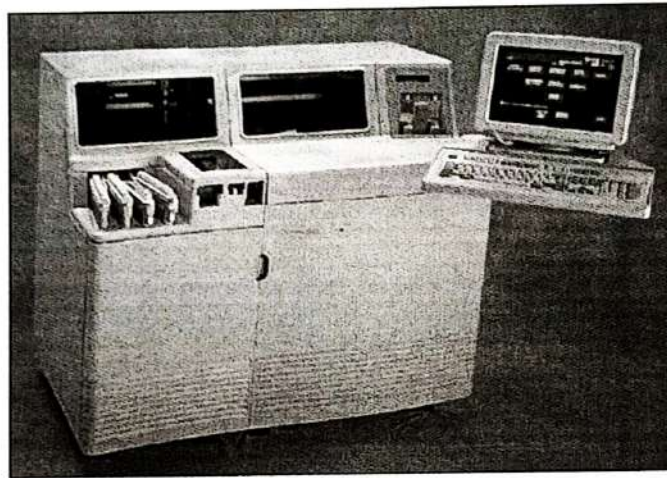


Ortho Clinical Diagnostics

INSTALLATION QUALIFICATION

For

VITROS 250




Manufactured by:
Ortho Clinical Diagnostics, Inc., US

Ortho Clinical Diagnostics

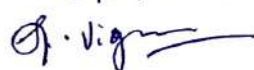
I. Approval of the IQ procedure

Both Lupin Diagnostics Limited , Athreya Hospital, Bangalore and Ortho-Clinical Diagnostics are jointly responsible for the installation of **VITROS 250, Sr. No. 27004829** in the Biochemistry Laboratory of Lupin Diagnostics Limited , Athreya Hospital, Bangalore.


Protocol Performed By: Ortho-Clinical Diagnostics Representative

Name : Mr. V. Vignesh Kanna Signature: 
Designation : Service Engineer - Ortho Care
Company : Ortho Clinical Diagnostics Date: 10/06/2023

Validation Team from Lupin Diagnostics Limited , Athreya Hospital, Bangalore:

Name : Vigneshwaran S Signature: 11/6/2023
Designation : Lab Incharge Date: 
Department : Biochemistry

Customer Authorizations:

Name : Vigneshwaran S
Designation: Lab Incharge . Signature: 
Site : Lupin Diagnostics Limited , Athreya Hospital, Bangalore Date: 11/6/2023

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 Limited , Athreya Hospital, Bangalore 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 Limited , Athreya Hospital, Bangalore.

III. SCOPE

This Installation Qualification protocol will be performed on the VITROS 250 bearing Sr. No. 27004829 located at Lupin Diagnostics Limited , Athreya Hospital, Bangalore. This Installation protocol will define the documentation that will be used to evaluate the instrument installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Installation checks will also be performed to verify that the Instrument has been installed with proper connections and utilities.

Trained, knowledgeable personnel will perform qualification studies.

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

IV. Ancillary Information.

A. Certification of Purchase Order Compliance

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

Verified By: V. Vignesh Kanna

Date: 10/06/2023

B. Utilities

Sr. No	Utility	Verified by	Date
1.	Environmental conditions:	V. Vignesh Kanna	10/06/2023
	a. Analyzer will be placed away from the direct sunlight.	V. Vignesh Kanna	10/06/2023
	b. Installation site shall be free from dust, significant vibrations and shall be well ventilated.	V. Vignesh Kanna	10/06/2023
	c. Installation site floor construction shall be able to support approximately 272 kg.	V. Vignesh Kanna	10/06/2023
	d. Room temperature will be maintained between 15°C to 27°C and the temperature fluctuation during analysis shall not be more than $\pm 2^\circ\text{C}$.	V. Vignesh Kanna	10/06/2023
	e. The analyzer shall be kept away from strong electromagnetic sources and electrical interferences.	V. Vignesh Kanna	10/06/2023
	f. It will be kept near to the power sources.	V. Vignesh Kanna	10/06/2023
	g. Maximum relative humidity allowed up to 70%.	V. Vignesh Kanna	10/06/2023
	h. If the temperature and humidity fluctuations are not within the specified range, the analyzer cannot maintain data reliability.	V. Vignesh Kanna	10/06/2023
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)]	V. Vignesh Kanna	10/06/2023
3.	Electrical Outlets: Actual Voltage on site [AC 220-230 Volts 16A 50 HZ]	V. Vignesh Kanna	10/06/2023

