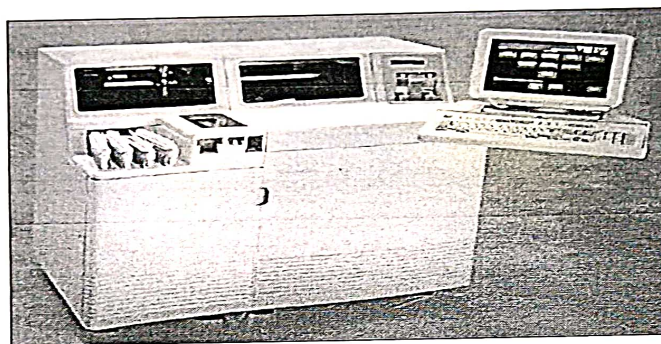


Ortho Clinical Diagnostics

INSTALLATION QUALIFICATION

**For
VITROS 250**



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

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Ortho Clinical Diagnostics

I. Approval of the IQ procedure

Both **Shruti Clinical Lab** and Ortho-Clinical Diagnostics are jointly responsible for the installation of *VITROS 250*, Sr. No. 25016108 in the PATHOLOGY Laboratory of **Shruti Clinical Lab**

Protocol Performed By: Ortho-Clinical Diagnostics Representative

Name : Imran Ali Signature: 

Designation : Service Engineer

Company : Ortho-Clinical Diagnostics Date: 06/10/2010

Validation Team from : Shruti Clinical Lab

Name : MD ANAYATULLAH KHAN Signature: 

Designation : S.R. SCIENTIFIC OFFICER Date: 06/10/2010

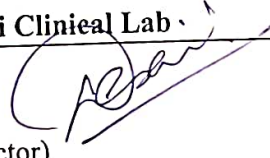
Department : BIOCHEMISTRY

Name : Signature :

Designation : Date :

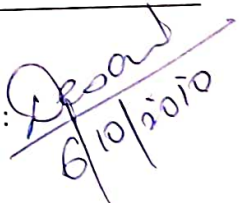
Department :

Customer Authorizations: Shruti Clinical Lab

Name : Dr. Krishna Desai 

Designation : M.D Path (Lab Director)

Site : Shruti Clinical Lab

Signature : 

Date: 6/10/2010

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) **Shruti Clinical Lab** 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 **Shruti Clinical Lab** _____.

III. SCOPE

This Installation Qualification protocol will be performed on the VITROS 250 bearing Sr. No.25016108 located at PATHOLOGY Department, **Shruti Clinical Lab**. 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.

Ortho Clinical Diagnostics

IV. Ancillary Information.

A. Certification of Purchase Order Compliance

I certify to the best of my knowledge, the instrument installed In Shruti Clinical Lab is in compliance with the specifications of the purchase order.

Verified By:

Date: 06/10/2010

Sr. No	Utility	Verified by	Date
1.	Environmental conditions:	Imran Ali	06/10/2010
	a. Analyzer will be placed away from the direct sunlight.	Imran Ali	06/10/2010
	b. Installation site shall be free from dust, significant vibrations and shall be well ventilated.	Imran Ali	06/10/2010
	c. Installation site floor construction shall be able to support approximately 272 kg.	Imran Ali	06/10/2010
	d. Room temperature will be maintained between 15°C to 27°C and the temperature fluctuation during analysis shall not be more than ± 2°C.	Imran Ali	06/10/2010
	e. The analyzer shall be kept away from strong electromagnetic sources and electrical interferences.	Imran Ali	06/10/2010
	f. It will be kept near to the power sources.	Imran Ali	06/10/2010
	g. Maximum relative humidity allowed up to 70%.	Imran Ali	06/10/2010
	h. If the temperature and humidity fluctuations are not within the specified range, the analyzer cannot maintain data reliability.	Imran Ali	06/10/2010
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)]	Imran Ali	06/10/2010
3.	Electrical Outlets: Actual Voltage on site [AC 220-230 Volts 16A 50 HZ]	Imran Ali	06/10/2010

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

Ortho Clinical Diagnostics

C. The instrument has been verified for the following

Sr. No.	Verification		Verified by	Date
1.	Instrument is identified	Yes	Imran Ali	06/10/2010
2.	Manufacturer's specifications are included	Yes	Imran Ali	06/10/2010
3.	Accessories / Consumables are listed	Yes	Imran Ali	06/10/2010
4.	Equipment manual from the manufacturer is documented	Yes	Imran Ali	06/10/2010
5.	Manufacturer's Certificate attached	Yes	Imran Ali	06/10/2010

Ortho Clinical Diagnostics

V. Installation Qualification

A. Equipment Description

The VITROS 250 is a fully automated Dry chemistry analyzer

Instrument Identification		Verified by	Date
Equipment Name:	Dry Chemistry Analyzer	Imran Ali	06/10/2010
Manufacturer:	Ortho-Clinical Diagnostics	Imran Ali	06/10/2010
Model:	VITROS 250	Imran Ali	06/10/2010
Serial Number:	25016108	Imran Ali	06/10/2010
Size (in cm):	115 (L) x 71 (W) x 120 (H)	Imran Ali	06/10/2010
Power:	AC 220-230 V 16A 50Hz±2Hz	Imran Ali	06/10/2010
Power consumption:	6880KW hours per year	Imran Ali	06/10/2010

Ortho Clinical Diagnostics

B. Accessories/Consumables

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

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

250 ANALYZER SPARE PART KIT 356704			
355637	Air Filter		1 no.
TL 3225	Serial Loop Back Connector TL 3225		1 no.
999339	10 ml Diluent Vials (3 Nos)		1 no.
999340	5 ml Diluent Vials (3 Nos)		1 no.
1C3197	Dispense blade		1 no.
3380/3381	Wrist strap Elastic		1 no.
J02315	White Reference Slide Box		1 no.
J02316	Black Reference Slide Box		1 no.
356666	Lamp		1 no.
583561	Lamp Extractor		1 no.
995298	RM / IR TL 4538		1 no.
356864	Reservoir Seal (3 Nos)		1 no.
356497	Reservoir Cap (3 Nos)		1 no.
J02253 / J02255	Evaporation Cap (23 Nos)		1 no.
1H0116	Evaporation Cap Spring (5 Nos)		1 no.
339739	Proboscis Screw (2 Nos)		1 no.
994654	Tubing (2 Nos)		1 no.
356526	Read Sync Tool TL 4502		1 no.
	Monitor with stand		1 no.
	Touch Screen		1 no.

B. 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.

C. 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 **Shruti Clinical Lab**.

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 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.

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

The system has a preloaded operating software

The Analyzer has been installed satisfactorily: **Yes**

Verified by : Imran Ali

VI. COMMENTS: NIL

VII. System Certification

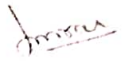
Study data has determined that the system described in this document either meets all criteria outlined in this Installation Qualification Protocol, or exceptional conditions have been identified and documentation included.

