

Ortho Clinical Diagnostics

**INSTALLATION QUALIFICATION**

**For**

**VITROS 350**



Manufactured by:  
Ortho Clinical Diagnostics, Inc., US

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I. Approval of the IQ procedure

Both **LUPIN HEALTHCARE LIMITED** and Ortho-Clinical Diagnostics are jointly responsible for the installation of **VITROS 350, Sr. No. 25014391** in the **LUPIN HEALTHCARE LTD LAB.**

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

Name : SARAS RAJENDRA WADHONKAR

Signature: 

Designation : SERVICE ENGINEER, ORTHO CARE- SERVICE

Company : Ortho-Clinical Diagnostics

Date: 30/07/2022

**Validation Team from LUPIN HEALTHCARE LIMITED:**


Name : Dr Sagar Kulat

Signature: 

Designation : Lab Head

Date: 30/7/22

Department Name : Clinical Chemistry

Signature: 

Designation : → Mahesh Bhulsing  
→ Lab Tech.

Date: 30/7/22

Department : →


**LUPIN DIAGNOSTIC**  
Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savedi, Ahmednagar-414001

**Customer Authorizations:**

Name : Dr Sagar Kulat

Designation : Lab Head

Site : Lupin Diagnostics, Ahmednagar

Signature: 

Date: 30/07/22

**LUPIN DIAGNOSTIC**  
Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savedi, Ahmednagar-414001

## 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 (customer) **LUPIN HEALTHCARE LIMITED** 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 **LUPIN HEALTHCARE LIMITED**.

### III. SCOPE

This Installation Qualification protocol will be performed on the VITROS 350 bearing Sr. No. 25014391 located at **LUPIN HEALTHCARE LIMITED**. This Installation protocol will define the documentation that will be used to evaluate the instrument 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 on 30/07/2022 is in compliance with the specifications of the purchase order.

Verified By: SARAS RAJENDRA WADHONKAR

Date:30/07/2022

**B. Utilities**

Sr. No	Utility	Verified by	Date
	<b>Environmental conditions:</b>		
1.	a. Analyzer will be placed away from the direct sunlight.	SARAS WADHONKAR	30/07/2022
	b. Installation site shall be free from dust, significant vibrations and shall be well ventilated.	SARAS WADHONKAR	30/07/2022
	c. Installation site floor construction shall be able to support approximately 272 kg.	SARAS WADHONKAR	30/07/2022
	d. Room temperature will be maintained between 15 <sup>o</sup> C to 27 <sup>o</sup> C and the temperature fluctuation during analysis shall not be more than ± 2 <sup>o</sup> C.	SARAS WADHONKAR	30/07/2022
	e. The analyzer shall be kept away from strong electromagnetic sources and electrical interferences.	SARAS WADHONKAR	30/07/2022
	f. It will be kept near to the power sources.	SARAS WADHONKAR	30/07/2022
	g. Maximum relative humidity allowed up to 70%.	SARAS WADHONKAR	30/07/2022
	h. If the temperature and humidity fluctuations are not within the specified range, the analyzer cannot maintain data reliability.	SARAS WADHONKAR	30/07/2022
2.	Adequate space for installation will be provided on all 5 sides of the instrument [1.15m (L) x 71m (W) x 1.2m (H)]	SARAS WADHONKAR	30/07/2022
3.	Electrical Outlets: Actual Voltage on site [AC 220-230 Volts 16A 50 HZ]	SARAS WADHONKAR	30/07/2022

*Note: Document any significant changes in Comments section on page 12.*

**C. The instrument has been verified for the following**

## Ortho Clinical Diagnostics

Sr. No.	Verification	Verified by	Date
1.	Instrument is identified	Yes SARAS WADHONKA R	30/07/2022
2.	Manufacturer's specifications are included	Yes SARAS WADHONKA R	30/07/2022
3.	Accessories / Consumables are listed	Yes SARAS WADHONKA R	30/07/2022
4.	Equipment manual from the manufacturer is documented	Yes SARAS WADHONKA R	30/07/2022
5.	Manufacturer's Certificate attached	Yes SARAS WADHONKA R	30/07/2022

**V. Installation Qualification****A. Equipment Description**

The VITROS 350 is a fully automated Dry chemistry analyzer

Instrument Identification		Verified by	Date
Equipment Name:	Dry Chemistry Analyzer	SARAS WADHONKAR	30/07/2022
Manufacturer:	Ortho-Clinical Diagnostics	SARAS WADHONKAR	30/07/2022
Model:	VITROS 350	SARAS WADHONKAR	30/07/2022
Serial Number:	25014391	SARAS WADHONKAR	30/07/2022
Size (in cm):	115 (L) x 71 (W) x 120 (H)	SARAS WADHONKAR	30/07/2022
Power:	AC 220-230 V 16A 50Hz±2Hz	SARAS WADHONKAR	30/07/2022
Power consumption:	6880KW hours per year	SARAS WADHONKAR	30/07/2022



**B. Accessories/Consumables**

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

<b>START UP KIT 1H4182</b>			
353999	350 TIP RACK		1 no.
354009	350 MICRO COLLECTION TUBE ADAPTER		1 no.
354007	350 SAMPLE CUP ADAPTER		1 no.
354000	350 UNIVERSAL SAMPLE TRAY		1 no.
354011	350 DILUENT TRAY		1 no.
354002	350 HEIGHT ADAPTER		1 no.
353671	LINE CORD CONTINENTAL		1 no.
354004	MIXING CUP ARRAY		1 no.
8251878	CAL DISK (ver. 5609)		1 no.
8321622	CLIN CHEM PROD INSTRUCTION USE		1 no.
6801855/8175333	350 SYS SOFTWARE (ver. 9.2)		1 no.
<b>250 ANALYZER SPARE PART KIT 356704</b>			
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.

