GSTIN : 09AAKFP4281G1ZY

POCT SERVICES
Complete Medical Solution
298-281, Transport Nagar, Kanpur Road, Adjacent
Transport Nagar Metro Station, Lucknow- 226 023, UP. INDIA
Tel.: 0522-2433023
E-mail: poctlko@poctservices.com www.poctservices.com

Date: 29-April 2024

Certificate of Calibration

Name & Address of Customer: Department of Pathology

AHM Hospital Kanpur

City: Kanpur State: U.P. PIN: ----------

Phone ---------- E-Mail ----------

Name of Instrument: Selectra PRO M

Type: Random Access Fully Automatic Biochemistry Analyser

Serial No: 16-4071

Calibration Date: 05 April 2024

Next Calibration Due: 04 April 2025

This is to certify that above said instrument has been validated of hardware calibration for Filters, Aspiration, and Temperature & Lamp according to the procedures provided by Elitech Group Clinical Systems, France.

This calibration is carried out by using Standard Operating Procedures (S.O.P.) provided by Elitech Group, shown in the attachment.

These instruments conform to CE-IVD & EU directives of use.

Calibration carried out on site by: - Mr.Manish Singh

Signature & Stamp
Name of Engineer/ Application Specialist: - Ajit Mohan Dubey
Asst. Sr. Manager Application
POCT Services

Encls. - SOP of Validation/Calibration along with data.

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Validation / Calibration - SOP

Selectra ProM

Name of the Customer & Address : Department of pathology

Address:, AHM Hospital Kanpur (U.P.)

Sr No: 16-4071

Status : Under warranty **Validation & Preventive Maintenance**

- Power Supply

  Measure Input power Supply Voltage:229 V (230 V AC ± 10 V)

  Check Earthling: 2.2 V (0 - 5 V)

- Ambient temperature: 26 ° C (10 - 35 ° C)

- Appearance : Clean (Clean/Dusty)

- Bellow Pumps: Open the pump assays and clean it thoroughly.

- **Analyser Control**

  Filter: Select the desired position through the Service menu.
  Filter wheel sets the desired Filter: **Yes**

  Filter Status: Needs replacement (Yes/ NO)
  ρ 340nm ρ 405nm ρ 505nm ρ 546 nm ρ 578 nm ρ 620 nm ρ 660 nm ρ 700 nm

  Note: Filter checked status was ok no need of replacement.

  Temperature: Select the desired Options through the Service mode.
  Temperature OK: **Yes**

  Pump: Select the desired volume through the Service mode
  Verify by aspirating the same Quantity : **OK**

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Valve: Select the desired position through the service mode.
Valve is energized: Yes

Syringes: Check for syringe leakage by physical inspection of syringes.
No water leakage Found.

Cuvette Drier Block: Check the condition of cuvette drier block by removing the cover of cuvette rotor and lifting the wash arm through service menu. It should be reasonably clean. If dirty please change the drier block.

Note:- Condition of cuvette drier block is clean. No need to change.

Mixer Belts – Check the elasticity of mixer belts. Should be reasonably good or replace the belts.

Note:- Mixer belts are good no need to change.

Cuvette Rotor Blank : Perform rotor blank and check the OD values of cuvettes. All cuvette blank OD values should be within acceptable range. If required replace the cuvette rotor.

Note:- All cuvette blank OD values are in range no need to replace

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Hardware Calibration of Selectra Pro S/Pro M

➢ Lamp Calibration/Alignment

Lamp Adjustment :-

1. Flush the system with distilled water by doing Rotor Blank.
2. Select Adjust Lamp in service menu. Check Value obtained on Display. (Adjust the lamp, if it is out of 1.800 to 4.000, to as low as possible)

Do not touch lamp !! It may be Hot !!

Lamp alignment Data @ 340 nm wavelength			
Lamp Abs Obtained	Acceptable Range	Alignment	Remarks
3.9143 Abs	1.800 to 4.200abs	Done	Lamp O.D.in acceptable range. No replacement required.

➢ Checking the filters

Perform filter check in adjust lamp mode in service menu.

All the arrows must be in Green area. If not, then adjust lamp or replace filter if necessary.

Note :

When the absorbance value is too low to measure, i.e., the gain is too high, in this case, instead of the absorbance value, the value -99999 is shown.

