

Ortho Clinical Diagnostics

INSTALLATION QUALIFICATION

For

VITROS 350



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

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I. Approval of the IQ procedure

Both **LUPIN HEALTHCARE LIMITED** and Ortho-Clinical Diagnostics are jointly responsible for the installation of **VITROS 350, Sr. No. 25014391** in the **LUPIN HEALTHCARE LTD LAB.**

Protocol Performed By: Ortho-Clinical Diagnostics Representative

Name : SARAS RAJENDRA WADHONKAR

Signature: 

Designation : SERVICE ENGINEER, ORTHO CARE- SERVICE

Company : Ortho-Clinical Diagnostics

Date: 30/07/2022

Validation Team from LUPIN HEALTHCARE LIMITED:


Name : Dr Sagar Kulat

Signature: 

Designation : Lab Head

Date: 30/7/22

Department Name : Clinical Chemistry

Signature: 

Designation : → Mahesh Bhulsing
→ Lab Tech.

Date: 30/7/22

Department : →


LUPIN DIAGNOSTIC
Behind Zopadi Cantin,
Opp. Monica D.Ed. College
Savedi, Ahmednagar-414001

Customer Authorizations:

Name : Dr Sagar Kulat

Designation : Lab Head

Site : Lupin Diagnostics, Ahmednagar

Signature: 

Date: 30/07/22

LUPIN DIAGNOSTIC
Behind Zopadi Cantin,
Opp. Monica D.Ed. College
Savedi, Ahmednagar-414001

II. INSTRUCTIONS:

1. This document is to be completed at the time the system is installed and set up for operation.
2. An authorized Ortho Clinical Diagnostics representative will check the system and enter the specific data as outlined in the appropriate Installation Qualification. Each result will be initialed and dated.
3. Employees of (customer) **LUPIN HEALTHCARE LIMITED** will verify each result and sign in the last page.
4. ALL deviations from 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 installation protocol for the same.
5. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization from Ortho-Clinical Diagnostics and **LUPIN HEALTHCARE LIMITED**.

III. SCOPE

This Installation Qualification protocol will be performed on the VITROS 350 bearing Sr. No. 25014391 located at **LUPIN HEALTHCARE LIMITED**. This Installation 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 the instrument identified 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 conditions 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.

IV. Ancillary Information.**A. Certification of Purchase Order Compliance**

I certify to the best of my knowledge, the instrument installed on 30/07/2022 is in compliance with the specifications of the purchase order.

Verified By: SARAS RAJENDRA WADHONKAR

Date:30/07/2022

B. Utilities

| Sr. No | Utility | Verified by | Date |
|--------|---|-----------------|------------|
| | Environmental conditions: | | |
| 1. | a. Analyzer will be placed away from the direct sunlight. | SARAS WADHONKAR | 30/07/2022 |
| | b. Installation site shall be free from dust, significant vibrations and shall be well ventilated. | SARAS WADHONKAR | 30/07/2022 |
| | c. Installation site floor construction shall be able to support approximately 272 kg. | SARAS WADHONKAR | 30/07/2022 |
| | d. Room temperature will be maintained between 15°C to 27°C and the temperature fluctuation during analysis shall not be more than ± 2°C. | SARAS WADHONKAR | 30/07/2022 |
| | e. The analyzer shall be kept away from strong electromagnetic sources and electrical interferences. | SARAS WADHONKAR | 30/07/2022 |
| | f. It will be kept near to the power sources. | SARAS WADHONKAR | 30/07/2022 |
| | g. Maximum relative humidity allowed up to 70%. | SARAS WADHONKAR | 30/07/2022 |
| | h. If the temperature and humidity fluctuations are not within the specified range, the analyzer cannot maintain data reliability. | SARAS WADHONKAR | 30/07/2022 |
| 2. | Adequate space for installation will be provided on all 5 sides of the instrument [1.15m (L) x 71m (W) x 1.2m (H)] | SARAS WADHONKAR | 30/07/2022 |
| 3. | Electrical Outlets: Actual Voltage on site [AC 220-230 Volts 16A 50 HZ] | SARAS WADHONKAR | 30/07/2022 |

Note: Document any significant changes in Comments section on page 12.

C. The instrument has been verified for the following

Ortho Clinical Diagnostics

| Sr. No. | Verification | Verified by | Date |
|---------|--|-------------------------------|------------|
| 1. | Instrument is identified | Yes SARAS WADHONKA R | 30/07/2022 |
| 2. | Manufacturer's specifications are included | Yes SARAS WADHONKA R | 30/07/2022 |
| 3. | Accessories / Consumables are listed | Yes SARAS WADHONKA R | 30/07/2022 |
| 4. | Equipment manual from the manufacturer is documented | Yes SARAS WADHONKA R | 30/07/2022 |
| 5. | Manufacturer's Certificate attached | Yes SARAS WADHONKA R | 30/07/2022 |

V. Installation Qualification**A. Equipment Description**

The VITROS 350 is a fully automated Dry chemistry analyzer

| Instrument Identification | | Verified by | Date |
|---------------------------|----------------------------|--------------------|------------|
| Equipment Name: | Dry Chemistry Analyzer | SARAS WADHONKAR | 30/07/2022 |
| Manufacturer: | Ortho-Clinical Diagnostics | SARAS WADHONKAR | 30/07/2022 |
| Model: | VITROS 350 | SARAS WADHONKAR | 30/07/2022 |
| Serial Number: | 25014391 | SARAS WADHONKAR | 30/07/2022 |
| Size (in cm): | 115 (L) x 71 (W) x 120 (H) | SARAS WADHONKAR | 30/07/2022 |
| Power: | AC 220-230 V 16A 50Hz±2Hz | SARAS WADHONKAR | 30/07/2022 |
| Power consumption: | 6880KW hours per year | SARAS WADHONKAR | 30/07/2022 |

B. Accessories/Consumables

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

| START UP KIT 1H4182 | | | |
|---|------------------------------------|--|-------|
| 353999 | 350 TIP RACK | | 1 no. |
| 354009 | 350 MICRO COLLECTION TUBE ADAPTER | | 1 no. |
| 354007 | 350 SAMPLE CUP ADAPTER | | 1 no. |
| 354000 | 350 UNIVERSAL SAMPLE TRAY | | 1 no. |
| 354011 | 350 DILUENT TRAY | | 1 no. |
| 354002 | 350 HEIGHT ADAPTER | | 1 no. |
| 353671 | LINE CORD CONTINENTAL | | 1 no. |
| 354004 | MIXING CUP ARRAY | | 1 no. |
| 8251878 | CAL DISK (ver. 5609) | | 1 no. |
| 8321622 | CLIN CHEM PROD INSTRUCTION USE | | 1 no. |
| 6801855/8175333 | 350 SYS SOFTWARE (ver. 9.2) | | 1 no. |
| 250 ANALYZER SPARE PART KIT 356704 | | | |
| 355637 | Air Filter | | 1 no. |
| TL 3225 | Serial Loop Back Connector TL 3225 | | 1 no. |
| 999339 | 10 ml Diluent Vials (3 Nos) | | 1 no. |
| 999340 | 5 ml Diluent Vials (3 Nos) | | 1 no. |
| 1C3197 | Dispense blade | | 1 no. |
| 3380/3381 | Wrist strap Elastic | | 1 no. |
| J02315 | White Reference Slide Box | | 1 no. |
| J02316 | Black Reference Slide Box | | 1 no. |
| 356666 | Lamp | | 1 no. |
| 583561 | Lamp Extractor | | 1 no. |
| 995298 | RM / IR TL 4538 | | 1 no. |
| 356864 | Reservoir Seal (3 Nos) | | 1 no. |

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| | | |
|--------------------|--------------------------------|-------|
| 356497 | Reservoir Cap (3 Nos) | 1 no. |
| J02253 / J02255 | Evaporation Cap (23 Nos) | 1 no. |
| 1H0116 | Evaporation Cap Spring (5 Nos) | 1 no. |
| 339739 | Proboscis Screw (2 Nos) | 1 no. |
| 994654 | Tubing (2 Nos) | 1 no. |
| 356526 | Read Sync Tool TL 4502 | 1 no. |
| Monitor with stand | | 1 no. |
| Touch Screen | | 1 no. |

C. List of Manuals, Certificates and Drawings:

Ortho Clinical Diagnostics provides the following with the instrument.

| | | |
|---------|-------------------------------------|-------|
| 8986507 | 250 REFERENCE SET consist of: | 1 set |
| | 119017 - Operators Manual | 1 no. |
| | 1053032 - Operators Quick Guide | 1 no. |
| | 8044505 - Maintenance & Diag. Guide | 1 no. |
| | J04190 - Accessories Guide | 1 no. |

D. Change Control Procedure:

The instrument will not be altered, enhanced, modified or substituted for another system until a formal Change Control Authorization is approved from Ortho Clinical Diagnostics and Micro Therapeutic Research Labs Pvt. Ltd., Chennai.

E. Maintenance:

The instrument listed within this document will be placed under the control of the purchasing 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 Ortho Clinical 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 for additional Service Agreement can supply additional information.

