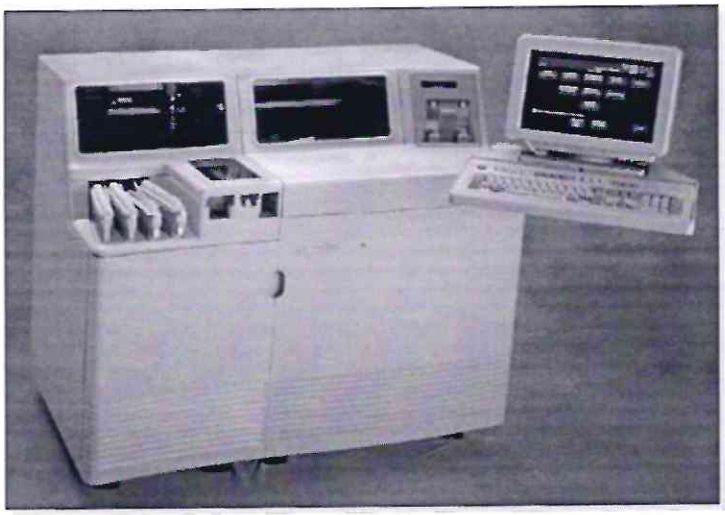
INSTALLATION QUALIFICATION

For

VITROS 250



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

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I. Approval of the IQ procedure

Both **Lupin Diagnostics, Bhopal** and Ortho-Clinical Diagnostics are jointly responsible for the installation of ***VITROS 250,*** **Sr. No. J6183** in the Biochemistry Laboratory of **Lupin Diagnostics, Bhopal**

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

Name	:	Vaibhav James	Signature:
Designation	:	Sr.Territory Manager	
Company	:	Ortho-Clinical Diagnostics	Date: 03-12-22

Validation Team from Lupin Diagnostics, Bhopal:

Name	: Manish patel	Signature:	Manish
Designation	: Lab supervisor	Date:	03/12/22
Department	: Biochemistry		
Name	: Salman Shaikh	Signature :	
Designation	: Lab technician	Date :	03/12/22
Department	: Biochemistry		

Customer Authorizations:

Name : Manish patel
Designation : Lab supervisor
Site : Bhopal

Signature : Manish
Date: 03/12/22

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 Diagnostics, Bhopal**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, Bhopal**.

III. SCOPE

This Installation Qualification protocol will be performed on the VITROS 250 bearing Sr. No. J6183 located at Biochemistry Department of **Lupin Diagnostics, Bhopal**. 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 **Lupin Diagnostics, Bhopal** is in compliance with the specifications of the purchase order.

Verified By: Vaibhav James **Date: 03-12-22**

B. Utilities

Sr. No	Utility	Verified by	Date
1.	**Environmental conditions:**		
	a. Analyzer will be placed away from the direct sunlight.		**03-12-22**
	b. Installation site shall be free from dust, significant vibrations and shall be well ventilated.		**03-12-22**
	c. Installation site floor construction shall be able to support approximately 272 kg.		**03-12-22**
	d. Room temperature will be maintained between 15^0C to 27^0C and the temperature fluctuation during analysis shall not be more than ± 2^0C.		**03-12-22**
	e. The analyzer shall be kept away from strong electromagnetic sources and electrical interferences.		**03-12-22**
	f. It will be kept near to the power sources.		**03-12-22**
	g. Maximum relative humidity allowed up to 70%.		**03-12-22**
	h. If the temperature and humidity fluctuations are not within the specified range, the analyzer cannot maintain data reliability.		**03-12-22**
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)]		**03-12-22**
3.	Electrical Outlets: Actual Voltage on site [AC 220-230 Volts 16A 50 HZ]		**03-12-22**

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 / No		**03-12-22**
2.	Manufacturer's specifications are included	Yes / No		**03-12-22**
3.	Accessories / Consumables are listed	Yes / No		**03-12-22**
4.	Equipment manual from the manufacturer is documented	Yes / No		**03-12-22**
5.	Manufacturer's Certificate attached	Yes / No		**03-12-22**