Filter (Wavelength)	Gain Range	Gain Achieved	Remarks	Corrective Action
340	0.1 – 3.5	2.9035	OK	Not required
405	0.1 - 2.6	1.8054	OK	Not required
505	0.1 - 2.6	0.7957	OK	Not required
546	0.1 - 2.6	0.7704	OK	Not required
578	0.1 - 2.6	0.6693	OK	Not required
620	0.1 – 1.2	0.6626	OK	Not required
660	0.1 – 0.7	0.6019	OK	Not required
700	0.1 – 0.7	0.5750	OK	Not required
Over all Remarks	Filter gains within acceptable range. No replacement required.			

If it is necessary to replace defective filters, please contact service department.

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➢Calibration/Verification of performance of Pipetting system & measuring unit

- Install dichromate solution on reagent rotor(s) & as sample on sample rotor (Use service disk which has Pre-defined protocol installed for dichromate run).
- Run 10x "Check-S" or 10x "Check-R" as QC samples.

Test	Target Value	Target CV [%]	Mean Result	CV [%]
Check-S	0.08(0.060-0.100)	≤2%	0.074	0.645
Check-R	1.75(1.500-2.000)	≤2%	1.638	0.753

Remarks:

Rotor Blank acceptable. Instrument ready for chemical installation & calibration.

- Change reagent disk from Service to Standard
- Install the various reagents on reagent rotor(s)
- Install ISE reagents on reagent rotor(s) (If applicable)
- Run Reagent Blanks(s)
- Run Calibrations

Volume calibration of pipettors:-

It is possible to check a predetermined amount of water to check the correct functioning of the pump. Before carrying out this check, the instrument must first carry out a flush routine to ensure that all system tubes are completely filled with water by doing fill system.

1. Go to Sample syringe full stroke. (For Pro M Model Only)
2. Collect the dispensed water. Check the dispensed volume using calibrated pipette. (For Pro M only)

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Pipettor Calibration Data using distilled Water		
Full stroke volume to be dispensed (µl)	Dispensed volume checked and found complying as full stroke volume? (Yes/No)	Remarks
Sample Syringe:		
100	Yes	OK
100	Yes	OK
100	Yes	OK
Reagent syringe:		
1000	Yes	OK
1000	Yes	OK
1000	Yes	OK

Data for volumes other than full stroke:-

This can be verified using pre-determined amount of distilled water in sample/regent cups and running any dummy program. As soon as the reagent probe/sample probe takes up the sample/reagent, those cups/bottles are taken back and verified for remaining volume using calibrated pipette. Same can be repeated for variable volumes by changing the aspiration volumes in test programmes.

Pippetor Calibration Data using distilled Water				
Measured Volume taken in sample cup(µL) (A)	Water to be aspirated by syringe(µL) (B)	Water that should be remaining in cup after aspiration(µL) (C=A-B)	Is the remaining volume inside the cup was found to be the same as in column C? (Yes/No)	Remarks
Reagent syringe:				
5000 µL	300 µL X 3 test =900 µL	4100 µL	Yes	OK
Sample syringe:				
300 µL	30 µL X 3 test =90 µL	210 µL	Yes	OK

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➢ Temperature Calibration

Select Temperature in Service Menu. It should be **37 °C** ± 2 °C
Verify with temperature Indicator by surface probe in cuvette rotor. If any discrepancy add the offset of difference in actual & desired temperature.

Temperature Calibration Data				
Displayed Temp	Ref. Range	Temp. Indicator	Temp Offset Required	Temp. offset Value
37°C	**37 °C** ± 2 °C	36.7°C	No	0 °C
Remarks	Temp. Calibration OK. No offset required.			

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➢Reagent Calibration of the Instrument

Customer is advised to verify the hardware calibration by reagent calibration. Use Elitech Calibrator Elical 2 for the calibration of all parameters.
User can do the same & attach the results in separate sheet with factors after verifying the same with Elitech Elitrol I & Elitrol II controls.All control values should fall within acceptable range.
Data sheets of the same should be attached along with this document.

- Switch Off the instrument.
- Ensure all the Recommended Spares / Consumables have been replaced.(if not done during PM and required)
- Clean the instrument.
- Close the cover.

Recommended Spares for replacement : NIL

We hereby certify that Validation have been carried out under the MOU. Hardware Calibration of Lamp, Filters, Temperature & Aspiration (Pump) has been done successfully.
Please perform the standardization / Calibration and verify by evaluating controls before processing patient samples.