F. Spare Parts:

Ortho Clinical Diagnostics recommends the end user to maintain a basic of consumable parts onsite to minimize down time due to minor failures. The list of such consumable parts provided by them is included in the Operator's Manual.

G. Installation Procedure:

1. Installation Process:

The analyzer PC comes with preinstalled Analyzer Application Software. For any reasons, if the software is to be installed on another PC, the PC will meet the following requirements.

| Environment | System Requirement |
|-------------------|---|
| Desktop | PII |
| Key Board | English Key Board or Standard 101/102 or Microsoft Natural Key Board |
| Operating System | Qunix |
| Port | <ul style="list-style-type: none"> ➤ 2 ports for printer ➤ One port for LIS |
| Regional settings | <ul style="list-style-type: none"> ➤ Language English. |

The system has a preloaded operating software

The Analyser has been installed satisfactorily : No Yes

Verified by : SARAS RAJENDRA WADHONKAR

VI. COMMENTS:

VII. 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 been identified and documentation included.

Report Performed By: Ortho Clinical Diagnostics Representative

Name : SARAS RAJENDRA WADHONKAR

Signature: 

Designation : SERVICE ENGINEER, ORTHO CARE- SERVICE

Company: Ortho Clinical Diagnostics

Date: 30/07/2022

Customer Authorizations:

Name : Dr. Sagar Kulat

Designation : Lab Head

Organization : Lupin Diagnostics,
Ahmednagar

Signature : 

Date : 30/07/2022

LUPIN DIAGNOSTIC
Behind Zopadi Cantin,
Opp. Monica D.Ed. College
Savadi, Ahmednagar-414001

Ortho Clinical Diagnostics

OPERATION QUALIFICATION

For

VITROS 350



**Manufactured by:
Ortho Clinical Diagnostics, Inc., US**

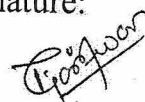
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I. Approval of the IQ procedure

Both Lupin Diagnostics, Ahmednagar and Ortho Clinical Diagnostics are jointly responsible for the operation qualification of VITROS 350, Sr. No. 25014391 in the Laboratory of Lupin Diagnostics, Ahmednagar, as per the Operational Qualification Protocol.

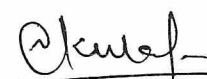
Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : Mr. Pankaj Paitwar Signature: 
Designation : Application Support
Company : Ortho Clinical Diagnostics Date: 1/8/2022

Validation Team from Lupin Diagnostics, Ahmednagar:

Name : Bhalsing mahesh Signature: 
Designation : Lab Tec. Date: 01/08/22
Department : Department of
Name Biochemistry
Designation : Sagar malave Signature : 01/08/22
Date : 
Department : Department of
Biochemistry

Customer Authorizations:

Name : Dr. Sagar Kulkarni Signature: 
Designation : Chief of Laboratories
Site : Ahmednagar Date: 1/8/2022

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Savadi, Ahmednagar-414001

II. INSTRUCTIONS

1. An authorized Ortho Clinical Diagnostics representative will check each module and enter the specific data as outlined in the Operational Qualification. Each result will be noted and dated.
2. The concerned employees of **Lupin Diagnostics, Ahmednagar** will verify each result and sign in the each page. The member of the validation team will carry this out.
3. ALL deviations from the acceptance criteria detailed in this document will be noted in the 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.

III. SCOPE

This Operational Qualification protocol will be performed on the VITROS 350, Sr. No. 25014391 located at Biochemistry Department, **Lupin Diagnostics, Ahmednagar**. This OQ protocol will define the documentation that will be used to evaluate the completion of the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions 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.

OPERATIONAL QUALIFICATION:**A. Instrument Identification**a. Model Name **VITROS 350**2. Serial Number **25014391****B. Following is a list of tests to be performed and verified:**

| Test No. | Test Name | Test purpose | Verified By and date |
|-----------------|---------------------------------------|--|---------------------------------------|
| 01 | Start up | To make the equipment ready for operation | Mr. Pankaj Paitwar Date – 1/8/2022 |
| 02 | Daily maintenance | To clean appropriate modules so as to maintain accuracy and precision | Mr. Pankaj Paitwar Date – 1/8/2022 |
| 03 | Inventory of reagents and consumables | To check the slide supply of installed Vitros 350 | Mr. Pankaj Paitwar Date – 1/8/2022 |
| 04 | Calibration for the assays used | To calibrate the system for every new lot of assay | Mr. Pankaj Paitwar Date – 1/8/2022 |
| 05 | QC check | To confirm that systems, reagents & consumables are acceptable and working within specifications for each assay used | Mr. Pankaj Paitwar Date – 1/8/2022 |
| 06 | Sample programming and Analysis | To run the samples | Mr. Pankaj Paitwar Date – 1/8/2022 |

Test: 1: Starting the system

Purpose: To make the instrument READY for operation

Summary:

Instrument checks functioning of different parts of the instrument automatically; if there is an error code, initialize the system and follow corrective action instructions provided for the error code.

Procedure:

- Check the room temperature and switch on the Air Conditioner.
- Check the UPS.
- Switch on the Vitros V 350 system by pressing the main switch and hold it for about 10 – 15 sec.
- Wait for the instrument to get ready after initialization
- The machine is ready for next step if it displays “READY” on the status console
- If not, initialize by pressing the initialize button on the error code screen
- Follow instructions provided for the error codes

Acceptance criteria: System to display READY status

| <u>PARAMETER</u> | <u>PASS</u> | <u>FAIL</u> |
|--|-------------|-------------|
| Parameter values for verification: “READY” on Status console | <u>PASS</u> | |

Test: 2: Daily Maintenance

Purpose: To clean appropriate modules so as per the daily maintenance protocol on the display

Method:

Refer detailed procedure for Daily Maintenance

| Sr No | Activity | Done by | Date |
|-------|--|-------------------|----------|
| 01 | Empty waste container | Mr Pankaj Paitwar | 1/8/2022 |
| 02 | Clean ERF Reservoir Holder & Base | Mr.Pankaj Paitwar | 1/8/2022 |
| 03 | Replace ERF Reservoir | Mr.Pankaj Paitwar | 1/8/2022 |
| 04 | Replace ERF Tip | Mr.Pankaj Paitwar | 1/8/2022 |
| 05 | Clean ERF Tip Sleeve | Mr.Pankaj Paitwar | 1/8/2022 |
| 06 | Clean IWF Reservoir Holder & Base | Mr.Pankaj Paitwar | 1/8/2022 |
| 07 | Replace IWF Reservoir | Mr.Pankaj Paitwar | 1/8/2022 |
| 08 | Replace IWF Tip | Mr.Pankaj Paitwar | 1/8/2022 |
| 09 | Clean IWF Tip Sleeve | Mr.Pankaj Paitwar | 1/8/2022 |
| 10 | Load supplies and remove outdated and empty reagents | Mr.Pankaj Paitwar | 1/8/2022 |
| 11 | Perform Quality Control | Mr.Pankaj Paitwar | 1/8/2022 |

Acceptance criteria System should be "Ready" after daily maintenance without any error

PARAMETER

PASS

FAIL

Parameter values for verification : System found "Ready"
after daily maintenance

PASS

Test: 3: Inventory of reagents and consumables

Purpose: To check the reagent management module of VITROS 350 Dry Chemistry system

Procedure:

| Sr No | Activity | Done By | Date |
|-------|---|--------------------|----------|
| 01 | Loading of Reagent cartridge in the appropriate slide supply – Supply 1 and Supply 2. | Mr. Pankaj Paitwar | 1/8/2022 |
| 02 | Verify the status of reagents loaded. | Mr. Pankaj Paitwar | 1/8/2022 |

Acceptance criteria:

- No error codes
- All reagents should show “Ready”/cal status

PARAMETER PASS FAIL

Parameter values for verification: No Error codes PASS

Test: 4: Calibration of the assays used

Purpose: To calibrate the system for every new lot of assay

Procedure:

| Sr. No. | Activity | Done By | Date |
|---------|--|--------------------|----------|
| 01 | Reconstitution of the cal kits for appropriate reagent | Mr. Pankaj Paitwar | 1/8/2022 |
| 02 | Performing Calibration with calibration programming screen | Mr. Pankaj Paitwar | 1/8/2022 |
| 03 | Verification of Calibration report | Mr. Pankaj Paitwar | 1/8/2022 |

Acceptance criteria: "Calibration Successful" should come on screen

PARAMETER PASS FAIL

Parameter values for verification : "Calibration Successful"
 found and the report of **PASS**
 the same from the analyzer

Test: 5: QC check

Purpose: To confirm that systems, reagents and consumables are acceptable & working within specifications for each assay used.