## Ortho Clinical Diagnostics

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 - Maintenance & 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 Micro Therapeutic Research Labs Pvt. Ltd., Chennai.

### 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 for 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. For any reasons, if the software is to be installed on another PC, the PC will meet the following requirements.

Environment	System Requirement
Desktop	PII
Key Board	English Key Board or Standard 101/102 or Microsoft Natural Key Board
Operating System	Qunix
Port	<ul style="list-style-type: none"> <li>➤ 2 ports for printer</li> <li>➤ One port for LIS</li> </ul>
Regional settings	<ul style="list-style-type: none"> <li>➤ Language English.</li> </ul>

The system has a preloaded operating software

The Analyser has been installed satisfactorily :    No  Yes

Verified by : SARAS RAJENDRA WADHONKAR

**VI. COMMENTS:**

**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.

Report Performed By: Ortho Clinical Diagnostics Representative

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Name : SARAS RAJENDRA WADHONKAR

Signature: 

Designation : SERVICE ENGINEER, ORTHO CARE- SERVICE

Company: Ortho Clinical Diagnostics

Date: 30/07/2022

**Customer Authorizations:**

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Name : Dr. Sagar Kulat

Designation : Lab Head

Organization : Lupin Diagnostics,  
Ahmednagar

Signature : 

Date : 30/07/2022

**LUPIN DIAGNOSTIC**  
Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savadi, Ahmednagar-414001

**Ortho Clinical Diagnostics**

**OPERATION QUALIFICATION**

**For**

**VITROS 350**



**Manufactured by:  
Ortho Clinical Diagnostics, Inc., US**

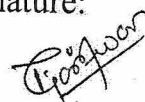
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I. Approval of the IQ procedure

Both Lupin Diagnostics, Ahmednagar and Ortho Clinical Diagnostics are jointly responsible for the operation qualification of VITROS 350, Sr. No. 25014391 in the Laboratory of Lupin Diagnostics, Ahmednagar, as per the Operational Qualification Protocol.

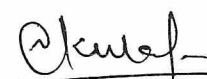
**Protocol Performed By: Ortho Clinical Diagnostics Representative**

Name : Mr. Pankaj Paitwar Signature:   
Designation : Application Support  
Company : Ortho Clinical Diagnostics Date: 1/8/2022

**Validation Team from Lupin Diagnostics, Ahmednagar:**

Name : Bhalsing mahesh Signature:   
Designation : Lab Tec. Date: 01/08/22  
Department : Department of  
Name Biochemistry  
Designation : Sagar malave Signature : 01/08/22  
Date :   
Department : Department of  
Biochemistry

**Customer Authorizations:**

Name : Dr. Sagar Kulkarni Signature:   
Designation : Chief of Laboratories  
Site : Ahmednagar Date: 1/8/2022

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Opp. Monica D.Ed. College  
Savadi, Ahmednagar-414001



## 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 **Lupin Diagnostics, Ahmednagar** will verify each result and sign in the each page. The member of the validation team will carry this out.
3. ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of the OQ protocol. All resolution to such problems will also be noted in the COMMENTS section, and must be resolved prior to issuance of a SYSTEM CERTIFICATION.

### III. SCOPE

This Operational Qualification protocol will be performed on the VITROS 350, Sr. No. 25014391 located at Biochemistry Department, **Lupin Diagnostics, Ahmednagar**. This OQ protocol will define the documentation that will be used to evaluate the completion of the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

**OPERATIONAL QUALIFICATION:****A. Instrument Identification**a. Model Name      **VITROS 350**2. Serial Number    **25014391****B. Following is a list of tests to be performed and verified:**

<b>Test No.</b>	<b>Test Name</b>	<b>Test purpose</b>	<b>Verified By and date</b>
01	Start up	To make the equipment ready for operation	Mr. Pankaj Paitwar Date – 1/8/2022
02	Daily maintenance	To clean appropriate modules so as to maintain accuracy and precision	Mr. Pankaj Paitwar Date – 1/8/2022
03	Inventory of reagents and consumables	To check the slide supply of installed Vitros 350	Mr. Pankaj Paitwar Date – 1/8/2022
04	Calibration for the assays used	To calibrate the system for every new lot of assay	Mr. Pankaj Paitwar Date – 1/8/2022
05	QC check	To confirm that systems, reagents & consumables are acceptable and working within specifications for each assay used	Mr. Pankaj Paitwar Date – 1/8/2022
06	Sample programming and Analysis	To run the samples	Mr. Pankaj Paitwar Date – 1/8/2022

**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 350 system by pressing the main switch and hold it for about 10 – 15 sec.
- Wait for the instrument to get ready after initialization
- The machine is ready for next step if it displays “READY” on the status console
- If not, initialize by pressing the initialize button on the error code screen
- Follow instructions provided for the error codes

