

Registered Office:
BioSystems Diagnostics Pvt. Ltd.,
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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

Hannah Joseph Hospital

BioSystems Diagnostics Pvt. Ltd



CERTIFICATE OF INSTALLATION


Instrument Name: A15C Auto Analyzer

Serial Number : 83105C0880

Customer : Madurai – Tuticorin Ring, Chithamani – Madurai -625009

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

Engineer

Signature : 
Name : Mr. Alaguraj
Designation : Service Engineer
Company : BioSystems Diagnostics Pvt. Ltd



Customer

Signature :
Name : Dr. Abarna Pandey
Designation : Quality Manager
Company : Hannah Joseph Hospital

INSTALLATION REPORT

Customer Name : Hannah Joseph Hospital
Department : Bio-chemistry
Contact Person : Dr. Abarna Pandey
Instrument Model : A15C
Serial Number : 83105C0880
Date of Installation : 19-07-2021

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 5.4 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.,



Mr. Alaguraj
Service Engineer



INSTALLATION QUALIFICATION

Customer Name : CM Best Hospitals

Address : Hannah Joseph Hospital
Madurai – Tuticorin Ring, Chithamani
Madurai -625009

Instrument Model : A15C

Serial No. : 83105C0880

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



Mr. Alaguraj
Service Engineer

A15C – Fully Auto Biochemistry Analyzer

Operational Qualification

For

Hannah Joseph Hospital

BioSystems Diagnostics Pvt. Ltd



OPERATIONAL QUALIFICATION


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

CERTIFICATE OF OPERATION

Instrument Name : A15C Auto Analyzer
Serial Number : 83105C0880
Customer : Hannah Joseph Hospital
Madurai – Tuticorin Ring, Chithamani
Madurai -625009

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

Engineer

Signature : 
Name : Mr. Alaguraj
Designation : Service Engineer
Company : BioSystems Diagnostics Pvt. Ltd



Customer

Signature :
Name : Dr. Abarna Pandey
Designation : Quality Manager
Company : Hannah Joseph Hospital

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. Alaguraj
Title : Service Engineer
Company: Biosystems Diagnostics Pvt Ltd

Customer Authorization: Hannah Joseph Hospital
Name: Dr. Abarna Pandey
Title: Quality Manager



ENGINEER SIGNATURE

CUSTOMER SIGNATURE

DATE:

DATE:

A15C - Fully Auto Biochemistry Analyzer

Performance Qualification

For

Hannah Joseph Hospital

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 : 83105C0880
Customer : Hannah Joseph Hospital
Madurai – Tuticorin Ring, Chithamani
Madurai -625009

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

Engineer

Signature : 
Name : Mr. Alaguraj
Designation : Service Engineer
Company : BioSystems Diagnostics Pvt. Ltd



Customer

Signature :
Name : Dr. Abarna Pandey
Designation : Quality Manager
Company : Hannah Joseph Hospital

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Date: 19-07-2021

CALIBRATION CERTIFICATE OF A15C

CUSTOMER NAME – HANNAH JOSEPH HOSPITAL PVT.LTD , CHINTHAMANI.

Serial Number = 83105C0880

Firmware = 6.19

Firmware integrity checksum value = 0xD13D

Firmware integrity checksum size = 442472

A15 - Configuration checksum value = 0xF3AD

A15 - Configuration checksum size = 988

Rotor Temperature = 37.06

Prove Temperature = 39

Fridge Temperature = 0

System liquid scale sensivity = 155

Waste scale sensivity = 174

Metal filled Racks (grey color) = 1

Sensitivity: (Tube Rack) = 44

Sensitivity: (Pediatric Rack) = 111

Sensitivity: (Out fridge reagents) = 14

Sensitivity: (Fridge reagents) = 48

Sensitivity: (Stool Collection) = 110

X - Origin = 36

Y - Origin = 264

Z - Origin = 430

X - Washing Station = 362

Y - Washing Station = 97

Z - Washing Station = 540

X - Reactions Rotor = 91

Y - Reactions Rotor = 1043

Z - Reactions Rotor = 600

XYZ Tray - Pediatric Rack

X1 (Rack3, 4) = 1610, 1060

X2 (Rack3, 4) = 1615, 1063

Y1 (Rack3, 4) = 103, 105

Y2 (Rack3, 4) = 1455, 1456

Z1 (Rack3, 4) = 737, 733

Z2 (Rack3, 4) = 721, 717

Z Pediatric -> Tube = 458

Z Pediatric -> Stool tube = -500

XYZ Tray - Reagent Rack

X1 (Rack3, 4) = 1347, 798

X2 (Rack3, 4) = 1352, 795

Y1 (Rack3, 4) = 119, 121

Y2 (Rack3, 4) = 1454, 1452

Z1 (Rack3, 4) = 1210, 1210

Z2 (Rack3, 4) = 1186, 1180

XYZ Tray - Fridge

Corporate Office:
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X1 (Rack1, 2) = 2538, 2023

