

CALIBRATION CERTIFICATE

This is to certify that the System Maintenance and Calibration (Preventative Maintenance) was performed on 24th DECEMBER 2022 for the Machine, Vitros 250 SYSTEM Serial No: - 27000340, Installed at LUPIN HEALTHCARE LIMITED GANGPUR, NH2, Grand Trunk Road, Gangpur, West Bengal 713104

The System Maintenance includes Checking the Reproducibility Performance of the instrument as per the guidelines provided by the Manufacturer. The System Maintenance and Calibration is due in JUNE 2023.

Sattwik Haldar
Engineer- CTS
Ortho Clinical Diagnostics

Ortho Clinical Diagnostics India Private Limited
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Ortho Clinical Diagnostics

INSTALLATION QUALIFICATION

For

VITROS 250



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

Table of Contents

| Sr. No. | Contents | Page No. |
|---------|------------------------------|----------|
| I | Approval of the IQ procedure | 3 |
| II | Instructions | 4 |
| III | Scope | 5 |
| IV | Ancillary Information | 6 |
| V | Installation Qualification | 8 |
| VI | Comments | 12 |
| VII | System certification | 13 |

I. Approval of the IQ procedure:

Both **Lupin Health Care Ltd.** and **Ortho Clinical Diagnostics** are jointly responsible for the installation of **VITROS 250, Sr. No. 27000340** in the Central Laboratory of **CAMRI Hospital, Gangpur, East Bardwan.**

Protocol Performed By: Ortho-Clinical Diagnostics Representative

Name : Mr. SOUMITRA JENA

Signature: 

Designation : Service Engineer

Date: 24/11/2021

Company : Ortho-Clinical Diagnostics

Validation Team from:

Name : DIPANKAR MAJHI

Signature: Dipankar Majhi

Designation : Sr. Lab Tech

Date: 24.11.21

Department :

Name : SOUVIK PAL

Signature: Souvik Pal

Designation : Lab Tech.

Date: 24.11.21

Department :

Customer Authorizations:

Name : Eushadeel Pal

Designation : Senior Lab Tech.

Signature: 

Site : Bardwan

Date: 24/11/21

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 Health Care Ltd.** 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 Health Care Ltd.**

III. SCOPE:

This Installation Qualification protocol will be performed on the VITROS 250 bearing Sr. No. **27000340** located at Central lab Department, **Lupin Health Care Ltd, CAMRI Hospital, Gangpur, East Bardwan**. 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 24/11/2021 is in compliance with the specifications of the purchase order.

Verified By: Mr. SOUMITRA JENA

Date: 24/11/2021

b. Utilities

| Sr. No | Utility | Verified by | Date |
|--------|---|-------------------|------------|
| 1. | Environmental conditions: | Mr. SOUMITRA JENA | 24/11/2021 |
| | a. Analyzer will be placed away from the direct sunlight. | ” | ” |
| | b. Installation site shall be free from dust, significant vibrations and shall be well ventilated. | ” | ” |
| | c. Installation site floor construction shall be able to support approximately 272 kg. | ” | ” |
| | d. Room temperature will be maintained between 15 ⁰ C to 27 ⁰ C and the temperature fluctuation during analysis shall not be more than $\pm 2^{\circ}$ C. | ” | ” |
| | e. The analyzer shall be kept away from strong electromagnetic sources and electrical interferences. | ” | ” |
| | f. It will be kept near to the power sources. | ” | ” |
| | g. Maximum relative humidity allowed up to 70%. | ” | ” |
| | h. If the temperature and humidity fluctuations are not within the specified range, the analyzer cannot maintain data reliability. | ” | ” |
| 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)] | ” | ” |
| 3. | Electrical Outlets: Actual Voltage on site [AC 220-230 Volts 16A 50 HZ] | ” | ” |

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

c. The instrument has been verified for the following

| Sr. No. | Verification | | Verified by | Date |
|---------|--|-----|----------------------|------------|
| 1. | Instrument is identified | Yes | Mr. SOUMITRA JENA | 24/11/2021 |
| 2. | Manufacturer's specifications are included | Yes | ” | ” |
| 3. | Accessories / Consumables are listed | Yes | ” | ” |
| 4. | Equipment manual from the manufacturer is documented | Yes | ” | ” |
| 5. | Manufacturer's Certificate attached | Yes | ” | ” |

