Ortho Clinical Diagnostics

WI-OCDIN-004/F04
Issue No. 4

Sr. 9136

UNIVERSAL INSTALLATION REPORT - ORTHO INDIA

Customer Details :

Name & Address of Customer : KRM Healthcare
436/437 Laxmi plaza Laxmi Industrial area
Estate, Andheri West, Mumbai - 400-053.
MAHARASHTRA.

Department : LABORATORY MEDICINE,
Contact Person : Kumudhini Rawool
Phone & Extn. No : 7066236831
E-mail ID : Kumudhinirawool95@gmail.com

Instrument Details :

Name of the Instrument : V5600
J Number : J5600185 4
Serial Number : 5600185 4

Instrument Type :
☐ NEW ☐ SALE
☑ Refurbished ☑ RRC

Check List :

UPS Rating : 6K-AV
Current Software Version : V.3.7.2
Calibration Diskette /ADD No. 6224

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 :
A1, Ag, B3, B4, B5, B8, C3, C9, 14, 53, 76, 79, 80, 90, 91, 92, 93, 94, 99.

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
NA	NA	NA	NA	NA

Time Log :

Date	Travel Hrs.	Work Hrs.
20/5/2023	2 hours 15 mins	8 hours
22/5/2023	2 hours 15 mins	9 hours
	Total : 4 hours 30 mins	Total : 17 hours

Installation Completed Date : 22/05/2023

Customer Training Details :

	Name of the Operator Trained	Date
1	Kumudhini Rawool	29/05/2023
2	Bhoomika Naresh Ranva	29/05/2023
3	Aashish Arjun Kalambate	29/05/2023
4	Ajay Tunjus	02/06/2023
5	Feezal Abdul Bari Lentia	02/06/2023

Trained by : Name : Raj Kumar Dandotiya
Sign :

Did precision marker pass the first time?
Yes ☑ No ☐
If not explain

Customer's Remarks :

Engineer's Remarks :
Functioning well.

KRM Healthcare Private Limited Mumbai

Customer's Seal & Signature K Rawool
Name

Company's Personnel (sign)
Name Kiran Savant

INSTALLATION QUALIFICATION DATA SHEET

(Use appropriate qualification table)

☐ **V250 / 350 Installation Precision** Serial Number : _____

QC Fluid	QC Lot No.	Assay	Result	SPECS.
Performance Verifier I	NA	ALKP		SD ≤ 2.0
		NA+	NA	%CV < 0.8
TDM III		CRBM/DGXN		%CV < 4.2

☐ **VECI / ECI Q Installation Precision** Serial Number : _____

QC Fluid	QC Lot No.	Assay	Result	SPECS.
Total Thyroid Control L1	NA	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	NA	%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
		TUR		SD ≤ 7.10
Total Thyroid Control L2	NA	TSH	NA	%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** Serial Number : _____

QC Fluid	QC Lot No.	Assay	Result	SPECS.
Performance Verifier I	NA	ALKP		SD ≤ 2.00
		dLDL		SD ≤ 2.40
		NA+	NA	%CV ≤ 0.65
		Bu		SD ≤ 0.024
		Bc		SD ≤ 0.047
TDM Verifier 3		CRBM/DGXN		%CV ≤ 4.20
Microsensor Check fluid 1	NA	HEM		SD ≤ 0.70
		ICT		SD ≤ 0.10
		TUR	NA	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 : FE**

☑ **V5600 Installation Precision** Serial Number : J5G001854

QC Fluid	QC Lot No.	Assay	Result	SPECS.
Performance Verifier I	M9814	ALKP	1.142	SD ≤ 2.00
		dLDL	0.851	SD ≤ 2.40
		NA+	0.4	%CV ≤ 0.65
		Bu	0.010	SD ≤ 0.024
		Bc	0.025	SD ≤ 0.047
TDM Verifier 3	X1172	CRBM/DGXN	2.0	%CV ≤ 4.20
Microsensor Check fluid 1	X1108	HEM	0.25	SD ≤ 0.70
		ICT	0.073	SD ≤ 0.10
		TUR	6.5	SD ≤ 7.10
TDM Verifier 1	V1170	GENT	0.063	SD ≤ 0.063
IgM Protein Ver 1	89681	IgM	0.767	SD ≤ 1.60
Total Thyroid Control L2	0870	TSH	2.1	%CV ≤ 5.27
Total Thyroid Control L1		TT4	0.9	%CV ≤ 3.93
Total Thyroid Control L3		TT4	2.8	%CV ≤ 3.69

☐ **XT 3400 Installation Precision** Serial Number : _____

QC Fluid	QC Lot No.	Assay	Result	SPECS.
Performance Verifier I	NA	ALKP		SD ≤ 2.00
		NA+		%CV ≤ 0.65
		Bu	NA	SD ≤ 0.024
		Bc		SD ≤ 0.047
		XT UREA		%CV ≤ 2.2
		XT CREA		%CV ≤ 1.73
TDM Verifier 3		CRBM/DGXN		%CV ≤ 4.20
Microsensor Check fluid 1	NA	HEM		SD ≤ 0.70
		ICT	NA	SD ≤ 0.10
		TUR		SD ≤ 7.10

☐ **XT 7600 Installation Precision** Serial Number : _____

QC Fluid	QC Lot No.	Assay	Result	SPECS.
Performance Verifier I	NA	ALKP		SD ≤ 2.00
		dLDL		SD ≤ 2.40
		NA+		%CV ≤ 0.65
		Bu	NA	SD ≤ 0.024
		Bc		SD ≤ 0.047
		XT UREA		%CV ≤ 2.2
		XT CREA		%CV ≤ 1.73
TDM Verifier 3		CRBM/DGXN		%CV ≤ 4.20
Microsensor Check fluid 1	NA	HEM		SD ≤ 0.70
		ICT	NA	SD ≤ 0.10
		TUR		SD ≤ 7.10
TDM Verifier 1		GENT		SD ≤ 0.063
IgM Protein Ver 1		IgM		SD ≤ 1.60
Total Thyroid Control L2	NA	TSH		%CV ≤ 5.27
Total Thyroid Control L1		TT4	NA	%CV ≤ 3.93
Total Thyroid Control L3		TT4		%CV ≤ 3.69

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

Ortho Clinical Diagnostics

OPERATIONAL QUALIFICATION

For

VITROS® 5600 INTEGRATED SYSTEM

Manufactured by:

Ortho Clinical Diagnostics, Inc., US

Table of Contents

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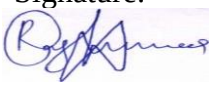
I. APPROVAL OF THE OQ PROCEDURE:

Both KRM Healthcare and Ortho Clinical Diagnostics are responsible for Operational check of VITROS® 5600 Integrated System bearing Sr. No 56001854 installed in Department of Laboratory as per the attached protocol.

