

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

Transasia Bio-Medicals Ltd., 109-110, 1st Floor, 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 08/02/2024

*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

Rahul Kumar

www.transasia.co.in



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



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



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
512

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

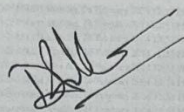
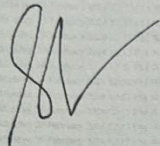
Part Number	Description	Quantity	Invoice Type
08425094001-KIT MAINTENANCE W/O ISE TUBING I400PLUS	KIT MAINTENANCE W/O ISE TUBING I400PLUS	1	Customer Invoice

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

TD

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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 Shafts	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	Yes	
6 Init Position Accuracy	Yes	
7 Prime ISE and conditioning of ISE tubings	Not Applicable	
8 Check ISE Performance Attach Printout	Not Applicable	
9 ISE Washtime M85.1 Attach Printout	Not Applicable	
10 Pipetting Accuracy Check Attach Printout	Yes	
11 QC Check (Few Parameters) Attach Printout	Yes	
FSE Name : Devendra Mani Bharti	FSE Signature :	
Customer Name Dr Satvinder	Customer Signature & Seal	

डा. सतावन्दर सिंह / DR. SATVINDER SINGH
 अनुसंधान अधिकारी (बिब रसायन) / Research Officer (Biochemistry) Scientist
 डी.डी.पी.आर. केन्द्रीय होम्योपैथिक अनुसंधान संस्थान /
 D.D.P.R. Central Research Institute of Homoeopathy
 अक्षांश-18° 40' 18" N, देशांतर-73° 01' 18" E, Silver Utopia, Cardinal Gracias
 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

TD
10058
76612

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: only

Logfile Print Cancel

UA 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 main interface of the INTEGRA 400 plus software. It features a menu bar at the top with options like 'File', 'Edit', 'View', 'Tools', 'Database', and 'Help'. Below the menu bar is a toolbar with various icons. The main area is divided into several sections: a 'Sample' list on the left, a 'Calibration' section, and a 'Quality Control' section. The 'Quality Control' section contains a table with columns for 'Test', 'Result', 'Unit', 'Range / Action', and 'Fail Flags'. The table lists several tests, all of which are marked as 'ASTL' and have results within the specified ranges. A 'Print' button is visible on the right side of the interface. At the bottom of the window, there is a status bar showing the date and time: '2/26/2024 12:41'.

Sample	Test	Result	Unit	Range / Action	Fail Flags
HB-1	ASTL	138.7	uL		
HB-10	ASTL	138.5	uL		
HB-11	ASTL	138.6	uL		
HB-13	ASTL	138.7	uL		
HB-15	ASTL	138.3	uL		
HB-16	ASTL	137.9	uL		
HB-2	ASTL	138.4	uL		
HB-3	ASTL	137.9	uL		
HB-5	ASTL	138.3	uL		
HB-6	ASTL	138.3	uL		
HB-8	ASTL	138.3	uL		
HB-9	ASTL	138.3	uL		
HB-14	ASTL	138.3	uL		
HB-17	ASTL	138.3	uL		
HB-18	ASTL	138.3	uL		
HB-19	ASTL	138.3	uL		
HB-20	ASTL	138.3	uL		
HB-21	ASTL	138.3	uL		
HB-22	ASTL	138.3	uL		
HB-23	ASTL	138.3	uL		
HB-24	ASTL	138.3	uL		
HB-25	ASTL	138.3	uL		
HB-26	ASTL	138.3	uL		
HB-27	ASTL	138.3	uL		
HB-28	ASTL	138.3	uL		
HB-29	ASTL	138.3	uL		
HB-30	ASTL	138.3	uL		
HB-31	ASTL	138.3	uL		
HB-32	ASTL	138.3	uL		
HB-33	ASTL	138.3	uL		
HB-34	ASTL	138.3	uL		
HB-35	ASTL	138.3	uL		
HB-36	ASTL	138.3	uL		
HB-37	ASTL	138.3	uL		
HB-38	ASTL	138.3	uL		
HB-39	ASTL	138.3	uL		
HB-40	ASTL	138.3	uL		
HB-41	ASTL	138.3	uL		
HB-42	ASTL	138.3	uL		
HB-43	ASTL	138.3	uL		
HB-44	ASTL	138.3	uL		
HB-45	ASTL	138.3	uL		
HB-46	ASTL	138.3	uL		
HB-47	ASTL	138.3	uL		
HB-48	ASTL	138.3	uL		
HB-49	ASTL	138.3	uL		
HB-50	ASTL	138.3	uL		
HB-51	ASTL	138.3	uL		
HB-52	ASTL	138.3	uL		
HB-53	ASTL	138.3	uL		
HB-54	ASTL	138.3	uL		
HB-55	ASTL	138.3	uL		
HB-56	ASTL	138.3	uL		
HB-57	ASTL	138.3	uL		
HB-58	ASTL	138.3	uL		
HB-59	ASTL	138.3	uL		
HB-60	ASTL	138.3	uL		
HB-61	ASTL	138.3	uL		
HB-62	ASTL	138.3	uL		
HB-63	ASTL	138.3	uL		
HB-64	ASTL	138.3	uL		
HB-65	ASTL	138.3	uL		
HB-66	ASTL	138.3	uL		
HB-67	ASTL	138.3	uL		
HB-68	ASTL	138.3	uL		
HB-69	ASTL	138.3	uL		
HB-70	ASTL	138.3	uL		
HB-71	ASTL	138.3	uL		
HB-72	ASTL	138.3	uL		
HB-73	ASTL	138.3	uL		
HB-74	ASTL	138.3	uL		
HB-75	ASTL	138.3	uL		
HB-76	ASTL	138.3	uL		
HB-77	ASTL	138.3	uL		
HB-78	ASTL	138.3	uL		
HB-79	ASTL	138.3	uL		
HB-80	ASTL	138.3	uL		
HB-81	ASTL	138.3	uL		
HB-82	ASTL	138.3	uL		
HB-83	ASTL	138.3	uL		
HB-84	ASTL	138.3	uL		
HB-85	ASTL	138.3	uL		
HB-86	ASTL	138.3	uL		
HB-87	ASTL	138.3	uL		
HB-88	ASTL	138.3	uL		
HB-89	ASTL	138.3	uL		
HB-90	ASTL	138.3	uL		
HB-91	ASTL	138.3	uL		
HB-92	ASTL	138.3	uL		
HB-93	ASTL	138.3	uL		
HB-94	ASTL	138.3	uL		
HB-95	ASTL	138.3	uL		
HB-96	ASTL	138.3	uL		
HB-97	ASTL	138.3	uL		
HB-98	ASTL	138.3	uL		
HB-99	ASTL	138.3	uL		
HB-100	ASTL	138.3	uL		

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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576612

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