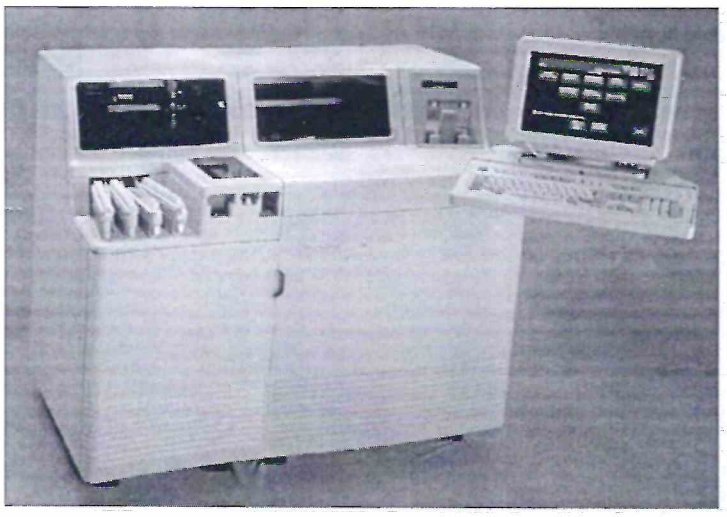
Ortho Clinical Diagnostics

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 Bhalsing / → 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
1.	**Environmental conditions:**		
	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 15^0C to 27^0C and the temperature fluctuation during analysis shall not be more than ± 2^0C.	**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

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

START UP KIT	**1H4182**		
	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.

250 ANALYZER SPARE PART KIT	**356704**		
	355637	Air Filter	1 no.
	TL 3225	Serial Loop Back Connector TL 3225	1 no.
	999339	10 ml Diluent Vials (3 Nos)	1 no.
	999340	5 ml Diluent Vials (3 Nos)	1 no.
	1C3197	Dispense blade	1 no.
	3380/3381	Wrist strap Elastic	1 no.
	J02315	White Reference Slide Box	1 no.
	J02316	Black Reference Slide Box	1 no.
	356666	Lamp	1 no.
	583561	Lamp Extractor	1 no.
	995298	RM / IR TL 4538	1 no.
	356864	Reservoir Seal (3 Nos)	1 no.

356497	Reservoir Cap (3 Nos)	1 no.
J02253 / J02255	Evaporation Cap (23 Nos)	1 no.
1H0116	Evaporation Cap Spring (5 Nos)	1 no.
339739	Proboscis Screw (2 Nos)	1 no.
994654	Tubing (2 Nos)	1 no.
356526	Read Sync Tool TL 4502	1 no.
	Monitor with stand	1 no.
	Touch Screen	1 no.

C. List of Manuals, Certificates and Drawings:

Ortho Clinical Diagnostics provides the following with the instrument.

8986507	250 REFERENCE SET consist of:	1 set
	119017 - Operators Manual	1 no.
	1053032 - Operators Quick Guide	1 no.
	8044505 - 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	➢ 2 ports for printer ➢ One port for LIS
Regional settings	➢ Language English.

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

Name : SARAS RAJENDRA WADHONKAR Signature:

Designation : SERVICE ENGINEER, ORTHO CARE- SERVICE

Company: Ortho Clinical Diagnostics Date: 30/07/2022

Customer Authorizations:

Name : Dr. Sagar Kulat

Designation : Lab Head

Organization : Lupin Diagnostics, Ahmednagar

Signature : @kulat

Date : 30/07/2022

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

Ortho Clinical Diagnostics

OPERATION QUALIFICATION

For

VITROS 350

Manufactured by:
Ortho Clinical Diagnostics, Inc., US

Table of Contents

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

Customer Authorizations:

Name : Dr. Sagar Kulal

Designation : Chief of Laboratory

Site : Ahmednagar

Signature :

Date: 1/8/2022

LUPIN DIAGNOSTIC
Behind Zopadi Cantin,
Opp. Monica D.Ed. College
Savedi, 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:

Test No.	Test Name	Test purpose	Verified By and date
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

PARAMETER	PASS	FAIL
Parameter values for verification: "READY" on Status console	**PASS**	

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 the same from the analyzer	**PASS**	

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 ± 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 without any error	**PASS**	

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.

Sr. No.	Training program	Initials	Date
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 Mulve	CC	SAM	1/8/22
3	Amol Sutale	CC	ACS	1/8/22
4	Jukir Shaikh	CC	JRS	1/8/22
5	Meghana Kalapurekh	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 Signature:

Company: Ortho Clinical Diagnostics Date: 1/8/2022

Customer Authorizations:

Name : Dr. Sagar Kulat

Designation : chief of Lab Signature :

Organization : Lupin Diagnostics Date : 1/8/2022

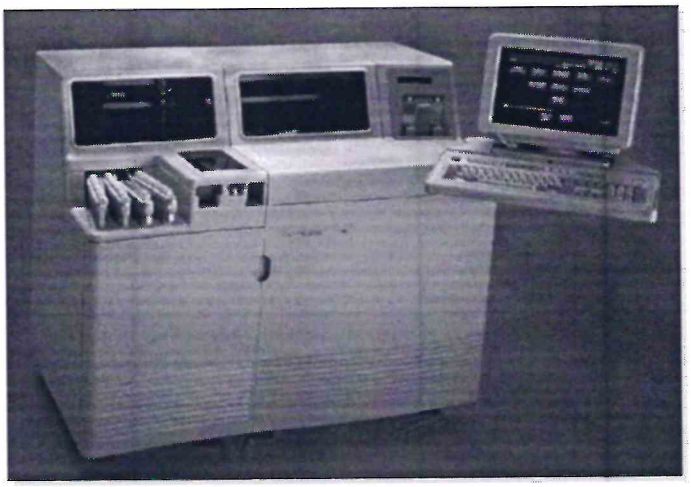
LUPIN DIAGNOSTIC
Behind Zopadi Cantin,
Opp. Monica D.Ed. College
Savedi, Ahmednagar 414001

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, 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: Paitwar

Designation : Application Support Date: 1/8/2022

Company : Ortho Clinical Diagnostics

Validation Team from Lupin Diagnostics, Ahmednagar :

Name : Bhushan Mahale Signature:

Designation : Lab Tech Date: 01/8/22

Department :

Name : Sagar Malve Signature :

Designation : Lab Tech Date : 1/8/22

Department : CC

Customer Authorizations:

Name : Dr. Sagar Kulat

Designation : Chief of Laboratory Signature :

Site : Ahmednagar Date : 01/08/2022

LUPIN DIAGNOSTIC
Behind Zopadi Cantin,
Opp. Monica D.Ed. College
Savedi, 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

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 Chemsitry;

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 Pass/Fail	Done By 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

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 Pass/Fail	Done By 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

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+ (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	≤ 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 : 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 Signature:
Designation : Chief of Lab Date: 1/8/22
Department : CC

Name : Bhalsing mahesh Signature :
Designation : Lab Tec. Date : 1/8/22
Department : CC.

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
Savedi, 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

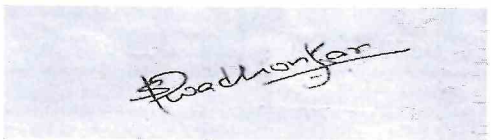
The below mentioned instrument has been calibrated and tests performed to check the system performance.

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.

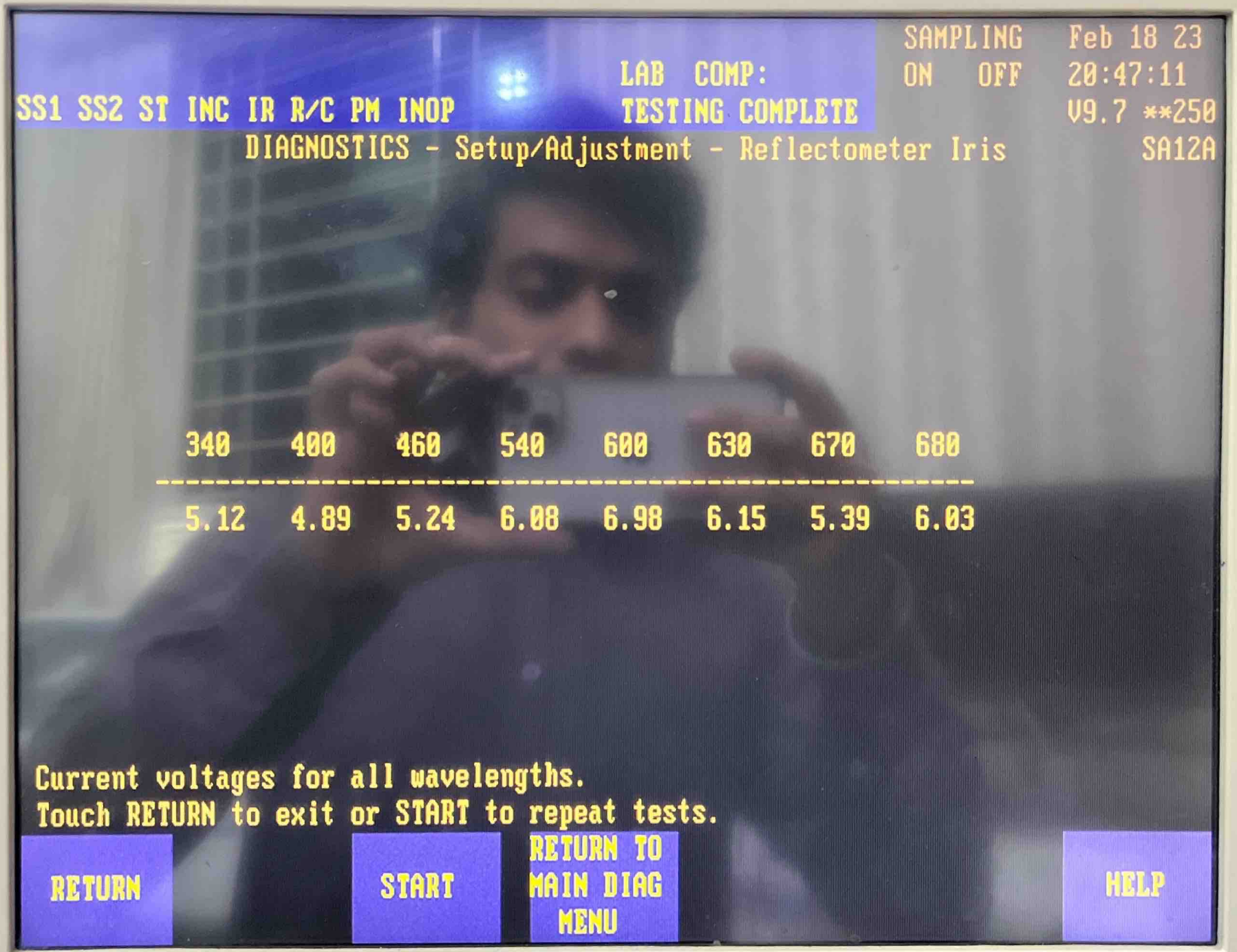
Next Calibration will be performed in **AUGEST 2023**

