

AutoQuant 100 Amara
Fully Automated Biochemistry Analyzer



Installation Qualification

Operational Qualification

Performance Qualification

FOR

Success Diagnostic Center- Shyam Bazar

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Meril Diagnostics Pvt. Ltd.
Survey No.135/2/B, Bilakhia House
Muktanand Marg, Chala
Vapi - 396191. Gujarat, India.



AutoQuant 100 Amara
Fully Automated Biochemistry Analyzer

INSTALLATION QUALIFICATION

FOR

Success Diagnostic Center- Shyam Bazar

INSTALLATION QUALIFICATION#01

MARKETED BY:

MERIL DIAGNOSTICS PVT. LIMITED

MUKTANAND MARG, CHALA

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- i. IQ/OQ/PQ dot.
- ii. Sample page of the log book
- iii. Company Certificate

I. APPROVAL OF THE IQ PROCEDURE:

Meril Diagnostics Pvt. Ltd. Is responsible for the installation of the automated Biochemistry Analyzer, model - AutoQuant 100 Amara, Sr. No. **AQ080890** at **Success Diagnostic Center- Shyam Bazar** as per the attached protocol.

Protocol Performed By: Meril Diagnostics Pvt. Ltd. Representative

Name: Mr. Partha Chakraborty

Signature:



Title: Date: 08-Oct-2024

Company: MERIL DIAGNOSTICS PVT. LIMITED

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Title: Date: 08-Oct-2024

Department: Service Engineer

Customer Authorizations:

Name :

Signature:

Title : Date: 08-Oct-2024 .

Site : Success Diagnostic Center- Shyam Bazar

II. INSTRUCTIONS

1. This document is to be completed at the time is shifted to its current location (new) and set up for operation.
2. An authorized Meril Diagnostics representative will check the system and enter the specific data as outlined in the appropriate Installation Qualification.
3. Employees of **Success Diagnostic Center- Shyam Bazar** will verify each result and sign in the last page. The members of the validation will carry this out.
4. All deviation from the normal specification to include any problems with installation will be noted under COMMENTS. All resolution to such problems will also be noted in the COMMENTS section. Additional space is provided at the end of this protocol for the same.
5. This document propriety information and is in no way to be copied, photographed or duplicated in any way without expressed authorization from Meril Diagnostics Pvt. Limited.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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III. SCOPE

This installation Qualification protocol will be performed on the automated Biochemistry Analyzer, Model - AutoQuant 100 Amara, Sr. No. **AQ080890** located at **Success Diagnostic Center- Shyam Bazar**. This protocol will define the documentation that will be used to evaluate the instrument installation in accordance with the manufacturer's specifications and intended use.

Successful completion of this protocol will verify that this instrument has been installed in accordance with the intended usage.

Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional condition encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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IV. ANCILLARY INFORMATION.

a. Certificate of Purchase Order Compliance

I certify to the best of my knowledge, the instrument installed on 08-Oct-2024 , has been purchased under purchase order No. _____ dated _____ OR contracted for period of *** years is in compliance with the specifications of the purchase order or contract.

Verified By:

Date: 08-Oct-2024

b. Utilities

Sr. No.	Utility	Verified by & Date
1.	Environmental conditions as per required (free from dust, ambient light & electrical, yes / no magnetic interference)	Mr. Partha Chakraborty Date : 08-Oct-2024
2.	Adequate space for installation: (Minimum mm 600 X 450 X 400) yes / no	YES
3.	Electrical Outlets: Actual voltage on site [230VAC] yes / no	YES

c. The instrument has been checked for the following:

Sr. No.	Verification	Verified by & Date
1.	Instrument is identified yes / no	YES
2.	Manufacturer's specifications are included yes / no	YES
3.	Accessories / consumables are listed yes / no	YES
4.	Equipment manual from the manufacturer yes / no	YES
5.	Manufacturer Certificate of Compliance is attached yes / no	YES

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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V. INSTALLATION QUALIFICATION

a. Equipment Description

The Automated Biochemistry Analyzer is a walk away system with simultaneous processing clinical chemistry samples. The data files created can be printed in report form or stored as data files for a variety of clinical chemistry-based applications.

Instrument Identification	Verified By	Date
Equipment Name : Automated Biochemistry Analyzer	Mr. Partha Chakraborty	08-Oct-2024
Model : AutoQuant 100 Amara		
Manufacturer : Meril Diagnostics Pvt. Ltd. India		
Marketed By : MERIL DIAGNOSTICS PVT. LTD.		
Equipment # : Biochemistry Analyzer		
Serial Number : <u>AQ080890</u>		
Size : 548 X 422 X 383 (mm)		
Power : AC 230 V		

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Applications & Scientific Support

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b. Accessories/Consumables

The following accessories were supplied with the instrument. Check 'verified by' in case they are found to be in order.