Procedure:

| Sr. No. | Activity | Done By | Date |
|---------|--|--------------------|----------|
| 01 | Preparing Liquid or Lyophilized control fluids | Mr. Pankaj Paitwar | 1/8/2022 |
| 02 | Creating QC file | Mr. Pankaj Paitwar | 1/8/2022 |
| 03 | QC sample programming and analysis | Mr. Pankaj Paitwar | 1/8/2022 |
| 04 | Verification of QC results obtained | Mr. Pankaj Paitwar | 1/8/2022 |

Acceptance criteria: QC results within specified limits mentioned on the control product insert

PARAMETER PASS FAIL

Parameter values for verification: QC values within $\pm 2SD$ **PASS**

Test: 6: Sample programming and Analysis

Purpose: To run the samples

Procedure:

| Sr. No. | Activity | Done By | Date |
|---------|------------------------------------|--------------------|----------|
| 01 | Loading and Processing of samples | Mr. Pankaj Paitwar | 1/8/2022 |
| 02 | Programming samples | Mr. Pankaj Paitwar | 1/8/2022 |
| 03 | Unloading the samples | Mr. Pankaj Paitwar | 1/8/2022 |
| 04 | Viewing samples in process | Mr. Pankaj Paitwar | 1/8/2022 |
| 05 | Review results: Monitoring results | Mr. Pankaj Paitwar | 1/8/2022 |

Acceptance criteria: Samples Analysis & Report without any error

PARAMETER PASS FAIL

Parameter values for verification: Sample analysis & Report **PASS**
without any error

H. Operational procedure:**a. Certificate of Training****1. Technician Training**

This certifies that the technicians have received basic user training in the following categories for the system described in this Operational Qualification.

Mr. Pankaj Paitwar from Ortho Clinical Diagnostics has conducted the training.

| Sr. No. | Training program | Initials | Date |
|----------------|-------------------------|--------------------|-------------|
| 1. | Instrument Setup | Mr. Pankaj Paitwar | 1/8/2022 |
| 2. | System Operation | Mr. Pankaj Paitwar | 1/8/2022 |
| 3. | Calibration | Mr. Pankaj Paitwar | 1/8/2022 |
| 4. | Quality Control | Mr. Pankaj Paitwar | 1/8/2022 |
| 5. | Maintenance | Mr. Pankaj Paitwar | 1/8/2022 |
| 6. | Basic trouble shooting | Mr. Pankaj Paitwar | 1/8/2022 |

2. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

| Sr. No. | Operators | Department | Initials | Date |
|---------|--------------------|------------|----------|--------|
| 1 | Bhalsing mahesh | CC | MTB | 1/8/22 |
| 2 | Sagar malve | CC | SAM | 1/8/22 |
| 3 | Amol Satule | CC | ACS | 1/8/22 |
| 4 | Jukir shaikh | CC | JRS | 1/8/22 |
| 5 | Meghuna Kalapurthy | CC | MVK | 1/8/22 |

V. COMMENTS:

VI. SYSTEM CERTIFICATION:

Study data has determined that the system described in this document either meets all criteria outline in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Performance Qualification.

Report Performed By: Ortho Clinical Diagnostics Representative

Name : Mr. Pankaj Paitwar

Designation : Application Support

Company: Ortho Clinical Diagnostics

Signature: 

Date: 1/8/2022

Customer Authorizations:

Name : Dr. Sagar Kulkarni

Designation : chief of Lab

Organization : Lupin Diagnostics

Signature : 

Date : 1/8/2022

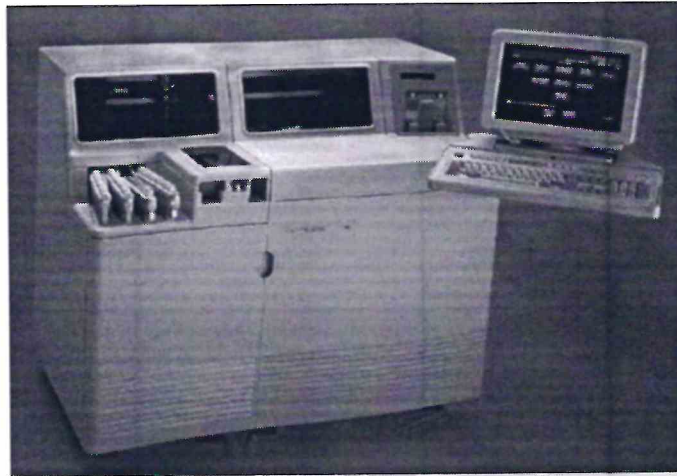
LUPIN DIAGNOSTIC
Behind Zopadi Cantin,
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Savadi, Ahmednagar-431001

Ortho Clinical Diagnostics

PERFORMANCE QUALIFICATION

For

VITROS 350



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

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Ortho Clinical Diagnostics

I. Approval of the PQ procedure

Both **Lupin Diagnostics, Ahmednagar** and **Ortho Clinical Diagnostics** are jointly responsible for conducting the Performance Check of the Biochemistry Analyzer, Model – VITROS 350, Serial. No. 25014391 in the Biochemistry Department of **Lupin Diagnostics, Ahmednagar** as per the attached protocol.

Protocol Performed By : Ortho Clinical Diagnostics Representative

Name : Mr. Pankaj Paitwar


Signature: 


Designation : Application Support

Date: 1/8/2022

Company : Ortho Clinical Diagnostics

Validation Team from Lupin Diagnostics, Ahmednagar :

Name : 

Signature: 

Designation : Lab Tech

Date: 01/08/22

Department :

Name : Sagar Malve

Signature: 

Designation : Lab Tech

Date: 11/08/22

Department : CL

Customer Authorizations:

Name : Dr. Sagar Keelat

Designation : Chief of Laboratory

Site : Ahmednagar

Signature: 

Date: 01/08/2022

LUPIN DIAGNOSTIC
Behind Zopadi Cantin,
Opp. Monica D.Ed. College
Savadi, Ahmednagar-414001

II. Instructions.

1. An authorized Ortho Clinical Diagnostics representative will check for the performance of the instrument and enter the specific data as outlined in the Performance Qualification. Each result will be noted and dated.
2. Performance checks on a regular basis described in the Further Performance Checks will be the responsibility of customer's personnel.
3. Employees of **Lupin Diagnostics, Ahmednagar** will verify each result and sign in the last page.
4. ALL deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end of the PQ 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**.
5. Any test data 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.
6. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by **Lupin Diagnostics, Ahmednagar** and Ortho-Clinical Diagnostics.

III. Scope

This Performance Qualification protocol will be performed on the VITROS 350 Serial No. 25014391 located in Biochemistry Department of **Lupin Diagnostics**, , located in **Ahmednagar**. This Performance qualification 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 conditions encountered during the Performance qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All data will be documented.

IV. Performance Qualification

A. Instrument Identification

Verified Date

- | | | |
|------------------|------------|----------|
| 1. Model Name | VITROS 350 | 1/8/2022 |
| 2. Serial Number | 25014391 | 1/8/2022 |

B. Following is a list of tests to be performed and verified:

| Sr.No | Test Name | Test Purpose | Initial / Date |
|-------|-----------------|--|----------------|
| 01 | QC Run | To see the performance of quality control material on the equipment on selected assay parameters as per the specifications given | 1/8/2022 |
| 02 | Accuracy Study | To compare the obtained value with true values of processed control. | 1/8/2022 |
| 03 | Precision Study | To check the precision performance of the equipment | 1/8/2022 |

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C. Performance Testing:

Test I

Test Name : **QC Run**

Purpose : To see the performance of quality control material on the equipment as per the specifications given

Method : Microslide – Rate Chemistry
Microslide - Endpoint Chemistry
Microslide – Potentiometric Chemistry;
Microslide – Immunorate Chemsitry;

Analysis of controls:

Note: Analyze controls for ALT (Microslide Rate Chemistry);
Amylase (Microslide – Two point rate Chemistry);
Sodium (Potentiometric Chemistry);
Potassium (Potentiometric Chemistry);

| Sr. No. | Activity | Procedure done as per the protocol defined in VITROS 350 Chemistry System Operator's manual – Quality Control | Remarks | Done By |
|---------|--|---|-----------|--------------------------------|
| | | | Pass/Fail | Date |
| 01 | Preparing Liquid or Lyophilized control fluids | “Instructions for use” of QC material | PASS | Mr. Pankaj Paitwar 1/8/2022 |
| 02 | Creating QC file | Quality Control – Define control fluids | PASS | Mr. Pankaj Paitwar 1/8/2022 |
| 03 | QC sample programming and analysis | Quality Control – Process Control fluid samples & Review the Control sample results. | PASS | Mr. Pankaj Paitwar 1/8/2022 |

Ortho Clinical Diagnostics

Test II

Test Name : Accuracy
Purpose : To see the accuracy of obtained quality control value in comparison with the expected mean values.
Method : Microslide method as mentioned above

Analysis of controls:

Note: Analyze controls as mentioned above.

| Sr. No. | Activity | Procedure done as per the protocol defined in VITROS 350 System Operator's manual - Quality Control | Remarks | Done By |
|---------|--|---|-----------|--------------------------------|
| | | | Pass/Fail | Date |
| 01 | Preparing Liquid or Lyophilized control fluids | 'Instructions for use' of QC material | PASS | Mr. Pankaj Paitwar 1/8/2022 |
| 02 | QC sample programming and analysis | Quality Control – Process Control fluid samples & Review the Control sample results. | PASS | Mr. Pankaj Paitwar 1/8/2022 |
| 03 | Accuracy Analysis | Compare the obtained Q.C value with mean of expected value as mentioned in the Performance verifier / QC Value chart. | PASS | Mr. Pankaj Paitwar 1/8/2022 |

Ortho Clinical Diagnostics

Test III :

Test Name : Precision Study (As per criteria attached)

Purpose : To estimate the imprecision or random error of the analytical method

Procedure:

Analyze Performance Verifier Level 1 control for tests ALT (2 x 12 times), Amylase and Na⁺ (3 x 10 times).

