



**Calibration cum validation  
certificate selectra series**

DOC:QBPL/CALV/Selectra series  
Release Date : 6-03-20  
Revision:0  
Revision Date:02 4

## 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: sanjaybatra@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..... Kaushik Catataniya Date : 01-01-2022

Name of Engineer : Kaushik Catataniya

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

# Validation & Preventive Maintenance - SOP

Selectra Pro S/ Pro M

<b>Name of the Customer :Dr.Batra laboratory(Dr.Sanjay j. Batra)</b>	
<b>Address:</b>	
Sr No : <u>14-9437</u>	
<b>Status : Warranty/ <u>AMC</u></b>	<b>Validation &amp; Preventive Maintenance</b>

➤ Power Supply

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

Earthing: 0.359V (0 - 5 V)

➤ Ambient temperature: 30° C ( 10 - 35 ° C )

➤ Appearance : Clean (Clean/Dusty)

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

For more info, refer to Service manual.

Power On Instrument and allow 10 minutes warm -up

➤ **Analyzer Control**

Filter : Select the desired position through the Service menu.

Filter wheel sets the desired Filter : (Yes / No )

Filter Status : Needs replacement (Yes/ NO )

ρ340nm, ρ405nm, ρ 505nm,ρ 546 nm,ρ 578 nm,ρ 620 nm ρ 660 nm, ρ 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

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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 pls change the drier block

(Recommended once in six months for Pro S & once in Four months for Pro M)

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

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.

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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 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
<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.

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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
<b>37°C</b>	<b>37 °C ± 0.2 °C</b>	°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 Elitol I (Normal Control) & Elitol 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**

.....  
Signature of Service Engineer

Date 01-01-2022

Name : Kaushik Khataniya

Instrument Service Division

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**DR. BATRA'S LABORATORY**

102, Samrat Chambers, Opp. Madhyavarti School,  
Poonam Studio lane, Dandia Bazar, Vadodara - 390 001.  
Ph. : 0265 - 2427570, 9714727623, 9824507570

**DR. SANJAY J. BATRA**

M.D. (PATH)

Reg. No. G - 5801

Time : 8.00 a.m. to 7.00 p.m.

(Sunday Closed)

## INTERNAL QUALITY CONTROL FOR JULY 2022

(CLINICAL BIOCHEMISTRY)

RANDOX LEVEL 3 LOT NO. 1195UE

S.No.	Analyte	Method	Target	Value obtained	Range	Is result satisfactory
1.	Albumin	Bromocresol green	3.15	3.1	2.67-3.63	YES
2.	Alkaline phosphatase	AMP(IFCC)	340	309	289-391	YES
3.	ALT(GPT)	Tris buffer without P5P	145	151	116-174	YES
4.	AST(GOT)	Tris Buffer without P5P	145	137	116-174	YES
5.	Bilirubin Total	Diazo with Sulphanilic acid	5.23	5.5	4.14-6.32	YES
6.	Cholesterol	Cholesterol oxidase	287	286	250-324	YES
7.	Creatinine	Alkaline picrate no deproteinization	4.61	4.37	3.68-5.54	YES
8.	Glucose	Glucose oxidase	287	266	243-331	YES
9.	HDL Cholesterol	Direct	86.5	93.9	73.7-99.3	YES
10.	Protein Total	Biuret	4.96	4.8	3.97-5.95	YES
11.	Triglycerides	Lipase/GPO PAP	253	243	212-294	YES
12.	Urea	Urease kinetic	119	113.7	102-136	YES
13.	Uric acid	Uricase peroxidase	10.4	9.6	9.04-11.8	YES