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

Name	:	**Rajkumar Dandotikar** Application Specialist	Signature: 
Company	:	Ortho Clinical Diagnostics	Date: 29/05/2023

Customer Authorizations:

Name: Dr. Neeraj Gujar

Title: Laboratory Director Signature:

Site : KRM Healthcare, Mumbai. Date:

II. INSTRUCTIONS:

1. This document is to be verified / completed at the time, the system is going for operational check of each purpose 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 Operational Qualification.

3. Employees of M/S KRM Healthcare, will verify result and sign. The member of the validation team will carry out this procedure.

4. ALL deviations from normal specification during operation check 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 protocol for the same.

III. SCOPE

This Operational Qualification protocol will be performed on the VITROS® 5600 Integrated System, bearing Sr. No. 56001854 located at Department of Laboratory at KRM Healthcare.

This protocol will define the documentation that will be used to evaluate the instrument's operational check in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been operated in accordance with the intended usage.

Operational checks will also be performed to verify that the Instrument has been operated with proper information / sequence and utilities.

Trained, knowledgeable personnel will perform operational 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: 29-5-2023

1. Model Name VITROS® 5600 Integrated System

2. Serial Number 56001854

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

Test No.	Test Name	Test purpose	Initial / Date
01	System centers Overview	To make the operator to identify the instrument subsystem.	29-5-2023
02	Start up & Shutdown	To make the equipment ready for operation.	31-5-2023
03	User Inter Face Overview	Different functionality of software utility available for the operator interaction.	29-5-2023
04	Sample programming and Analysis	To process samples either by manual assigning or through LIS.	29-5-2023
05	Performing Calibration	To calibrate the system for every new lot of assay or after calibration expiry.	29-5-2023
06	Maintenance & System clean	To perform maintenance process to keep the system operating properly.	30-5-20233
07	Reagent Management & supply	To update & monitor the status of reagents required for assay processing.	31-5-2023
08	Performing Quality control	To confirm that systems, reagents and consumables are acceptable and working within specifications for each assay used	31-5-2023
09	Result Review	To review the processed results in the system.	30-5-2023
10	Result Intellicheck.	To check the Intellicheck function of the system.	30-5-2023
11	Option & Configuration	To setup the system as per Laboratory requirement.	31-5-2023

Test: 1 **: System Hardware Overview**

Purpose : To make the operator to identify the instrument subsystem.

Reference **:** Operator Reference Guide - Pages 4-1 to 4-5

Summary:

For better understanding purpose, Instrument has been divided into several parts according to its operation mode, so we call this partition as centers. And those centers are named as mention below.

Procedure:

This will list the available system centers in the instrument and its subsystem content to operator understanding. The operator has to overview the Service V-Docs to get an idea about the system centers overview.

- Sampling Centers
  - Sample Supply
  - Primary Tip sealer
  - Micro sensor subsystem
- Micro Immunoassay Center
  - Micro Immunoassay Metering & Reagent Metering
  - Micro Immunoassay Versa Tip Ring
  - Micro Well Incubator
  - Micro Well Wash Assembly
  - Signal Reagent Assembly
  - Luminometer
- Command Center
  - Master Computer & Monitor
  - Keyboard & Touch system
- System Frame and Cabinetry

Test: 2 **: Starting Up and Shutting Down**

Purpose : To make the instrument 'READY' for operation

Reference **:** Operator Reference Guide - Pages 3-0 to 3-25

Summary:

Instrument will check status of different parts of the instrument automatically after booting up to system status screen; if there is an error code posted, initialize the system and follow corrective action instructions provided for the error code.

Procedure:

Starting Up the System

- Check the room temperature and switch on the Air Conditioner.
- Check the UPS.
- Switch on the Printer & Load the paper.
- Switch on the VITROS® 5600 Integrated System by lift the main switch up and hold it for about 5 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 the instructions provided for the error codes.

Shutting Down the system

- Touch **Shutdown** in the main menu.
- Press '**Y/N**' to continue the shutdown process.
- Desire normal shutdown or final shutdown and then select desired menu.
- If, you selected **Final Shutdown,** press the RESET button to restart the instrument, or press the Main power switch down to make it OFF.

Observation	System status console shows "Ready". Instrument is ready for operation	**Remarks**	**Initial/Date**
		Pass	30-5-2023