Analyze Performance Verifier Level 2 for Potassium (3 x 10 times) and Phenytoin (3 x 6 times).

Calculate the Mean, SD and CV%.

Acceptance Criteria :

| Sr. No. | Analyte | Control Level | Precision Limit |
|---------|-----------|---------------|-----------------|
| 01 | ALT | PV I | ≤ 2.3 SD |
| 02 | Amylase | PV I | ≤ 3.9 SD |
| 03 | Sodium | PV I | $\leq 0.8\%$ CV |
| 04 | Potassium | PV I | $\leq 1.0\%$ CV |
| 05 | CRBM | TDM | $\leq 4\%$ CV |


COMMENTS: NIL

V. System Certification

Study data has determined that the VITROS 350 Dry Chemistry system described in this document either meets all criteria outline in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

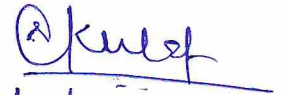

Report Performed By : Ortho Clinical Diagnostics Representative

Name : Mr. Pankaj Paitwar
Designation : Application Support
Company : Ortho Clinical Diagnostics

Signature : 
Date : 1/8/2022


Validation Team from Lupin Diagnostics, Ahmednagar:

Name : Dr. Sagar Kulat
Designation : Chief of Lab
Department : CC
Name : Bhalsing mahesh
Designation : Lab Tee
Department : CC

Signature: 
Date: 1/8/22
Signature: 
Date: 1/8/22

Customer Authorizations:

Name : Dr. Sagar Kulat
Designation : Chief of Lab
Site : Lupin Diagnostics

Signature: 
Date : 1/8/22

LUPIN DIAGNOSTIC
Behind Zopadi Cantin,
Opp. Monica D.Ed. College
Savadi, Ahmednagar-414001

Ortho Clinical Diagnostics

403, Leela Business Park, Andheri Kurla Road,
Andheri East, Mumbai – 400059
T : +91 22 6787 9300
F : +91 22 6787 9333

Calibration Certificate

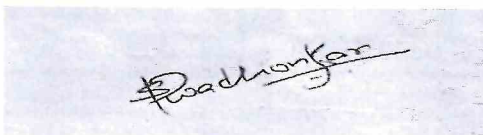
The below mentioned instrument has been calibrated and tests performed to check the system performance.

Instrument : VITROS 350
Serial No 25014391
Customer Name : LUPIN HEALTHCARE LIMITED, AHMEDNAGAR
Calibration performed on : 18/02/2023

The system's calibration includes optics calibration and checking the reproducibility performance of the instrument as per the guidelines provided by the manufacturer.

Next Calibration will be performed in **AUGEST 2023**

For **Ortho Clinical Diagnostics India Pvt Ltd.**



Saras Wadhonkar
Service Engineer, Ortho Care Service
Pune

Date: 18/02/2023

SS1 SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF Feb 18 23 20:47:11

DIAGNOSTICS - Setup/Adjustment - Reflectometer Iris SA12A

| | | | | | | | |
|------|------|------|------|------|------|------|------|
| 340 | 400 | 460 | 540 | 600 | 630 | 670 | 680 |
| 5.12 | 4.89 | 5.24 | 6.08 | 6.98 | 6.15 | 5.39 | 6.03 |

Current voltages for all wavelengths.
Touch RETURN to exit or START to repeat tests.

RETURN

START

RETURN TO MAIN DIAG MENU

HELP

SH SM SSI SS2 ST INC IR R/C PM INOP LAB COMP: TESTING COMPLETE

SAMPLING Feb 18 23
ON OFF 20:48:03
PT04A **250

SAMPLE METERING PERFORMANCE TESTS
Leak Test - A/D Ref. Voltage Check

Reference
4.961 Vdc

Resolution
0.039 Vdc

Ambient Pressure = 2.578

- > Compare Precision Reference Voltage, Resolution Voltage and Ambient
- > Pressure to current specifications.
- > Do you wish to continue with the Leak Test? (Y/N): ■

RETURN

RETURN TO
MAIN DIAG
MENU

HELP

SH SM SSI SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING Feb 18 23
ON OFF 20:49:33
U9.7 **250
PT01B

SAMPLE METERING PERFORMANCE TESTS
Leak Test - Voltage Differential

Aspirate = 0.059 Vdc Dispense = 0.039 Vdc

Ambient Pressure = 2.578 Vdc

> Compare dispense and aspirate leak voltages to current specifications.
> Do you wish to continue to Hysteresis Test? (Y/N):

RETURN

DISPLAY
PREVIOUS
SCREEN

DISPLAY
NEXT
SCREEN

HELP

SH SM S51 S52 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING Feb 18 23
ON OFF 20:53:07
PT01C 09.7 **250

SAMPLE METERING PERFORMANCE TESTS

Hysteresis Test

| | MEAN | MAX | MIN |
|--------------|-------|-------|-------|
| Hysteresis : | 0.590 | 3.676 | 0.000 |
| Pressure P0: | 2.598 | 2.617 | 2.598 |
| Pressure P1: | 3.906 | 4.199 | 3.711 |
| Pressure P2: | 2.598 | 2.617 | 2.559 |

- > Compare all mean, max, min values to current specifications.
- > Touch DISPLAY NEXT SCREEN to view data.

RETURN

DISPLAY
PREVIOUS
SCREEN

DISPLAY
NEXT
SCREEN

HELP

SH SM SSI SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF Feb 18 23
20:53:15

09.7 **250
PT01H

SAMPLE METERING PERFORMANCE TESTS

Hysteresis Test

| Revolution | Hysteresis | P0 | P1 | P2 |
|------------|------------|-------|-------|-------|
| 1 | 0.000 | 2.598 | 3.730 | 2.598 |
| 2 | 0.000 | 2.598 | 3.711 | 2.598 |
| 3 | 0.000 | 2.598 | 3.711 | 2.598 |
| 4 | 0.000 | 2.598 | 3.711 | 2.598 |
| 5 | 0.000 | 2.598 | 3.730 | 2.598 |
| 6 | 0.000 | 2.598 | 3.730 | 2.598 |
| 7 | 0.000 | 2.598 | 3.750 | 2.598 |
| 8 | 0.000 | 2.598 | 3.750 | 2.598 |
| 9 | 0.000 | 2.598 | 3.750 | 2.598 |
| 10 | 0.000 | 2.598 | 3.770 | 2.598 |

RETURN

DISPLAY
PREVIOUS
SCREEN

DISPLAY
NEXT
SCREEN

HELP

SH SM SSI SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF Feb 18 23 20:55:25

DIAGNOSTICS - PERFORMANCE TESTS - INCUBATOR PAD REFLECTANCE TEST

09.7 **250 PT16B

MEAN MIN. = 0.9144 REFLECTANCE VALUE

MEAN MAX. = 0.9263 REFLECTANCE VALUE

RANGE = 0.0120 (MAX. MEAN - MIN. MEAN)

GRAND MEAN = 0.9220 (MEAN OF ALL SLOT MEANS)

STAND DEV = 0.0035 (STD. DEV. OF ALL SLOTS)

> COMPARE RANGE AND GRAND MEAN TO CURRENT SPECIFICATIONS
> PRESS DISPLAY_MORE_DATA TO VIEW THE MEANS AND RAW DATA

RETURN

DISPLAY MORE DATA

START

RETURN TO MAIN DIAG MENU

HELP

SH SM SS1 SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF Feb 18 23
20:55:33
09.7 **250

DIAGNOSTICS - PERFORMANCE TESTS - INCUBATOR P116C
PAD REFLECTANCE TEST

| SLOT | REFL1 | REFL2 | REFL3 | MEAN |
|------|---------|---------|---------|---------|
| 1 | 0.92282 | 0.92270 | 0.92268 | 0.92273 |
| 2 | 0.92299 | 0.92289 | 0.92287 | 0.92292 |
| 3 | 0.92223 | 0.92202 | 0.92197 | 0.92207 |
| 4 | 0.92367 | 0.92367 | 0.92358 | 0.92364 |
| 5 | 0.92504 | 0.92502 | 0.92485 | 0.92497 |
| 6 | 0.91579 | 0.91572 | 0.91560 | 0.91570 |
| 7 | 0.91940 | 0.91928 | 0.91914 | 0.91927 |
| 8 | 0.92516 | 0.92499 | 0.92490 | 0.92502 |
| 9 | 0.92407 | 0.92386 | 0.92374 | 0.92389 |
| 10 | 0.92056 | 0.92046 | 0.92032 | 0.92045 |
| 11 | 0.91711 | 0.91706 | 0.91708 | 0.91709 |
| 12 | 0.92410 | 0.92395 | 0.92388 | 0.92398 |

> PRESS RETURN TO VIEW THE PREVIOUS PAGE OF DATA
> PRESS DISPLAY_MORE_DATA TO VIEW THE MEANS AND RAW DATA

| | | | |
|--------|---------|-----------|------|
| RETURN | DISPLAY | RETURN TO | HELP |
| MORE | MORE | MAIN DIAG | |
| DATA | DATA | MENU | |

SH SM SSI SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF Feb 18 23 20:57:08 09.7 **250 PT22B

DIAGNOSTICS - Performance Test
Reference Metering - System Check

Signal Processing Check

COARSE GAIN

2.500 Vdc

>Compare the values to current specifications.
 Do you wish to continue with the Leak Test?

