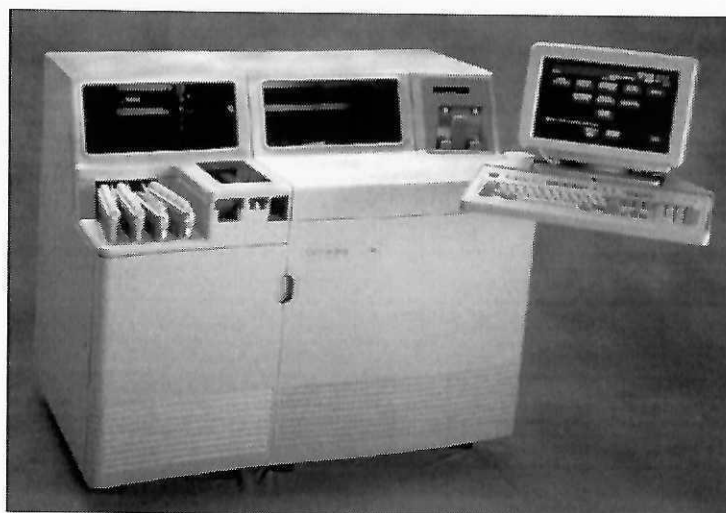


**OPERATION
QUALIFICATION**

For

System
VITROS[®] 250
Chemistry



ORTHOCLINICAL DIAGNOSTICS

Ortho Clinical Diagnostics

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Ortho Clinical Diagnostics


I. Approval of the OQ procedure

Both ESIC Hospital, KK Nagar, Chennai, and Ortho-Clinical Diagnostics are jointly responsible for the operation qualification of **VITROS 250/350, Sr. No. 27005110** in the ESIC Hospital, KK Nagar, Chennai as per the Operational Qualification Protocol.

Protocol Performed By: Representative from Ortho Clinical Diagnostics, India


Name : Ukendiran. D
Designation : Associate Lab Specialist Signature: Ukendiran. D
Company : Ortho-Clinical Diagnostics Date: 13-02-2018

Operational Qualification Verification Team: Respective Department Personal/Technologist

Name : DR. V. MADHUBALA.
Designation : Professor & HOD Signature: 
Department : Biochemistry Date: 13.02.2018

डॉ. वि. मधुबाला / Dr. V. MADHUBALA, M.D.,
प्रोफेसर एंड एचओडी / Professor & HOD
जीव रसायन विभाग / Department of Biochemistry
क.रा.बी.नि. चिकित्सा महाविद्यालय एवं पी.जी.आई.एम.एस.आर
E.S.I.C. Medical College & PGIMSAR,
के.के.नगर चेन्नई-78 / K. Nagar Chennai-78.

Customer Authorizations:

Name : DR. V. MADHUBALA.
Designation : Professor & HOD Signature: 
Site : E.S.I.C. Medical College.
K.K. Nagar, Chennai. Date: 13.02.2018

डॉ. वि. मधुबाला / Dr. V. MADHUBALA, M.D.,
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के.के.नगर, चेन्नई-78 / K.K. Nagar, Chennai-78.

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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 ESIC Hospital, KK Nagar, Chennai 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 250/350*, Sr. No. **27005110** located at ESIC Hospital, KK Nagar, Chennai. 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.

Ortho Clinical Diagnostics

OPERATIONAL QUALIFICATION:

A. Instrument Identification

1. Model Name VITROS 250/350

2. Serial Number 27005110

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	Ukendiran. D 13-02-2018
02	Daily maintenance	To clean appropriate modules so as to maintain accuracy and precision	Ukendiran. D 13-02-2018
03	Inventory of reagents and consumables	To check the slide supply of installed Vitros 250/350	Ukendiran. D 13-02-2018
04	Calibration for the assays used	To calibrate the system for every new lot of assay	Ukendiran. D 13-02-2018
05	QC check	To confirm that systems, reagents & consumables are acceptable and working within specifications for each assay used	Ukendiran. D 13-02-2018
06	Sample programming and Analysis	To run the samples	Ukendiran. D 13-02-2018

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 250/350 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

<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
Parameter values for verification: “READY” on Status console	YES	-

Ortho Clinical Diagnostics

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	Ukendiran. D	13-02-2018
02	Clean ERF Reservoir Holder & Base	Ukendiran. D	13-02-2018
03	Replace ERF Reservoir	Ukendiran. D	13-02-2018
04	Replace ERF Tip	Ukendiran. D	13-02-2018
05	Clean ERF Tip Sleeve	Ukendiran. D	13-02-2018
06	Clean IWF Reservoir Holder & Base	Ukendiran. D	13-02-2018
07	Replace IWF Reservoir	Ukendiran. D	13-02-2018
08	Replace IWF Tip	Ukendiran. D	13-02-2018
09	Clean IWF Tip Sleeve	Ukendiran. D	13-02-2018
10	Load supplies and remove outdated and empty reagents	Ukendiran. D	13-02-2018
11	Perform Quality Control	Ukendiran. D	13-02-2018

