



Euro Diagnostic Systems Pvt. Ltd.

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Phone: 044-2496 0541, Fax: 044-2496 2825, email: eurods@vsnl.net, WWW.eurodiagnostics.in

**iCubio iMagic- M7
Chemistry Analyzer**

Installation Qualification

Chemistry Analyzer – iCubio iMagic- M7

For

COSMOS CLINICS & DIAGNOSTICS

**#503 SMV ARCADE ANDRAHALLI MAINROAD SYNDICATE BANK
LAYOUT, BENGALURU, 560091,
lab@cosmosdiagnostics.in,9945670868**



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Chemistry Analyzer – iMagic- M7

Installation Qualification for Chemistry Analyzer – iMagic- M7

Product	: Chemistry Analyzer
Special Tools	: Standard Field Engineer's Tool Kit
Reference	: CHEMISTRY Analyzer User's Manual
Prepared by	: Technical Service Team
Facility	: Chennai
Location	: Chennai

Purpose

This section provides detailed installation protocol for the Chemistry Analyzer. You must follow the installation steps correctly to ensure proper installation, operation and service.

Scope

To be performed during new installation and relocation



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INTRODUCTION:

- Chemistry Analyzer is an automated In-Vitro Diagnostic Equipment for research purpose and can be used in laboratory
- Chemistry Analyzer is a kind of semi-automatic optic-electric color comparator

Accessories for CHEMISTRY Analyzer

Standard Accessories

- **Power wire**
- **Power adaptor**
- **Waste tube**
- **Print paper**
- **Reaction Cuvettes**
- **Reagent Bottles**
- **Personal Computer**



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Preparing for Installation

Pre Site Survey

The pre site survey is conducted by the Field Engineer to qualify and prepare a customer site before installation of an CHEMISTRY Analyzer. The CHEMISTRY Analyzer pre site survey is provided as an attachment to this document.

1. Complete the survey with the assistance of the Laboratory personnel
2. Indicate any abnormalities on the form
3. Indicate any un resolved issues
4. When all unresolved issues are closed, sign the appropriate section on the Approval sheet so that the Analyzer can be installed.

Installation Procedure

SAFETY NOTES



Follow the Operator's Manual!

Precise knowledge and attention to these operating instructions is required. Use On-line UPS with at least 45-60 minutes power backup.



DANGER! Danger of fatal electric shock!

Do not open the power adaptor. There are no elements inside which require servicing or maintenance. Never use a mechanically damaged power adaptor (or) plug – live connections might be exposed. The power adaptor plug is not insulated against fluid ingress. Never let liquids come into contact with it. Check that the mains voltage and frequency printed on the power adaptor plug type label match your mains socket and whether the shape and configuration of the plug contacts are compatible for the connection.



WARNING! Keep The Analyzer Away From Liquids!

The Analyzer is not insulated against fluid ingress. Take care that no liquids enters the analyzer. There is no Protection provided for the same.

IQ/ Chemistry Analyzer – **iMagic-M7**



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Operating Condition:

Temperature: 15 °C to 35 °C & Relative Humidity: 75%



WARNING! Never Open The Analyzer!

Maintenance and Repairs can only be carried out by us or by our Authorized Service Agent, using original spare parts that will maintain the high quality of the Analyzer.



Make your contribution to a clean environment!

Electrical and electronic device may contain endangering substances which have potential influence on the environment and human health. Old electrical and electronic equipment may not be disposed of under any circumstances in the unsorted domestic garbage.



Symbols used on the Shipper Carton

Symbols	Description
	Keep Away from Sunlight
	Fragile, Handle with Care
	Keep Dry
	This way up
	Do Not Pile Up More than 2
	Handle With Care



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	Manufacturer
	In-Vitro Diagnostic <i>Equipment</i>

Selecting a location for CHEMISTRY Analyzer

- Installation should be planned in a dust free area.
- Keep the analyzer on a stable and horizontal flat surface.
- Keep adequate space on all the sides of the analyzer, to ensure proper air circulation.
- Keep the analyzer away from centrifuge; oscillating agitators or other vibrating machines. CHEMISTRY is very sensitive to vibrations which can cause a false increase of results.
- Keep the analyzer away from electromagnetic devices that produce magnetic field.
- Keep the analyzer away from extreme changes of temperature; direct sunlight and humidity.