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	V. Vignesh Kanna	10/06/2023
2.	Manufacturer's specifications are included	Yes / No	V. Vignesh Kanna	10/06/2023
3.	Accessories / Consumables are listed	Yes / No	V. Vignesh Kanna	10/06/2023
4.	Equipment manual from the manufacturer is documented	Yes / No	V. Vignesh Kanna	10/06/2023
5.	Manufacturer's Certificate attached	Yes / No	V. Vignesh Kanna	10/06/2023

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	V. Vignesh Kanna	10/06/2023
Manufacturer:	Ortho-Clinical Diagnostics	V. Vignesh Kanna	10/06/2023
Model:	<i>VITROS 250</i>	V. Vignesh Kanna	10/06/2023
Serial Number:	27004829	V. Vignesh Kanna	10/06/2023
Size (in cm):	115 (L) x 71 (W) x 120 (H)	V. Vignesh Kanna	10/06/2023
Power:	AC 220-230 V 16A 50Hz±2Hz	V. Vignesh Kanna	10/06/2023
Power consumption:	6880KW hours per year	V. Vignesh Kanna	10/06/2023

Ortho Clinical Diagnostics

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:

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.	Vigneshwaran. S	Biochemistry		18/6/23
2.	Magesh Boopathi. M	Biochemistry		18/6/23
3.	Fazil	Biochemistry		18/6/23
4.	Sandhya	Biochemistry		18/6/23
5.	Lakshmi	Biochemistry		18/6/23

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. V. Vignesh Kanna

Designation: Service Engineer - Ortho Care

Company : Ortho Clinical Diagnostics

Signature: 

Date: 10/06/2023

Customer Authorizations:

Name : Vigneshwaran.S

Designation : Lab Incharge

Organization: LUPIN DIAGNOSTICS.

Date: 10/6/23

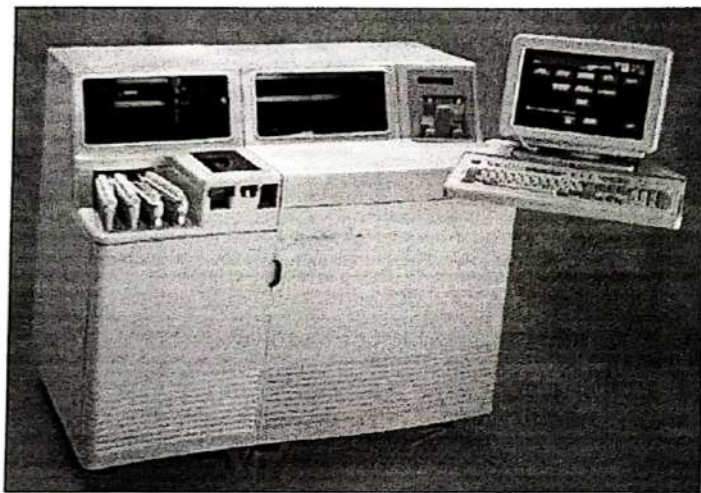
Signature : 

Ortho Clinical Diagnostics

OPERATION QUALIFICATION

For

VITROS 250



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

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Ortho Clinical Diagnostics

I. Approval of the OQ procedure

Both Lupin Diagnostics Limited, Athreya Hospital, Bangalore and Ortho Clinical Diagnostics are jointly responsible for the Operation qualification of VITROS 250, Sr. No. 27004829 in the Biochemistry Laboratory of Lupin Diagnostics Limited, Athreya Hospital, Bangalore as per the Operational Qualification Protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : Mr. Pralay Jyoti Dey

Signature: 


Designation : Technical Support Associate

Company : Ortho Clinical Diagnostics

Date: 16.06.2023

Validation Team from Lupin Diagnostics Limited, Athreya Hospital, Bangalore:

Name : Vigneshwaran S
Designation : Lab Incharge .

Signature: 
Date: 17/6/23

Department : Biochemistry

Customer Authorizations:

Name : Vigneshwaran S

Designation : Lab Incharge .

Signature : 

Site : Lupin Diagnostics Limited, Athreya Hospital, Bangalore

Date: 17/06/23

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 Limited, Athreya Hospital, Bangalore 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. 27004829 located at Biochemistry Laboratory Department, Lupin Diagnostics Limited, Athreya Hospital, Bangalore. This OQ protocol will define the documentation that will be used to evaluate the completion of the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

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

OPERATIONAL QUALIFICATION:**A. Instrument Identification**

- a. Model Name VITROS 250
2. Serial Number 27004829

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	Pralay 16.06.2023
02	Daily maintenance	To clean appropriate modules so as to maintain accuracy and precision	Pralay 16.06.2023
03	Inventory of reagents and consumables	To check the slide supply of installed Vitros 250	Pralay 16.06.2023
04	Calibration for the assays used	To calibrate the system for every new lot of assay	Pralay 16.06.2023
05	QC check	To confirm that systems, reagents & consumables are acceptable and working within specifications for each assay used	Pralay 16.06.2023
06	Sample programming and Analysis	To run the samples	Pralay 16.06.2023