V. Installation Qualification:**a. Equipment Description**

The VITROS 250 is a fully automated Dry chemistry analyzer

| Instrument Identification | | Verified by | Date |
|---------------------------|---------------------------------|----------------------|------------|
| Equipment Name: | Dry Chemistry Analyzer | Mr. SOUMITRA JENA | 24/11/2021 |
| Manufacturer: | Ortho-Clinical Diagnostics | ” | ” |
| Model: | <i>VITROS 250</i> | ” | ” |
| Serial Number: | 27000340 | ” | ” |
| Size (in cm): | 115 (L) x 71 (W) x 120 (H) | ” | ” |
| Power: | AC 220-230 V 16A 50Hz \pm 2Hz | ” | ” |
| Power consumption: | 6880KW hours per year | ” | ” |

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 | 250 TIP RACK | | 1 no. |
| 354009 | 250 MICRO COLLECTION TUBE ADAPTER | | 1 no. |
| 354007 | 250 SAMPLE CUP ADAPTER | | 1 no. |
| 354000 | 250 UNIVERSAL SAMPLE TRAY | | 1 no. |
| 354011 | 250 DILUENT TRAY | | 1 no. |
| 354002 | 250 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 | 250 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. |
| 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. |

A. 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. |

B. 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.

C. 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.

D. 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 |
| Keyboard | English Keyboard or Standard 101/102 or Microsoft Natural Keyboard |
| 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 : Mr. SOUMITRA JENA

Date: 24/11/2021

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 : Mr. SOUMITRA JENA

Designation : Service Engineer

Company : Ortho Clinical Diagnostics

Signature:



Date: 24/11/2021

Customer Authorizations:

Name : Subhadeer Pal

Designation : Senior Lab Tech.

Organization : Lupin Diagnostics
(HLM- eAMRI)

Signature:



Date: 24/11/21

Ortho Clinical Diagnostics

OPERATION QUALIFICATION

For

VITROS 250



Manufactured by:
Ortho Clinical Diagnostics, Inc., US


Table of Contents

| Sr. No. | Contents | Page No. |
|---------|------------------------------|----------|
| I | Approval of the OQ procedure | 3 |
| II | Instructions | 4 |
| III | Scope | 5 |
| IV | Operation Qualification | 6 |
| V | Comments | 15 |
| VI | System certification | 15 |



I. Approval of the OQ procedure:

Both **Lupin Health Care Ltd.** and **Ortho Clinical Diagnostics** are jointly responsible for the operation qualification of **VITROS 250, Sr. No. 27000340** in the Central Laboratory of **CAMRI Hospital, Gangpur, East Bardwan** as per the Operational Qualification Protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : Mr. JAYANTA PAUL Signature: 
Designation : Service Engineer
Company : Ortho Clinical Diagnostics Date: 01/12/2021

Validation Team from:

Name : DIPANKAR MAJHI Signature: 
Designation : Sp. Lab Tech Date: 01/12/21
Department : Diagnostics
Name : Souvik Pal Signature: 
Designation : Lab. Tech. Date: 01/12/21
Department : Diagnostics

Customer Authorizations:

Name : Subhadeep Pal
Designation : Senior Lab Tech Signature: 
Site : Bardwan Date: 01/12/21

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 Health Care Ltd.** will verify each result and sign in 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 250, Sr.No. 27000340 located at Central Laboratory, **Lupin Health Care Ltd.** This OQ protocol will define the documentation that will be used to evaluate the completion of the instrument's 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 250

2. **Serial Number:** 27000340

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 | JAYANTA PAUL 01/12/2021 |
| 02 | Daily maintenance | To clean appropriate modules so as to maintain accuracy and precision | ” |
| 03 | Inventory of reagents and consumables | To check the slide supply of installed Vitros 250 | ” |
| 04 | Calibration for the assays used | To calibrate the system for every new lot of assay | ” |
| 05 | QC check | To confirm that systems, reagents & consumables are acceptable and working within specifications for each assay used | ” |
| 06 | Sample programming and Analysis | To run the samples | ” |

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 250 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

PARAMETER

PASS

FAIL

PASSES

Parameter values for verification: “READY” on Status console

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 | SUBHASIS MITRA | 02/12/2021 |
| 02 | Clean ERF Reservoir Holder & Base | ” | ” |
| 03 | Replace ERF Reservoir | ” | ” |
| 04 | Replace ERF Tip | ” | ” |
| 05 | Clean ERF Tip Sleeve | ” | ” |
| 06 | Clean IWF Reservoir Holder & Base | ” | ” |
| 07 | Replace IWF Reservoir | ” | ” |
| 08 | Replace IWF Tip | ” | ” |
| 09 | Clean IWF Tip Sleeve | ” | ” |
| 10 | Load supplies and remove outdated and empty reagents | ” | ” |
| 11 | Perform Quality Control | ” | ” |