Optimum Environmental Conditions:-

- Temperature: 15 °C to 35 °C
- Relative Humidity: 75%

Adaptor Power requirements:-

- Type: Switching Power Supply
- Adaptor Input Voltage: AC100/240V±10% 50/60±1 Hz





Symbols used on the Analyzer

Symbols	Description
	Before Operating the CHEMISTRY Analyzer Please Read the Operator's Manual , Caution



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	Disposal and Recycling
	In-Vitro Diagnostic
	Manufactured Year
	Manufacturer

Connections

Attach the cables in the following order:

- Connect the Computer (PC) to the USB socket, if you intend to use the Data Management Software (DMS).
- Connect the power Cable provided to the power socket on the back of the analyzer.
- Plug the power Cable into the main power outlet and put ON the power switch on the rear of the analyzer. The display will show the software version
- **Note: It is recommended that the analyzer be plugged into a power surge protector for additional protection from power surges and fluctuations.**
-

Dis-Connections

- Switch OFF the power switch on the rear of the analyzer.
- To disconnect the analyzer, unplug the power adaptor from the wall outlet / on-line UPS.
- If required Unplug the Power Cable from main supply and disconnect the cable, connector & other accessories.
- It is not necessary to routinely disconnect the Analyzer when it is not in use.



WARNING! Note: Turn off the main power before removing or reinstalling any connectors on the analyzer.



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It is prohibited to use power supply with high-power equipment together, and it's better to equip with voltage-regulated power supply.

In areas with unstable voltage, use UPS to ensure the normal working of the analyzer.

- User Qualification: Only appropriately trained operators are qualified to operate the analyzer.

Note: Power cords and electrical outlets vary in appearance by region and country

Safety measures

- Environmental conditions: The analyzer is approved for indoor use only.
- Temperature: 15 °C to 35 °C, Relative Humidity: 75%
- **Electrical Safety:** As in all electrical equipments, the power supply is a potential source of danger.



WARNING! Never carry out maintenance on the equipment when it is under

Electrical tension.

- Until the analyzer remains closed as supplied, the operator is protected against electric shock.
- The analyzer is powered by low voltage and thus does not present the same dangers of the equipment's powered by an electrical line.
- The analyzer has a voltage elevator circuit, so it can provoke electrical shocks, but it is not dangerous for the trained personnel dedicated to the service assistance.
- Disconnect the power supply when the operator intervenes on the Analyzer's internal parts.
- Do not open or move the analyzer with the mechanical parts in movement.
- Read the instructions carefully before testing with the analyzer.
- **Mechanical Safety:** Do not open the analyzer without disconnecting it from the mains.
- Do not make contact with the mechanical parts in movement.
- The safety rules also apply even for the technically qualified service staff/operator while intervening on the analyzer.

Reagents: QC Reagents if in use follow the safety as well as the operating instructions of the manufacturers.



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Biological Safety: Liquid waste is potentially biologically



Hazardous: Always wear gloves if handling those materials.

Consult the laboratory protocol for handling bio-hazardous materials.

Unpacking & Installation

- Carefully unpack the Analyzer, removing it from its plastic bag.
- Keep the original boxes and packaging material until being assured that nothing is missing, that the unit has no (internal) transport damage and are working properly.
- It is recommended to securely keep the original packing and packaging material for further use. It can be used to transport the analyzer from one location to another and even for transportation for a service issue.

