Ortho Clinical Diagnostics

INSTALLATION QUALIFICATION

For

VITROS 350

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 Diagnostics Ltd. Jalna and Ortho-Clinical Diagnostics are jointly responsible for the installation of *VITROS 350*, Sr. No. J27002696 .

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

Name	:	Mr. Deovrath Duratkar	Signature:
Designation	:	Service Engineer	
Company	:	Ortho-Clinical Diagnostics	Date: 24/05/2023

Validation Team from Lupin Diagnostics Ltd. Jalna:

Name	:	Santosh Mohan Bhaskare	Signature:
Designation	:	Lab Tech.	Date: 24/05/2023
Department Name	:	Amol Rajaram Adle	Signature :
Designation	:	Lab Tech	Date : 24/05/2023
Department	:	Department of Biochemistry	

Customer Authorizations:

Name	:	Dr. Arunkumar Chaudhari.	Signature :
Designation:		MD (PATHOLOGY)	Date: 24/05/2023
Site	:	HLM – JALNA. LUPIN DIAGNOSTICS.	

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 Ltd. Jalna 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. Jalna .

III. SCOPE

This Installation Qualification protocol will be performed on the VITROS 350 bearing Sr. No.27002696 located at Lupin Diagnostics Ltd. Jalna. 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 at Lupin Diagnostics Ltd. Jalna, is in compliance with the specifications of the purchase order.

Verified By: Mr. Deovrath Duratkar **Date: 24/05/2023**

B. Utilities

Sr. No	Utility	Verified by	Date
1.	**Environmental conditions:**		
	a. Analyzer will be placed away from the direct sunlight.	Mr. Deovrath Duratkar	24/05/2023
	b. Installation site shall be free from dust, significant vibrations and shall be well ventilated.	Mr. Deovrath Duratkar	24/05/2023
	c. Installation site floor construction shall be able to support approximately 272 kg.	Mr. Deovrath Duratkar	24/05/2023
	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.	Mr. Deovrath Duratkar	24/05/2023
	e. The analyzer shall be kept away from strong electromagnetic sources and electrical interferences.	Mr. Deovrath Duratkar	24/05/2023
	f. It will be kept near to the power sources.	Mr. Deovrath Duratkar	24/05/2023
	g. Maximum relative humidity allowed up to 70%.	Mr. Deovrath Duratkar	24/05/2023
	h. If the temperature and humidity fluctuations are not within the specified range, the analyzer cannot maintain data reliability.	Mr. Deovrath Duratkar	24/05/2023
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)]	Mr. Deovrath Duratkar	24/05/2023

3.	Electrical Outlets: Actual Voltage on site [AC 220-230 Volts 16A 50 HZ]	Mr. Deovrath Duratkar	24/05/2023

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 / No	Mr. Deovrath Duratkar	24/05/2023
2.	Manufacturer's specifications are included	Yes / No	Mr. Deovrath Duratkar	24/05/2023
3.	Accessories / Consumables are listed	Yes / No	Mr. Deovrath Duratkar	24/05/2023
4.	Equipment manual from the manufacturer is documented	Yes / No	Mr. Deovrath Duratkar	24/05/2023
5.	Manufacturer's Certificate attached	Yes / No	Mr. Deovrath Duratkar	24/05/2023

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	Mr. Deovrath Duratkar	24/05/2023
Manufacturer:	Ortho-Clinical Diagnostics	Mr. Deovrath Duratkar	24/05/2023
Model:	*VITROS 350*	Mr. Deovrath Duratkar	24/05/2023
Serial Number:	25015038	Mr. Deovrath Duratkar	24/05/2023
Size (in cm):	115 (L) x 71 (W) x 120 (H)	Mr. Deovrath Duratkar	24/05/2023
Power:	AC 220-230 V 16A 50Hz±2Hz	Mr. Deovrath Duratkar	24/05/2023
Power consumption:	6880KW hours per year	Mr. Deovrath Duratkar	24/05/2023

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 Analyzer has been installed satisfactorily: No **Yes**

Verified by : Mr. Deovrath Duratkar

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. Deovrath Duratkar

Designation: Service Engineer Signature:

Company: Ortho Clinical Diagnostics Date: 24/05/2023

Customer Authorizations:

Name : Dr. Amrutkumar Chaudhary.

