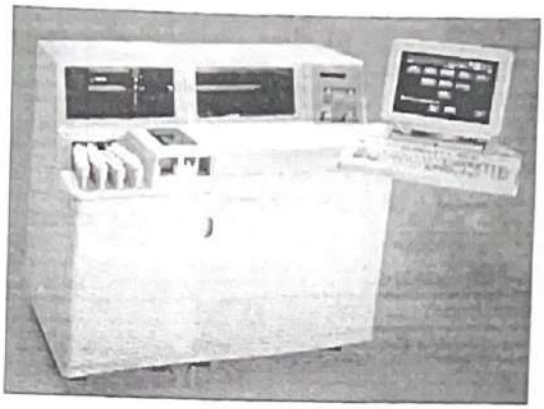
Ortho Clinical Diagnostics

INSTALLATION QUALIFICATION

For

VITROS 250



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

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I. Approval of the IQ procedure

Both Lupin Diagnostics Ltd and Ortho-Clinical Diagnostics are jointly responsible for the installation of VITROS 250, Sr. No. J27003358 in the Laboratory of Lupin Diagnostics Ltd.

Protocol Performed By: **Ortho-Clinical Diagnostics Representative**

Name	:	Mr. Vignesh	Signature: V. Vignesh
Designation	:	Service Engineer	
Company	:	Ortho-Clinical Diagnostics	Date: 20.03.2023

Validation Team from Lupin Diagnostics Ltd:

Name	: Sweani Nath Singh	Signature: S.	
Designation	: Manager	Date: 20/03/23	
Department	: Operations.		
Name	:	Signature:	
Designation	:	Date:	
Department	:		

Customer Authorizations:

Name : Sweani Nath Singh.
Designation: Manager.
Site : Bangalore.

Signature: S.
Date: 20/03/23

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 Lupin Diagnostics 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 Diagnostics Ltd.

III. SCOPE

This Installation Qualification protocol will be performed on the VITROS 250 bearing Sr. No. 27003510 located at Biochemistry Department, Lupin Diagnostics Ltd. 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 initiated and dated.

IV. Ancillary Information.

A. Certification of Purchase Order Compliance

I certify to the best of my knowledge, the instrument installed on Lupin Diagnostics Ltd is in compliance with the specifications of the purchase order.

Verified By: Vignesh **Date: 20.03.2023**

B. Utilities

Sr. No	Utility	Verified by	Date
1.	**Environmental conditions:**	Vignesh	20.03.2023
	a. Analyzer will be placed away from the direct sunlight.	Vignesh	20.03.2023
	b. Installation site shall be free from dust, significant vibrations and shall be well ventilated.	Vignesh	20.03.2023
	c. Installation site floor construction shall be able to support approximately 272 kg.	Vignesh	20.03.2023
	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 ± 2^{0}C.	Vignesh	20.03.2023
	e. The analyzer shall be kept away from strong electromagnetic sources and electrical interferences.	Vignesh	20.03.2023
	f. It will be kept near to the power sources.	Vignesh	20.03.2023
	g. Maximum relative humidity allowed up to 70%.	Vignesh	20.03.2023
	h. If the temperature and humidity fluctuations are not within the specified range, the analyzer cannot maintain data reliability.	Vignesh	20.03.2023
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)]	Vignesh	20.03.2023
3.	Electrical Outlets: Actual Voltage on site [AC 220-230 Volts 16A 50 HZ]	Vignesh	20.03.2023

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	Vignesh	20.03.2023
2.	Manufacturer's specifications are included	Yes	Vignesh	20.03.2023
3.	Accessories / Consumables are listed	Yes	Vignesh	20.03.2023
4.	Equipment manual from the manufacturer is documented	Yes	Vignesh	20.03.2023
5.	Manufacturer's Certificate attached	Yes	Vignesh	20.03.2023

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	Vignesh	20.03.2023
Manufacturer:	Ortho-Clinical Diagnostics	Vignesh	20.03.2023
Model:	*VITROS 250*	Vignesh	20.03.2023
Serial Number:	27003510	Vignesh	20.03.2023
Size (in cm):	115 (L) x 71 (W) x 120 (H)	Vignesh	20.03.2023
Power:	AC 220-230 V 16A 50Hz±2Hz	Vignesh	20.03.2023
Power consumption:	6880KW hours per year	Vignesh	20.03.2023

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.

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	➢ ...2 ports for printer ➢ ...One port for LIS
Regional settings	➢ Language English.

The system has a preloaded operating software

The Analyser has been installed satisfactorily : No Yes☐ ☐

Verified by : Vignesh

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. Vignesh

Designation: Service Engineer Signature:

Company : Ortho Clinical Diagnostics Date: 20.02.2023

Customer Authorizations:

Name : Swami Nath Singh.