**Acceptance criteria:** System to display READY status

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

**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	Mr Pankaj Paitwar	1/8/2022
02	Clean ERF Reservoir Holder & Base	Mr.Pankaj Paitwar	1/8/2022
03	Replace ERF Reservoir	Mr.Pankaj Paitwar	1/8/2022
04	Replace ERF Tip	Mr.Pankaj Paitwar	1/8/2022
05	Clean ERF Tip Sleeve	Mr.Pankaj Paitwar	1/8/2022
06	Clean IWF Reservoir Holder & Base	Mr.Pankaj Paitwar	1/8/2022
07	Replace IWF Reservoir	Mr.Pankaj Paitwar	1/8/2022
08	Replace IWF Tip	Mr.Pankaj Paitwar	1/8/2022
09	Clean IWF Tip Sleeve	Mr.Pankaj Paitwar	1/8/2022
10	Load supplies and remove outdated and empty reagents	Mr.Pankaj Paitwar	1/8/2022
11	Perform Quality Control	Mr.Pankaj Paitwar	1/8/2022

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

**PASS**

**Test: 3: Inventory of reagents and consumables**

**Purpose:** To check the reagent management module of VITROS 350 Dry Chemistry system

**Procedure:**

Sr No	Activity	Done By	Date
01	Loading of Reagent cartridge in the appropriate slide supply – Supply 1 and Supply 2.	Mr. Pankaj Paitwar	1/8/2022
02	Verify the status of reagents loaded.	Mr. Pankaj Paitwar	1/8/2022

**Acceptance criteria:**

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

PARAMETER      PASS      FAIL

Parameter values for verification:    No Error codes      PASS

**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	Mr. Pankaj Paitwar	1/8/2022
02	Performing Calibration with calibration programming screen	Mr. Pankaj Paitwar	1/8/2022
03	Verification of Calibration report	Mr. Pankaj Paitwar	1/8/2022

**Acceptance criteria:** "Calibration Successful" should come on screen

PARAMETER      PASS      FAIL

**Parameter values for verification** : "Calibration Successful"  
 found and the report of                      **PASS**  
 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	Mr. Pankaj Paitwar	1/8/2022
02	Creating QC file	Mr. Pankaj Paitwar	1/8/2022
03	QC sample programming and analysis	Mr. Pankaj Paitwar	1/8/2022
04	Verification of QC results obtained	Mr. Pankaj Paitwar	1/8/2022

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

**PARAMETER    PASS    FAIL**

**Parameter values for verification:** QC values within  $\pm 2SD$  **PASS**



**Test: 6: Sample programming and Analysis**

**Purpose: To run the samples**

**Procedure:**

Sr. No.	Activity	Done By	Date
01	Loading and Processing of samples	Mr. Pankaj Paitwar	1/8/2022
02	Programming samples	Mr. Pankaj Paitwar	1/8/2022
03	Unloading the samples	Mr. Pankaj Paitwar	1/8/2022
04	Viewing samples in process	Mr. Pankaj Paitwar	1/8/2022
05	Review results: Monitoring results	Mr. Pankaj Paitwar	1/8/2022

**Acceptance criteria: Samples Analysis & Report without any error**

**PARAMETER      PASS   FAIL**

**Parameter values for verification:**      Sample analysis & Report      **PASS**  
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.

Mr. Pankaj Paitwar from Ortho Clinical Diagnostics has conducted the training.

<b>Sr. No.</b>	<b>Training program</b>	<b>Initials</b>	<b>Date</b>
1.	Instrument Setup	Mr. Pankaj Paitwar	1/8/2022
2.	System Operation	Mr. Pankaj Paitwar	1/8/2022
3.	Calibration	Mr. Pankaj Paitwar	1/8/2022
4.	Quality Control	Mr. Pankaj Paitwar	1/8/2022
5.	Maintenance	Mr. Pankaj Paitwar	1/8/2022
6.	Basic trouble shooting	Mr. Pankaj Paitwar	1/8/2022

## 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	Bhalsing mahesh	CC	MTB	1/8/22
2	Sagar malve	CC	SAM	1/8/22
3	Amol Satule	CC	ACS	1/8/22
4	Jukir shaikh	CC	JRS	1/8/22
5	Meghuna Kalapurthy	CC	MVK	1/8/22

**V. COMMENTS:**

**VI. SYSTEM CERTIFICATION:**

Study data has determined that the system described in this document either meets all criteria outline in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Performance Qualification.

Report Performed By: Ortho Clinical Diagnostics Representative

Name : Mr. Pankaj Paitwar

Designation : Application Support

Company: Ortho Clinical Diagnostics

Signature: 

Date: 1/8/2022

**Customer Authorizations:**

Name : Dr. Sagar Kulat

Designation : chief of Lab

Organization : Lupin Diagnostics

Signature : 

Date : 1/8/2022

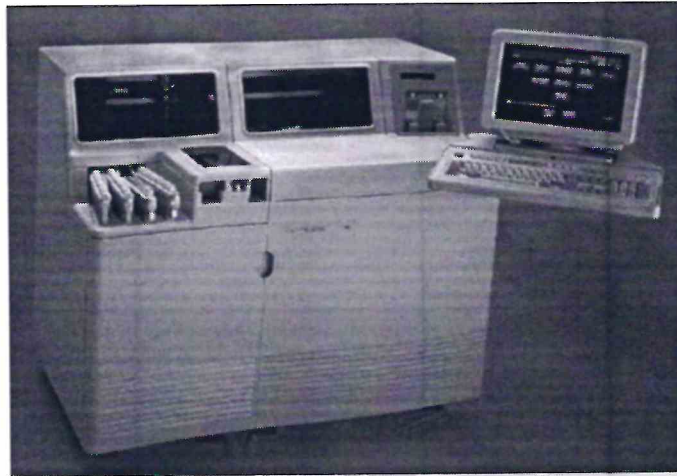
**LUPIN DIAGNOSTIC**  
Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savadi, Ahmednagar-431001

