

Ortho Clinical Diagnostics

Complaint Information

SO No : 1167539

Common Information	
Type*: Field Engineer	J Number*: J27003641
Complaint Call Date & Time: 09-07-2024 12:27	Created Time: 09-07-2024 12:27:02
Nature of call*: Preventive Maintenance(PM)	Modified Time: 00-00-0000 00:00:00
Customer Name: DR B LAL CLINICAL LABORATORY PRIVATE LIMITED	Address: 6-E,MALVIYA INDUSTRIAL AREA,
Contact Person*: Mandeep sarsar	Mobile No.*: 9649337122
Email Id*: VIVEKCHOUDHARY@BLALLABS.COM	Lab Phone No:
Instrument Type*: RRC	End Usercode: 1395265
Service cd Description: VITROS 250/350 SYSTEM	Serial No: 27003641
Observed details of Instrument*: Functioning well	Status: Closed
SO No./ TRR NO: 98274761	PRR & SAP Order No:

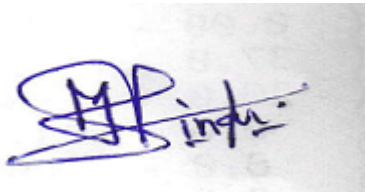
Assign To and Share With Information	
Assign To: MAHENDER PRATAP SINGH	Share With: ANIL KUMAR CHAUDHARY,HIMANSHU JOSHI,Lalit Kumar,MAHENDER PRATAP SINGH,Manish Kumar,Manvendra Singh,Ravi Ranjan,VINAY PARAJAPATI

Customer Details
Report No:

Problem Reported	
Primary Error Code*: Xpm	Primary Error Code PM Due Description*:
Second Error Code:	Second Error Code Date & -- Time:
Second Error Code Description:	Third Error Code Date & Time: --
Third Error Code:	Third Error Code Description:

Customer Information
Customer Message: Plz visit

Customer Uploaded Images

Call Closure Information	
Date of complaint closure: 10-07-2024	Is verification of closure done by LS?:
Closure statement:	Probable root cause*: MAINTENANCE RELATED
Preventive Action:	Remark:
LS / FE Signature: 	Attach Service Report/PRR:

Ortho Clinical Diagnostics

Complaint Information

SO No : 1167539

Spare Parts Requisition Information								
PurchaseRequisition Id	Part Number	Part Name	Quantity	Source	SPRN No /Order No	Remarks	Mode	Status
1167543	J10537	BELT - ROTOR	1	Company	1000241732	PART IS USED		Closed Consumption status:Consumed Remarks :PART IS USED
1167542	J10944	BLADE-DISPENSE	1	Company	1000241732	PART IS USED		Closed Consumption status:Consumed Remarks :PART IS USED
1167541	994659	TUBING	1	Company	1000241732	PART IS USED		Closed Consumption status:Consumed Remarks :PART IS USED
1167540	J18830	>EJECT BLADE	1	Company	1000241732	PART IS USED		Closed Consumption status:Consumed Remarks :PART IS USED

Customer Call Closure Information

Customer Comment*: **NOW MACHINE IS WORKING FINE**

Customer Signature:



Ortho Clinical Diagnostics

Complaint Information

SO No : 1167539

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	
MAHENDER PRATAP SINGH	2024-07-10 09:14:00	Visit	0000-00-00 0:0	0.00	2024-07-09 12:27	2024-07-09 12:30	2024-07-09 12:30	2024-07-09 15:30	3.00	0.30	4.00	0.00	NIL	No	PM WAS DUE AS PER SCHEDULE	DONE ALL MODULE CLEANING AND USE PM KIT SPARES, CHECK AND VERIFY ALL THE ADJUSTMENTS AND PERFORMANCE TEST, NOW MACHINE IS WORKING FINE	Job Complete		NA	0000-00-00						0
Total									3 Hours	30 Minutes	4 Hours		Grand Total:	7 Hours 30 Minutes												

**PERFORMANCE
QUALIFICATION**

For

**FULLY AUTOMATED CHEMISTRY SYSTEM
VITROS 250**

**Manufactured BY:
ORTHOCLINICAL DIAGNOSTICS**

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I. APPROVAL OF THE PQ PROCEDURE

Both Dr B Lal Laboratories, Sikar and Ortho-Clinical Diagnostics are jointly responsible for the installation of *VITROS 250* in Laboratory of Dr B Lal Laboratories, Sikar as per the attached Performance Qualification protocol.

