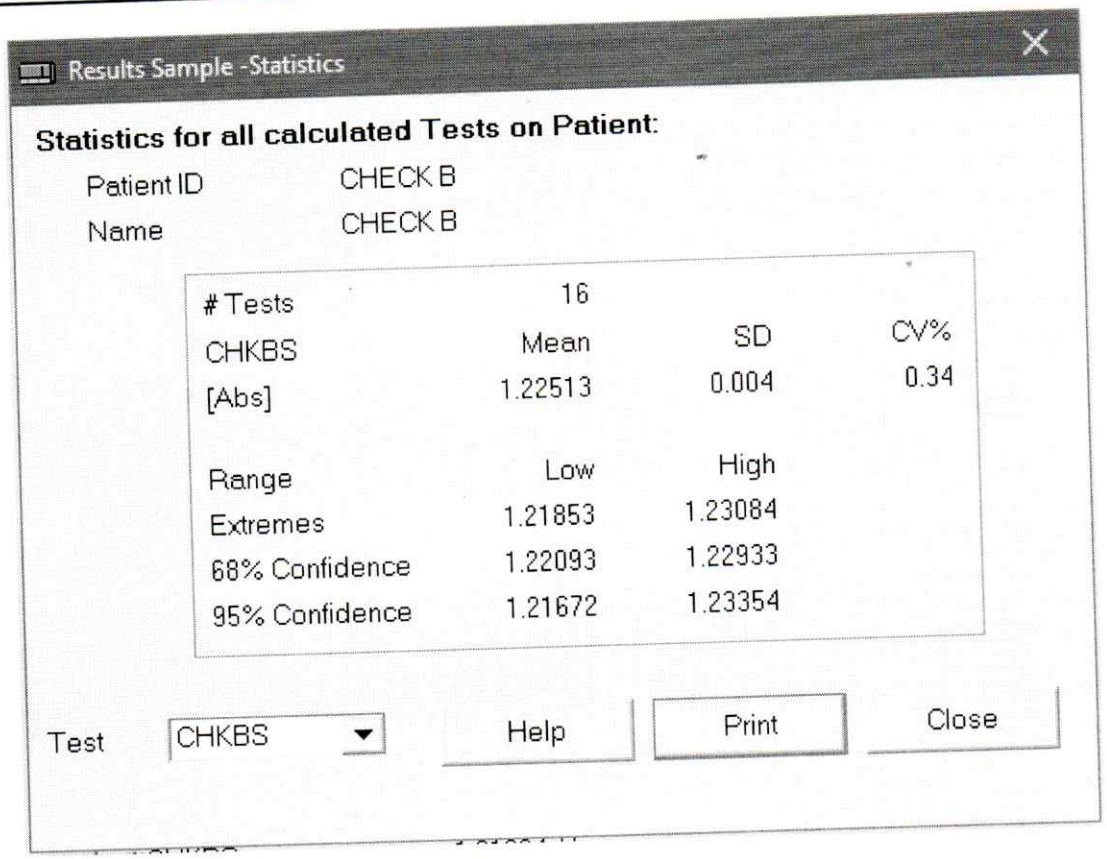
**System Serial Number:** 420027 Wednesday, February 19, 2020 / 13:33



