Ortho Clinical Diagnostics

INSTALLATION QUALIFICATION

For

VITROS 350

Manufactured by:
Ortho Clinical Diagnostics, Inc., US

Table of Contents

I. Approval of the IQ procedure

Both **Lupin Diagnostics** and **Ortho-Clinical Diagnostics** are jointly responsible for the installation of VITROS 350**, Sr. No. 27001181** in the Biochemistry Laboratory of **Lupin Diagnostics, Bhubaneswar.**

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

Name	:	Mr. RAM MISHRA	Signature:
Designation	:	Service Engineer	Date:
Company	:	Ortho-Clinical Diagnostics	

Validation Team from:

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

Customer Authorizations:

Name	:	
Designation	:	Signature:
Site	:	Date:

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 **Lupin Diagnostics, Bhubaneswar** 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 Diagnostics, Bhubaneswar.**

III. SCOPE

This Installation Qualification protocol will be performed on the VITROS 350 bearing Sr. No. **27001181** located at Biochemistry Department, Lupin Diagnostics, Bhubaneswar. 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 11/09/2023 is in compliance with the specifications of the purchase order.

Verified By: Mr. RAM MISHRA Date: 11/09/2023

b. Utilities

Sr. No	Utility	Verified by	Date
1.	**Environmental conditions:**	RAM MISHRA	11/09/2023
	a. Analyzer will be placed away from the direct sunlight.	”	”
	b. Installation site shall be free from dust, significant vibrations and shall be well ventilated.	”	”
	c. Installation site floor construction shall be able to support approximately 272 kg.	”	”
	d. Room temperature will be maintained between 15^0C to 27^0C and the temperature fluctuation during analysis shall not be more than ± 2^0C.	”	”
	e. The analyzer shall be kept away from strong electromagnetic sources and electrical interferences.	”	”
	f. It will be kept near to the power sources.	”	”
	g. Maximum relative humidity allowed up to 70%.	”	”
	h. If the temperature and humidity fluctuations are not within the specified range, the analyzer cannot maintain data reliability.	”	”
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)]	”	”
3.	Electrical Outlets: Actual Voltage on site [AC 220-230 Volts 16A 50 HZ]	”	”

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

c. The instrument has been verified for the following

Sr. No.	Verification		Verified by	Date
1.	Instrument is identified	Yes	RAM MISHRA	11/09/2023
2.	Manufacturer's specifications are included	Yes	,,	,,
3.	Accessories / Consumables are listed	Yes	,,	,,
4.	Equipment manual from the manufacturer is documented	Yes	,,	,,
5.	Manufacturer's Certificate attached	Yes	,,	,,

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	RAM MISHRA	11/09/2023
Manufacturer:	Ortho-Clinical Diagnostics	,,	,,
Model:	*VITROS 350*	,,	,,
Serial Number:	27001181	,,	,,
Size (in cm):	115 (L) x 71 (W) x 120 (H)	,,	,,
Power:	AC 220-230 V 16A 50Hz±2Hz	,,	,,
Power consumption:	6880KW hours per year	,,	,,

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.

A. 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.

B. 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.

C. 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.

D. 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	➢ 2 ports for printer ➢ One port for LIS
Regional settings	➢ Language English.

The system has preloaded operating software

The Analyzer has been installed satisfactorily: No ☐ Yes ☑

Verified by : Mr. RAM MISHRA Date: 11/09/2023

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 : Mr. RAM MISHRA

Designation : Service Engineer Signature:

Company : Ortho Clinical Diagnostics Date:

Customer Authorizations:

Name :

Designation : Signature:

Organization : Date:

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** and **Ortho Clinical Diagnostics** are jointly responsible for the operation qualification of VITROS 350**, Sr. No. 27001181** in the **Biochemistry** Laboratory of **Lupin Diagnostics** as per the Operational Qualification Protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name	:	Mr. SUMAN OJHA	Signature:
Designation	:	Application Support	
Company	:	Ortho Clinical Diagnostics	Date:

Validation Team from:

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

Customer Authorizations:

Name	:	
Designation	:	Signature:
Site	:	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 **Lupin Diagnostics** 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 350, **Sr.No. 27001181** located at Biochemistry Department, **Lupin Diagnostics** 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 350