Test: 3 **: User Interface Overview**

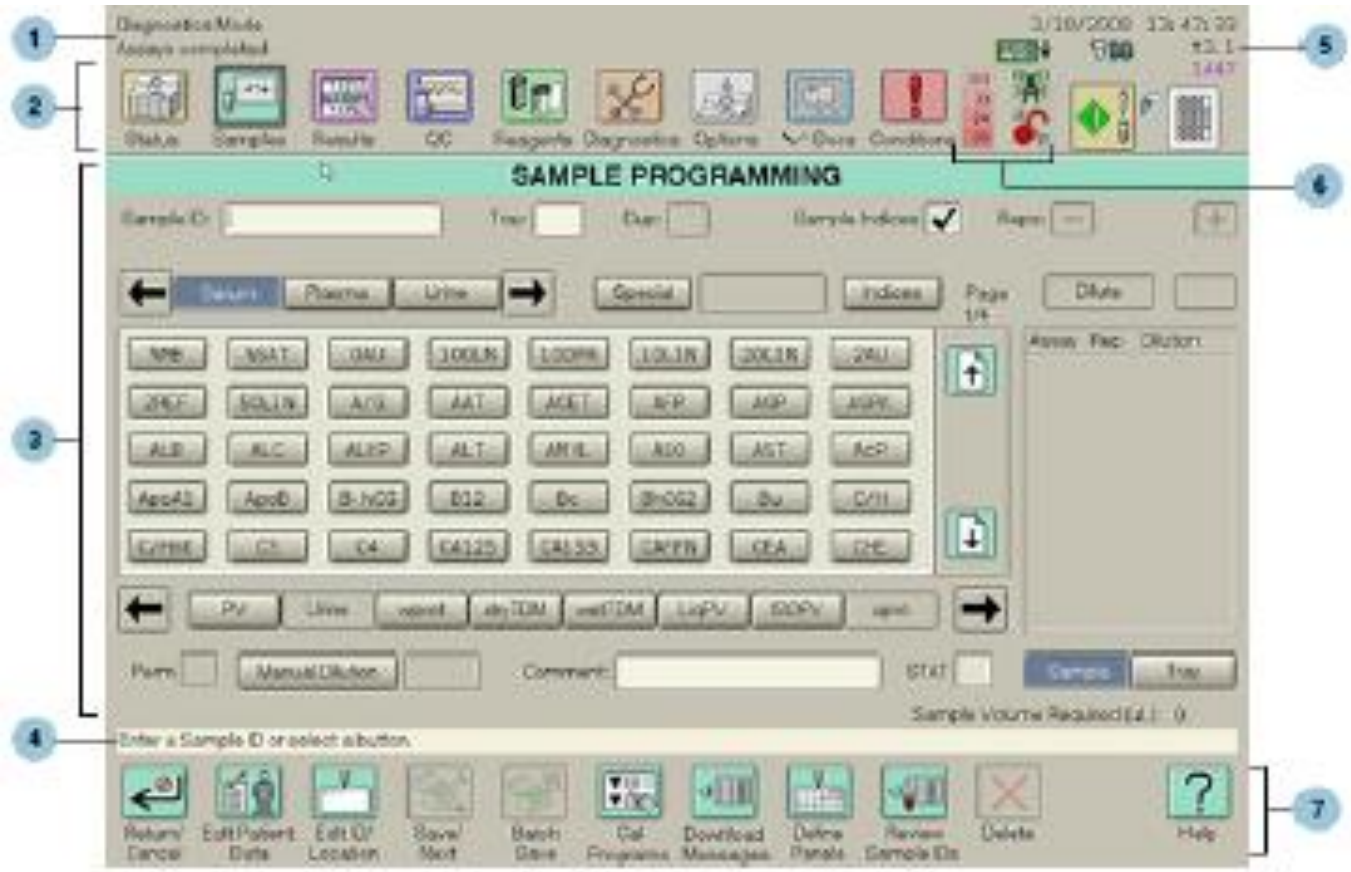
Purpose : To make the operator to understand the system screens.

Reference **:** Operator Reference Guide - Pages 6-0 to 6-12

Summary:

The System status screen will make the operator to understand of different functionality of software utility available for the operator. This will helps operator to check system status as well as to instruct any commands to the system for required operation.

Procedure:



The above (as shown in the Previous Page) picture is actual system software screen and the number in the blue circle is to identify the several functionality of the software icons designed for the operator to interact with the system. We call these software icon as mentioned below.,

1. Status Line
2. Status Console
3. Function Screen
4. Prompt Line
5. Time, Date and Version Display
6. Status Indicators
7. Process Buttons

Test: 4 **: Sample programming and Analysis**

Purpose **:** To program and process the samples

Reference **:** Operator Reference Guide (pages 9-1 to 9-13)

Summary: The operator can process assay by assigning program manually in the Universal Sample tray in **'Sample Program'** menu or they can download sample program through **'LIS'**. Sample programming is the process of selecting assays and programming characteristics for samples. The system uses the sample program to meter appropriate sample and select the right reagent for the assay, process and then report results with the correct identification.

Procedure:

Sr. No.	Activity	**Observation**	Remarks Pass / Fail	Done By Date
01	Sample Programming methods & Overview	Desire the sample Programming method.	Pass	30-5-2023
02	Loading and Processing of samples	Tray cover opened and samples loaded in sample tray placed in sample supply.	Pass	30-5-2023
03	Programming samples	Sample program assigned for selected tray.	Pass	30-5-2023
04	Processing samples	Samples are processed automatically by the system.	Pass	30-5-2023
05	Unloading the samples	Tray cover opened and processed sample tray unloaded.	Pass	30-5-2023
06	Viewing samples in process	Sample under process are	Pass	30-5-2023

		displayed on the 'View Sample Status' Screen.		

Test: 5 **: Performing Calibration**

Purpose **:** To calibrate the system for every new lot of assay

Reference **:** Operator Reference Guide (pages 10-1 to 10-9)

Summary: The system requires its own calibration for every individual assay to measure the analytic concentration as well as to accept reagent pack status ready for processing. Assay calibration is a process that relates the response of the system to analyte concentration or activities. Calibration is performed periodically to adjust for changes in the system, assay protocols, or assay reagent lots.

The system requires calibration for individual assays when:

- A new assay is uploaded to the system
- The calibration expires (up to 28 days after it is processed, depending on the assay; refer to the package insert for expiration information)
- An assay reagent lot number changes
- Government regulations specified
- An assay's protocol changes

You also may need to perform calibration when:

- Certain service procedures are performed
- Quality control performance is out of range

Procedure:

Sr. No.	Activity	**Observation**	Remarks	Done By
			Pass / Fail	Date
01	Load New ADD via CD or Downloaded file (New Gen Lot, Protocol , reagent lot calibration , Diluents lot information).	Calibrator identified and updated for protocol & master calibration data.	Pass	31-5-2023
02	Preparing calibrators.	Calibrators are ready for processing.	Pass	30-5-2023
03	Performing Calibration with Bar code label.	System recognizes the barcode and processing the calibration automatically.	Pass	30-5-2023
04	Performing Calibration with Sample processing screen.	In the sample programming, the calibration program is assigned and processed the calibration assigned for each assay.	Pass	31-5-2023

05	Calibration report.	Calibration completed successfully. Report printed.	Pass	30-5-2023

Test: 6 **: Maintenance & System Clean**

Purpose **:** Clean appropriate modules to maintain Accuracy and precision.

Reference **:** Operator Reference Guide 16-13 to 16-17

Summary:

Maintenance procedures are tasks that are performed to keep the system operating properly. Maintenance protocols to be performed according to the recommended schedule (daily, weekly, monthly, or as required). Ensure that we need to use 70% Isopropyl alcohol to disinfect the appropriate module to keep cleanliness and maintain the accuracy & precision.