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		**03-12-22**
Manufacturer:	Ortho-Clinical Diagnostics		**03-12-22**
Model:	*VITROS 250*		**03-12-22**
Serial Number:	J15977		**03-12-22**
Size (in cm):	115 (L) x 71 (W) x 120 (H)		**03-12-22**
Power:	AC 220-230 V 16A 50Hz±2Hz		**03-12-22**
Power consumption:	6880KW hours per year		**03-12-22**

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 : Vaibhav James

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 : Vaibhav James

Designation : Sr.Territory Manager Signature:

Company: Ortho Clinical Diagnostics Date: 03-12-22

Customer Authorizations:

Name : Manish patel

Designation : Lab supervisor Signature : Manish

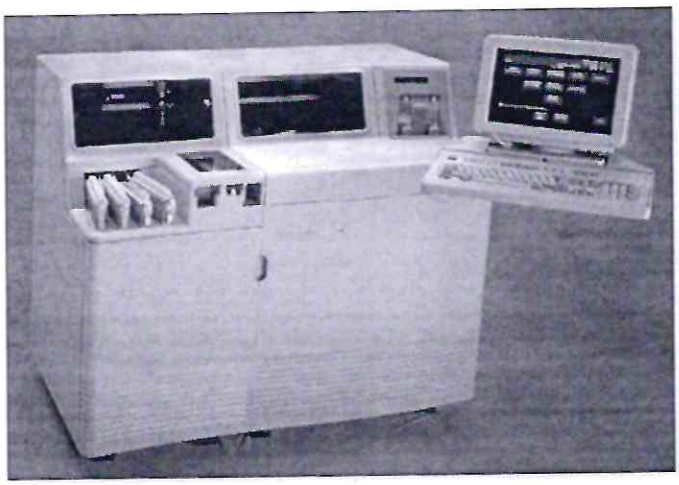
Organization : Bhopal Lupin Diagnostics Date : 03/12/22

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 Ltd, Bhopal and Ortho Clinical Diagnostics are jointly responsible for the operation qualification of VITROS 250/350, **Sr. No. 25015361** in the Laboratory of Lupin Diagnostics Ltd, Bhopal, as per the Operational Qualification Protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name	:	Mr. Nikhil Dandekar	Signature:
Designation	:	Application Specialist	
Company	:	Ortho Clinical Diagnostics	Date: 03/12/22

Validation Team from Lupin Diagnostics Ltd, Bhopal**:**

Name	:	Manisha patel	Signature: Manisha
Designation	:	Lab supervisor	Date: 03/12/2022
Department	:	Department of Biochemistry	
Name	:	salman shaikh	Signature:
Designation	:	Lab technician	Date : 03/12/2022
Department	:	Department of Biochemistry	

Customer Authorizations:

Name	:	Manisha patel	Manisha
Designation:		Lab supervisor	Signature :
Site	:	Bhopal	Date: 03/12/2022

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, Bhopal, 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 250/350, Sr. No. 25015361 located at Biochemistry Department, Lupin Diagnostics Ltd, Bhopal. 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 250/350**

2. **Serial Number** **25015361**

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.Nikhil Dandekar Date – 03/12/2022
02	Daily maintenance	To clean appropriate modules to maintain accuracy and precision	Mr.Nikhil Dandekar Date – 03/12/2022
03	Inventory of reagents and consumables	To check the slide supply of installed Vitros 350	Mr.Nikhil Dandekar Date – 03/12/2022
04	Calibration for the assays used	To calibrate the system for every new lot of assays	Mr.Nikhil Dandekar Date – 03/12/2022
05	QC check	To confirm that systems, reagents & consumables are acceptable and working within specifications for each assay used	Mr.Nikhil Dandekar Date – 03/12/2022
06	Sample programming and Analysis	To run the samples	Mr.Nikhil Dandekar Date – 03/12/2022

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

	PARAMETER	**PASS**	**FAIL**
Parameter values for verification: "READY" on Status console		**PASS**	