# INTEGRA 400 plus

**System Version:** 3.6.2.1904 **Cui Version:** 3.6.2 **Cui Build:** 1904

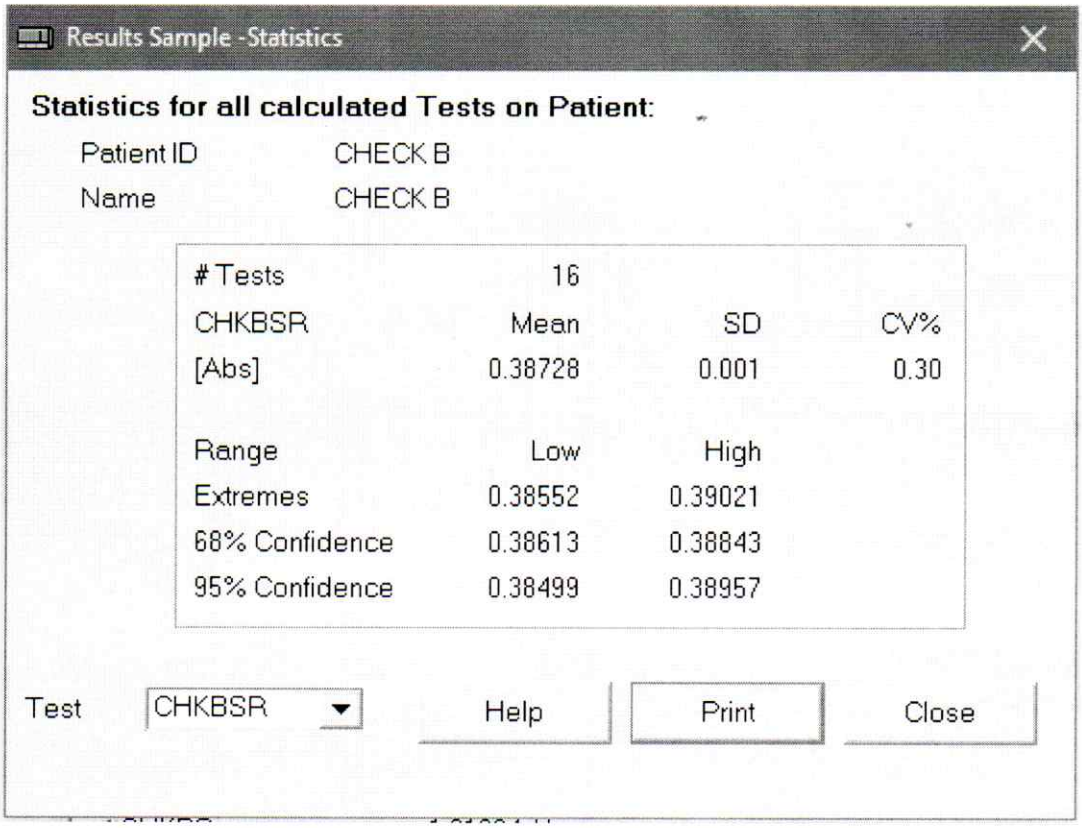
**System Serial Number:** 420027 Wednesday, February 19, 2020 / 13:33



# INTEGRA 400 plus

**System Version:** 3.6.2.1904 **Cui Version:** 3.6.2 **Cui Build:** 1904

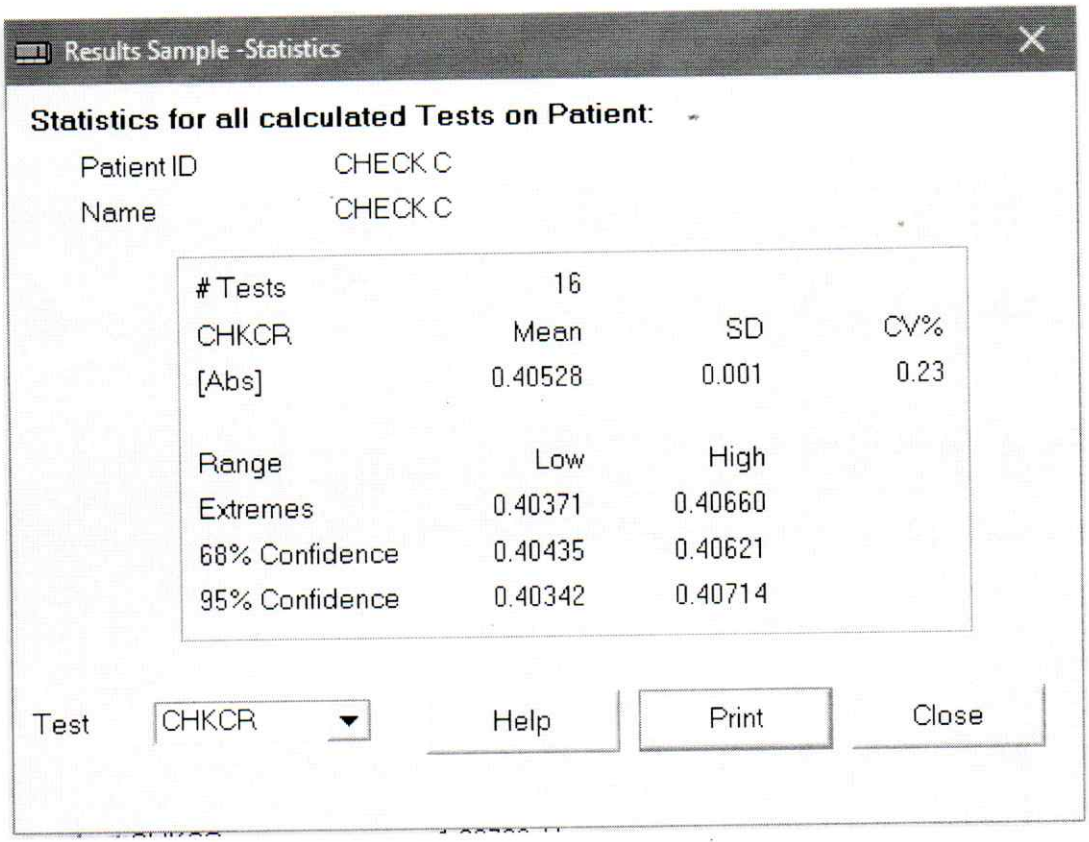
**System Serial Number:** 420027 Wednesday, February 19, 2020 / 13:33



