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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