2. Serial Number: 27001181

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	SUMAN OJHA 27/09/2023
02	Daily maintenance	To clean appropriate modules so as to maintain accuracy and precision	”
03	Inventory of reagents and consumables	To check the slide supply of installed Vitros 350	”
04	Calibration for the assays used	To calibrate the system for every new lot of assays	”
05	QC check	To confirm that systems, reagents & consumables are acceptable and working within specifications for each assay used	”
06	Sample programming and Analysis	To run the samples	”

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

PARAMETER	**PASS**	**FAIL**
	PASSES	

Parameter values for verification: "READY" on Status console

Test: 2: Daily Maintenance

Purpose: To clean appropriate modules so as per the daily maintenance protocol on the display

Method:

Refer detailed procedure for Daily Maintenance

Sr No	Activity	Done by	Date
01	Empty waste container	SUMAN OJHA	27/09/2023
02	Clean ERF Reservoir Holder & Base	,,	,,
03	Replace ERF Reservoir	,,	,,
04	Replace ERF Tip	,,	,,
05	Clean ERF Tip Sleeve	,,	,,
06	Clean IWF Reservoir Holder & Base	,,	,,
07	Replace IWF Reservoir	,,	,,
08	Replace IWF Tip	,,	,,
09	Clean IWF Tip Sleeve	,,	,,
10	Load supplies and remove outdated and empty reagents	,,	,,
11	Perform Quality Control	,,	,,

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

PARAMETER	**PASS**	**FAIL**
	PASSES	

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 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.	SUMAN OJHA	27/09/2023
02	Verify the status of reagents loaded.	"	"

Acceptance criteria:

- **No error codes**
- **All reagents should show "Ready"/cal status**

PARAMETER	PASS	FAIL
	PASSES	

Parameter values for verification: No Error codes

Test: 4: Calibration of the assays used

Purpose: To calibrate the system for every new lot of assays

Procedure:

Sr. No.	Activity	Done By	Date
01	Reconstitution of the cal kits for appropriate reagent	SUMAN OJHA	28/09/2023
02	Performing Calibration with calibration programming screen	”	”
03	Verification of Calibration report	”	”

Acceptance criteria: “Calibration Successful” should come on screen

PARAMETER **PASS** **FAIL**

PASSES

Parameter values for verification **:** “Calibration Successful” found and the report of the same from the analyzer

Test: 5: QC check

Purpose: To confirm that systems, reagents and consumables are acceptable & working within specifications for each assay used.

Procedure:

Sr. No.	Activity	Done By	Date
01	Preparing Liquid or Lyophilized control fluids	SUMAN OJHA	28/09/2023
02	Creating QC file	,,	,,
03	QC sample programming and analysis	,,	,,
04	Verification of QC results obtained	,,	,,

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

PARAMETER	**PASS**	**FAIL**
	PASSES	

Parameter values for verification: QC values within ± 2SD

Test: 6: Sample programming and Analysis

Purpose: To run the samples

Procedure:

Sr. No.	Activity	Done By	Date
01	Loading and Processing of samples	SUMAN OJHA	29/09/2023
02	Programming samples	,,	,,
03	Unloading the samples	,,	,,
04	Viewing samples in process	,,	,,
05	Review results: Monitoring results	,,	,,

Acceptance criteria: Samples Analysis & Report without any error

PARAMETER	**PASS**	**FAIL**
	PASSES	

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.

Mr. SUMAN OJHA from Ortho Clinical Diagnostics has conducted the training.

Sr. No.	Training program	Initials	Date
1.	Instrument Setup	Suman Ojha	29/09/2023
2.	System Operation	„	„
3.	Calibration	„	„
4.	Quality Control	„	„
5.	Maintenance	„	„
6.	Basic trouble shooting	„	„

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.	MANAS KUMAR SAHOO	Biochemistry		29/09/2023
2.	PRIYABRATA SAHOO	Biochemistry		29/09/2023
3.	JITENDRA MANTRY	Biochemistry		29/09/2023
4.	CHITTA RANJAN BARAL	Biochemistry		29/09/2023

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 : Mr. SUMAN OJHA

Designation : Application Support Signature:

Company : Ortho Clinical Diagnostics Date:

Customer Authorizations:

Name :

Designation : Signature :

Organization : Date :

Ortho Clinical Diagnostics

PERFORMANCE QUALIFICATION

For

VITROS 350

Manufactured by:
Ortho Clinical Diagnostics, Inc., US

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I. Approval of the PQ procedure

Both **Lupin Diagnostics** and **Ortho Clinical Diagnostics** are jointly responsible for conducting the Performance Check of the Biochemistry Analyzer, Model – VITROS 250, **Serial. No. 27001181** in the Biochemistry Department of c/o: **Lupin Diagnostics** as per the attached protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name	:	Mr. SUMAN OJHA	Signature:
Designation	:	Application	Date:
Company	:	Ortho clinical Diagnostics	

Validation Team from Lupin Diag**.:**

Name	:	Signature:
Designation	:	Date:
Department	:	

Name	:	Signature:
Designation	:	Date:
Department	:	

Customer Authorizations:

Name	:	
Designation	:	Signature:
Site	:	Date:

II. Instructions.

1. An authorized Ortho Clinical Diagnostics representative will check for the performance of the instrument and enter the specific data as outlined in the Performance Qualification. 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, Bhubaneswar.** 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** and **Ortho-Clinical Diagnostics.**

III. Scope

This Performance Qualification protocol will be performed on the VITROS 350 **Serial No. 27001181** located in Biochemistry Department of **Lupin Diagnostics** located in **Bhubaneswar**. 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 — 29/09/2023
2. Serial Number: 27001181

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	SUMAN OJHA 29/09/2023
02	Accuracy Study	To compare the obtained value with true values of processed control.	”
03	Precision Study	To check the precision performance of the equipment	”

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);
Phenytoin (Microslide – Immunorate Chemistry)

Sr. No.	**Activity**	**Procedure done as per the protocol defined in VITROS 350 Chemistry System Operator's manual – Quality Control**	**Remarks** **Pass/Fail**	**Done By** **Date**
01	Preparing Liquid or Lyophilized control fluids	"Instructions for use" of QC material	Pass	29/09/2023
02	Creating QC file	Quality Control – Define control fluids	Pass	„
03	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	Pass	„

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	29/09/2023
02	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	Pass	„
03	Accuracy Analysis	Compare the obtained Q.C value with mean of expected value as mentioned in the Performance verifier / QC Value chart.	Pass	„

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 all Parameters (1 x 5 times).

Calculate the Mean, SD and CV%.

Acceptance Criteria:

Sr. No.	Analyte	Control Level	Precision Limit
01	ALT	PV I	≤ 2.3 SD
02	Amylase	PV I	≤ 3.9 SD
03	Sodium	PV I	≤ 0.8% CV
04	Potassium	PV I	≤ 1.0% CV
05	CRBM	TDM	≤ 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 : SUMAN OJHA
Designation : Application Support Signature:
Company : Ortho Clinical Diagnostics Date:

Validation Team from Lupin Diag**.:**

Name : Signature:
Designation : Date:
Department :

Name : Signature:
Designation : Date:
Department :

Customer Authorizations:

Name :
Designation : Signature:
Site : Date:

SAMPLING Aug 26 24
LAB COMP: ON OFF 11:21:06
READY TESTING COMPLETE V9.7 CWELL
DIAGNOSTICS - Setup/Adjustments - Current Setup Values SA25A

TRUCK:	Sample	60	SLIDE TRANSPORT:	Disp to Metering	71
	Tip Pick Up	28		Inc/Disp Path	27
	Mixing Cup Left	30		Inc RT/CM Depth	40
	Mixing Cup Right	29		Inc PM Depth	37
	Diluent Tray	28		PM Eject Depth	19
	RT/CM Slide	70		Inc Steps/Rev	14363
	PM Slide	29	SAMPLE TRANSPORT:	Tray Fin Reference	312
				Carriage Meter Pos	-51
				Mixing Cup Trans	20
PROBOSCIS:	Mixing Cup Bottom	285		Diluent Tray Trans	0
	Sample Cup Bottom	190		Tray Hook	-90
	Prob. Compression	147		Psid Scan	0
	Tip Height	814	REFERENCE SLIDE CENTER:		175
			READ SYNC:		4.5ms

