



Calibration Certificate

To,

This is to Certify that **Electrolyte Analyzer Meril Quantilyte** Instrument Sr.No. **QN0171002** Installed at **IVY Hospital, Nawanshahar** has been calibrated by our engineer on **01-May-2021** with appropriate and sophisticated tools. Bellow parameters are been calibrated:

TEST ITEMS AND RESULT

Appearance	OK
Air Tube	OK
Pressure Sensor	OK
Vacuum Pump	OK
Air Circuit	OK
Reaction Liquid Interface	OK
Sample Injection Interface	OK
Waste Liquid Interface	OK
Measuring Speed	≤ 25 seconds
Operating Temperature	10°C to 30°C
Relative Humidity	< 80%
Atmospheric Pressure	86 - 106 kPa
Power	120W
Power Supply and Earthing	220V ± 22V, 50 ± 1Hz

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**



A 41.0 53.0 82.5
B 61.3 50.3 94.7
A 41.0 53.3 82.7
B 61.3 50.5 94.8
SP 77.5 26.7 87.9
SP 78.7 24.4 89.7

3.

S.No. 3

Date
1/7/21

Meril

Diagnostics

For in vitro diagnostic use
Read this pack insert thoroughly before use

BioNORM Values on AutoQuant Systems			Lot: MB122020	2022-02
Analyte	Method	Units	AutoQuant 100/200i	AutoQuant 400/400i
			AriQuant MR/ER	
ALB: Albumin	Bromocresol Green	g/dL	3.50[3.15 - 3.85]	3.50[3.15 - 3.85]
		g/L	35.0[31.5 - 38.5]	35.0[31.5 - 38.5]
AMYL: Amylase	CNP _{G2}	U/L	75.55[62.71 - 88.39]	75.55[62.71 - 88.39]
		μKat/L	1.28[1.07 - 1.50]	1.28[1.07 - 1.50]
ALP: Alkaline phosphatase	Modified IFCC (AMP Buffer)	U/L	68.50[56.86 - 80.15]	70.67[58.66 - 82.68]
		μKat/L	1.16[0.96 - 1.36]	1.20[1.00 - 1.40]
ALT /SGPT: Alanine amino transferase	IFCC without pyridoxal phosphate	U/L	52.22[43.34 - 61.10]	52.22[43.34 - 61.10]
		μKat/L	0.89[0.74 - 1.04]	0.89[0.74 - 1.04]
AST /SGOT: Aspartate amino transferase	IFCC without pyridoxal phosphate	U/L	39.23[32.56 - 45.90]	39.23[32.56 - 45.90]
		μKat/L	0.67[0.55 - 0.78]	0.67[0.55 - 0.78]
BIL- D: Bilirubin Direct	Diazo	mg/dL	0.75[0.53 - 0.98]	0.80[0.56 - 1.04]
		μmol/L	12.83[8.98 - 16.77]	13.68[9.58 - 17.78]
BIL- T: Bilirubin Total	Diazo	mg/dL	1.67[1.17 - 2.17]	1.67[1.17 - 2.17]
		μmol/L	28.56[20.00 - 37.12]	28.56[20.00 - 37.12]
Ca: Calcium	Arsenazo III	mg/dL	7.99[7.19 - 8.79]	7.99[7.19 - 8.79]
		mmol/L	2.00[1.80 - 2.20]	2.00[1.80 - 2.20]