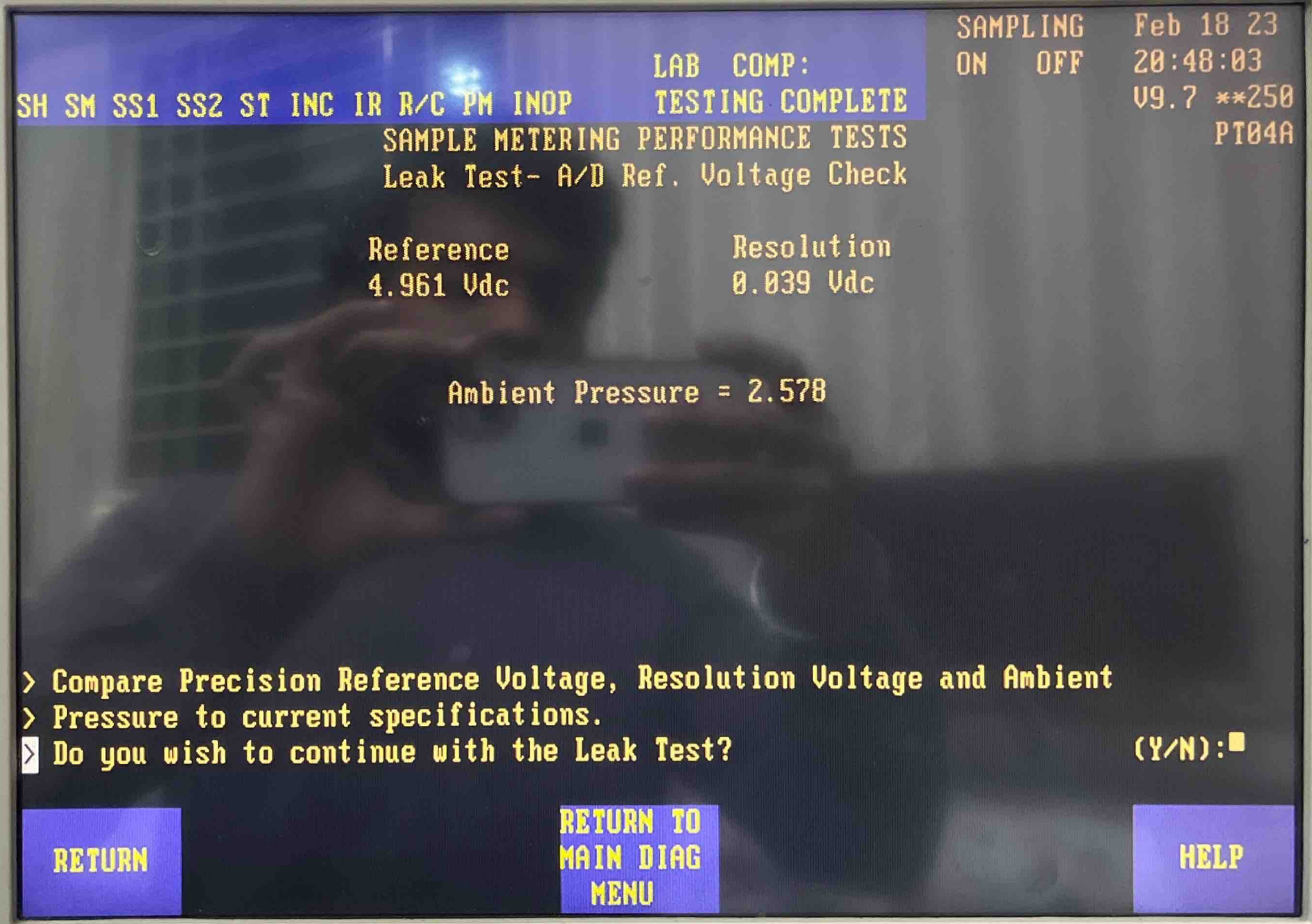
For **Ortho Clinical Diagnostics India Pvt Ltd.**

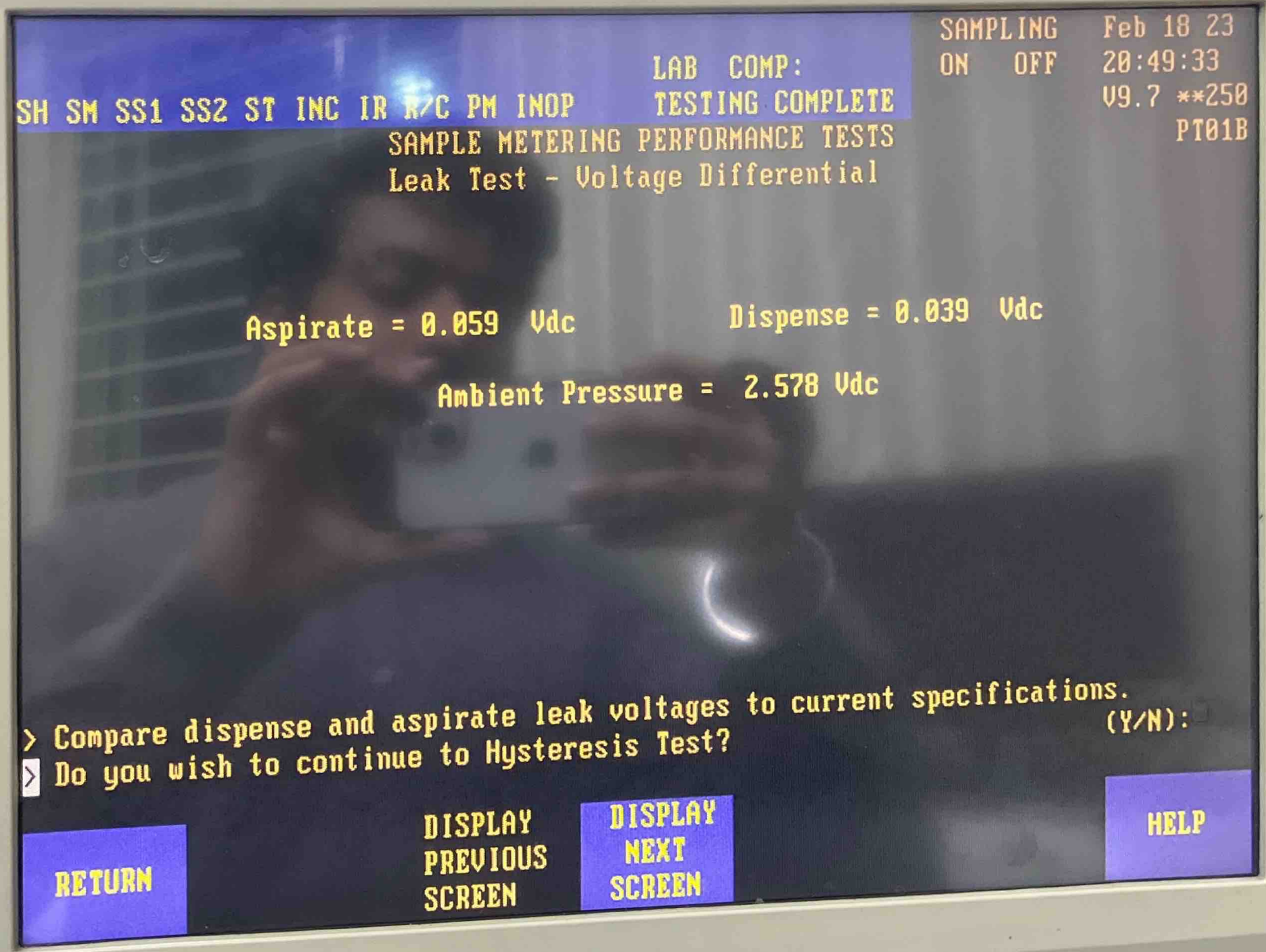


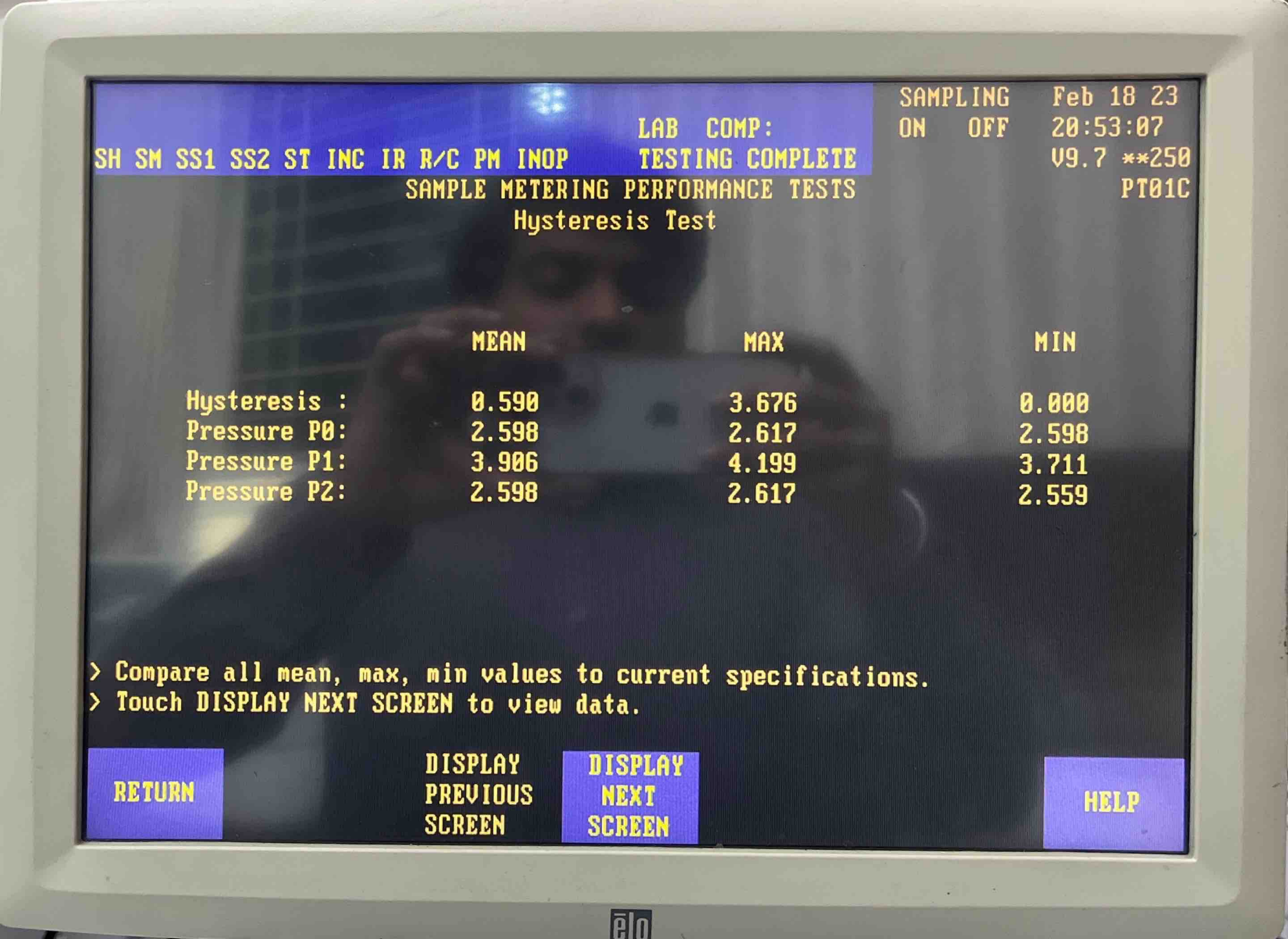
Saras Wadhonkar
Service Engineer,Ortho Care Service
Pune

Date: 18/02/2023


SAMPLING
Feb 18 23
LAB COMP:
ON OFF
20:47:11
SS1 SS2 ST INC IR R/C PM INOP
TESTING COMPLETE
V9.7 **250
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


SAMPLING
ON OFF
Feb 18 23
20:48:03
V9.7 **250
PT04A
LAB COMP:
SH SM SS1 SS2 ST INC IR R/C PM INOP TESTING COMPLETE
SAMPLE METERING PERFORMANCE TESTS
Leak Test- A/D Ref. Voltage Check
Reference
4.961 Vdc
Resolution
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


SAMPLING
ON OFF
Feb 18 23
20:49:33
V9.7 **250
PT01B
LAB COMP:
TESTING COMPLETE
SH SM SS1 SS2 ST INC IR R/C PM INOP
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.
(Y/N):
> Do you wish to continue to Hysteresis Test?
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
20:53:07
V9.7 **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 SS1 SS2 ST INC IR R/C PM INOP