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

340	400	460	540	600	630	670	680
3.18	3.29	4.10	5.69	6.49	7.04	7.04	5.91

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

RETURN START RETURN TO MAIN DIAG MENU HELP

SAMPLING Aug 26 24
LAB COMP: ON OFF 11:24:55
SH SM SS1 SS2 ST INC IR R/C FM INOP TESTING COMPLETE V9.7 CWELL
ENVIRONMENTAL MONITORING ME15A

	Temperature 1	Temperature 2	Relative Humidity
Incubator	37.06	36.96	
Slide Supply 1	22.14		33.16
Slide Supply 2	22.16		17.18
Reflectometer	75.00		
Ambient	26.27		

POWER SUPPLY	5V	12V	-12V	15V	-15V	24VM	24VF
Slide Supply/Cart.Load	5.04	11.96	-12.23	14.70	-14.85	24.79	24.24
Incubator/Immuno-Rate	5.04	11.96	-12.18	14.80	-14.95	24.05	24.05
Ref.Mtrng/Slide Transport	5.00	11.96	-12.23	14.70	-14.80	24.24	24.24
Sample Handler	5.00					24.42	24.24
Sample Metering	4.92					24.24	24.05
Electrometer	4.96			14.76			24.14
Reflectometer	5.17						

> Station and voltage readings are updated on a twenty-second interval.
NOTE: Flashing * indicates station or voltage readings not within spec.

RETURN HELP

SAMPLING Aug 26 24
LAB COMP: ON OFF 11:33:41
SH SM INOP TESTING COMPLETE V9.7 CWELL
SAMPLE METERING PERFORMANCE TESTS PTO1I
Leak Test - Voltage Differential

Aspirate = 0.156 Vdc Dispense = 0.039 Vdc

Ambient Pressure = 2.383 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

SAMPLING ON OFF Aug 26 24
11:37:27
V9.7 CWELL
PT01C

SH SM IHOP

LAB COMP:
TESTING COMPLETE

SAMPLE METERING PERFORMANCE TESTS
Hysteresis Test

	MEAN	MAX	MIN
Hysteresis :	0.545	1.904	0.000
Pressure P0:	2.402	2.422	2.402
Pressure P1:	3.049	4.199	3.633
Pressure P2:	2.402	2.422	2.402

> 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 INOP

LAB COMP:
TESTING COMPLETE

SAMPLING
ON OFF

Aug 26 24
11:27:48
V9.7 CWELL
PTO4/

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

Reference	Resolution
4.961 Vdc	0.039 Vdc

Ambient Pressure = 2.383

> 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

SAMPLING Aug 26 24
ON OFF 11:40:11
LAB COMP: V9.7 CWELL
SH SM FM INOP TESTING COMPLETE PT22E
DIAGNOSTICS - Performance Test
Reference Metering - System Check

Signal Processing Check

COARSE GAIN

2.520 Vdc

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

RETURN RETURN TO MAIN DIAG MENU HELP

REFERENCE METERING * REFERENCE ARM * PROBE POSITION ERROR

LAB COMP: ON OFF 11:45:55

SH SM FM INOP

TESTING COMPLETE V9.7 CWELL

PT22D

DIAGNOSTICS - Performance Test

Leak Test - Voltage Differential

Aspirate = 0.059 Vdc Dispense = 0.020 Vdc

Ambient Pressure = 2.400 Vdc

>Compare the values to current specifications.

> Do you wish to continue to Hysteresis Test? (Y):

RETURN DISPLAY PREVIOUS SCREEN DISPLAY NEXT SCREEN HELP

SAMPLING Aug 26 24
LAB COMP: ON OFF 11:42:37
SH SH FN INOP TESTING COMPLETE V9.7 CWELI
DIAGNOSTICS - Performance Test PT22L
Reference Metering - System Check
Hysteresis Check

	MEAN	MAX	MIN
Hysteresis:	0.134	1.387	0.000
Pressure P0:	2.520	2.539	2.520
P1:	4.590	4.727	4.512
P2:	2.559	2.598	2.539

>Compare the values to current specifications.

RETURN | DISPLAY DATA | RETURN TO MAIN DIAG MENU | HELP