PERFORMANCE QUALIFICATION

For

FULLY AUTOMATED CHEMISTRY SYSTEM VITROS 250

Manufactured BY: ORTHOCLINICAL DIAGNOSTICS

Table of Contents

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**

Designation : Application Manager

Company : OCD

Signature: 

Date: 1 Aug, 2020

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:

Test No.	Test Name	Test purpose	Verified date
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**

Designation : Application Manager

Company : OCD

Signature: 

Date: 1 Aug, 2020

Customer Authorizations:

_____

Name : _**Mohar Singh**_____

Designation : __**Lab Incharge**_____

Signature : _____

Date : ___4Aug, 2020_____

INSTALLATION REPORT

Ortho Clinical Diagnostics

WI-OCDIN-004/F04
Issue No. 4

Sr. 005011

UNIVERSAL INSTALLATION REPORT - ORTHO INDIA

Customer Details :

Name & Address of Customer : Bilal Clinical Laboratory Pvt Ltd, C/o Rathi Hospital, Sikar, Rajasthan

Department : Biochemistry

Contact Person : Mohan Saini

Phone & Extn. No : 9929660011

E-mail ID : mohansaini@bilalkbs.com

Instrument Details :

Name of the Instrument : V250

J Number : J2700 3641

Serial Number : J2701 3641

Instrument Type : ☐ NEW ☐ SALE ☑ Refurbished ☑ ARC

Check List :

UPS Rating : 2.20V

Current Software Version : V9.7

Calibration Diskette /ADD No : DRV 6085

Are pre installation requirements met ? Yes ☑ No ☐

If not specify.

Was there shipping damage? Yes ☐ No ☑

If yes, what was the shipping damage ?

Modification Numbers already circled :

1,2,3,5,6,7,8,9,10,11,12,13,15,17,19,20,21,23,24,25,26,27,28,29,31,33,34,35,37,38,40,41,42,43,45,47,48,49,51,54,55,56,57,58,59,61,62,63,64,65,66,67,75,77,78,79,80,81,82,83,84,85,86,87,88,A1,A3,A6,B4,B8

Was troubleshooting adjustments required ? Yes ☐ No ☑

If yes, specify & mention module and condition code.

Did all the accessories arrive prior to installation ? Yes ☑ No ☐

If no list the missing items.

Were any parts replaced during installation ? Yes ☐ No ☑

If yes, then please mention the details below

Part No	Part Name	SPR No.	Quantity	Remarks

Time Log :

Date	Travel Hrs	Work Hrs
1 Aug	6 HR	6 HR
	Total : 6 HR	Total : 6 HR

Installation Completed Date : 1 Aug, 2020

Customer Training Details :

	Name of the Operator Trained	Date
1	MOHAN SINGH SAINI	1-4 Aug
2	MAHIPAL YADAV	
3	RAJENDER MEHRA	
4	MANDEEP	
5	ALVANDANA TIWARI	

Trained by : Name : HARKESH

Sign :

Did precision marker pass the first time? Yes ☑ No ☐

If not explain

Customer's Remarks : OK

Engineer's Remarks : Working OK

Customer's Seal & Signature

Name

Company's Personnel Ravi Ranjan (sign)

Name RAVI RANJAN

Page 1 of 3

INSTALLATION QUALIFICATION DATA SHEET

(Use appropriate qualification table)

☐ **V250 / 350 Installation Precision**

Serial Number J27003641

QC Fluid	QC Lot No.	Assay	Result	SPECS.
Performance Verifier I	N7649	ALKP	1.5	SD ≤ 2.0
TDM III	Q7653	NA+	0.27	%CV ≤ 0.8
		CRBMDGXN	2.14	%CV ≤ 4.2

☐ **VECI / ECI Q Installation Precision**

Serial Number

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**

Serial Number

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

☐ **Fusion 5.1 / V4600 Installation Precision**

Serial Number :

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

Send Report to : Original : Service Centre 1st Copy : Customer 2nd Copy : FE

INSTALLATION
QUALIFICATION

For

FULLY AUTOMATED SYSTEM
VITROS 250

ORTHOCLINICAL DIAGNOSTICS

Table of Contents

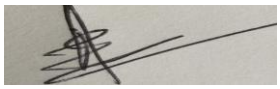
I. Approval of the IQ procedure

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.

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 15^0C to 27^0C and the temperature fluctuation during analysis shall not be more than ± 2^0C.	**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 :	*VITROS 250*	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:

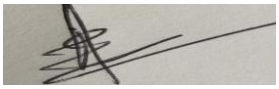
NA

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

Table of Contents

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 ± 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

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.

Instrument Identification

1. **Model Name** **VITROS-250** Signature: 

2. **Serial Number:** **J 27003641** **Verified Date:** 4 Aug, 2020

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

Name **:** Harkesh

Title **:** Application Manager **Date:** 4 Aug, 2020

Customer Authorizations:

Name **:** _Mohar Singh_____

Designation : __Lab Incharge_____

Signature : _____

Date : ___4Aug, 2020_____