LAB COMP:
TESTING COMPLETE

SAMPLING
ON OFF

Feb 18 23
20:53:15
V9.7 **250
PT01H

SAMPLE METERING PERFORMANCE TESTS

Hysteresis Test

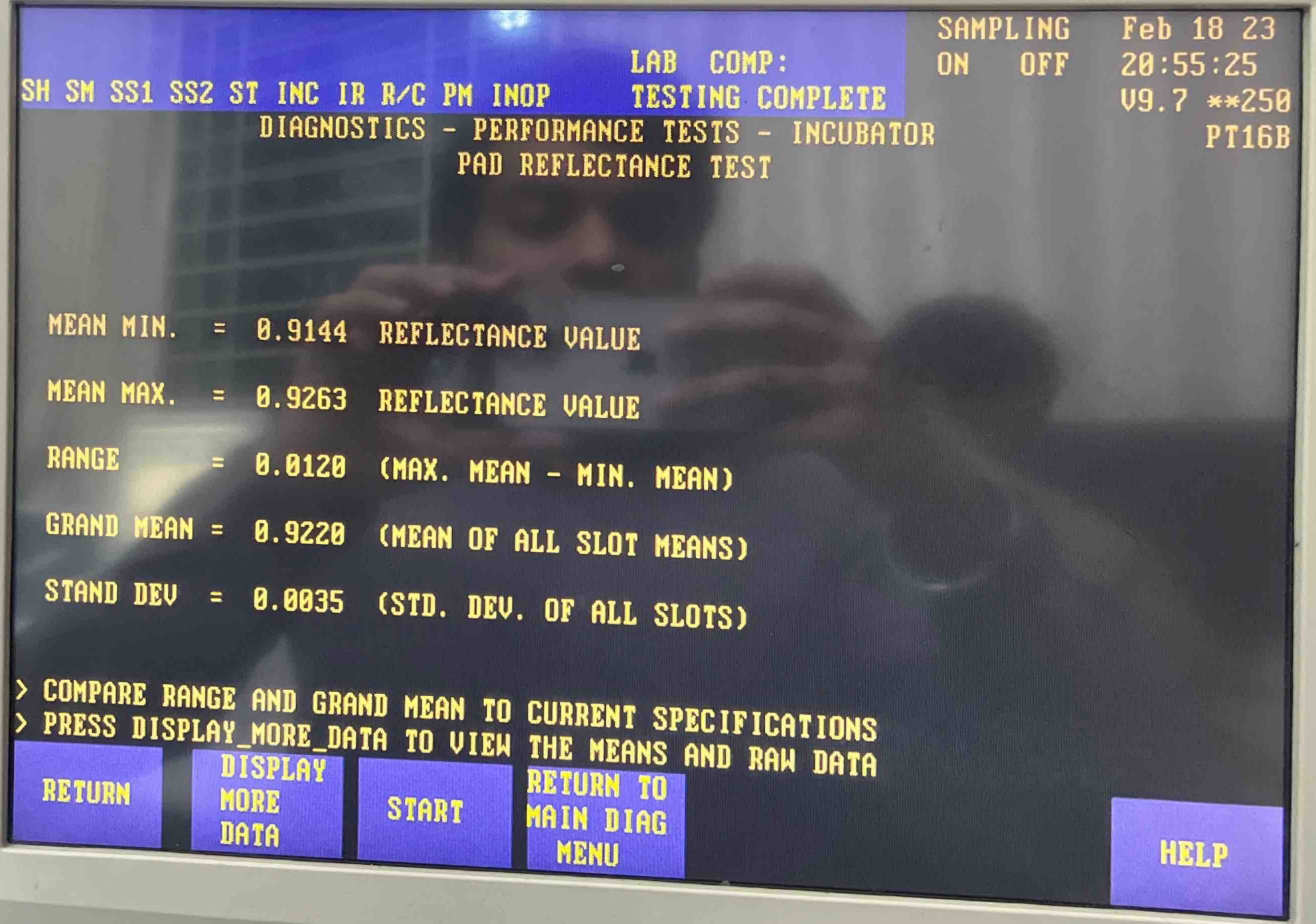
Revolution	Hysteresis	P0	P1	P2
1	0.000	2.598	3.730	2.598
2	0.000	2.598	3.711	2.598
3	0.000	2.598	3.711	2.598
4	0.000	2.598	3.711	2.598
5	0.000	2.598	3.730	2.598
6	0.000	2.598	3.730	2.598
7	0.000	2.598	3.750	2.598
8	0.000	2.598	3.750	2.598
9	0.000	2.598	3.750	2.598
10	0.000	2.598	3.770	2.598

RETURN

DISPLAY PREVIOUS SCREEN

DISPLAY NEXT SCREEN

HELP


SAMPLING
Feb 18 23
ON OFF
20:55:25
V9.7 **250
PT16B
LAB COMP:
SH SM SS1 SS2 ST INC IR R/C PM INOP
TESTING COMPLETE
DIAGNOSTICS - PERFORMANCE TESTS - INCUBATOR
PAD REFLECTANCE TEST
MEAN MIN. = 0.9144 REFLECTANCE VALUE
MEAN MAX. = 0.9263 REFLECTANCE VALUE
RANGE = 0.0120 (MAX. MEAN - MIN. MEAN)
GRAND MEAN = 0.9220 (MEAN OF ALL SLOT MEANS)
STAND DEV = 0.0035 (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 MORE DATA
START
RETURN TO MAIN DIAG MENU
HELP

SAMPLING Feb 18 23
ON OFF 20:55:33
V9.7 **250
PT16C

LAB COMP:
SH SM SS1 SS2 ST INC IR R/C PM INOP TESTING COMPLETE

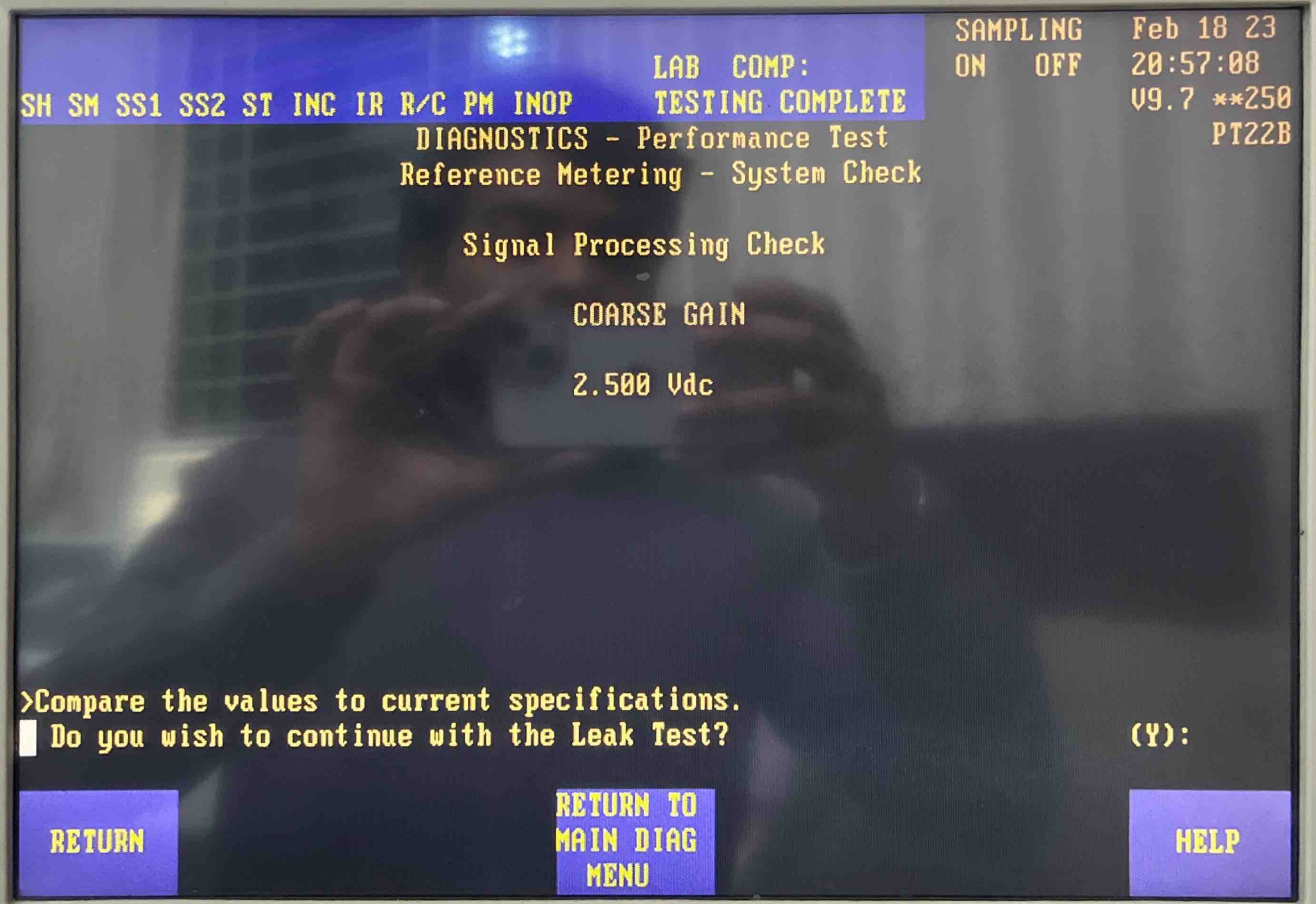
DIAGNOSTICS - PERFORMANCE TESTS - INCUBATOR