The Maintenance is classified into four-category ie.,

1. Daily Maintenance
2. Weekly Maintenance
3. Monthly Maintenance
4. As required Maintenance

Daily Maintenance: Pages from 16-14 to 16-15

Sr. No.	Activity	Observation	Remarks Pass/Fail	Done By Date
01	Perform Metering Maintenance	Metering Maintenance Performed	Pass	30-5-2023
02	Empty Solid and Liquid waste container	Solid & Liquid waste containers are emptied.	Pass	30-5-2023
03	Remove outdated or empty reagent packs, Signal Reagent packs and Universal Wash Buffer	Outdated empty Reagent packs, SR packs and UWR bottles are removed & discarded.	Pass	30-5-2023
04	Inspect sample trays and adaptors	Sample Trays are cleaned.	Pass	30-5-2023
05	Clean the SR Probe assembly	SR Probes are cleaned.	Pass	30-5-2023
06	Load required reagent packs, Signal Reagent pack and Universal Wash Buffer.	All the required reagent packs are loaded and updated in the system as required.	Pass	30-5-2023

07	Run Q.C fluids	Q.C samples are processed successfully.	Pass	30-5-2023

Weekly Maintenance: Pages from 16-15 to 16-16

Sr. No.	Activity	Observation	Remarks Pass/Fail	Done By Date
01	Clean the Micro well Incubator.	Micro well incubator – Inner ring, outer ring, middle ring, shuttle weight, drop holes, Luminometer FOB, Wash reagent and signal reagent probes are cleaned.	Pass	31-5-2023
02	Clean the Primary tip sealer.	Primary Tip Sealer cleaned.	Pass	31-5-2023
03	Clean the Secondary Tip Sealer.	Secondary Tip Sealer cleaned.	Pass	31-5-2023
04	Clean the Sample Supply and Cap Retainer.	Cap Retainer & Sample Supply cleaned.	Pass	31-5-2023
05	Clean the Touch Screen Monitor & Keyboard.	Touch Screen Monitor & Key board Clean Done.	Pass	31-5-2023
06	Run the maintenance Pack for Subsystem cleaning.	Maintenance pack is loaded; subsystem cleaning done automatically by the system.	Pass	31-5-2023
07	Run QC Fluids	Q.C Processed successfully.	Pass	31-5-2023

Monthly Maintenance: Pages from 16-15 to 16-16

Sr. No.	Activity	Observation	Remarks Pass/Fail	Done By Date
01	Clean Micro sensor Cover & Ring Area.	Micro Sensor Cover & Ring Surface cleaned.	Pass	31-5-2023
02	Inspect/Clean Micro Immuno Assay reagent Supply top Cover.	Micro Immuno Assay Reagent Supply top Cover Inspected and Cleaned.	Pass	31-5-2023
03	Clean VITROS Versa Tip supply Registration Rail.	Versa tip Supply Registration Rail cleaned.	Pass	31-5-2023
04	Inspect Reagent cooler filter for cleanliness.	Reagent cooler filter removed & cleaned.	Pass	31-3-2023
05	Replace Vapors adsorption cartridge for every two months.	Every two months once, VAC replaced.	Pass	31-5-2023
06	Make a backup of Q.C, Calibration and Configuration.	Backup of QC, Calibration and Configuration made successfully.	Pass	31-5-2023
07	Inspect / Clean Master Computer Filter.	Inspected and Cleaned Master computer Air Filter.	Pass	31-5-2023

Test: 7 **: Managing reagents Inventory and Supply**

Purpose **:** To Maintain & monitor the status of reagents or supply required for assay processing.

Reference **:** Operator Reference Guide (pages 15-1 to 15-7)

Summary: The Reagent Management feature enables you to review current inventory Information for the reagents loaded on the system. Using this function, you can load and unload reagents as necessary. To maintain the required reagents in the system for processing, the operator should review the Reagent management screen.

Procedure:

Sr. No.	Activity	**Observation**	Remarks Pass/Fail	Done By Date
01	Review the reagent inventory to plan for the day.	The reagent inventory for the day planned.	Pass	01-6-2023
02	Loading of Reagent Pack automatically	Required Reagent Packs loaded automatically by software request.	Pass	01-6-2023
03	Loading of Reagent Pack with help of Manual Lot Entry button.	Requested Lot Information fed and the reagent pack loaded.	Pass	01-6-2023
04	Loading of Signal Reagent automatically.	SR Pack loaded in position 1 & 2 and accepted by barcode reading.	Pass	01-6-2023
05	Loading of Signal Reagent with Manual Load Button.	SR packs information fed and loading done.	Pass	01-6-2023
06	Loading of Universal Wash Buffer	UWR buffer loading done through Load supply Software icons.	Pass	01-6-2023
07	Unloading of Reagents	The entire Empty & expired reagents packs are unloaded by Load/Unload software icons.	Pass	01-6-2023

Test: 8 : Performing Quality control

Purpose : Quality Control (QC) is important in determining the performance and accuracy of the system. To perform Quality Control, QC materials are run with either known, or unknown values along with patient samples to determine whether the system is functioning within the established ranges for your lab.

Reference : Operator Reference Guide (Pages 9-6 to 9-8)

Summary: Performing quality control procedures is an important part of using or maintaining the system. This section explains:

- When you should perform quality control
- How to choose a control fluid

The recommended frequency for processing quality control fluids is once in every 24 hours. However, the frequency with which you perform quality control procedures may vary, depending on the requirements and regulations for processing control fluids by your national, state, provincial, and local governments. Quality control procedures within your own Laboratory may also require a different frequency. You should also perform quality control procedures when:

- Assays have been calibrated
- Certain service procedures are performed, other than routine maintenance

Procedure:

Sr. No.	Activity	**Observation**	Remarks	Done By
			Pass / Fail	Date
01	Choosing the Control fluid	Required control fluid identified.	Pass	31-5-2023
02	Preparing Liquid or Lyophilized control fluids	Control fluid prepared and ready for processing.	Pass	31-5-2023
03	Creating QC file.	Q.C file created for assay in the system according to control fluid.	Pass	31-5-2023
04	Process QC samples	QC samples are programmed in the sample programming window and the QC samples are loaded and processed automatically	Pass	31-5-2023
05	Review Q.C result.	Processed Q.C results are reviewed and found satisfactory.	Pass	31-5-2023
06	Display & printing graph.	Q.C graph reviewed and printed.	Pass	31-5-2023
07	Managing Quality control Reports	Required reports printed and filed.	Pass	31-5-2023

Test: 9 **: Result Review.**

Purpose **:** To review the processed results in the system.