Report Performed By: Ortho Clinical Diagnostics Representative

Name : Imran Ali

Designation: Service Engineer

Company: Ortho Clinical Diagnostics

Signature: 


Date: 06/10/2010

Customer Authorizations:

Name : Dr. Krishna Desai

Designation : MD Path (Lab Director)

Organization : Shruti Clinical Lab

Signature: 

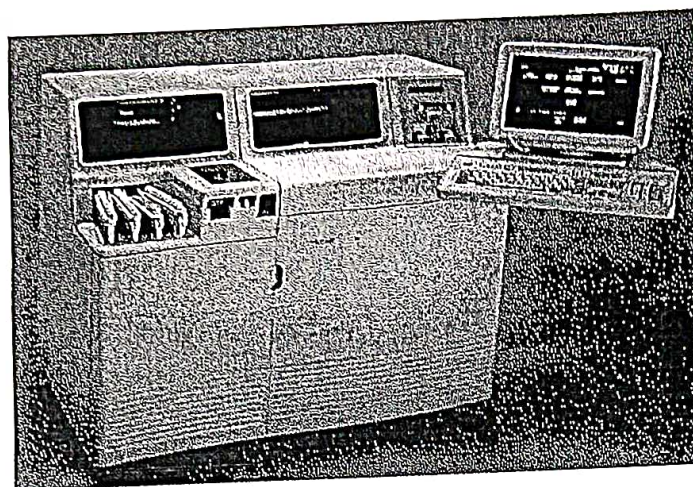
Date : 6/10/2010

Ortho Clinical Diagnostics

OPERATION QUALIFICATION

For

VITROS 250



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

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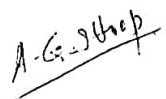
Ortho Clinical Diagnostics

I. Approval of the IQ procedure

Both **Shruti Clinical Lab** and Ortho Clinical Diagnostics are jointly responsible for the Operational qualification of VITROS 250, Sr. No. 25016108 in the PATHOLOGY Laboratory of **Shruti Clinical Lab**, as per the Operational Qualification Protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : Dr. Anita Ittoop

Signature: 

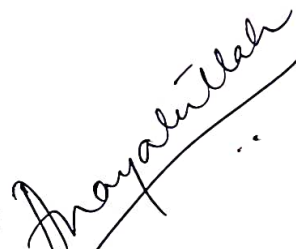
Designation : Application Support

Company : Ortho Clinical Diagnostics

Date: 06/10/2010

Validation Team from : Shruti Clinical Lab

Name : MOHD ANAYATULLAH
RADHIKA KARIHA

Signature: 

Designation : SR. SCIENTIFIC
OFFICER

Date: 06/10/2010

Department : PATHOLOGY

Name :

Signature:

Designation :

Date:

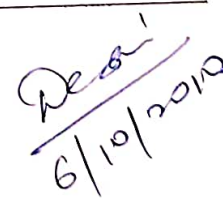
Department : PATHOLOGY

Customer Authorizations:

Name : **Shruti Clinical Laboratory (Dr. Krishna Desai)**

Designation : MD Path (Lab Director)

Site : **Shruti Clinical Lab**

Signature : 

Date:

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

III. SCOPE

This Operational Qualification protocol will be performed on the VITROS 250, Sr. No. 25016108 located at PATHOLOGY Department, **Shruti Clinical Lab**. This OQ protocol will define the documentation that will be used to evaluate the completion of 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.

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 250**2. Serial Number **25016108****B. Following is a list of tests to be performed and verified:**

Test No.	Test Name	Test purpose	Verified By and date
01	Start up	To make the equipment ready for operation	Dr. Anita Ittoop
02	Daily maintenance	To clean appropriate modules so as to maintain accuracy and precision	Dr. Anita Ittoop
03	Inventory of reagents and consumables	To check the slide supply of installed Vitros 250	Dr. Anita Ittoop
04	Calibration for the assays used	To calibrate the system for every new lot of assay	Dr. Anita Ittoop
05	QC check	To confirm that systems, reagents & consumables are acceptable and working within specifications for each assay used	Dr. Anita Ittoop
06	Sample programming and Analysis	To run the samples	Dr. Anita Ittoop

Test: 1: Starting the system

Purpose: To make the instrument READY for operation

Summary:

Instrument checks functioning of different parts of the instrument automatically; if there is an error code, initialize the system and follow corrective action instructions provided for the error code.

Procedure:

- Check the room temperature and switch on the Air Conditioner.
- Check the UPS.
- Switch on the Vitros V 250 system by pressing the main switch and hold it for about 10 – 15 sec.
- Wait for the instrument to get ready after initialization
- The machine is ready for next step if it displays “READY” on the status console
- If not, initialize by pressing the initialize button on the error code screen
- Follow instructions provided for the error codes

Acceptance criteria: System to display READY status

PARAMETER

PASS

Parameter values for verification: “READY” on Status console

Ortho Clinical Diagnostics

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	Dr.Anita Ittoop	06/10/2010
02	Clean ERF Reservoir Holder & Base	Dr.Anita Ittoop	06/10/2010
03	Replace ERF Reservoir	Dr.Anita Ittoop	06/10/2010
04	Replace ERF Tip	Dr.Anita Ittoop	06/10/2010
05	Clean ERF Tip Sleeve	Dr.Anita Ittoop	06/10/2010
06	Clean IWF Reservoir Holder & Base	Dr.Anita Ittoop	06/10/2010
07	Replace IWF Reservoir	Dr.Anita Ittoop	06/10/2010
08	Replace IWF Tip	Dr.Anita Ittoop	06/10/2010
09	Clean IWF Tip Sleeve	Dr.Anita Ittoop	06/10/2010
10	Load supplies and remove outdated and empty reagents	Dr.Anita Ittoop	06/10/2010
11	Perform Quality Control	Dr.Anita Ittoop	06/10/2010

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

PARAMETER

PASS

Parameter values for verification: System found "Ready" after daily maintenance

Test: 3: Inventory of reagents and consumables

Purpose: To check the reagent management module of VITROS 250 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.	Dr.Anita Ittoop	06/10/2010
02	Verify the status of reagents loaded.	Dr.Anita Ittoop	06/10/2010

Acceptance criteria:

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

PARAMETER PASS

Parameter values for verification: No Error codes

Ortho Clinical Diagnostics

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	Dr.Anita Ittoop	06/10/2010
02	Performing Calibration with calibration programming screen	Dr.Anita Ittoop	06/10/2010
03	Verification of Calibration report	Dr.Anita Ittoop	06/10/2010

Acceptance criteria: "Calibration Successful" should come on screen

PARAMETER PASS

Parameter values for verification : "Calibration Successful" found and the report of the same from the analyzer

Ortho Clinical Diagnostics

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	Dr.Anita Ittoop	06/10/2010
02	Creating QC file	Dr.Anita Ittoop	06/10/2010
03	QC sample programming and analysis	Dr.Anita Ittoop	06/10/2010
04	Verification of QC results obtained	Dr.Anita Ittoop	06/10/2010

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

PARAMETER PASS

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

Ortho Clinical Diagnostics

Test: 6: Sample programming and Analysis

Purpose: To run the samples

Procedure:

Sr. No.	Activity	Done By	Date
01	Loading and Processing of samples	Dr.Anita Ittoop	06/10/2010
02	Programming samples	Dr.Anita Ittoop	06/10/2010
03	Unloading the samples	Dr.Anita Ittoop	06/10/2010
04	Viewing samples in process	Dr.Anita Ittoop	06/10/2010
05	Review results: Monitoring results	Dr.Anita Ittoop	06/10/2010

Acceptance criteria: Samples Analysis & Report without any error

PARAMETER

PASS

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

Dr. Anita Ittoop from Ortho Clinical Diagnostics has conducted the training.