Re-Packing Instructions

- The Analyzer contains delicate electrical components and needs to be properly packed in the original packing & packaging material before shipping. Please contact us with any questions or to obtain the correct packaging materials.
- Unplug the Analyzer. Remove the cables, connectors and other accessories.
- Place the Analyzers in the thermo Cole packing and further in the shipper carton securely.
- Place all the Standard Accessories in the designated place along with the Analyzer.
- **Always ship the Analyzers and components as "FRAGILE"!**

Maintenance

- The electronic; electrical and mechanical component parts are simple & inside the analyzer and do not require special maintenance.
- The most sensitive part is the flow cell, please clean it every day after testing, do not leave reaction liquid in flow cell overnight.



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Customer Responsibilities

The safety of the unit and of the operator cannot be guaranteed if the following conditions are not satisfied:

- The mains should be "compatible" with the voltage and current specifications indicated on the nameplate placed on the rear of the unit. It is also advisable to periodically check the efficiency of the electric system.
- The mains should be equipped with a ground connection, as per current law requirements.
- It is recommended that the analyzer be plugged into a power surge protector for additional protection from power surges and fluctuations.
- Before connecting or disconnecting the external device, Analyzer should be switched off.
- Before connecting the unit with external devices (power input, LPT, etc.,) check that these are compatible with the technical specifications set.
- Individual safety means (gloves, disinfectant solution, etc.,) must always be made available.
- Operators should be familiar with the procedures, prohibitions and warning described in this manual, in addition with safety regulations applicable in the workplace.

Limited Warranty

- CHEMISTRY Analyzer is warranted to be free from defects in materials and workmanship under normal use and service, for a period of one year.
- The warranty is extended only to the original purchaser.
- The warranty shall not apply to any product or parts which have been damaged on account of improper installation without a online UPS and a CVT, improper connections, misuse, neglect, accident or abnormal conditions of operation.
- Any attempt to tamper with the product as evidenced by disruption of warranty sticker and/or unauthorised repair/modification of the product shall render this warranty null and void.
- If CHEMISTRY Analyzer is used in ways other than as specified in this User's Manual, the protection provided by the Analyzer may be impaired.



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Installation Checklist

S. No	Activity	Remarks (to be filled in by Field Engineer)
1	Un packing the instrument	Ok
2	Checking Contents	Ok
3	Installation & Repacking	Ok
4	Installation of Instrument a. Locating instrument b. Checking Power Supply c. Optional Accessories	OK
5	Verification of Analyzer Level Surface	OK
6	Switch On a. Start Up sequence (Please record any abnormalities)	OK



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Installation Qualification Report

Equipment Name : **iMagic- M7**
Equipment Serial No : **31187417**
Software Version (if valid) : 6.4
Date of Installation / **Relocation** : 20/07/2020
Observation : Installation Requirements found to be satisfactory..

The installation/**relocation** protocol has been successfully completed as per the standard procedure and the instrument was found to be functioning satisfactorily. The instrument is ready for operational qualifications and further validations.

Performed by	
Name	NIKHIL K
Designation	SE
Signature and Date	
Reviewed by	
Name	GEORGE THOMAS
Designation	AREA MANAGER
Signature and Date	
Approved by	
Name	NIKHIL K
Designation	SERVICE ENGINEER
Signature and Date	



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**iCubio iMagic- M7
Chemistry Analyzer**

Operational Qualification

Chemistry Analyzer – iCubio iMagic- M7

For

COSMOS CLINICS & DIAGNOSTICS

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iMagic M7 Chemistry Analyzer

Operational Qualification for Autolab Versa Chemistry Analyzer

Product	: iMagic M7 Chemistry Analyzer
Special Tools	: Standard Field Engineer's Tool Kit
Reference	: iMagic M7 Chemistry Analyzer User's Manual
Prepared by	: Technical Service Team
Facility	: Chennai
Location	: Chennai

Purpose

This section provides detailed operational protocol for the Chemistry Analyzer. You must follow the installation steps correctly to ensure proper installation, operation and service.

