

Biochemistry parameters and HbA1c are performed on Roche Cobas Integra 400 plus and electrolytes are performed on Erba EC90



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

Roche Diagnostics India Pvt. Ltd.
Field Service Report



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058
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Case number CAS-0019632961

Order Number WO-26884691 | Ser. Report Created Date 26/02/2024

Instrument Details

Instrument/Module COBAS INTEGRA 400 plus
Serial Number 420468

Internal Instrument Name

Additional Details

Customer details

Customer Number 0052614262
Customer Name Dr D.P.Rastogi Central
Research Institute Of
Homoeopathy
Street Address A-1/1, Sector-24
Zip 201301 - Noida
Contact Name Dr Satvinder Singh
Contact Phone +911202411323

Service Activity Code PM Visit

Purpose of Visit

PM Visit

Performed Activities

Activity- Preventive Maintenance Cobas Integra 400
Performed PM as per check list.
Replaced kit maintenance.
Performed cleaning and lubrication.
Performed post PM checks and found ok
Performed QC/ samples results were fine.
System is working fine

Time Report

| Category | Start | End | Hours | Invoice Type |
|---------------------------------|--------------------|---------------------|-------|----------------|
| 05913616001-Service labour time | 26/02/2024 9:45 am | 26/02/2024 12:50 pm | 3.08 | Free of Charge |

Travel

| Category | Hours |
|----------|-------|
| Travel | 0.5 |

Spare Parts


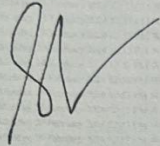
| Part Number | Description | Quantity | Invoice Type |
|---|---|----------|------------------|
| 08425094001-KIT MAINTENANCE W/O ISE TUBING I400PLUS | KIT MAINTENANCE W/O ISE TUBING I400PLUS | 1 | Customer Invoice |

Signature

Customer Signature
Dr Satvinder Singh

Roche support
Devendra Mani Bharti

Sign Here



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.

Customer Support Center No

Toll Free No: 1800-123-7599 || Phone No: 044-43900345 || (Mon to Sat 8 AM to 8 PM)

e-mail: customersupportcenterIndia@roche.com || Roche DiaLog:

<https://dialog.roche.com>

Service Report Version Number: 1

Thank You

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0058
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COBAS® Integra 400 Plus Preventive Maintenance Checklist

Account Name: Dr DP Rastogi CRH , Noida Type: Half Yearly
 Instrument S/N: 420468 Date: 26/02/24
 Case ID: CAS-0019632961 PM Communication Yes ISE Active No