Sr. No.	Training program	Initials	Date
1.	Instrument Setup	Dr.Anita Ittoop	06/10/2010
2.	System Operation	Dr.Anita Ittoop	06/10/2010
3.	Calibration	Dr.Anita Ittoop	06/10/2010
4.	Quality Control	Dr.Anita Ittoop	07/10/2010
5.	Maintenance	Dr.Anita Ittoop	07/10/2010
6.	Basic trouble shooting	Dr.Anita Ittoop	07/10/2010

Ortho Clinical Diagnostics

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.	Anayatullah Khan	Haemat	Dr	6/10/2010
2.	Radhika Karia	Haemat.	Dr	6/10/2010
3.	Dr Krishna Desai	" "	Desai	6/10/2010

V. COMMENTS: NIL

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 : Dr. Anita Ittoop

Designation: Application Support

Company : Ortho Clinical Diagnostics

Signature: *A. G. Ittoop*

Date: 07/10/2010

Customer Authorizations:

Name : MD. ANAYATULLAH KHAN

Designation : Sr. Scientific Officer

Organization : Shruti Clinical Lab

Signature: *Anayatullah Khan*

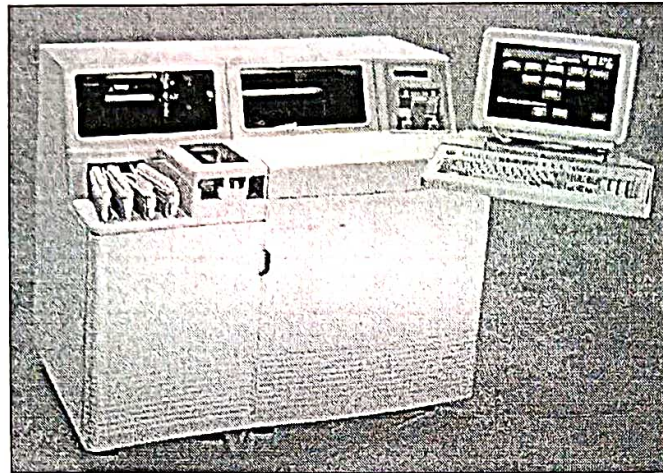
Date : 07/10/2010

Ortho Clinical Diagnostics

PERFORMANCE QUALIFICATION

For

VITROS 250



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

Ortho Clinical Diagnostics

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Ortho Clinical Diagnostics

I. Approval of the PQ procedure

Both **Shruti Clinical Lab** and Ortho Clinical Diagnostics are jointly responsible for conducting the Performance Check of the Biochemistry Analyzer, Model – VITROS 250, Serial. No. 25016108 in the PATHOLOGY Department of **Shruti Clinical Lab** as per the attached protocol.

Protocol Performed By : Ortho Clinical Diagnostics Representative

Name : Dr. Anita Ittoop Signature: A. G. Ittoop
Designation : Application Support Date: 06/10/2010
Company : Ortho Clinical
Diagnostics _____

Validation Team from : Shruti Clinical Lab

Name : MD. ANAYATULLAH KHAN Signature: Anayatullah
Designation : Sr. Scientific Officer Date: 06/10/2010
Department : PATHOLOGY
Name : Signature:
Designation : Date:
Department :

Customer Authorizations:

Name : **Shruti Clinical Lab (Dr. Krishna Desai)**
Designation: MD. PATH (LAB DIRECTOR) Signature: Desai
Site : **Shruti Clinical Lab** Date : 6/10/2010

Ortho Clinical Diagnostics

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 **Shruti Clinical Lab** 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 **Shruti Clinical Lab** and Ortho-Clinical Diagnostics.

III. Scope

This Performance Qualification protocol will be performed on the VITROS 250 Serial No. V25016108 located in PATHOLOGY Department of **Shruti Clinical Lab**. 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.

Ortho Clinical Diagnostics

IV. Performance Qualification

A. Instrument Identification

1. Model Name VITROS 250
2. Serial Number 25016108

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	Dr. Anita Ittoop
02	Precision Study	To check the precision performance of the equipment	Dr. Anita Ittoop

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 – Potentiometric Chemistry.
 Microslide – Immunorate Chemistry.

Analysis of controls:

Note: Analyze controls for ALT (Microslide Rate Chemistry).
 Sodium (Potentiometric Chemistry).
 Carbamazepine (Microslide – Immunorate Chemistry)

Acceptable Criteria: QC results within specified limits mentioned on the product insert.

Sr. No.	Activity	Procedure done as per the protocol defined in VITROS 250 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	Dr. Anita
02	Creating QC file	Quality Control – Define control fluids	PASS	Dr. Anita
03	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	PASS	Dr. Anita

Ortho Clinical Diagnostics

Test II :

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), Na⁺ (3 x 10 times).

Analyze TDM Level 3 PHYT (3 x 6 times).

Calculate the Mean, SD and CV%.

Acceptance Criteria:

Sr. No.	Analyte	Control Level	Precision Limit	Obtained value
01	ALT	PV I	≤ 2.3 SD	1.5
02	Sodium	PV I	$\leq 0.8\%$ CV	0.36%
03	PHYT	TDM III	$\leq 4.2 \%$ CV	2.3%

Ortho Clinical Diagnostics

COMMENTS: NIL

Ortho Clinical Diagnostics

V. System Certification

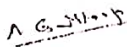
Study data has determined that the VITROS 250 Dry Chemistry system described in this document either meets all criteria outline in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Report Performed By : Ortho Clinical Diagnostics Representative

Name : Dr. Anita Ittoop

Designation : Application Support


Company : Ortho Clinical Diagnostics

Signature : 

Date : 06/10/2010

Validation Team from _____ :

Name MD. ANAYATULLAH KHAN

Signature: 

Designation : Sr. Scientific Officer

Date: 06/10/2010

Department : Pathology

Name :

Signature:

Designation :

Date:

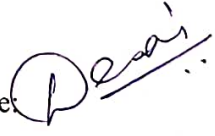
Department :

Customer Authorizations:

Name : Dr. Krishna Desai

Designation : MD Path (Lab Director)

Site : Shruti Clinical LAB

Signature: 

Date : 06/10/2010

SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure

SAMPLING
ON OFF

Oct 06 10
13:09:58
V9.2 6108
PT15B

SS1 SS2 ST INC IR R/C PM INOP

TESTING COMPLETE

DIAGNOSTICS - PERFORMANCE TESTS - INCUBATOR
PAD REFLECTANCE TEST

MEAN MIN. = 0.9438 REFLECTANCE VALUE

MEAN MAX. = 0.9650 REFLECTANCE VALUE

RANGE = 0.0212 (MAX. MEAN - MIN. MEAN)

GRAND MEAN = 0.9475 (MEAN OF ALL SLOT MEANS)

STAND DEV = 0.0041 (STD. DEV. OF ALL SLOTS)

> COMPARE RANGE AND GRAND MEAN TO CURRENT SPECIFICATIONS

> PRESS DISPLAY_MORE_DATA TO VIEW THE MEANS AND RAW DATA

RETURN DISPLAY START RETURN TO
 MORE MAIN DIAG
 DATA MENU

HELP

011

1

SAMPLING Oct 06 10
 ON OFF 13:07:49
 V9.2 6108
 SA25A

SS1 SS2 ST INC IR R/C PM INOP TESTING COMPLETE
 DIAGNOSTICS - Setup/Adjustments - Current Setup Values