CHOL : Cholesterol	CHOD – Trinder	mg/dL	139.00[115.37 - 162.63]	139.00[115.37 - 162.63]
		mmol/L	3.60[2.99 - 4.21]	3.60[2.99 - 4.21]
HDL C : HDL Cholesterol	Direct	mg/dL	41.78[33.42 - 50.14]	41.78[33.42 - 50.14]
		mmol/L	1.08[0.86 - 1.30]	1.08[0.86 - 1.30]
LDL C : LDL Cholesterol	Direct	mg/dL	81.61[65.29 - 97.93]	81.61[65.29 - 97.93]
		mmol/L	2.11[1.69 - 2.53]	2.11[1.69 - 2.53]
CK: Creatine Kinase	NAC Activated	U/L	150.0[124.50 - 175.50]	150.0[124.50 - 175.50]
		μKat/L	2.55[2.12 - 2.98]	2.55[2.12 - 2.98]
CK:CK MB	IFCC Method, Kinetic	U/L	26.50[22.00 - 31.01]	32.58[27.04 - 38.12]
		μKat/L	0.45[0.37 - 0.53]	0.55[0.46 - 0.64]
Cl: Chloride	Mercuric Thiocyanate	mEq/L	97.25[87.53 - 106.98]	97.25[87.53 - 106.98]
		mmol/L	97.25[87.53 - 106.98]	97.25[87.53 - 106.98]
Cl: Chloride	ISE	mEq/L	95.27[85.74 - 104.80]	95.27[85.74 - 104.80]
		mmol/L	95.27[85.74 - 104.80]	95.27[85.74 - 104.80]
CREA: Creatinine	Jaffe, Initial rate	mg/dL	1.40[1.16 - 1.64]	1.46[1.21 - 1.71]
		μmol/L	123.76 [102.72 - 144.80]	129.06[107.11 - 151.00]
CREA: Creatinine	Enzymatic	mg/dL	1.50[1.25 - 1.75]	1.50[1.25 - 1.75]
		μmol/L	132.06[110.05 - 154.51]	132.06[110.05 - 154.51]
GGT: GAMMA GT	Glupa – C	U/L	31.18[25.88 - 36.48]	31.18[25.88 - 36.48]
		μKat/L	0.53[0.44 - 0.62]	0.53[0.44 - 0.62]
GLU: Glucose	GOD – Trinder	mg/dL	85.20[70.72 - 99.68]	85.20[70.72 - 99.68]
		mmol/L	4.73[3.92 - 5.53]	4.73[3.92 - 5.53]
K: Potassium	ISE	mEq/L	4.05[3.56 - 4.54]	4.05[3.56 - 4.54]
		mmol/L	4.05[3.56 - 4.54]	4.05[3.56 - 4.54]
LDH-P: Lactate dehydrogenase	DGKC (Pyruvate to Lactate)	U/L	267.36[221.91 - 312.81]	270.00[224.10 - 315.90]
		μKat/L	4.55[3.77 - 5.32]	4.59[3.81 - 5.37]
LIP: Lipase	Ad. Homogeneous, Micelle Tech.	U/L	55.21[45.82 - 64.60]	55.21[45.82 - 64.60]
		μKat/L	0.94[0.78 - 1.10]	0.94[0.78 - 1.10]
Mg: Magnesium	Xylidyl blue	mg/dL	1.85[1.63 - 2.07]	1.80[1.58 - 2.02]
		mmol/L	0.76[0.67 - 0.85]	0.74[0.65 - 0.83]
Na: Sodium	ISE	mEq/L	135.70[122.13 - 149.27]	135.70[122.13 - 149.27]
		mmol/L	135.70[122.13 - 149.27]	135.70[122.13 - 149.27]
PHOS: Phosphorus	Ammonium molybdate	mg/dL	2.99[2.69 - 3.29]	2.99[2.69 - 3.29]
		mmol/L	0.97[0.87 - 1.06]	0.97[0.87 - 1.06]

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1.

