

Date: \_\_\_ 01-03-2023 \_\_\_

## Certificate of Calibration

Name & Address of Customer: \_\_\_\_\_ Pathology Lab, Sadar Hospital, Sasaram

Rohtas, Bihar

City -Sasaram

State- Bihar

PIN : 821115

Name of Instrument : Selectra Pro-M

Type: Fully Automatic Biochemistry Analyser

Serial No: 22-4128

Calibration Date: 01-03-2023

Next Calibration Due: 29-02-2024

This is to certify that above mentioned instrument has been validated of hardware calibration for filters, aspiration and temperature & Imp according to the procedure 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

Signature



Name of Engineer : Mr. Sushil Pandey

POCT Services

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

## Validation / Calibration - SOP

### Selectra Pro-M

<b>Name of the Customer :</b> Pathology Lab, Sadar Hospital, Sasaram, Rohtas, Bihar	
<b>Address:</b> Rauja Road, Rohtas, Bihar	
<b>Sr No:</b> 22-4128	
<b>Status : Warranty/ AMC</b>	<b>Validation &amp; Preventive Maintenance</b>

➤ Power Supply

Measure Input power Supply Voltage: 228V (230 V AC  $\pm$  10 V )

Check Earthing: 2V ( 0 - 5 V)

➤ Ambient temperature: 27.5° C ( 10 - 35 ° C )

➤ Appearance : Clean\_ (Clean/Dusty)

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

➤ **Analyzer Control**

Filter : Select the desired position through the Service menu.

Filter wheel sets the desired Filter : Yes

Filter Status : Needs replacement (Yes)

$\rho$  340nm  $\rho$ 405nm  $\rho$  505nm  $\rho$  546 nm  $\rho$  578 nm  $\rho$  620 nm  $\rho$  660 nm  $\rho$  700 nm

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

**Valve** : Select the desired position through the service menu.  
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 change.



## 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
3.393 Abs	1.800 to 4.000 abs	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 - 3.2	2.40	OK	Not required
405	0.1 - 2.6	1.41	OK	Not required
505	0.1 - 2.6	0.71	OK	Not required
546	0.1 - 2.6	0.55	OK	Not required
578	0.1 - 2.6	0.44	OK	Not required
620	0.1 - 0.9	0.39	OK	Not required
660	0.1 - 0.9	0.37	OK	Not required
700	0.1 - 0.7	0.30	OK	Not required
<b>Over all Remarks</b>	Filter gains within acceptable range. No replacement required.			

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

## ➤ 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 5x "Check-S" and 5x "Check-R" as QC samples.

Test	Target Value	Target CV%	Mean Result	CV[%]
Check-S	0.080(0.060-0.100)	≤2%	0.071	1.80
Check-R	1.750(1.500-2.000)	≤2%	1.532	0.30

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)



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	Pass
100	Yes	Pass
100	Yes	Pass
Reagent syringe:		
1000	Yes	Pass
1000	Yes	Pass
1000	Yes	Pass

**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.

Pipettor 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 * 3 test = 900 µl	4100 µl	Yes	OK
Sample syringe:				
300 µl	30 µl * 3 test = 90 µl	210 µl	Yes	OK

## ➤ Temperature Calibration

Select Temperature in Service Menu. It should be  $37\text{ }^{\circ}\text{C} \pm 0.2\text{ }^{\circ}\text{C}$   
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	$37\text{ }^{\circ}\text{C} \pm 0.2\text{ }^{\circ}\text{C}$	35.2 °C	No	0 °C
Remarks	Temp. Calibration OK. No offset required.			

## ➤ 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.

- 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 AMC/Warranty. 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 -29/02/2024**

  
Signature of Service Engineer

Place: Sasaram  
Date. 01-03-2023

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▶ Adjust Lamp

Reagent Arm

Sample Arm

Reagent Disk

Sample Disk / Barcode

Measurement Disc/Filter

Wash Arm

Pipettor

Vacuum system

Water system

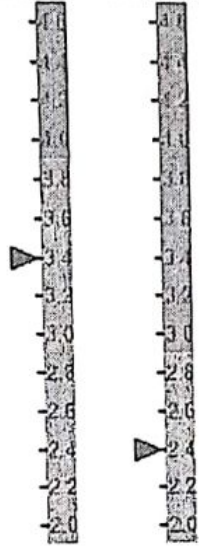
Optical electronics

Electronics

Lamp adjustment

Lamp absorbance      Cuvette absorbance

04 : 16



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.