TRUCK:	Sample	62	SLIDE TRANSPORT:	Disp to Metering	68
	Tip Pick Up	35		Inc/Disp Path	39
	Mixing Cup Left	24		Inc RT/CM Depth	38
	Mixing Cup Right	36		Inc PM Depth	36
	Diluent Tray	34		PM Eject Depth	30
	RT/CM Slide	67		Inc Steps/Rev	14369
	PM Slide	27	SAMPLE TRANSPORT:	Tray Fin Reference	318
				Carriage Meter Pos	-78
				Mixing Cup Trans	38
				Diluent Tray Trans	19
PROBOSCIS:	Mixing Cup Bottom	213		Tray Hook	-95
	Sample Cup Bottom	235		Psid Scan	0
	Prob. Compression	88	REFERENCE SLIDE CENTER:		169
	Tip Height	814	READ SYNC:		0.5ms

RETURN INPUT SETUP VALUES DISPLAY MORE DATA RETURN TO MAIN DIAG MENU HELP

SAMPLING Oct 06 10
 ON OFF 13:07:52
 V9.2 6108
 SA25B

SS1 SS2 ST INC IR R/C PM INOP TESTING COMPLETE
 DIAGNOSTICS - Setup/Adjustments - Current Setup Values

RATE/CM CORRECTION FACTOR:

WHITE		BLACK	
340nm	0.409	340nm	-0.002
400nm	0.770	400nm	-0.001
460nm	0.953	460nm	-0.000
540nm	0.965	540nm	-0.000
600nm	0.967	600nm	-0.001
630nm	0.965	630nm	-0.001
670nm	0.969	670nm	-0.000
680nm	0.965	680nm	-0.001

RETURN RETURN TO MAIN DIAG MENU HELP

SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure SAMPLING Oct 06 10
 ON OFF 13:10:45
 SH SM SS1 SS2 ST INC IR R/C PM INOP TESTING COMPLETE V9.2 6108
 QUALITY CONTROL - Review & Edit QC Results QC10A

111111 ALT BL:MEAN= 49. SD= 1.5 %CV= 3.09 SERUM

#	Time	U/L	SDI	F	D	Comments	#	Time	U/L	SDI	F	D	Comments
10/06/10													
1	09:50	50.	0.79				14	09:50	49.	0.08			
2	09:50	50.	0.41				15	09:50	50.	0.50			
3	09:50	50.	0.27				16	09:50	49.	-0.4			
4	09:50	50.	0.71				17	09:50	50.	0.51			
5	09:50	51.	1.16				18	09:50	50.	0.29			
6	09:50	51.	1.54				19	09:50	50.	0.65			
7	09:50	52.	1.64				20	09:50	50.	0.65			
8	09:50	50.	0.67				21	09:50	52.	1.87			
9	09:50	51.	1.23				22	09:50	52.	1.67			
10	09:50	51.	1.34				23	09:50	52.	1.58			
11	09:50	52.	2.14	F2			24	09:50	50.	0.29			
12	09:50	49.	-0.0				25	09:50	50.	0.46			
13	09:50	47.	-1.1				26	09:43	50.	0.63			
							27	09:43	51.	1.41			

>To change delete status or add comment, type line # and press ENTER.
 File: 10/06/10 - 10/06/10

RETURN	NEW	DISPLAY	DISPLAY	
	ENDING	MORE	COMMENT	HELP
	DATE	RESULTS	CHOICES	

SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure SAMPLING Oct 06 10
 ON OFF 13:10:47
 SH SM SS1 SS2 ST INC IR R/C PM INOP TESTING COMPLETE V9.2 6108
 QUALITY CONTROL - Review & Edit QC Results QC10A

111111 ALT BL:MEAN= 49. SD= 1.5 %CV= 3.09 SERUM

#	Time	U/L	SDI	F	D	Comments	#	Time	U/L	SDI	F	D	Comments
10/06/10													
28	09:43	50.	0.89				41	09:43	49.	0.11			
29	09:43	52.	1.59				42	09:43	49.	0.21			
30	09:43	51.	1.22				43	09:43	49.	-0.1			
31	09:43	51.	1.53				44	09:43	49.	-0.1			
32	09:43	49.	-0.2				45	09:43	48.	-0.7			
33	09:43	47.	-1.2				46	09:43	49.	-0.1			
34	09:43	48.	-0.9				47	09:43	48.	-0.5			
35	09:43	46.	-2.4	F2			48	09:43	48.	-1.0			
36	09:43	48.	-0.5				49	09:43	48.	-0.8			
37	09:43	47.	-1.2				50	09:43	48.	-0.6			
38	09:43	50.	0.25				51	09:37	50.	0.67			
39	09:43	49.	0.07				52	09:37	50.	0.48			
40	09:43	48.	-0.5				53	09:37	49.	-0.2			
							54	09:37	49.	0.10			

>To change delete status or add comment, type line # and press ENTER.
 File: 10/06/10 - 10/06/10

RETURN	NEW	DISPLAY	DISPLAY	
	ENDING	PREVIOUS	COMMENT	HELP
	DATE	RESULTS	CHOICES	

READY TESTING COMPLETE

QUALITY CONTROL - Review & Edit QC Results

BL:MEAN= 144.7 SD= .52 %CV= .36 SERUM

#	Time	Na+ mmol/L	SDI	F	D	Comments	#	Time	mmol/L	SDI	F	D	Comments
10/06/10													
1	10:50	144.6	-0.1				14	10:50	144.1	-1.1			
2	10:50	145.2	1.06				15	10:50	143.6	-2.1	F2		
3	10:50	145.5	1.57				16	10:50	145.0	0.72			
4	10:50	144.9	0.39				17	10:50	144.7	0.13			
5	10:50	144.1	-1.0				18	10:50	144.6	-0.0			
6	10:50	144.8	0.22				19	10:50	145.3	1.32			
7	10:50	144.7	0.05				20	10:50	145.1	0.89			
8	10:50	145.3	1.32				21	10:50	143.9	-1.4			
9	10:50	144.5	-0.3				22	10:50	144.2	-1.0			
10	10:50	145.0	0.72				23	10:50	144.7	0.13			
11	10:50	143.6	-2.1	F2			24	10:50	145.4	1.40			
12	10:50	145.0	0.56				25	10:50	144.7	0.13			
13	10:50	144.7	0.13				26	10:50	144.6	-0.1			
							27	10:50	144.0	-1.2			

To change delete status or add comment, type line # and press ENTER.
File: 10/06/10 - 10/06/10

RETURN NEW ENDING DATE DISPLAY MORE RESULTS DISPLAY COMMENT CHOICES HELP

READY TESTING COMPLETE

QUALITY CONTROL - Review & Edit QC Results

BL:MEAN= 144.7 SD= .52 %CV= .36 SERUM

#	Time	Na+ mmol/L	SDI	F	D	Comments	#	Time	mmol/L	SDI	F	D	Comments
10/06/10													
28	10:50	144.1	-1.1										
29	10:50	144.8	0.22										
30	10:50	145.0	0.56										

To change delete status or add comment, type line # and press ENTER.
File: 10/06/10 - 10/06/10

