

Date: 08/08/2023

CURRENT CALIBRATION CERTIFICATE OF A15

CUSTOMER NAME –RAINBOW DIAGNOSTIC PATHOLOGICAL LABORATORY

Serial Number = 83105C1409
Firmware = A15 User V6.50
A15 Configuration checksum value = 0xE70A
A15 Configuration checksum size = 988
Rotor Temperature = 36.79
Probe Temperature = 38
System Liquid Scale Sensivity = 156
Waste Scale Sensivity = 197
Level Detection Improved Rack = 1
Sensitivity: (Tube Rack) = 38
Sensitivity: (Pediatric Rack) = 80
Sensitivity: (Out Fridge Reagent Rack) = 12
Sensitivity: (Fridge Reagent Rack) = 38
X - Origin = 30
Y - Origin = 244
Z - Origin = 430
X - Washing Station = 351
Y - Washing Station = 76
Z - Washing Station = 540
X - Reactions Rotor = 84
Y - Reactions Rotor = 1028
Z - Reactions Rotor = 600
Tray XYZ- Pediatric Rack
X1 (Rack3, 4) = 1598, 1048
X2 (Rack3, 4) = 1592, 1050
Y1 (Rack3, 4) = 90, 86
Y2 (Rack3, 4) = 1441, 1437
Z1 (Rack3, 4) = 729, 733
Z2 (Rack3, 4) = 704, 706
Z Relation Pediatric-Tube = 457
Tray XYZ- Reagent Rack
X1 (Rack3, 4) = 1355, 794
X2 (Rack3, 4) = 1339, 793
Y1 (Rack3, 4) = 100, 100
Y2 (Rack3, 4) = 1438, 1438
Z1 (Rack3, 4) = 1195, 1202
Z2 (Rack3, 4) = 1169, 1169
Tray XYZ- Fridge
X1 (Rack1, 2) = 2544, 2028
X2 (Rack1, 2) = 2526, 2011
Y1 (Rack1, 2) = 45, 50
Y2 (Rack1, 2) = 1397, 1399
Z1 (Rack1, 2) = 1228, 1235
Z2 (Rack1, 2) = 1225, 1227
Rotor Position correction regarding to the dispensation point = 106
Rotor Position correction regarding to the optical system = -7
Filters wheel correction = 0
Filter 0 = 0 (nm) IT = 10.2 (ms) Ref. IT = 9.7 (ms)
Filter 1 = 340 (nm) IT = 248.3 (ms) Ref. IT = 204.8 (ms)

Filter 2 = 405 (nm) IT = 75.8 (ms) Ref. IT = 67.1 (ms)
Filter 3 = 505 (nm) IT = 86 (ms) Ref. IT = 76.8 (ms)
Filter 4 = 535 (nm) IT = 68.1 (ms) Ref. IT = 62.5 (ms)
Filter 5 = 560 (nm) IT = 70.1 (ms) Ref. IT = 64 (ms)
Filter 6 = 600 (nm) IT = 96.8 (ms) Ref. IT = 89.1 (ms)
Filter 7 = 635 (nm) IT = 81.9 (ms) Ref. IT = 76.3 (ms)
Filter 8 = 670 (nm) IT = 89.6 (ms) Ref. IT = 84.5 (ms)
Filter 9 = 0 (nm) IT = 10.2 (ms) Ref. IT = 9.7 (ms)

X - axis = 43584 (x1000 steps)

Y - axis = 24379 (x1000 steps)

Z - axis = 57977 (x1000 steps)

Reaction Rotor = 2653 (x10000 steps)

Filter Wheel = 126903 (x100 steps)

Dispensing Pump = 52359 (x10000 steps)

Membrane pumps = 9473 (Commutation)

3-way electrovalve = 41628 (Commutation)

Lamp = 673 (Hours)

Biochemical preparation = 5090 (Cicles)

Turbidimetry preparation = 28 (Cicles)

Bireagent Biochemical preparation = 625 (Cicles)

Bireagent Turbidimetry preparation = 0 (Cicles)

Predilution = 0 (Cicles)

Start/End Washings = 416 (Cicles)

WS Washings = 1200 (Cicles)

H2O Washings = 358 (Cicles)

New Rotor = 49 (Rotors)

Contaminations detected = 99 Contaminations detected

Next Calibration due on – 07/08/2024

For BIOSYSTEMS DIAGNOSTICS PVT. LTD.