Designation : Operations Manager Signature :

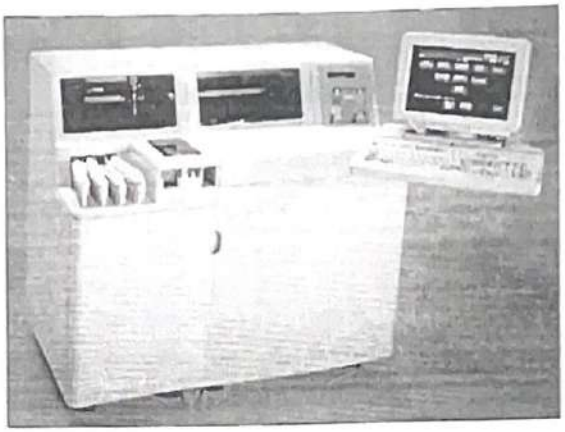
Organization: Unpin Diagnostics. Date: 20/02/23

Ortho Clinical Diagnostics

OPERATION QUALIFICATION

For

VITROS 250



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

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I. Approval of the OQ procedure

Both Lupin Diagnostics Ltd and Ortho Clinical Diagnostics are jointly responsible for the Operation qualification of VITROS 250, Sr. No. 27003358 in Biochemistry Laboratory of Lupin Diagnostics Ltd, as per the Operational Qualification Protocol.

Protocol Performed By: **Ortho Clinical Diagnostics Representative**

Name	:	Mr. Dilliram Silpakar	Signature:
Designation	:	Zonal Manager – Ortho Care	
Company	:	Ortho Clinical Diagnostics	Date: 5.04.2023

Validation Team from Lupin Diagnostics Ltd:

Name	:	Sweani Nath Singh	Signature:
Designation	:	Manager	Date: 05/04/23.
Department	:	Operations	
Name	:		Signature:
Designation	:		Date:
Department	:		

Customer Authorizations:

Name	:	Sweani Nath Singh.	Signature :
Designation	:	Manager.	Date: 05/04/23
Site	:	Bangalore.	

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 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. 27003358 located at Biochemistry Department, Lupin Diagnostics Ltd. 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 initiated and dated.

OPERATIONAL QUALIFICATION:

A. **Instrument Identification**

a. **Model Name** VITROS 250

2. **Serial Number** 27003358

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	Dilliram 05.04.2023
02	Daily maintenance	To clean appropriate modules so as to maintain accuracy and precision	Dilliram 05.04.2023
03	Inventory of reagents and consumables	To check the slide supply of installed Vitros 250	Dilliram 05.04.2023
04	Calibration for the assays used	To calibrate the system for every new lot of assay	Dilliram 05.04.2023
05	QC check	To confirm that systems, reagents & consumables are acceptable and working within specifications for each assay used	Dilliram 05.04.2023
06	Sample programming and Analysis	To run the samples	Dilliram 05.04.2023

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 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

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	Dilliram	05.04.2023
02	Clean ERF Reservoir Holder & Base	Dilliram	05.04.2023
03	Replace ERF Reservoir	Dilliram	05.04.2023
04	Replace ERF Tip	Dilliram	05.04.2023
05	Clean ERF Tip Sleeve	Dilliram	05.04.2023
06	Clean IWF Reservoir Holder & Base	Dilliram	05.04.2023
07	Replace IWF Reservoir	Dilliram	05.04.2023
08	Replace IWF Tip	Dilliram	05.04.2023
09	Clean IWF Tip Sleeve	Dilliram	05.04.2023
10	Load supplies and remove outdated and empty reagents	Dilliram	05.04.2023
11	Perform Quality Control	Dilliram	05.04.2023

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

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.	Dilliram	05.04.2023
02	Verify the status of reagents loaded.	Dilliram	05.04.2023

Acceptance criteria:

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

PARAMETER ✓PASS FAIL

Parameter values for verification: No Error codes

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	Dilliram	05.04.2023
02	Creating QC file	Dilliram	05.04.2023
03	QC sample programming and analysis	Dilliram	05.04.2023
04	Verification of QC results obtained	Dilliram	05.04.2023

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

PARAMETER ~~PASS~~ FAIL

Parameter values for verification: QC values within ± 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	Dilliram	05.04.2023
02	Programming samples	Dilliram	05.04.2023
03	Unloading the samples	Dilliram	05.04.2023
04	Viewing samples in process	Dilliram	05.04.2023
05	Review results: Monitoring results	Dilliram	05.04.2023

Acceptance criteria: Samples Analysis & Report without any error

PARAMETER PASS FAIL

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. Dilliram Silpakar from Ortho Clinical Diagnostics has conducted the training.