Description	Quantity	Verified by	Date
User's manual	1	Mr. Partha Chakraborty	08-Oct-2024
Application Software	1		
CPU+Monitor+Keyboard+Mouse+Speakers+Printer	1		
Reagent Vials (20 ml)	50		
Distilled Water Can	1		
Waste Can	1		
Sample Cups	200		
RS 232 Cable	1		
RS 232 to USB Cable	1		
Sample Racks	1		
Reagent Rack	1		
Probe Cleaning Wire	1		
D.W & Waste Tubings	2		
Sample Probe	1		
Power Cords	1		

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Date: 08-Oct-2024

Title: Department: Service Engineer

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C. List of Manuals, Certificates and Drawings

Meril Diagnostics Pvt. Ltd. provides the following with the instrument.

1. Operator's/User's manual for AutoQuant 100 Amara.

D. Change Control Procedure

The instrument will not be altered, enhanced or substituted for another system until a formal change Control Authorization is approved from Meril Diagnostics Pvt. Limited.

E. Maintenance

The instrument listed within this document will placed under the control of purchasing / contracted institution with respect to proper maintenance procedures as detailed in the operations manual. The maintenance procedures will be filed separately.

A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period Meril Diagnostics offers several level of maintenance agreements and performance testing services to assist you in maintaining GLP/GMP compliance. Containing your local representative and requesting the additional service Agreement can supply additional information.

F. Spare Parts

Meril Diagnostics Pvt. Ltd. strongly recommends the end user maintain a basic of consumable parts onsite to minimize down time due to minor failures. They have provided the list of such consumable parts.

For RRC, maintenance will be taken care as per contractual agreement.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:

Date: 08-Oct-2024



Title: Department: Service Engineer

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VI. INSTALLATION PROCEDURE:

(These have been performed at the time of original installation at the initial location)

1. Installation of Hardware

Follow the instructions mentioned in section 1 of the operator's manual for installation of the hardware.

2. Installation of Software

(Pre installed software is provided with the system.)

3. Installation of Printer

Follow the instructions mentioned in Setup Guide of HP color ink jet printer.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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VII. COMMENTS

VIII. SYSTEM CERTIFICATION

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

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

Customer Authorizations:

Name :

Signature:

Title :

Date: 08-Oct-2024 .

Site : Success Diagnostic Center- Shyam Bazar



AutoQuant 100 Amara
Fully Automated Biochemistry Analyzer

OPERATIONAL QUALIFICATION

FOR

Success Diagnostic Center- Shyam Bazar

OPERATIONAL QUALIFICATION#02

MARKETED BY:

MERIL DIAGNOSTICS PVT. LIMITED

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I. Approval of the OQ procedure

II. Instructions

III. Scope

IV. Operational Qualification

V. Comments

VI. System Certification

I. APPROVAL OF THE OQ PROCEDURE:

Meril Diagnostics Pvt. Ltd. is responsible for the installation of the automated Biochemistry Analyzer, model- AutoQuant 100 Amara, Sr. No. **AQ080890** at **Success Diagnostic Center- Shyam Bazaras** per the attached protocol.

Protocol Performed By: Meril Diagnostics Pvt. Ltd. Representative

Name: Mr. Partha Chakraborty

Signature:



Title: Date: 08-Oct-2024

Company: MERIL DIAGNOSTICS PVT. LIMITED

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:

Title: Date: 08-Oct-2024

Department: Service Engineer

Customer Authorizations:

Name :

Signature:

Title : Date: 08-Oct-2024 .

Site : Success Diagnostic Center- Shyam Bazar

II. INSTRUCTIONS

1. An authorized Meril Diagnostics Pvt. Ltd. representative will check each module and enter the specific data as outlined in the appropriate Operational Qualification. Each result will be noted and dated.
2. Employees of **Success Diagnostic Center- Shyam Bazar** will verify each result and sign in the last page. The members of the validation will carry this out.
3. All deviation from the acceptance criteria detailed in this document will be noted under COMMENTS section at the end of the OQ protocol. All resolution to such problems will also be noted in the COMMENTS section and must be resolved prior to issuance of a SYSTEM CERTIFICATION.
4. Any test data, which does not meet the specified acceptance criteria, will be submitted to the appropriate laboratory personnel for solution. All steps taken subsequently will be documented.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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II. SCOPE

