Ortho Clinical Diagnostics

OPERATIONAL QUALIFICATION

For

VITROS 4600 BIOCHEMISTRY SYSTEM

Manufactured by:
Ortho Clinical Diagnostics, Inc., US

Table of Contents

I. Approval of the OQ procedure

Both ESIC Hospital, KK Nagar, Chennai and Ortho-Clinical Diagnostics are jointly responsible for the installation of *VITROS 4600* in the ESIC Hospital, KK Nagar, Chennai as per the attached OPERATIONAL Qualification protocol.

Protocol Performed By: Representative of Ortho Clinical diagnostics

Name	:	Mr. Ukendiran. D
Title	:	Associate Lab Specialist
Company	:	Ortho-Clinical Diagnostics

Customer Authorizations: ESIC Hospital, KK Nagar,, Chennai

Name : DR. V. MADHUBALA.

Title : Professor & HOD.

Site : Esic Medical College
K. K. Nagar
Chennai.

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 & PGIMSR,
के.के. नगर, चेन्नई-78 / K.K. Nagar, Chennai-78.

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. Employees of (customer) ESIC Hospital, KK Nagar, Chennai will verify & sign in the last page.

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 4600* Located in ESIC Hospital, KK Nagar, Chennai. This Installation protocol will define the documentation that will be used to evaluate 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.

IV. OPERATIONAL QUALIFICATION:

A. Instrument Identification

Verified Date: 24-04-2014

1. Model Name VITROS 4600
2. Serial Number 46000347

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 24-04-2014
02	Daily maintenance	To clean appropriate modules so as to maintain accuracy and precision	Ukendiran. D 24-04-2014
03	Inventory of reagents and consumables	To check the slide supply of installed Vitros 4600	Ukendiran. D 24-04-2014
04	Calibration for the assays used	To calibrate the system for every new lot of assay	Ukendiran. D 24-04-2014
05	QC check	To confirm that systems, reagents and consumables are acceptable and working within specifications for each assay used	Ukendiran. D 24-04-2014
06	Sample programming and Analysis	To run the samples	Ukendiran. D 24-04-2014

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 4600 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

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	Ukendiran. D	24-04-2014
02	Clean ERF Reservoir Holder & Base	Ukendiran. D	24-04-2014
03	Replace ERF Reservoir	Ukendiran. D	24-04-2014
04	Replace ERF Tip	Ukendiran. D	24-04-2014
05	Clean ERF Tip Sleeve	Ukendiran. D	24-04-2014
06	Clean IWF Reservoir Holder & Base	Ukendiran. D	24-04-2014
07	Replace IWF Reservoir	Ukendiran. D	24-04-2014
08	Replace Wash Fluid Tip	Ukendiran. D	24-04-2014
09	Clean Wash Fluid Tip Sleeve	Ukendiran. D	24-04-2014
10	Load supplies and remove outdated and empty reagents	Ukendiran. D	24-04-2014
11	Perform Quality Control	Ukendiran. D	24-04-2014

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

PARAMETER PASS

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 installed Vitros 4600 Procedure:

Sr. No.	Activity	Done By	Date
01	Loading of Reagent cartridge in the appropriate slide supply	Ukendiran. D	24-04-2014

Acceptance criteria:

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

PARAMETER	PASS

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	Ukendiran. D	24-04-2014
02	Performing Calibration with calibration programming screen	Ukendiran. D	24-04-2014

Acceptance criteria: "Calibration Successful" should come on screen

PARAMETER PASS

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	Ukendiran. D	24-04-2014
02	Creating QC file	Ukendiran. D	24-04-2014
03	QC sample programming and analysis	Ukendiran. D	24-04-2014

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

PARAMETER PASS

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	Ukendiran. D	24-04-2014
02	Programming samples	Ukendiran. D	24-04-2014
03	Unloading the samples	Ukendiran. D	24-04-2014
04	Viewing samples in process	Ukendiran. D	24-04-2014
05	Review results: Monitoring results	Ukendiran. D	24-04-2014

Acceptance criteria: Samples Analysis without any error

PARAMETER	PASS

Parameter values for verification: Sample analysis 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. Ukendiran. D, Lab specialist from Ortho Clinical Diagnostics Ltd has conducted the training.