Reference **:** Operator Reference Guide (Pages 11-1 to 11-6)

Summary: The Results Review function helps to evaluate result records for patient and quality control samples. The results will be displayed along with the Reagents Lot information, Dilution information & if there is any error codes or Flags.

Result records contain the data generated by the system when assays are processed. The system can store up to 25,000 result records. When this limit is reached, new result records overwrite the oldest records. The system permanently deletes the overwritten records from computer memory.

Procedure:

Sr. No.	Activity	**Observation**	Remarks	Done By
			Pass / Fail	Date
01	Update List.	Sample under process status displayed with all information.	Pass	31-5-2023
02	Monitoring Results.	Completed Recent Assay Results displayed on the screen.	Pass	31-5-2023
03	Filter Results.	Processed Assay Results displayed as per the selected criteria.	Pass	31-5-2023
04	Edit Patient Data	User can Edit/Add Patient Demography information, but the Patient ID will remain same.	Pass	31-5-2023
05	Retrieving and Reviewing Archive Results by Set Report Status.	Archived Results are updated successfully in the CD/Pen Drive. The same Retrieved from the CD/Pen Drive.	Pass	31-5-2023
06	Managing Reports by Set Report Status.	Required Reports got printed and filed.	Pass	31-5-2023
07	Integrated Codes and Flags	Reported Codes and Flags are referred in Flags and Code chart. Necessary corrective action taken.	Pass	31-5-2023

Test: 10 : Result Intellicheck.

Purpose : To check the Integrity of Performed assays.

Reference : Operator Reference Guide (Pages 11-8 to 11-9).

Summary: The Result Intellicheck screen to view Intellicheck Technology
Verifications performed for each sample and assay processed. For the selected result record, you can view verification data and detected exceptions for each analyte.

Example:

- To Analyze Intelli Report, select the sample ID listed on result review screen.
- On Review results screen, touch the 'Result Intellicheck' Icon.
- Result Intellicheck report comes on the screen.
- Check the parameters of Sample Metering, Sample + Reagent volume, Signal reagent volume and well wash verification for their acceptance.
- Take print of the Result intellicheck report.

Acceptance criteria:

Sr. No.	Parameter	Acceptance limit	Remarks Pass / Fail	Done By Date
01	**Sample Metering** • Clot • Bubble • Short sample • Viscosity • Thin layer of fluid	Against all the parameters, "No" should be displayed on screen	Pass	30-5-2023
02	**Reagent Metering** Sample + Reagent volume	No Exception. Range: 12700 – 19000	Pass	30-5-2023
03	Signal Reagent	No Exception Range: 17500 – 22800	Pass	30-5-2023
04	Well wash verification	No Exception Range: 21300 – 25000	Pass	30-5-2023
05	Luminometer – Self calibration	No Exception	Pass	30-5-2023

Test: 9 : Option & Configuration

Purpose : To setup the system as per laboratory requirement

Reference : Operator Guide (Pages 11-8 to 11-14)

Summary: The Options & Configuration function provides many features for customizing your VITROS® 5600 Integrated System. It is organized into three main groups:

- Configure Analyte Data & Review/Edit Calibration Data
- System Setup
- System Services

Selections within these groups allow you to customize analyte parameters, review calibration data, perform user calibrations, configure and set system parameters, review usage inventory, configure e-Connectivity® and network device parameters, configure printer, laboratory computer and auxiliary ports, perform backup for quality control, calibration and configuration files and perform an archive procedure for result records.

Procedure:

Sr. No.	Activity	Observation	Remarks Pass / Fail	Done By Date
01	Configure Assays	Analyte parameters are configured as desired by laboratory.	Pass	31-5-2023
02	Review / Edit Calibration Data	Calibration data updated.	Pass	31-5-2023
03	Configure System Setup	Required subsystem configuration is done successfully.	Pass	31-5-2023
04	Configure Subsystem Setup	The required subsystem can be disabled / deactivated as per needs.	Pass	31-5-2023
05	Configure Report Control	System report parameter has set for printer & LIS.	Pass	31-5-2023
06	Configure Communication	System interface protocol set for Laboratory Information System (LIS), Ethernet and e-Connectivity® communications,	Pass	31-5-2023
07	Configure Demography	Global demographic attributes to be used when configuring age, sex, and normal ranges for specific assay/body fluids is defined.	Pass	31-5-2023
08	System Services 1.Datalogger 2.Perform Backup 3.Usage Counters 4.Option Summary 5.Load System Data	Shall be performed and reviewed as & when required.	Pass	31-5-2023

V. 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.

Sr. No.	Training program	Done	Date
1.	Instrument Setup	Rajkumar	30-5-2023
2.	System Operation	Rajkumar	31-5-2023
3.	Basic trouble shooting and Maintenance	Rajkumar	01-6-2023

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.	Kumudhini Bhikaji Rawool	Biochemistry		
2.	Bhoomika Naresh Ranva	Biochemistry		
3.	Ashish Arjun Kalambate	Microbiology		
4.	Feeza Abdul Bari Rentia	Microbiology		
5.	Karishma Ramesh More	Biochemistry		
6.	Tejal Nthin Nayak	Biochemistry		
7.	Amar Chandrakant Malap	Biochemistry		
8.	Ajay Anji Junjur	Biochemistry		
9.	Vikrant Vijay Lingayath	Biochemistry		

b. Customer SOP / Manuals:

Title	Number	Version	Verified by	Date

VI. COMMENTS :

VII. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outlined in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been / not been addressed. The system is ready for Performance Qualification.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name	:	Rajkumar Dandotikar	Signature: 
Designation	:	Application Specialist	Date: 02/06/2023
Company	:	Ortho Clinical Diagnostics	

Customer Authorizations:

Name: Dr. Neeraj Gujar,

Title: Laboratory Director, Signature:

Site : KRM Healthcare, Mumbai. Date:

Ortho Clinical Diagnostics

PERFORMANCE QUALIFICATION

For

VITROS® 5600 INTEGRATED SYSTEM

Manufactured by:

Ortho Clinical Diagnostics, Inc., US

Table of Contents

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IV	Performance Qualification	6
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V	Performance Qualification Report	10
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VII	System Certification	12

I. APPROVAL OF THE PQ PROCEDURE:

Both **KRM Healthcare** and Ortho Clinical Diagnostics are responsible for Performance check of VITROS® 5600 Integrated System bearing Sr. No 56001854 in Laboratory at KRM Healthcare as per the attached protocol.