# INTEGRA 400 plus

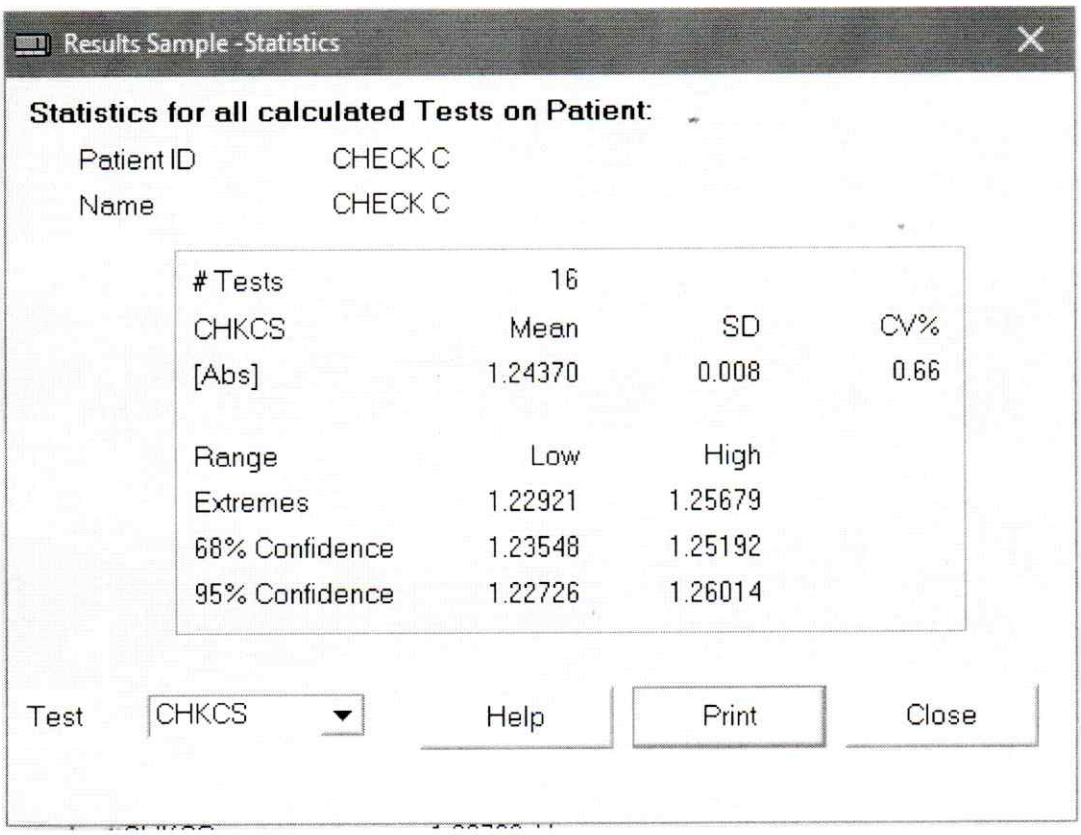
**System Version:** 3.6.2.1904 **Cui Version:** 3.6.2 **Cui Build:** 1904