(Y):

RETURN

RETURN TO MAIN DIAG MENU

HELP

SH SM SSI SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF Feb 18 23 20:58:29 09.7 **250 PT22D

DIAGNOSTICS - Performance Test
Leak Test - Voltage Differential

Aspirate = -0.039 Vdc

Dispense = -0.039 Vdc

Ambient Pressure = 2.578 Vdc

>Compare the values to current specifications.
Do you wish to continue to Hysteresis Test?

(Y): ■

RETURN

DISPLAY PREVIOUS SCREEN

DISPLAY NEXT SCREEN

HELP

SH SM SSI SSI ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING Feb 18 23
ON OFF 20:59:12
PT22L 09.7 **250

DIAGNOSTICS - Performance Test
Reference Metering - System Check
Hysteresis Check

| | MEAN | MAX | MIN |
|--------------|-------|-------|-------|
| Hysteresis: | 0.163 | 1.633 | 0.000 |
| Pressure P0: | 2.617 | 2.637 | 2.617 |
| P1: | 4.473 | 4.609 | 4.375 |
| P2: | 2.598 | 2.617 | 2.578 |

>Compare the values to current specifications.

RETURN

DISPLAY DATA

RETURN TO MAIN DIAG MENU

HELP

SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure

SAMPLING Feb 18 23
ON OFF 21:21:36

SM S51 S52 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

DIAGNOSTICS - Setup/Adjustments - Read Sync

SA15B

| Delay Time | Signal | Delay Time | Signal |
|------------|---------|------------|--------|
| 0.0 ms | 10716 | 5.5 ms | 11084 |
| 0.5 ms | 10481 | 6.0 ms | 11450 |
| 1.0 ms | 10347 | 6.5 ms | 11795 |
| 1.5 ms | 10250 | 7.0 ms | 12228 |
| 2.0 ms | 10156 | 7.5 ms | 12650 |
| 2.5 ms | 10142 | 8.0 ms | 13177 |
| 3.0 ms | 10136 * | 8.5 ms | 13716 |
| 3.5 ms | 10238 | 9.0 ms | 14072 |
| 4.0 ms | 10334 | 9.5 ms | 14621 |
| 4.5 ms | 10503 | 10.0 ms | 15123 |
| 5.0 ms | 10745 | | |

> Lowest signal is marked by flashing *. Save new setting?

Touch RETURN or RETURN_TO_MAIN_DIAG_MENU to abort the changes.

(Y/N): █

RETURN

RETURN TO MAIN DIAG MENU

HELP

SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure

SAMPLING Feb 18 23
ON OFF 21:30:29

SM S51 S52 ST INC IR R/C PM INDP TESTING COMPLETE

DIAGNOSTICS - Setup/Adjustments - Slide Transport SA05B

| DISPENSE TO METERING | INCUBATOR RT/CM DEPTH | DISPENSE OFFSET | SIGNAL | DISPENSE OFFSET | SIGNAL |
|----------------------|-----------------------|-----------------|--------|-----------------|--------|
| 25 | | 12138 | 45 | 9866 | |
| 27 | | 11853 | 47 | 10163 | |
| 29 | | 11182 | 49 | 10483 | |
| 31 | | 10678 | 51 | 11005 | |
| 33 | | 10172 | 53 | 11381 | |
| 35 | | 9898 | 55 | 11985 | |
| 37 | | 9631 | 57 | 12672 | |
| 39 | | 9511 | 59 | 13250 | |
| 41 | | 9467 * | 61 | 13995 | |
| 43 | | 9605 | 63 | 14771 | |

INCUBATOR W/ DISP. PATH

INCUBATOR PM DEPTH

INCUBATOR PM DEPTH

INCUBATOR EJECT DEPTH

INCUBATOR PM DEPTH

INCUBATOR ROTOR SIZING

Lowest signal is marked by flashing *. Save new setting? (Y):

Touch RETURN or RETURN_TO_MAIN_DIAG_MENU to abort the changes.

RETURN TO MAIN DIAG MENU

RESET DISPENSE/ INCUBATOR

HELP

SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure SAMPLING Feb 18 23

LAB COMP: ON OFF 21:45:52

SM SSI SS2 ST INC IR R/C PM INOP TESTING COMPLETE U9.7 **250

DIAGNOSTICS - Setup/Adjustments - Slide Transport SA05B

| DISPENSE TO METERING | INCUBATOR RT/CM DEPTH | DISPENSE OFFSET | SIGNAL | DISPENSE OFFSET | SIGNAL |
|----------------------|-----------------------|-----------------|--------|-----------------|--------|
| 25 | | 12323 | 45 | 9652 | |
| 27 | | 11880 | 47 | 9951 | |
| 29 | | 11648 | 49 | 10202 | |
| 31 | | 10939 | 51 | 10678 | |
| 33 | | 10571 | 53 | 11143 | |
| 35 | | 10118 | 55 | 11815 | |
| 37 | | 9796 | 57 | 12288 | |
| 39 | | 9565 | 59 | 12998 | |
| 41 | | 9487 * | 61 | 13637 | |
| 43 | | 9536 | 63 | 14566 | |

| INCUBATOR W/ DISP. PATH | INCUBATOR PM DEPTH | INCUBATOR PM DEPTH |
|-------------------------|--------------------|--------------------|
| 25 | | |
| 27 | | |
| 29 | | |
| 31 | | |
| 33 | | |
| 35 | | |
| 37 | | |
| 39 | | |
| 41 | | |
| 43 | | |

| INCUBATOR ROTOR SIZING | INCUBATOR PM DEPTH | INCUBATOR PM DEPTH |
|------------------------|--------------------|--------------------|
| 25 | | |
| 27 | | |
| 29 | | |
| 31 | | |
| 33 | | |
| 35 | | |
| 37 | | |
| 39 | | |
| 41 | | |
| 43 | | |

> Lowest signal is marked by flashing *. Save new setting? Touch RETURN or RETURN_TO_MAIN_DIAG_MENU to abort the changes. (Y): ■

| | | | |
|--------|--------------------------|---------------------------|------|
| RETURN | RETURN TO MAIN DIAG MENU | RESET DISPENSE/ INCUBATOR | HELP |
|--------|--------------------------|---------------------------|------|

SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure

SAMPLING Feb 18 23

SM S51 S52 ST INC IR R/C PM INDP

LAB COMP: TESTING COMPLETE

ON OFF 22:02:48 09.7 **250 SA20G

DIAGNOSTICS - Setup/Adjustments - Rate/CM Correction Factors

Summary

Wavelength New MCF White Dr S.D. New BCF Black Dr S.D.

| Wavelength | New MCF | White Dr S.D. | New BCF | Black Dr S.D. |
|------------|---------|---------------|-------------|---------------|
| 340 nm | 0.46718 | ** 0.00032 | ** -0.0041 | ** 0.00058 |
| 400 nm | 0.80650 | 0.00012 | ** -0.0037 | ** 0.00061 |
| 460 nm | 0.90825 | 0.00006 | *** -0.0022 | ** 0.00063 |
| 540 nm | 0.98995 | 0.00007 | *** -0.0021 | ** 0.00096 |
| 600 nm | 0.99223 | 0.00005 | *** -0.0029 | ** 0.00029 |
| 630 nm | 0.98754 | 0.00006 | *** -0.0025 | ** 0.00099 |
| 670 nm | 0.98699 | 0.00006 | *** -0.0022 | ** 0.00051 |
| 680 nm | 0.98292 | 0.00007 | *** -0.0029 | ** 0.00071 |

> Automatic update?

(Y/N):

RETURN

RETURN TO MAIN DIAG MENU

HELP

SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure

SAMPLING Feb 18 23
ON OFF 22:02:57

SM SS1 SS2 ST INC IR R/C PM INDP

LAB COMP: TESTING COMPLETE

09.7 **250

DIAGNOSTICS - Setup/Adjustments - Rate/CM Correction Factors

SA21A

White Correction Factors

Wavelength White Assay Current MCF New MCF Dr. S. D.

DISPLAY
WHITE
DATA

| | | | | |
|--------|---------|---------|---------|------------|
| 340 nm | 0.56340 | 0.45900 | 0.46718 | ** 0.00032 |
| 400 nm | 0.85820 | 0.77518 | 0.80650 | 0.00012 |
| 460 nm | 0.85850 | 0.95256 | 0.98825 | 0.00006 |
| 540 nm | 0.85820 | 0.95716 | 0.98995 | 0.00007 |
| 600 nm | 0.85470 | 0.96079 | 0.99223 | 0.00005 |
| 630 nm | 0.85430 | 0.95771 | 0.98754 | 0.00006 |
| 670 nm | 0.86050 | 0.95840 | 0.98699 | 0.00006 |
| 680 nm | 0.85660 | 0.95449 | 0.98292 | 0.00007 |

DISPLAY
BLACK
DATA

> Touch DISPLAY BLACK DATA to display more data.