# Ortho Clinical Diagnostics

## PERFORMANCE QUALIFICATION

For

VITROS 350



Manufactured by:  
Ortho Clinical Diagnostics, Inc., US

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## Ortho Clinical Diagnostics

### I. Approval of the PQ procedure

Both **Lupin Diagnostics, Ahmednagar** and Ortho Clinical Diagnostics are jointly responsible for conducting the Performance Check of the Biochemistry Analyzer, Model – VITROS 350, Serial. No. 25014391 in the Biochemistry Department of **Lupin Diagnostics, Ahmednagar** as per the attached protocol.

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

Name : Mr. Pankaj Paitwar


Signature: 


Designation : Application Support

Date: 1/8/2022

Company : Ortho Clinical Diagnostics

**Validation Team from Lupin Diagnostics, Ahmednagar :**

Name : 


Signature: 

Designation : Lab Tech

Date: 01/08/22

Department :

Name : Sagar Malve

Signature: 

Designation : Lab Tech

Date: 11/08/22

Department : CL

**Customer Authorizations:**

Name : Dr. Sagar Keelat

Designation : Chief of Laboratory

Site : Ahmednagar

Signature: 

Date: 01/08/2022

**LUPIN DIAGNOSTIC**  
Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savadi, Ahmednagar-414001

**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. Each result will be noted and dated.
2. Performance checks on a regular basis described in the Further Performance Checks will be the responsibility of customer's personnel.
3. Employees of **Lupin Diagnostics, Ahmednagar** will verify each result and sign in the last page.
4. ALL deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end of the 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**.
5. Any test data that does not meet the specified acceptance criteria will be submitted to the appropriate laboratory personnel for solution. All steps taken subsequently will be documented.
6. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by **Lupin Diagnostics, Ahmednagar** and Ortho-Clinical Diagnostics.



### III. Scope

This Performance Qualification protocol will be performed on the VITROS 350 Serial No. 25014391 located in Biochemistry Department of **Lupin Diagnostics**, , located in **Ahmednagar**. This Performance qualification protocol will define the documentation that will be used to evaluate the instrument 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 Performance 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**

**A. Instrument Identification**

**Verified Date**

- |                  |            |          |
|------------------|------------|----------|
| 1. Model Name    | VITROS 350 | 1/8/2022 |
| 2. Serial Number | 25014391   | 1/8/2022 |

**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	1/8/2022
02	Accuracy Study	To compare the obtained value with true values of processed control.	1/8/2022
03	Precision Study	To check the precision performance of the equipment	1/8/2022

## Ortho Clinical Diagnostics

### 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  
Microslide - Endpoint Chemistry  
Microslide – Potentiometric Chemistry;  
Microslide – Immunorate Chemistry;

**Analysis of controls:**

**Note:** Analyze controls for ALT (Microslide Rate Chemistry);  
Amylase (Microslide – Two point rate Chemistry);  
Sodium (Potentiometric Chemistry);  
Potassium (Potentiometric Chemistry);

Sr. No.	Activity	Procedure done as per the protocol defined in VITROS 350 Chemistry System Operator's manual – Quality Control	Remarks	Done By
			Pass/Fail	Date
01	Preparing Liquid or Lyophilized control fluids	"Instructions for use" of QC material	PASS	Mr. Pankaj Paitwar 1/8/2022
02	Creating QC file	Quality Control – Define control fluids	PASS	Mr. Pankaj Paitwar 1/8/2022
03	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	PASS	Mr. Pankaj Paitwar 1/8/2022

## Ortho Clinical Diagnostics

**Test II**

**Test Name** : Accuracy

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

**Method** : Microslide 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 350 System Operator's manual - Quality Control	Remarks	Done By
			Pass/Fail	Date
01	Preparing Liquid or Lyophilized control fluids	'Instructions for use' of QC material	PASS	Mr. Pankaj Paitwar 1/8/2022
02	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	PASS	Mr. Pankaj Paitwar 1/8/2022
03	Accuracy Analysis	Compare the obtained Q.C value with mean of expected value as mentioned in the Performance verifier / QC Value chart.	PASS	Mr. Pankaj Paitwar 1/8/2022

## Ortho Clinical Diagnostics

### Test III :

**Test Name** : Precision Study (As per criteria attached)

**Purpose** : To estimate the imprecision or random error of the analytical method

### Procedure:

Analyze Performance Verifier Level 1 control for tests ALT (2 x 12 times), Amylase and Na<sup>+</sup> (3 x 10 times).

Analyze Performance Verifier Level 2 for Potassium (3 x 10 times) and Phenytoin (3 x 6 times).

Calculate the Mean, SD and CV%.

### Acceptance Criteria :

Sr. No.	Analyte	Control Level	Precision Limit
01	ALT	PV I	$\leq 2.3$ SD
02	Amylase	PV I	$\leq 3.9$ SD
03	Sodium	PV I	$\leq 0.8\%$ CV
04	Potassium	PV I	$\leq 1.0\%$ CV
05	CRBM	TDM	$\leq 4\%$ CV


COMMENTS: NIL

**V. System Certification**

Study data has determined that the VITROS 350 Dry Chemistry 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.

