

AGD Biomedicals (P) Ltd

AGD2020 Semi-Automatic Clinical Chemistry Analyzer

IQ-OQ-PQ DOCUMENT

MAKE	:	AGD, India
MODEL NO	:	AGD2020 Semi-Automatic Clinical Chemistry Analyzer
SERIAL NO	:	A0190945
INSTALLATION NO	:	1
PURCHASE ORDER NO	:	102/KMML/2021-22

QUALIFICATION OF AGD2020 Semi-Automatic Clinical Chemistry Analyzer

DESCRIPTION OF SYSTEM/EQUIPMENTS

AGD Biomedicals' experience and understanding of laboratory needs has led to an innovative product developed with one key objective – provide excellent Chemistry Analyzer, resulting in the ultimate customer satisfaction. AGD2020 is a compact, convenient, new generation analyzer most suitable for medium and small sized laboratories, also as a backup for large laboratories.

- Touchscreen Display
- Online Graphics
- Collated Patients Reports
- L-J Chart for Quality Control

SAFETY REQUIREMENT

- Ensure that only trained staff work with the appliance
- Set up the appliances in a spacious area on an even, stable, clean, non-slip, dry and fireproof surface.

QUALIFICATION OF AGD2020 Semi-Automatic Clinical Chemistry Analyzer

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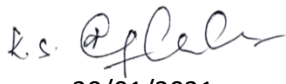
QUALIFICATION OF AGD2020 Semi-Automatic Clinical Chemistry Analyzer

CHECKLIST FOR INSPECTION OF AGD2020 Semi-Automatic Clinical Chemistry Analyzer

(To be checked on receipt of the equipment)

SL. NO	ITEM	QTY	ACCEPTANCE CRITERIA	OBSERAVATION
1	AGD2020 Semi-Automatic Clinical Chemistry Analyzer	1 No	Available along with Package	Available
2	Standard Attachment	1 No	Available along with Package	Available
3	Operating Manual	1 No	Available along with Package	Available
4	Warranty Registration Card	1 No	Available along with Package	Available

Checking sign off:

Name of the Person	Signature / Date
KAJA BASHEER AHAMED	 20/01/2021

QUALIFICATION OF AGD2020 Semi-Automatic Clinical Chemistry Analyzer

INSTALLATION QUALIFICATION

1. **Purpose:** The purpose of Installation Qualification is to establish that the AGD2020 Semi-Automatic Clinical Chemistry Analyzer and its Components are as per the specifications and are installed as per the approved procedure

2. **Scope:** Installation Qualification to be performed at the time of installation

3. **Responsibility:** R&D, Personing, Safety and Quality Assurance

4. **Critical Variables to be met:**


CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION
1.0 Location Suitability		
1.1 Size & Location of AGD2020 Semi-Automatic Clinical Chemistry Analyzer	The instruments should not be exposed to direct sunlight and placed rigid table	Yes
Weight & Structural suitability	The civil structure should be suitable to accommodate the AGD2020 Semi-Automatic Clinical Chemistry Analyzer	Yes
1.3 Utilities Electrical Supply: Safety provisions: Environmental condition:	Should be 100 - 240V AC $\pm 10\%$, 50/60 Hz Proper Earthing should be provided Temperature: 15°C to 40°C, Relative Humidity : up to 85%	Yes
2.0 Installation as per manufacturers instruction	Personing / Production / Quality Assurance to certify.	Yes
3.0 Safety		
3.1 Earthing	Should be provided with Electric supply	Yes
4.0 Documentation		
4.1 Manuals	Manufacturer's manual	Yes
4.2 Training	No. of personnel to be trained <u>One Person</u>	

QUALIFICATION OF AGD2020 Semi-Automatic Clinical Chemistry Analyzer

TECHNICAL DETAILS

Assay types	Absorbance, Endpoint, Kinetic, Fixed Time, Coagulation
Wavelengths	Interference Filters: 340nm, 405nm, 450nm, 505nm, 546nm, 578nm, 630nm, 670nm + 10nm
Photometer range	-0.1-3.000Abs
Aspiration Volume	0.2mL to 1.0mL
Cuvette Volume	500µL
Flow Cell	18µL
Storage Capacity	196 Programs, 5000 Test records with reaction curve
Light Source	6V/10W, Tungsten Halogen Lamp
Temperature Control	25,30,37°C by Peltier Effect
Display	7" Graphic colour LCD with resistive touch screen, Resolution - 800 X 480 Pixels
Printer	Built-in 2"Thermal Printer (can be switched ON/OFF, when desired)
Interface	External Keyboard/ Mouse
External Dimensions	360mm(L) x 355mm(B) x 170mm(H)
Weight	6.5Kg(approx)