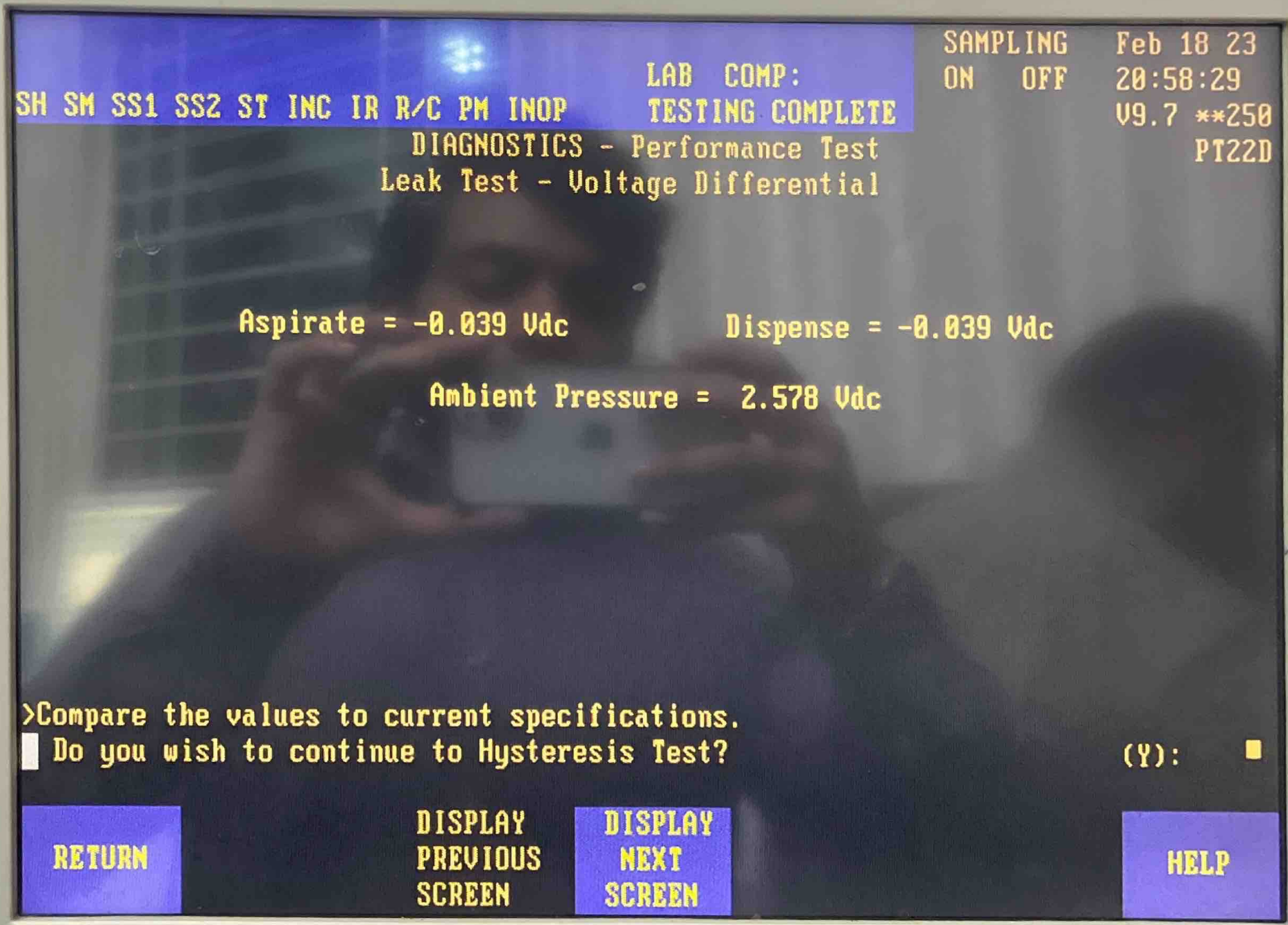
PAD REFLECTANCE TEST

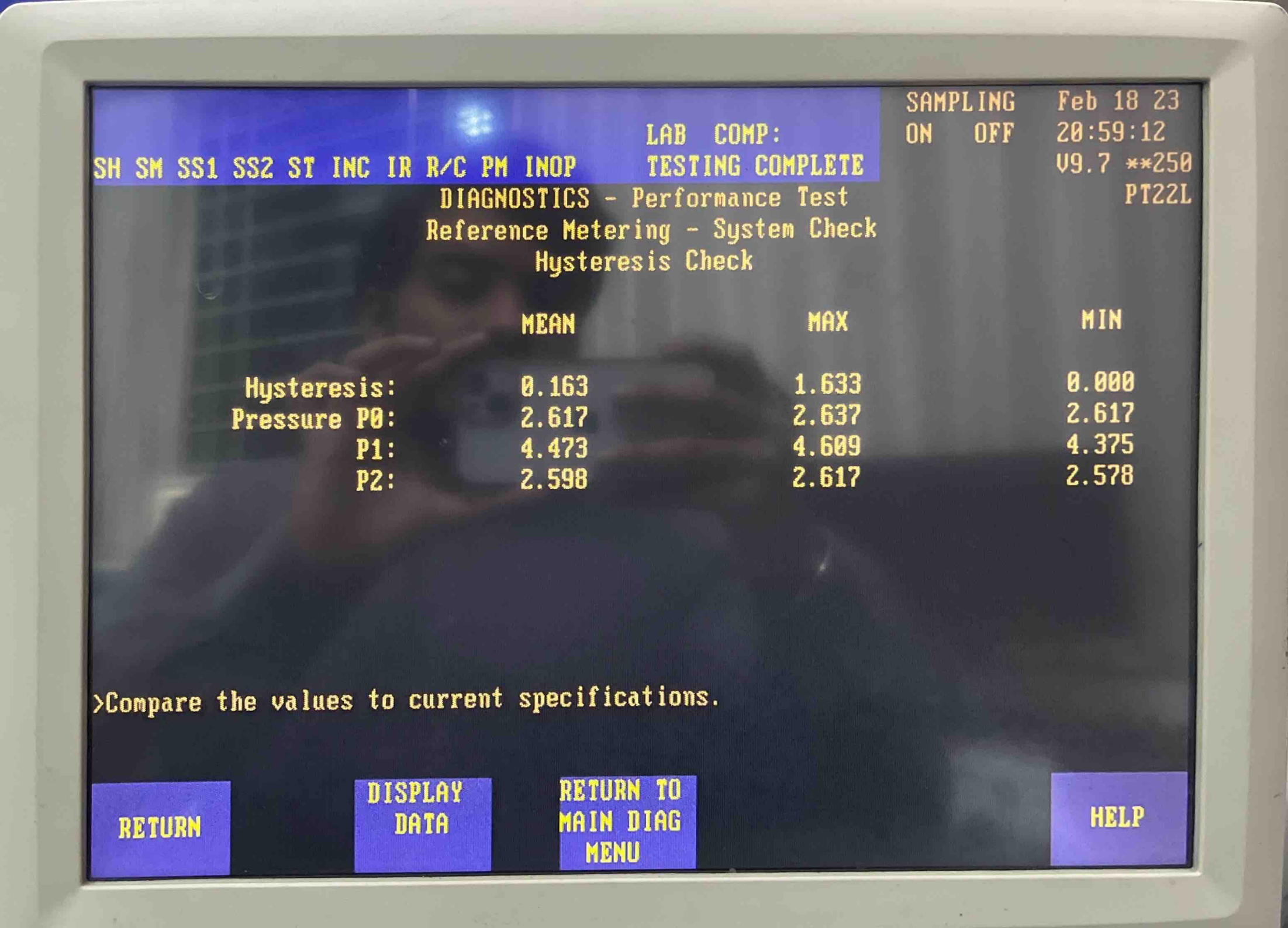
SLOT	REFL1	REFL2	REFL3	MEAN
1	0.92282	0.92270	0.92268	0.92273
2	0.92299	0.92289	0.92287	0.92292
3	0.92223	0.92202	0.92197	0.92207
4	0.92367	0.92367	0.92358	0.92364
5	0.92504	0.92502	0.92485	0.92497
6	0.91579	0.91572	0.91560	0.91570
7	0.91940	0.91928	0.91914	0.91927
8	0.92516	0.92499	0.92490	0.92502
9	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

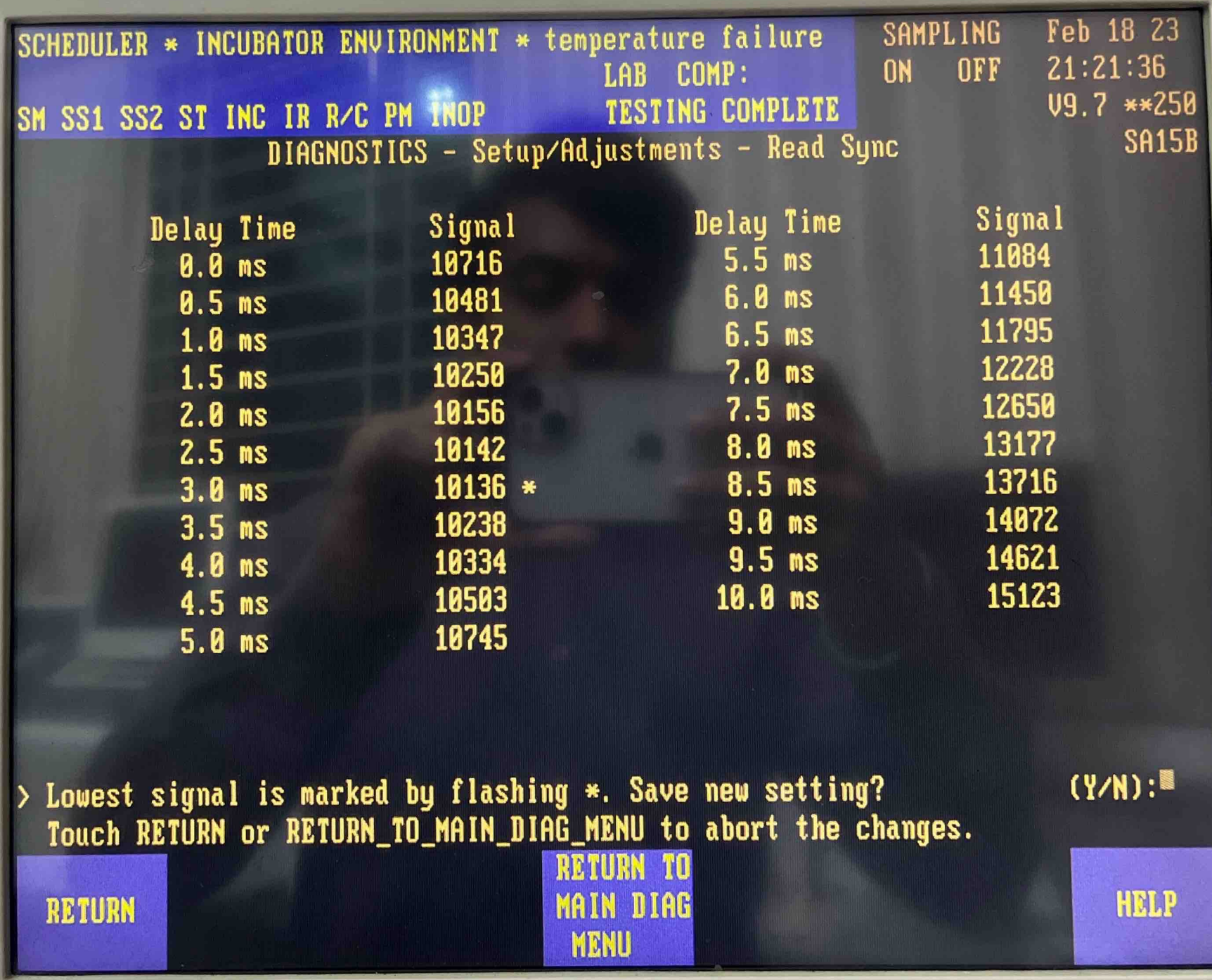
> PRESS RETURN TO VIEW THE PREVIOUS PAGE OF DATA
> PRESS DISPLAY_MORE_DATA TO VIEW THE MEANS AND RAW DATA

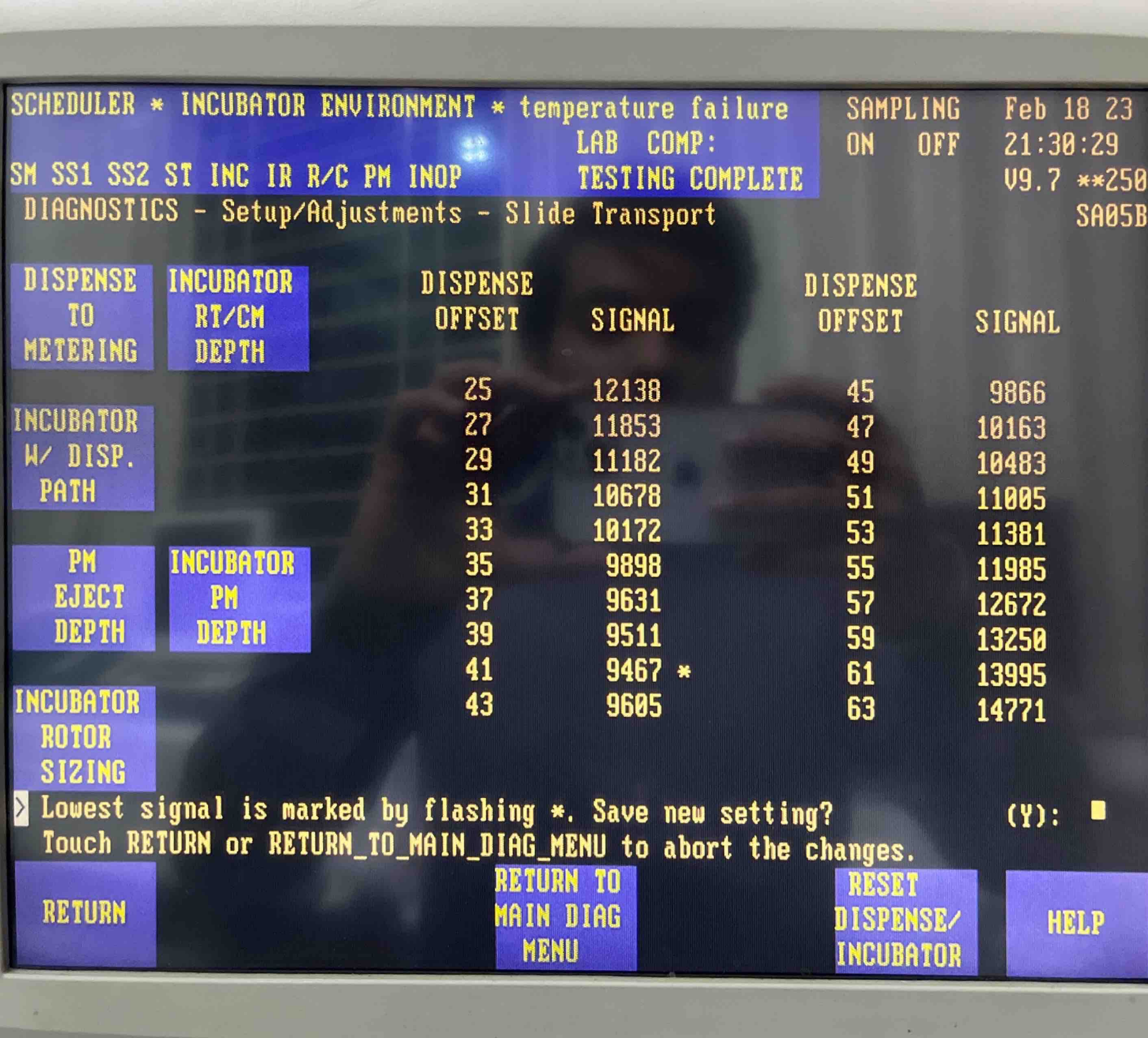
RETURN | DISPLAY MORE DATA | RETURN TO MAIN DIAG MENU | HELP


SAMPLING
ON OFF
Feb 18 23
20:57:08
V9.7 **250
PT22B
LAB COMP:
TESTING COMPLETE
SH SM SS1 SS2 ST INC IR R/C PM INOP
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

