



Registered Office:

BioSystems Diagnostics Pvt. Ltd.,
A4, SIPCOT Industrial Park, Irungattukottai,
Thandalam Village, Sriperumbudur - 602105.
Ph: +91 - 44 - 3034 1911 / 12 /13
E-mail: customersupport@biosystems.in
Website: www.biosystems.in
CIN – U29297TN2003PTC051492



A15C – Fully Auto Biochemistry Analyzer

Installation Qualification Certificate

For

Lakshmi Lab Digital x-ray

Aruppukottai

BioSystems Diagnostics Pvt. Ltd



CERTIFICATE OF INSTALLATION

Instrument Name : A15C Auto Analyzer
Serial Number : 83105C0659
Customer : Lakshmi Lab Digital x-ray
346 Thiruchuli Road ,
Aruppukottai-629 101

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

Engineer

For
A. Pradyumn Ramesh



Signature :
Name : Mr.G.Ramesh
Designation : Assistant Manager Service
Company : BioSystems Diagnostics Pvt. Ltd

Customer

Signature :
Name : Mr.Ramesh Kumar
Designation : Quality Manager
Company : Lakshmi Lab Digital x-ray, Aruppukottai

INSTALLATION REPORT

Customer Name : Lakshmi Lab Digital x-ray, Aruppukottai
Department : Bio-chemistry
Contact Person : Mr.Ramesh Kumar
Instrument Model : A15C
Serial Number : 83105C0659
Date of Installation : 10-01-2021

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.,

For

A. Pradyumnachandran



Mr.G.Ramesh
Assistant Manager Service

INSTALLATION QUALIFICATION

Customer Name : Lakshmi Lab Digital x-ray, Aruppukottai

Address : Lakshmi Lab Digital x-ray
346 Thiruchuli Road ,
Aruppukottai-629 101

Instrument Model : A15C

Serial No. : 83105C0659

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	22 deg. C
Distill Water	Type II NCCLS	Available

For Biosystems Diagnostics Pvt. Ltd

For

A. Pradyumn



Mr.G.Ramesh
Assistant Manager Service

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Operational Qualification

For

Lakshmi Lab Digital x-ray

Aruppukottai

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OPERATIONAL QUALIFICATION

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

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SYSTEM PERFORMANCE CHECK PROCEDURE

SYSTEM CHECK	PERFORMANCE
System Decontamination	Done
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.G.Ramesh
Title : Assistant Manager Service
Company : Biosystems Diagnostics Pvt Ltd

Customer Authorization: Lakshmi Lab Digital x-ray,Aruppukottai
Name: Mr.Ramesh Kumar
Title: Quality Manager

POR

A. Pradyumn



ENGINEER SIGNATURE

CUSTOMER SIGNATURE

DATE:

DATE:

Registered Office:

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A15C - Fully Auto Biochemistry Analyzer

Performance Qualification

For

Lakshmi Lab Digital x-ray

Aruppukottai

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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 : 83105C0659
Customer : Lakshmi Lab Digital x-ray,
346 Thiruchuli Road ,
Aruppukottai-629 101

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

For

A. P. Ramesh



Engineer
Signature :
Name : Mr.G.Ramesh
Designation : Assistant Manager Service
Company : BioSystems Diagnostics Pvt. Ltd

Customer
Signature :
Name : Mr.Ramesh Kumar
Designation : Quality Manager
Company : Lakshmi Lab Digital x-ray,Aruppukottai

