



## Calibration Certificate

This is to Certify that Biochemistry Analyzer Meril **AutoQuant-200i** Instrument Sr. No. **AQ050221** Installed at **IVY Hospital, Nawanshahar** has been calibrated by our engineer on **01-May-2021** with appropriate and sophisticated tools. Below parameter has been calibrated:

### TEST ITEMS AND RESULT

Appearance	No Imbalance Probe Movement
Leakage in Water tubing or CRU	No water leakage
Ambient temp ( 15- 32 ) Degree	24.0 degree C
Lamp Check	Ok
Sample Dispensing Volume	In range ( 0 to 30 ul)
Reagent cooling Temperature	2.8 ° C ( 0 to 15 Degree)
Optical Path length	0.65
Waster & Water Sensor	Working Properly
Threshold value	±34000 (≥25,000)
Valve & Motor	Working Properly
Reagent Dispensing Volume	In range ( 0 to 150 ul)
Power Supply and Earthing	230 Volts and Grounding less then 5 V
CV-Kinetic/End point/two Point	CV- 1.77% /2.42% /2.80%
SD-Kinetic/End point/two Point	SD- 1.15/0.39/0.69
Mean-Kinetic/End point/two Point	Mean- 97.55/14.34/24.79
Hardware Check-Functional Test	OK5415152524141112
Light Quality Check	OK
Cuvette Absorbance	OK
Cuvette Blank Value	OK >33000
Incubation temp.	37.0 ° C
Room temp.	25.0 degree C

This Calibration Certificate is Valid Up to **30-April-2022**.

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

Engineer Name: **Mr. Amit Kumar**

Designation: **Service Specialist**





CUSTOMER DATA



PARAMETER



QUALITY CONTROL

Samples

██████████

Samples

Reagent Lot number

Position

Cup or Tube

NO

1

Cup

Result

Lab ID	Test name	State	Result	Prompt	Unit	Low	High
Calib.	GLUC	██████████	300.14				
Calib.	SGPT	██████████	2544.25				
Calib.	SGOT	██████████	2307.69				
Calib.	UREA	██████████	278.94				
Calib.	CREAT	██████████	157.07				
Calib.	TG	██████████	822.46				
Calib.	TP	██████████	14.58				
Calib.	ALB	██████████	6.97				
Calib.	CHOL	██████████	607.27				
Calib.	UA	██████████	48.48				
Calib.	DBIL	██████████	67.72				
Calib.	TBIL	██████████	13.51				
Calib.	ALP	██████████	3201.71				

# Patient report

Name: ID:039  
 Patient ID: REPEATABILITY Age:  
 Sample type: Serum Lab name:  
 Patient remarks: Department: Check date: 05/01/2021

NO	Test	Test name	Result	Flag	Unit	Reference
1	GLUC	GLUCOSE	148.78	H	mg/dL	70.00-110.00
2	GLUC	GLUCOSE	150.37	H	mg/dL	70.00-110.00
3	GLUC	GLUCOSE	148.54	H	mg/dL	70.00-110.00
4	GLUC	GLUCOSE	152.20	H	mg/dL	70.00-110.00
5	GLUC	GLUCOSE	147.67	H	mg/dL	70.00-110.00
6	GLUC	GLUCOSE	149.56	H	mg/dL	70.00-110.00
7	GLUC	GLUCOSE	149.95	H	mg/dL	70.00-110.00
8	GLUC	GLUCOSE	150.43	H	mg/dL	70.00-110.00
9	GLUC	GLUCOSE	147.91	H	mg/dL	70.00-110.00
10	GLUC	GLUCOSE	147.55	H	mg/dL	70.00-110.00
11	SGPT	SGPT	19.59		U/L	0.00-45.00
12	SGPT	SGPT	20.10		U/L	0.00-45.00
13	SGPT	SGPT	20.10		U/L	0.00-45.00
14	SGPT	SGPT	19.08		U/L	0.00-45.00
15	SGPT	SGPT	19.34		U/L	0.00-45.00
16	SGPT	SGPT	19.85		U/L	0.00-45.00
17	SGPT	SGPT	19.85		U/L	0.00-45.00
18	SGPT	SGPT	19.85		U/L	0.00-45.00
19	SGPT	SGPT	19.34		U/L	0.00-45.00
20	SGPT	SGPT	16.79		U/L	0.00-45.00
21	UREA	UREA	25.63		mg/dL	13.00-45.00
22	UREA	UREA	25.55		mg/dL	13.00-45.00
23	UREA	UREA	25.33		mg/dL	13.00-45.00
24	UREA	UREA	25.83		mg/dL	13.00-45.00
25	UREA	UREA	26.33		mg/dL	13.00-45.00
26	UREA	UREA	25.30		mg/dL	13.00-45.00
27	UREA	UREA	24.80		mg/dL	13.00-45.00
28	UREA	UREA	25.94		mg/dL	13.00-45.00
29	UREA	UREA	25.86		mg/dL	13.00-45.00