RETURN

RETURN TO
MAIN DIAG
MENU

HELP

SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure SAMPLING Feb 18 23
 SM S51 S52 ST INC IR R/C PM INOP LAB COMP: ON OFF 22:03:03
 TESTING COMPLETE U9.7 **250

DIAGNOSTICS - Setup/Adjustments - Rate/CM Correction Factors SA21B

Black Correction Factors

Wavelength Black Assay Current BCF New BCF Dr. S. D.

| Wavelength | Black Assay | Current BCF | New BCF | Dr. S. D. |
|------------|-------------|-------------|-------------|-------------|
| 340 nm | 0.01890 | -0.0038 | ** -0.0041 | ** 0.00058 |
| 400 nm | 0.02280 | -0.0034 | ** -0.0037 | ** 0.00061 |
| 460 nm | 0.02110 | -0.0018 | *** -0.0022 | *** 0.00063 |
| 540 nm | 0.02190 | -0.0014 | *** -0.0021 | *** 0.00096 |
| 600 nm | 0.02210 | -0.0023 | *** -0.0029 | *** 0.00029 |
| 630 nm | 0.02310 | -0.0018 | *** -0.0025 | ** 0.00099 |
| 670 nm | 0.02460 | -0.0015 | *** -0.0022 | *** 0.00051 |
| 680 nm | 0.02430 | -0.0022 | *** -0.0029 | *** 0.00071 |

> Touch DISPLAY WHITE DATA to display more data.

RETURN

RETURN TO
MAIN DIAG
MENU

HELP

SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure

SAMPLING Feb 18 23
ON OFF 22:08:32

SS1 SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

U9.7 **250

DIAGNOSTICS - Performance Tests - Reflectometer - Static test PT31D

- Summary Screen -

| WaveLength (nm) | Mean | | SD | | %CV*1K |
|--------------------|------|--------|--------|--------|--------|
| | Dark | Signal | Dark | Signal | |
| 340 | 284 | 33601 | 0.4795 | 1.0743 | 3.20 |
| 400 | 284 | 31930 | 0.4983 | 1.4527 | 4.55 |
| 460 | 284 | 34477 | 0.4795 | 1.7207 | 4.99 |
| 540 | 284 | 39670 | 0.4498 | 1.7927 | 4.52 |
| 600 | 285 | 45747 | 0.4795 | 1.7876 | 3.91 |
| 630 | 284 | 40274 | 0.5040 | 2.0126 | 5.00 |
| 670 | 285 | 35459 | 0.5085 | 1.0854 | 3.06 |
| 680 | 284 | 39788 | 0.4795 | 1.9945 | 5.01 |

- > Compare SD of Dark and/or Signal reads to current specifications.
- > Compare %CV*1K to current specification.
- > Touch DISPLAY MORE DATA to view detailed data.

RETURN DISPLAY MORE DATA RETURN TO MAIN DIAG MENU HELP

READY
REVIEW RESULTS - Verification and Edit
LAB COMP: ON OFF
TESTS IN PROCESS
 Feb 18 23
 22:30:09
 RV06A
 09.7 **250

Sample ID 89711
 Pos Track Tray 1 1
 Run Date Run Time Priority Fluid Man Dil
 02/18/23 22:20:25 ROUTINE SERUM 1.000

| | | | | | |
|------|-------|------|------|----|------|
| GLU | 84.0 | AMYL | AST | F2 | 43. |
| UREA | 29.60 | LIPA | LDH | | |
| CREA | 1.83 | Ca | CK | | |
| AMON | | Mg | CKMB | | |
| Na+ | 143.7 | PHOS | | | |
| K+ | 3.75 | CHOL | ALKP | F2 | 83. |
| Cl- | 92.2 | TRIG | GGT | | |
| ECO2 | | | TBIL | | 1.00 |
| THEO | | URIC | Bu | | .93 |
| Fe | | TP | Bc | | 0.00 |
| | | F2 | | | |
| | | 4.65 | | | |

Touch targets to review results and data - CONTROL sample is not editable

| | | | | | | |
|--------|-------------------|----------------------|--------------------|-------------------|-----------------------|------|
| RETURN | EDIT PATIENT DATA | DELETE RESULT RECORD | REVIEW NEXT SAMPLE | REVIEW NEXT GROUP | REVIEW PREVIOUS GROUP | HELP |
|--------|-------------------|----------------------|--------------------|-------------------|-----------------------|------|



READY

LAB COMP: TESTS IN PROCESS

SAMPLING ON OFF Feb 18 23 22:30:17 09.7 **250 RY06A

REVIEW RESULTS - Verification and Edit

Sample ID 89711 Pos Track Tray 1 1 Run Date Run Time Priority Fluid Man Dil 02/18/23 22:20:25 ROUTINE SERUM 1.000

K+ 3.75 CHOL ALKP F2 83.
Cl- 92.2 TRIG GGT

ECO2 THEO URIC TBIL 1.00
Fe TP F2 4.65 Bu .93
Bc 0.00

TIBC ALB 4.30 LAC

SALI DGXN ALC
Li CHE
CRP PHBR PHYT
CRBM

> Touch targets to review results and data - CONTROL sample is not editable

| | | | | | | |
|--------|-------------------|----------------------|--------------------|-------------------|-----------------------|------|
| RETURN | EDIT PATIENT DATA | DELETE RESULT RECORD | REVIEW NEXT SAMPLE | REVIEW NEXT GROUP | REVIEW PREVIOUS GROUP | HELP |
|--------|-------------------|----------------------|--------------------|-------------------|-----------------------|------|



READY

LAB SOMP: TESTS IN PROCESS

SAMPLING ON OFF Feb 18 23 22:30:30 09.7 **250 R006A

REVIEW RESULTS - Verification and Edit

Sample ID 89711 Pos Track Tray 1 1 Run Date Run Time Priority Fluid Man Di1 02/18/23 22:20:25 ROUTINE SERUM 1.000

LDLC
VLDL

OSMO
%SAT

DELB
% MB
LDL

C/H

ASTJ

ALTU

25.

ALTZ

> Touch targets to review results and data - CONTROL sample is not editable

RETURN

EDIT
PATIENT
DATA

DELETE
RESULT
RECORD

REVIEW
NEXT
SAMPLE

REVIEW
NEXT
GROUP

REVIEW
PREVIOUS
GROUP

HELP

READY

LAB COMP: TESTING COMPLETE

SAMPLING Feb 18 23
ON OFF 22:33:12

REVIEW RESULTS - Verification and Edit

RV06A

Sample ID 89712
Pos Track Tray 1 2
Run Date Run Time Priority Fluid Man Dil
02/18/23 22:23:41 ROUTINE SERUM 1.000

| | | | | | |
|------|-------|------|------|----|------|
| GLU | 246.8 | AMYL | AST | F2 | 187. |
| UREA | 83.01 | LIPA | LDH | | |
| CREA | 5.48 | Ca | CK | | |
| AMON | | Mg | CKMB | | |
| Na+ | 122.9 | PHOS | | | |
| K+ | 5.83 | CHOL | ALKP | F3 | 377. |
| Cl- | 82.8 | TRIG | GGT | | |
| ECO2 | | | TBIL | | 4.72 |
| THEO | | URIC | Bu | F2 | 4.47 |
| Fe | | TP | Bc | F3 | 0.00 |

Touch targets to review results and data - CONTROL sample is not editable

| | | | | | | |
|--------|-------------------|----------------------|--------------------|-------------------|-----------------------|------|
| RETURN | EDIT PATIENT DATA | DELETE RESULT RECORD | REVIEW NEXT SAMPLE | REVIEW NEXT GROUP | REVIEW PREVIOUS GROUP | HELP |
|--------|-------------------|----------------------|--------------------|-------------------|-----------------------|------|



READY

LAB COMP: TESTING COMPLETE

SAMPLING Feb 18 23
ON OFF 22:33:19
V9.7 **250

REVIEW RESULTS - Verification and Edit

RV06A

Sample ID 89712
Pos Track Tray 1 2
Run Date Run Time Priority Fluid Man Dil
02/18/23 22:23:41 ROUTINE SERUM 1.000

| | | | | | |
|------|------|------|------|----|------|
| K+ | 5.83 | CHOL | ALKP | F3 | 377. |
| Cl- | 82.8 | TRIG | GGT | | |
| ECO2 | | | TBIL | F2 | 4.72 |
| THEO | | URIC | Bu | F2 | 4.47 |
| Fe | | TP | Bc | F3 | 0.00 |
| TIBC | | ALB | LAC | | |
| | | DGXN | ALC | | |
| SALI | | CHE | PHYT | | |
| Li | | PHBR | | | |
| CRP | | CRBM | | | |

> Touch targets to review results and data - CONTROL sample is not editable

| | | | | | | |
|--------|-------------------|----------------------|--------------------|-------------------|-----------------------|------|
| RETURN | EDIT PATIENT DATA | DELETE RESULT RECORD | REVIEW NEXT SAMPLE | REVIEW NEXT GROUP | REVIEW PREVIOUS GROUP | HELP |
|--------|-------------------|----------------------|--------------------|-------------------|-----------------------|------|

READY

LAB COMP: TESTING COMPLETE

SAMPLING Feb 18 23
ON OFF 22:33:28
V9.7 **250

REVIEW RESULTS - Verification and Edit

Sample ID 89712
Pos Track Tray 1 2
Run Date Run Time Priority Fluid Man Dil
02/18/23 22:23:41 ROUTINE SERUM 1.000

LDLC
VLDL

OSMO
%SAT

DELB
% MB
LDL

C/H

ASTJ

ALTU

80.