S.No-1

3/8/21

Meril

Diagnostics

(iv) For in vitro diagnostic use
Read this pack insert thoroughly before use

BioPATH Values on AutoQuant Systems			Lot: MB122021	2022-05
Analyte	Method	Units	AutoQuant 100/200i	AutoQuant 400/400i
			AriQuant MR/ER	
ALB: Albumin	Bromocresol Green	g/dL	4.33[3.90 - 4.76]	4.33[3.90 - 4.76]
		g/L	43.3[39.0 - 47.6]	43.3[39.0 - 47.6]
AMYL: Amylase	CNP ₂	U/L	266.95[221.57 - 312.33]	266.95[221.57 - 312.33]
		μKat/L	4.54[3.77 - 5.31]	4.54[3.77 - 5.31]
ALP: Alkaline phosphatase	Modified IFCC (AMP Buffer)	U/L	190.0[157.7 - 222.3]	195.05[161.89 - 228.21]
		μKat/L	3.23[2.68 - 3.78]	3.32[2.76 - 3.88]
ALT /SGPT: Alanine amino transferase	IFCC without pyridoxal phosphate	U/L	113.78[94.44 - 133.12]	113.78[94.44 - 133.12]
		μKat/L	1.93[1.61 - 2.26]	1.93[1.61 - 2.26]
AST /SGOT: Aspartate amino transferase	IFCC without pyridoxal phosphate	U/L	171.65[142.47 - 200.83]	171.65[142.47 - 200.83]
		μKat/L	2.92[2.42 - 3.42]	2.92[2.42 - 3.42]
BIL- D: Bilirubin Direct	Diazo	mg/dL	2.35[1.65 - 3.06]	2.35[1.65 - 3.06]
		μmol/L	40.19[28.13 - 52.25]	40.19[28.13 - 52.25]
BIL- T: Bilirubin Total	Diazo	mg/dL	5.15[3.61 - 6.70]	5.15[3.61 - 6.70]
		μmol/L	88.07[61.65 - 114.49]	88.07[61.65 - 114.49]
Ca: Calcium	Arsenazo III	mg/dL	11.0[9.90 - 12.10]	11.0[9.90 - 12.10]
		mmol/L	2.75[2.48 - 3.03]	2.75[2.48 - 3.03]
CHOL: Cholesterol	CHOD - Trinder	mg/dL	190.09[157.78 - 222.41]	190.09[157.78 - 222.41]
		mmol/L	4.92[4.08 - 5.76]	4.92[4.08 - 5.76]
HDL C: HDL Cholesterol	Direct	mg/dL	53.71[42.97 - 64.45]	53.71[42.97 - 64.45]
		mmol/L	1.39[1.11 - 1.67]	1.39[1.11 - 1.67]
LDL C: LDL Cholesterol	Direct	mg/dL	111.36[89.09 - 133.62]	111.36[89.09 - 133.62]
		mmol/L	2.88[2.31 - 3.46]	2.88[2.31 - 3.46]
CK: Creatine Kinase	NAC Activated	U/L	196.44[163.05 - 229.83]	196.44[163.05 - 229.83]
		μKat/L	3.34[2.77 - 3.91]	3.34[2.77 - 3.91]
CK:CK MB	IFCC Method, Kinetic	U/L	41.50[34.45 - 48.56]	44.35[36.81 - 51.89]
		μKat/L	0.71[0.59 - 0.83]	0.75[0.63 - 0.88]
Cl: Chloride	Mercuric Thiocyanate	mEq/L	118.94[107.05 - 130.83]	118.94[107.05 - 130.83]
		mmol/L	118.94[107.05 - 130.83]	118.94[107.05 - 130.83]
Cl: Chloride	ISE [Quantilyte]	mEq/L	120.06[108.05 - 132.07]	120.06[108.05 - 132.07]
		mmol/L	120.06[108.05 - 132.07]	120.06[108.05 - 132.07]
CREA: Creatinine	Jaffe, Initial rate	mg/dL	3.60[2.99 - 4.21]	3.73[3.10 - 4.36]
		μmol/L	318.24[264.14 - 372.34]	329.73[273.68 - 385.78]
CREA: Creatinine	Enzymatic	mg/dL	4.45[3.69 - 5.21]	4.45[3.69 - 5.21]
		μmol/L	393.38[326.51 - 460.25]	393.38[326.51 - 460.25]
GGT: GAMMA GT	Glupa - C	U/L	95.48[79.25 - 111.71]	95.48[79.25 - 111.71]
		μKat/L	1.62[1.34 - 1.90]	1.62[1.34 - 1.90]
GLU: Glucose	GOD - Trinder	mg/dL	257.94[214.09 - 301.79]	257.94[214.09 - 301.79]
		mmol/L	14.32[11.89 - 16.75]	14.32[11.89 - 16.75]
K: Potassium	ISE [Quantilyte]	mEq/L	7.50[6.60 - 8.40]	7.50[6.60 - 8.40]
		mmol/L	7.50[6.60 - 8.40]	7.50[6.60 - 8.40]
LDH-P: Lactate dehydrogenase	DGKC (Pyruvate to Lactate)	U/L	540.0[448.2 - 631.8]	555.0[460.65 - 649.35]
		μKat/L	9.18[7.62 - 10.74]	9.44[7.84 - 11.04]
LIP: Lipase	Ad. Homogeneous, Micelle Tech.	U/L	103.08[85.56 - 120.60]	103.08[85.56 - 120.60]
		μKat/L	1.75[1.45 - 2.05]	1.75[1.45 - 2.05]
Mg: Magnesium	Xylidyl blue	mg/dL	4.54[4.00 - 5.08]	4.54[4.00 - 5.08]
		mmol/L	1.87[1.65 - 2.09]	1.87[1.65 - 2.09]
Na: Sodium	ISE [Quantilyte]	mEq/L	165.60[149.04 - 182.16]	165.60[149.04 - 182.16]
		mmol/L	165.60[149.04 - 182.16]	165.60[149.04 - 182.16]
PHOS: Phosphorus	Ammonium molybdate	mg/dL	7.44[6.70 - 8.18]	7.44[6.70 - 8.18]
		mmol/L	2.40[2.16 - 2.64]	2.40[2.16 - 2.64]