Scope

To be performed during new installation, Modification and relocation



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Powering up the system

Adaptor Power requirements:-

- Type: Switching Power Supply



It is prohibited to use power supply with high-power equipment's together, and it's better to equip with voltage-regulated power Supply.

- In areas with unstable voltage, use UPS to ensure the normal working of the analyzer.
- User Qualification: Only appropriately trained operators are qualified to operate the analyzer.

Note: Power cords and electrical outlets vary in appearance by region and country



Optimum Environmental Conditions:-

- Temperature: 15 °C to 35 °C
- Relative Humidity: 75%

Connections

Attach the cables in the following order:

- Connect the Computer (PC) to the socket marked RS 232, if you intend to use the Data Management Software (DMS).
- Connect the power Cable provided to the power socket on the back of the analyzer.
- Plug the power Cable into the main power outlet and put ON the power switch on the rear of the analyzer. The display will show the software version and the printer self-check by printing some characters like "Testing Report" before motor initiation begins.
- **Note: It is recommended that the analyzer be plugged into a power surge protector for additional protection from power surges and fluctuations.**

Dis-Connections

- Switch OFF the power switch on the rear of the analyzer.
- To disconnect the analyzer, unplug the power adaptor from the wall outlet / on-line UPS.
- If required Unplug the Power adaptor from main supply and disconnect the cable, connector & other accessories.
- It is not necessary to routinely disconnect the Analyzer when it is not in use.



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WARNING! Note: Turn off the main power before removing or reinstalling any connectors on the analyzer.

SETTING UP AN ANALYZER & Selecting a location for Chemistry Analyzer

- Installation should be planned in a dust free area.
- Keep the analyzer on a stable and horizontal flat surface.
- Keep adequate space on all the sides of the analyzer, to ensure proper air circulation.
- Keep the analyzer away from centrifuge; oscillating agitators or other vibrating machines.
- Keep the analyzer away from electromagnetic devices that produce magnetic field.
- Keep the analyzer away from extreme changes of temperature; direct sunlight and humidity.
- Connect the power supply of the Chemistry Analyzer through an online UPS.

Performing instrument Calibrations

- The analyzer is pre-set, no configuration is necessary after switching ON.

Verifying Performance / Operating Procedure

- Connect the power supply through an online UPS.
- Connect a computer to the RS 232 port of the analyzer if you intend to you a Data Management Software (DMS) if required.
(Refer the separate instruction sheet for installation of DMS on the PC given in the CD supplied along with the Analyzer.)
- Switch ON the analyzer.
- Go to water blank, reagent blank, standard, QC, sample menu to do the tests.

Quality Control Tests for Labs

In order to make sure the correctness of the test result, the quality control sample should be tested on machine to verify the machine status.



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Operator Training

The operator training is conducted in two parts one for operating the instrument effectively, including principles of operation and performance of samples / controls.

The second part of training covers basic trouble shooting procedures which help to maintain and handle common errors. This training will be conducted by the Technical team.

For basic trouble shooting please refer User's Manual.

NOTE:

- **For safety reasons** it is advisable to **read carefully** the recommendations and instructions contained in this manual before installing and using the unit
- The User's Manual should be kept together with the analyzer for consultation when necessary.
- If Chemistry Analyzer is sold or transferred, make sure that the User's Manual is supplied along with the unit so that the new user receives all the necessary information regarding its functions and safety instructions. It is also suggested to store the original primary and secondary packing and packaging material received by you at the time of purchase of the unit so that the new user receives all the same which helps in shifting and transfer the unit safely.



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Technical Assistance Requests:

If technical assistance is required, contact the name supplier at the address indicated on the invoice at the time of delivery of the unit; otherwise contact the local Engineer or Technician suggested by the Supplier.