Protocol Performed By: Representative of Ortho Clinical Diagnostics.

Name : **Harkesh**

Signature:



Designation : Application Manager

Date: 1 Aug, 2020

Company : OCD

Customer Authorizations:

Name : **Mohar Singh**

Designation : **Lab Incharge**

Signature : _____

Date : **4Aug, 2020**

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.
2. The concerned lab personnel are responsible for performance checks described in the Performance testing.
3. The concerned employees of **Dr B Lal Laboratories, Sikar** will verify each result and sign in the each page. The member of the validation team will carry this out.
4. ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of each 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.

III. SCOPE

Both **Dr B Lal Laboratories, Sikar** and Ortho-Clinical Diagnostics are jointly responsible for the installation of *VITROS 250 analyzer*, in the Laboratory_.

This protocol will define the documentation that will be used to evaluate the instruments 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 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

Instrument Identification

Verified Date: 1Aug, 2020

- a. **Model Name** **VITROS-250**
- 2. **Serial Number:** **J 27003641**

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

<u>Test No.</u>	<u>Test Name</u>	<u>Test purpose</u>	<u>Verified date</u>
01	QC Run	To see the performance of quality control material on the equipment on selected assay parameters as per the specifications given	1 Aug, 2020
02	Precision Study	To check the precision performance of the equipment	1 Aug, 2020

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

Acceptance criteria:

QC results within specified limits mentioned on the control product insert

PARAMETER

PASS

FAIL

Parameter values for verification: QC values within manufacturer's specified limits

Test II

Test Name: Precision Study

Purpose: To see the precision performance of the equipment

Method:

Precision result

Analyte	Expected	Obtained
ALKP	SD < 2.3	1.6
NA+	CV% < 0.8	0.27
CRBM	CV% < 4.2	2.14

VI. System Certification

Study data has determined that the 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.

Protocol Performed By: Representative of Ortho Clinical Diagnostics.

Name : **Harkesh**

Signature:



Designation : Application Manager

Date: 1 Aug, 2020

Company : OCD

Customer Authorizations:

Name : Mohar Singh

Designation : Lab Incharge

Signature : _____

Date : 4Aug, 2020

INSTALLATION REPORT

Ortho Clinical Diagnostics

WI-OC-DIN-004/F04
Issue No. 4

Sr. 005011

UNIVERSAL INSTALLATION REPORT - ORTHO INDIA

Customer Details :				
Name & Address of Customer : <u>Bial Clinical Laboratory Pvt Ltd</u> <u>C/o Rishi Hospital,</u> <u>Sikar, Rajasthan</u>	Department : <u>Prothrombin</u> Contact Person : <u>Mohan Saini</u> Phone & Extn No : <u>9929660011</u> E-mail ID : <u>mohan.saini@bialkbs.com</u>			
Instrument Details :				
Name of the Instrument : <u>V250</u>	Instrument Type			
J Number : <u>527003641</u>	<input type="checkbox"/> NEW <input type="checkbox"/> SALE			
Serial Number : <u>527013641</u>	<input checked="" type="checkbox"/> Refurbished <input checked="" type="checkbox"/> RRC			
Check List :				
UPS Rating : <u>2-20V</u>	Are pre installation requirements met ?			
Current Software Version : <u>V9.7</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			
Calibration Diskette /ADD No : <u>DRV 6085</u>	If not specify.			
Was there shipping damage ?	Modification Numbers already circled :			
Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	<u>1,2,3,4,5,6,7,10,11,12,13,15,17,18,20,21</u>			
If yes, what was the shipping damage ?	<u>22,24,25,26,27,28,29,31,33,34,35,37,38</u>			
	<u>40,41,42,43,45,47,48,49,51,54,55,56,57,58,59,63,</u>			
	<u>68,69,70,71,72,73,74,75,76,77,78,79,80,81,82,83,84,85,86,87,88</u>			
Was troubleshooting adjustments required ?	Did all the accessories arrive prior to installation ?			
Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			
If yes, specify & mention module and condition code.	If no list the missing items.			
Were any parts replaced during installation ?				
Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>				
If yes, then please mention the details below				
Part No	Part Name	SPR No.	Quantity	Remarks
Time Log :		Customer Training Details :		
Date	Travel Hrs	Work Hrs	Name of the Operator Trained	
<u>1 Aug</u>	<u>6HR</u>	<u>8HR</u>	<u>MOHAN SINGH SAINI</u>	
			<u>MAHESH YADAV</u>	
			<u>RATENDER MEHRA</u>	
			<u>MAN DEEP</u>	
			<u>AL VANDANATHIWAR</u>	
Total : <u>6HR</u>			Date : <u>1-Aug</u>	
Total : <u>8HR</u>			Trained by : Name : <u>HARDESH</u>	
Installation Completed Date : <u>1 Aug, 2020</u>			Sign : <u>[Signature]</u>	
Did precision marker pass the first time?				
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>				
If not explain				
Customer's Remarks : <u>OK</u>		Engineer's Remarks : <u>Nothing OK</u>		
Customer's Seal & Signature : <u>[Signature]</u>		Company's Personnel : <u>Ravi Ranjan</u> (sign)		
Name : <u>[Name]</u>		Name : <u>RAVIRANJAN</u>		