Next Calibration is due on: 4 April 2025

Signature of Application Specialist

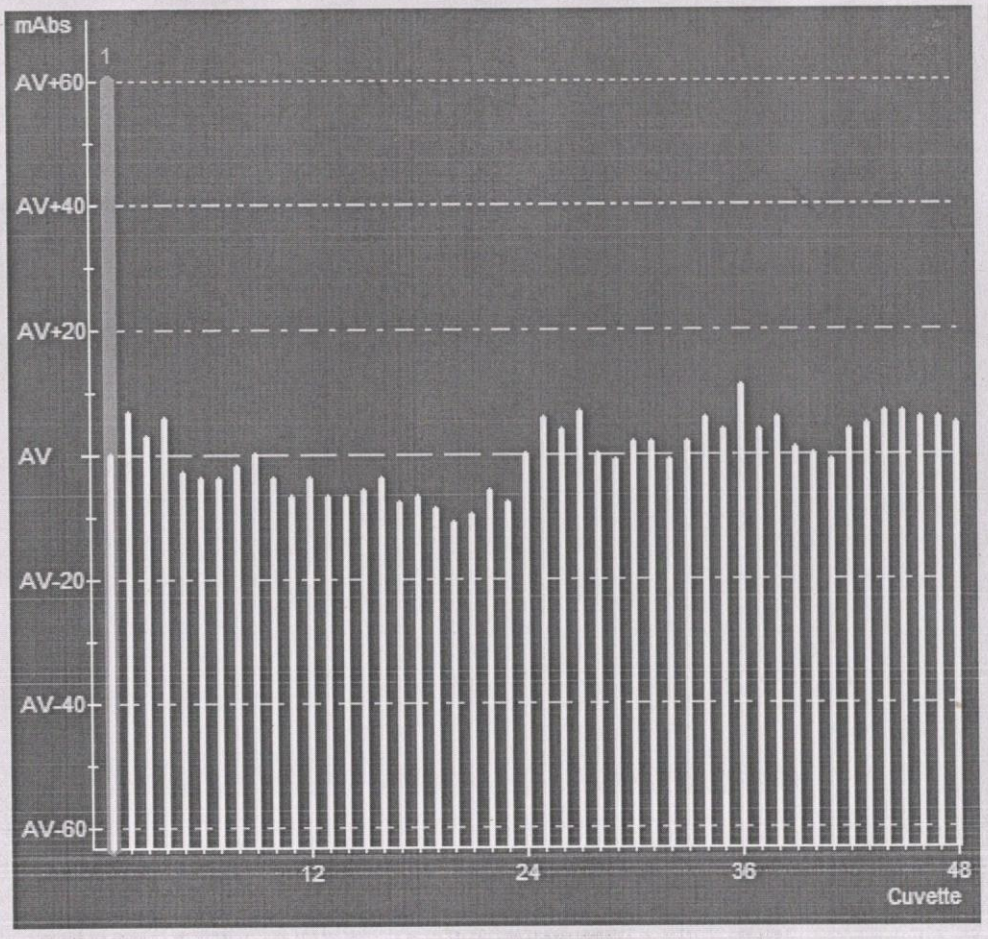
Place
Date.

Active | Loadable | DUAL MODE | Req./tray buffer:0/3 | Service | 05:27:41 PM | 05-Apr-2024

Rotor/System

- Reset system
- Change cuvette rotor
- Change syringes
- Fill/Empty system
- Clean system
- Rotor/Needle rinse
- ▶Blank rotor

340 nm
405 nm
505 nm
546 nm
578 nm
620 nm
660 nm
700 nm



Cuvette AV:	0.3330	SD:	0.0056	Cuvette Gain:	11.0000
Lamp AV:	2.5655	SD:	0.0038	Lamp Gain:	15.0000

Last blank date: 05-Apr-2024
time: 04:47:23 PM

F1	F2	F4	F5	F6	F7	F8	F10
Print	Blank Rotor	Exclude/ Include	Previous	Next	Table Mode	Maintenance Report	Special Functions

Evaluate Results

Control name: Water
Batch number: Check R
Expiry date:

Measurement date: 05-Apr-2024 05:21:14 PM
Sample type: **Control**
Status: **READY** **A1**

Test name	Value		Flags
– **Check R**	**1.638 dAbs**		
#1 Check R	1.645 dAbs		
#2 Check R	1.653 dAbs		
#3 Check R	1.649 dAbs		
#4 Check R	1.656 dAbs		
#5 Check R	1.628 dAbs		
#6 Check R	1.632 dAbs		
#7 Check R	1.640 dAbs		
#8 Check R	1.623 dAbs		
#9 Check R	1.623 dAbs		
#10 Check R	1.630 dAbs		