Sr. No.	Training program	Done by	Date
1.	Instrument Setup	Ukendiran. D	24-04-2014
2.	System Operation	Ukendiran. D	24-04-2014
3.	Basic trouble shooting and Maintenance	Ukendiran. D	24-04-2014

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: Ukendiran. D

Title: Associate Lab Specialist

Company: Ortho Clinical Diagnostics

Customer Authorizations: ESIC Hospital, KK Nagar, Chennai

Name : DR. V. MADHU BALA.

Title : Professor & HOD.

Site : ESIC Medical College., K.K. Nagar, Chennai.

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

:

Ortho Clinical Diagnostics

Complaint Information

SO No : 1107039

Common Information

Type*:	**Field Engineer**	J Number*:	**J46000347**
Complaint Call Date & Time:	**05-10-2023 21:34**	Created Time:	**05-10-2023 21:34:49**
Nature of call*:	**Preventive Maintenance(PM)**	Modified Time:	**05-10-2023 21:34:49**
Customer Name:	**ESIC Hospital**	Address:	**K.K. Nagar, Chennai,Tamil Nadu,**
Contact Person*:	**Giri**	Mobile No.*:	**9488080236**
Email Id*:	**esicchennailab@GMAIL.COM**	Lab Phone No:	
Instrument Type*:	**SOLD**	End Usercode:	**5006351**
Service cd Description:	**VITROS 4600 CHEMISTRY SYSTEM**	Serial No:	**?46000347**
Observed details of Instrument*:	**Functioning well**	Status:	**Closed**
SO No./ TRR NO:	**98249368**	PRR & SAP Order No:	

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

Customer Information

Customer Message:	

Customer Uploaded Images

Call Closure Information

Date of complaint closure:	**09-10-2023**	Is verification of closure done by LS?:	**No**
Closure statement:		Probable root cause*:	**MAINTENANCE RELATED**
Preventive Action:		Remark:	
LS / FE Signature:		Attach Service Report/PRR:	**No**

Ortho Clinical Diagnostics

Complaint Information

SO No : 1107039

Spare Parts Requisition Information

PurchaseRequisition Id	Part Number	Part Name	Quantity	Source	SPRN No /Order No	Remarks	Mode	Status
1107043	J23940	ERF Assy tub 5.1/4600/5600 CRU	1	Company	1000204578	SPARE CONSUMED		Closed Consumption status:Consumed Remarks :SPARE CONSUMED
1107042	J27110	EVAP CAP ASSY, SORTED	1	Company	1000204578	SPARE CONSUMED		Closed Consumption status:Consumed Remarks :SPARE CONSUMED
1107041	J24980	BEARING PAD	3	Company	1000204578	SPARE CONSUMED		Closed Consumption status:Consumed Remarks :SPARE CONSUMED
1107040	1C3537	IR WASH CAM	1	Company	1000204578	SPARE CONSUMED		Closed Consumption status:Consumed Remarks :SPARE CONSUMED

Customer Call Closure Information

Customer Comment*: **Pm completed. Equipment working satisfactorily.**

Customer Signature:

Ortho Clinical Diagnostics

Complaint Information

SO No : 1107039

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
Suresh J	2023-10-08 11:14:00	Visit	0000-00-00 0:0	0.00	2023-10-07 13:0	2023-10-07 13:15	2023-10-07 13:30	2023-10-07 20:30	7.00	0.30	2.00	0.45	NA	No	NEED TO DO THE PM	CLEANED FUL INSTRUMENT AND MODULES. DONE ADJUSTMENT AND PERFORMANCE TEST RUN QC MACHINE WORKING FINE .	Job Complete		NA	0000-00-00					0
NAVEEN KUMARASAMY	2023-10-09 19:02:00	Visit	0000-00-00 0:0	0.00	2023-10-07 13:0	2023-10-07 13:15	2023-10-07 13:30	2023-10-07 21:0	7.30	0.00	2.30	0.00	NA	No	XOSA	ONSITE ASSISTANCE WITH MR.SURESH	Job Complete		0000	0000-00-00					0
Total									**14 Hours 30 Minutes**	**30 Minutes**	**4 Hours 30 Minutes**	**45 Minutes**	**Grand Total:**	**20 Hours 15 Minutes**											

CALIBRATION CERTIFICATE

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

CALIBRATION DATE : 05/10/2023
CALIBRATION DUE : 04/04/2024
CALIBRATED AT : BIOCHEMISTRY

SPECIFICATION OF INSTRUMENT :