QC results

No.	Test name	QC lot	Result	Run date	Concentration:	Flag	High	QC range
1	ALB	MB122021	4.37	05/01/2021::14:56:34		+1SD	3.90-4.76	
2	ALP	MB122021	204.27	05/01/2021::14:59:33		+1SD	157.70-222.30	
3	AMYL	MB122021	279.54	05/01/2021::15:00:12		+1SD	221.57-312.33	
4	CHOL	MB122021	201.74	05/01/2021::15:04:57		+1SD	157.78-222.40	
5	CREAT	MB122021	3.75	05/01/2021::14:58:13		+1SD	2.99-4.21	
6	DBIL	MB122021	2.32	05/01/2021::14:56:12		-1SD	1.64-3.06	
7	GLUC	MB122021	271.05	05/01/2021::15:02:09		+1SD	214.09-301.79	
8	HDLC	MB122021	57.18	05/01/2021::15:03:54		+1SD	42.97-64.45	
9	SGOT	MB122021	170.69	05/01/2021::15:42:04		-1SD	142.47-200.83	
10	SGPT	MB122021	120.09	05/01/2021::14:56:34		+1SD	94.44-133.12	
11	TBIL	MB122021	4.10	05/01/2021::15:40:07		-2SD	3.60-6.70	
12	TG	MB122021	211.78	05/01/2021::15:04:07		+1SD	173.98-245.24	
13	TP	MB122021	7.56	05/01/2021::15:04:44		+1SD	6.68-8.16	
14	UA	MB122021	10.01	05/01/2021::15:01:17		+1SD	7.89-11.13	
15	UREA	MB122021	141.53	05/01/2021::14:55:23		+1SD	116.84-164.70	

# IVY HOSPITAL

## Installation Qualification

## Operational Qualification

## Performance Qualification



AutoQuant 200 Excellus

Fully Automated Biochemistry Analyzer



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

AutoQuant 200i  
Fully Automated Biochemistry Analyzer

INSTALLATION QUALIFICATION

FOR

IVY HOSPITAL , Nawanshehar

INSTALLATION QUALIFICATION#01

MARKETED BY:

MERIL DIAGNOSTICS PVT. LIMITED

MUKTANAND MARG, CHALA

VAPI - 396191

INDIA

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F +91 260 3052125

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Survey No.135/2/B, Bilakhia House  
Muktanand Marg, Chala  
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### Appendices

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



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## I. APPROVAL OF THE IQ PROCEDURE:

Meril Diagnostics Pvt. Ltd. is responsible for the installation of the **Fully Automatic Biochemistry Analyzer, Merilyzer - AutoQuant 200 excellus, Sr. No. 50221** at IVY Hospital , Nawanshahr.

as per the attached protocol.

**Protocol Performed By: Meril Diagnostics Pvt. Ltd. Representative**



Name: Mr. **Daljeet Singh**

Signature:

Title: INSTALLATION QUALIFICATION

Date: 19/08/2021

Company: MERIL DIAGNOSTICS PVT. LIMITED

### Customer Authorizations:

Name :

Signature:

Title :

Date:

Site :NAWANSHEHAR

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## 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 (customer) IVY Hospital , Nawanshahr.