INSTALLATION QUALIFICATION DATA SHEET

(Use appropriate qualification table)

□ V250 / 350 Installation Precision

QC Fluid	QC Lot No.	Assay	Result	SPECS.
Performance Verifier 1	N7649 Q7653	ALKP	1.8	SD ≤ 2.0
TDM III		NA*	0.27	%CV ≤ 0.8
		CRBM/DGXN	2.14	%CV ≤ 4.2

Serial Number: J27003641

□ VECI / ECI Q Installation Precision

QC Fluid	QC Lot No.	Assay	Result	SPECS.
Total Thyroid Control L1		TSH		%CV ≤ 10.9
Total Thyroid Control L2		TSH		%CV ≤ 5.3
Total Thyroid Control L3		TSH		%CV ≤ 4.7
Total Thyroid Control L1		TT4		%CV ≤ 4.9
Total Thyroid Control L2		TT4		%CV ≤ 4.6
Total Thyroid Control L3		TT4		%CV ≤ 6.0



□ V3600 Installation Precision

QC Fluid	QC Lot No.	Assay	Result	SPECS.
Microsensor Check fluid 1		HEM		SD ≤ 0.70
		ICT		SD ≤ 0.10
		TUR		SD ≤ 7.10
Total Thyroid Control L2		TSH		%CV ≤ 5.27
Total Thyroid Control L1		TT4		%CV ≤ 3.93
Total Thyroid Control L3		TT4		%CV ≤ 3.69

□ Fusion 5.1 / V4600 Installation Precision

QC Fluid	QC Lot No.	Assay	Result	SPECS.
Performance Verifier 1		ALKP		SD ≤ 2.00
		dLDL		SD ≤ 2.40
		NA*		%CV ≤ 0.65
		Bu		SD ≤ 0.024
		Bc		SD ≤ 0.047
		CRBM/DGXN		%CV ≤ 4.20
TDM Verifier 3		HEM		SD ≤ 0.70
Microsensor Check fluid 1		ICT		SD ≤ 0.10
		TUR		SD ≤ 7.10
TDM Verifier 1		GENT		SD ≤ 0.063
IgM Protein Ver 1		IgM		SD ≤ 1.60

Send Report To : Original : Service Centre 1st Copy : Customer 2nd Copy : FF

**INSTALLATION
QUALIFICATION**

For

**FULLY AUTOMATED SYSTEM
VITROS 250**

ORTHOCLINICAL DIAGNOSTICS

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I. Approval of the IQ procedure

Both Dr B Lal Laboratories Sikar and Ortho-Clinical Diagnostics are jointly responsible for the installation of **VITROS 250** in Laboratory of Dr BLal Laboratories Sikaras per the attached Installation Qualification protocol.