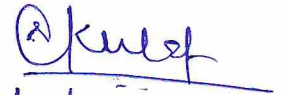

**Report Performed By : Ortho Clinical Diagnostics Representative**

Name : Mr. Pankaj Paitwar  
Designation : Application Support  
Company : Ortho Clinical Diagnostics

Signature :   
Date : 1/8/2022


**Validation Team from Lupin Diagnostics, Ahmednagar:**

Name : Dr. Sagar Kulat  
Designation : Chief of Lab  
Department : CC  
Name : Bhalsing mahesh  
Designation : Lab Tee  
Department : CC

Signature:   
Date: 1/8/22  
Signature:   
Date: 1/8/22

**Customer Authorizations:**

Name : Dr. Sagar Kulat  
Designation : Chief of Lab  
Site : Lupin Diagnostics

Signature:   
Date : 1/8/22

**LUPIN DIAGNOSTIC**  
Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savadi, Ahmednagar-414001

## Ortho Clinical Diagnostics

403, Leela Business Park, Andheri Kurla Road,  
Andheri East, Mumbai – 400059  
T : +91 22 6787 9300  
F : +91 22 6787 9333

# Calibration Certificate

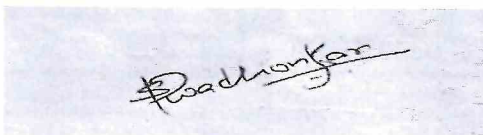
The below mentioned instrument has been calibrated and tests performed to check the system performance.

Instrument : VITROS 350  
Serial No : 25014391  
Customer Name : LUPIN HEALTHCARE LIMITED, AHMEDNAGAR  
Calibration performed on : 18/02/2023

The system's calibration includes optics calibration and checking the reproducibility performance of the instrument as per the guidelines provided by the manufacturer.

Next Calibration will be performed in **AUGEST 2023**

For **Ortho Clinical Diagnostics India Pvt Ltd.**



**Saras Wadhonkar**  
Service Engineer, Ortho Care Service  
Pune

**Date: 18/02/2023**

SS1 SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF Feb 18 23 20:47:11

DIAGNOSTICS - Setup/Adjustment - Reflectometer Iris SA12A

340	400	460	540	600	630	670	680
5.12	4.89	5.24	6.08	6.98	6.15	5.39	6.03

Current voltages for all wavelengths.  
Touch RETURN to exit or START to repeat tests.

RETURN

START

RETURN TO MAIN DIAG MENU

HELP



SH SM SSI SS2 ST INC IR R/C PM INOP      LAB COMP:      TESTING COMPLETE

SAMPLING      Feb 18 23  
ON      OFF      20:48:03  
PT04A      \*\*250

SAMPLE METERING PERFORMANCE TESTS  
Leak Test - A/D Ref. Voltage Check

Reference      Resolution  
4.961 Vdc      0.039 Vdc

Ambient Pressure = 2.578

- > Compare Precision Reference Voltage, Resolution Voltage and Ambient
- > Pressure to current specifications.
- > Do you wish to continue with the Leak Test?      (Y/N): ■

RETURN

RETURN TO  
MAIN DIAG  
MENU

HELP

SH SM SSI SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING Feb 18 23  
ON OFF 20:49:33  
U9.7 \*\*250  
PT01B

SAMPLE METERING PERFORMANCE TESTS  
Leak Test - Voltage Differential

Aspirate = 0.059 Vdc      Dispense = 0.039 Vdc

Ambient Pressure = 2.578 Vdc

> Compare dispense and aspirate leak voltages to current specifications.  
> Do you wish to continue to Hysteresis Test? (Y/N):

RETURN

DISPLAY  
PREVIOUS  
SCREEN

DISPLAY  
NEXT  
SCREEN

HELP

SH SM S51 S52 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF Feb 18 23 20:53:07 09.7 \*\*250 PT01C

SAMPLE METERING PERFORMANCE TESTS

Hysteresis Test

	MEAN	MAX	MIN
Hysteresis :	0.590	3.676	0.000
Pressure P0:	2.598	2.617	2.598
Pressure P1:	3.906	4.199	3.711
Pressure P2:	2.598	2.617	2.559

- > Compare all mean, max, min values to current specifications.
- > Touch DISPLAY NEXT SCREEN to view data.

RETURN

DISPLAY PREVIOUS SCREEN

DISPLAY NEXT SCREEN

HELP

SH SM SSI SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF Feb 18 23  
20:53:15

09.7 \*\*250  
PT01H

SAMPLE METERING PERFORMANCE TESTS

Hysteresis Test

Revolution	Hysteresis	P0	P1	P2
1	0.000	2.598	3.730	2.598
2	0.000	2.598	3.711	2.598
3	0.000	2.598	3.711	2.598
4	0.000	2.598	3.711	2.598
5	0.000	2.598	3.730	2.598
6	0.000	2.598	3.730	2.598
7	0.000	2.598	3.750	2.598
8	0.000	2.598	3.750	2.598
9	0.000	2.598	3.750	2.598
10	0.000	2.598	3.770	2.598

RETURN

DISPLAY  
PREVIOUS  
SCREEN

DISPLAY  
NEXT  
SCREEN

HELP



SH SM SS1 SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF Feb 18 23  
20:55:33  
09.7 \*\*250