Designation: MD (PATHOLOGY). Signature:

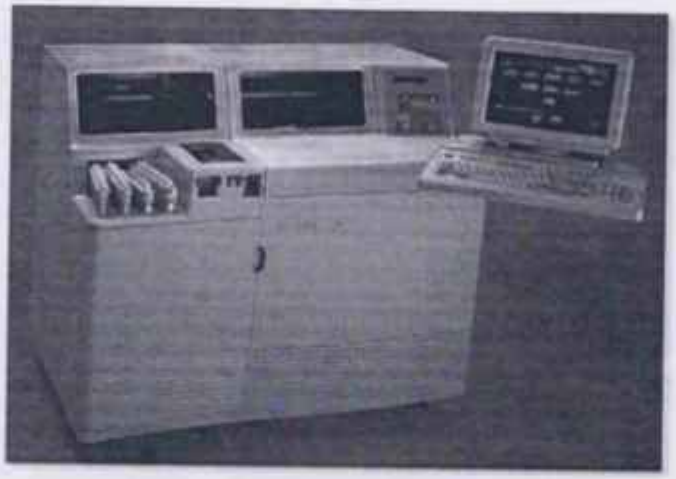
Organization: HLM - JALNA Date : 24/05/2023.
LUPIN DIAGNOSTICS.

Ortho Clinical Diagnostics

OPERATION QUALIFICATION

For

VITROS 350



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 IQ procedure

Both and Lupin Diagnostics Ltd. Jalna Ortho Clinical Diagnostics are jointly responsible for the operation qualification of VITROS 350, Sr. No. 27002696 in the Laboratory of Lupin Diagnostics Ltd. Jalna 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: 25/05/2023

Validation Team from Lupin Diagnostics Ltd. Jalna :

Name : Santosh Mohan Bhaskar Signature:

Designation : Lab. Tech

Department : Department of Biochemistry

Date: 25/05/2023

Name : Amol Rajaram Adh Signature:

Designation : Lab Tech

Department : Department of Biochemistry

Date : 25/05/2023

Customer Authorizations:

Name : Dr. Anandkumar Chaki.

Designation: MD (PATHOLOGY)

Site : HLM – JALNA LUPIN DIAGNOSTICS.

Signature :

Date: 25/05/2023

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. Jalna 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 350, Sr. No. 27002696 located at Biochemistry Department, Lupin Diagnostics Ltd. Jalna .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 350

2. Serial Number : 27002696

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 – 25/05/2023
02	Daily maintenance	To clean appropriate modules to maintain accuracy and precision	Mr. Nikhil Dandekar Date – 25/05/2023
03	Inventory of reagents and consumables	To check the slide supply of installed Vitros 350	Mr. Nikhil Dandekar Date – 25/05/2023
04	Calibration for the assays used	To calibrate the system for every new lot of assays	Mr. Nikhil Dandekar Date – 25/05/2023
05	QC check	To confirm that systems, reagents & consumables are acceptable and working within specifications for each assay used	Mr. Nikhil Dandekar Date – 25/05/2023
06	Sample programming and Analysis	To run the samples	Mr. Nikhil Dandekar Date – 25/05/2023

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 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	

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	25/05/2023
02	Clean ERF Reservoir Holder & Base	Mr. Nikhil Dandekar	25/05/2023
03	Replace ERF Reservoir	Mr. Nikhil Dandekar	25/05/2023
04	Replace ERF Tip	Mr. Nikhil Dandekar	25/05/2023
05	Clean ERF Tip Sleeve	Mr. Nikhil Dandekar	25/05/2023
06	Clean IWF Reservoir Holder & Base	Mr. Nikhil Dandekar	25/05/2023
07	Replace IWF Reservoir	Mr. Nikhil Dandekar	25/05/2023
08	Replace IWF Tip	Mr. Nikhil Dandekar	25/05/2023
09	Clean IWF Tip Sleeve	Mr. Nikhil Dandekar	25/05/2023
10	Load supplies and remove outdated and empty reagents	Mr. Nikhil Dandekar	25/05/2023
11	Perform Quality Control	Mr. Nikhil Dandekar	25/05/2023