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

PARAMETER

PASS

FAIL

PASSES

Parameter values for verification: System found “Ready” after daily maintenance

Test: 3: Inventory of reagents and consumables

Purpose: To check the reagent management module of VITROS 250 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. | SUBHASIS MITRA | 02/12/2021 |
| 02 | Verify the status of reagents loaded. | ” | ” |

Acceptance criteria:

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

PARAMETER PASS FAIL

PASSES

Parameter values for verification: No Error codes

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 | SUBHASIS MITRA | 02/12/2021 |
| 02 | Performing Calibration with calibration programming screen | ” | ” |
| 03 | Verification of Calibration report | ” | ” |

Acceptance criteria: “Calibration Successful” should come on screen

| <u>PARAMETER</u> | <u>PASS</u> | <u>FAIL</u> |
|------------------|-------------|-------------|
|------------------|-------------|-------------|

| | | |
|--------|--|--|
| PASSES | | |
|--------|--|--|

Parameter values for verification : “Calibration Successful” found and the report of 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 | SUBHASIS MITRA | 03/12/2021 |
| 02 | Creating QC file | ” | ” |
| 03 | QC sample programming and analysis | ” | ” |
| 04 | Verification of QC results obtained | ” | ” |

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

PARAMETER PASS FAIL

PASSES

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

Test: 6: Sample programming and Analysis

Purpose: To run the samples

Procedure:

| Sr. No. | Activity | Done By | Date |
|---------|------------------------------------|----------------|------------|
| 01 | Loading and Processing of samples | SUBHASIS MITRA | 03/12/2021 |
| 02 | Programming samples | ” | ” |
| 03 | Unloading the samples | ” | ” |
| 04 | Viewing samples in process | ” | ” |
| 05 | Review results: Monitoring results | ” | ” |

Acceptance criteria: Samples Analysis & Report without any error

PARAMETER PASS FAIL

PASSES

Parameter values for verification: Sample analysis & Report 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. SUBHASIS MITRA from Ortho Clinical Diagnostics has conducted the training.

| Sr. No. | Training program | Initials | Date |
|----------------|-------------------------|-------------------|-------------|
| 1. | Instrument Setup | SUBHASIS MITRA | 04/12/2021 |
| 2. | System Operation | ” | ” |
| 3. | Calibration | ” | ” |
| 4. | Quality Control | ” | ” |
| 5. | Maintenance | ” | ” |
| 6. | Basic trouble shooting | ” | ” |

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. | MR SUBHADEEP PAL | Central lab | <i>SPal</i> | 01.12.21 |
| 2. | MR PRITHWIS NANDI | Central lab | <i>P.Nandi</i> | 01.12.21 |
| 3. | MR SOUMYAJIT BANERJEE | Central lab | <i>S.Banerjee</i> | 01.12.21 |
| 4. | MS SURAVI MUKHERJEE | Central lab | <i>Suravi Mukherjee</i> | 01/12/21 |

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. JAYANTA PAUL

Designation : Service Engineer

Company : Ortho Clinical Diagnostics

Signature: 


Date: 01/12/2021

Customer Authorizations:

Name : *Subhadeep Pal*

Designation : *Senior Lab Tech*

Organization : *Lupin Diagnostics
(HLM-CAMRI)*

Signature : 

Date : 01/12/21

Ortho Clinical Diagnostics

PERFORMANCE QUALIFICATION

For
VITROS 250



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

Table of Contents

| Sr. No. | Contents | Page No. |
|---------|------------------------------|----------|
| I | Approval of the PQ procedure | 3 |
| II | Instructions | 4 |
| III | Scope | 5 |
| iV | Performance Qualification | 6 |
| V | Comments | 9 |
| VI | System certification | 10 |

Ortho Clinical Diagnostics

I. Approval of the PQ procedure:

Both **Lupin Health Care Ltd.** and **Ortho Clinical Diagnostics** are jointly responsible for conducting the Performance Check of the Biochemistry Analyzer, Model – **VITROS 250**, **Serial. No. 27000340** in the Central lab Department of c/o: **CAMRI Hospital, GANGPUR, East Bardwan** as per the attached protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : Mr. SUBHASIS MITRA

Signature: 

Designation : Application

Date: 04/12/2021

Company : Ortho Clinical
Diagnostics

Validation Team from:

Name : DIPANKAR MATHI


Signature: 

Designation : Sp. Lab Tech

Date: 4.12.21

Department : Diagnostics.