| Sequence Item/Procedure | FSE Action | Remarks (If any) |
|---|---------------------------|------------------|
| * Things to be Clean | | |
| 1 Analyser Area | Yes | |
| 2 Cuvette Transport Area | Yes | |
| 3 Robotic Transfer Area | Yes | |
| 4 Fluid and Pipetting Area | Yes | |
| 5 Rack Area and Cooling Unit Area | Yes | |
| 6 Power Supply Main | Yes | |
| 7 Photometer Lens and Housing | Yes | |
| 8 ISE Module Area | Yes | |
| 9 Controller Rack | Yes | |
| 10 Datastation | Yes | |
| Things to be Lubricate | | |
| 1 All Workstations | Yes | |
| 2 X- and Y-Transfer Guide Rails | Yes | |
| 3 Transfer-Head Linear Bearing and Worm Gears | Yes | |
| 4 Wash Syringe, Toothed bar Cogs, Bearing Sharfts | Yes | |
| * Things to be Replace | | |
| 1 Halogen Lamp | Yes | |
| 2 Filter Ligacon | Yes | |
| 3 Ligacon Filter of the Air Pump(ISE Only) | Not Applicable | |
| 4 Filter Water Sterapore-H | Yes | |
| 5 ISE Module tubing | Not Applicable | |
| 6 Cooling Box Fluid Filter | Yes | |
| 7 Seal Teflon 250uL | Yes | |
| 8 Seal Cap Pipette | Yes | |
| 9 Seal Inlet Filter, D7/11.5x4 | Yes | |
| 10 Seal Bal D9/12x2.5(Wash Seal) | Yes | |
| 11 Spring Washers | Yes | |
| 12 Seal Quad Ring(ISE Only) | Not Applicable | |
| * Things to be Inspect | | |
| 1 All Tubes, Connectors, Fittings, Vacuum Pump | Yes | |
| 2 Fans of the Fan Assembly Power Supply Main | Yes | |
| 3 Kit Belt Analyzer Motor | Yes | |
| 4 X-Motor Belt | Yes | |
| 5 Pivot Lever | Yes | |
| 6 Shock absorber (Auxiliary Front Panel) | Yes | |
| * Things to Adjust | | |
| 1 Dry and Mix pressures(With ISE Only) | Not Applicable | |
| * Post PM Check | | |
| 1 Check ABS Halogen Lamp | Yes | |
| 2 Cuvette Transport | Yes | |
| 3 Analyzer Rotor Init. Position | Yes | |
| 4 Workstation Accuracy | Yes | |
| 5 Abs Air/Water Calibration | Attach Printout | |
| 6 Init Position Accuracy | Yes | |
| 7 Prime ISE and conditioning of ISE tubings | Not Applicable | |
| 8 Check ISE Performance | Attach Printout | |
| 9 ISE WashTime M85.1 | Attach Printout | |
| 10 Pipetting Accuracy Check | Attach Printout | |
| 11 QC Check (Few Parameters) | Attach Printout | |
| FSE Name : Devendra Mani Bharti | FSE Signature : | |
| Customer Name: Dr Satvinder | Customer Signature & Seal | |

डा. सतावन्दी सिंह / DR. SATVINDER SINGH
 अनुसंधान अधिकारी (सिंह रावत) / Research Officer (Bhoochemistry) Scientist
 डी.डी.पी.आर. केन्द्रीय होम्योपैथिक अनुसंधान संस्थान /
 D.D.P.R. Central Research Institute of Homoeopathy
 जलसिन्धु रोड, 601, B Silver Utopia, Cardinal Gracious
 केन्द्रीय होम्योपैथी अनुसंधान संस्थान /
 Central Council for Research in Homoeopathy
 आयुष मंत्रालय, भारत सरकार / Ministry of AYUSH, Govt of India
 ए-1/1, सेक्टर-24, नोएडा / A-1/1, Sector-24, Noida

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EGRA 400 plus

System Version: 3.6.1.1801
System Build: 1801
System Serial Number: 420468

Cui Version: 3.6.1
Cui Build: 1801

Monday, February 26, 2024 / 13:18

Results QC Statistics - MULTI-1 - Lot 564978 (From 2/26/2024 To 2/26/2024)

| Precision Test | Assigned | | n | Calculated | | Calculated CV% |
|----------------|----------|------|---|------------|-----|----------------|
| | Mean | SD | | Mean | SD | |
| ALB2 | 3.32 | 0.20 | 1 | 3.26 | ??? | ??? |
| ALP2L | 109.0 | 7.0 | 1 | 103.6 | ??? | ??? |
| ALTL | 50.8 | 3.0 | 1 | 48.3 | ??? | ??? |
| ASTL | 44.7 | 2.7 | 1 | 44.5 | ??? | ??? |
| BILD2 | 0.91 | 0.07 | 1 | 0.88 | ??? | ??? |
| BILT3 | 0.96 | 0.06 | 1 | 0.91 | ??? | ??? |
| CA2 | 8.7 | 0.4 | 1 | 8.5 | ??? | ??? |
| CHOL2 | 102 | 5 | 1 | 106 | ??? | ??? |
| CREJ2 | 1.03 | 0.06 | 1 | 1.05 | ??? | ??? |
| GLUC3 | 101.0 | 5.0 | 1 | 100.0 | ??? | ??? |
| HDLC4 | 29.7 | 2.4 | 1 | 29.1 | ??? | ??? |
| LDLC3 | 64.20 | 5.10 | 1 | 63.69 | ??? | ??? |
| PHOS2 | 3.66 | 0.18 | 1 | 3.81 | ??? | ??? |
| TP2 | 4.8 | 0.2 | 1 | 4.6 | ??? | ??? |
| TRIGL | 116.00 | 6.00 | 1 | 118.56 | ??? | ??? |
| UA2 | 4.9 | 0.2 | 1 | 5.2 | ??? | ??? |
| UREL | 38.60 | 1.90 | 1 | 36.33 | ??? | ??? |