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Digitally signed by S SENTHIL
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Date: 2023.12.26 12:24:42 +05'30'

AUTHORISED SIGNATORY

A15 – Fully Auto Biochemistry Analyser

Installation Qualification Certificate

For

***RAINBOW DIAGNOSTIC PATHOLOGICAL
LABORATORY***

Purba Medinipur

BioSystems Diagnostics Pvt. Ltd

CERTIFICATE OF INSTALLATION

Instrument Name: A15 Auto Analyzer

Serial Number : 83105C1409

Customer : RAINBOW DIAGNOSTIC PATHOLOGICAL LABORATORY
Kshudiram Square, Haldia,
Purba Medinipur - 721602

The undersigned performer certifies that the installation Qualification Protocol has been successfully completed for the instrument stated above.

Authorized

Signature

Name

Designation

Company

S

: SENTHIL

: Mr. Sumon Mondal

: Junior Service Engineer

: BioSystems Diagnostics Pvt. Ltd.,

Digitally signed by S SENTHIL
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Date: 2023.12.26 12:32:14 +05'30'

Customer

Signature

Name

Designation

Company

:

: Mr. Purnendu Purkait

: Lab Incharge

: RAINBOW DIAGNOSTIC PATHOLOGICAL

LABORATORY

INSTALLATION REPORT

Customer Name : RAINBOW DIAGNOSTIC PATHOLOGICAL
LABORATORY

Department : Bio-chemistry

Contact Person : Mr. Purnendu Purkait

Instrument Model : A15

Serial Number : 83105C1409

Date of Installation : 08/08/2023

The System was installed along with the necessary accessories. All basic requirements and adjustments were checked and are found to be satisfactory Preliminary customer training was provided and standardization of all parameters was done. The Instrument is found to be working satisfactorily.

INSTRUMENT SETUP :

- Instrument and computer installed
- Printer Installed
- User software 6.50 installed
- All necessary cable connections given

OPERATION INSPECTION :

- No air bubbles found in the Tubing
- Temperature of the Needles/Reaction & Rotor Chamber are within range
- No unusual noises produced in the system
- Warm up procedure within time limit
- Internal Dosing of all Needle's were fine
- External Dosing of all Wash Station is perfect
- Conditioning of Machine with Air/Wash solution/Distilled water done

For Biosystems Diagnostics Pvt. Ltd

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Authorized Signature

INSTALLATION QUALIFICATION

Customer Name : RAINBOW DIAGNOSTIC PATHOLOGICAL
LABORATORY

Address : RAINBOW DIAGNOSTIC PATHOLOGICAL
LABORATORY
Kshudiram Square, Haldia,
Purba Medinipur - 721602

Instrument Model : A15C

Serial No. : 83105C1409

Operational requirement for the Instrument:

Requirement	Acceptable Range	Observed Range
Input Voltage	220 \pm 10 V	221 V
Line Frequency	50 or 60 Hz	50 Hz
Ambient Temperature	18 – 30 deg. C	23 deg. C
Distill Water	Type II NCCLS	Available

For Biosystems Diagnostics Pvt. Ltd

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Date: 2023.12.26 12:33:31 +05'30'

Authorized Signature

A15 - Fully Auto Biochemistry Analyzer

Operational Qualification

For

RAINBOW DIAGNOSTIC PATHOLOGICAL LABORATORY

Purba Medinipur

BioSystems Diagnostics Pvt. Ltd

OPERATIONAL QUALIFICATION

1. System Decontamination
2. Maintenance Procedures
3. System Performance check procedures
4. Customer Training Operation and Maintenance

System Decontamination

Users carrying out disinfection processes must wear gloves and protective apparel. All consumable materials (reaction rotor, reagent bottles and sample tubes) will be treated as potentially infectious waste.

Check whether there are any reaction rotors in their compartments or reagent bottles in the refrigerator. If there are, dispose of them.

Clean the fluidics of the instrument with 4% Hypo chloride.

Empty the high contamination waste tank and washing solution tank periodically.

