Ortho Clinical Diagnostics

INSTALLATION QUALIFICATION

For

VITROS® 250

ORTHO CLINICAL DIAGNOSTICS

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I. Approval of the IQ procedure

Both **Lupin Diagnostics, Balanagar, Hyderabad** and Ortho-Clinical Diagnostics are jointly responsible for the installation of ***VITROS 250,*** **Sr. No.** 2501-4996 in the Laboratory of **Lupin Diagnostics, Balanagar, Hyderabad.**

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name	:	R. Raghavendra Rao	Signature:
Designation	:	Zonal Manager Ortho care – Service support	Date: 13/02/2023
Company	:	Ortho Clinical Diagnostics India Pvt ltd	

Validation Team from Lupin Diagnostics, Balanagar, Hyderabad :

Name	:	Mr. Nagendra Babu	Signature
Designation	:	Lab Incharge	Date: 13/02/2023

Customer Authorizations: **Lupin Diagnositcs, Balagnagar** Hyderabad

Name : Dr.A.Meghana

Designation : Lab Director

Signature : A. Meghana

Date : 13/2/23

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, Balanagar, Hyderabad. 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, Balanagar, Hyderabad.

III. Scope

This Installation Qualification protocol will be performed on the VITROS 250 bearing Sr. No: 2501-4996 located at Laboratory Medicine. 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 in Lupin Diagnostics, Balanagar, Hyderabad. is in compliance with the specifications of the purchase order.

Verified By: Mr. Raghavendra rao **Date: 13/02/2023**

B. Utilities

Sr. No	Utility	Verified by	Date
1.	**Environmental conditions:**	**Raghavendra rao**	**13/02/23**
	a. Analyzer will be placed away from the direct sunlight.	**Raghavendra rao**	**13/02/23**
	b. Installation site shall be free from dust, significant vibrations and shall be well ventilated.	**Raghavendra rao**	**13/02/23**
	c. Installation site floor construction shall be able to support approximately 272 kg.	**Raghavendra rao**	**13/02/23**
	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.	**Raghavendra rao**	**13/02/23**
	e. The analyzer shall be kept away from strong electromagnetic sources and electrical interferences.	**Raghavendra rao**	**13/02/23**
	f. It will be kept near to the power sources.	**Raghavendra rao**	**13/02/23**
	g. Maximum relative humidity allowed up to 70%.	**Raghavendra rao**	**13/02/23**
	h. If the temperature and humidity fluctuations are not within the specified range, the analyzer cannot maintain data reliability.	**Raghavendra rao**	**13/02/23**
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)]	**Raghavendra rao**	**13/02/23**
3.	Electrical Outlets: Actual Voltage on site [AC 220-230 Volts 16A 50 HZ]	**Raghavendra rao**	**13/02/23**

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~~	**Raghavendra rao**	**13/02/2023**
2.	Manufacturer's specifications are included	Yes / ~~No~~	**Raghavendra rao**	**13/02/2023**
3.	Accessories / Consumables are listed	Yes / ~~No~~	**Raghavendra rao**	**13/02/2023**
4.	Equipment manual from the manufacturer is documented	Yes / ~~No~~	**Raghavendra rao**	**13/02/2023**
5.	Manufacturer's Certificate attached	Yes / ~~No~~	**Raghavendra rao**	**13/02/2023**

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	**Raghavendra rao**	**13/02/2023**
Manufacturer:	Ortho-Clinical Diagnostics	**Raghavendra rao**	**13/02/2023**
Model:	*VITROS 250*	**Raghavendra rao**	**13/02/2023**
Serial Number:	2700-4846	**Raghavendra rao**	**13/02/2023**
Size (in cm):	115 (L) x 71 (W) x 120 (H)	**Raghavendra rao**	**13/02/2023**
Power:	AC 220-230 V 16A 50Hz±2Hz	**Raghavendra rao**	**13/02/2023**
Power consumption:	6880KW hours per year	**Raghavendra rao**	**13/02/2023**

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. 9.7)	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
	994131UC - Operators Manual	1 no.
	994130UC - 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

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.
Hardware Reassembling & Adjustment	➢ All the subsystem verification/Calibration

The system has preloaded operating software

VII. COMMENTS:

Deviation: NA

Impact On Operation: NA

Corrective Action: NA

VIII. 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. Exceptional conditions, if any, have been/not been addressed. The system is ready for Operation Qualification.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name	:	R. Raghavendra Rao	Signature:
Designation	:	Zonal Manager Ortho care – Service support	Date: 13/02/2023
Company	:	Ortho Clinical Diagnostics India Pvt ltd	

Validation Team from Lupin Diagnostics, Balanagar, Hyderabad :

Name	:	Mr.Nagendra Babu	Signature:
Designation	:	Lab Incharge	Date: 13/02/2023

Customer Authorizations: Lupin Diagnostics, Balanagar, Hyderabad

Name : Dr.A.Meghana

Designation : Lab Director

Signature : D. Meghana

Date : 13/2/23

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, and Ortho Clinical Diagnostics are jointly responsible for the Operation qualification of VITROS 250, **Sr. No.** J25014996 in the Laboratory of Lupin Diagnostics as per the Operational Qualification Protocol.