Date:

Signature:

QC Report

Thursday, February 22, 2024 16:18

Precision From 2/21/2024 To 2/22/2024

CHOL2 ■ MULTI-1

| Date & Time | mg/dl | -3s | -2s | -1s | X | +1s | +2s | +3s | Flags / Action |
|-------------------|-------|-----|-----|-----|---|-----|-----|-----|----------------|
| 22 Feb 2024 10:21 | 106 | | | | ■ | | | | |
| 21 Feb 2024 10:39 | 109 | | | | | ■ | | | |

| Precision Control | Lot | Assigned Mean | Assigned SD | n | Calculated Mean | Calculated SD | Calculated CV% |
|-------------------|----------|---------------|-------------|---|-----------------|---------------|----------------|
| MULTI-1 | 564978 | 102 | 5 | 2 | 107 | 2 | 2.18 |
| PCCC2 | 59539301 | 166 | 8 | 2 | 170 | 3 | 1.87 |

Date:

Signature:

INTEGRA 400 plus

System Version: 3.6.1.1801

System Serial Number: 420468

Cui Version: 3.6.1

Cui Build: 1801

Monday, February 26, 2024 / 12:15

M74.1 Get Abs Air/Water Calibration Values

Description

PURPOSE

The Abs Photometer Calibration determines the Air/Water Correction values. These values are needed for result calculations. Displays the number of cuvettes outside the range for every measurement procedure.

Abs Air/Water Calibration

Number of Cuvettes: 20

Number of Measurements: 20

Calibrate

Nr. of Cuvettes outside Range

| | |
|------------------------|---|
| Air Measurements | 1 |
| H2O Measurements | 0 |
| H2O - Air Measurements | 0 |
| Total | 1 |

Accepted Nr. of Cuvettes outside Range (not more than 20%)

Store Calibration Data

View Calibration Data

Abs Air/Water Calibration: copy

Logfile Print Cancel

CA 400 plus

System Version: 3.6.1.1801
System Build: 1801
System Serial Number: 420468

Cui Version: 3.6.1
Cui Build: 1801

Monday, February 26, 2024 / 12:45

Results QC Statistics - PCCC2 - Lot 59539301 (From 2/26/2024 To 2/26/2024)

| Precision Test | Assigned Mean | Assigned SD | n | Calculated Mean | Calculated SD | Calculated CV% |
|----------------|---------------|-------------|---|-----------------|---------------|----------------|
| ALB2 | 5.38 | 0.32 | 1 | 5.28 | ??? | ??? |
| ALP2L | 260.0 | 16.0 | 1 | 255.7 | ??? | ??? |
| ALTL | 127.0 | 8.0 | 1 | 119.5 | ??? | ??? |
| ASTL | 140.0 | 8.0 | 1 | 138.6 | ??? | ??? |
| BILD2 | 2.61 | 0.20 | 1 | 2.48 | ??? | ??? |
| BILT3 | 3.64 | 0.22 | 1 | 3.43 | ??? | ??? |
| CA2 | 13.5 | 0.5 | 1 | 13.1 | ??? | ??? |
| CHOL2 | 166 | 8 | 1 | 168 | ??? | ??? |
| CREJ2 | 3.55 | 0.21 | 1 | 3.58 | ??? | ??? |
| GLUC3 | 243.0 | 12.0 | 1 | 233.9 | ??? | ??? |
| HDLC4 | 50.3 | 4.0 | 1 | 48.1 | ??? | ??? |
| LDLC3 | 102.00 | 8.00 | 1 | 100.12 | ??? | ??? |
| PHOS2 | 8.31 | 0.42 | 1 | 8.47 | ??? | ??? |
| TP2 | 8.1 | 0.3 | 1 | 7.8 | ??? | ??? |
| TRIGL | 215.00 | 11.00 | 1 | 216.89 | ??? | ??? |
| UA2 | 10.1 | 0.5 | 1 | 10.6 | ??? | ??? |
| UREL | 122.00 | 6.00 | 1 | 116.44 | ??? | ??? |