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Immunology- Quantilyte (NA/K/CL)



INSTALLATION QUALIFICATION OPERATIONAL QUALIFICATION PERFORMANCE QUALIFICATION (IQ/OQ/PQ)

MARKETED BY:

MERIL DIAGNOSTICS PVT. LIMITED

MUKTANAND MARG, CHALA

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Meril Diagnostics Pvt. Ltd.
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CERTIFICATE OF INSTALLATION

INSTRUMENT NAME : Quantilyte
SERIAL NUMBER : QN0171002
CUSTOMER NAME : Ivy Diagnostic laboratory
ADDRESS : Chandigarh , Punjab

The undersigned performers certify that the Installation Qualification Protocol has been successfully completed for the instrument stated above.

Validation Team,

Name : Mr Daljeet Singh
Designation : Area Service Manager
Company : Meril Diagnostics Pvt. Ltd.
Date : 16-June-2019

User Team,

Name : Mr Ravi Kumar
Designation : Lab Manager
Company : **Ivy Diagnostic laboratory**
Signature :

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INSTALLATION REPORT

Customer Name : Ivy Diagnostic laboratory
Place : Chandigarh , Punjab
Contact Person : Mr. Ravi Kumar
Instrument Name : Quantilyte
Serial Number : QN0171002
Date of Installation : 16-June-2019
Warranty Expiry : 15-Jun-2020

The Analyzer was installed along with the necessary standard accessories. All basic requirements and adjustments were checked and are found to be satisfactory. The preliminary standardization of the analyzer and the training were provided to the complete satisfaction of the customer. The analyzer is found to be working satisfactorily.

By, Meril Diagnostics Pvt. Ltd.