INSTRUMENT	MODEL	SERIAL NO
VITROS CHEMISTRY SYSTEM	VITROS 4600	46000347
	J NUMBER	J46000347

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 & Annexure No**

1. Slide Supply 1& 2 ☑
   Software Adjustment:
   * Supply 1 (Outer) Stopping At Dispense
   * Supply 2 (Inner) Stopping At Dispense
   * Supply 1 & 2 Plunger Position
   * Dispense Blade At Tip Locator Position
   * Dispense Blade At PM Ring Depth
   * CM Tip Locator X, Y & Z
   * Leak Pad X & Z
   * Slide Align Guide
2. Reagent Supply 3 ☑
   Software Adjustment:
   * Secondary Metering to Supply 3 Outer & Inner Reagent Aspiration
   * Supply 3 Bottom
   * Supply 3 Barcode reader & Load Position
   * Pack Opener Theta & Z Position
   * Secondary Metering Leak Pad X & Z
3. Tip Processing Center ☑
   * Versa Tip Loading Position
   * Versa Tip Ring to Primary Metering Pickup X & Z
   * Versa Tip Ring to Secondary Metering Pickup X & Z
   * Primary Metering to Primary Tip Sealer X,Y& Z
   * Primary Metering to Cuve tip Dropoff X & Z
   * Secondary Metering to Cuvetip Aspirate X & Z

* CuveTip Discard Position Theta & ARM
* Micro Sensor CuveTip Position
* Micro Sensor CuveTip Lifter Z

4. Sample Supply ☑
* Triflex Sample Position X
* Stat Sample Position X
* Primary Sample Position X

5. Primary Metering
Software Adjustment: ☑
* VersaTip Ring Truck X & Z
* Secondary Tip Sealer Truck X & Z
* TipLocator Truck X & Z
* Primary Tip Sealer X & Z
* Cuvette Incubator Truck X & Bottom

6. ERF Metering ☑
Mechanical Adjustment:
* Metering Dispense PositionCenter, Initial
* Dispense Position Verification

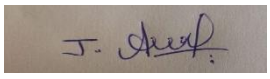
7. Micro Slide Incubator
Mechanical Adjustment: ☑
*CM/RT Ring Belt Tension
* V- Three Wheel Alignment
Software Adjustment: ☑
* PM Ring Stopping Position
* Dispense Blade to PM Ring Depth
* CM/RT Ring Stopping Position
* Depth of Insert Blades, CM & RT
* RT Depth Of Discard Blade
* WF Shuttle Home & Discard
* WF Re-Insert Blade
* Slide Align Guide

8. Reflectometer Assembly
Mechanical Adjustment: ☑
* Continuity Test
Software Adjustment: ☑
* Read Sync
* Correction Factors

9.Wash Fluid Metering ☑
* WF Shuttle Home & Z
* WF Metering Theta
* Primary Well Theta
* Leak Pad Z
* WF Re-insert Blade
* WF Shuttle Discard Position

10. Cuvette Supply ☑
    * Cuvette Rack
    * Transport Arm at Row Retrieve
11. MicroTip Supply ☑
    * Secondary Metering MicroTip Pickup X
    * Secondary Metering MicroTip Pickup Z
12. Secondary Metering ☑
    * VersaTip Ring Truck X & Z
    * Secondary Tip Sealer Truck X & Z
    * Cuvette Tip Aspirate Truck X & Z
    * Cuvette Incubator Truck X & Bottom
    * Micro Tip Pickup Truck X,Y& Z
    * Supply 3 Outer , Inner & Bottom
    * Leak Pad Truck X & Z
13. Cuvette Incubator ☑
    * Transport Arm at Row Retrieve
    * Transport Arm to Incubator Slot X, Y
    * Transport Arm to Pick up, Read, Discard
    * Primary Metering to Cuvette Incubator & Cuvette Bottom
    * Secondary Metering to Cuvette Incubator & Cuvette Bottom
14. Photometer
    Software Adjustment: ☑
    * Transport Arm at Read
    * Water Blanking
15. MicroSensor ☑
    * Micro Sensor CuveTip Position
    * Micro Sensor CuveTip Lifter Z
16. Master Computer ☑
    * System Full Backup

CALLIBRATED BY



Suresh J (Sr Territory Manager)

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.