DIAGNOSTICS - PERFORMANCE TESTS - INCUBATOR  
PAD REFLECTANCE TEST

P116C

SLOT	REFL1	REFL2	REFL3	MEAN
1	0.92282	0.92270	0.92268	0.92273
2	0.92299	0.92289	0.92287	0.92292
3	0.92223	0.92202	0.92197	0.92207
4	0.92367	0.92367	0.92358	0.92364
5	0.92504	0.92502	0.92485	0.92497
6	0.91579	0.91572	0.91560	0.91570
7	0.91940	0.91928	0.91914	0.91927
8	0.92516	0.92499	0.92490	0.92502
9	0.92407	0.92386	0.92374	0.92389
10	0.92056	0.92046	0.92032	0.92045
11	0.91711	0.91706	0.91708	0.91709
12	0.92410	0.92395	0.92388	0.92398

> PRESS RETURN TO VIEW THE PREVIOUS PAGE OF DATA  
> PRESS DISPLAY\_MORE\_DATA TO VIEW THE MEANS AND RAW DATA

RETURN  
DISPLAY  
MORE  
DATA

RETURN TO  
MAIN DIAG  
MENU

HELP

SH SM SSI SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF Feb 18 23 20:57:08 09.7 \*\*250 PT22B

PT22B

DIAGNOSTICS - Performance Test  
Reference Metering - System Check

Signal Processing Check

COARSE GAIN

2.500 Vdc

>Compare the values to current specifications.  
 Do you wish to continue with the Leak Test?

(Y):

RETURN

RETURN TO MAIN DIAG MENU

HELP

SH SM SSI SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING Feb 18 23  
ON OFF 20:58:29  
09.7 \*\*250  
PT22D

DIAGNOSTICS - Performance Test  
Leak Test - Voltage Differential

Aspirate = -0.039 Vdc

Dispense = -0.039 Vdc

Ambient Pressure = 2.578 Vdc

>Compare the values to current specifications.  
Do you wish to continue to Hysteresis Test?

(Y): ■

RETURN

DISPLAY  
PREVIOUS  
SCREEN

DISPLAY  
NEXT  
SCREEN

HELP



SH SM SSI SSI ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

SAMPLING Feb 18 23  
ON OFF 20:59:12  
PT22L 09.7 \*\*250

DIAGNOSTICS - Performance Test  
Reference Metering - System Check  
Hysteresis Check

	MEAN	MAX	MIN
Hysteresis:	0.163	1.633	0.000
Pressure P0:	2.617	2.637	2.617
P1:	4.473	4.609	4.375
P2:	2.598	2.617	2.578

>Compare the values to current specifications.

RETURN

DISPLAY DATA

RETURN TO MAIN DIAG MENU

HELP

SCHEDULER \* INCUBATOR ENVIRONMENT \* temperature failure

SAMPLING Feb 18 23  
ON OFF 21:21:36

SM S51 S52 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

DIAGNOSTICS - Setup/Adjustments - Read Sync

SA15B

Delay Time	Signal	Delay Time	Signal
0.0 ms	10716	5.5 ms	11084
0.5 ms	10481	6.0 ms	11450
1.0 ms	10347	6.5 ms	11795
1.5 ms	10250	7.0 ms	12228
2.0 ms	10156	7.5 ms	12650
2.5 ms	10142	8.0 ms	13177
3.0 ms	10136 *	8.5 ms	13716
3.5 ms	10238	9.0 ms	14072
4.0 ms	10334	9.5 ms	14621
4.5 ms	10503	10.0 ms	15123
5.0 ms	10745		

> Lowest signal is marked by flashing \*. Save new setting?  
Touch RETURN or RETURN\_TO\_MAIN\_DIAG\_MENU to abort the changes.

(Y/N): █

RETURN

RETURN TO  
MAIN DIAG  
MENU

HELP





SCHEDULER \* INCUBATOR ENVIRONMENT \* temperature failure SAMPLING Feb 18 23

LAB COMP: ON OFF 21:45:52

SM SSI SS2 ST INC IR R/C PM INOP TESTING COMPLETE U9.7 \*\*250

DIAGNOSTICS - Setup/Adjustments - Slide Transport SA05B

DISPENSE TO METERING	INCUBATOR RT/CM DEPTH	DISPENSE OFFSET	SIGNAL	DISPENSE OFFSET	SIGNAL
25		12323	45	9652	
27		11880	47	9951	
29		11648	49	10202	
31		10939	51	10678	
33		10571	53	11143	
35		10118	55	11815	
37		9796	57	12288	
39		9565	59	12998	
41		9487 *	61	13637	
43		9536	63	14566	

INCUBATOR W/ DISP. PATH	INCUBATOR PM DEPTH	INCUBATOR PM DEPTH
25		
27		
29		
31		
33		
35		
37		
39		
41		
43		

INCUBATOR ROTOR SIZING	INCUBATOR PM DEPTH	INCUBATOR PM DEPTH
25		
27		
29		
31		
33		
35		
37		
39		
41		
43		

> Lowest signal is marked by flashing \*. Save new setting? (Y): ■  
Touch RETURN or RETURN\_TO\_MAIN\_DIAG\_MENU to abort the changes.