RETURN NEW ENDING DATE DISPLAY PREVIOUS RESULTS DISPLAY COMMENT CHOICES HELP

222222 AMYL BL:MEAN= 80. SD= 1.8 %CV= 2.25 SERUM

QUALITY CONTROL - Review & Edit QC Results

#	Time	U/L	SDI	F	D	Comments	#	Time	U/L	SDI	F	D	Comments
1	10:11	80.	0.03				14	10:04	82.	1.34			
2	10:11	82.	1.39				15	10:04	83.	1.63			
3	10:11	82.	0.90				16	10:04	79.	-0.4			
4	10:11	80.	0.04				17	10:04	80.	0.25			
5	10:11	81.	0.37				18	10:04	82.	1.29			
6	10:11	80.	0.08				19	10:04	73.	-3.9	F3		
7	10:11	79.	-0.7				20	10:04	78.	-1.3			
8	10:11	82.	1.39				21	10:04	80.	-0.1			
9	10:11	79.	-0.5				22	10:04	80.	-0.1			
10	10:11	82.	0.91				23	10:04	80.	0.13			
11	10:04	82.	1.40				24	10:04	78.	-1.1			
12	10:04	85.	2.53	F2			25	10:04	78.	-0.8			
13	10:04	80.	0.22				26	10:04	79.	-0.6			
							27	10:04	78.	-1.0			

>To change delete status or add comment, type line # and press ENTER.
File: 10/06/10 - 10/06/10

RETURN NEW ENDING DATE DISPLAY MORE RESULTS DISPLAY COMMENT CHOICES HELP

222222 AMYL BL:MEAN= 80. SD= 1.8 %CV= 2.25 SERUM

QUALITY CONTROL - Review & Edit QC Results

#	Time	U/L	SDI	F	D	Comments	#	Time	U/L	SDI	F	D	Comments
2	09:58	80.	-0.2				41	09:58	80.	-0.1			
29	10:04	81.	0.31				42	09:58	79.	-0.7			
30	10:04	80.	0.03				43	09:58	78.	-1.0			
31	10:04	82.	1.15				44	09:58	81.	0.62			
32	10:04	80.	-0.1				45	09:58	79.	-0.5			
33	10:04	79.	-0.4				46	09:58	80.	-0.1			
34	10:04	80.	-0.2				47	09:58	81.	0.82			
35	10:04	83.	1.82				48	09:58	79.	-0.6			
36	09:58	78.	-1.3				49	09:58	79.	-0.4			
37	09:58	80.	-0.2				50	09:58	79.	-0.4			
38	09:58	79.	-0.6				51	09:58	79.	-0.7			
39	09:58	80.	0.24				52	09:58	78.	-0.8			
40	09:58	79.	-0.5				53	09:58	78.	-1.1			
							54	09:58	82.	1.15			

>To change delete status or add comment, type line # and press ENTER.
File: 10/06/10 - 10/06/10

RETURN NEW ENDING DATE DISPLAY PREVIOUS RESULTS DISPLAY COMMENT CHOICES HELP

Calibration Certificate

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

Instrument : Vitros 250
Serial No. : 25016108
Customer Name : Shruti Clinical Lab

Calibration performed on: 31st March 2022

Carried out checks for mechanism through system intellicheck software and found O.K.

Run control and results were satisfactory

Next Calibration will be performed on **Sept, 2022**

For **Ortho Clinical Diagnostics**



Rahul Bhand
Service Engineer

Date : 31st March 2022

SH SM SS1 SS2 ST INC R/C PM INOP TESTING COMPLETE
SAMPLE METERING PERFORMANCE TESTS
Leak Test- A/D Ref. Voltage Check

SAMPLING
ON OFF

Mar 31 22
13:18:07
V9.7 **250
PT04A

Reference Resolution
4.961 Vdc 0.039 Vdc

Ambient Pressure = 2.676

- > 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



Vipul : 8080 234 235

SM SS1 SS2 ST INC R/C FM INOP

TESTING COMPLETE

SAMPLING
ON OFF

Mar 31 22
13:03:53
V9.7 **250
SA11A

DIAGNOSTICS - Setup/Adjustment - Reflectometer Iris

630 nm Wavelength
7.32 Voltage

> Use IRIS controls to set Voltage to current specification.

RETURN

RETURN TO
MAIN DIAG
MENU

DONE

HELP



SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure

SAMPLING
ON OFF

Mar 31 22
13:47:00
V9.7 **250
PT16B

INC R/C INOP

TESTING COMPLETE

DIAGNOSTICS - PERFORMANCE TESTS - INCUBATOR
PAD REFLECTANCE TEST

MEAN MIN. = 0.9417 REFLECTANCE VALUE

MEAN MAX. = 0.9585 REFLECTANCE VALUE

RANGE = 0.0167 (MAX. MEAN - MIN. MEAN)

GRAND MEAN = 0.9499 (MEAN OF ALL SLOT MEANS)

STAND DEV = 0.0043 (STD. DEV. OF ALL SLOTS)

- > COMPARE RANGE AND GRAND MEAN TO CURRENT SPECIFICATIONS
- > PRESS DISPLAY_MORE_DATA TO VIEW THE MEANS AND RAW DATA

RETURN DISPLAY START RETURN TO
 MORE MAIN DIAG
 DATA MENU

HELP



SCHEDULER * ENVIRONMENT * REF. METERING -12V low

SAMPLING
ON OFF

Mar 31 22
13:29:15
V9.7 **250
PT01B

SH SM SS1 SS2 ST INC R/C PM INOP TESTING COMPLETE
SAMPLE METERING PERFORMANCE TESTS
Leak Test - Voltage Differential

Aspirate = 0.137 Vdc

Dispense = 0.137 Vdc

Ambient Pressure = 2.656 Vdc



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

RETURN

DISLAY
PREVIOUS

DISLAY
NEXT

HELP

Xipul 8080 234 235

SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure
SH SM SS1 SS2 ST INC R/C PM INOP TESTING COMPLETE
SAMPLE METERING PERFORMANCE TESTS
Hysteresis Test

SAMPLING Mar 31 22
ON OFF 13:43:48
V9.7 **250
PT01C

	MEAN	MAX	MIN
Hysteresis :	0.986	2.049	0.000
Pressure F0:	2.676	2.695	2.676
Pressure F1:	4.082	4.375	3.848
Pressure F2:	2.695	2.715	2.676

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

RETURN	DISPLAY PREVIOUS SCREEN	DISPLAY NEXT SCREEN	HELP
--------	-------------------------------	---------------------------	------

SCHEDULER * ENVIRONMENT * REF. METERING -12V low

SAMPLING Mar 31 22
ON OFF 09:05:59
V9.7 **250

READY

TESTING COMPLETE

QUALITY CONTROL - Print Charts & Save Statistics

QC12A

RIOL1

SERUM

#	Test	Mean	SD	N	Flg	Del	P	S	#	Test	Mean	SD	N	Flg	Del	P	S
1	GLU	89.6	0.00	1	0	0			14	LDH	159.	0.0	1	0	0		
2	TP	5.19	0.000	1	0	0			15	dHDL	70.6	0.00	1	0	0		
3	Bu	.57	0.000	1	0	0			16	URIC	4.25	0.000	1	0	0		
4	AST	48.	0.0	1	0	0			17	PHOS	3.17	0.000	1	0	0		
5	ALKP	63.	0.0	1	0	0			18	ALTV	24.	0.0	1	0	0		
6	TRIG	201.2	0.00	1	0	0			19								
7	BUN	13.5	0.00	1	0	0			20								
8	ALB	4.59	0.000	1	0	0			21								
9	Bc	0.00	0.000	1	0	0			22								
10	CHOL	252.	0.0	1	0	0			23								
11	CREA	2.02	0.000	1	0	0			24								
12	Ca	8.62	0.000	1	0	0			25								
13	TBIL	1.08	0.000	1	0	0			26								

>Touch NEW DATES or type line # and press ENTER (for all tests type 99).