Protocol Performed By: Ortho Clinical Diagnostics representative

Name	:	Mr.Ketan Sawant	Signature: Ketan
Designation	:	Sr. Territory Manager - Service	Date: 02-06-2023
Company	:	Ortho Clinical Diagnostics	

Customer Authorizations:

Name: Dr. Neeraj Gujar

Title: Laboratory Director Signature:

Site : KRM Healthcare, Mumbai. Date:

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 KRM Healthcare, Department of Laboratory will verify result and sign. 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

This Performance Qualification protocol will be performed on the VITROS® 5600 Integrated System, and the Sr. No.56001854 located at KRM Healthcare.

This protocol will define the documentation that will be used to evaluate the instrument's performance check in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been performed in accordance with the intended usage.

Performance checks will also be performed to verify that the Instrument has been operated with proper information/sequence and utilities.

Trained, knowledgeable personnel will perform Performance 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. PERFORMANCE QUALIFICATION

A. Instrument Identification — Verified Date

1. Model Name VITROS 5600 02-06-2023
2. Serial Number 56001854

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	Pass 22-05-2023
02	Accuracy Study	To compare the obtained value with true values of processed control.	Pass
03	Precision Study	To check the precision performance of the equipment	Pass 22-05-2023

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 & Endpoint Chemistry Microslide – Potentiometric Chemistry; Microslide – Immunorate Chemsitry; Microtip Chemistry Microsensor Chemistry Microwell - Chemiluminescence Immunoassay

Analysis of controls:

Note: Analyze controls for ALKP (Microslide Rate Chemistry);
Sodium (Potentiometric Chemistry);
BuBc (Microslide End point Chemistry)
Gent (Microslide – Immunorate Chemistry)
dLDL (Microtip Chemistry)
Gentamycin (Microtip Chemistry)
HIT (Microsensor Chemistry)
TSH (Microwell - Immunometric assay) &
TT4 (Microwell - Competitive assay).

Sr. No.	**Activity**	**Procedure done as per the protocol defined in Vitros 5600 V Docs – System Operation – Quality Control**	**Remarks**	**Done By**
			Pass/Fail	**Date**
01	Preparing Liquid or Lyophilized control fluids	"Instructions for use" of QC material	Pass	31-5-2023
02	Creating QC file	V Docs – System Operation – Quality Control – Define control fluids	Pass	31-5-2023
03	QC sample programming and analysis	V Docs – System Operation – Quality Control – Process Control fluid samples & Review the Control sample results.	Pass	31-5-2023

Test II

Test Name : **Accuracy**

Purpose : To see the accuracy of obtained quality control value in comparison with the expected mean values.

Method : Microslide; Microtip; Microsensor and Microwell 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 5600 V Docs – System Operation – Quality Control**	**Remarks**	**Done By**
			Pass/Fail	**Date**
01	Preparing Liquid or Lyophilized control fluids	'Instructions for use' of QC material	Pass	31-5-2023
02	QC sample programming and analysis	V Docs – System Operation – Quality Control – Process Control fluid samples & Review the Control sample results.	Pass	31-5-2023
03	Accuracy Analysis	Compare the obtained Q.C value with mean of expected value as mentioned in the QC Value chart.	Pass	31-5-2023

Test III

Test Name : **Precision Study**

Purpose : To see the precision performance of the equipment

Method : Microslide – Rate Chemistry & Endpoint Chemistry
Microslide – Potentiometric Chemistry;
Microslide – Immunorate Chemsitry;
Microtip Chemistry
Microsensor Chemistry
Microwell - Chemiluminescence Immunoassay

- Analyze Vitros Performance Verifier Level 1 control for the following tests : ALKP (5 x 7 times), Na+ (5 x 8 times), dLDL (6 x 6 times), BuBc (5 x 7 times)
- Analyze TDM Performance Verifier Level 3 for Gentamycin (5 x 7 times).
- Analyze TDM Performance Verifier Level 1 for Gentamycin (6 x 6 times).
- Analyze Microsensor Check Fluid Level I for Hemolysis, Icterus and Turbidity (20 times each).
- Analyze all the three levels of Vitros Total Thyroid controls for Microwell – Chemiluminescence Immunoassay TT4 and TSH (10 times each).
- Calculate the Mean, SD and CV%.

Acceptance Criteria :

Sr. No.	Analyte	Control Level	Precision Limit
01	ALKP	PV I	≤ 2.0 SD
02	Sodium	PV I	≤ 0.65% CV
03	dLDL	PV I	< 2.4 SD
04	Bu	PV I	≤ 0.024 SD
05	Bc	PV I	≤ 0.047 SD
06	Gentamycin	TDM PV I	< 0.063 SD
07			
08			

09	Hemolysis	MS Check Fluid Level I	SD < 0.70
10	Icterus	MS Check Fluid Level I	SD < 0.10
11	Turbidity	MS Check Fluid Level I	SD < 14.8
12	TT4	Total Thyroid Control Level 1	CV% ≤ 3.93
		Level 3	CV% ≤ 3.93
13	TSH		
		Level 2	CV% ≤ 5.27

The result of Precision Study is in the accepted limits. Please check the installation report for result details.

* Reference: The acceptance SD & CV% has been taken from Manufacturer's recommended limits.