▶ 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

	340	405	505	546	578	620	660	700
	-2.0	-2.6	-2.8	-2.6	-2.8	-2.6	-2.6	-2.6
	▽ -2.4	-2.4	-2.4	-2.4	-2.4	-2.4	-2.4	-2.4
	-2.2	-2.2	-2.2	-2.2	-2.2	-2.2	-2.2	-2.2
	-2.0	-2.0	-2.0	-2.0	-2.0	-2.0	-2.0	-2.0
	-1.8	-1.8	-1.8	-1.8	-1.8	-1.8	-1.8	-1.8
	-1.6	-1.6	-1.6	-1.6	-1.6	-1.6	-1.6	-1.6
	-1.4	▽ -1.4	-1.4	-1.4	-1.4	-1.4	-1.4	-1.4
	-1.2	-1.2	-1.2	-1.2	-1.2	-1.2	-1.2	-1.2
	-1.0	-1.0	-1.0	-1.0	-1.0	-1.0	-1.0	-1.0
	-0.8	-0.8	▽ -0.8	-0.8	-0.8	-0.8	-0.8	-0.8
	-0.6	-0.6	-0.6	-0.6	-0.6	-0.6	-0.6	-0.6
	-0.4	-0.4	-0.4	-0.4	▽ -0.4	▽ -0.4	▽ -0.4	-0.4
	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2	▽ -0.2
	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0
	2.4044	1.4155	0.7139	0.5559	0.4422	0.3983	0.3723	0.3031

340 nm	1-12	13-24	25-36	37-48
405 nm	0.53207	0.55762	0.52410	0.49181
505 nm	0.51252	0.52726	0.51613	0.52713
546 nm	0.53382	0.54358	0.52814	0.51613
578 nm	0.51366	0.52661	0.56590	0.51389
620 nm	0.50525	0.51263	0.52989	0.50289
660 nm	0.51243	0.56754	0.53209	0.48815
700 nm	0.50731	0.53476	0.50657	0.49497
	0.55376	0.52349	0.50770	0.50626
	0.50316	0.51093	0.50810	0.52179
	0.51086	0.52991	0.50740	0.51030
	0.51717	0.51748	0.50826	0.51450
	0.56236	0.58509	0.50931	0.53920

Cuvette AV: 0.5216      SD: 0.0203      Cuvette Gain: 8.0000  
 Lamp AV: 1.8498      SD: 0.0001      Lamp Gain: 12.0000  
 Last blank date: 3/1/2023  
 time: 11:59:05 AM



Control name: 8 Abs  
 Batch number: Check S  
 Expiry date:  
 Measurement date: 3/1/2023 3:14:40 PM  
 Sample type: Control  
 Status: UNLOADED

**Check S**                      **0.071 Abs**  
**COMPLETED**  
**TEST CHANGED**

Test name	Value	Flags
Check S	0.071 Abs	
#1 Check S	0.072 Abs	
#2 Check S	0.072 Abs	
#3 Check S	0.072 Abs	
#4 Check S	0.069 Abs	
#5 Check S	0.071 Abs	

Graph    Info

**Target:**                      **0.080 Abs**  
**Low limit:**                **0.060 Abs**  
**High limit:**              **0.100 Abs**  
**Max value:**               **0.072 Abs**  
**Min value:**               **0.069 Abs**  
**Max diff:**                **0.003 Abs**  
**SD:**                        **0.001 Abs**  
**CV:**                        **1.507 %**  
**AV:**                        **0.071 Abs**

	Concentration [Abs]	Absorbance [Abs]
#1	0.070	0.0697
#2	0.072	0.0717
#3	0.072	0.0720
#4	0.069	0.0690
#5	0.071	0.0712