RETURN TO MAIN DIAG MENU

RESET DISPENSE/ INCUBATOR

HELP

SCHEDULER \* INCUBATOR ENVIRONMENT \* temperature failure

SAMPLING Feb 18 23  
ON OFF 22:02:48

SM S51 S52 ST INC IR R/C PM INDP

LAB COMP: TESTING COMPLETE

U9.7 \*\*250

DIAGNOSTICS - Setup/Adjustments - Rate/CM Correction Factors

SA20G

Summary

Wavelength New MCF White Dr S.D. New BCF Black Dr S.D.

Wavelength	New MCF	White Dr S.D.	New BCF	Black Dr S.D.
340 nm	0.46718	** 0.00032	** -0.0041	** 0.00058
400 nm	0.80650	0.00012	** -0.0037	** 0.00061
460 nm	0.98825	0.00006	*** -0.0022	** 0.00063
540 nm	0.98995	0.00007	*** -0.0021	** 0.00096
600 nm	0.99223	0.00005	*** -0.0029	** 0.00029
630 nm	0.98754	0.00006	*** -0.0025	** 0.00099
670 nm	0.98699	0.00006	*** -0.0022	** 0.00051
680 nm	0.98292	0.00007	*** -0.0029	** 0.00071

> Automatic update?

(Y/N):

RETURN

RETURN TO MAIN DIAG MENU

HELP

SCHEDULER \* INCUBATOR ENVIRONMENT \* temperature failure

SAMPLING Feb 18 23  
ON OFF 22:02:57

SM SS1 SS2 ST INC IR R/C PM INDP

LAB COMP: TESTING COMPLETE

09.7 \*\*250

DIAGNOSTICS - Setup/Adjustments - Rate/CM Correction Factors

SA21A

White Correction Factors

Wavelength White Assay Current MCF New MCF Dr. S. D.

DISPLAY  
WHITE  
DATA

340 nm	0.56340	0.45900	0.46718	** 0.00032
400 nm	0.85820	0.77518	0.80650	0.00012
460 nm	0.85850	0.95256	0.98825	0.00006
540 nm	0.85820	0.95716	0.98995	0.00007
600 nm	0.85470	0.96079	0.99223	0.00005
630 nm	0.85430	0.95771	0.98754	0.00006
670 nm	0.86050	0.95840	0.98699	0.00006
680 nm	0.85660	0.95449	0.98292	0.00007

DISPLAY  
BLACK  
DATA

> Touch DISPLAY BLACK DATA to display more data.

RETURN

RETURN TO  
MAIN DIAG  
MENU

HELP

SCHEDULER \* INCUBATOR ENVIRONMENT \* temperature failure      SAMPLING      Feb 18 23  
 SM S51 S52 ST INC IR R/C PM INOP      LAB COMP:      ON      OFF      22:03:03  
    TESTING COMPLETE      U9.7 \*\*250

DIAGNOSTICS - Setup/Adjustments - Rate/CM Correction Factors      SA21B

Black Correction Factors

Wavelength      Black Assay      Current BCF      New BCF      Dr. S. D.

Wavelength	Black Assay	Current BCF	New BCF	Dr. S. D.
340 nm	0.01890	-0.0038	** -0.0041	** 0.00058
400 nm	0.02280	-0.0034	** -0.0037	** 0.00061
460 nm	0.02110	-0.0018	*** -0.0022	*** 0.00063
540 nm	0.02190	-0.0014	*** -0.0021	*** 0.00096
600 nm	0.02210	-0.0023	*** -0.0029	*** 0.00029
630 nm	0.02310	-0.0018	*** -0.0025	** 0.00099
670 nm	0.02460	-0.0015	*** -0.0022	*** 0.00051
680 nm	0.02430	-0.0022	*** -0.0029	*** 0.00071

> Touch DISPLAY WHITE DATA to display more data.

RETURN

RETURN TO  
MAIN DIAG  
MENU

HELP



SCHEDULER \* INCUBATOR ENVIRONMENT \* temperature failure

SAMPLING Feb 18 23  
ON OFF 22:08:32

SS1 SS2 ST INC IR R/C PM INOP

LAB COMP: TESTING COMPLETE

U9.7 \*\*250

DIAGNOSTICS - Performance Tests - Reflectometer - Static test PT31D

- Summary Screen -

WaveLength (nm)	Mean		SD		%CV*1K
	Dark	Signal	Dark	Signal	
340	284	33601	0.4795	1.0743	3.20
400	284	31930	0.4983	1.4527	4.55
460	284	34477	0.4795	1.7207	4.99
540	284	39670	0.4498	1.7927	4.52
600	285	45747	0.4795	1.7876	3.91
630	284	40274	0.5040	2.0126	5.00
670	285	35459	0.5085	1.0854	3.06
680	284	39788	0.4795	1.9945	5.01

- > Compare SD of Dark and/or Signal reads to current specifications.
- > Compare %CV\*1K to current specification.
- > Touch DISPLAY MORE DATA to view detailed data.