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

PARAMETER

PASS

FAIL

Parameter values for verification: System found "Ready"

YES

-

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Test: 3: Inventory of reagents and consumables

Purpose: To check the reagent management module of Vitros 250/350 Dry Chemistry system

Procedure:

Sr No	Activity	Done By	Date
01	Loading of Reagent cartridge in the appropriate slide supply	Ukendiran. D	13-02-2018

Acceptance criteria:

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

Parameter values for verification:

<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
No Error codes	YES	-

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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	Ukendiran. D	13-02-2018
02	Performing Calibration with calibration programming screen	Ukendiran. D	13-02-2018

Acceptance criteria: "Calibration Successful" should come on screen

	<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
Parameter values for verification:	"Calibration Successful" found and the report of the same from the analyzer	YES	-

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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	Ukendiran. D	13-02-2018
02	Creating QC file	Ukendiran. D	13-02-2018
03	QC sample programming and analysis	Ukendiran. D	13-02-2018

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

<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
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Parameter values for verification: QC values within $\pm 2SD$	YES	-
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Test: 6: Sample programming and Analysis

Purpose: To run the samples

Procedure:

Sr. No.	Activity	Done By	Date
01	Loading and Processing of samples	Ukendiran. D	13-02-2018
02	Programming samples	Ukendiran. D	13-02-2018
03	Unloading the samples	Ukendiran. D	13-02-2018
04	Viewing samples in process	Ukendiran. D	13-02-2018
05	Review results: Monitoring results	Ukendiran. D	13-02-2018

Acceptance criteria: Samples Analysis & Report without any error

	<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
Parameter values for verification:	Sample analysis & Report without any error	YES	-

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. Ukendiran. D from Ortho Clinical Diagnostics has conducted the training.

Sr. No.	Training program	Initials	Date
1.	Instrument Setup	Ukendiran. D	13-02-2018
2.	System Operation	Ukendiran. D	13-02-2018
3.	Calibration	Ukendiran. D	13-02-2018
4.	Quality Control	Ukendiran. D	13-02-2018
5.	Maintenance	Ukendiran. D	13-02-2018
6.	Basic trouble shooting	Ukendiran. D	13-02-2018

V. COMMENTS:

Deviation:

NIL

Impact on Operation:

NIL

Corrective Action:

NIL

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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/have not been addressed. The system is ready for Performance Qualification.

Protocol Performed By: Representative from Ortho Clinical Diagnostics, India

Name : Ukendiran. D
Designation : Associate Lab Specialist Signature: Ukendiran. D
Company : Ortho-Clinical Diagnostics Date : 13-02-2018

Operational Qualification Verification Team: Respective Department Personal/Technologist

Name : DR. V. MADHUBALA
Designation : Professor & HOD Signature: *[Signature]*
Department : Biochemistry Date: 13.02.2018
डॉ. वि. मधुबाला / Dr. V. MADHUBALA, M.D.,
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Customer Authorizations:

Name : DR. V. MADHUBALA
Designation : Professor & HOD Signature: *[Signature]*
Site : E.S.I.C. Medical College
K.K. Nagar, Chennai. Date: 13.02.2018
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Ortho Clinical Diagnostics

Complaint Information

SO No : 1092096

Common Information	
Type*: Field Engineer	J Number*: J27005110
Complaint Call Date & Time: 02-08-2023 7:37	Created Time: 02-08-2023 07:38:21
Nature of call*: Preventive Maintenance(PM)	Modified Time: 02-08-2023 07:38:21
Customer Name: ESIC Hospital	Address: ,,
Contact Person*: Arumana	Mobile No.*: 7994008653
Email Id*: DRVEERENDRAARUMALLA@GMAIL.COM	Lab Phone No:
Instrument Type*: SOLD	End Usercode: 5006351
Service cd Description: VITROS 250/350 SYSTEM	Serial No: 27005110
Observed details of Functioning well	Status: Closed
Instrument*:	PRR & SAP Order No:
SO No./ TRR NO: 98243078	


Assign To and Share With Information	
Assign To: Suresh J	Share With: Anu Mohan,DINESH KUMAR V,Girish Nair,Justus M,Karthikeyan G,MOHAN RAJ M,NARESH SEKAR,NAVEEN KUMARASAMY,Ramkumar ,THIYAGARAJAN

Customer Details
Report No:

Problem Reported	
Primary Error Code*: XPM	Primary Error Code PREVENTIVE MAINTENANCE
Second Error Code:	Description*:
Second Error Code Description:	Second Error Code Date & 00-00-0000 1:1
Third Error Code:	Time: -- 1:1
Third Error Code Description:	Third Error Code Date & Time:
	Third Error Code Description:

Customer Information
Customer Message:

Customer Uploaded Images

Call Closure Information	
Date of complaint closure: 07-08-2023	Is verification of closure done No
Closure statement:	by LS?:
Preventive Action:	Probable root cause*: PREVENTIVE MAINTAINANCE
LS / FE Signature: 	Remark:
	Attach Service Report/PRR:

Spare Parts Requisition Information								
PurchaseRequisition Id	Part Number	Part Name	Quantity	Source	SPRN No /Order No	Remarks	Mode	Status
1092098	994659	TUBING	1	Company	1000196720	USED		Closed Consumption status:Consumed Remarks :USED
1092097	J18830	>EJECT BLADE	2	Company	1000196720	USED		Closed Consumption status:Consumed Remarks :USED

Ortho Clinical Diagnostics

Complaint Information

SO No : 1092096

Customer Call Closure Information

Customer Comment*: **Working satisfactorily**

Customer Signature:

ifakhbala

Ortho Clinical Diagnostics

Complaint Information

SO No : 1092096

Update Call Information

Call updated by	Update Call Date	Solved By	If solved over phone ? Date & Time	Time spend on phone	Call Received Date & Time	Call Attended Date & Time	Actual Start Time	Actual End Time	Actual work hours	Observation hours	Travel hours	Waiting hours	Observed damage before service/Complaint Description	PHS	Diagnosis Description	Action Taken	Status	Product	Lot No.	Date of Expiry	Supporting Evidence if any	Action taken to resolve the problem	Other Specify	Is product replacement recommended	Quantity	
NAVEEN KUMARASAMY	2023-08-04 10:50:00	Visit	0000-00-00 0:0	0.00	2023-08-02 9:0	2023-08-02 15:48	2023-08-02 15:48	2023-08-02 20:48	5.00	0.30	2.00	0.00	NEED TONDO PREVENTIVE MAINTENANCE	No	NIL	NEED TO DO PREVENTIVE MAINTAINANCE .REMOVED , CLEANED REFIXED AND ADJUSTMENT DONE BY THE PROTOCOL .PM KIT REPLACED .MACHINE IS NOW WORKING GOOD	Job Complete		0000	0000-00-00						0
NAVEEN KUMARASAMY	2023-08-07 12:45:00	Solved on phone	2023-08-07 10:0	0.15	0000-00-00	0000-00-00	0000-00-00 9:0	0000-00-00 0:0	0.00	0.00	0.00	0.00	COMPLAINT CLOSURE	No	NIL	ASKED TO CUSTOMER MACHINE IS WORKING GOOD .	Job Complete		0000	0000-00-00						0
Total				15 Minutes					5 Hours	30 Minutes	2 Hours		Grand Total:	7 Hours 45 Minutes												

CALIBRATION CERTIFICATE

CERTIFICATE NO : OCD/9
CALIBRATED FOR : ESIC HOSPITAL
LOCATION : CHENNAI

CALIBRATION DATE : 02/08/2023
CALIBRATION DUE : 01 /03/2024
CALIBRATED AT : LABORATORY

SPECIFICATION OF INSTRUMENT :

INSTRUMENT	MODEL	SERIAL NO
VITROS CHEMISTRY SYSTEM	VITROS 250/350	27005110
	J NUMBER	J27005110

Specification of Software:

SOFTWARE NAME	SOFTWARE VERSION	UPDATED ON
DOS Rmx os	V9.7	2019

The Reference of Calibration: The performance/Adjustments of various subsystems has been calibrated/tested by trained site engineer with pre-designed /calibrated tools provided for the particular subsystems by the company.

Preventive maintenance Procedure Checklists:

Subsystem Name

Adjusted/Verified

1. Sample Supply

* Hook Drive Belt



Software Adjustment:

* Tray Transport Hook Position

2. Slide Supply 1, 2 & slide transport

Mechanical Adjustment:

* Dispense Blade Centering Adjustment

* Dispense Blade Drive Belt Tension

* Plunger Centering Alignment

Software Adjustment:

* Dispense To Metering Position



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Email ID: connectoed@orthoclinicaldiagnostics.com
Website: www.orthoclinicaldiagnostics.com

Ortho Clinical Diagnostics

3. Sample Metering

Mechanical Adjustment:

- * Truck Sensor
- * Truck Guide Button
- * Metering Truck



4. Software Adjustment:

- * Tip Pickup X,Y and Height
- * Sample Tray at Sample Position –Auto Sample Tray
- * Proboscis Centering and Sample Cup Depth
- * Mixing Cup X,Y and its Depth
- * Diluents Tray
- * Rate / Colorimetric Metering Position
- * Potentiometric Metering Position
- * Proboscis Compression
- * Wetness Detector



5. Slide Incubator

Software Adjustment:

- * Incubator Disk Sizing
- * Incubator Disk Stopping
- * PM Slide Insertion Depth
- * Slide Read Position (RT/CM Depth & Read Sync)
- * Potentiometric Eject Blade Depth



6. Reflectometer

- * IRIS Lamp Output Voltage
- * Correction Factor



7. Master Computer

- * Touch Screen Calibration
- * System Full Backup



CALIBRATED BY



J.SURESH
Sr Territory Manager

NOTE:

1. This certificate refers only to the particular item submitted for calibration.
2. The calibration result reported in the certificate is valid at the time of and under the stated condition of the measurement.

Ortho Clinical Diagnostics India Private Limited
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