X2 (Rack1, 2) = 2544, 2029

Y1 (Rack1, 2) = 53, 64

Y2 (Rack1, 2) = 1409, 1416

Z1 (Rack1, 2) = 1237, 1240

Z2 (Rack1, 2) = 1230, 1240

Rotor Position correction regarding to the dispensation point = 111

Rotor Position correction regarding to the optical system = -9

Filters wheel correction = 0

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

Filter 1 = 340 (nm) IT = 296.4 (ms) Ref. IT = 275.5 (ms)

Filter 2 = 405 (nm) IT = 98.8 (ms) Ref. IT = 93.7 (ms)

Filter 3 = 505 (nm) IT = 98.3 (ms) Ref. IT = 95.2 (ms)

Filter 4 = 535 (nm) IT = 85 (ms) Ref. IT = 82.4 (ms)

Filter 5 = 560 (nm) IT = 92.2 (ms) Ref. IT = 90.6 (ms)

Filter 6 = 600 (nm) IT = 89.1 (ms) Ref. IT = 88.1 (ms)

Filter 7 = 635 (nm) IT = 90.6 (ms) Ref. IT = 89.6 (ms)

Filter 8 = 670 (nm) IT = 111.1 (ms) Ref. IT = 110.6 (ms)

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

X - axis = 57742 (x1000 steps)

Y - axis = 33206 (x1000 steps)

Z - axis = 74264 (x1000 steps)

Reaction Rotor = 2281 (x10000 steps)

Filter Wheel = 99997 (x100 steps)

Dispensing Pump = 55465 (x10000 steps)

Membrane pumps = 12160 (Commutation)

3-way electrovalve = 47667 (Commutation)

Lamp = 1336 (Hours)

Biochemical preparation = 6620 (Cycles)

Turbidimetry preparation = 38 (Cycles)

Bi-reagent Biochemical preparation = 1156 (Cycles)

Bi-reagent Turbidimetry preparation = 0 (Cycles)

Pre-dilutions = 0 (Cycles)

Start/End Washes = 109 (Cycles)

Wash Solution Washes = 1592 (Cycles)

Water Washes = 285 (Cycles)

New Rotor = 74 (Rotors)

Contamination detected = 112 (Contaminations)

Next Calibration due on - 24/07/2022

For BIOSYSTEMS DIAGNOSTICS PVT. LTD.



AUTHORISED SIGNATORY

Corporate Office:
BioSystems S.A. Costa Brava 30, 08030 Barcelona (Spain)
Tel +34-93 311 00 00, Fax+34-93 346 77 99
<http://www.biosystems.es>



New Samples

Samples sent

Patients

Blanks and Calibrators

Controls

| Lot | Test | Type | New | #Rep | Abs | Date | Factor |
|-----|------------------|------|--------------------------|------|------------|---------------------|----------|
| | GLUCOSE | | <input type="checkbox"/> | 1 | 0.0292 | 02/12/2021 06:49:35 | |
| | CREATININE | | <input type="checkbox"/> | 1 | 0.0017 | 03/01/2022 07:25:44 | |
| | UREA UV | | <input type="checkbox"/> | 1 | 0.0004 | 04/01/2022 04:49:00 | |
| | CHOLESTEROL | | <input type="checkbox"/> | 1 | 0.0458 | 17/12/2021 12:21:57 | |
| | TRIGLYCERIDES | | <input type="checkbox"/> | 1 | 0.1477 | 05/01/2022 07:20:34 | |
| | AST | | <input type="checkbox"/> | 1 | -0.0020 | 20/10/2021 22:26:20 | |
| | ALT | | <input type="checkbox"/> | 1 | 0.0009 | 06/11/2021 03:41:30 | |
| | ALP:AMP | | <input type="checkbox"/> | 1 | 0.0010 | 19/11/2021 08:04:00 | |
| | ALBUMIN | | <input type="checkbox"/> | 1 | 0.0855 | 28/11/2021 04:37:09 | |
| | PROTEIN TOTAL | | <input type="checkbox"/> | 1 | -0.0667 | 21/11/2021 07:00:42 | |
| | BILIRUBIN DIRECT | | <input type="checkbox"/> | 1 | 0.0096 | 09/01/2022 07:21:23 | |
| | BILIRUBIN TOTAL | | <input type="checkbox"/> | 1 | 0.0046 | 08/01/2022 06:28:31 | |
| | URIC ACID | | <input type="checkbox"/> | 1 | 0.0700 | 07/11/2021 08:08:28 | |
| | CALCIUM ARSENAZO | | <input type="checkbox"/> | 1 | 0.5648 | 31/12/2021 07:11:18 | |
| | PHOSPHORUS | | <input type="checkbox"/> | 1 | 0.2406 | 17/11/2021 06:51:33 | |
| | MAGNESIUM | | <input type="checkbox"/> | 1 | 0.5599 | 01/01/2022 07:24:56 | |
| | CHOL HDL DIRECT | | <input type="checkbox"/> | 1 | 0.0068 | 04/08/2021 12:36:32 | |
| | CHOL LDL DIRECT | | <input type="checkbox"/> | 1 | 0.0012 | 04/08/2021 12:36:56 | |
| 073 | GLUCOSE | SER | <input type="checkbox"/> | 1 | 1 : 0.5806 | 02/12/2021 06:51:35 | 324.6123 |

Patients 0 Calibrators 0
 Controls 0 Total 0