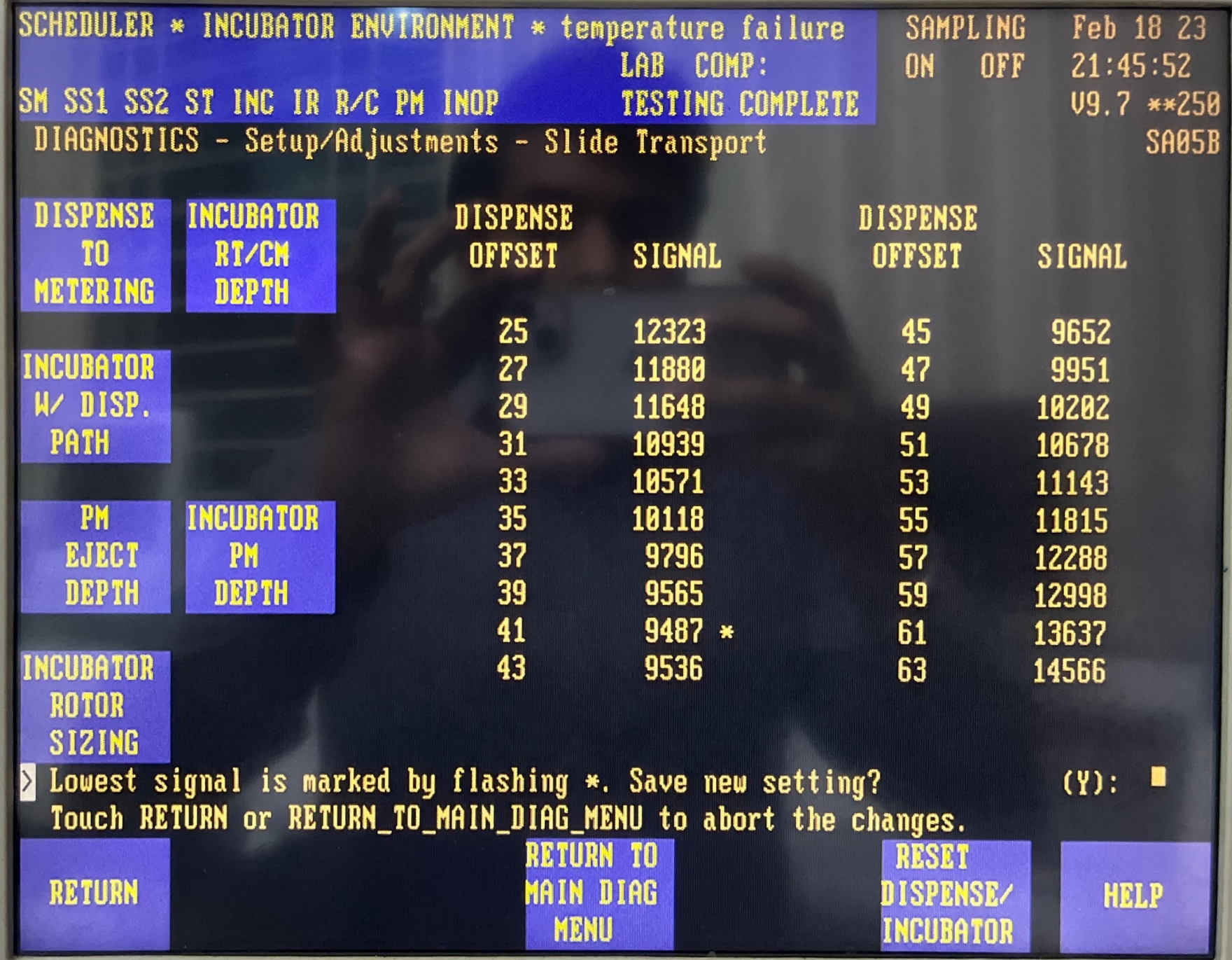

SH SM SS1 SS2 ST INC IR R/C PM INOP
LAB COMP:
TESTING COMPLETE
SAMPLING
ON OFF
Feb 18 23
20:58:29
V9.7 **250
PT22D
DIAGNOSTICS - Performance Test
Leak Test - Voltage Differential
Aspirate = -0.039 Vdc
Dispense = -0.039 Vdc
Ambient Pressure = 2.578 Vdc
>Compare the values to current specifications.
Do you wish to continue to Hysteresis Test?
(Y):
RETURN
DISPLAY PREVIOUS SCREEN
DISPLAY NEXT SCREEN
HELP

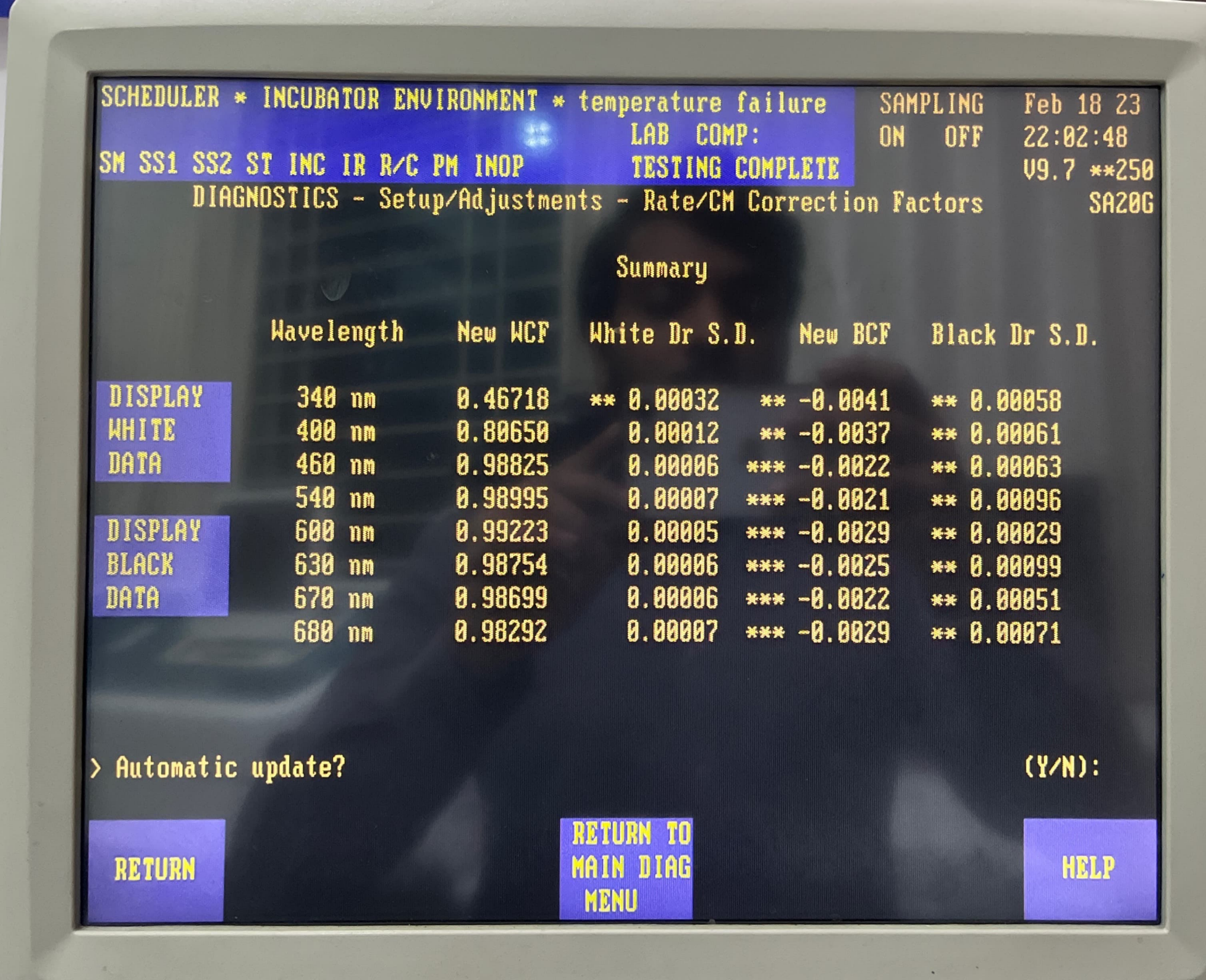

SH SM SS1 SS2 ST INC IR R/C PM INOP
LAB COMP:
TESTING COMPLETE
SAMPLING
ON OFF
Feb 18 23
20:59:12
V9.7 **250
PT22L
DIAGNOSTICS - Performance Test
Reference Metering - System Check
Hysteresis Check
MEAN
MAX
MIN
Hysteresis: 0.163 1.633 0.000
Pressure P0: 2.617 2.637 2.617
P1: 4.473 4.609 4.375
P2: 2.598 2.617 2.578
>Compare the values to current specifications.
RETURN
DISPLAY DATA
RETURN TO MAIN DIAG MENU
HELP


SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure
LAB COMP:
TESTING COMPLETE
SM SS1 SS2 ST INC IR R/C PM INOP
SAMPLING
ON OFF
Feb 18 23
21:21:36
V9.7 **250
SA15B
DIAGNOSTICS - Setup/Adjustments - Read Sync
Delay Time Signal
0.0 ms 10716
0.5 ms 10481
1.0 ms 10347
1.5 ms 10250
2.0 ms 10156
2.5 ms 10142
3.0 ms 10136 *
3.5 ms 10238
4.0 ms 10334
4.5 ms 10503
5.0 ms 10745
Delay Time Signal
5.5 ms 11084
6.0 ms 11450
6.5 ms 11795
7.0 ms 12228
7.5 ms 12650
8.0 ms 13177
8.5 ms 13716
9.0 ms 14072
9.5 ms 14621
10.0 ms 15123
> Lowest signal is marked by flashing *. Save new setting? (Y/N):
Touch RETURN or RETURN_TO_MAIN_DIAG_MENU to abort the changes.
RETURN
RETURN TO MAIN DIAG MENU
HELP


SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure
SAMPLING
Feb 18 23
LAB COMP:
ON OFF
21:30:29
SM SS1 SS2 ST INC IR R/C PM INOP
TESTING COMPLETE
V9.7 **250
DIAGNOSTICS - Setup/Adjustments - Slide Transport
SA05B
DISPENSE TO METERING
INCUBATOR RT/CM DEPTH
INCUBATOR W/ DISP. PATH
PM EJECT DEPTH
INCUBATOR PM DEPTH
INCUBATOR ROTOR SIZING
DISPENSE OFFSET
SIGNAL
DISPENSE OFFSET
SIGNAL
25 12138
27 11853
29 11182
31 10678
33 10172
35 9898
37 9631
39 9511
41 9467 *
43 9605
45 9866
47 10163
49 10483
51 11005
53 11381
55 11985
57 12672
59 13250
61 13995
63 14771
Lowest signal is marked by flashing *. Save new setting? (Y):
Touch RETURN or RETURN_TO_MAIN_DIAG_MENU to abort the changes.
RETURN
RETURN TO MAIN DIAG MENU
RESET DISPENSE/ INCUBATOR
HELP


SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure
SAMPLING
Feb 18 23
LAB COMP:
ON OFF
21:37:34
SM SS1 SS2 ST INC IR R/C PM INOP
TESTING COMPLETE
V9.7 **250
DIAGNOSTICS - Setup/Adjustments - Read Sync
SA15B
Delay Time
Signal
Delay Time
Signal
0.0 ms
10134
5.5 ms
10368
0.5 ms
9890
6.0 ms
10775
1.0 ms
9729
6.5 ms
11214
1.5 ms
9591
7.0 ms
11634
2.0 ms
9499
7.5 ms
12120
2.5 ms
9480
8.0 ms
12639
3.0 ms
9479 *
8.5 ms
13098
3.5 ms
9571
9.0 ms
13601
4.0 ms
9679
9.5 ms
14158
4.5 ms
9857
10.0 ms
14743
5.0 ms
10109
> Lowest signal is marked by flashing *. Save new setting?
(Y/N):
Touch RETURN or RETURN_TO_MAIN_DIAG_MENU to abort the changes.
RETURN
RETURN TO MAIN DIAG MENU
HELP


SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure
SAMPLING
Feb 18 23
LAB COMP:
ON OFF
21:45:52
SM SS1 SS2 ST INC IR R/C PM INOP
TESTING COMPLETE
V9.7 **250
DIAGNOSTICS - Setup/Adjustments - Slide Transport
SA05B
DISPENSE TO METERING
INCUBATOR RT/CM DEPTH
INCUBATOR W/ DISP. PATH
PM EJECT DEPTH
INCUBATOR PM DEPTH
INCUBATOR ROTOR SIZING
DISPENSE OFFSET
SIGNAL
DISPENSE OFFSET
SIGNAL
25 12323
27 11880
29 11648
31 10939
33 10571
35 10118
37 9796
39 9565
41 9487 *
43 9536
45 9652
47 9951
49 10202
51 10678
53 11143
55 11815
57 12288
59 12998
61 13637
63 14566
Lowest signal is marked by flashing *. Save new setting? (Y):
Touch RETURN or RETURN_TO_MAIN_DIAG_MENU to abort the changes.
RETURN
RETURN TO MAIN DIAG MENU
RESET DISPENSE/ INCUBATOR
HELP


SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure
SAMPLING
Feb 18 23
LAB COMP:
ON OFF
22:02:48
SM SS1 SS2 ST INC IR R/C PM INOP
TESTING COMPLETE
V9.7 **250
DIAGNOSTICS - Setup/Adjustments - Rate/CM Correction Factors
SA20G
Summary
Wavelength
New WCF
White Dr S.D.
New BCF
Black Dr S.D.
DISPLAY WHITE DATA
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
DISPLAY BLACK DATA
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
SM SS1 SS2 ST INC IR R/C PM INOP

LAB COMP:
TESTING COMPLETE

SAMPLING
ON OFF

Feb 18 23
22:02:57
V9.7 **250
SA21A

DIAGNOSTICS - Setup/Adjustments - Rate/CM Correction Factors

White Correction Factors

DISPLAY WHITE DATA

DISPLAY BLACK DATA

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

> Touch DISPLAY BLACK DATA to display more data.