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	Pralay	16.06.2023
02	Clean ERF Reservoir Holder & Base	Pralay	16.06.2023
03	Replace ERF Reservoir	Pralay	16.06.2023
04	Replace ERF Tip	Pralay	16.06.2023
05	Clean ERF Tip Sleeve	Pralay	16.06.2023
06	Clean IWF Reservoir Holder & Base	Pralay	16.06.2023
07	Replace IWF Reservoir	Pralay	16.06.2023
08	Replace IWF Tip	Pralay	16.06.2023
09	Clean IWF Tip Sleeve	Pralay	16.06.2023
10	Load supplies and remove outdated and empty reagents	Pralay	16.06.2023
11	Perform Quality Control	Pralay	16.06.2023

Acceptance criteria System should be "Ready" after daily maintenance without any error

PARAMETER

PASS

FAIL

Parameter values for verification: System found "Ready" after daily maintenance

Test: 3: Inventory of reagents and consumables

Purpose: To check the reagent management module of VITROS 250 Dry Chemistry system

Procedure:

Sr No	Activity	Done By	Date
01	Loading of Reagent cartridge in the appropriate slide supply – Supply 1 and Supply 2.	Pralay	16.06.2023
02	Verify the status of reagents loaded.	Pralay	16.06.2023

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	Pralay	16.06.2023
02	Performing Calibration with calibration programming screen	Pralay	16.06.2023
03	Verification of Calibration report	Pralay	16.06.2023

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	Pralay	16.06.2023
02	Creating QC file	Pralay	16.06.2023
03	QC sample programming and analysis	Pralay	16.06.2023
04	Verification of QC results obtained	Pralay	16.06.2023

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

PARAMETER PASS FAIL

Parameter values for verification: QC values within $\pm 2SD$

Test: 6: Sample programming and Analysis**Purpose: To run the samples****Procedure:**

Sr. No.	Activity	Done By	Date
01	Loading and Processing of samples	Pralay	16.06.2023
02	Programming samples	Pralay	16.06.2023
03	Unloading the samples	Pralay	16.06.2023
04	Viewing samples in process	Pralay	16.06.2023
05	Review results: Monitoring results	Pralay	16.06.2023

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

H. Operational procedure:

a. Certificate of Training

1. Technician Training

This certifies that the technicians have received basic user training in the following categories for the system described in this Operational Qualification.

Pralay Jyoti Dey from Ortho Clinical Diagnostics has conducted the training.

Sr. No.	Training program	Initials	Date
1.	Instrument Setup	Pralay	16.06.2023
2.	System Operation	Pralay	16.06.2023
3.	Calibration	Pralay	16.06.2023
4.	Quality Control	Pralay	16.06.2023
5.	Maintenance	Pralay	16.06.2023
6.	Basic trouble shooting	Pralay	16.06.2023

V. COMMENTS:

OK Pass Successfully

VI. SYSTEM CERTIFICATION:

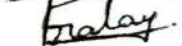
Study data has determined that the system described in this document either meets all criteria outline in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Performance Qualification.

Report Performed By: Ortho Clinical Diagnostics Representative

Name : Mr. Pralay Jyoti Dey

Designation : Technical Support Associate

Company: Ortho Clinical Diagnostics

Signature: 

Date: 16.06.2023

Customer Authorizations:

Name : Vigneshwaran S.

Designation : Lab Incharge .

Organization : **Lupin Diagnostics Limited, Athreya Hospital, Bangalore**

Date : 17/6/23

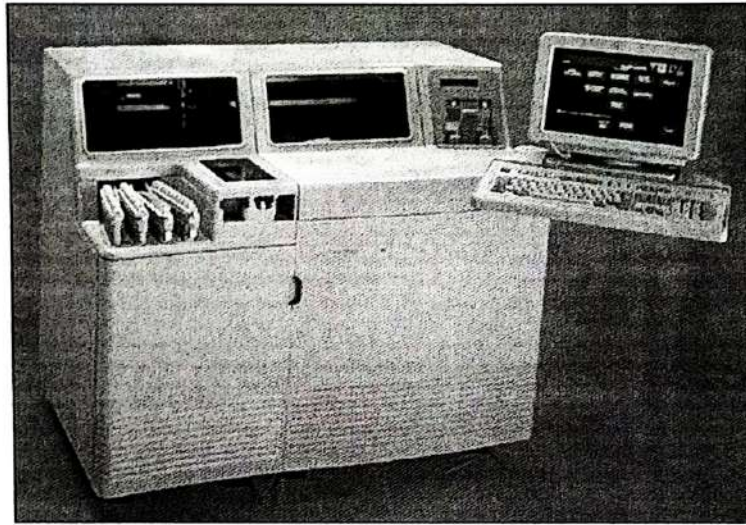
Signature : 