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 **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. Nikhil Dandekar	25/05/2023
02	Verify the status of reagents loaded.	Mr. Nikhil Dandekar	25/05/2023

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	25/05/2023
02	Performing Calibration with calibration programming screen	Mr. Nikhil Dandekar	25/05/2023
03	Verification of Calibration report	Mr. Nikhil Dandekar	25/05/2023

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. Nikhil Dandekar	25/05/2023
02	Creating QC file	Mr. Nikhil Dandekar	25/05/2023
03	QC sample programming and analysis	Mr. Nikhil Dandekar	25/05/2023
04	Verification of QC results obtained	Mr. Nikhil Dandekar	25/05/2023

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

PARAMETER **PASS** **FAIL**

Parameter values for verification: QC values within ± 2SD **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	25/05/2023
02	Programming samples	Mr. Nikhil Dandekar	25/05/2023
03	Unloading the samples	Mr. Nikhil Dandekar	25/05/2023
04	Viewing samples in process	Mr. Nikhil Dandekar	25/05/2023
05	Review results: Monitoring results	Mr. Nikhil Dandekar	25/05/2023

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	25/05/2023
2.	System Operation	Mr. Nikhil Dandekar	25/05/2023
3.	Calibration	Mr. Nikhil Dandekar	25/05/2023
4.	Quality Control	Mr. Nikhil Dandekar	25/05/2023
5.	Maintenance	Mr. Nikhil Dandekar	25/05/2023
6.	Basic trouble shooting	Mr. Nikhil Dandekar	25/05/2023

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	AJAY WAYAL	CC	Mr. Nikhil Dandekar	25/05/2023
2	SANTOSH BHASKAR	CC	Mr. Nikhil Dandekar	25/05/2023
3	KAVITA BALAP	CC	Mr. Nikhil Dandekar	25/05/2023
4	AKASH DUBEY	CC	Mr. Nikhil Dandekar	25/05/2023
5	ANAND GHADAGE	CC	Mr. Nikhil Dandekar	25/05/2023
6	AMOL AADHE	CC	Mr. Nikhil Dandekar	25/05/2023

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. Nikhil Dandekar

Signature:

Designation : Application Specialist

Company : Ortho Clinical Diagnostics

Date: 25/05/2023

Customer Authorizations:

Name : Dr. Anandkumar Chavan

Designation : MD (PATHOLOGY)

Signature :

Organization : HLM – JALNA
LUPIN DIAGNOSTICS

Date : 25/05/2023

Ortho Clinical Diagnostics

PERFORMANCE QUALIFICATION

For

VITROS 350

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

I. Approval of the PQ procedure

Both Lupin Diagnostics Ltd. Jalna. and Ortho Clinical Diagnostics are jointly responsible for conducting the Performance Check of the Biochemistry Analyzer, Model – VITROS 350, Serial. No. 27002696 in the Biochemistry Department of Lupin Diagnostics Ltd. Jalna. 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: 26/05/2023

Validation Team from Lupin Diagnostics Ltd. Jalna.:

Name	: Santosh Mohan Bhaskare	Signature:	
Designation	: Lab Tech.	Date:	26/05/2023
Department	: Department of Biochemistry		
Name	: Amol Pasanam Adke	Signature:	
Designation	: Lab Tech	Date:	26/05/2023
Department	: Biochemistry		

Customer Authorizations:

Name	: Dr. Anandkumar Chavan.		
Designation:	MD (PATHOLOGY)	Signature :	
Site	: HLM – JALNA. LUPIN DIAGNOSTICS.	Date :	26/05/2023

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. Jalna. 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. Jalna. and Ortho-Clinical Diagnostics.