Name : SOUVIK PAL

Signature: 

Designation : Lab. Tech.

Date: 4.12.21


Department : Diagnostics.

Customer Authorizations:

Name : Subhadeep Pal

Designation : Senior Lab Tech.

Site : Bardwan

Signature: 

Date: 4/12/21

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 Health Care Ltd.** 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 Health Care Ltd.** and Ortho-Clinical Diagnostics.

III. Scope:

This Performance Qualification protocol will be performed on the **VITROS 250 Serial No. 27000340** located in Central Lab of **CAMRI Hospital, Gangpur, East Bardwan**. 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 250
2. Serial Number: 27000340

04/12/2021

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 | SUBHASIS MITRA 04/12/2021 |
| 02 | Accuracy Study | To compare the obtained value with true values of processed control. | ” |
| 03 | Precision Study | To check the precision performance of the equipment | ” |

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 Chemistry;

Analysis of controls:

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

| Sr. No. | Activity | Procedure done as per the protocol defined in VITROS 250 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 | 04/12/2021 |
| 02 | Creating QC file | Quality Control – Define control fluids | Pass | " |
| 03 | QC sample programming and analysis | Quality Control – Process Control fluid samples & Review the Control sample results. | Pass | " |

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 250 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 | 04/12/2021 |
| 02 | QC sample programming and analysis | Quality Control – Process Control fluid samples & Review the Control sample results. | Pass | ” |
| 03 | Accuracy Analysis | Compare the obtained Q.C value with mean of expected value as mentioned in the Performance verifier / QC Value chart. | Pass | ” |

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 all Parameters (1 x 5 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:

V. System Certification

Study data has determined that the VITROS 250 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 : SUBHASIS MITRA
Designation : Application
Company : Ortho Clinical Diagnostics


Signature: 
Date: 04/12/2021

Validation Team from:

Name : DIPANKAR MAJHI
Designation : Sp. Lab Tech
Department : Diagnostics


Signature: 
Date: 4.12.21

Name : SOUVIK PAL
Designation : Lab. Tech.
Department : Diagnostics

Signature: 
Date: 4.12.21

Customer Authorizations:

Name : Subhadeep Pal
Designation : Senior Lab Tech.
Site : Bwedwan

Signature: 
Date: 4/12/21

Ortho Clinical Diagnostics

Complaint Information

SO No : 1015995

| Common Information | |
|---|---|
| Type*: Field Engineer | J Number*: J27000340 |
| Complaint Call Date & Time: 01-07-2022 13:26 | Created Time: 01-07-2022 13:32:54 |
| Nature of call*: Preventive Maintenance(PM) | Modified Time: 01-07-2022 13:32:54 |
| Customer Name: LUPIN HEALTHCARE LIMITED GANGPUR | Address: ,, |
| Contact Person*: UNKNOWN | Mobile No.*: 5555555555 |
| Email Id*: ABCD@GMAIL.COM | Lab Phone No: 5555555555 |
| Instrument Type*: RRC | End Usercode: 1397568 |
| Service cd Description: VITROS 250 SYSTEM - REFURB | Serial No: 27000340 |
| Observed details of Open? | Status: Closed |
| Instrument*: | PRR & SAP Order No: |
| SO No./ TRR NO: 98208966 | |


| Assign To and Share With Information | |
|--------------------------------------|---|
| Assign To: SATTWIK HALDAR | Share With: Aniruddha ,BIPLAB SAMANTA,Dipankar Mujumdar,JAYANTA PAUL,JAYANTA MADHAB SAIKIA,Kalyan Das,KAUSHIK DAS,Monuj Saikia,Mridul Deka,Pritish Biswas,Rahul Das ,Rajiv Roy,Ram Mishra,ROHIT KUMAR,Samananda Singh,SHOUVIK BHATTACHARYA,Soumitra Jena |

| Customer Details |
|------------------|
| Report No: |

| Problem Reported | |
|---------------------------------|--|
| Primary Error Code*: XPM | Primary Error Code PREVENTIVE MAINTENANCE |
| Second Error Code: | Description*: |
| Second Error Code Description: | Second Error Code Date & 00-00-0000 1:1 |
| Third Error Code: | Time: -- 1:1 |
| Third Error Code Description: | Third Error Code Date & Time: |
| | Third Error Code Description: |

| Customer Information |
|----------------------|
| Customer Message: |

| Customer Uploaded Images |
|--------------------------|
| |

| Call Closure Information | |
|--|---|
| Date of complaint closure: 07-07-2022 | Is verification of closure done by LS?: |
| Closure statement: | Probable root cause*: XPM |
| Preventive Action: | Remark: |
| LS / FE Signature:  | Attach Service Report/PRR: |