RETURN

RETURN TO MAIN DIAG MENU

HELP

SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure
SM SS1 SS2 ST INC IR R/C PM INOP

LAB COMP:
TESTING COMPLETE

SAMPLING
ON OFF

Feb 18 23
22:03:03
V9.7 **250

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

Black Correction Factors

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

DISPLAY WHITE DATA

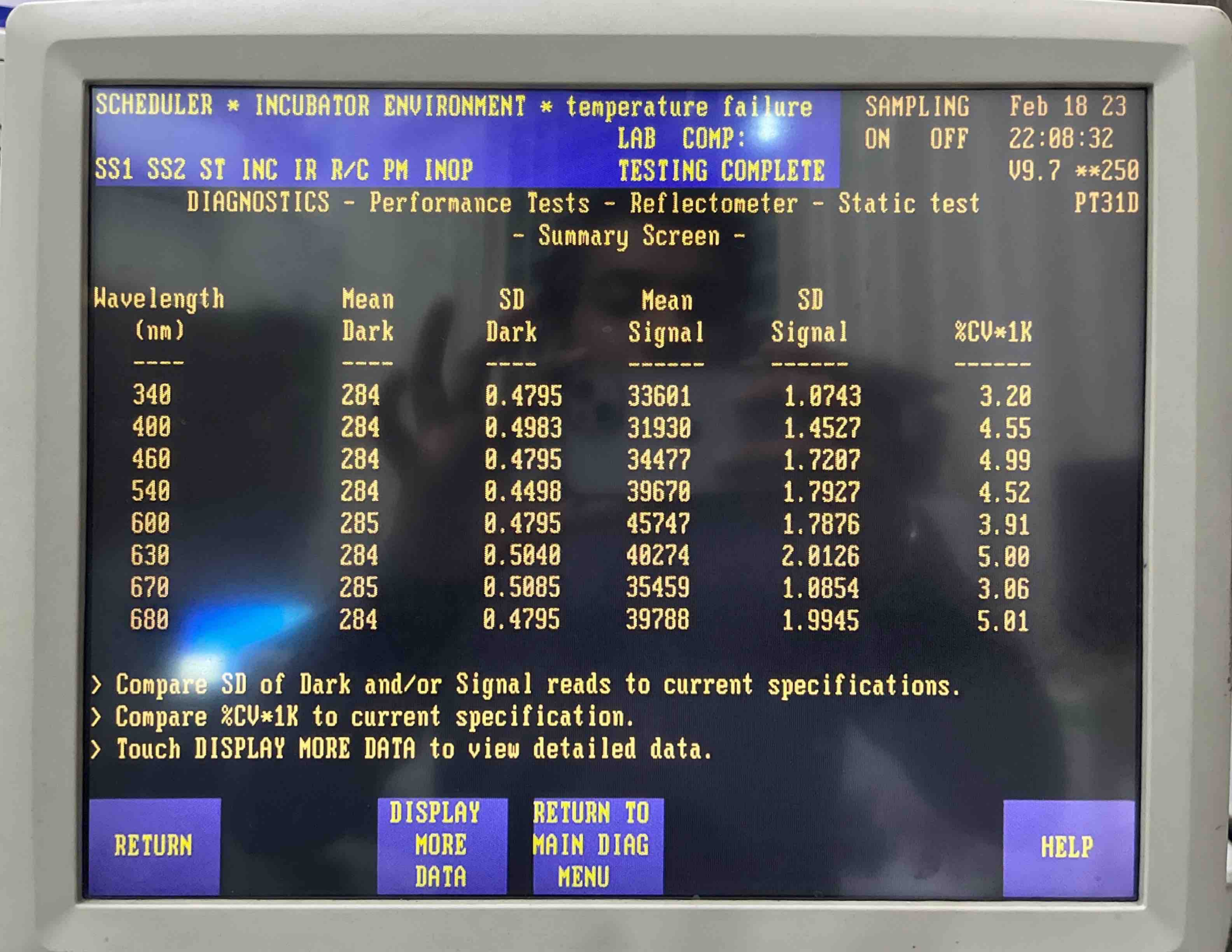
DISPLAY BLACK DATA

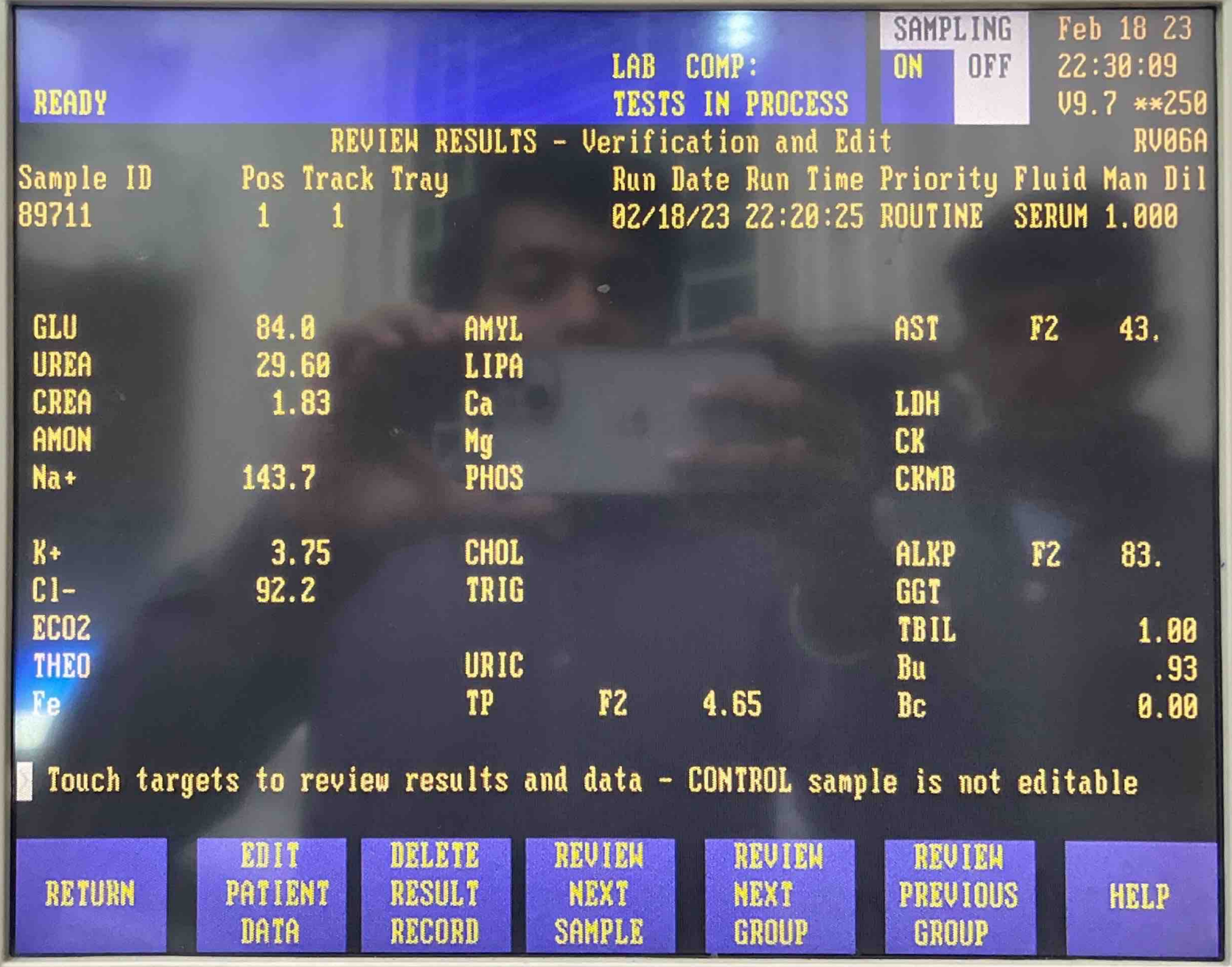
> Touch DISPLAY WHITE DATA to display more data.