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

Name	:	Naveen Kumar Billa Sr.Zonal Manager – Application Support	Signature:
Company	:	Ortho Clinical Diagnostics	Date: 17/03/2023

Customer Authorizations:

Name : **Dr A. Meghana**

Designation : Lab Director Signature :

Site : Lupin Diagnostics, Balanagar. Date: 17/03/2023

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 will verify each result and sign in the each page. The member of the validation team will carry this out.

3. ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of the OQ protocol. All resolution to such problems will also be noted in the COMMENTS section, and must be resolved prior to issuance of a SYSTEM CERTIFICATION.

III. SCOPE

This Operational Qualification protocol will be performed on the VITROS 250, Sr. No. J25014996 located at Laboratory, Lupin Diagnostics. This OQ protocol will define the documentation that will be used to evaluate the completion of the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

OPERATIONAL QUALIFICATION:

A. Instrument Identification

a. **Model Name** **VITROS 250**

2. **Serial Number** J25014996

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	14/02/2023
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 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		
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		**15/02/2023**
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**
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.		15/02/2023
02	Verify the status of reagents loaded.		

Acceptance criteria:

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

PARAMETER **PASS** **FAIL**

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		
02	Performing Calibration with calibration programming screen		15/02/2023
03	Verification of Calibration report		

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		

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		
02	Creating QC file		16/02/2023
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

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		
02	Programming samples		
03	Unloading the samples		15/02/2023
04	Viewing samples in process		
05	Review results: Monitoring results		

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 technician's already undergone training when the machine was installed 1st time hence training not conducted.

S No	Participant Name	Signature
1	Nagendra Babu	
2	Sajin Kumar P	
3	Malika K	
4	K Venkatesh	
5	G Rajesh	

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.Naveen Kumar Billa

Sr.Zonal Manager – Application Support Signature:

Company: Ortho Clinical Diagnostics Date: 17/03/2023

Customer Authorizations:

Name : Dr. A Meghana

Designation : Lab Director Signature :

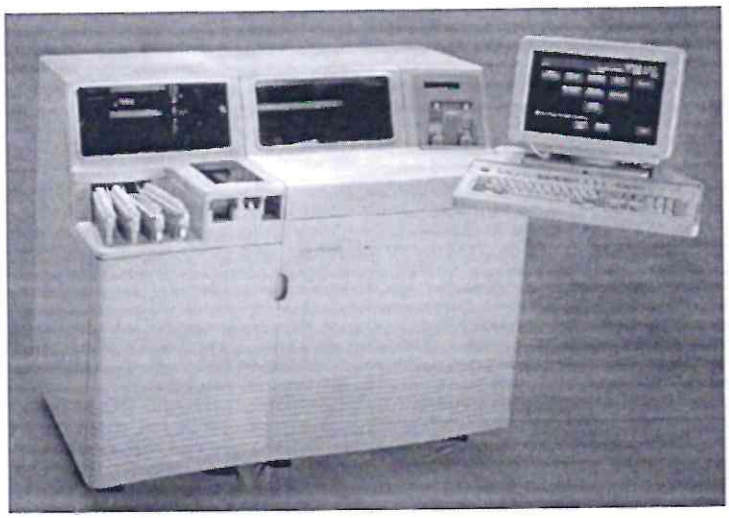
Site : Lupin Diagnostics, Balanagar. Date: 17/03/2023

Ortho Clinical Diagnostics

PERFORMANCE QUALIFICATION

For

VITROS 250



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

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I. Approval of the PQ procedure

Both Lipin Diagnostics, Balanagar and Ortho Clinical Diagnostics are jointly responsible for conducting the Performance Check of the Biochemistry Analyzer, Model – VITROS 250, Serial. No. J25014996 in the Laboratory of Lupin Diagnostics, Balanagar as per the attached protocol.

Protocol Performed By : Ortho Clinical Diagnostics Representative

Name : Mr.Naveen Kumar Billa

Signature:

Sr.Zonal Manager - Application

Date: 17/03/2023

Company : Ortho Clinical Diagnostics

Customer Authorizations:

Name : **Dr A Meghana**

Designation : Lab Director

Site : Lupin Diagnostics, Balanagar.

Signature:

Date: 17/03/2023

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, 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, Balanagar and Ortho-Clinical Diagnostics.

III. Scope

This Performance Qualification protocol will be performed on the VITROS 250 Serial No. J25014996 located in Laboratory of Lupin diagnostics, Balanagar. 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	J25014996	14/02/2023

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	15/02/2023
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 Chemsitry;

Analysis of controls:

Note: Analyze controls for ALKP (Microslide Rate Chemistry);
Sodium (Potentiometric Chemistry);
Potassium (Potentiometric Chemistry);
CRBM (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	15-02-2023
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	

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	
02	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	Pass	15-02-2023
03	Accuracy Analysis	Compare the obtained Q.C value with mean of expected value as mentioned in the Performance verifier / QC Value chart.	Pass	

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 : Mr.Naveen Kumar Billa

Sr.Zonal Manager - Application Signature :

Company : Ortho Clinical Diagnostics Date : 17/03/2023

Customer Authorizations:

Name : **Dr A Meghana**

Designation : Lab Director Signature :

Site : Lupin Diagnostics, Balanagar. Date : 17/03/2023