START: 03/31/22 FINISH: 03/31/22

RETURN NEW SAVE PRINT PRINT
 DATES STATISTICS INDIVIDUAL DAILY HELP

Performed by:- Radhika

Check by:-

Janday

CALIBRATION REPORT

ANALYZER NAME: **250*

TEST: PHOS
 CAL DATE: Jul 29 22
 FLUID: SERUM KIT #: 1 SITE TEMP: 25.5 C LOT/GENERATION: 1248-3461
 CAL TIME: 12:15

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
INTERCEPT	0131	01	1.2	2.30445 E-
01 SLOPE	0131	02	5.3	4.59081 E-
01 CURVATURE	0131	03	13.1	6.99494 E-
01				

TEST: PHOS
 CAL DATE: Jul 29 22
 FLUID: URINE KIT #: 1 SITE TEMP: 25.5 C LOT/GENERATION: 1248-3461
 CAL TIME: 12:15

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
INTERCEPT	0131	01	1.3	2.30445 E-
01 SLOPE	0131	02	5.8	4.59081 E-
01 CURVATURE	0131	03	13.7	6.99494 E-
01				

performed by: Shardha

Check by: JTB

CALIBRATION REPORT

ANALYZER NAME: **250*

TEST: Mg
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 1 SITE TEMP: 25.5 C LOT/GENERATION: 3208-6887
CAL TIME: 12:16

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
INTERCEPT	0131	01	.7	9.86126 E-
01 SLOPE	0131	02	3.6	1.39540
CURVATURE	0131	03	9.3	2.06145

TEST: Mg
CAL DATE: Jul 29 22
FLUID: URINE KIT #: 1 SITE TEMP: 25.5 C LOT/GENERATION: 3208-6887
CAL TIME: 12:16

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
INTERCEPT	0131	01	.9	9.86126 E-
01 SLOPE	0131	02	3.7	1.39540
CURVATURE	0131	03	9.2	2.06145

performed by: Shawradha

Checked by: JILL

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: BUN
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 1 SITE TEMP: 25.4 C LOT/GENERATION: 0131-8385
CAL TIME: 12:13

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
INTERCEPT	0131	01	3.	1.28934 E-
01 SLOPE	0131	02	51.	8.89182 E-
01 CURVATURE	0131	03	112.	1.56444

TEST: BUN
CAL DATE: Jul 29 22
FLUID: URINE KIT #: 1 SITE TEMP: 25.4 C LOT/GENERATION: 0131-8385
CAL TIME: 12:13

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
INTERCEPT	0131	01	4.	1.28934 E-
01 SLOPE	0131	02	55.	8.89182 E-
01 CURVATURE	0131	03	126.	1.56444

Performed by: Shardha check by: JSD

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: Fe
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 4 SITE TEMP: 25.4 C LOT/GENERATION: 5028-5534
CAL TIME: 20:48

PARAMETERS	KIT LOT	BOTTLE	SAV -ug/dL	RESPONSE
INTERCEPT -1.90761	0481	01	15.	4.88148 E-
03 SLOPE 1.10681 E+02	0481	04	192.	1.68292 E-
02 CURVATURE 5.64032 E-01	0481	03	586.	3.77654 E-
02 SUB DEP:				
DENSITY 4.88371 E-01				

20:57:44

END OF CALIBRATION REPORT

07/29/22

Performed by: Strindberg

Check by: Jules

CALIBRATION REPORT

ANALYZER NAME: **250*

TEST: Fe

CAL DATE: Jul 29 22

FLUID: SERUM KIT #: 4

SITE TEMP: 25.4 C

LOT/GENERATION: 5028-5534

PARAMETERS

KIT LOT

BOTTLE

SAV -ug/dL

RESPONSE

03	INTERCEPT	-1.90761	0481	01	15.	4.88148 E-
02	SLOPE	1.10681 E+02	0481	04	192.	1.68292 E-
02	CURVATURE	5.64032 E-01	0481	03	586.	3.77654 E-
	SUB DEF:					
	DENSITY	4.88371 E-01				

20:57:44

END OF CALIBRATION REPORT

07/29/22

Performed by: Shardha

Check by: Juli

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: dHDL
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 25 SITE TEMP: 25.2 C LOT/GENERATION: 1135-6778
CAL TIME: 21:01

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
INTERCEPT 01	2571	01	6.	3.19842 E-
SLOPE 01	2571	02	38.	6.07864 E-
CURVATURE 01	2571	03	106.	8.41750 E-

21:04:15

END OF CALIBRATION REPORT

07/29/22

Performed by: shanelle

Checked by: Jess

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: Bc
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 4 SITE TEMP: 25.1 C LOT/GENERATION: 0213-6237
CAL TIME: 20:48

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
INTERCEPT	0481	01	0.0	1.25726 E-
01				1.63741 E-
SLOPE	0481	03	1.0	4.74721 E-
01				3.17633 E-
CURVATURE	0481	04	8.2	8.06196 E-
01				5.39705 E-
	0481	02	19.8	6.48646 E-
01				5.71980 E-

20:56:12

END OF CALIBRATION REPORT

07/29/22

Performed by: *Shamsaddha*

Check by: *Jitu*

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: ALB
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 4 SITE TEMP: 25.1 C LOT/GENERATION: 0927-5733
CAL TIME: 20:47

PARAMETERS	KIT LOT	BOTTLE	SAV -q/dL	RESPONSE
01 INTERCEPT -1.36464 E-02	0481	01	1.2	5.97729 E-
01 SLOPE 1.15508 E+02	0481	02	3.4	8.32469 E-
01 CURVATURE 2.42589 E-02	0481	03	6.2	1.01222

20:54:38

END OF CALIBRATION REPORT

07/29/22

Performed by: Sharddha

Check by: Jus

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: TF
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 4 SITE TEMP: 25.1 C LOT/GENERATION: 0605-9980
CAL TIME: 20:47

	PARAMETERS	KIT LOT	BOTTLE	SAV -g/dL	RESPONSE	
01	INTERCEPT	2.94465 E-01	0481	01	1.9	5.46851 E-
01	SLOPE	9.39099 E+01	0481	02	6.5	7.69213 E-
01	CURVATURE	3.62179 E+01	0481	03	10.4	8.90792 E-

Performed by: Shanidha

Check by: JTB

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: GGT
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 3 SITE TEMP: 25.2 C LOT/GENERATION: 6749-6229
CAL TIME: 20:32

PARAMETERS	KIT LOT	BOTTLE	SAV -U/L	RESPONSE
INTERCEPT	0341	01	26.	6.84276 E-
04 SLOPE	0341	02	109.	3.73076 E-
03 CURVATURE	0341	03	1262.	3.77902 E-
02 SUB DEP:				
DENSITY				3.80248 E-01
1ST PT REF				9.81143

