

Calibration Certificate

Name & Address of Customer: Dr. Batra laboratory (Dr. Sanjay J. Batra),

102, samrat chamber, off. Madhyavarthi school, dandia bazar

City : Vadodara State: Gujarat PIN : 390001

Phone: 9824507570 E-Mail: sanjayjbatra@gmail.com

Name / Model of Instrument : Selectra pro-xs

Instrument Type: Random Access Fully Automatic Biochemistry Analyzer

Serial No: 14-9437

Calibration Date: 01-01-2022 Valid Till : 31-12-2022

Next Calibration Due on: 01-01-2023

This is to certify that above said instrument has been validated for hardware calibration for Filters, Aspiration, 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

Signature.....  Date : 01-01-2022

Name of Engineer : Kaushik Katariya

Instrument Service Division

Q-Line Biotech Pvt. Ltd

Encls.- SOP of Calibration along with Calibration data

SHAYONA BIOMEDICAL
402, Exiito Commercial Hub,
Near Testy Restaurant,
Jahangirpura, Olpad - Surat Main Road,
Surat - 395 005. (Guj.) India.
Mob.: 98790 72373, 99044 95304

Q-LINE BIOTECH PRIVATE LIMITED (Formerly known as "POCT Services Pvt. Ltd.")

Corp. Office: 20A (Basement), Main Shivaji Marg, Najafgarh Road, Near Moti Nagar Police Station, New Delhi-110015, INDIA. Tel.: 011-45577407
Regd. Office: 298-281, Transport Nagar, Kanpur Road, Adjacent Transport Nagar Metro Station, Lucknow-226023 (U.P.), INDIA. Tel.: 0522-2433023 E-mail: info@qlinebiotech.com | Website: www.qlinebiotech.com

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 3.800, 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
<u>3.600</u> Abs	1.800 to 3.800 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 - 2.6	<u>2.6230</u>	OK	Not required
405	0.1 - 2.6	<u>1.6025</u>	OK	Not required
505	0.1 - 2.6	<u>0.7953</u>	OK	Not required
546	0.1 - 2.6	<u>0.9861</u>	OK	Not required
578	0.1 - 2.6	<u>0.6617</u>	OK	Not required
620	0.1 - 0.7	<u>0.8576</u>	OK	Not required
660	0.1 - 0.7	<u>0.7570</u>	OK	Not required
700	0.1 - 0.7	<u>-NA-</u>	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 of Aspiration Pipettor System

It is possible to weigh 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. Weigh the same on weighing scale. (For Pro M only)
3. Repeat the same with Reagent syringe Full stroke.
4. Collect the dispensed water. Weigh the same on weighing scale.

Pipettor Calibration Data using distilled Water				
Volume Weighed (mg)	Water Aspiration	Water in Cup (µL)	Acceptable Range	Remarks
100	100 µL	100	± 0.1 µL	Aspiration precision ok
100	100 µL	200	± 0.1 µL	Aspiration precision ok
100	100 µL	300	± 0.1 µL	Aspiration precision ok
100	100 µL	400	± 0.1 µL	Aspiration precision ok
100	100 µL	500	± 0.1 µL	Aspiration precision ok
100	100 µL	600	± 0.1 µL	Aspiration precision ok
1000	1000 µL	1600	± 1 µL	Aspiration precision ok
1000	1000 µL	2600	± 1 µL	Aspiration precision ok
1000	1000 µL	3600	± 1 µL	Aspiration precision ok
1000	1000 µL	4600	± 1 µL	Aspiration precision ok
1000	1000 µL	5600	± 1 µL	Aspiration precision ok
1000	1000 µL	6600	± 1 µL	Aspiration precision ok

➤ Temperature Calibration

Select Temperature in Service Menu. It should be **37 °C ± 0.2 °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 ± 0.2 °C	°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 or any other commercially available calibrator 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 (Normal Control) & Elitrol II (Pathological Control) or by any other commercially available 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.
- Clean the instrument.
- Close the cover.

Recommended Spares for replacement : NIL

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

Next Calibration is due on: 01-01-2023

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Signature of Service Engineer

Date 01-01-2022

Name : Kaushik Khataniya

Instrument Service Division

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