Sr. No.	Training program	Initials	Date
1.	Instrument Setup	Dilliram	05.04.2023
2.	System Operation	Dilliram	05.04.2023
3.	Calibration	Dilliram	05.04.2023
4.	Quality Control	Dilliram	05.04.2023
5.	Maintenance	Dilliram	05.04.2023
6.	Basic trouble shooting	Dilliram	05.04.2023

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. Dilliram Silpakar

Designation : Zonal Manager - Ortho Care Signature:

Company : Ortho Clinical Diagnostics Date: 5.04.2023.

Customer Authorizations:

Name : Swami Nath Singh.

Designation : Manager Signature :

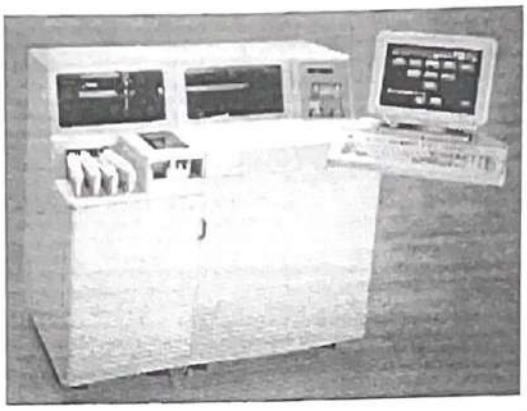
Organization : Operations- Date : 05/04/23

Ortho Clinical Diagnostics

PERFORMANCE QUALIFICATION

For

VITROS 250



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

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III. Scope

This Performance Qualification protocol will be performed on the VITROS 250 Serial No. 27003358 located in Biochemistry Department of Biochemistry located in Lupin Diagnostics Ltd. 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.

I. Approval of the PQ procedure

Both Lupin Diagnostics Ltd and Ortho Clinical Diagnostics are jointly responsible for conducting the Performance Check of the Biochemistry Analyzer, Model – VITROS 250, Serial. No.27003358 in the Biochemistry Department of Lupin Diagnostics Ltd as per the attached protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : Dilliram Silpakar Signature:

Designation : Zonal Manager - Ortho Care Date: 14.4.2023

Company : Ortho Clinical Diagnostics

Validation Team from Lupin Diagnostics Ltd:

Name : Swami Nath Singh Signature:

Designation : Manager Date: 14/04/23.

Department : Operations

Name :

Designation :

Department :

Signature:

Date:

Customer Authorizations:

Name : Swami Nath Singh.

Designation : Manager

Site : Bangalore.

Signature:

Date : 14/04/23

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 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 Diagnostics Ltd and Ortho-Clinical Diagnostics.

IV. Performance Qualification

A. Instrument Identification

		Verified Date
1. Model Name	VITROS 250	06.04.2023
2. Serial Number	27003358	06.04.2023

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	Dilliram 06.04.2023
02	Accuracy Study	To compare the obtained value with true values of processed control.	Dilliram 06.04.2023
03	Precision Study	To check the precision performance of the equipment	Dilliram 06.04.2023

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);
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 Pass/Fail	Done By Date
01	Preparing Liquid or Lyophilized control fluids	"Instructions for use" of QC material	Pass	Dilliram 06.04.2023
02	Creating QC file	Quality Control – Define control fluids	Pass	Dilliram 06.04.2023
03	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	Pass	Dilliram 06.04.2023

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 Pass/Fail	Done By Date
01	Preparing Liquid or Lyophilized control fluids	'Instructions for use' of QC material	Pass	Dilliram 06.04.2023
02	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	Pass	Dilliram 06.04.2023
03	Accuracy Analysis	Compare the obtained Q.C value with mean of expected value as mentioned in the Performance verifier / QC Value chart.	Pass	Dilliram 06.04.2023

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 ALTv (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	ALTv	PV I	≤ 2.3 SD
02	Amylase	PV I	≤ 3.9 SD
03	Sodium	PV I	≤ 0.8% CV
04	Potassium	PV II	≤ 1.0% CV
05	CRBM	PV III	≤ 4 % CV

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 : Dilliram Silpakar
Designation : Zonal Manager – Ortho Care
Company : Ortho Clinical Diagnostics

Signature :
Date: 14.04.2023

Validation Team from Lupin Diagnostics Ltd:

Name : Sumani Nath Singh Signature:
Designation : Manager Date: 14/04/23
Department : Operations

Name : Signature:
Designation : Date:
Department :

Customer Authorizations:

Name : Sumani Nath Singh.
Designation: Manager.
Site : Bangalore.

Signature:
Date: 14/04/23.