III. Scope

This Performance Qualification protocol will be performed on the VITROS 350 Serial No. 27002696 located in Biochemistry Department of Lupin Diagnostics Ltd. Jalna. 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	26/05/2023
2. Serial Number	J27002696	26/05/2023

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	26/05/2023
02	Accuracy Study	To compare the obtained value with true values of processed control.	26/05/2023
03	Precision Study	To check the precision performance of the equipment	26/05/2023

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 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	Mr. Nikhil Dandekar 26/05/2023
02	Creating QC file	Quality Control – Define control fluids	PASS	Mr. Nikhil Dandekar 26/05/2023
03	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	PASS	Mr. Nikhil Dandekar 26/05/2023

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 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 26/05/2023
02	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	PASS	Mr. Nikhil Dandekar 26/05/2023
03	Accuracy Analysis	Compare the obtained Q.C value with mean of expected value as mentioned in the Performance verifier / QC Value chart.	PASS	Mr. Nikhil Dandekar 26/05/2023

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 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: 26/05/2023

Validation Team from Lupin Diagnostics Ltd. Jalna:

Name : Santosh Mohan Bhuskare

Signature:

Designation : Lab Tech.

Date: 26/05/2023

Department : Department of Biochemistry

Name : Amol Laxman Actle

Signature:

Designation : Lab Tech

Date: 26/05/2023

Department : Department of Biochemistry

Customer Authorizations:

Name : Dr. Anandkumar Chaudiya.

Designation: M.D. (Pathology)

Site : HLM - JALNA LUPIN DIAGNOSTICS

Signature:

Date : 26/05/2023.

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.

Calibration Certificate No.	: 2023/2711
Instrument	: VITROS 250/350
Serial No	: 2700-2696
J.No.	: J27002696
Customer Name	: Lupin Diagnostics, Jalna.
Calibration performed on	: 27/11/2023

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 May **2024**.