Manisg

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.Nikhil Dandekar	03/12/2022
02	Clean ERF Reservoir Holder & Base	Mr.Nikhil Dandekar	03/12/2022
03	Replace ERF Reservoir	Mr.Nikhil Dandekar	03/12/2022
04	Replace ERF Tip	Mr.Nikhil Dandekar	03/12/2022
05	Clean ERF Tip Sleeve	Mr.Nikhil Dandekar	03/12/2022
06	Clean IWF Reservoir Holder & Base	Mr.Nikhil Dandekar	03/12/2022
07	Replace IWF Reservoir	Mr.Nikhil Dandekar	03/12/2022
08	Replace IWF Tip	Mr.Nikhil Dandekar	03/12/2022
09	Clean IWF Tip Sleeve	Mr.Nikhil Dandekar	03/12/2022
10	Load supplies and remove outdated and empty reagents	Mr.Nikhil Dandekar	03/12/2022
11	Perform Quality Control	Mr.Nikhil Dandekar	03/12/2022

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

Manish

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.Nikhil Dandekar	03/12/2022
02	Verify the status of reagents loaded.	Mr.Nikhil Dandekar	03/12/2022

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 assays

Procedure:

Sr. No.	Activity	Done By	Date
01	Reconstitution of the cal kits for appropriate reagent	Mr.Nikhil Dandekar	03/12/2022
02	Performing Calibration with calibration programming screen	Mr.Nikhil Dandekar	03/12/2022
03	Verification of Calibration report	Mr.Nikhil Dandekar	03/12/2022

Acceptance criteria: "Calibration Successful" should come on screen

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

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.Nikhil Dandekar	03/12/2022
02	Creating QC file	Mr.Nikhil Dandekar	03/12/2022
03	QC sample programming and analysis	Mr.Nikhil Dandekar	03/12/2022
04	Verification of QC results obtained	Mr.Nikhil Dandekar	03/12/2022

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

PARAMETER **PASS** **FAIL**

Parameter values for verification: QC values within ± 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.Nikhil Dandekar	03/12/2022
02	Programming samples	Mr.Nikhil Dandekar	03/12/2022
03	Unloading the samples	Mr.Nikhil Dandekar	03/12/2022
04	Viewing samples in process	Mr.Nikhil Dandekar	03/12/2022
05	Review results: Monitoring results	Mr.Nikhil Dandekar	03/12/2022

Acceptance criteria: Samples Analysis & Report without any error

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

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. Nikhil Dandekar from Ortho Clinical Diagnostics has conducted the training.

Sr. No.	Training program	Initials	Date
1.	Instrument Setup	Mr.Nikhil Dandekar	03/12/2022
2.	System Operation	Mr.Nikhil Dandekar	03/12/2022
3.	Calibration	Mr.Nikhil Dandekar	03/12/2022
4.	Quality Control	Mr.Nikhil Dandekar	03/12/2022
5.	Maintenance	Mr.Nikhil Dandekar	03/12/2022
6.	Basic trouble shooting	Mr.Nikhil Dandekar	03/12/2022

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	Mr. Manish Patel	CC	Mr.Nikhil Dandekar	03/12/2022
2	Mr. Salman Sheikh	CC	Mr.Nikhil Dandekar	03/12/2022
3	Ms. Pooja Surjuse	CC	Mr.Nikhil Dandekar	03/12/2022
4	Ms. Sapana Kaurav	CC	Mr.Nikhil Dandekar	03/12/2022

V. COMMENTS:

Manish

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. Nikhil Dandekar

Signature:

Designation : Application Specialist

Company : Ortho Clinical Diagnostics

Date: 03/12/2022

Customer Authorizations:

Name : Mahesh patel

Designation : Lab supervisor

Organization : Lupin Diagnostics

Signature : Mahesh

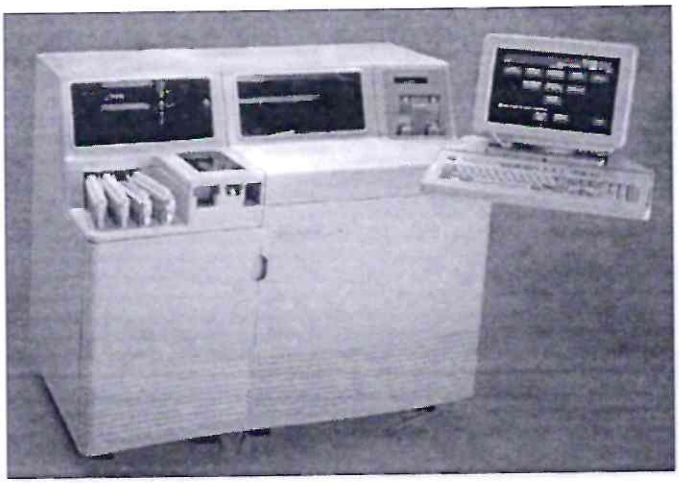
Date : 03/12/2022

Ortho Clinical Diagnostics

PERFORMANCE QUALIFICATION

For

VITROS 350



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

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I. Approval of the PQ procedure

Both Lupin Diagnostics Ltd, Bhopal. and Ortho Clinical Diagnostics are jointly responsible for conducting the Performance Check of the Biochemistry Analyzer, Model – VITROS 350, Serial. No. 25015361 in the Biochemistry Department of Lupin Diagnostics Ltd, Bhopal. as per the attached protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name	:	Mr. Nikhil Dandekar	Signature:
Designation	:	Application Specialist	
Company	:	Ortho Clinical Diagnostics	Date: 04/12/2022

Validation Team from Lupin Diagnostics Ltd, Bhopal.:

Name	:	Manish patel	Signature: Manish
Designation	:	Lab supervisor	Date: 04/12/2022
Department	:	Biochemistry	
Name	:	salman shaikh	Signature:
Designation	:	Lab technician	Date: 04/12/2022
Department	:	Biochemistry	

Customer Authorizations:

Name	:	Manish patel	Signature : Manish
Designation:		Lab supervisor	
Site	:	Bhopal	Date : 04/12/2022

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, Bhopal. 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, Bhopal and Ortho-Clinical Diagnostics.

III. Scope

This Performance Qualification protocol will be performed on the VITROS 350 Serial No. 25015361 located in Biochemistry Department of Lupin Diagnostics Ltd, Bhopal. 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	04/12/2022
2. Serial Number	J25015361	04/12/2022

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	04/12/2022
02	Accuracy Study	To compare the obtained value with true values of processed control.	04/12/2022
03	Precision Study	To check the precision performance of the equipment	04/12/2022

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);

Sr. No.	Activity	Procedure done as per the protocol defined in VITROS 350 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	Nikhil Dandekar 04/12/2022
02	Creating QC file	Quality Control – Define control fluids	PASS	Nikhil Dandekar 04/12/2022
03	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	PASS	Nikhil Dandekar 04/12/2022

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 Pass/Fail	Done By Date
01	Preparing Liquid or Lyophilized control fluids	'Instructions for use' of QC material	PASS	Mr. .Nikhil Dandekar 04/12/2022
02	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	PASS	Mr. Nikhil Dandekar 04/12/2022
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. .Nikhil Dandekar 04/12/2022

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	≤ 0.8% CV
04	Potassium	PV I	≤ 1.0% CV
05	CRBM	TDM	≤ 4 % CV

COMMENTS:

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. Nikhil Dandekar	Signature:
Designation	:	Application Specialist	
Company	:	Ortho Clinical Diagnostics	Date: 04/12/2022

Validation Team from Lupin Diagnostics Ltd, Indore.:

Name	: Manish patel	Signature:	Manish
Designation	: Lab supervisor	Date:	04/12/2022
Department	: Biochemistry		
Name	: Salman Shaikh	Signature:	
Designation	: Lab technician	Date:	04/12/2022
Department	: Biochemistry		

Customer Authorizations:

Name	: Manish patel	Signature:	Manish
Designation:	Lab supervisor		
Site	: Bhopal	Date :	04/12/2022

Ortho Clinical Diagnostics

TO WHOM SO IT MAY EVER CONCERN

CALIBRATION CERTIFICATE

This is to certify that the system calibration was performed on **13-December-2023** for the instrument, **VITROS V250** Biochemistry Fully Automatic Analyzer, installed at **Lupin Diagnostics, Bhopal** bearing Serial **No. J6183.**

The calibration process includes optics calibration, and the performance verification tests as per the manufacturer's procedures.