Date: 01/12/2021

CURRENT CALIBRATION CERTIFICATE OF A15C

CUSTOMER NAME – LAKSHMI LAB DIGITAL X-RAY, Aruppukottai

Serial Number = 83105C0659

Firmware = 6.19

Firmware integrity checksum value = 0xD13D

Firmware integrity checksum size = 442472

A15 Configuration checksum value = 0xF27E

A15 Configuration checksum size = 988

Rotor Temperature = 37.18

Probe Temperature = 39.4

Fridge Temperature = 0

System liquid scale sensitivity = 0

Waste scale sensitivity = 0

Metal filled Racks (grey color) = 1

Sensitivity: (Diam. Rack 13/15mm) = 45

Sensitivity: (Pediatric Rack) = 94

Sensitivity: (Out fridge reagents) = 10

Sensitivity: (Fridge reagents) = 34

X - Origin = 62

Y - Origin = 260

Z - Origin = 430

X - Washing Station = 387

Y - Washing Station = 101

Z - Washing Station = 540

X - Reactions Rotor = 96

Y - Reactions Rotor = 1039

Z - Reactions Rotor = 600

XYZ Tray - Pediatric Rack

X1 (Rack3, 4) = 1632, 1082

X2 (Rack3, 4) = 1626, 1076

Y1 (Rack3, 4) = 103, 104

Y2 (Rack3, 4) = 1452, 1451

Z1 (Rack3, 4) = 751, 748

Z2 (Rack3, 4) = 739, 735

Z relationship Pediatric - Tube = 454

XYZ Tray - Reagent Rack

X1 (Rack3, 4) = 1400, 850

X2 (Rack3, 4) = 1389, 852

Y1 (Rack3, 4) = 120, 121

Y2 (Rack3, 4) = 1455, 1454

Z1 (Rack3, 4) = 1207, 1206

Z2 (Rack3, 4) = 1197, 1194

XYZ Tray - Fridge

X1 (Rack1, 2) = 2564, 2046

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X2 (Rack1, 2) = 2561, 2066

Y1 (Rack1, 2) = 52, 63

Y2 (Rack1, 2) = 1412, 1408

Z1 (Rack1, 2) = 1239, 1239

Z2 (Rack1, 2) = 1239, 1239

Rotor Position correction regarding to the dispensation point = 102

Rotor Position correction regarding to the optical system = -4

Filters wheel correction = 2

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

Filter 1 = 340 (nm) IT = 329.2 (ms) Ref. IT = 289.8 (ms)

Filter 2 = 405 (nm) IT = 93.2 (ms) Ref. IT = 82.4 (ms)

Filter 3 = 505 (nm) IT = 80.4 (ms) Ref. IT = 72.2 (ms)

Filter 4 = 535 (nm) IT = 71.7 (ms) Ref. IT = 64.5 (ms)

Filter 5 = 560 (nm) IT = 85 (ms) Ref. IT = 76.8 (ms)

Filter 6 = 600 (nm) IT = 97.8 (ms) Ref. IT = 89.1 (ms)

Filter 7 = 635 (nm) IT = 82.9 (ms) Ref. IT = 75.8 (ms)

Filter 8 = 670 (nm) IT = 100.9 (ms) Ref. IT = 92.2 (ms)

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

X - axis = 258138 (x1000 steps)

Y - axis = 175808 (x1000 steps)

Z - axis = 398404 (x1000 steps)

Reaction Rotor = 17845 (x10000 steps)

Filter Wheel = 826334 (x100 steps)

Dispensing Pump = 321580 (x10000 steps)

Membrane pumps = 67301 (Commutation)

3-way electrovalve = 268827 (Commutation)

Lamp = 455 (Hours)

Biochemical preparation = 32059 (Cycles)

Turbidimetry preparation = 657 (Cycles)

Bi-reagent Biochemical preparation = 6726 (Cycles)

Bi-reagent Turbidimetry preparation = 370 (Cycles)

Pre-dilutions = 0 (Cycles)

Start/End Washes = 1358 (Cycles)

Wash Solution Washes = 10500 (Cycles)

Water Washes = 2117 (Cycles)

New Rotor = 364 (Rotors)

Contamination detected = 441 (Contaminations)

Next Calibration due on – 30/11/2022

For BIOSYSTEMS DIAGNOSTICS PVT. LTD.

A. Pradyumn Reddy

AUTHORISED SIGNATORY

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