Ortho Clinical Diagnostics

PERFORMANCE QUALIFICATION

For

VITROS 250



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

Ortho Clinical Diagnostics

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Ortho Clinical Diagnostics

I. Approval of the PQ procedure

Both Lupin Diagnostics Limited, Athreya Hospital, Bangalore and Ortho Clinical Diagnostics are jointly responsible for conducting the Performance Check of the Biochemistry Analyzer, Model – VITROS 250, Serial. No.27004829 in the Biochemistry Laboratory Department of Lupin Diagnostics Limited, Athreya Hospital, Bangalore as per the attached protocol.

Protocol Performed By : Ortho Clinical Diagnostics Representative

Name : Mr. Pralay Jyoti Dey

Signature: 

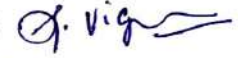
Designation : Technical Support Associate – Ortho Care

Date: 16.06.2023

Company : Ortho Clinical Diagnostics

Validation Team from Lupin Diagnostics Limited, Athreya Hospital, Bangalore:

Name : Vigneshwaran. S

Signature: 

Designation : Lab Incharge


Date: 17/6/2023

Department : Biochemistry

Customer Authorizations:

Name : Vigneshwaran. S

Designation : Lab Incharge

Signature: 

Site : Lupin Diagnostics Limited, Athreya Hospital, Bangalore

Date : 17/6/2023

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 Limited, Athreya Hospital, Bangalore 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 Biochemistry 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 Limited, Athreya Hospital, Bangalore and Ortho-Clinical Diagnostics.

III. Scope

This Performance Qualification protocol will be performed on the VITROS 250 Serial No. 27004829 located in General Biochemistry Laboratory located in Lupin Diagnostics Limited, Athreya Hospital, Bangalore. 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.

Ortho Clinical Diagnostics

IV. Performance Qualification

A. Instrument Identification

Verified Date

1. Model Name	VITROS 250	16.06.2023
2. Serial Number	27004829	16.06.2023

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	Pralay 16.06.2023
02	Accuracy Study	To compare the obtained value with true values of processed control.	Pralay 16.06.2023
03	Precision Study	To check the precision performance of the equipment	Pralay 16.06.2023

C. Performance Testing:

Test I

Test Name : **QC Run**
Purpose : To see the performance of quality control material on the equipment as per the specifications given
Method : Microslide – Rate Chemistry
 Microslide - Endpoint Chemistry
 Microslide – Potentiometric Chemistry;
 Microslide – Immunorate Chemsitry;

Analysis of controls:

Note: Analyze controls for ALT (Microslide Rate Chemistry);
 Amylase (Microslide – Two point rate Chemistry);
 Sodium (Potentiometric Chemistry);
 Potassium (Potentiometric Chemistry);
 Phenytoin (Microslide – Immunorate Chemistry)

Sr. No.	Activity	Procedure done as per the protocol defined in VITROS 250 Chemistry System Operator’s manual – Quality Control	Remarks	Done By
			Pass/Fail	Date
01	Preparing Liquid or Lyophilized control fluids	“Instructions for use” of QC material	Pass	Pralay 16.06.2023
02	Creating QC file	Quality Control – Define control fluids	Pass	Pralay 16.06.2023
03	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	Pass	Pralay 16.06.2023

Ortho Clinical Diagnostics

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	$\leq 0.8\%$ CV
04	Potassium	PV II	$\leq 1.0\%$ CV
05	CRBM	PV III	$\leq 4\%$ CV

COMMENTS:

PQ Pass Successfully.

Ortho Clinical Diagnostics

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 : Pralay Jyoti Dey

Designation : Technical Support Associate – Ortho Care


Company : Ortho Clinical Diagnostics

Signature : 

Date: 16.06.2023

Validation Team from Lupin Diagnostics Limited, Athreya Hospital, Bangalore:

Name : Vigneshwaram S
Designation : Lab Incharge
Department : Biochemistry

Signature: 17/6/23
Date: 

Customer Authorizations:

Name : Vigneshwaram S

Designation: Biochemistry

Site : Lupin Diagnostics Limited, Athreya Hospital, Bangalore

Date: 17/6/23

Signature: 