This operational Qualification protocol will be performed on the Fully Automated Biochemistry Analyzer, Model AutoQuant 100 Amara, Sr. No. **AQ080890** located at **Success Diagnostic Center- Shyam Bazar**. This protocol will define the documentation that will be used to evaluate the instrument operation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that this instrument has been installed in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional condition encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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II. OPERATIONAL QUALIFICATION

A. Instrument Identification Verified Date

1. Model Name **AutoQuant 100 Amara**
2. Serial Number **AQ080890**

B. Following is the list of test performed and verified

Test No.	Test Name	Test Purpose	Verified Date
1.	Assay Programming	Programming a test as per the kit insert	08-Oct-2024
2.	Worklist Programming	In order to set up for a RUN	
3.	Initialize	To do the initialization of daily activity	
4.	Print	Printing Of Results	
5.	End of Work	For maintenance of the instrument	

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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C. Operational Testing

Test I

Test Name: Assay Programming

Purpose: To program the specified test

Procedure:

1. Open AutoQuant 100 Amara Operating Software.
2. Click on Parameter button
3. Enter test name, test code, define Method, Filter and other details menu.
4. Define Reference range in Reference Range window.
5. Define Calibrator in Calibration Window.
6. Input Control values in QC window.
7. Input Calculation formula in calculation item setting window.
8. Click on Save to save the protocol.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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D. Creating & Processing a Worklist

Test II

Purpose: In order to set up for a worklist of same type of multiple tests to be run together.

Method:

1. Click on Schedule button.
2. Click on sample button.
3. Select test to be processed.
4. Input patient information.
5. Click on Add and Modify button,
6. Click ID++ to programme next sample,
7. Put samples on designated positions,
8. Click Save then Test button to start processing.
9. Refer Operators manual section 4 for more details.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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E. Initialization

Test III

Test Name: **Initialization**

Purpose: In order to check the proper working of the instrument

Method:

1. The machine performs a self-test at the time of initialization to check if all the mechanics of the machine are working OK.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

G. OPERATIONAL PROCEDURE

Certificate of training

1. **Technician Training:** This certifies that the technicians listed below have received basic user training in the following categories for the system described in this installation qualification.

Mr. Partha Chakraborty who is certified by Meril Diagnostics Pvt. Ltd. Has conducted the training.

Sr. No.	Training Program	Initials	Date
1.	Instrument Setup	OK	08-Oct-2024
2.	System operation	OK	08-Oct-2024
3.	Basic troubleshooting	OK	08-Oct-2024
4.	Routine Maintenance	OK	08-Oct-2024

2. **Operator Training:** The users responsible for the operation of this instrument will be trained in the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of the operators will be documented and the training records will be filled as indicated below:

Sr. No.	Operators	Location	Initials	Date
1.		Success Diagnostic Center- Shyam Bazar	OK	08-Oct-2024
2.				

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

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V. COMMENTS

VI. 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 identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title: _____ Date: 08-Oct-2024

Department: Service Engineer

Customer Authorizations:

Name : _____ Signature:

Title : _____ Date: 08-Oct-2024 .

Site : Success Diagnostic Center- Shyam Bazar

AutoQuant 100 Amara
Fully Automated Biochemistry Analyzer

PERFORMANCE QUALIFICATION

FOR

Success Diagnostic Center- Shyam Bazar

PERFORMANCE QUALIFICATION#01

MARKETED BY:

MERIL DIAGNOSTICS PVT. LIMITED

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Sr. No. CONTENTS

I. Approval of the PQ procedure

II. Instructions

III. Scope

IV. Performance Qualification

V. Comments

VI. System Certification

I. APPROVAL OF THE PQ PROCEDURE:

Meril Diagnostics Pvt. Ltd. is responsible for the installation of the Automated Biochemistry Analyzer, model- AutoQuant 100 Amara, Sr. No. **AQ080890at Success Diagnostic Center- Shyam Bazar** as per the attached protocol.

Protocol Performed By: Meril Diagnostics Pvt. Ltd. Representative

Name: Mr. Partha Chakraborty

Signature:



Title: Date: 08-Oct-2024

Company: MERIL DIAGNOSTICS PVT. LIMITED

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:

Title: Date: 08-Oct-2024

Department: Service Engineer

Customer Authorizations:

Name :

Signature:

Title : Date: 08-Oct-2024 .