AL TZ

> Touch targets to review results and data - CONTROL sample is not editable

| | | | | | | |
|--------|-------------------|----------------------|--------------------|-------------------|-----------------------|------|
| RETURN | EDIT PATIENT DATA | DELETE RESULT RECORD | REVIEW NEXT SAMPLE | REVIEW NEXT GROUP | REVIEW PREVIOUS GROUP | HELP |
|--------|-------------------|----------------------|--------------------|-------------------|-----------------------|------|



ISO/IEC 17025:2017
Certificate No.: CC-2705

Print Date: 16/11/2022

CALIBRATION REPORT

STATUS : PASSED

DESCRIPTION : Variable Volume Pipette VV-200 (20-200 μ l)

DEVICE ID : 21400599

CALIBRATION DATE : 16/11/2022 10:50 AM

Method ID : VV/20-200

TERMINAL ID : 19

ULR No. : CC270521000091802F

Location : Lucknow (Permanent Lab)

ENVIRONMENTAL FACTORS

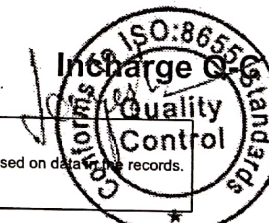
TEMP : 25.00 $^{\circ}$ C **Z FACTOR :** 1.0026 mm³/mg **BARO. PRESSURE :** 80.00 KPa **REL. HUMIDITY :** 60.00%

CALIBRATION STATISTICS

| Vol (μ l) | No | Cum Wt (mg) | Vol (μ l) | Mean (μ l) | SD (μ l) | Inaccuracy E% | | Imprecision CV% | | Status |
|----------------|----|-------------|----------------|-----------------|---------------|---------------|--------|-----------------|--------|--------|
| | | | | | | Actual | Target | Actual | Target | |
| 20.000 | 1 | 20.600 | 20.654 | 20.754 | 0.459 | 3.770 | 6.00 | < 2.00 | 2.00 | PASSED |
| | 2 | 40.900 | 20.353 | | | | | | | |
| | 3 | 62.100 | 21.255 | | | | | | | |
| 100.000 | 1 | 99.300 | 99.558 | 99.625 | 0.058 | 0.375 | 1.20 | < 0.40 | 0.40 | PASSED |
| | 2 | 198.700 | 99.658 | | | | | | | |
| | 3 | 298.100 | 99.658 | | | | | | | |
| 200.000 | 1 | 199.000 | 199.517 | 199.852 | 0.495 | 0.074 | 0.60 | < 0.20 | 0.20 | PASSED |
| | 2 | 398.900 | 200.420 | | | | | | | |
| | 3 | 598.000 | 199.618 | | | | | | | |

| Volume | Above 10 μ l to 100 μ l | Above 100 μ l to 1000 μ l | Above 1 ml to 10 ml | Above 10 ml to 100 ml |
|-------------------|---------------------------------|-----------------------------------|---------------------|-----------------------|
| Uncertainty (k=2) | 0.1 μ l | 0.1 μ l | 0.1 μ l | 4 μ l |

Based on data and records.



- * Specifications conform to ISO:8655 standards.
- * Each instrument is individually calibrated on electronic balance.
- * 750 mmHg = 99.98 kPa.
- * Weight in mg or g.
- * Volume, Mean & S.D. in ml or μ l.

Reference standard
The instrument is calibrated using a standard electronic balance with calibration traceability to NPL.

The reported expanded uncertainty of measurement is calculated by multiplying the standard uncertainty of measurement by the coverage factor k=2, which for normal distribution corresponds to a coverage probability of approximately 95%.





CALIBRATION REPORT

STATUS : PASSED

DESCRIPTION : Variable Volume Pipette VV-1000 (100-1000 µl)

DEVICE ID : 21400612

CALIBRATION DATE : 15/11/2022 2:52 PM

Method ID : VV/100-1000

TERMINAL ID : 19

ULR No. : CC270521000091812F

Location : Lucknow (Permanent Lab)

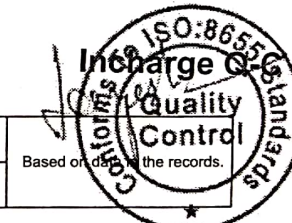
ENVIRONMENTAL FACTORS

TEMP : 25.00 °C **Z FACTOR :** 1.0026 mm³/mg **BARO. PRESSURE :** 80.00 KPa **REL. HUMIDITY :** 60.00%

CALIBRATION STATISTICS

| Vol (µl) | No | Cum Wt (mg) | Vol (µl) | Mean (µl) | SD (µl) | Inaccuracy E% | | Imprecision CV% | | Status |
|----------|----|-------------|----------|-----------|---------|---------------|--------|-----------------|--------|--------|
| | | | | | | Actual | Target | Actual | Target | |
| 100.000 | 1 | 98.400 | 98.656 | 98.221 | 0.587 | 1.779 | 6.00 | < 2.00 | 2.00 | PASSED |
| | 2 | 196.600 | 98.455 | | | | | | | |
| | 3 | 293.900 | 97.553 | | | | | | | |
| 500.000 | 1 | 499.900 | 501.200 | 500.231 | 1.127 | 0.046 | 1.20 | < 0.40 | 0.40 | PASSED |
| | 2 | 999.100 | 500.498 | | | | | | | |
| | 3 | 1496.800 | 498.994 | | | | | | | |
| 1000.000 | 1 | 997.300 | 999.893 | 1000.227 | 0.948 | 0.023 | 0.60 | < 0.20 | 0.20 | PASSED |
| | 2 | 1994.200 | 999.492 | | | | | | | |
| | 3 | 2992.900 | 1001.297 | | | | | | | |

| Volume | Above 10 µl to 100 µl | Above 100 µl to 1000 µl | Above 1 ml to 10 ml | Above 10 ml to 100 ml |
|-------------------|-----------------------|-------------------------|---------------------|-----------------------|
| Uncertainty (k=2) | 0.1 µl | 0.1 µl | 0.1 µl | 4 µl |



- * Specifications conform to ISO:8655 standards.
- * Each instrument is individually calibrated on electronic balance.
- * 750 mmHg = 99.98 kPa.
- * Weight in mg or g.
- * Volume, Mean & S.D. in ml or µl.

Reference standard

The instrument is calibrated using a standard electronic balance with calibration traceability to NPL.

The reported expanded uncertainty of measurement is calculated by multiplying the standard uncertainty of measurement by the coverage factor k=2, which for normal distribution corresponds to a coverage probability of approximately 95%.



CALIBRATION REPORT

Print Date: 15/11/2022

STATUS : PASSED

DESCRIPTION : Variable Volume Pipette VV-200 (20-200 μ l)

DEVICE ID : 21400602

CALIBRATION DATE : 15/11/2022 2:56 PM

Method ID : VV/20-200

TERMINAL ID : 19

ULR No. : CC270521000091800F

Location : Lucknow (Permanent Lab)

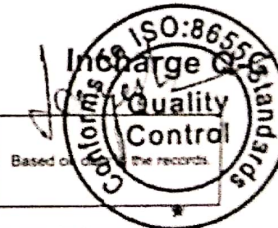
ENVIRONMENTAL FACTORS

TEMP : 25.00 $^{\circ}$ C Z FACTOR : 1.0026 mm³/mg BAKO. PRESSURE : 80.00 KPa REL. HUMIDITY : 60.00%

CALIBRATION STATISTICS

| Vol (μ l) | No | Cum Wt (mg) | Vol (μ l) | Mean (μ l) | SD (μ l) | Inaccuracy E% | | Imprecision CV% | | Status |
|----------------|----|-------------|----------------|-----------------|---------------|---------------|--------|-----------------|--------|--------|
| | | | | | | Actual | Target | Actual | Target | |
| 20.000 | 1 | 20.700 | 20.754 | 20.787 | 0.058 | 3.937 | 6.00 | < 2.00 | 2.00 | PASSED |
| | 2 | 41.500 | 20.854 | | | | | | | |
| | 3 | 62.200 | 20.754 | | | | | | | |
| 100.000 | 1 | 99.600 | 99.859 | 99.725 | 0.116 | 0.275 | 1.20 | < 0.40 | 0.40 | PASSED |
| | 2 | 199.000 | 99.658 | | | | | | | |
| | 3 | 298.400 | 99.658 | | | | | | | |
| 200.000 | 1 | 200.000 | 200.520 | 199.885 | 0.604 | 0.058 | 0.60 | < 0.20 | 0.20 | PASSED |
| | 2 | 399.300 | 199.818 | | | | | | | |
| | 3 | 598.100 | 199.317 | | | | | | | |

| Volume | Above 10 μ l to 100 μ l | Above 100 μ l to 1000 μ l | Above 1 ml to 10 ml | Above 10 ml to 100 ml |
|-------------------|---------------------------------|-----------------------------------|---------------------|-----------------------|
| Uncertainty (k=2) | 0.1 μ l | 0.1 μ l | 0.1 μ l | 4 μ l |



- Specifications conform to ISO:8655 standards.
- Each instrument is individually calibrated on electronic balance.
- 750 mmHg = 99.98 kPa.
- Weight in mg or g.
- Volume, Mean & S.D. in ml or μ l.