RETURN      DISPLAY MORE DATA      RETURN TO MAIN DIAG MENU      HELP

**READY**  
**REVIEW RESULTS - Verification and Edit**  
**LAB COMP: ON OFF**  
**TESTS IN PROCESS**  
 Feb 18 23  
 22:30:09  
 RV06A  
 09.7 \*\*250

Sample ID 89711  
 Pos Track Tray 1 1  
 Run Date Run Time Priority Fluid Man Dil  
 02/18/23 22:20:25 ROUTINE SERUM 1.000

GLU	84.0	AMYL	AST	F2	43.
UREA	29.60	LIPA	LDH		
CREA	1.83	Ca	CK		
AMON		Mg	CKMB		
Na+	143.7	PHOS			
K+	3.75	CHOL	ALKP	F2	83.
Cl-	92.2	TRIG	GGT		
ECO2			TBIL		1.00
THEO		URIC	Bu		.93
Fe		TP	Bc		0.00
		F2			
		4.65			

Touch targets to review results and data - CONTROL sample is not editable

RETURN	EDIT PATIENT DATA	DELETE RESULT RECORD	REVIEW NEXT SAMPLE	REVIEW NEXT GROUP	REVIEW PREVIOUS GROUP	HELP
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READY

LAB COMP: TESTS IN PROCESS

SAMPLING ON OFF Feb 18 23 22:30:17 09.7 \*\*250 RY06A

REVIEW RESULTS - Verification and Edit

Sample ID 89711 Pos Track Tray 1 1 Run Date Run Time Priority Fluid Man Dil 02/18/23 22:20:25 ROUTINE SERUM 1.000

K+ 3.75 CHOL ALKP F2 83.  
Cl- 92.2 TRIG GGT

ECO2 THEO URIC TBIL 1.00  
Fe TP F2 4.65 Bu .93  
Bc 0.00

TIBC ALB 4.30 LAC

SALI DGXN ALC  
Li CHE  
CRP PHBR PHYT  
CRBM

> Touch targets to review results and data - CONTROL sample is not editable

RETURN	EDIT PATIENT DATA	DELETE RESULT RECORD	REVIEW NEXT SAMPLE	REVIEW NEXT GROUP	REVIEW PREVIOUS GROUP	HELP
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READY

LAB SOMP: TESTS IN PROCESS

SAMPLING ON OFF Feb 18 23 22:30:30 09.7 \*\*250 R006A

REVIEW RESULTS - Verification and Edit

Sample ID 89711 Pos Track Tray 1 1 Run Date Run Time Priority Fluid Man Di1 02/18/23 22:20:25 ROUTINE SERUM 1.000

LDLC OSMD %SAT  
VLDL %SAT

DELB % MB  
LDL

C/H

ASTJ

ALTU

25.

ALTZ

> Touch targets to review results and data - CONTROL sample is not editable

RETURN

EDIT PATIENT DATA

DELETE RESULT RECORD

REVIEW NEXT SAMPLE

REVIEW NEXT GROUP

REVIEW PREVIOUS GROUP

HELP

READY

LAB COMP: TESTING COMPLETE

SAMPLING Feb 18 23  
ON OFF 22:33:12

REVIEW RESULTS - Verification and Edit

RV06A

Sample ID 89712  
Pos Track Tray 1 2  
Run Date Run Time Priority Fluid Man Dil  
02/18/23 22:23:41 ROUTINE SERUM 1.000

GLU	246.8	AMYL	AST	F2	187.
UREA	83.01	LIPA	LDH		
CREA	5.48	Ca	CK		
AMON		Mg	CKMB		
Na+	122.9	PHOS			
K+	5.83	CHOL	ALKP	F3	377.
Cl-	82.8	TRIG	GGT		
ECO2			TBIL		4.72
THEO		URIC	Bu	F2	4.47
Fe		TP	Bc	F3	0.00

Touch targets to review results and data - CONTROL sample is not editable

RETURN	EDIT PATIENT DATA	DELETE RESULT RECORD	REVIEW NEXT SAMPLE	REVIEW NEXT GROUP	REVIEW PREVIOUS GROUP	HELP
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READY

LAB COMP: TESTING COMPLETE

SAMPLING Feb 18 23  
ON OFF 22:33:19  
V9.7 \*\*250

REVIEW RESULTS - Verification and Edit

RV06A

Sample ID 89712  
Pos Track Tray 1 2  
Run Date Run Time Priority Fluid Man Dil  
02/18/23 22:23:41 ROUTINE SERUM 1.000

K+	5.83	CHOL	ALKP	F3	377.
Cl-	82.8	TRIG	GGT		
ECO2			TBIL	F2	4.72
THEO		URIC	Bu	F2	4.47
Fe		TP	Bc	F3	0.00
TIBC		ALB	LAC		
		DGXN	ALC		
SALI		CHE	PHYT		
Li		PHBR			
CRP		CRBM			

> Touch targets to review results and data - CONTROL sample is not editable

RETURN

EDIT PATIENT DATA

DELETE RESULT RECORD

REVIEW NEXT SAMPLE

REVIEW NEXT GROUP

REVIEW PREVIOUS GROUP

HELP

READY

LAB COMP: TESTING COMPLETE

SAMPLING Feb 18 23  
ON OFF 22:33:28  
V9.7 \*\*250

REVIEW RESULTS - Verification and Edit

Sample ID Pos Track Tray Run Date Run Time Priority Fluid Man Dil  
89712 1 2 02/18/23 22:23:41 ROUTINE SERUM 1.000

LDLC  
VLDL

OSMO  
%SAT

DELB  
% MB  
LDL

C/H

ASTJ

ALTU

80.

ALTZ

> Touch targets to review results and data - CONTROL sample is not editable

RETURN	EDIT PATIENT DATA	DELETE RESULT RECORD	REVIEW NEXT SAMPLE	REVIEW NEXT GROUP	REVIEW PREVIOUS GROUP	HELP
--------	-------------------	----------------------	--------------------	-------------------	-----------------------	------