

# INSTALLATION QUALIFICATION

For

**VITROS 250**



Manufactured by:  
Ortho Clinical Diagnostics, Inc., US

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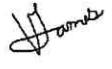
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I. Approval of the IQ procedure

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: 

Designation : Lab supervisor  
: Biochemistry

Date: 03/12/22

Department Name : Salman Shakti

Signature: 

Designation : Lab technician

Date: 03/12/22

Department : Biochemistry

**Customer Authorizations:**

Name : Manish Patel

Designation : Lab supervisor

Site : Bhopal

Signature: 

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**.

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### 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.

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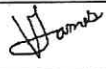

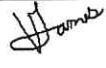
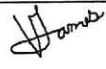

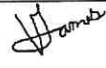
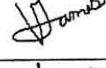
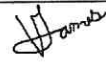


**IV. Ancillary Information.****A. Certification of Purchase Order Compliance**

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**





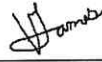
**B. Utilities**

Sr. No	Utility	Verified by	Date
	<b>Environmental conditions:</b>		
1.	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 <sup>0</sup> C to 27 <sup>0</sup> C and the temperature fluctuation during analysis shall not be more than ± 2 <sup>0</sup> C.		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**






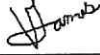
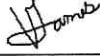
Sr. No.	Verification	Verified by	Date	
1.	Instrument is identified	Yes / No		03-12-22
2.	Manufacturer's specifications are included	Yes / No		03-12-22
3.	Accessories / Consumables are listed	Yes / No		03-12-22
4.	Equipment manual from the manufacturer is documented	Yes / No		03-12-22
5.	Manufacturer's Certificate attached	Yes / No		03-12-22

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**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

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**B. Accessories/Consumables**

The following accessories were supplied with the instrument. Check (✓) 'verified by' in case they are found to be in order.

<b>START UP KIT 1H4182</b>			
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.

<b>250 ANALYZER SPARE PART KIT 356704</b>			
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.

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**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.

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**VI. COMMENTS:**

*Handwritten signature*

**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

Company: Ortho Clinical Diagnostics

Signature: 

Date: 03-12-22

**Customer Authorizations:**

Name : Manish Patel  
Designation : Lab supervisor  
Organization : Bhopal Lepin  
diagnostics

Signature: 

Date : 03/12/22