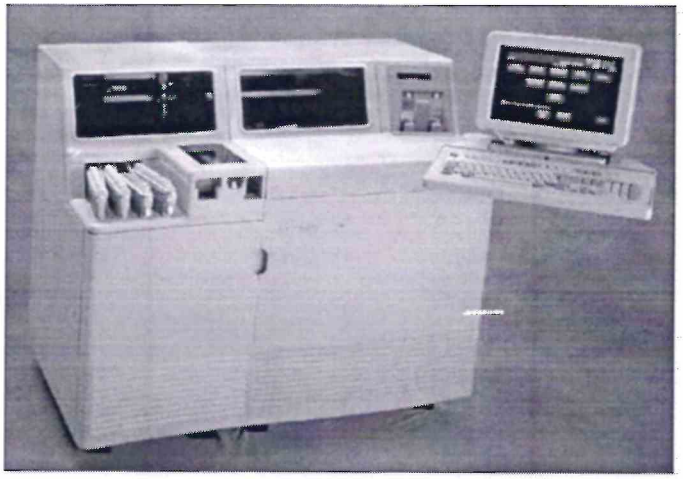
Ortho Clinical Diagnostics

PERFORMANCE QUALIFICATION

For

VITROS 350



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

Table of Contents

I. Approval of the PQ procedure

Both Lupin HLM Fertility Center Pvt. Ltd, Latur. and Ortho Clinical Diagnostics are jointly responsible for conducting the Performance Check of the Biochemistry Analyzer, Model – VITROS 350, Serial. No. 25015830 in the Biochemistry Department of Lupin HLM Fertility Center Pvt. Ltd, Latur. 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: 16/07/22

Validation Team from Lupin HLM Fertility Center Pvt. Ltd, Latur. :

Name : Shaikh Mustkim Signature:

Designation : Lab Supervisor Date: 16/07/22

Department : Biochemestry

Name : Signature:

Designation : Date:

Department :

Customer Authorizations:

Name : Shaikh Mustkim

Designation: Lab Supervisor Signature :

Site : Latur Date : 16/7/22

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 HLM Fertility Center Pvt. Ltd, Latur. 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 Bundelkhand Diagnostics Center .Sagar.MP and Ortho-Clinical Diagnostics.

III. Scope

This Performance Qualification protocol will be performed on the VITROS 350 Serial No. 250-15380 located in Biochemistry Department of Lupin HLM Fertility Center Pvt. Ltd, Latur. in Sagar. 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	16/7/2022
2. Serial Number	J25015830	16/7/2022

B. Following is a list of tests to be performed and verified:

Sr. No	Test Name	Test Purpose	Initial / Date
01	QC Run	To see the performance of quality control material on the equipment on selected assay parameters as per the specifications given	16/7/2022
02	Accuracy Study	To compare the obtained value with true values of processed control.	16/7/2022
03	Precision Study	To check the precision performance of the equipment	16/7/2022

C. Performance Testing:

Test I

Test Name : **QC Run**

Purpose : To see the performance of quality control material on the equipment as per the specifications given

Method : Microslide – Rate Chemistry
Microslide - Endpoint **Chemistry**
Microslide – Potentiometric Chemistry;
Microslide – Immunorate Chemistry;

Analysis of controls:

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

Sr. No.	**Activity**	**Procedure done as per the protocol defined in VITROS 350 Chemistry System Operator's manual – Quality Control**	**Remarks**	**Done By**
			Pass/Fail	**Date**
01	Preparing Liquid or Lyophilized control fluids	"Instructions for use" of QC material	PASS	Nikhil Dandekar 16/7/2022
02	Creating QC file	Quality Control – Define control fluids	PASS	Nikhil Dandekar 16/7/2022
03	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	PASS	Nikhil Dandekar 16/7/2022

Test II

Test Name	:	**Accuracy**
Purpose	:	To see the accuracy of obtained quality control value in comparison with the expected mean values.
Method	:	Microslide method as mentioned above

Analysis of controls:

Note: Analyze controls as mentioned above.

Sr. No.	Activity	Procedure done as per the protocol defined in VITROS 350 System Operator's manual - Quality Control	Remarks Pass/Fail	Done By Date
01	Preparing Liquid or Lyophilized control fluids	'Instructions for use' of QC material	PASS	Nikhil Dandekar 16/7/2022
02	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	PASS	Nikhil Dandekar 16/7/2022
03	Accuracy Analysis	Compare the obtained Q.C value with mean of expected value as mentioned in the Performance verifier / QC Value chart.	PASS	Nikhil Dandekar 16/7/2022

Test III :

Test Name : Precision Study (As per criteria attached)

Purpose : To estimate the imprecision or random error of the analytical method

Procedure:

Analyze Performance Verifier Level 1 control for tests ALT (2 x 12 times), Amylase and Na+ (3 x 10 times).

Analyze Performance Verifier Level 2 for Potassium (3 x 10 times) and Phenytoin (3 x 6 times).

Calculate the Mean, SD and CV%.

Acceptance Criteria:

Sr. No.	Analyte	Control Level	Precision Limit
01	ALT	PV I	≤ 2.3 SD
02	Amylase	PV I	≤ 3.9 SD
03	Sodium	PV I	≤ 0.8% CV
04	Potassium	PV I	≤ 1.0% CV
05	CRBM	TDM	≤ 4 % CV

COMMENTS:

V. System Certification

Study data has determined that the VITROS 350 Dry Chemistry system described in this document either meets all criteria outline in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Report Performed By : Ortho Clinical Diagnostics Representative

Name	:	Mr. Nikhil Dandekar	Signature:
Designation	:	Application Specialist	
Company	:	Ortho Clinical Diagnostics	Date: 16/07/22

Validation Team from Lupin HLM Fertility Center Pvt. Ltd, Latur:

Name	:	Shaikh Mustkim	Signature:
Designation	:	Lab Supervisor	Date: 16/7/22
Department	:	Biochemistry	
Name	:		Signature:
Designation	:		Date:
Department	:		

Customer Authorizations:

Name	:	Shaikh Mustkim	
Designation:		Lab Supervisor	Signature:
Site	:	Latur	Date : 16/07/22