Site : Success Diagnostic Center- Shyam Bazar

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II. INSTRUCTIONS

1. An authorized Meril Diagnostics Pvt. Ltd. representative will check for the performance of the system and enter the specific data as outlined in the appropriate Performance Qualification.
2. Performance checks on a regular basis described in the Further Performance Checks (vide-infra) will be responsibility of the customer's personnel.
3. Employees of (customer) **Success Diagnostic Center- Shyam Bazar** will verify each result and sign in the last page. The members of the validation will carry this out.
4. All deviation from the acceptance criteria detailed in this document will be noted under COMMENTS section at the end of PQ section. All resolution to such problems will also be noted in the COMMENTS section and must be resolved prior to issuance of a SYSTEM CERTIFICATION.
5. Any test that does not meet the specified acceptance criteria will be submitted to the appropriate laboratory personnel for solution. All steps taken subsequently will be documented.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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III. SCOPE

This Performance Qualification protocol will be performed on the Automated Biochemistry Analyzer, Model AutoQuant 100 Amara, Sr. No **AQ080890** located at Success Diagnostic Center- Shyam Bazar. This protocol will define the documentation that will be used to evaluate the instrument operation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified is performing in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional condition encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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IV. PERFORMANCE QUALIFICATION

A. Instrument Identification Verified Date

1. Model Name AutoQuant 100 Amara.
2. Serial Number **AQ080890**

B. Following is the list of test performed and verified

Test No. Test Name Test Purpose Verified Date

- 01: SELF TEST : In order to check the proper working of the instrument.
- 02: DAILY MAINTENANCE : To eliminate unexpected errors.
- 03: RUN A TEST : To check the instrument performance.
04. CARRY OVER STUDY : To check carry over possibilities.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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C. Performance Testing

Test I

Test Name: **Self-Test**

Purpose: In order to check the proper working of the instrument

Method: Switch ON the machine and Initialize the machine.

Acceptance Criteria: The machine passes Self Test and comes to main menu screen.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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CARRY OVER CHECK :

Validation of Glucose/Urea/SGOT test run:

Replicates processed : 20

Number of Test & Samples processed : 10

Carry over found during performance check : YES / NO

(Data Sheet Attached for reference)

PARAMETER: PASS / FAIL

During sample analysis run control samples with each test run. Validate test run as per the criteria stated in the respective kit inserts.

Accept the sample results only on meeting of the validation criteria.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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Validation of Instrument performance:

Validation Criteria	Result obtained	Criteria pass/fail	Verified by
Glucose Test	Ok	Pass	
Urea Test	Ok	Pass	
SGOT Test	Ok	Pass	

PARAMETER: PASS / FAIL

During sample analysis run control samples with each test run. Validate test run as per the criteria stated in the respective kit inserts.

Accept the sample results only on meeting of the validation criteria.

Validation Team from Meril:

Name: Mr. Partha Chakraborty

Signature:



Title:

Date: 08-Oct-2024

Department: Service Engineer

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V. COMMENTS

VI. 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 identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Protocol Performed By: Meril Diagnostics Pvt. Ltd. Representative

Name: Mr. Partha Chakraborty

Signature:



Title: Date: 08-Oct-2024

Company: MERIL DIAGNOSTICS PVT. LIMITED

Customer Authorizations:

Name :

Signature:

Title : Date: 08-Oct-2024 .

Site : Success Diagnostic Center- Shyam Bazar

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Meril Diagnostics Pvt. Ltd.
Survey No.135/2/B, Bilakhia House
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CALIBRATION CERTIFICATE

To,
Success Diagnostic Center- Shyam Bazar
8C Mohanlal Street, Shyam Bazar, Kolkata: 700004

Instruments : **AutoQuant 100**
Machine Serial Number : **AQ080890**

Software Version : 4.5Ver

Issued On : **09th Oct 2024**
Valid Upto : **08th Oct 2025**

TEST ITEMS AND RESULT

Appearance	No Imbalance Probe Movement
Leakage in Water tubing or CRU	No water leakage
Ambient temp (15- 32) Degree	25 Degree
Lamp Check	Ok
Threshold Value	34,000 ($\geq 25,000$)
Sample Dispersing Volume	In range (0 to 30 ul)
Reagent cooling Temperature	7 Degree (0 to 15 Degree)
Optical Path length	0.65
Waster & Water Sensor	Working Properly
Valve & Motor	Working Properly
Reagent Dispersing Volume	In range (0 to 150 ul)
Power Supply and Earthing	230 Volts and Grounding less then 5 V

Conclusion : All parameter are within range. The Machine is working Properly.(as per Meril terms.)

Engineer Name : **Mr. Partha Chakraborty (Service Engineer)**

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