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:

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:**



**Date: 19/08/202**

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### III. SCOPE

This installation Qualification protocol will be performed on the **Fully Automatic Biochemistry Analyzer, Merilyzer - AutoQuant 200 excellus, Sr. No. 050221** located at IVY Hospital , Nawanshahr.. 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:

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:**



**Date: 19/08/2021**

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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 19/04/2021, has been purchased under purchase order No. \_\_\_\_\_ dated \_\_\_\_\_ OR contracted for period of five years is in compliance with the specifications of the purchase order or contract.

Verified By:

Date:

**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.Daljeet Singh  Date : 11/04/2021
2.	Adequate space for installation: (Minimum mm 600 X 450 X 400)      yes / no	YES
	Electrical Outlets:	YES

3.	Actual voltage on site [ 230VAC]      yes / no	
----	--	--

**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

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:** 

**Date: 19/08/2021**

## 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	<b>Mr. Daljeet Singh</b>	14/04/2021
Model : AutoQuant 200 Excellus		
Manufacturer : Meril Diagnostics Pvt. Ltd. India		
Marketed By : MERIL DIAGNOSTICS PVT. LIMITED		
Equipment # : Biochemistry Analyzer		
Serial Number : 020451		
Size : 548 X 422 X 383 (mm)		
Power : AC 230 V		

#### Validation Team:

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

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**Signature:** 

**Date:** 19/08/2021

**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 <b>Daljeet Singh</b>	19/04/2021
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:**

**Name: Mr. Daljeet Singh**

**Signature:**



**Designation: Area Service Manager**

**Date: 19/08/2021**

**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 200 excellus.

**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.

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## E. Maintenance

The instrument listed within this document will be 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 levels of maintenance agreements and performance testing services to assist you in maintaining GLP/GMP compliance. Contacting 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 stock 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:

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:**



**Date: 19/08/2021**



## 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:

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:**



**Date: 19/08/2021**

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## VII. COMMENTS

**Validation Team:**

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:**



**Date: 19/08/2021**



## 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.

### Protocol Performed By: Meril Diagnostics Pvt. Ltd. Representative

Name: **Daljeet Singh**

Signature: 

Title: INSTALLATION QUALIFICATION

Date: 19/08/2021

Company: MERIL DIAGNOSTICS PVT. LIMITED



### Customer Authorizations:

Name :

Signature:

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Title :

Date:

Site : NAWANSHEHAR

**AutoQuant 200 Excellus**  
**Fully Automated Biochemistry Analyzer**

**OPERATIONAL QUALIFICATION**

**FOR**

**IVY Hospital , Nawanshahr.**

**OPERATIONAL QUALIFICATION#02**

**MARKETED BY:**

**MERIL DIAGNOSTICS PVT. LIMITED**

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**VAPI - 396191**

**INDIA**

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Vapi - 396191. Gujarat, India.

## I. APPROVAL OF THE OQ PROCEDURE:

Meril Diagnostics Pvt. Ltd. is responsible for the installation of the **Fully Automatic Biochemistry Analyzer, Merilyzer - AutoQuant 200 excellus, Sr. No. 050221** at IVY Hospital , Nawanshahr. as per the attached protocol.

### Protocol Performed By: Meril Diagnostics Pvt. Ltd. Representative

Name: Mr. **Daljeet Singh**

Signature:



Title: OPERATIONAL QUALIFICATION

Date: 19/08/2021

Company: MERIL DIAGNOSTICS PVT. LTD.

### Customer Authorizations:

Name :

Signature:

Title :

Date:

Site :

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## 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 (customer) IVY Hospital , Nawanshahr. 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:

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:**



**Date: 19/08/2021**

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Muktanand Marg, Chala  
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## II. SCOPE

This operational Qualification protocol will be performed on the **Fully Automatic Biochemistry Analyzer, Merilyzer AutoQuant 200 excellus, Sr. No. 050221** located at IVY Hospital , Nawanshahr.. 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:

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:**



**Date: 19/08/2021**



**II. OPERATIONAL QUALIFICATION**

**A. Instrument Identification Verified Date**

- 1. Model Name **AutoQuant 200 Excellus**
- 2. Serial Number **050221**

**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	19/08/2021
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:**

**Name: Mr. Daljeet Singh**

**Designation: Sr. Area Service Manager**



**Signature:**

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## C. Operational Testing

### Test I

**Test Name: Assay Programming**

**Purpose: To programme the specified test**

#### Procedure:

1. Open AutoQuant 200 excellus 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:

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:**



**Date: 19/08/2021**

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## D. Creating & Processing a Work list

### Test II

**Purpose: In order to set up for a work list 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:

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:**



**Date: 19/08/2021**

## **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:**

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:**



**Date: 19/08/2021**

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## G. OPERATIONAL PROCEDURE

### A. 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. Daljeet Singh is certified by Meril Diagnostics Pvt. Ltd. Has conducted the training.