Check R **1.638 dAbs**

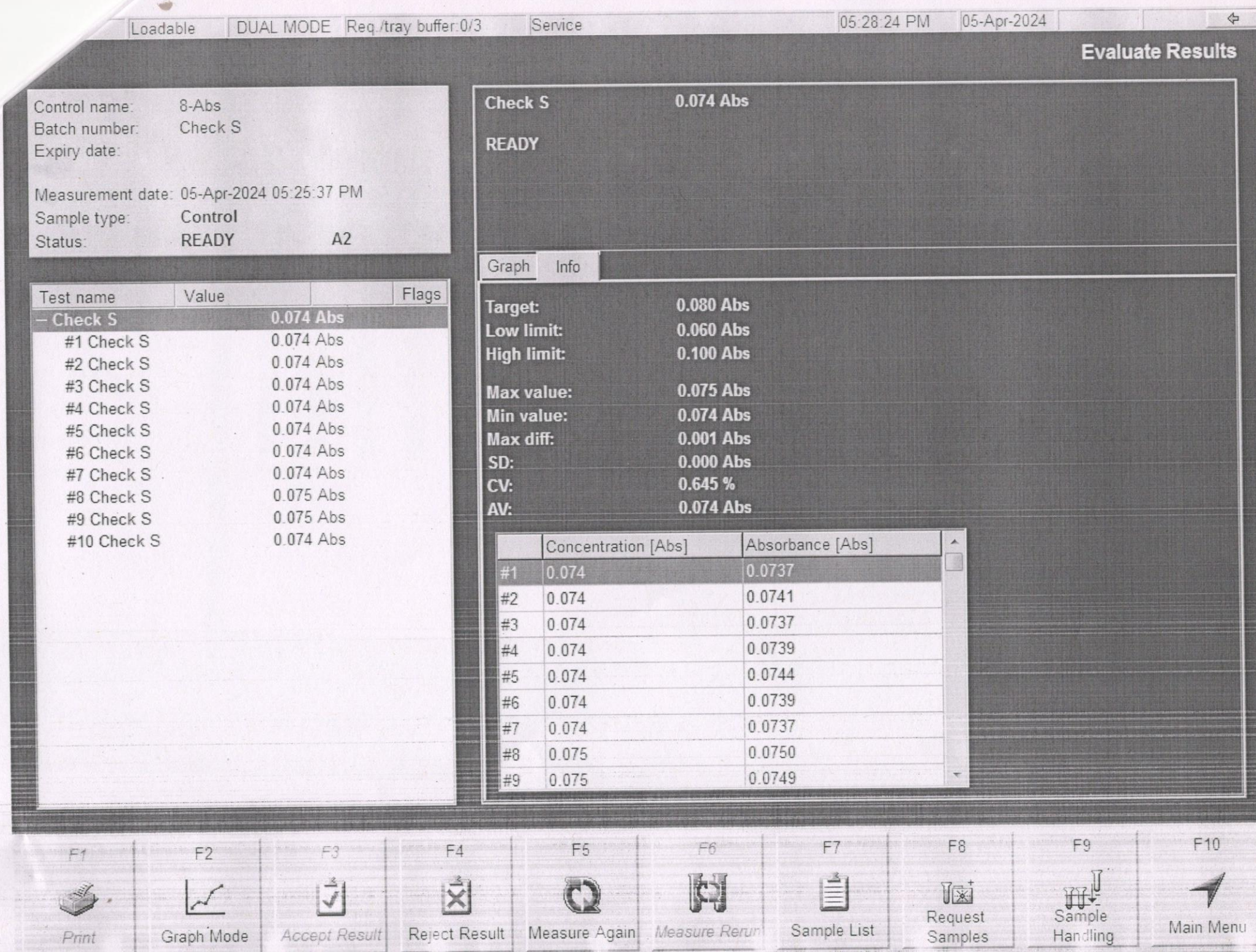
COMPLETED

Graph | Info

Target: **1.750 dAbs**
Low limit: **1.500 dAbs**
High limit: **2.000 dAbs**

Max value: **1.656 dAbs**
Min value: **1.623 dAbs**
Max diff: **0.033 dAbs**
SD: **0.012 dAbs**
CV: **0.753 %**
AV: **1.638 dAbs**

