

Date: 21/02/2024

CURRENT CALIBRATION CERTIFICATE OF A15C

CUSTOMER NAME -EVER GREEN HEALTH CENTRE

A15C Parameters Values

Serial Number =83105C1481
Firmware = 6.50
A15 - Configuration checksum value = 0xF348
A15 - Configuration checksum size = 988
Rotor Temperature = 36.41
Prove Temperature = 38.9
System Liquid Scale Sensivity = 148
Waste Scale Sensivity = 202
Level Detection Improved Rack = 1
Sensitivity: (Tube Rack) = 44
Sensitivity: (Pediatric Rack) = 56
Sensitivity: (Out Fridge Reagent Rack) = 12
Sensitivity: (Fridge Reagent Rack) = 32
Sensitivity: (Stool Collector) = 110
X - Origin = 71
Y - Origin = 259
Z - Origin = 430
X - Washing Station = 390
Y - Washing Station = 87
Z - Washing Station = 540
X - Reactions Rotor = 133
Y - Reactions Rotor = 1040
Z - Reactions Rotor = 600
Tray XYZ- Pediatric Rack
X1 (Rack3, 4) = 1645, 1087
X2 (Rack3, 4) = 1641, 1085
Y1 (Rack3, 4) = 99, 99
Y2 (Rack3, 4) = 1452, 1454
Z1 (Rack3, 4) = 734, 733
Z2 (Rack3, 4) = 693, 697
Z Relation Pediatric-Tube = 468
Z Pediatric -> Stool tube = -500
Tray XYZ- Reagent Rack
X1 (Rack3, 4) = 1378, 835
X2 (Rack3, 4) = 1386, 838
Y1 (Rack3, 4) = 114, 112
Y2 (Rack3, 4) = 1445, 1443
Z1 (Rack3, 4) = 1202, 1203
Z2 (Rack3, 4) = 1167, 1166
Tray XYZ- Fridge
X1 (Rack1, 2) = 2575, 2055
X2 (Rack1, 2) = 2562, 2055
Y1 (Rack1, 2) = 49, 53
Y2 (Rack1, 2) = 1406, 1411
Z1 (Rack1, 2) = 1234, 1238
Z2 (Rack1, 2) = 1225, 1226

Rotor Position correction regarding to the dispensation point = 113

Rotor Position correction regarding to the optical system = -10

Filters wheel correction = 0

Filter 0 = 0 (nm) IT = 10.2 (ms) Ref. IT = 9.7 (ms)

Filter 1 = 340 (nm) IT = 249.3 (ms) Ref. IT = 247.3 (ms)

Filter 2 = 405 (nm) IT = 87 (ms) Ref. IT = 85 (ms)

Filter 3 = 505 (nm) IT = 80.9 (ms) Ref. IT = 79.9 (ms)

Filter 4 = 535 (nm) IT = 71.2 (ms) Ref. IT = 70.7 (ms)

Filter 5 = 560 (nm) IT = 77.3 (ms) Ref. IT = 76.8 (ms)

Filter 6 = 600 (nm) IT = 85 (ms) Ref. IT = 84.5 (ms)

Filter 7 = 635 (nm) IT = 87 (ms) Ref. IT = 86 (ms)

Filter 8 = 670 (nm) IT = 101.4 (ms) Ref. IT = 100.9 (ms)

Filter 9 = 0 (nm) IT = 10.2 (ms) Ref. IT = 9.7 (ms)

X - axis = 2426 (x1000 steps)

Y - axis = 1649 (x1000 steps)

Z - axis = 3188 (x1000 steps)

Reaction Rotor = 75 (x10000 steps)

Filter Wheel = 4068 (x100 steps)

Dispensing Pump = 3036 (x10000 steps)

Membrane pumps = 544 (Commutation)

3-way electrovalve = 2571 (Commutation)

Lamp = 10 (Hours)

Biochemical preparation = 259 (Cicles)

Turbidimetry preparation = 56 (Cicles)

Bireagent Biochemical preparation = 18 (Cicles)

Bireagent Turbidimetry preparation = 0 (Cicles)

Predilution = 0 (Cicles)

Start/End Washings = 10 (Cicles)

WS Washings = 8 (Cicles)

H2O Washings = 9 (Cicles)

New Rotor = 3 (Rotors)

Contaminations detected = 6 Contaminations detected

Next Calibration due on – 20/02/2025

For BIOSYSTEMS DIAGNOSTICS PVT. LTD.

AUTHORISED SIGNATORY

A15C – Fully Auto Biochemistry Analyser

Installation Qualification Certificate

For

EVER GREEN HEALTH CENTRE

Howrah

BioSystems Diagnostics Pvt. Ltd

CERTIFICATE OF INSTALLATION

Instrument Name: A15C Auto Analyzer

Serial Number : 83105C1481

Customer : EVER GREEN HEALTH CENTRE
241/43, G. T. Road, Liluah
Howrah - 711204

The undersigned performer certifies that the installation 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.,

Digitally signed by S SENTHIL
DN: cn=S SENTHIL, c=IN,
o=PERSONAL,
email=SENTHIL@BIOSYSTEMS.IN
Date: 2024.04.06 11:51:50 +05'30'

Customer Signature :
Name : Ms. Saumitra Bhunia
Designation : Lab Incharge
Company : EVER GREEN HEALTH CENTRE

INSTALLATION REPORT

Customer Name : EVER GREEN HEALTH CENTRE
Department : Bio-chemistry
Contact Person : Ms. Saumitra Bhunia
Instrument Model : A15C
Serial Number : 83105C1481
Date of Installation : 20/02/2024

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 5.5.0 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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SENTHIL

Digitally signed by S SENTHIL
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Authorized Signature

INSTALLATION QUALIFICATION

Customer Name : EVER GREEN HEALTH CENTRE

Address : EVER GREEN HEALTH CENTRE
241/43, G. T. Road, Liluah
Howrah - 711204

Instrument Model : A15C

Serial No. : 83105C1481

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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A15C - Fully Auto Biochemistry Analyzer

Operational Qualification

For

EVER GREEN HEALTH CENTRE

Howrah

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 : A15C Auto Analyzer
Serial Number : 83105C1481
Customer : EVER GREEN HEALTH CENTRE
241/43, G. T. Road, Liluah
Howrah - 711204

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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Date: 2024.04.06 11:53:01 +05'30'

Customer Signature :
Name : Ms. Saumitra Bhunia
Designation : Lab Incharge
Company : EVER GREEN HEALTH CENTRE

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:

EVER GREEN HEALTH CENTRE

Name: Ms. Saumitra Bhunia

Title: Lab Incharge

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Date: 2024.04.06 11:53:27 +05'30'

AUTHORIZED SIGNATURE

CUSTOMER SIGNATURE

DATE:

DATE:

A15C - Fully Auto Bio Chemistry Analyzer

Performance Qualification

For

EVER GREEN HEALTH CENTRE

Howrah

BioSystems Diagnostics Pvt. Ltd

A15C 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 : A15C Auto Analyzer
Serial Number : 83105C1481
Customer : EVER GREEN HEALTH CENTRE
241/43, G. T. Road, Liluah
Howrah - 711204

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Name : Mr. Sumon Mondal
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Company : BioSystems Diagnostics Pvt Ltd.,

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Signature :
Name : Ms. Saumitra Bhunia
Designation : Lab Incharge
Company : EVER GREEN HEALTH CENTRE