Sr. No.	Training Program	Initials	Date
1.	Instrument Setup	OK	19/04/2021
2.	System operation	OK	19/04/2021
3.	Basic troubleshooting	OK	19/04/2021
4.	Routine Maintenance	OK	19/04/2021

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.		IVY HOSPITAL NAWANSHAHR	OK	19/04/2021
2.			OK	

**Validation Team:**

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:** 

**Date: 19/08/2021**

**V. COMMENTS**

**Validation Team:**

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:** 

**Date: 19/08/2021**



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Muktanand Marg, Chala  
Vapi - 396191. Gujarat, India.

## 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. **Daljeet Singh**

Signature:



Title: OPERATIONAL QUALIFICATION

Date: 19/08/2021

Company: MERIL DIAGNOSTICS PVT. LIMITED



### Customer Authorizations:

Name :

Signature:

Title :

Date:

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AutoQuant 200i  
Fully Automated Biochemistry Analyzer

PERFORMANCE QUALIFICATION

FOR

**IVY Hospital , Nawanshahr.**

PERFORMANCE QUALIFICATION#01

MARKETED BY:

MERIL DIAGNOSTICS PVT. LIMITED

MUKTANAND MARG, CHALA

VAPI - 396191

INDIA

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Survey No.135/2/B, Bilakhia House  
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**I. APPROVAL OF THE PQ PROCEDURE:**

Meril Diagnostics Pvt. Ltd. is responsible for the installation of the **Fully Automatic Biochemistry Analyzer, Merilyzer - AutoQuant 200 excellus, Sr. No.050221** at IVY Hospital , Nawanshahr. as per the attached protocol.

**Protocol Performed By: Meril Diagnostics Pvt. Ltd. Representative**

Name: Mr. **Daljeet Singh**

Signature: 

Title: OPERATIONAL QUALIFICATION

Date: 19/08/2021

Company: MERIL DIAGNOSTICS PVT. LTD.

**Customer Authorizations:**

Name :

Signature:

Title :

Date:

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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) IVY Hospital , Nawanshahr. 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:

**Name: Mr. Daljeet Singh**

**Designation: Sr. Area Service Manager**

**Signature:**



**Date: 19/08/2021**

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### III. SCOPE

This Performance Qualification protocol will be performed on the **Fully Automatic Biochemistry Analyzer, Merilyzer AutoQuant 200 excellus, Sr. No. 050221** located at IVY Hospital , Nawanshahr.. 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:

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:**



**Date: 19/08/2021**

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#### IV. PERFORMANCE QUALIFICATION

##### A. Instrument Identification Verified Date

1. Model Name AutoQuant 200 Excellus.
2. Serial Number 050221

##### 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:

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:**



**Date: 19/08/2021**

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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:

**Name:** Mr. Daljeet Singh

**Designation:** Area Service Manager

**Signature:**



**Date:** 19/08/2021

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## **CARRY OVER CHECK :**

### **Validation of Glucose/Urea/SGP**

#### **T 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:**

**Name: Mr. Daljeet Singh**

**Designation: Area Service Manager**

**Signature:**



**Date: 19/08/2021**

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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	
SGPT 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**

**Name: Mr. DALJEET SINGH**

**Designation: Area Service Manager**



**Signature:**

**Date:** 19/08/2021

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## V. COMMENTS

### Validation Team:

**Name: Mr. DALJEET SINGH**

**Designation: Area Service Manager**

**Signature:**



**Date: 19/08/2021**



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## 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. DALJEET SINGH

Signature:



Title: PERFORMANCE QUALIFICATION

Date: 19/08/2021

Company: MERIL DIAGNOSTICS PVT. LIMITED



### Customer Authorizations:

Name :