User Team,

Name : Mr. Ravi Kumar
Designation : Lab Manager
Company : Ivy Diagnostic laboratory
Signature :

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INSTALLATION QUALIFICATION

IQ PROTOCOL

1. System Unpacking
2. System Checking For any Damages
3. All accessories as per check List verification
4. Space Requirement
5. Power Requirement
6. Reagents, Control, Calibrators verification.

1. SYSTEM UNPACKING ; Done

2. SYSTEM CHECKING ;

LumiQuant is unpacked and checked for physical Damages as per protocol and found to be in good condition.

3. ACCESSORIES CHECK -

Check all accessories as per check List.

4. SPACE REQUIREMENT -

- **Checked site for proper space allocation. At least 100 CM on each side and enough room on the countertop to accommodate the System and waste containers.**

PARAMETER	Analyzer OV
Width cm	33,5cm
Height cm	29,0cm
Length cm	47,5cm
Weight Kg	13kg

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5. POWER REQUIREMENT -

Requirement	Acceptable Range	Observed Ranged
Input Voltage	90-130 V & 180-250 V	218 V
Line Frequency	47-63 Hz	50 Hz
Ambient Temperature	10 °C – 40 °C	23°C
Output Voltage	24V	24V

6. Control, Calibrators Check -

NAME	Status	Remark
Controls	YES	OK
Calibrator	YES	OK

OPERATIONAL QUALIFICATION

The Operational Qualification procedure specifies the methodology for installation of specified system after successful installation qualification. Successful completion of procedure identifies that system is ready for operation and subsequent performance analysis.

OQ PROTOCOL

- 1. System Connections**
- 2. Customizing the Analyzer Software**
- 3. System Booting , Initialization & Check**
- 4. Maintenance procedures.**
- 5. Customer Training – Operation & Maintenance.**

1. SYSTEM CONNECTION -

SYSTEM CONNECTIONS			
S/N	NAME	Check	Remark
1	Input Power supply	Operation Manual 3.1	OK
2	Ambient Environment	Operation Manual page 3.1	OK

2. CUSTOMIZING ANALYZER SOFTWARE -

CUSTOMIZING ANALYZER SOFTWARE			
S/N	Parameters	Check	Remark
1	System parameters	Operation Manual 2	OK
2	Main Menu	Operation Manual 2.2	OK
3	System Setting	Operation Manual 2.3	OK
4	Printer Setup	Operation Manual 2.6	OK

3. SYSTEM BOOTING, INITIALIZATION & Check -

Power ON System and check instrument Initialization successfully.

Check following Parameters.

TEMPERATURES & WAVELENGTHS				
S/N	Parameters	Actual	Range	Remark
1.	Operating temperature humidity	10°C to 40°C 15% - 75% RH non-condensing	37.0	Ok
2.	Storage temperature humidity	-10°C to 50°C <95% RH non-condensing	10 to 35	Ok

NORMAL BACKGROUND CHECK				
S/N	PARAMETER	Actual	Remark	Remark
1	Water Abs.	0.00	0.00	OK

4. MAINTENANCE PROCEDURES:-

MAINTENANCE			
S/N	Parameters	Check	Remark
1	Using Maintenance Menu	Operation Manual 4	OK
3	Daily Maintenance	Operation Manual 4.1	OK

ADJUSTMENT			
S/N	Parameters	Check	Remark
1	Absorbance	Operator Manual 4.5	OK
2	Error Messages	Operator Manual 4	OK

Validation Team.

Name : Mr Daljeet Singh
 Designation : Area Service Manager
 Company : Meril Diagnostics Pvt. Ltd.
 Date : 16-June-2019

PERFORMANCE QUALIFICATION

The Performance of system is to be verified by the accuracy and precision analysis of the parameters by running 3 Levels of controls. The results should be with in control range as per the assay sheet.