**System Serial Number:** 420027 Wednesday, February 19, 2020 / 13:32



# INTEGRA 400 plus

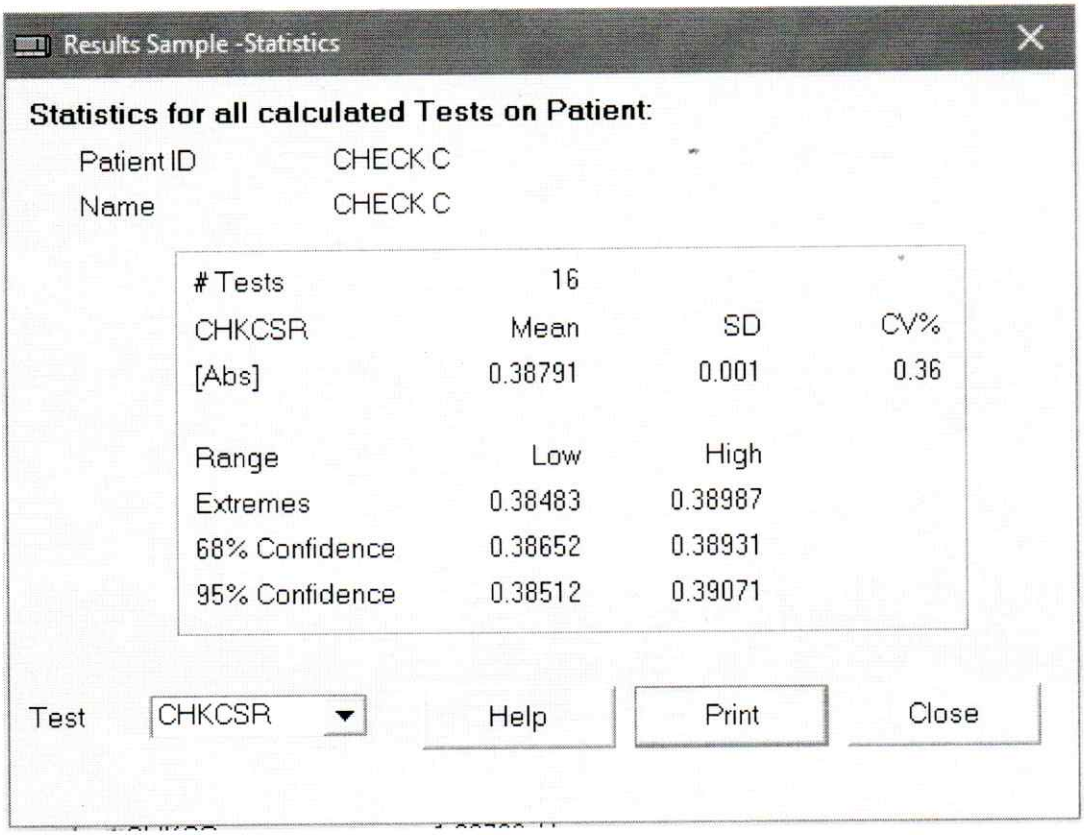
| | | | | | |
|---|---|---|---|---|---|
| **System Version:** | 3.6.2.1904 | **Cui Version:** | 3.6.2 | **Cui Build:** | 1904 |
| **System Serial Number:** | 420027 | | | | Wednesday, February 19, 2020 / 13:32 |



# INTEGRA 400 plus

**System Version:** 3.6.2.1904 **Cui Version:** 3.6.2 **Cui Build:** 1904

**System Serial Number:** 420027 Wednesday, February 19, 2020 / 13:32



# CALIBRATION CERTIFICATE

| | |
|---|---|
| HOSPITAL/LAB NAME | CARE DIAGNOSTICS |
| ADDRESS, | BANGALORE.<br>KARNATAKA |
| ANALYSER | COBAS INTEGRA 400 PLUS |
| SERIAL NO | 420027 |
| INSTALLATION PLACE | LABORATORY. |
| DATE | 20, FEBRUARY, 2020 |

This is to certify that the above mentioned analyzer was calibrated by the following procedure as per manufacturer's recommendations

1. Calibration of FP High Voltage and k/l factors
2. Workstation Accuracy check
3. Analyzer Rotor Init position check
4. Check Abs sensitivity 100% and 0%
5. Cuvette transport performance check
6. CHECK INIT POSITION ACCURACY

All the checks and calibration were done and system is being used under recommended conditions. Next calibration is due on 19th February 2021.