Wash the inside of the equipment using a damp cloth and neutral soap. If there are splashes, wash them with alcohol

Follow the applicable national guidelines for disposing of waste that is considered potentially infectious.

Maintenance Procedures

Activities at the start of the day

- 1 Replenish the washing solution bottle.
- 2 Initialise the analyser. Perform the warm-up with the programme.
- 3 Perform 2 conditioning cycles (only when the analyser has been switched off for several days).
- 4 Check the temperature of the reaction rotor and the reagent rotor.
- 5 Check the reagent volume.
- 6 Calibrate the ISE module peristaltic pumps.
- 7 Calibrate the ISE electrodes.

Activities at the end of the day

- 1 Wash the ISE module.
- 2 Switch off the analyser by executing the Shut-down with the program.
- 3 Empty the high contamination bottle.
- 4 Remove the calibration solutions, controls and samples from the sample rotor.


Activities to be executed every week

- 1 Change the reaction rotor.
- 2 Calibrate the ISE module air bubble detector.
- 3 Clean the ISE module inlet cup with a cotton bud.
- 4 Clean the working surface.
- 5 Clean the interior of the samples and reagents rotor vessel.
- 6 Check the capacity of the ISE module reagent pack and replace it, if used up.
- 7 Rinse the ISE module waste tubes with distilled water.
- 8 Clean the stirrer paddle with a cloth soaked in washing solution.

CERTIFICATE OF OPERATION

Instrument Name : A15 Auto Analyzer
Serial Number : 83105C1409
Customer : RAINBOW DIAGNOSTIC PATHOLOGICAL
LABORATORY
Kshudiram Square, Haldia,
Purba Medinipur - 721602

The undersigned performer certifies that the Operational Qualification Protocol has been successfully completed for the instrument stated above.

Authorized Signature :  S SENTHIL
Name : Mr. Sumon Mondal
Designation : Junior Service Engineer
Company : BioSystems Diagnostics Pvt. Ltd

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Customer Signature :
Name : Mr. Purnendu Purkait
Designation : Lab Incharge
Company : RAINBOW DIAGNOSTIC PATHOLOGICAL
LABORATORY

SYSTEM PERFORMANCE CHECK PROCEDURE

SYTEM CHECK	PERFORMANCE
LED Photometric Check	Done
Warm Up	Done
Mechanical Adjustments	Done
Temperature Check	Done
Internal/External Dosing Check	Done

Customer Signature:

OPERATIONAL QUALIFICATION

System Certification:

Study data has determined that the System described in this document either meets all criteria outlined in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any have been addressed. The system is ready for specified usage.

Protocol Performed By : BioSystems Diagnostics Pvt. Ltd
Name Mr. Sumon Mondal
Title : Junior Service Engineer
Company: Biosystems Diagnostics Pvt Ltd

Customer Authorization: RAINBOW DIAGNOSTIC PATHOLOGICAL
LABORATORY

Name: Mr. Purnendu Purkait

Title: Lab Incharge

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Date: 2023.12.26 12:34:21 +05'30'

AUTHORIZED SIGNATURE

CUSTOMER SIGNATURE

DATE:

DATE:

A15 - Fully Auto Bio Chemistry Analyzer

Performance Qualification

For

RAINBOW DIAGNOSTIC PATHOLOGICAL LABORATORY

Purba Medinipur

BioSystems Diagnostics Pvt. Ltd

A15 Auto Analyzer

PERFORMANCE QUALIFICATION:

The following parameters were checked and found to be within acceptable limits.

S. No	Parameters	Result	Limit
1.	Dispensing Ratio	15.10	14.8 – 17.2
2.	Photometric noise	0.43	< 3.0
3.	Darkness count	4021	3000 – 5000
4.	Slope	0.0031	+/- 0.02

CERTIFICATE OF PERFORMANCE

Instrument Name : A15 Auto Analyzer

Serial Number : 83105C1409

Customer : RAINBOW DIAGNOSTIC PATHOLOGICAL
LABORATOTY

Kshudiram Square, Haldia,
Purba Medinipur - 721602

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Authorized Signature : **S SENTHIL**

Name : Mr. Sumon Mondal

Designation : Junior Service Engineer

Company : BioSystems Diagnostics Pvt Ltd.,

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LABORATOTY