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

Mitesh Shah **Date: 27/11/2023**

Sr.Zonal Service Manager-Ortho Care

Pune

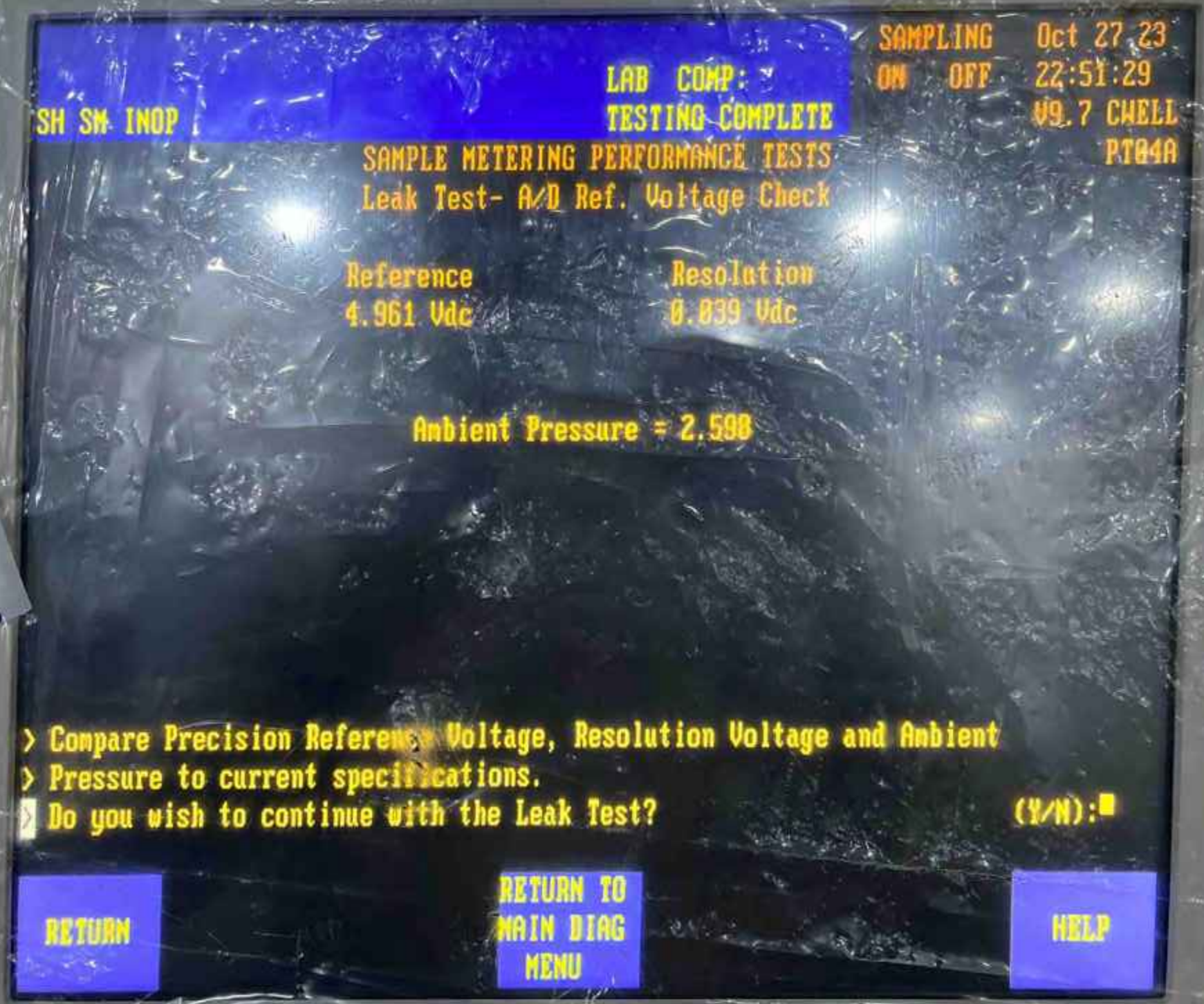

SAMPLING
ON OFF
Oct 27 23
20:41:24
LAB COMP:
TESTING COMPLETE
SS1 SS2 ST INC IR R/C PM INOP
V9.7 CHELL
DIAGNOSTICS - Setup/Adjustment - Spectrometer Iris
SA12A
340 400 460 540 600 630 670 680
5.54 5.11 5.65 6.27 6.59 7.64 5.96 5.40
Current voltages for all wavelengths.
Touch RETURN to exit or START to repeat tests.
RETURN
START
RETURN TO MAIN DIAG MENU
HELP
elo

SAMPLING Oct 27 23
ON OFF 20:42:12
LAB COMP: V9.7 CHELL
SS1 SS2 ST INC IR R/C PM INOP TESTING COMPLETE SA25A
DIAGNOSTICS - Setup/Adjustments - Current Setup Values

TRUCK:	Sample	45	SLIDE TRANSPORT:	Disp to Metering	72
	Tip Pick Up	17		Inc/Disp Path	30
	Mixing Cup Left	42		Inc RT/CM Depth	37
	Mixing Cup Right	18		Inc PM Depth	40
	Diluent Tray	44		PM Eject Depth	21
	RT/CM Slide	82		Inc Steps/Rev	14347
	PM Slide	41	SAMPLE TRANSPORT:	Tray Fin Reference	313
				Carriage Meter Pos	-69
				Mixing Cup Trans	30
PROBOSCIS:	Mixing Cup Bottom	298		Diluent Tray Trans	5
	Sample Cup Bottom	179		Tray Hook	-84
	Prob. Compression	101		Psid Scan	0
	Tip Height	814	REFERENCE SLIDE CENTER:		169
			READ SYNC:		2.5ms

RETURN | INPUT SETUP VALUES | DISPLAY MORE DATA | RETURN TO MAIN DIAG MENU | HELP

elo


SAMPLING
ON OFF
Oct 27 23
22:51:29
V9.7 CWELL
PT04A
SH SM INOP
LAB COMP:
TESTING COMPLETE
SAMPLE METERING PERFORMANCE TESTS
Leak Test- A/D Ref. Voltage Check
Reference
4.961 Vdc
Resolution
0.039 Vdc
Ambient Pressure = 2.598
> 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