For Roche Diagnostics India Pvt. Ltd.

Sumith P
Sr.Technical Service Specialist
Bangalore

# CALIBRATION CERTIFICATE

**Customer Name** : Care Diagnostics
3rd cross, Neeladri Nagar,
Electronic City Phase I, opposite to ICICI Bank,
Bengaluru, Karnataka 560100

**Instrument Model** : **DIESTRO ELECTROLYTE INSTRUMENT**

**Instrument Serial No.** : **2157**

**Calibration Done on** : **06/03/2020**

**Calibration Due on** : **05/03/2021**

THE FOLLOWING CHECKS AND SETUPS ARE CARRIED OUT FOR **DIESTRO ELECTROLYTE INSTRUMENT** FOR PERFORMANCE QUALIFICATION.

**TRI LEVEL QC Exp Date 2021/10 Level -1**

| PARAMETER | MEASURED (MMOL/L) | RANGE (MMOL/L) |
|---|---|---|
| Na+ | 121.1 | 110 – 122 MEAN (116) |
| K+ | 2.01 | 1.85- 2.16 MEAN(2.00) |
| Cl- | 83.0 | 71 – 85 MEAN (77) |

**TRI LEVEL QC Exp Date 2021/10 Level -2**

| PARAMETER | MEASURED (MMOL/L) | RANGE (MMOL/L) |
|---|---|---|
| Na+ | 140.6 | 132 – 147 MEAN (140) |
| K+ | 3.98 | 4.13 – 4.51 MEAN( 4.47) |
| Cl- | 100.2 | 89 – 104 MEAN( 99) |



Communication : # 157, 1st Floor, 12th Main Nagendra Block, BSK 3rd Stage Bangalore - 560050. Ph. : 080 - 26725522
Corporate : # 55/1, 1st Floor, 2nd Main, 6th Cross Byatarayanapura, Bangalore - 560026. Ph. : 080 - 26758990
DL No. : 21B-KA-B21-171806, 21B-KA-B21-171805, E-Mail : info@jkbiomed.com, varadharajan@jkbiomed.com

TRILEVEL QC Exp Date 2021/10 Level -3

| PARAMETER | MEASURED (MMOL/L) | RANGE (MMOL/L) |
|---|---|---|
| Na+ | 157.3 | 153– 160 MEAN ( 161) |
| K+ | 8.03 | 6.61 – 7.70 MEAN (7.15) |
| Cl- | 120.1 | 107 – 125 MEAN( 116) |

**TWO POINT CALIBRATION FOR ELECTRODES**

| PARAMETER | CAL VALUES (MMOL/L) | SLOPE (MMOL/L) |
|---|---|---|
| Na+ | 57.61<br>57.30 | 50 – 64 |
| K+ | 61.04<br>60.63 | 50 – 64 |
| Cl- | 50.86<br>49.19 | 40 – 64 |

**REPEATABILITY TEST FOR SAMPLE**

| PARAMETER | CAL VALUES (MMOL/L) | RANGES (MMOL/L) |
|---|---|---|
| Na+ | 134.5<br>134.4 | 135 – 148 |
| K+ | 4.87<br>4.80 | 3.50 – 5.30 |
| Cl- | 99.8<br>98.8 | 99 – 107 |

REMARKS: ALL MEASURED VALUE IS WITHIN THE TARGET RANGE FOR ALL THREE LEVELS OF CONTROLS AND CALIBRATION.

**Protocol performed by: JK Biomed**

Name : KALAIARASAN TR

Signature : 

Designation: SERVICE MANAGER

Date : **06/03/2020**

**Customer Authorization:**

Name : SUDHARSAN. M

Designation: LAB MANAGER

Signature : 

Date : 09/03/2020.