S. No	Activity	Observations & Remarks
1.	Powering up the system	Passed
2.	Checking Errors	Passed
3.	Procedures	
	a. Sampling	Working Fine
	b. Recording results	Working Fine
4.	Errors List	Working Fine
5.	Operator Training	Working Fine



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Operational Qualification Report

Equipment Name : **iMagic M7**

Equipment Serial No : **31187417**

Equipment ID No : **NA**

Software Version (if valid) : **6.2**

Date of Installation / Relocation : **20/07/2020**

Observation : **OK**

Deviation and Acceptance : **OK**

Conclusion

With reference to the Operational Procedure and the studies carried out in the OK laboratory, Chemistry Analyzer meets all criteria outlined for Operational Qualification.

Exceptional conditions, have been successfully addressed.



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The Analyzer is ready for Performance Qualification.

Performed by	
Name	NIKHIL K
Designation	SE
Date	20.07.2020
Reviewed and Approved by	
Name	GEORGE THOMAS
Designation	AREA MANAGER



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**iCubio- iMagic-
M7 Chemistry
Analyzer**

Performance Qualification

**Chemistry Analyzer – iCubio iMagic- M7
For**

COSMOS CLINICS & DIAGNOSTICS

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Chemistry Analyzer – iMagic M7

Performance Qualification for Autolab VERSA Chemistry Analyzer

Product : Chemistry Analyzer – iMagic

M7 Special Tools : Standard Field

Engineer's ToolKit

Reference : Chemistry Analyzer iMagic M7 User's

Manual Prepared by: Technical Service Team

Facility : Chennai

Location : Chennai



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Purpose

To determine that the Chemistry Analyzer performs as intended by repeatedly running the instrument on its intended schedules and recording all relevant information and data. Results must demonstrate that performance consistently meets pre-determined specifications under normal conditions.

Scope

To be performed after the Installation and Operational Qualification have been completed and approved. To be performed after installation, modification or relocation and for re – validation at appropriate intervals



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Materials, Equipment, Documents

Laboratory's SOPs for normal operation of the instrument under test. Quality control Material

Accuracy: The test parameter should fall within the manufacturer specified reference range.

Precision: The test parameter should be within the manufacturer specified reference range.

Quality Control Tests for Labs

- Good Laboratory Practices is to test every day at least one control (1 normal and 1 abnormal) to check if the analyzer is working correctly.
- This control stimulates the behavior of normal and abnormal human serum so can be used to test the analyzer's performances.
- Controls must be tested exactly as normal patient's specimen and results should be recorded on Quality Control Charts.
- Each laboratory can establish its own acceptability ranges if needed.

Automated Chemistry testing solution

Chemistry Analyzer is an automated In-Vitro Diagnostic Equipment for research purpose and can be used in laboratory for Clinical determination of biochemical component according to the color change caused by the reaction between serum & reagent.

Chemistry Analyzer can constantly and simultaneously.



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Technical Specifications for Chemistry Analyzer

Analysis method	1 point end, 2 point end (Sample blank), Kinetics, Fixed-time.
Optics	7 filters, 340, 405, 450, 505, 546, 578, 630. 2 more for optional
Lamp house	Long-life Tungsten Halogen Lamp(6V 10W), Auto- Sleep Function
Sample Position	20+2 positions, up to 71
Sample and reagent Probe	One Independent Probe with stirring function
Temperature	25, 30, 37°C and Room temperature. By means of Peltier elements
Reagent position	50 Positions, Refrigerated Reagent tray
Cuvette Specification	Optical diameter is 5.8mm
Photometric range	0.0000-3.0000 Abs
Operating system	Windows XP/7/8
Interface	Standard RS 232 with Multi Language
Interface	4 USB Host; 1 USB Slave; 1 Ethernet port USB ports(host) for Keyboard, Mouse, Printer, disk, Bar code reader etc. USB ports(slave) for PC connection(support PC software control function)
Operational Environment	Temperature: 10°C~37°C; Humidity: ≤85%
Power requirement	Wide power supply AC100-240V, 50/60Hz
Dimension	500mmx440mmx470mm
Weight	40Kg



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Performance Qualification Report

Equipment Name : iMagic M7
Equipment Serial No : 31187417
Equipment ID No : 31187417
Software Version (if valid) : 6.4
Date of Installation / Relocation : 20/07/2020
Observation :
Deviation and Acceptance :



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Conclusion

With reference to the studies carried out in the Laboratory, it is determined that the analyzer meets all performance criteria and has passed Performance Qualification.