SAMPLING
ON OFF
Oct 27 23
22:53:13
V9.7 CWELL
PT81B
SH SM INOP
LAB COMP:
TESTING COMPLETE
SAMPLE METERING PERFORMANCE TESTS
Leak Test - Voltage Differential
Aspirate = -0.098 Vdc
Dispense = -0.078 Vdc
Ambient Pressure = 2.598 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 INOP
LAB COMP:
TESTING COMPLETE
SAMPLING
ON OFF
Oct 27 23
22:56:47
V9.7 CWELL
RT01C
SAMPLE METERING PERFORMANCE TESTS
Hysteresis Test
MEAN
MAX
MIN
Hysteresis :
0.960
2.016
0.000
Pressure P0:
2.617
2.617
2.617
Pressure P1:
3.945
4.238
3.730
Pressure P2:
2.617
2.637
2.617
> Compare all mean, max, min values to current specifications.
> Touch DISPLAY NEXT SCREEN to view data.
RETURN
DISPLAY PREVIOUS SCREEN
DISPLAY NEXT SCREEN
HELP
elo


SAMPLING Oct 27 23
ON OFF 22:58:45
LAB COMP:
SH SM INC IR R/C INOP
TESTING COMPLETE
V9.7 CWELL
DIAGNOSTICS - PERFORMANCE TESTS - INCUBATOR
RT16B
PAD REFLECTANCE TEST
MEAN MIN. = 0.8937 REFLECTANCE VALUE
MEAN MAX. = 0.9074 REFLECTANCE VALUE
RANGE = 0.0138 (MAX. MEAN - MIN. MEAN)
GRAND MEAN = 0.9001 (MEAN OF ALL SLOT MEANS)
STAND DEV = 0.0034 (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

SAMPLING Oct 27 23
ON OFF 22:58:54
LAB COMP:
SH SM INC IR R/C INOP TESTING COMPLETE V9.7 CWELL
DIAGNOSTICS - PERFORMANCE TESTS - INCUBATOR PT16C
PAD REFLECTANCE TEST

SLOT	REFL1	REFL2	REFL3	MEAN	
1	0.89673	0.89656	0.89654	0.89661	
2	0.90080	0.90049	0.90048	0.90059	
3	0.90435	0.90435	0.90427	0.90432	
4	0.90379	0.90394	0.90375	0.90383	
5	0.90099	0.90077	0.90078	0.90085	
6	0.89377	0.89356	0.89365	0.89366	* Min. Refl.
7	0.90114	0.90092	0.90093	0.90100	
8	0.90752	0.90741	0.90735	0.90743	* Max. Refl.
9	0.90150	0.90135	0.90125	0.90137	
10	0.90067	0.90052	0.90029	0.90049	
11	0.90253	0.90249	0.90228	0.90243	
12	0.90161	0.90137	0.90131	0.90143	

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

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

elo


SAMPLING Oct 27 23
ON OFF 23:00:06
LAB COMP:
SH SM SS1 SS2 ST INC IR R/C PM INOP TESTING COMPLETE V9.7 CHELL
DIAGNOSTICS - Setup/Adjustment - Reflectometer Iris SA12A
340 400 460 540 600 630 670 680
5.20 4.70 5.17 5.73 5.92 6.07 5.36 4.84
Current voltages for all wavelengths.
Touch RETURN to exit or START to repeat tests.
RETURN
START
RETURN TO MAIN DIAG MENU
HELP

SAMPLING Oct 27 23
ON OFF 23:14:30
LAB COMP: V9.7 CWELL
SH SM SS1 SS2 ST INC IR R/C PM INOP TESTING COMPLETE PT31D

DIAGNOSTICS - Performance Tests - Reflectometer - Static test

- Summary Screen -

Wavelength (nm)	Mean Dark	SD Dark	Mean Signal	SD Signal	%CV*1K
340	475	0.4661	34928	1.9561	5.74
400	475	0.4138	30844	1.8270	5.92
460	475	0.4901	33970	2.2358	6.58
540	475	0.5074	37547	2.7759	7.39
600	475	0.3198	38894	2.8760	7.39
630	475	0.4026	45156	2.8519	6.32
670	475	0.3790	35276	2.2733	6.44
680	475	0.4842	31877	3.0164	9.46

> 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