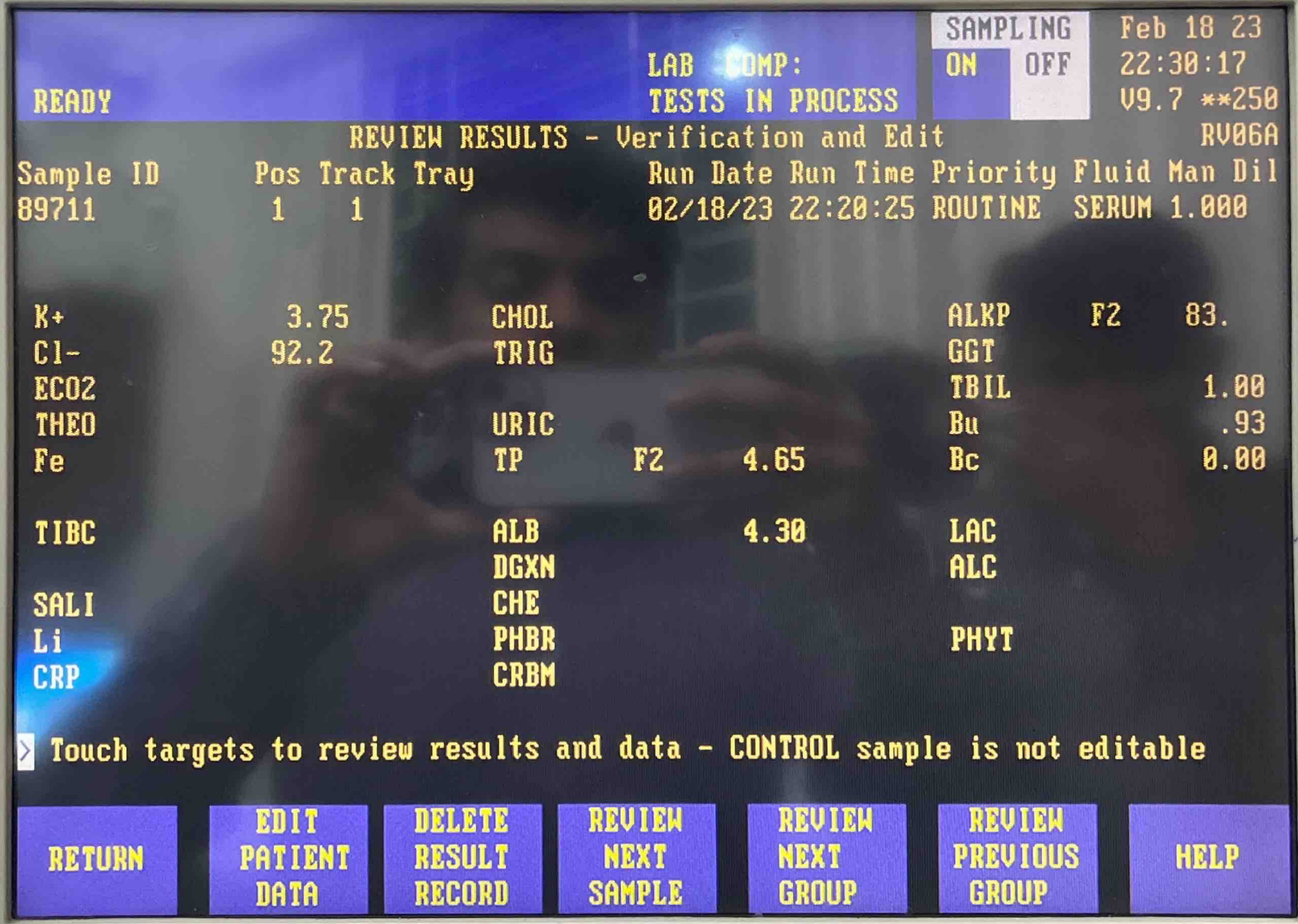
RETURN

RETURN TO MAIN DIAG MENU

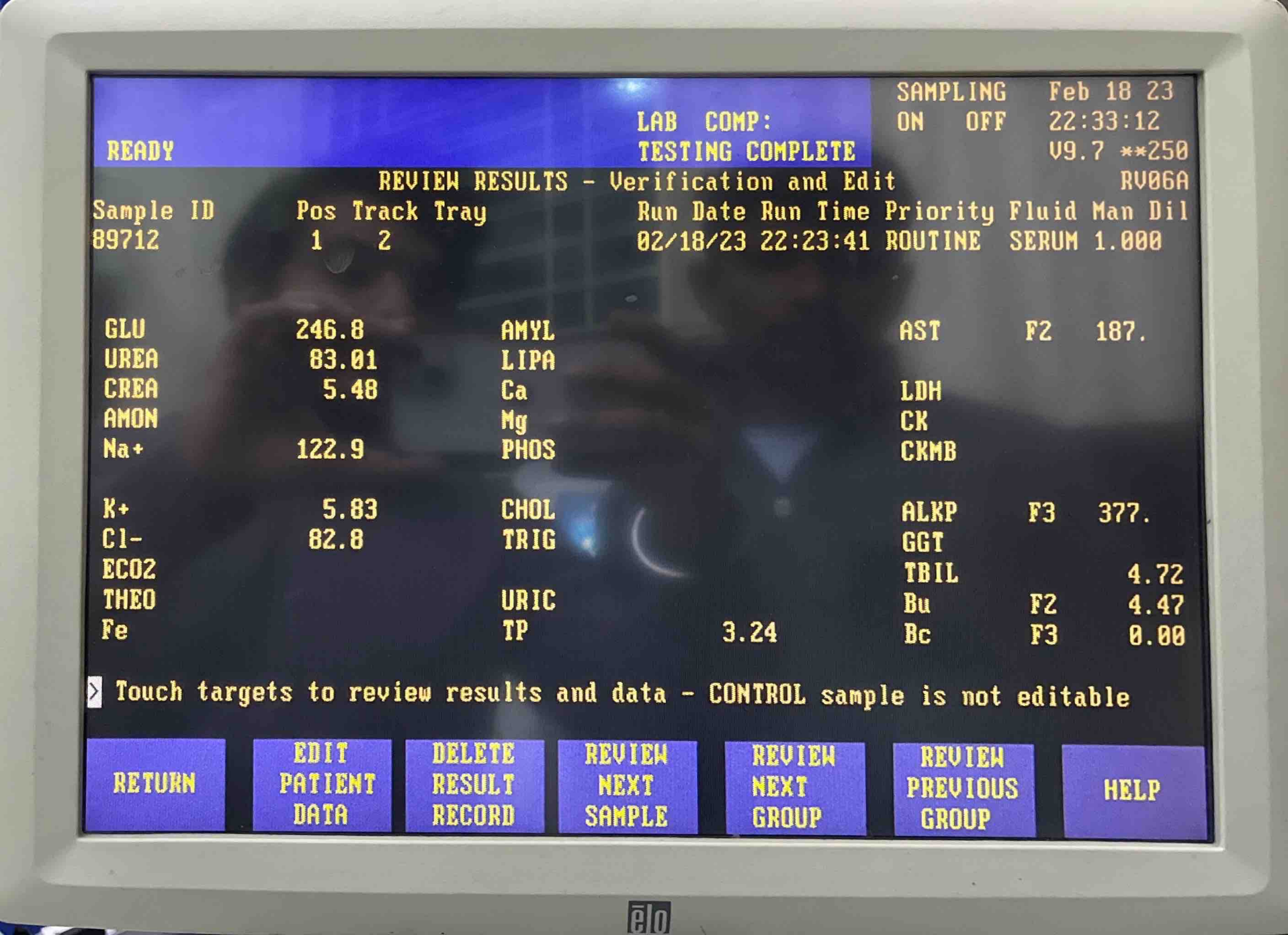
HELP

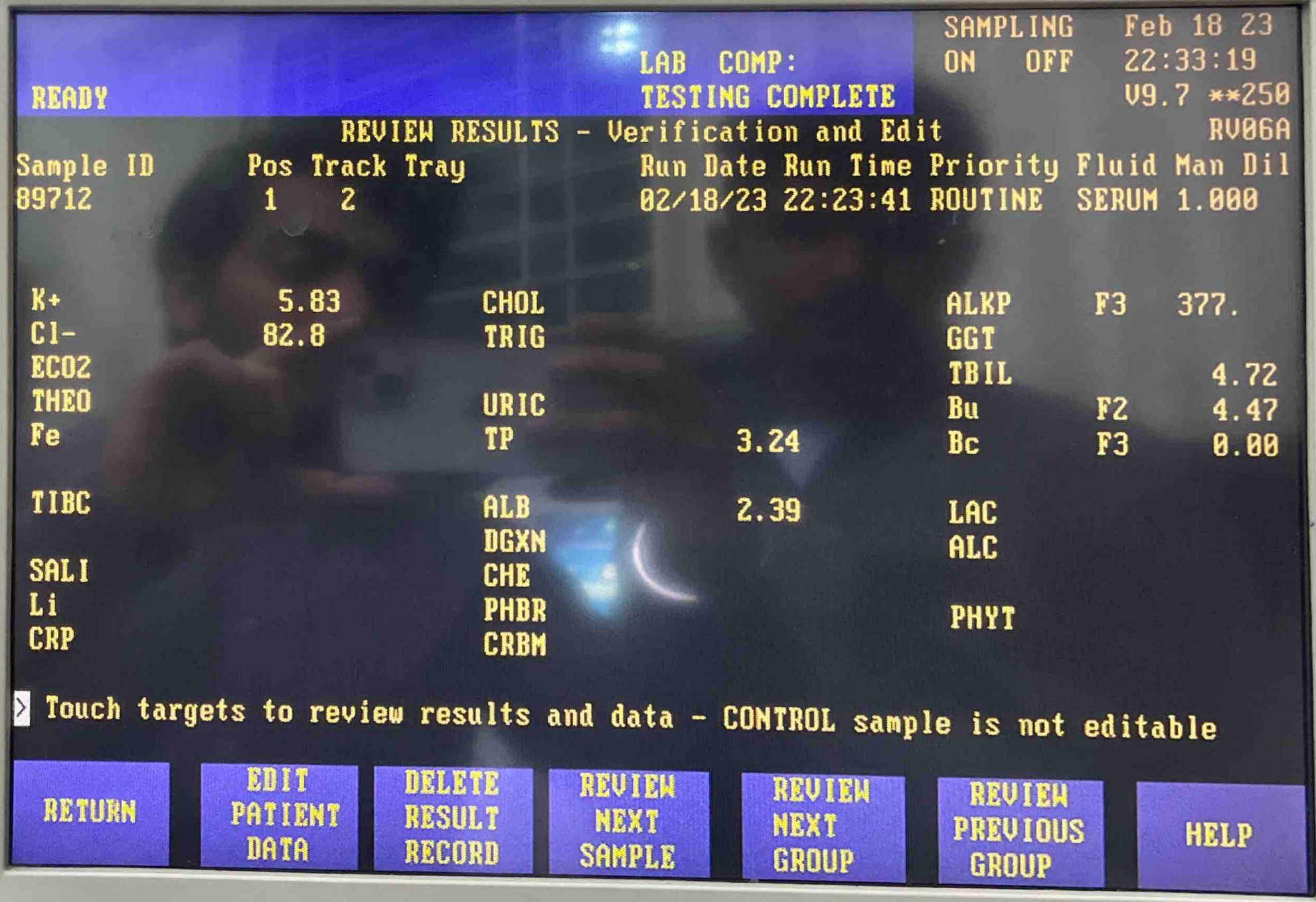

SCHEDULER * INCUBATOR ENVIRONMENT * temperature failure
SAMPLING
Feb 18 23
LAB COMP:
ON OFF
22:08:32
SS1 SS2 ST INC IR R/C PM INOP
TESTING COMPLETE
V9.7 **250
DIAGNOSTICS - Performance Tests - Reflectometer - Static test
PT31D
- Summary Screen -
Wavelength (nm)
Mean Dark
SD Dark
Mean Signal
SD Signal
%CV*1K
340 284 0.4795 33601 1.0743 3.20
400 284 0.4983 31930 1.4527 4.55
460 284 0.4795 34477 1.7207 4.99
540 284 0.4498 39670 1.7927 4.52
600 285 0.4795 45747 1.7876 3.91
630 284 0.5040 40274 2.0126 5.00
670 285 0.5085 35459 1.0854 3.06
680 284 0.4795 39788 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

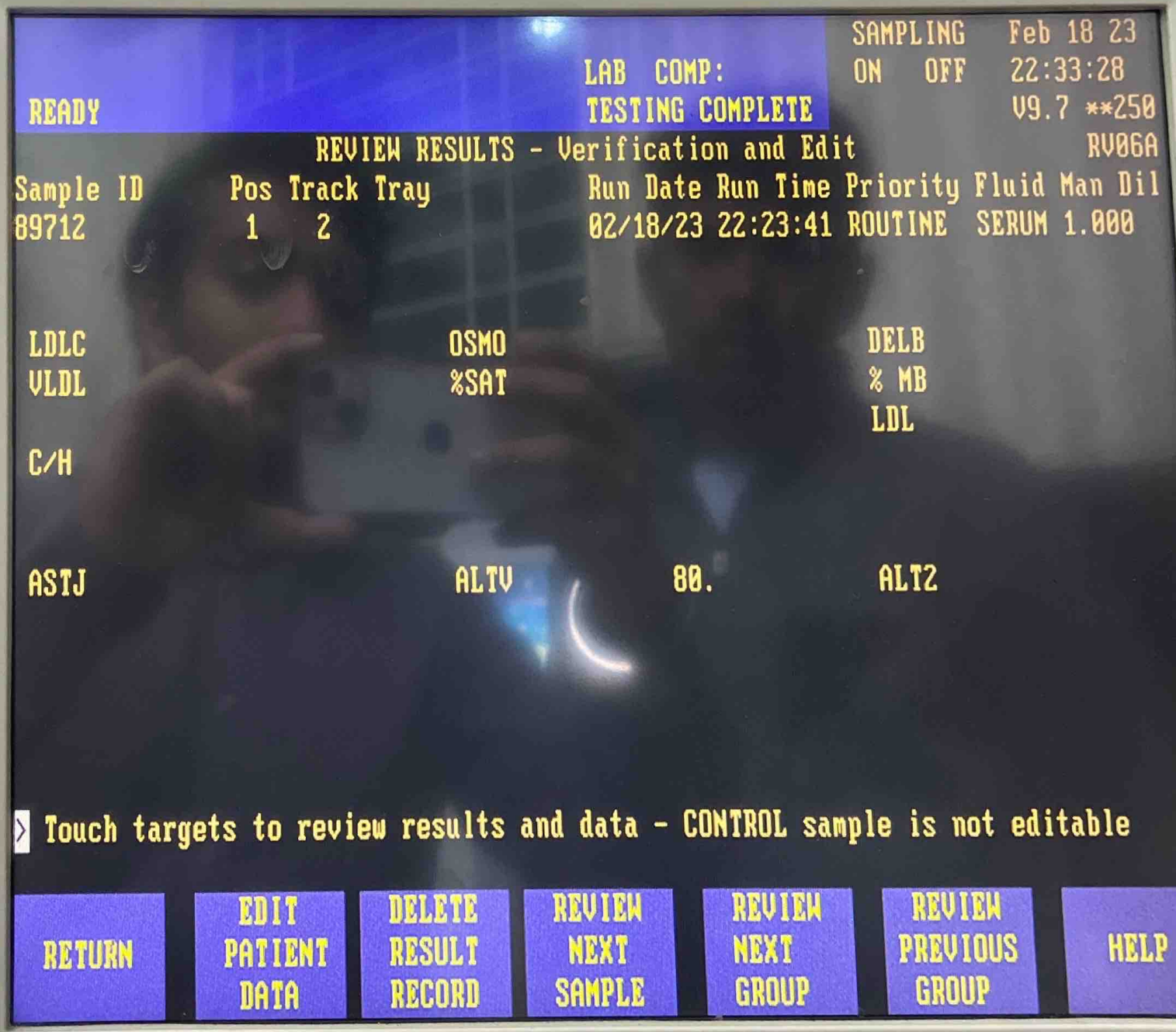

READY
LAB COMP:
TESTS IN PROCESS
SAMPLING
ON
OFF
Feb 18 23
22:30:09
V9.7 **250
REVIEW RESULTS - Verification and Edit
RV06A
Sample ID Pos Track Tray Run Date Run Time Priority Fluid Man Dil
89711 1 1 02/18/23 22:20:25 ROUTINE SERUM 1.000
GLU 84.0
UREA 29.60
CREA 1.83
AMON
Na+ 143.7
K+ 3.75
Cl- 92.2
ECO2
THEO
Fe
AMYL
LIPA
Ca
Mg
PHOS
CHOL
TRIG
URIC
TP F2 4.65
AST F2 43.
LDH
CK
CKMB
ALKP F2 83.
GGT
TBIL 1.00
Bu .93
Bc 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


READY
LAB COMP:
TESTS IN PROCESS
SAMPLING
ON
OFF
Feb 18 23
22:30:17
V9.7 **250
REVIEW RESULTS - Verification and Edit
RV06A
Sample ID Pos Track Tray Run Date Run Time Priority Fluid Man Dil
89711 1 1 02/18/23 22:20:25 ROUTINE SERUM 1.000
K+ 3.75
Cl- 92.2
ECO2
THEO
Fe
TIBC
SALI
Li
CRP
CHOL
TRIG
URIC
TP F2 4.65
ALB 4.30
DGXN
CHE
PHBR
CRBM
ALKP F2 83.
GGT
TBIL 1.00
Bu .93
Bc 0.00
LAC
ALC
PHYT
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:
TESTS IN PROCESS
SAMPLING
ON
OFF
Feb 18 23
22:30:30
V9.7 **250
RV06A
REVIEW RESULTS - Verification and Edit
Sample ID
Pos
Track
Tray
Run Date
Run Time
Priority
Fluid
Man Dil
89711
1
1
02/18/23
22:20:25
ROUTINE
SERUM
1.000
LDLC
VLDL
OSMO
%SAT
DELB
% MB
LDL
C/H
ASTJ
ALTV
25.
ALT2
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
ON OFF
Feb 18 23
22:33:12
V9.7 **250
REVIEW RESULTS - Verification and Edit
RV06A
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
GLU 246.8
UREA 83.01
CREA 5.48
AMON
Na+ 122.9
K+ 5.83
Cl- 82.8
ECO2
THEO
Fe
AMYL
LIPA
Ca
Mg
PHOS
CHOL
TRIG
URIC
TP 3.24
AST F2 187.
LDH
CK
CKMB
ALKP F3 377.
GGT
TBIL 4.72
Bu F2 4.47
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