Checking sign off:

Name of the Person	Signature / Date
KAJA BASHEER AHAMED	 20/01/2021

QUALIFICATION OF AGD2020 Semi-Automatic Clinical Chemistry Analyzer
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OPERATIONAL QUALIFICATION

1. **Purpose:** The purpose of Operational Qualification is to establish that the AGD2020 Semi-Automatic Clinical Chemistry Analyzer and its Components are as per the specifications and are installed as per the approved procedure

2. **Scope:** Operation Qualification to be performed at the time of installation

3. **Responsibility:** R&D, Personing, Safety and Quality Assurance

4. **Critical Variables to be met:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION
1.0 Operate the instrument as per manufacturer's manual	Should function as desired	Yes
2.0 Press the ON / OFF key to switch on the unit	Display glowing indication	Yes
3.0 Maintenance and cleaning	As per given in the manual	Yes
4.2 Training	No. of personnel to be trained <u>One Person</u>	

Checking sign off:


Name of the Person	Signature / Date
KAJA BASHEER AHAMED	 20/01/2021

QUALIFICATION OF AGD2020 Semi-Automatic Clinical Chemistry Analyzer

PERFORMANCE QUALIFICATION

1. **Purpose:** The purpose of Operational Qualification is to establish that the AGD2020 Semi-Automatic Clinical Chemistry Analyzer and its Components are as per the specifications and are installed as per the approved procedure
2. **Scope:** Operation Qualification to be performed at the time of installation
3. **Responsibility:** R&D, Personing, Safety and Quality Assurance
4. **Calibration:** The Absorbance Factor according to the Factory sec calibration.
The Read Cell Temperature according 10 the Factory sec calibration.

Checking sign off:

Name of the Person	Signature / Date
KAJA BASHEER AHAMED	 20/01/2021

QUALIFICATION OF AGD2020 Semi-Automatic Clinical Chemistry Analyzer

TRAINING CERTIFICATE

This is to certify that the following personal of **M/s K.M. MICRO LAB** are trained how to use the AGD2020 Semi-Automatic Clinical Chemistry Analyzer as per manual.

Checking sign off:

Name of the Person	Signature / Date
KAJA BASHEER AHAMED	<i>K.S. @pleh</i> 20/01/2021

QUALIFICATION OF AGD2020 Semi-Automatic Clinical Chemistry Analyzer

EQUIPMENT HANDOVER CERTIFICATE


This is to certify that the AGD2020 Semi-Automatic Clinical Chemistry Analyzer Make AGD Biomedicals (P) Ltd, India has been qualified and is here with approved for regular R&D experiments.

MAKE : AGD, India

MODEL NO : AGD2020 Semi-Automatic Clinical Chemistry
Analyzer

SERIAL NO : A0190945

Checking sign off:

Name of the Person	Signature / Date
KAJA BASHEER AHAMED	 20/01/2021

QUALIFICATION OF AGD2020 Semi-Automatic Clinical Chemistry Analyzer

INSTALLATION QUALIFICATION REPORT


This is to certify that the AGD2020 Semi-Automatic Clinical Chemistry Analyzer Make AGD Biomedicals (P) Ltd, India has been installed successfully as per user requirement

MAKE : AGD, India

MODEL NO : AGD2020 Semi-Automatic Clinical Chemistry
Analyzer

SERIAL NO : AO190945

Checking sign off:

Name of the Person	Signature / Date
KAJA BASHEER AHAMED	 20/01/2021

QUALIFICATION OF AGD2020 Semi-Automatic Clinical Chemistry Analyzer

OPERATION QUALIFICATION REPORT


This is to certify that the AGD2020 Semi-Automatic Clinical Chemistry Analyzer Make AGD Biomedicals (P) Ltd, India has been installed and its operating as per user manual.

MAKE : AGD, India

MODEL NO : AGD2020 Semi-Automatic Clinical Chemistry Analyzer

SERIAL NO : A0190945

Checking sign off:

Name of the Person	Signature / Date
KAJA BASHEER AHAMED	 20/01/2021

QUALIFICATION OF AGD2020 Semi-Automatic Clinical Chemistry Analyzer

PERFORMANCE QUALIFICATION REPORT

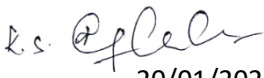
This is to certify that the AGD2020 Semi-Automatic Clinical Chemistry Analyzer Make AGD Biomedicals (P) Ltd, India has been installed and performing as per specifications.

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MODEL NO : AGD2020 Semi-Automatic Clinical Chemistry
Analyzer

SERIAL NO : A0190945

Checking sign off:

Name of the Person	Signature / Date
KAJA BASHEER AHAMED	 20/01/2021

- End Report -