Ortho Clinical Diagnostics

Complaint Information

SO No : 1015995

| Spare Parts Requisition Information | | | | | | | | |
|-------------------------------------|-------------|-----------------------|----------|---------|-------------------|----------|------|--|
| PurchaseRequisition Id | Part Number | Part Name | Quantity | Source | SPRN No /Order No | Remarks | Mode | Status |
| 1016523 | 356500 | THERM AY | 1 | Company | 1000154105 | CONSUMED | | Closed Consumption status:Consumed Remarks :CONSUMED |
| 1016002 | 356501 | THERMISTR INCUBATR A | 1 | Company | 1000154105 | CONSUMED | | Closed Consumption status:Consumed Remarks :CONSUMED |
| 1016001 | 1h1745 | THERMO ELECTRIC ASSY | 1 | Company | 1000154105 | CONSUMED | | Closed Consumption status:Consumed Remarks :CONSUMED |
| 1016000 | 1h1744 | >THERMO ELECTRIC AY | 1 | Company | 1000154105 | CONSUMED | | Closed Consumption status:Consumed Remarks :CONSUMED |
| 1015999 | 994659 | TUBING | 1 | Company | 1000154105 | CONSUMED | | Closed Consumption status:Consumed Remarks :CONSUMED |
| 1015998 | J24003 | EVAPORATION CAP, SORT | 1 | Company | 1000154105 | CONSUMED | | Closed Consumption status:Consumed Remarks :CONSUMED |
| 1015997 | J18830 | >EJECT BLADE | 1 | Company | 1000154105 | CONSUMED | | Closed Consumption status:Consumed Remarks :CONSUMED |
| 1015996 | 999125 | WEAR PAD | 3 | Company | 1000154105 | CONSUMED | | Closed Consumption status:Consumed Remarks :CONSUMED |

| Customer Call Closure Information | |
|---|--------------------------------|
| Customer Comment*: INSTRUMENT WORKING NORMALLY | Customer Signature: <i>N.A</i> |

Ortho Clinical Diagnostics

Complaint Information

SO No : 1015995

| Update Call Information | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---------------------|-----------------|------------------------------------|---------------------|---------------------------|---------------------------|-------------------|------------------|---------------------------|-------------------|----------------|-------------------|--|----------------------------|-----------------------|--|--------------|---------|---------|----------------|----------------------------|-------------------------------------|---------------|------------------------------------|----------|---|
| Call updated by | Update Call Date | Solved By | If solved over phone ? Date & Time | Time spend on phone | Call Received Date & Time | Call Attended Date & Time | Actual Start Time | Actual End Time | Actual work hours | Observation hours | Travel hours | Waiting hours | Observed damage before service/Complaint Description | PHS | Diagnosis Description | Action Taken | Status | Product | Lot No. | Date of Expiry | Supporting Evidence if any | Action taken to resolve the problem | Other Specify | Is product replacement recommended | Quantity | |
| SATTWIK HALDAR | 2022-07-03 20:48:00 | Visit | 0000-00-00 0:0 | 0.00 | 2022-07-01 13:32 | 2022-07-03 10:50 | 2022-07-03 11:10 | 2022-07-03 17:20 | 6.10 | 0.30 | 7.00 | 0.20 | NO | No | XPM | PREVENTIVE MAINTENANCE DONE.RNADDRESSED ALL THE ISSUES.RNINSTRUMENT WORKING NORMALLY. | Job Complete | | 1234 | 0000-00-00 | | | | | | 0 |
| SATTWIK HALDAR | 2022-07-07 16:47:00 | Solved on phone | 2022-07-07 16:40 | 0.25 | 0000-00-00 | 0000-00-00 | 0000-00-00 0:0 | 0000-00-00 0:0 | 0.00 | 0.00 | 0.00 | 0.00 | NO | No | FOLLOW UP | FOLLOW UP AND GUIDED THE CUSTOMER OVER PHONE TO REPLACE THE AMBIENT THERMISTR .RNINSTRUMENT WORKING NORMALLY . | Job Complete | | 1234 | 0000-00-00 | | | | | | 0 |
| Total | | | | 25 Minutes | | | | | 6 Hours 10 Minutes | 30 Minutes | 7 Hours | 20 Minutes | Grand Total: | 14 Hours 25 Minutes | | | | | | | | | | | | |