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The Analyzer is ready for Specific Use.

Performed by	
Name	NIKHIL K
Designation	SE
Date	20.07.2020
Reviewed by	
Name	GEORGE THOMAS
Designation	AREA MANAGER
Date	20.07.2020



Euro Diagnostic Systems Pvt. Ltd.

36/37, 'Millenium House', M.K. Srinivasan Nagar Main Road, Rajiv Gandhi Salai, Perungudi, Chennai-600 096. Tamil nadu, INDIA
Phone: 044-2496 0541, Fax: 044-2496 2825, email: euroids@vsnl.net, WWW.eurodiagnostics.in



CALIBRATION CERTIFICATE

DIAGNOSTICNAME	COSMOS CLINIC & DIAGNOSTIC
ASSRESS	#503, SMV ARCADE ANDRAHALLI MAIN ROAD BANGALOREKARNATAKA
ANALYSER	ICUBIO (iMagic - M7)
DEPARTMENT	BIOCHEMISTRY DEPT.
DATE	JULY 20,2020

This is to certify that the above mentioned analyzer was calibrated by the following procedure as per manufacturer *s recommendations.

1. Analyser Rotor Init position check
2. Check Abs sensitivity100%
3. Check Init Position Accuracy
4. Check Pump Motor condition
5. Air/watercalibration

All the checks and calibration were done and system is being used under recommended conditions
Next calibration is due on July20, 2021

Euro Diagnostic Systems Pvt. Ltd.

Gopi SL
Technical Specialist
Bangalore



Preventive Maintenance Report (PM Visit)

CUSTOMER NAME : COSMOS DIAGNOSTIC **Date :** 08 08 2021

Address :
 Door No #503 Street Anandhalli Main Road
 Area SMV Arcade District Bengaluru Pincode 560091
 State Karnataka Landmark Syndicate Bank Layout
 Contact No 9945670868 Email lab@cosmosdiagnostics.in

PM Visit Number (Ex : 1st Visit or 2nd Visit) 2nd

WARRANTY
 AMC

Voltage : Line / Neutral 230 V, Line/Earth 230V, Earth/Neutral : 0 V (Should not >005)
Power Source : Direct / UPS / CVT

Instrument : J Magic M7 **WORK CARRIED OUT AT**
 SITE SERVICE CENTRE

SERIAL NO : 3 1 1 8 7 4 1 7

NEXT CALIBRATION 09/08/2022

PARAMETERS

T: OK A: OK Pump Speed: OK
 Pump: OK Front Board: OK Gain Cal: OK Pump Cal: OK

PARAMETERS : 950ul
 Pump Calibration : 500 ul (800-1200 ul)

FILTER STATUS :

Filters in nm	340	405	505	546	578	600	630	
Gain	15	OK	OK	OK	OK	OK	OK	
A/D Value	20	OK	OK	OK	OK	OK	OK	
Abs of D/Water	10	OK	OK	OK	OK	OK	OK	

Instrument Status :

Outer Body : OK Display : OK Key Pad : OK Pump Motor : OK Printer : OK
 Aspiration Button : OK Tubing Set : OK Flow Cell : OK Internal Connectors : OK Software : OK
 Remarks on the defective part / parts if any : OK

ENGINEER'S REMARKS Calibration Completed
 Calibration Period 08/08/21 to 08/08/22

CUSTOMER'S FEEDBACK

ENGINEER'S SIGNATURE & NAME :

Nikhil K

Note : Very Important

Seal & Signature of the Customer