READY
LAB COMP:
TESTING COMPLETE
SAMPLING
ON OFF
Feb 18 23
22:33:19
V9.7 **250
REVIEW RESULTS - Verification and Edit
RV06A
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
K+ 5.83
Cl- 82.8
ECO2
THEO
Fe
TIBC
SALI
Li
CRP
CHOL
TRIG
URIC
TP 3.24
ALB 2.39
DGXN
CHE
PHBR
CRBM
ALKP F3 377.
GGT
TBIL 4.72
Bu F2 4.47
Bc F3 0.00
LAC
ALC
PHYT
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
ON OFF
Feb 18 23
22:33:28
V9.7 **250
REVIEW RESULTS - Verification and Edit
RV06A
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
C/H
OSMO
%SAT
DELB
% MB
LDL
ASTJ
ALTV
80.
ALT2
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

ISO/IEC 17025:2017
Certificate No.: CC-2705

Print Date: 16/11/2022

CALIBRATION REPORT

STATUS : PASSED

DESCRIPTION : Variable Volume Pipette VV-200 (20-200 µl)

DEVICE ID : 21400599

CALIBRATION DATE : 16/11/2022 10:50 AM

Method ID : VV/20-200

TERMINAL ID : 19

ULR No. : CC270521000091802F

Location : Lucknow (Permanent Lab)

ENVIRONMENTAL FACTORS

TEMP : 25.00 °C **Z FACTOR :** 1.0026 mm³/mg **BARO. PRESSURE :** 80.00 KPa **REL. HUMIDITY :** 60.00%

CALIBRATION STATISTICS

						Inaccuracy E%		Imprecision CV%		
Vol (µl)	No	Cum Wt (mg)	Vol (µl)	Mean (µl)	SD (µl)	Actual	Target	Actual	Target	Status
20.000	1	20.600	20.654	20.754	0.459	3.770	6.00	< 2.00	2.00	PASSED
	2	40.900	20.353							
	3	62.100	21.255							
100.000	1	99.300	99.558	99.625	0.058	0.375	1.20	< 0.40	0.40	PASSED
	2	198.700	99.658							
	3	298.100	99.658							
200.000	1	199.000	199.517	199.852	0.495	0.074	0.60	< 0.20	0.20	PASSED
	2	398.900	200.420							
	3	598.000	199.618							

Volume	Above 10 µl to 100 µl	Above 100 µl to 1000 µl	Above 1 ml to 10 ml	Above 10 ml to 100 ml
Uncertainty (k=2)	0.1 µl	0.1 µl	0.1 µl	4 µl

Based on data of the records.

Incharge Q.C.
Quality Control
Calibration ISO:8655 Standards

- Specifications conform to ISO:8655 standards.
- Each instrument is individually calibrated on electronic balance.
- 750 mmHg = 99.98 kPa.
- Weight in mg or g.
- Volume, Mean & S.D. in ml or µl.

Reference standard

The instrument is calibrated using a standard electronic balance with calibration traceability to NPL.

The reported expanded uncertainty of measurement is calculated by multiplying the standard uncertainty of measurement by the coverage factor k=2, which for normal distribution corresponds to a coverage probability of approximately 95%.

ISO/IEC 17025:2017
Certificate No.: CC-2705

Print Date: 15/11/2022

CALIBRATION REPORT

STATUS : PASSED

DESCRIPTION : Variable Volume Pipette VV-200 (20-200 µl)

DEVICE ID : 21400602 **CALIBRATION DATE :** 15/11/2022 2:56 PM

Method ID : VV/20-200 **TERMINAL ID :** 19

ULR No. : CC270521000091800F **Location :** Lucknow (Permanent Lab)

ENVIRONMENTAL FACTORS

TEMP : 25.00 °C **Z FACTOR :** 1.0026 mm³/mg **BARO. PRESSURE :** 80.00 KPa **REL. HUMIDITY :** 60.00%

CALIBRATION STATISTICS

						Inaccuracy E%		Imprecision CV%		
Vol (µl)	No	Cum Wt (mg)	Vol (µl)	Mean (µl)	SD (µl)	Actual	Target	Actual	Target	Status
20.000	1	20.700	20.754	20.787	0.058	3.937	6.00	< 2.00	2.00	PASSED
	2	41.500	20.854							
	3	62.200	20.754							
100.000	1	99.600	99.859	99.725	0.116	0.275	1.20	< 0.40	0.40	PASSED
	2	199.000	99.658							
	3	298.400	99.658							
200.000	1	200.000	200.520	199.885	0.604	0.058	0.60	< 0.20	0.20	PASSED
	2	399.300	199.818							
	3	598.100	199.317							

Volume	Above 10 µl to 100 µl	Above 100 µl to 1000 µl	Above 1 ml to 10 ml	Above 10 ml to 100 ml
Uncertainty (k=2)	0.1 µl	0.1 µl	0.1 µl	4 µl

Conforms ISO:8655 Standards
Incharge Q.C.
Quality Control

Based on data of the records

- Specifications conform to ISO:8655 standards.
- Each instrument is individually calibrated on electronic balance.
- 750 mmHg = 99.98 kPa.
- Weight in mg or g.
- Volume, Mean & S.D. in ml or µl.

Reference standard

The instrument is calibrated using a standard electronic balance with calibration traceability to NPL.

The reported expanded uncertainty of measurement is calculated by multiplying the standard uncertainty of measurement by the coverage factor k=2, which for normal distribution corresponds to a coverage probability of approximately 95%.

National Accreditation Board for Testing and Calibration Laboratories

CERTIFICATE OF ACCREDITATION

MICROLIT - LABORATORY

has been assessed and accredited in accordance with the standard

ISO/IEC 17025:2017

"General Requirements for the Competence of Testing & Calibration Laboratories"

for its facilities at

629, PAKRAMAU, KURSI ROAD, LUCKNOW, UTTAR PRADESH, INDIA

in the field of

CALIBRATION

Certificate Number: CC-1032

Issue Date: 30/04/2023 **Valid Until:** 29/04/2025

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.
(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Name of Legal Identity : MICROLIT - LABORATORY

Signed for and on behalf of NABL

N. Venkateswaran
Chief Executive Officer

CC - 2267

FINIKS ENGINEERING COMPANY

Plot No. 21, Anand Nagar, Near Wasan Automobiles, Sahyadri Chowk, M.I.D.C.
A'nagar - 414111. [M.S.] Tel. [0241] 2778918, E-mail : finiks97@rediffmail.com

Calibration Certificate

ULR : CC226723000003632F

CALIBRATED ON	ISSUED ON	CERTIFICATE NO.	NEXT CALIBRATION DUE ON (suggested by customer)	Page 1 of 1
12/07/2023	15/07/2023	23-EGC-12-3-1	11/07/2024	

CALIBRATED FOR : **M/S. LUPIN DIAGNOSTICS LIMITED,**
Ahmednagar, Maharashtra

CUSTOMER'S CHALLAN NO. :

Dated : 12/07/2023 **Work Order No. :** 23/G/12/3

TYPE OF INSTRUMENT : **DIGITAL CENTRIFUGE MACHINE(RPM)**

IDENTIFICATION
MAKE : Remi **Sr.No.** : ZHIN/36370
RANGE : 0 to 5250 RPM **ID No.** : LOL/HLM/LAB/CEN/01
L.C. : 10 RPM **Model** : R-8C
TYPE : Digital

LAB ID NO. : 23/G/12/3/1
ENVIRONMENTAL CONDITION : 25°C±10°C /50%RH±10%RH **CONDITION AT RECEIPT :** OK
REFERENCE DOCUMENT USED : IS 12508 - 1988 & Sanas TR 45-01 (2008-2-15)
CALIBRATION PROCEDURE : CP/81 **CALIBRATION LOCATION :** At Site
Product Field Discipline : MECHANICAL-ACCELERATION AND SPEED

Equipment / Reference Standards Used For Calibration : Traceable to National / International standards.

Equipment / Reference Standard	Identification No.	Certificate No.	Date of Calibration	Valid Upto
DIGITAL TACHOMETER	FINIKS/TM-01	NI2023/06/0403	10/06/2023	09/06/2024

CALIBRATION RESULTS

Parameter : RPM (NON-CONTACT TYPE)

Calibration Point in RPM	Stanadard Reading in RPM	UUC Reading in RPM	Error in RPM	Stability (S) (RPM)	Measurement Uncertainty (±)
1000	999.5	1000	0.50	0.00	6.56 RPM
2000	1998.6	2000	1.40	0.00	10.30 RPM
3000	2995.6	3000	4.40	0.00	10.30 RPM
4000	3990.3	4000	9.70	0.00	10.30 RPM
5000	4980.1	5000	19.90	0.00	10.30 RPM

The reported uncertainty is at coverage factor K=2 which corresponds to a coverage probability of approximately 95.45% for normal distribution.

---- END OF CERTIFICATE ----

Calibrated By
Mr.Mokal M.S
Calibration Engineer

FINIKS ENGINEERING COMPANY * CALIBRATION LABORATORY * AHMEDNAGAR

Authorized By
Mr.Warpe B.S
Technical Manager

This Certificate refers only to the item (s) submitted for calibration
This calibration results in this certificate are valid at the time of and under the stated conditions of measurements.
This certificate shall note be reproduced, except in full without our prior permission in writing

FM/25

CC - 2267

FINIKS ENGINEERING COMPANY

Plot No. 21, Anand Nagar, Near Wasan Automobiles, Sahyadri Chowk, M.I.D.C.,
A'nagar - 414111. [M.S.] Tel. [0241] 2778918, E-mail : finiks97@rediffmail.com

Calibration Certificate

ULR : CC226723000003633F

CALIBRATED ON	ISSUED ON	CERTIFICATE NO.	NEXT CALIBRATION DUE ON (suggested by customer)	Page 1 of 1
12/07/2023	15/07/2023	23-EGC-12-3-2	11/07/2024	

CALIBRATED FOR : **M/S. LUPIN DIAGNOSTICS LIMITED,**
Ahmednagar, Maharashtra

CUSTOMER'S CHALLAN NO. :

Dated : 12/07/2023 **Work Order No. :** 23/G/12/3

TYPE OF INSTRUMENT : **DIGITAL CENTRIFUGE MACHINE(RPM)**

IDENTIFICATION

MAKE : Remi **Sr.No.** : ZHIN/36374
RANGE : 10 to 5250 RPM **ID No.** : LOL/HLM/LAB/CEN/02
L.C. : 10 RPM **Model** : R-8C
TYPE : Digital

LAB ID NO. : 23/G/12/3/2
ENVIRONMENTAL CONDITION : 25°C±10°C /50%RH±10%RH **CONDITION AT RECEIPT :** OK
REFERENCE DOCUMENT USED : IS 12508 - 1988 & Sanas TR 45-01 (2008-2-15)
CALIBRATION PROCEDURE : CP/81 **CALIBRATION LOCATION :** At Site
Product Field Discipline : MECHANICAL-ACCELERATION AND SPEED

Equipment / Reference Standards Used For Calibration : Traceable to National / International standards.

Equipment / Reference Standard	Identification No.	Certificate No.	Date of Calibration	Valid Upto
DIGITAL TACHOMETER	FINIKS/TM-01	NI2023/06/0403	10/06/2023	09/06/2024

CALIBRATION RESULTS

Parameter : RPM (NON-CONTACT TYPE)

Calibration Point in RPM	Stanadard Reading in RPM	UUC Reading in RPM	Error in RPM	Stability (S) (RPM)	Measurement Uncertainty (±)
1000	998.6	1000	1.40	0.00	6.56 RPM
2000	1997.5	2000	2.50	0.00	6.56 RPM
3000	2992.3	3000	7.70	0.00	6.56 RPM
4000	3986.5	4000	13.50	0.00	6.56 RPM
5000	4981.2	5000	18.80	0.00	6.56 RPM

The reported uncertainty is at coverage factor K=2 which corresponds to a coverage probability of approximately 95.45% for normal distribution.

--- END OF CERTIFICATE ---

Calibrated By
Mr.Mokal M.S
Calibration Engineer

FINIKS ENGINEERING COMPANY * CALIBRATION LABORATORY * AHMEDNAGAR *

Authorized By
Mr.Warpe B.S
Technical Manager

This Certificate refers only to the item (s) submitted for calibration
This calibration results in this certificate are valid at the time of and under the stated conditions of measurements.
This certificate shall note be reproduced, except in full without our prior permission in writing

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