Date:

Signature:

INTEGRA 400 plus

System Version: 3.6.1.1801
System Serial Number: 420468

Cui Version: 3.6.1 Cui Build: 1801

Monday, February 26, 2024

The screenshot displays the software interface with a tree view on the left and a data table on the right. The tree view shows a hierarchy of folders including 'Sample', 'Calibration', and 'Quality Control'. The data table contains the following information:

| Sample | Test | Result | List | Range/Action | Ref Range |
|----------|-------|-----------|------|--------------|-----------|
| 208/2024 | •ASTL | 138.7 U/L | | | |
| HB-1 | •ASTL | 138.5 U/L | | | |
| HB-10 | •ASTL | 138.5 U/L | | | |
| HB-11 | •ASTL | 138.5 U/L | | | |
| HB-13 | •ASTL | 138.7 U/L | | | |
| HB-15 | •ASTL | 138.3 U/L | | | |
| HB-16 | •ASTL | 137.5 U/L | | | |
| HB-2 | •ASTL | 138.4 U/L | | | |
| HB-3 | •ASTL | 137.5 U/L | | | |
| HB-5 | •ASTL | 137.5 U/L | | | |
| HB-6 | •ASTL | 138.3 U/L | | | |
| HB-8 | | | | | |
| HB-9 | | | | | |
| HB-10 | | | | | |
| HB-11 | | | | | |
| HB-13 | | | | | |
| HB-15 | | | | | |
| HB-16 | | | | | |
| HB-2 | | | | | |
| HB-3 | | | | | |
| HB-5 | | | | | |
| HB-6 | | | | | |
| HB-8 | | | | | |
| HB-9 | | | | | |
| HB-PATH | | | | | |
| 208/2024 | | | | | |
| 209/2024 | | | | | |
| 210/2024 | | | | | |
| 211/2024 | | | | | |
| 212/2024 | | | | | |
| 213/2024 | | | | | |
| 214/2024 | | | | | |
| 215/2024 | | | | | |
| 216/2024 | | | | | |
| 217/2024 | | | | | |
| 218/2024 | | | | | |
| 219/2024 | | | | | |
| 220/2024 | | | | | |
| 221/2024 | | | | | |
| 222/2024 | | | | | |
| 223/2024 | | | | | |
| 224/2024 | | | | | |
| 225/2024 | | | | | |
| 226/2024 | | | | | |
| 227/2024 | | | | | |
| 228/2024 | | | | | |
| 229/2024 | | | | | |
| 230/2024 | | | | | |
| 231/2024 | | | | | |
| 232/2024 | | | | | |
| 233/2024 | | | | | |
| 234/2024 | | | | | |
| 235/2024 | | | | | |
| 236/2024 | | | | | |
| 237/2024 | | | | | |
| 238/2024 | | | | | |
| 239/2024 | | | | | |
| 240/2024 | | | | | |