PQ Protocol:-

1. Carry over check
2. Precision Check
3. Control Check (Two Levels)
4. Calibration Factor Data .

1. Carry Over Check.

Measurement time	typical < 40 seconds@ 0.1 sec. integration time for a 96-well plate
Integration time	0.1 sec to 10 sec in increments of 0.1sec
Plate types	96-well and 48-well (4x12) microplates (max. height 15.2 mm)
Shaking	3 modes

2. Precision Check.

REPRODUCIABILITY CHECK				
S/N	PARAMETER	Actual	Range CV%	Remark
1	Control / Results	As per Protocol	2	OK

3. Control & Calibrator Check-

Name	Lot no	Result
Calibrator		OK
Control		OK

Calibration

Quantilyte is factory calibrated and ready to use.

List Attached.
Attachment:-

- 1. Packing list**
- 2. Software**
- 3. Calibrator data sheet**
- 4. Calibrator settings printout**
- 5. Control data sheet**
- 6. Control data printout**
- 7. Precision (reproducibility) data**
- 8. Method comparison data**
- 9. Training certificate**
- 10. Manufacturer authorization letter.**

Validation Team,

Name : Mr Daljeet Singh
Designation : Area Service Manager
Company : Meril Diagnostics Pvt. Ltd.
Date : 16-June-2019

User Team,

Name : Mr. Ravi Kumar
Designation : Lab Manager
Company : Ivy Diagnostic laboratory
Signature :



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Ivy Diagnostic Laboratory

Nawan Shahr,-Chandigarh Road,
NAWAN SHAHR, PUNJAB
Ph.: 7508402020, 7837242818

PARAMETER'S	NAME OF ANALYZER
GLUCOSE	MERILYZER AUTOQUANT 200
SERUM CREATININE	MERILYZER AUTOQUANT 200
ALT/SGPT	MERILYZER AUTOQUANT 200
AST/SGOT	MERILYZER AUTOQUANT 200
SERUM BILIRUBIN	MERILYZER AUTOQUANT 200
SERUM ALKALINE PHOSPHATE	MERILYZER AUTOQUANT 200
SERUM TRIGLYCERIDES	MERILYZER AUTOQUANT 200
SERUM CHOLESTROL	MERILYZER AUTOQUANT 200
SERUM MAGNISUM	MERILYZER AUTOQUANT 200
HDL- CHOLESTROL	MERILYZER AUTOQUANT 200
SERUM URIC ACID	MERILYZER AUTOQUANT 200
PHOSPHOURS	MERILYZER AUTOQUANT 200
SERUM UREA	MERILYZER AUTOQUANT 200
SERUM AMYLASE	MERILYZER AUTOQUANT 200
SERUM ALBUMIN	MERILYZER AUTOQUANT 200
TOTAL PROTEIN	MERILYZER AUTOQUANT 200
SERUM SODIUM	MERILYZER QUANTILYTE
SERUM POTASSIUM	MERILYZER QUANTILYTE
CHOLORIDE	MERILYZER QUANTILYTE
HEAMOGLOBIN	MERILYZER CEL QUANT 3 PRIME
TLC (TOTAL LEUCOCYTE COUNT)	MERILYZER CEL QUANT 3 PRIME
DLC (DIFFERENTIAL LEUKOCYTE COUNT)	MERILYZER CEL QUANT 3 PRIME
PLATELETS COUNT	MERILYZER CEL QUANT 3 PRIME
RED BLOOD CELLS	MERILYZER CEL QUANT 3 PRIME
HCT	MERILYZER CEL QUANT 3 PRIME
MCV	MERILYZER CEL QUANT 3 PRIME
MCH	MERILYZER CEL QUANT 3 PRIME
MCHC	MERILYZER CEL QUANT 3 PRIME

THIS REPORT IS NOT VALID FOR MEDICO LEGAL PURPOSE. IF RESULTS OF THE TESTS ARE ALARMING, UNEXPECTED OR DO NOT TALLY WITH CLINICAL DETAILS, THE PATIENT/CLINICIAN IS ADVISED TO CONTACT THE LABORATORY IMMEDIATELY.