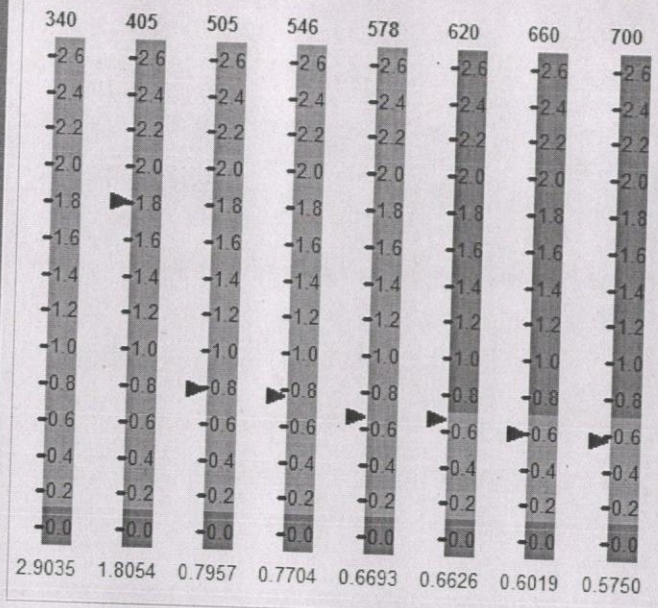
	Concentration [dAbs]	Absorbance [dAbs]
#1	1.645	1.6450
#2	1.653	1.6528
#3	1.649	1.6492
#4	1.656	1.6558
#5	1.628	1.6280
#6	1.632	1.6324
#7	1.640	1.6397
#8	1.623	1.6232
#9	1.623	1.6225


Loadable
DUAL MODE
Req./tray buffer:0/3
Service
05:28:24 PM
05-Apr-2024
Evaluate Results
Control name: 8-Abs
Batch number: Check S
Expiry date:
Measurement date: 05-Apr-2024 05:25:37 PM
Sample type: Control
Status: READY A2
Check S 0.074 Abs
READY
Graph
Info
Target: 0.080 Abs
Low limit: 0.060 Abs
High limit: 0.100 Abs
Max value: 0.075 Abs
Min value: 0.074 Abs
Max diff: 0.001 Abs
SD: 0.000 Abs
CV: 0.645 %
AV: 0.074 Abs
Test name
Value
Flags
– Check S 0.074 Abs
#1 Check S 0.074 Abs
#2 Check S 0.074 Abs
#3 Check S 0.074 Abs
#4 Check S 0.074 Abs
#5 Check S 0.074 Abs
#6 Check S 0.074 Abs
#7 Check S 0.074 Abs
#8 Check S 0.075 Abs
#9 Check S 0.075 Abs
#10 Check S 0.074 Abs
Concentration [Abs]
Absorbance [Abs]
#1 0.074 0.0737
#2 0.074 0.0741
#3 0.074 0.0737
#4 0.074 0.0739
#5 0.074 0.0744
#6 0.074 0.0739
#7 0.074 0.0737
#8 0.075 0.0750
#9 0.075 0.0749
F1 Print
F2 Graph Mode
F3 Accept Result
F4 Reject Result
F5 Measure Again
F6 Measure Rerun
F7 Sample List
F8 Request Samples
F9 Sample Handling
F10 Main Menu

adable | DUAL MODE | Req./tray buffer:0/9 | Standard | 05:10:31 PM | 05-Apr-2024 | HOST

- Adjust Lamp
- Reagent Arm
- Sample Arm
- Reagent Disk
- Sample Disk / Barcode
- Measurement Disc/Filter
- Wash Arm
- Pipettor
- Vacuum system
- Water system
- Optical electronics
- Electronics