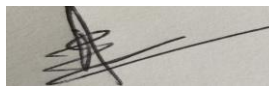
Instrument Identification

Verified Date: 31 July, 2020

1. Model Name **VITROS-250**
2. Serial Number: **J27003641**

Protocol Performed By: **Ortho-Clinical Diagnostics Representative**

Name : **Ravi Ranjan**

Signature: 

Title : **Service Engineer**

Date: 31 July, 2020

Company : **Ortho Clinical Diagnostics India
P Ltd.**

Customer Authorizations:

Name : **_Mohar Singh_**_____

Designation : **_Lab Incharge_**_____

Signature : _____

Date : **_31 July, 2020_**_____

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 Dr BLal Laboratories Sikar 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 Dr BLal Laboratories Sikar

III. Scope

This Installation Qualification protocol will be performed on the *VITROS 250*, located in Laboratory of **Dr BLal Laboratories Sikar**. 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.

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.

IV. Ancillary Information.

A. Certification of Purchase Order Compliance

I certify to the best of my knowledge, the instrument installed in Dr BLal Laboratories Sikaris in compliance with the specifications of the purchase order.

Verified By: Ravi Ranjan Date: 31 July, 2020

B. Utilities

Sr. No	Utility	Verified by	Date
1.	Environmental conditions:		
	a. Analyzer will be placed away from the direct sunlight.	Ravi Ranjan	31 July, 2020
	b. Installation site shall be free from dust, significant vibrations and shall be well ventilated.	Ravi Ranjan	31 July, 2020
	c. Installation site floor construction shall be able to support approximately 272 kg.	Ravi Ranjan	31 July, 2020
	d. Room temperature will be maintained between 15°C to 27°C and the temperature fluctuation during analysis shall not be more than $\pm 2^{\circ}\text{C}$.	Ravi Ranjan	31 July, 2020
	e. The analyzer shall be kept away from strong electromagnetic sources and electrical interferences.	Ravi Ranjan	31 July, 2020
	f. It will be kept near to the power sources.	Ravi Ranjan	31 July, 2020
	g. Maximum relative humidity allowed up to 70%.	Ravi Ranjan	31 July, 2020
	h. If the temperature and humidity fluctuations are not within the specified range, the analyzer cannot maintain data reliability.	Ravi Ranjan	31 July, 2020
2.	Adequate space for installation will be provided on all 5 sides of the instrument [129.54 (L) x 71 (W) x 142.24 (H)]	Ravi Ranjan	31 July, 2020
3.	Electrical Outlets: Actual Voltage on site [AC 220-230 Volts 16A 50 HZ]	Ravi Ranjan	31 July, 2020

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	Yes	31 July, 2020
2.	Manufacturer's specifications are included	Yes / No	Yes	31 July, 2020
3.	Accessories / Consumables are listed	Yes / No	Yes	31 July, 2020
4.	Equipment manual from the manufacturer is documented	Yes / No	Yes	31 July, 2020
5.	Manufacturer's Certificate attached	Yes / No	Yes	31 July, 2020

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	Ravi Ranjan	31 July, 2020
Manufacturer :	Ortho-Clinical Diagnostics	Ravi Ranjan	31 July, 2020
Model :	<i>VITROS 250</i>	Ravi Ranjan	31 July, 2020
Serial Number :	J27003641	Ravi Ranjan	31 July, 2020
Size (in cm) :	129.54 (L) x 71 (W) x 142.24 (H)	Ravi Ranjan	31 July, 2020
Power :	AC 220-230 V 16A 50Hz \pm 2Hz	Ravi Ranjan	31 July, 2020
Power consumption:	6880KW hours per year	Ravi Ranjan	31 July, 2020

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. 5385)	1 no.
	8321622	CLIN CHEM PROD INSTRUCTION USE	1 no.
	6801855/8175333	250 SYS SOFTWARE (ver. 7.21)	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 - Maint. & 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 Dr BLal Laboratories Sikar

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 the 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:

1. Installation Process:

The analyzer PC comes with preinstalled Analyzer Application Software. Reasons, if the software is to be installed on another PC, the PC will meet the following requirements.

The Analyzer has been installed satisfactorily: No **Yes** ✓

Verified by: Ravi Ranjan.

VI. COMMENTS:

NA

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.