Cut Build: 1801
Monday, February 26, 2024

Results - Sample

Monday, February 26, 2024 12:42

Order ID: precesion 2
Created: Monday, February 26, 2024 12:22

| Test | Result Unit | Flag | Ref. Range | Date / Time |
|------------|-------------|------|------------|-----------------|
| Unassigned | | | | |
| * ASTL | 138.7 U/L | | | |
| * ASTL | 138.5 U/L | | | 2/26/2024 12:25 |
| * ASTL | 138.0 U/L | | | 2/26/2024 12:25 |
| * ASTL | 138.7 U/L | | | 2/26/2024 12:25 |
| * ASTL | 138.3 U/L | | | 2/26/2024 12:26 |
| * ASTL | 137.9 U/L | | | 2/26/2024 12:26 |
| * ASTL | 138.4 U/L | | | 2/26/2024 12:26 |
| * ASTL | 137.9 U/L | | | 2/26/2024 12:26 |
| * ASTL | 137.9 U/L | | | 2/26/2024 12:26 |
| * ASTL | 138.3 U/L | | | 2/26/2024 12:27 |

Results - Sample

Monday, February 26, 2024 12:41

Order ID: precesion 1
Created: Monday, February 26, 2024 12:21

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| Test | Result Unit | Flag | Ref. Range | Date / Time |
|------------|-------------|------|------------|-----------------|
| Unassigned | | | | |
| * GLUC3 | 101.8 mg/dl | | | |
| * GLUC3 | 101.0 mg/dl | | | 2/26/2024 12:23 |
| * GLUC3 | 100.9 mg/dl | | | 2/26/2024 12:23 |
| * GLUC3 | 100.8 mg/dl | | | 2/26/2024 12:24 |
| * GLUC3 | 102.1 mg/dl | | | 2/26/2024 12:24 |
| * GLUC3 | 102.4 mg/dl | | | 2/26/2024 12:24 |
| * GLUC3 | 102.3 mg/dl | | | 2/26/2024 12:24 |
| * GLUC3 | 103.0 mg/dl | | | 2/26/2024 12:24 |
| * GLUC3 | 102.2 mg/dl | | | 2/26/2024 12:25 |
| * GLUC3 | 102.0 mg/dl | | | 2/26/2024 12:25 |

Transasia Bio-Medicals Ltd., 109-110, 1st Floor8, Deep Shikha Building, Rajendra Place, New Delhi - 110 008
Tel.: 011 - 25732223 Fax: 011-25785451 Email: nz1@transasia.co.in CIN: U33110MH1985PLC036198

TRANSASIA[®]



Calibration Certificate

Customer Name : Dr DP Rastogi CRIH Noida

Address Of Customer : CRIH Noida Sec 24 Noida UP 201301

Model : EC 90

Serial No. : 4566-2-202209

Calibration Done Date : 08/02/2024

Calibration Due Date : On or Before 08/02/2025

Rahul Kumar

This is to certify that we have calibrated the Electrolyte Analyzer Model : EC 90 bearing Sr. No. 4566-2-202209 and on inspection of the Cal Values of instrument it is observed that the results are well within the range and instrument is working fine

Thanking you,

For

Transasia Bio-Medicals Ltd.

Rahul Kumar

Sr. Service Engineer

www.transasia.co.in



HO : Transasia Bio - Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai - 400 072,



EC 90

SENSOR STATUS PROTOCOL
SN 04566 SW: v1.13.3

08/02/2024 12:18 PM

Na 1P: 64.4 mV
Na Slope: 9.0 mV
Na State: OK

K 1P: 96.65 mV
K Slope: 22.78 mV
K State: OK

CL 1P: 63.4 mV
CL Slope: -8.1 mV
CL State: OK

| Calibration Data | |
|------------------|----------|
| Na 1P | 64.4 mV |
| Na Slope | 9.0 mV |
| Na State | OK |
| K 1P | 96.65 mV |
| K Slope | 22.78 mV |
| K State | OK |
| CL 1P | 63.4 mV |
| CL Slope | -8.1 mV |
| CL State | OK |

Thanking you,

For

Transasia Bio-Medicals Ltd.

Rahul Kumar

Sr. Service Engineer