V. COMMENTS:

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: Ortho Clinical Diagnostics Representative

Name	:	Mr Ketan Sawant	Signature: Mr Ketan
Designation	:	Sr. Territory Manager - Service	Date: 02-6-2023
Company	:	Ortho Clinical Diagnostics	

Customer Authorizations:

Name: Dr Rajeev Gujar

Title: Laboratory Director Signature:

Site : KRM Healthcare, Mumbai. Date:

Ortho Clinical Diagnostics

INSTALLATION QUALIFICATION

For

VITROS® 5600 INTEGRATED SYSTEM

Manufactured by:

Ortho Clinical Diagnostics, Inc., US

Table of Contents

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	Appendix	
	I. Installation Certificate	

I. APPROVAL OF THE IQ PROCEDURE:

Both **KRM Healthcare, Mumbai** and Ortho Clinical Diagnostics are responsible for installation of VITROS® 5600 Immunodiagnostic System bearing Sr. No **56001854** in **KRM Healthcare** as per the attached protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name	:	Mr. Ketan Sawant	Signature: 
Designation	:	Sr. Territory Manager	Date: 22-05-2023
Company	:	Ortho Clinical Diagnostics	

Validation Team from (hospital name): **KRM Healthcare**

Name	:	Signature:
Designation	:	Date:
Department	:	
Name	:	Signature :
Designation	:	Date :
Department	:	

Customer Authorizations:

Name	:	
Designation	:	
Signature	:	_____
Date	:	_____

II. INSTRUCTIONS:

1. This document is to be completed at the time the system is installed to its location 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.

3. Employees of **Masina Hospital** will verify each result and sign in each page. The member of the validation team will carry out this procedure.

4. ALL deviations from normal specification during 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 protocol for the same.

III. SCOPE

This Installation Qualification protocol will be performed on the VITROS® 5600 Immunodiagnostic System, and the Sr. No. **56001854** located at **KRM Healthcare.**

This protocol will define the documentation that will be used to evaluate the instrument's 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 Installation 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 VITROS® 5600 Immunodiagnostic System and **Sr. No. 56001854** installed on 22-05-2023.

Verified By: Mr. Ketan Sawant Date: 22-05-2023

b. Utilities

Sr. No	Utility		Verified by & Date
1.	**Environmental condition:** As per requirement (To be free from Dust, Electrical & magnetic Interferences and free from vibration)	Yes	Ketan Sawant 22-05-2023
2.	**Adequate space for installation:** (Length 110 inches x Width 35 inches x Height 84 inches)	Yes	Ketan Sawant 22-05-2023
3.	**Electrical Outlets:** Actual Voltage on site [200 Vac – 240 Vac] **Electrical Input:** Voltage supplied through ONLINE UPS (232Vac @ 50Hz frequency, Earthing < 2.0Vac)	Yes	Ketan Sawant 22-05-2023
4.	**Capacities:** • 90 samples (80 Routine positions & 10 STAT positions are available) • 150 Reagent Positions are available.	Yes	Ketan Sawant 22-05-2023
5.	**Temperature:** 15° C to 30° C 15% to 75% relative humidity	Yes	Ketan Sawant 22-05-2023

The instrument has been verified for the following:

Sr. No.	Verification		Verified by & Date
1.	Equipment is identified	Yes	Ketan Sawant 22-05-2023
2.	Manufacturer's specifications are included	Yes	Ketan Sawant 22-05-2023
3.	Accessories / Consumables are listed	Yes	Ketan Sawant 22-05-2023
4.	Equipment manual from the manufacturer is documented	Yes	Ketan Sawant 22-05-2023
5.	Manufacturer's Certificate of compliance attached	Yes	Ketan Sawant 22-05-2023

V INSTALLATION QUALIFICATION:

A. Equipment Description

The VITROS® 5600 Integrated System is a Random access, walk away system intended for use in the *in vitro* quantitative, semi-quantitative, and qualitative measurement of a variety of analytes of clinical interest, using VITROS Chemistry Products Microslides, VITROS Chemistry Products Microtip reagents and VITROS Immunodiagnostic Products Reagents.

Instrument Identification		Verified by	Date
Equipment Name :	**Automated Integrated System**	Ketan Sawant	22-05-2023
Model :	VITROS® 5600	Ketan Sawant	22-05-2023
Manufacturer :	Ortho Clinical Diagnostics, Inc., US	Ketan Sawant	22-05-2023
Marketed by :	Ortho Clinical Diagnostics India Pvt. Ltd.	Ketan Sawant	22-05-2023
Serial Number :	56001854	Ketan Sawant	22-05-2023
Software Name :	QNX OS	Ketan Sawant	22-05-2023
Software Version :	V 3.7.2	Ketan Sawant	22-05-2023
Size (in inches) :	Adequate for installation: (Length 170 x Width 83 x Height 84).	Ketan Sawant	22-05-2023
Power :	1600W@ 50Hz of 220Vac – 240Vac	Ketan Sawant	22-05-2023

B. Accessories/Consumables

The following accessories were supplied with the instrument. Check (√) 'verified by' in case they are found to be in order.

Description	**Quantity**	**Verified**	**Date**
User Training Manual	1	Ketan Sawant	22-05-2023
Application Software-Revelation	1	Ketan Sawant	22-05-2023
Universal Sample Tray	12	Ketan Sawant	22-05-2023
Backup DVD R/w	3	Ketan Sawant	22-05-2023
Printer Cable	1	Ketan Sawant	22-05-2023
Printer Software	1	Ketan Sawant	22-05-2023
Power Cords	3	Ketan Sawant	22-05-2023
Printer	1	Ketan Sawant	22-05-2023
Air filter	1	Ketan Sawant	22-05-2023
Waste can 5L	1	Ketan Sawant	22-05-2023

C. List of Manuals:

Ortho Clinical Diagnostics has supplied following manual.

D. 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 Training and Reference Guide. 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 QuidelOrtho 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.

VI. INSTALLATION PROCEDURE

(The following steps Performed at the time of original installation at the initial location)

1. Locating & unpacking the instrument.
2. Reaffix/verify the circuits boards & CPU
3. Nominal Line voltage frequency selection of transformer.
4. Load Supply & Power ON the system.
5. System Configuration.
6. Systems Tests & Adjustments.
7. Subsystems Performance Verification & calibration
8. Setting and installing printer.

The Above-mentioned steps has completed successfully by trained field Engineer as described below.