Reference standard
The instrument is calibrated using a standard electronic balance with calibration traceability to NPL.

The reported expanded uncertainty of measurement is calculated by multiplying the standard uncertainty of measurement by the coverage factor k=2, which for normal distribution corresponds to a coverage probability of approximately 95%.



National Accreditation Board for
Testing and Calibration Laboratories

CERTIFICATE OF ACCREDITATION

MICROLIT - LABORATORY

has been assessed and accredited in accordance with the standard

ISO/IEC 17025:2017

**"General Requirements for the Competence of Testing &
Calibration Laboratories"**

for its facilities at

629, PAKRAMAU, KURSI ROAD, LUCKNOW, UTTAR PRADESH, INDIA

in the field of

CALIBRATION

Certificate Number: CC-1032

Issue Date: 30/04/2023

Valid Until: 29/04/2025

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Name of Legal Identity : MICROLIT - LABORATORY

Signed for and on behalf of NABL



N. Venkateswaran
Chief Executive Officer



FINIKS ENGINEERING COMPANY

Plot No. 21, Anand Nagar, Near Wasan Automobiles, Sahyadri Chowk, M.I.D.C
A'nagar - 414111. [M.S.] Tel. [0241] 2778918, E-mail : finiks97@rediffmail.com



Calibration Certificate

ULR : CG226723000003632F

| CALIBRATED ON | ISSUED ON | CERTIFICATE NO. | NEXT CALIBRATION DUE ON (suggested by customer) | Page 1 of 1 |
|---------------|------------|-----------------|--|-------------|
| 12/07/2023 | 15/07/2023 | 23-EGC-12-3-1 | 11/07/2024 | |

CALIBRATED FOR : M/S. LUPIN DIAGNOSTICS LIMITED,
Ahmednagar, Maharashtra

CUSTOMER'S CHALLAN NO. :

Dated : 12/07/2023

Work Order No. : 23/G/12/3

TYPE OF INSTRUMENT : DIGITAL CENTRIFUGE MACHINE(RPM)

IDENTIFICATION

| | | | |
|--------------|-----------------|---------------|----------------------|
| MAKE | : Remi | Sr.No. | : ZHIN/36370 |
| RANGE | : 0 to 5250 RPM | ID No. | : LOL/HLM/LAB/CEN/01 |
| L.C. | : 10 RPM | Model | : R-8C |
| TYPE | : Digital | | |

LAB ID NO. : 23/G/12/3/1

ENVIRONMENTAL CONDITION : 25°C±10°C /50%RH±10%RH **CONDITION AT RECEIPT** : OK

REFERENCE DOCUMENT USED : IS 12508 - 1988 & Sanas TR 45-01 (2008-2-15)

CALIBRATION PROCEDURE : CP/81 **CALIBRATION LOCATION** :At Site

Product Field Discipline : MECHANICAL-ACCELERATION AND SPEED

Equipment / Reference Standards Used For Calibration : Traceable to National / International standards.

| Equipment / Reference Standard | Identification No. | Certificate No. | Date of Calibration | Valid Upto |
|--------------------------------|--------------------|-----------------|---------------------|------------|
| DIGITAL TACHOMETER | FINIKS/TM-01 | NI2023/06/0403 | 10/06/2023 | 09/06/2024 |

CALIBRATION RESULTS

Parameter : RPM (NON-CONTACT TYPE)

| Calibration Point in RPM | Standard Reading in RPM | UUC Reading in RPM | Error in RPM | Stability (S) (RPM) | Measurement Uncertainty (±) |
|--------------------------|-------------------------|--------------------|--------------|---------------------|-----------------------------|
| 1000 | 999.5 | 1000 | 0.50 | 0.00 | 6.56 RPM |
| 2000 | 1998.6 | 2000 | 1.40 | 0.00 | 10.30 RPM |
| 3000 | 2995.6 | 3000 | 4.40 | 0.00 | 10.30 RPM |
| 4000 | 3990.3 | 4000 | 9.70 | 0.00 | 10.30 RPM |
| 5000 | 4980.1 | 5000 | 19.90 | 0.00 | 10.30 RPM |

The reported uncertainty is at coverage factor K=2 which corresponds to a coverage probability of approximately 95.45% for normal distribution.

--- END OF CERTIFICATE ---

Calibrated By
Mr.Mokal M.S

Calibration Engineer

This Certificate refers only to the item (s) submitted for calibration

This calibration results in this certificate are valid at the time of and under the stated conditions of measurements.

This certificate shall not be reproduced, except in full without our prior permission in writing



Authorized By
Mr. Warpe B.S
Technical Manager

FM/25





FINIKS ENGINEERING COMPANY

Plot No. 21, Anand Nagar, Near Wasan Automobiles, Sahyadri Chowk, M.I.D.C. A'nagar - 414111. [M.S.] Tel. [0241] 2778918. E-mail : finiks97@rediffmail.com



Calibration Certificate

ULR : CC226723000003633F

| | | | | |
|----------------------|------------------|------------------------|---|-------------|
| CALIBRATED ON | ISSUED ON | CERTIFICATE NO. | NEXT CALIBRATION DUE ON (suggested by customer) | Page 1 of 1 |
| 12/07/2023 | 15/07/2023 | 23-EGC-12-3-2 | 11/07/2024 | |

CALIBRATED FOR : M/S. LUPIN DIAGNOSTICS LIMITED,
Ahmednagar, Maharashtra

CUSTOMER'S CHALLAN NO. :

Dated: 12/07/2023 Work Order No. : 23/G/12/3

TYPE OF INSTRUMENT : DIGITAL CENTRIFUGE MACHINE(RPM)

IDENTIFICATION

| | | | |
|--------------|------------------|---------------|----------------------|
| MAKE | : Remi | Sr.No. | : ZHIN/36374 |
| RANGE | : 10 to 5250 RPM | ID No. | : LOL/HLM/LAB/CEN/02 |
| L.C. | : 10 RPM | Model | : R-8C |
| TYPE | : Digital | | |

LAB ID NO. : 23/G/12/3/2

ENVIRONMENTAL CONDITION : 25°C±10°C / 50%RH±10%RH **CONDITION AT RECEIPT** : OK

REFERENCE DOCUMENT USED : IS 12508 - 1988 & Sanas TR 45-01 (2008-2-15)

CALIBRATION PROCEDURE : CP/81 **CALIBRATION LOCATION** : At Site

Product Field Discipline : MECHANICAL-ACCELERATION AND SPEED

Equipment / Reference Standards Used For Calibration : Traceable to National / International standards.

| Equipment / Reference Standard | Identification No. | Certificate No. | Date of Calibration | Valid Upto |
|--------------------------------|--------------------|-----------------|---------------------|------------|
| DIGITAL TACHOMETER | FINIKS/TM-01 | NI2023/06/0403 | 10/06/2023 | 09/06/2024 |

CALIBRATION RESULTS

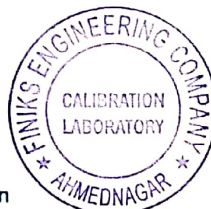
Parameter : RPM (NON-CONTACT TYPE)

| Calibration Point in RPM | Standard Reading in RPM | UUC Reading in RPM | Error in RPM | Stability (S) (RPM) | Measurement Uncertainty (±) |
|--------------------------|-------------------------|--------------------|--------------|---------------------|-----------------------------|
| 1000 | 998.6 | 1000 | 1.40 | 0.00 | 6.56 RPM |
| 2000 | 1997.5 | 2000 | 2.50 | 0.00 | 6.56 RPM |
| 3000 | 2992.3 | 3000 | 7.70 | 0.00 | 6.56 RPM |
| 4000 | 3986.5 | 4000 | 13.50 | 0.00 | 6.56 RPM |
| 5000 | 4981.2 | 5000 | 18.80 | 0.00 | 6.56 RPM |

The reported uncertainty is at coverage factor K=2 which corresponds to a coverage probability of approximately 95.45% for normal distribution.

— END OF CERTIFICATE —

Mr. Mokal
Calibrated By
Mr. Mokal M.S
Calibration Engineer



Mr. Warpe
Authorized By
Mr. Warpe B.S
Technical Manager

This Certificate refers only to the item (s) submitted for calibration
This calibration results in this certificate are valid at the time of and under the stated conditions of measurements.
This certificate shall not be reproduced, except in full without our prior permission in writing

FM/25