20:43:33

END OF CALIBRATION REPORT

07/29/22

Performed by: Pharmathia

Checked by: JTB

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: ALKP
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 3 SITE TEMP: 25.2 C LOT/GENERATION: 6524-2735
CAL TIME: 20:31

PARAMETERS	KIT LOT	BOTTLE	SAV	U/L	RESPONSE
INTERCEPT	0341	01	17.		5.21690 E-
04 SLOPE	0341	02	124.		4.32006 E-
03 CURVATURE	0341	03	1220.		3.80648 E-
02 SUB DEP:					
DENSITY					2.56443 E-01
1ST PT REF					8.71723

Performed by: Standard

Check by: Juu

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: AST
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 3 SITE TEMP: 25.2 C LOT/GENERATION: 7328-5045
CAL TIME: 20:31

	PARAMETERS	KIT LOT	BOTTLE	SAV -U/L	RESPONSE
03	INTERCEPT 4.49849 E-01	0341	01	10.	3.75358 E-
02	SLOPE 9.43890 E+01	0341	02	204.	7.13304 E-
01	CURVATURE 3.51956	0341	03	690.	2.06931 E-
	SUB DEP:				
	DENSITY 5.10499 E-01				
	1ST PT REF 7.28895				

Performed by: Shasriddha

Check by: JTB

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: ALTV
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 3 SITE TEMP: 25.2 C LOT/GENERATION: 5607-8377
CAL TIME: 20:30

PARAMETERS	KIT LOT	BOTTLE	SAV -U/L	RESPONSE
INTERCEPT -1.85729 E-01	0341	01	8.	1.06483 E-
02 SLOPE 9.96829 E+01	0341	02	209.	1.35802 E-
01 CURVATURE 2.51186 E-01	0341	03	736.	3.83814 E-
01 SUB DEP:				
DENSITY 6.08171 E-01				
1ST PT REF 3.79727				

Performed by: starraloha

Check by: Jill

CALIBRATION REPORT

ANALYZER NAME: **250*

TEST: LDH

CAL DATE: Jul 29 22

FLUID: SERUM KIT #: 3

CAL TIME: 20:30

SITE TEMP: 25.2 C LOT/GENERATION: 6354-6062

PARAMETERS	KIT LOT	BOTTLE	SAV -U/L	RESPONSE
INTERCEPT	0341	01	93.	-1.56003 E-
02 SLOPE	0341	02	330.	-5.51897 E-
02 CURVATURE	0341	03	834.	-1.25960 E-
01 SUB DEP:				
DENSITY				3.94795 E-01
DELTA DENS				9.74274 E-01
1ST PT REF				1.50597

Performed by: Sharda Datta

Check by: Jules

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: CK
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 3 SITE TEMP: 25.2 C LOT/GENERATION: 6417-5506
CAL TIME: 20:29

PARAMETERS	KIT LOT	BOTTLE	SAV -U/L	RESPONSE
INTERCEPT 3.98185	0341	01	36.	2.89434 E-
02 SLOPE 1.07327 E+02	0341	02	835.	2.69564 E-
01 CURVATURE -7.30430 E-01	0341	03	1525.	4.26979 E-
01 SUB DEP:				
DENSITY 2.22664				
1ST PT REF 2.02220 E+01				

Performed by: Shardha

Check by: Jit

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: LIPA
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 3 SITE TEMP: 25.2 C LOT/GENERATION: 5949-2827
CAL TIME: 20:28

	PARAMETERS	KIT LOT	BOTTLE	SAV -U/L	RESPONSE	
03	INTERCEPT	1.19306 E+01	0341	01	26.	1.78461 E-
02	SLOPE	9.12441 E+01	0341	02	188.	1.18212 E-
02	CURVATURE	1.13428	0341	03	1961.	9.08895 E-
	SUB DEF:					
	DENSITY	3.97721 E-01				

performed by: Sharalatha

check by: JTB

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: CHOL
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 2 SITE TEMP: 25.4 C LOT/GENERATION: 0845-9641
CAL TIME: 20:18

	PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
01	INTERCEPT 2.11657	0251	01	26.	3.78302 E-
01	SLOPE 1.02760 E+02	0251	02	178.	8.69450 E-
01	CURVATURE -1.57955 E-02	0251	03	432.	1.29452

Performed by: Sharedatta

Checked by: JLU

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: TRIG
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 2 SITE TEMP: 25.4 C LOT/GENERATION: 0747-5643
CAL TIME: 20:19

	PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
01	INTERCEPT 5.82328	0251	01	33.	2.71789 E-
01	SLOPE 1.01711 E+02	0251	03	198.	8.42812 E-
	CURVATURE 8.69174 E-01	0251	02	470.	1.54623

Performed by: Shaneltra

Check by: JLL

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: TBIL
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 4 SITE TEMP: 25.2 C LOT/GENERATION: 1448-3001
CAL TIME: 20:47

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
01 INTERCEPT -3.76640	0481	01	1.1	1.79794 E-
01 SLOPE 3.27329 E+01	0481	03	9.9	2.03811 E-
01 CURVATURE 6.57391	0481	02	17.8	4.07487 E-
01				3.30500 E-
01				5.16067 E-
01				4.18429 E-

Performed by: Shaydatha

Check by: Jeta

CALIBRATION REPORT
 ANALYZER NAME: **K250*

TEST: Bu
 CAL DATE: Jul 29 22
 FLUID: SERUM KIT #: 4 SITE TEMP: 25.1 C LOT/GENERATION: 0213-6237
 CAL TIME: 20:48

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
INTERCEPT 2.50876	0481	01	.6	1.25726 E-
01				1.63741 E-
SLOPE 2.61279 E+02	0481	02	6.7	6.48646 E-
01				5.71980 E-
CURVATURE -1.88972 E+02	0481	03	9.5	4.74721 E-
01				3.17633 E-
01	0481	04	21.0	8.06196 E-
01				5.39705 E-
01				

Performed by: Shandha

Check by: [Signature]

CALIBRATION REPORT

ANALYZER NAME: **250*

TEST: Ca

CAL DATE: Jul 29 22

FLUID: SERUM KIT #: 1

SITE TEMP: 25.5 C LOT/GENERATION: 0309-3342

CAL TIME: 12:16

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
INTERCEPT	0131	03	1.6	6.07340 E-
01 SLOPE	0131	02	8.9	1.07891
CURVATURE	0131	01	13.9	1.32085

TEST: Ca

CAL DATE: Jul 29 22

FLUID: URINE KIT #: 1

SITE TEMP: 25.5 C LOT/GENERATION: 0309-3342

CAL TIME: 12:16

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
INTERCEPT	0131	03	2.1	6.07340 E-
01 SLOPE	0131	02	9.3	1.07891
CURVATURE	0131	01	15.0	1.32085

Performed by: Shalalaha

Check by: JLU

CALIBRATION REPORT

ANALYZER NAME: **250*

TEST: CREA
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 1 SITE TEMP: 25.5 C LOT/GENERATION: 1537-6247
CAL TIME: 12:14

	PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
03	INTERCEPT	0131	01	.5	3.43199 E-
03	SLOPE	0131	02	1.5	9.11517 E-
02	CURVATURE	0131	03	13.4	6.45338 E-
	SUB DEP:				
	DENSITY				4.51850 E-01