VI.1 Locating & unpacking the VITROS® 5600 instrument:

(\ServicePublications\5600\5600Service\J32845_Unpack-Install_Intact\J32845.pdf**)**

- Check the Tip & Tell Label.
- Verify the serial no / J number of the system match those indented for delivery.
- Place the pallet in a position with a minimum of 7 m (24 ft.) of clearance in front of the end with the LABELS
- Remove the STRAPPING and the RAMPS from the pallet.
- Assemble the 2-piece RAMP and hook the RAMPS to the end of the pallet
- Move the system down the ramps. Do the same for the second half of the system.
- Place the instrument in the lab leveled floor.
- Join the two halves of the system as per manufacturer's instructions.
- Remove the packing material from
    - VERSATIP supply carousel
    - Under side of sample supply cover

- SR metering Nozzle
- Well Wash Nozzles
- Beneath SR Pumps
- Luminometer & Micro Immunoassay VERSATIP ring
- Supply 4 load doors & Reagent Well shuttle
- SR carousel
- Remove the wire Tie, tape & Foam from UIA REAGENT METERING ARM.
- Remove the moisture separators behind the compressor installed on it bracket.
- Remove the Foam supporting from the compressor.

VI.2 Reaffix/verify the circuits boards & CPU:

(\ServicePublications\5600\5600Service\J32845_Unpack-Install_Intact\J32845.pdf**)**

- Open the right-side front door and open the card rack metal cover.
- Remove the RC labeled DSP boards and reaffix it back.
- Open the right-side rear panel and open the card rack metal cover.
- Remove the UC labeled DSP boards and reaffix it back.
- Open the Middle front door and open the CPU top cover & verify the boards.

VI.3 Nominal Line voltage / frequency selection of transformer:

(\ServicePublications\5600\5600Service\J32845_Unpack-Install_Intact\J32845.pdf**)**

- Connect the Primary T2_H6 on Label no H6 for 0Vac.
- Connect the Primary T2_H# on label no H2 for 230Vac.
- Connect the Secondary T2_X1 on label no X1 for 230Vac.
- Connect the Secondary T2_X# on label no X2 for 200Vac.
- Connect the Secondary T2_X3 & T2_X3 on label no X3 for 0Vac.

VI.4 Load Supply & Power ON the system:

(\ServicePublications\5600\5600Service\J32845_Unpack-Install_Intact\J32845.pdf**)**

- Versa Tip & Sample Trays.
- Signal Reagent & Universal Reagent.
- Check the supply and Earthing voltage.
- Switch **ON** the Instrument.

VI.5 System Configuration.: (\6902906_3600-RefGd_Ltr-EN.pdf)

Click on Set Access Level from Status Menu and type password

Option -> Configure System ->

- **Configure Current Date & Time:**

  Select the format and set the **Date and Time**.

- **Configure System Name & J Number**

  Enter the System Name & J number.

- **Configure the Screen Saver**

  Set the Screen saver delay time.

- **Configure the Site Temperature**

  Set the site temperature tolerance for the nominal site temperature.

  Status -> Diagnostics -> Select the required task

- **Touch Screen Calibration:**

  Touch "Calibrate Touch screen" at the bottom of the DIAGNOSTICS Menu.

  Touch center of the target appear on the screen.

  When you have finished, touch "Save Calibration"

- **Country Code Selection:**

  Touch "Diagnostics" then Select "V-Docs"

  Press [Alt] and [S] to Access the service Scripts.

  Select "Configure Country Code"

  Select the appropriate country from the List.

  Select "Set country code"

Touch “Return “.

Touch “Shut Down”. Configure the Language from the System Menu button.

Touch “Final Shutdown”. Then reset the system.

VI.6 System Tests and Adjustments: (\6902906_3600-RefGd_Ltr-EN.pdf)

Adjustments are diagnostic functions used to fine-tune or define various system Parameters to ensure proper system performance. With the exception of the IRS Calibration, all other adjustments are available only to trained service personnel.

- MicroImmunnoassay (μIA) Metering
- MicroSensor
- MicroWell Reagent Metering
- MicroWell Wash Metering
- Signal Reagent Metering
- Luminometer
- Scrap Run

VI.7 Subsystems Performance Verification & Calibration: (\.6902906_3600-RefGd_Ltr-EN.pdfpdf**)**

- Well Wash Dispense & Aspiration Calibration.
- Signal reagent Dispense calibration.
- 30PSI & 10PSI calibration.
- Soak Volume Verification
- IRS Calibration

VI.8 Setting and installing printer: (\.6902906_3600-RefGd_Ltr-EN.pdf)

- Remove the Packing material form the printer and assemble the accessories.
- Connect the USB cable and Switch ON the Printer.
- Set report control and print the test page.

VII. Installation Report:

Activity	Observation	Remarks	Verified By / Date
Locating & unpacking the instrument.	Instrument was located and unpacked	**Ok**	Ketan Sawant 22-05-2023
Reaffix/verify the circuits boards & CPU	Reaffixed/verified the circuits boards & CPU	**Ok**	Ketan Sawant 22-05-2023
Nominal Line voltage frequency selection of transformer.	Nominal Line voltage frequency was sated.	**Ok**	Ketan Sawant 22-05-2023
Load Supply & Power ON the system.	Supply Loaded & Powered ON the system.	**Ok**	Ketan Sawant 22-05-2023
System Configuration.	System was configured as per the requirement.	**Ok**	Ketan Sawant 22-05-2023
System Tests and Adjustments	System Tested and Adjustments done.	**Ok**	Ketan Sawant 22-05-2023
Subsystems Performance Verification & calibration	Subsystems Performance Verified & calibrated successfully.	**Ok**	Ketan Sawant 22-05-2023
Setting and installing printer	Printer was installed and connected to the system.	**Ok**	Ketan Sawant 22-05-2023

VIII. COMMENTS:

Deviation: Nil

Impact On Operation: Nil

Corrective Action: Nil

IX. 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. Exceptional conditions, if any, have been / not been addressed. The system is ready for Operation Qualification.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name	:	Mr. Ketan Sawant	Signature: 
Designation	:	Sr. Territory Manager	Date: 22-05-2023
Company	:	Ortho Clinical Diagnostics	

Validation Team from : KRM Healthcare

Name	:	Signature:
Designation	:	Date:
Department	:	
Name	:	Signature:
Designation	:	Date:
Department	:	

Customer Authorizations: KRM Healthcare

Name	:	
Designation	:	
Signature	:	_____
Date	:	_____