Validity: Six months for Optics Calibration.

Ortho Clinical Diagnostics India Pvt. Ltd.

Vaibhav James
Sr. Territory Manager
Ortho Care- Service

Ortho Clinical Diagnostics India Private Limited
Regd Office 403, Leela Business Park, Andheri Kurla Road, Andheri - East, Mumbai – 400059.
T +912267879300 / F:+912267879333
Website: www.orthoclinicaldiagnostics.com

CALIBRATION REPORT

Name of Instrument	:	**VITROS 250**
Serial Number	:	**J6183**
Installed at	:	**Lupin Diagnostics, Bhopal**
Department	:	**Biochemistry**
Validity	:	**6-months**
Date of Report	:	**13-December-2023**

SECTION / TEST **RESULT**

SAMPLE METERING

a. Leak Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
The Dispense Leak Rate must < 0.210 V dc	Pass
The read-to-read leak rate should be < 0.030 V dc	Pass

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Hysteresis Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
The Maximum Hysteresis Value must be < 5.0 steps	Pass
Combined Hysteresis values of any 3 consecutive readings must be < 9.0 steps	Pass

REFERENCE METERING

a. Leak Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
The Aspirate Value < 0.175 V dc	Pass
The Ambient Pressure must in range of 2.25–2.75 V dc	Pass
Consecutive reading should not fall > 0.030 V dc	Pass

b. Hysteresis Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
Mean Value of Hysteresis should be <= 5.0 V dc	Pass
Maximum Value of Hysteresis should be <= 10.0 V dc	Pass

IMMUNO WASH METERING

a. Leak Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
The Aspirate Value < 0.175 V dc	Pass
The Ambient Pressure must in range of 2.25–2.75 V dc	Pass
Consecutive reading should not fall > 0.030 V dc	Pass

b. Hysteresis Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
Mean Value of Hysteresis should be <= 5.0 V dc	Pass
Maximum Value of Hysteresis should be <= 10.0 V dc	Pass

INCUBATOR

a. Pad Reflectance Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
Grand Mean Value must be in range of 0.75 – 0.99	Pass
Range must be <= 0.03	Pass

ELECTROMETER

a. Basic Mode Verification Test: PASS / FAIL

Parameters	Test 1	Test 2	Test 3	Test 4
Input	Test	Test	Test	Test
Source	Zero 0	Zero 0	Ref 1	Ref 1
Polarity	Neg 0	Neg 0	Neg 0	Neg 0
Ohm -	Low 0	High 1	Low 0	High 1
Ohm +	Low 0	High 1	Low 0	High 1
Read Type	One 0	One 0	One 0	One 0
Specifications	**0.0 mv ± 2.4mv**	**0.0 mv ± 2.4mv**	**-200 mv ± 8mv**	**-200 mv ± 8mv**

REFLECTOMETER

a. IRIS Adjustment : PASS / FAIL

SPECIFICATIONS	OBSERVATION
Lamp Output range 3.5 to 9.0 across all Filters	Pass

b. Static Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
All "%CV*K" must be <= 18.0	Pass
All "SD Dark" must be <= 1.3	Pass

c. Interleaved Static Test: PASS / FAIL

SPECIFICATIONS	OBSERVATION
All "%CV*K" must be <= 18.0	Pass
All "SD Dark" must be <= 1.3	Pass

d. Dynamic Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
All "%CV*K" must be <= 18.0	Pass
All "SD Dark" must be <= 1.3	Pass

OPTICS: CORRECTION FACTOR

SPECIFICATIONS	OBSERVATION
Automatic - set by software	Pass

FILTER nm	WHITE C.F.	BLACK C. F.
340	0.479	0.002
400	0.941	0.000
460	0.923	0.000
540	0.955	0.001
600	0.988	0.001
630	0.942	0.000
670	0.944	0.002
680	0.966	0.001

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Vaibhav James
Sr. Territory Manager
Ortho Care-Service

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