POCT SERVICES
Complete Medical Solution

POCT SERVICES
298-281, Transport Nagar, Kanpur Road,
Adjacent Transport Nagar Metro Station,
Lucknow-226023, UP. INDIA
Tel.: 0522-2433023
E-mail: poctlko@poctservices.com
www.poctservices.com

Date: 24 January 2020

Certificate of Calibration

Name & Address of Customer: Pathology Lab, District Hospital

City: Jhansi State: U.P. PIN: _____

Phone _____ E-Mail _____

Name of Instrument: Selectra PRO M

Type: Random Access Fully Automatic Biochemistry Analyser

Serial No: 17-4026

Calibration Date: 24/01/2020

Next Calibration Due: 23/01/2021

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: - Atul Chaturvedi

Certificate Issued by:-
Name of Engineer:
Sunil Kumar Yadav
Sr. Application Specialist
POCT Services.

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

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Validation / Calibration - SOP

Selectra ProM

Name of the Customer: Pathology Lab, District Hospital

Address: Jhansi
Sr No: 17-4026

Status: Warranty/AMC

Validation & Preventive Maintenance

- Power Supply

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

  Check Earthling: 2 V (0 - 5 V)

- Ambient temperature: 22 ° 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
3.8573 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 – 3.0	2.5790	OK	Not required
405	0.1 - 2.6	1.5927	OK	Not required
505	0.1 - 2.6	0.7926	OK	Not required
546	0.1 - 2.6	0.6933	OK	Not required
578	0.1 - 2.6	0.6093	OK	Not required
620	0.1 - 0.7	0.5398	OK	Not required
660	0.1 - 0.7	0.5161	OK	Not required
700	0.1 - 0.7	0.4231	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%	0.08	0.286
Check-R	1.75(1.500-2.000)	<2%	1.711	1.085

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**	36.9 **°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: 23 January 2021.

POCT SERVICES LUCKNOW

Certificate Issued by: - Sunil Kumar Yadav

Place: Lucknow
Date. 24 January 2020

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