Filter check

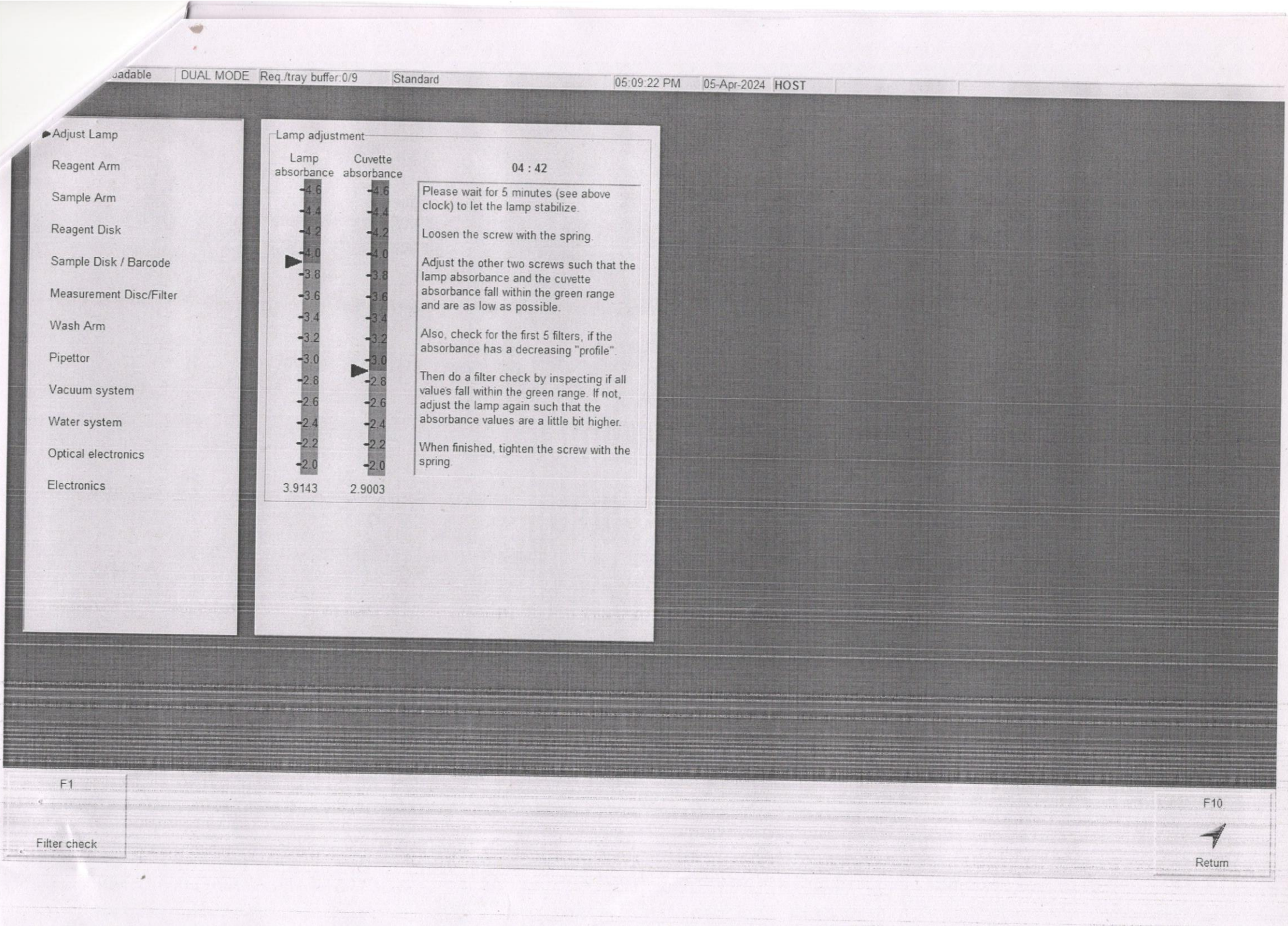


F1

Lamp adjustment

F10

Return


oadable
DUAL MODE
Req./tray buffer:0/9
Standard
05:09:22 PM
05-Apr-2024
HOST
Adjust Lamp
Reagent Arm
Sample Arm
Reagent Disk
Sample Disk / Barcode
Measurement Disc/Filter
Wash Arm
Pipettor
Vacuum system
Water system
Optical electronics
Electronics
Lamp adjustment
Lamp absorbance
Cuvette absorbance
04 : 42
4.6
4.4
4.2
4.0
3.8
3.6
3.4
3.2
3.0
2.8
2.6
2.4
2.2
2.0
3.9143
2.9003
Please wait for 5 minutes (see above clock) to let the lamp stabilize.
Loosen the screw with the spring.
Adjust the other two screws such that the lamp absorbance and the cuvette absorbance fall within the green range and are as low as possible.
Also, check for the first 5 filters, if the absorbance has a decreasing "profile".
Then do a filter check by inspecting if all values fall within the green range. If not, adjust the lamp again such that the absorbance values are a little bit higher.
When finished, tighten the screw with the spring.
F1
Filter check
F10
Return