Protocol Performed By: Ortho-Clinical Diagnostics Representative

Name : **Ravi Ranjan**

Signature:



Title : Service Engineer

Date: 31 July, 2020

Company : Ortho Clinical Diagnostics India
P.Ltd

Customer Authorizations:

Name : **_Mohar Singh_**

Designation : **_Lab Incharge_**

Signature : _____

Date : **_31 July, 2020_**

**OPERATIONAL
QUALIFICATION**

For

**FULLY AUTOMATED SYSTEM
VITROS 250**

ORTHOCLINICAL DIAGNOSTICS

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I. Approval of the OQ procedure

Both B Lal Laboratories Sikar and Ortho-Clinical Diagnostics are jointly responsible for the installation of *VITROS 250* in Laboratory of B Lal Laboratories Sikar, Jaipur as per the attached Operational Qualification protocol.

Instrument Identification

1. Model Name VITROS-250

Signature:



2. Serial Number: J27003641

Verified Date: 1Aug, 2020

Customer Authorizations:-

Name : _Mohar Singh_____

Designation : __Lab Incharge_____

Signature : _____

Date : __4Aug, 2020_____

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 B Lal Laboratories Sikar, Jaipur, will verify each result and sign in 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*, Located in Laboratory of B Lal Laboratories Sikar, Jaipur. 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:

B. Instrument Identification

Verified Date: 4 Aug, 2020

1. Model Name VITROS-250
2. Serial Number: J 27003641

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	Harkesh 1-4Aug, 2020
02	Daily maintenance	To clean appropriate modules so as to maintain accuracy and precision	Harkesh 1-4Aug, 2020
03	Inventory of reagents and consumables	To check the slide supply of installed Vitros 250	Harkesh 1-4Aug, 2020
04	Calibration for the assays used	To calibrate the system for every new lot of assay	Harkesh 1-4Aug, 2020
05	QC check	To confirm that systems, reagents and consumables are acceptable and working within specifications for each assay used	Harkesh 1-4Aug, 2020
06	Sample programming and Analysis	To run the samples	Harkesh 1-4Aug, 2020

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 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

FAIL

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	Harkesh	1Aug, 2020
02	Clean ERF Reservoir Holder & Base	Harkesh	1Aug, 2020
03	Replace ERF Reservoir	Harkesh	1Aug, 2020
04	Replace ERF Tip	Harkesh	1Aug, 2020
05	Clean ERF Tip Sleeve	Harkesh	1Aug, 2020
06	Clean IWF Reservoir Holder & Base	Harkesh	1Aug, 2020
07	Replace IWF Reservoir	Harkesh	1Aug, 2020
08	Replace Wash Fluid Tip	Harkesh	1Aug, 2020
09	Clean Wash Fluid Tip Sleeve	Harkesh	1Aug, 2020
10	Load supplies and remove outdated and empty reagents	Harkesh	1Aug, 2020
11	Perform Quality Control	Harkesh	1Aug, 2020

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 installed Vitros 250

Procedure:

Sr. No.	Activity	Done By	Date
01	Loading of Reagent cartridge in the appropriate slide supply	Harkesh	1Aug, 2020

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	Harkesh	2Aug, 2020
02	Performing Calibration with calibration programming screen	Harkesh	2Aug, 2020

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	Harkesh	2Aug, 2020
02	Creating QC file	Harkesh	2Aug, 2020
03	QC sample programming and analysis	Harkesh	2Aug, 2020

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	Harkesh	2Aug, 2020
02	Programming samples	Harkesh	2Aug, 2020
03	Unloading the samples	Harkesh	2Aug, 2020
04	Viewing samples in process	Harkesh	2Aug, 2020
05	Review results: Monitoring results	Harkesh	2Aug, 2020

Acceptance criteria:

Samples Analysis without any error

PARAMETER PASS FAIL

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.

Harkesh, Regional Application Manager- North from OCD- Ortho Clinical Diagnostics has conducted the training.

Sr. No.	Training program	Date
1.	Instrument Setup	1Aug, 2020
2.	System Operation	2 - 3Aug, 2020
3.	Basic trouble shooting and Maintenance	4Aug, 2020

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	Mohar Singh	Biochem		1-4Aug, 2020
2	Mahipal Yadav	Biochem		1-4Aug, 2020
3	Rajender Mehra	Biochem		1-4Aug, 2020
4	Mandeep	Biochem		1-4Aug, 2020
5	Dr Vandana	Biochem		1-4Aug, 2020

V. COMMENTS:

NA