TEST: CREA
CAL DATE: Jul 29 22
FLUID: URINE KIT #: 1 SITE TEMP: 25.5 C LOT/GENERATION: 1537-6247
CAL TIME: 12:14

	PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
03	INTERCEPT	0131	01	.5	3.43199 E-
03	SLOPE	0131	02	1.9	9.11517 E-
02	CURVATURE	0131	03	15.1	6.45338 E-
	SUB DEP:				
	DENSITY				7.01001 E-01

Performed by: *Shahidha*

Check by: *Jill*

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: URIC
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 1 SITE TEMP: 25.5 C LOT/GENERATION: 0548-6819
CAL TIME: 12:15

	PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
	INTERCEPT -2.61249 E-02	0131	01	.7	2.05869 E-
01	SLOPE 1.04066 E+02	0131	02	5.9	7.10441 E-
01	CURVATURE 7.96272 E-01	0131	03	16.3	1.36882

TEST: URIC
CAL DATE: Jul 29 22
FLUID: URINE KIT #: 1 SITE TEMP: 25.5 C LOT/GENERATION: 0548-6819
CAL TIME: 12:15

	PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
	INTERCEPT -2.64905 E-02	0131	01	.5	2.05869 E-
01	SLOPE 9.40004 E+01	0131	02	6.6	7.10441 E-
01	CURVATURE 1.42623 E+01	0131	03	17.9	1.36882

Performed by: Shardha

Check by: Juli

CALIBRATION REPORT
 ANALYZER NAME: **250*

TEST: GLU
 CAL DATE: Jul 29 22
 FLUID: SERUM KIT #: 1 SITE TEMP: 25.4 C LOT/GENERATION: 0015-6933
 CAL TIME: 12:14

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
INTERCEPT	0131	01	33.	2.57033 E-
⁰¹ SLOPE	0131	02	290.	1.05820
CURVATURE	0131	03	594.	1.49706

TEST: GLU
 CAL DATE: Jul 29 22
 FLUID: CSF KIT #: 1 SITE TEMP: 25.4 C LOT/GENERATION: 0015-6933
 CAL TIME: 12:14

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
INTERCEPT	0131	01	38.	2.57033 E-
⁰¹ SLOPE	0131	02	330.	1.05820
CURVATURE	0131	03	650.	1.49706

TEST: GLU
 CAL DATE: Jul 29 22
 FLUID: URINE KIT #: 1 SITE TEMP: 25.4 C LOT/GENERATION: 0015-6933
 CAL TIME: 12:14

PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE
INTERCEPT	0131	01	37.	2.57033 E-
⁰¹ SLOPE	0131	02	342.	1.05820
CURVATURE	0131	03	674.	1.49706

Check by: Shardha

Check by: [Signature]

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: AMYL
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 3 SITE TEMP: 25.2 C LOT/GENERATION: 6016-2828
CAL TIME: 20:29

	PARAMETERS	KIT LOT	BOTTLE	SAV -U/L	RESPONSE
03	INTERCEPT 1.62646	0341	01	49.	9.26995 E-
02	SLOPE 1.00018 E+02	0341	02	353.	4.54463 E-
02	CURVATURE 3.06704 E-01	0341	03	937.	9.39134 E-
	SUB DEP:				
	DENSITY 1.22383				

TEST: AMYL
CAL DATE: Jul 29 22
FLUID: URINE KIT #: 3 SITE TEMP: 25.2 C LOT/GENERATION: 6016-2828
CAL TIME: 20:29

	PARAMETERS	KIT LOT	BOTTLE	SAV -U/L	RESPONSE
03	INTERCEPT 1.26447 E+01	0341	01	71.	9.26995 E-
02	SLOPE 7.28835 E+01	0341	02	314.	4.54463 E-
02	CURVATURE 9.79243 E-01	0341	03	877.	9.39134 E-
	SUB DEP:				
	DENSITY 1.22383				

Performed by *Sharada*

Check by *John*

20:39:52

END OF CALIBRATION REPORT

07/29/22

CALIBRATION REPORT
ANALYZER NAME: **250*

TEST: URIC
CAL DATE: Jul 29 22
FLUID: SERUM KIT #: 1 SITE TEMP: 25.2 C LOT/GENERATION: 0548-6819
CAL TIME: 21:17

	PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE	
01	INTERCEPT	4.12623 E-03	0131	01	.7	2.02507 E-
01	SLOPE	1.02544 E+02	0131	02	5.9	7.12416 E-
	CURVATURE	9.78498	0131	03	16.3	1.36805

TEST: URIC
CAL DATE: Jul 29 22
FLUID: URINE KIT #: 1 SITE TEMP: 25.2 C LOT/GENERATION: 0548-6819
CAL TIME: 21:17

	PARAMETERS	KIT LOT	BOTTLE	SAV -mg/dL	RESPONSE	
01	INTERCEPT	7.80359 E-03	0131	01	.5	2.02507 E-
01	SLOPE	9.45470 E+01	0131	02	6.6	7.12416 E-
	CURVATURE	2.16223 E+01	0131	03	17.9	1.36805

Performed by: Shawdetha

Check by: JTB

21:20:48

END OF CALIBRATION REPORT

07/29/22

TEST: TIBC
 CAL DATE: Jul 30 22
 FLUID: SERUM KIT #: 4 SITE TEMP: 25.7 C LOT/GENERATION: 5028-5534
 CAL TIME: 11:26

	PARAMETERS	KIT LOT	BOTTLE	SAV -ug/dL	RESPONSE
	INTERCEPT	3.82115 E+01	0481	04.	5.20876 E-
03	SLOPE	1.10095 E+02	0481	020.	1.55630 E-
02	CURVATURE	0.00000	0481	2438.	3.55460 E-
02	SUB DEF:				
	DENSITY	4.83816 E-01			

Performed by: Shardha

Check by: Jilli

SCHEDULER * ENVIRONMENT * REF. METERING -12V low

SAMPLING Jul 30 22

READY

ON OFF

16:22:36

TESTS IN PROCESS

V9.7 **250

QUALITY CONTROL - Print Charts & Save Statistics

QC12A

BL2

								SERUM									
#	Test	Mean	SD	N	Flg	Del	P	S	#	Test	Mean	SD	N	Flg	Del	P	S
1	GLU	263.0	0.00	1	0	0			14	LDH	487.	0.0	1	0	0		
2	TP	3.65	0.000	1	0	0			15	dHDL	24.9	0.00	1	0	0		
3	Bu	3.76	0.000	1	0	0			16	URIC	8.69	0.000	1	0	0		
4	AST	198.	0.0	1	0	0			17	PHOS	6.88	0.000	1	0	0		
5	ALKP	292.	0.0	1	0	0			18	ALTV	75.	0.0	1	0	0		
6	TRIG	100.4	0.00	1	0	0			19								
7	BUN	39.6	0.00	1	0	0			20								
8	ALB	2.71	0.000	1	0	0			21								
9	Bc	.59	0.000	1	0	0			22								
10	CHOL	102.	0.0	1	0	0			23								
11	CREA	5.15	0.000	1	0	0			24								
12	Ca	11.63	0.000	1	0	0			25								
13	TBIL	4.31	0.000	1	0	0			26								

>Touch NEW DATES or type line # and press ENTER (for all tests type 99).

START: 07/29/22 FINISH: 07/29/22

RETURN NEW SAVE PRINT PRINT
 DATES STATISTICS INDIVIDUAL DAILY HELP

Performed by: *Shardeta*

Check by: *Jus*