Signature:

Title :

Date:

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**TRACEABILITY DOCUMENT**

**Product : BIOCAL**

**Lot No. : MB122019**

**Exp. : 2022-03**

Parameter	Reference Material	Selected Measurement Procedure	Calibrator Value	Uncertainty	Units
Albumin ( BCG )	CFAS 305596	Meril reagent procedure	3.30	0.06	g/dL
Amylase ( CNPG <sub>2</sub> )	CFAS 305596	Meril reagent procedure	177	1.42	U/L
ALP ( AMP buffer )	CFAS 305596	Meril reagent procedure	300	1.54	U/L
ALT ( Modified IFCC ) Without pyridoxal phosphate	CFAS 305596	Meril reagent procedure	115	1.83	U/L
AST ( Modified IFCC ) Without pyridoxal phosphate	CFAS 305596	Meril reagent procedure	102	1.10	U/L
Direct Bilirubin ( Diazo )	CFAS 305596	Meril reagent procedure	2.35	0.043	mg/dL
Total Bilirubin ( Diazo )	CFAS 305596	Meril reagent procedure	5.65	0.008	mg/dL

Parameter	Reference Material	Selected Measurement Procedure	Calibrator Value	Uncertainty	Units
Calcium (Arsenazo )	CFAS 305596	Meril reagent procedure	9.45	0.09	mg/dL
Cholesterol ( CHOD – PAP )	CFAS 305596	Meril reagent procedure	152	2.42	mg/dL
HDL Cholesterol Direct ( Direct )	2782CH	Meril reagent procedure	45	1.85	mg/dL
LDL Cholesterol Direct ( Direct )	2782CH	Meril reagent procedure	90	2.20	mg/dL
CK ( NAC –activated )	CFAS 305596	Meril reagent procedure	350	2.62	U/L
CK MB ( CK MB, Kinetic )	3980CK	Meril reagent procedure	165	1.22	U/L
Chloride ( Mercuric Thiocyanate )	CFAS 305596	Meril reagent procedure	103	0.90	mEq/L
Creatinine ( Jaffe's )	CFAS 305596	Meril reagent procedure	3.0	0.041	mg/dL
Creatinine ( Enzymatic )	CFAS 305596	Meril reagent procedure	3.68	0.048	mg/dL



Meril  
Diagnostics

Parameter	Reference Material	Selected Measurement Procedure	Calibrator Value	Uncertainty	Units
GGT ( GLUPA – C )	CFAS 305596	Meril reagent procedure	125	1.38	U/L
Glucose ( GOD – POD )	CFAS 305596	Meril reagent procedure	198	1.78	mg/dL
LDH – P ( DGKC )	CFAS 305596	Meril reagent procedure	495	3.37	U/L
Lipase ( Advanced Homogeneous Micelle Technology )	CFAS 305596	Meril reagent procedure	75	1.10	U/L
Magnesium ( Xylidyl blue )	CFAS 305596	Meril reagent procedure	2.64	0.042	mg/dL
Phosphorus ( UV Molybdate )	CFAS 305596	Meril reagent procedure	4.8	0.051	mg/dL
Triglyceride ( GPO – PAP )	CFAS 305596	Meril reagent procedure	145	0.78	mg/dL
Total Protein ( Biuret )	CFAS 305596	Meril reagent procedure	5.6	0.068	g/dL
Uric Acid ( Uricase – TOOS )	CFAS 305596	Meril reagent procedure	5.1	0.041	mg/dL



Diagnosics

Parameter	Reference Material	Selected Measurement Procedure	Calibrator Value	Uncertainty	Units
Urea ( Urease – GLDH )	CFAS 305596	Meril reagent procedure	180	0.82	mg/dL

2021-02-08

**C.F.A.S. - 324160**: Calibrator for automated systems whose values are traceable to Roche Master Calibrator 186488 – calibrated against CRM's.

**CRM** = certified reference material

**CK-MB CAL - 4410CK** calibrator for CK MB values traceable to Randox CRM

**D LDL/HDL CAL - 2826CH** Calibrator for HDL & LDL values traceable to Randox CRM

**Signature:**

**Name : Ram Kanoje**

**Designation: Q.A. Head**