Control name: Water  
 Batch number: Check R  
 Expiry date:  
 Measurement date: 3/1/2023 3:12:33 PM  
 Sample type: Control  
 Status: UNLOADED

**Check R** **1.532 dAbs**  
**COMPLETED**  
**TEST CHANGED**

Test name	Value	Flags
— Check R	1.532 dAbs	
#1 Check R	1.527 dAbs	
#2 Check R	1.529 dAbs	
#3 Check R	1.535 dAbs	
#4 Check R	1.538 dAbs	
#5 Check R	1.529 dAbs	

Graph Info

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

**Max value:** 1.538 dAbs  
**Min value:** 1.527 dAbs  
**Max diff:** 0.011 dAbs  
**SD:** 0.005 dAbs  
**CV:** 0.303 %  
**AV:** 1.532 dAbs

	Concentration [dAbs]	Absorbance [dAbs]
#1	1.527	1.5272
#2	1.529	1.5293
#3	1.535	1.5350
#4	1.538	1.5381
#5	1.529	1.5287



Control name: ELITROL 1  
 Batch number:  
 Expiry date:  
 Measurement date: 3/1/2023 3:44:40 PM  
 Sample type: Control  
 Status: UNLOADED

Type	Sample ID	Patient name
S	ELICAL	
S	HDL 2G CAL.	
C	ELITROL 1	
C	ELITROL 2	










Test name	Value	Flags
ALBUMIN	2.73 g/dl	
ALKALIN PHOS.	132 U/I	
ALAT/GPT	43 U/I	
ASAT/GOT	39 U/I	
TOTAL BILI.	1.54 mg/dl	
DIRECT BILI.	1.07 mg/dl	
CALCIUM	8.2 mg/dl	
CHOLESTEROL	117 mg/dl	
HDL CHOLESTEROL	26.6 mg/dl	
CREATININE	0.63 mg/dl	
GLUCOSE PP	104 mg/dl	
TRIGLYCERIDES	101 mg/dl	
UREA	40 mg/dl	
URIC ACID MONO	5.5 mg/dl	
TotPROTEIN PLUS	4.65 g/dl	

F1 Print	F2 Blank/Calib Info	F3 Result Handling	Alt + F4/Shift + F4 Measure Again/Rerun	F6 Quality Control	F7 Result Details	F8 Request Samples	F9 Sample Handling	F10 Main Menu
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Control name: ELITROL 2  
 Batch number:  
 Expiry date:  
 Measurement date: 3/1/2023 3:53:36 PM  
 Sample type: Control  
 Status: UNLOADED

Type	Sample ID	Patient name
S	ELICAL	
S	HDL 2G CAL.	
C	ELITROL 1	
C	ELITROL 2	

Test name	Value	Flags
ALBUMIN	4.63 g/dl	
ALKALIN PHOS.	289 U/l	
ALAT/GPT	136 U/l	
ASAT/GOT	141 U/l	
TOTAL BILI.	5.60 mg/dl	
DIRECT BILI.	3.06 mg/dl	
CALCIUM	11.7 mg/dl	
CHOLESTEROL	182 mg/dl	
HDL CHOLESTEROL	42.7 mg/dl	
CREATININE	3.41 mg/dl	
GLUCOSE PP	255 mg/dl	
TRIGLYCERIDES	207 mg/dl	
UREA	109 mg/dl	
URIC ACID MONO	11.8 mg/dl	
TotPROTEIN PLUS	7.29 g/dl	

<p>F1</p>  <p>Print</p>	<p>F2</p>  <p>Blank/Calib Info</p>	<p>F3</p>  <p>Result Handling</p>	<p>Alt + F4/Shift + F4</p>  <p>Measure Again/Rerun</p>	<p>F6</p>  <p>Quality Control</p>	<p>F7</p>  <p>Result Details</p>	<p>F8</p>  <p>Request Samples</p>	<p>F9</p>  <p>Sample Handling</p>	<p>F10</p>  <p>Main Menu</p>
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