

Date: 16-02-2024

## Certificate of Calibration

Name & Address of Customer: SANJIVINI HOSPITAL & RESEARCH CENTERCP-23,VIRAJ KHAND, GOMTI NAGAR, LUCKNOW, U.PCity: Lucknow State: U.P. PIN: 226010Name of Instrument: Selectra PRO-SType: Automatic Biochemistry AnalyserSerial No: 20-4520Calibration Date: 16-02-2024Next Calibration Due: 15-02-2025

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.

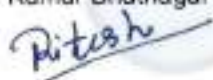
This calibration is carried out by using Standard Operating Procedures (S.O.P.) provided by Elitech Group, shown in the attachment.

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

Certificate Issued by

Name Of Engineer: -Mr Ritesh Kumar Bhatnagar

Q-LINE BIOTECH PVT LTD.



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

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

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Delhi Office: C-108, NARAINA INDUSTRIAL AREA PHASE -1, New Delhi, New Delhi, Delhi, 110028. Tel.: 011-45577407

E-mail: [info@qlinebiotech.com](mailto:info@qlinebiotech.com) | Website: [www.qlinebiotech.com](http://www.qlinebiotech.com) | CIN No.: U74120UP2010PTC042528

## Validation / Calibration - SOP

Selectra Pro S

<b>Name of the Customer</b> : <u>SANJIVINI HOSPITAL &amp; RESEARCH CENTER</u>	
<b>Address</b> : CP-23,VIRAJ KHAND, GOMTI NAGAR,LUCKNOW, U.P	
<b>Sr.No:</b> <u>20-4520</u>	
<b>Status</b> : <u>AMC</u>	<b>Validation &amp; Preventive Maintenance</b>

➤ **Power Supply**

Measure Input power Supply Voltage 229\_V (230 V AC  $\pm$  10 V )

Check Earthling: 1V ( 0 - 5 V )

➤ **Ambient temperature:** 28° 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)

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

## Hardware Calibration of Selectra Pro S

### ➤ 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
3.7082Abs	1.800 to 4.000abs	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	2.3096	OK	Not required
405	0.1 - 2.6	1.5605	OK	Not required
505	0.1 - 2.6	0.9071	OK	Not required
546	0.1 - 2.6	0.6261	OK	Not required
578	0.1 - 2.6	0.5656	OK	Not required
620	0.1 - 0.7	0.5784	OK	Not required
660	0.1 - 0.7	0.6109	OK	Not required
700	0.1 - 0.7	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/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%	0.096	0.659%

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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Head Office: 298-281, Transport Nagar, Kanpur Road, Adj. Transport Nagar Metro Station, Lucknow-226023 (U.P.), INDIA. Tel.: 0522-24330

Delhi Office: C-108, NARAINA INDUSTRIAL AREA PHASE -1, New Delhi, New Delhi, Delhi, 110028. Tel.: 011-45577407

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Pipettor Calibration Data using distilled Water		
Full stroke volume to be dispensed ( $\mu\text{L}$ )	Dispensed volume checked and found complying as full stroke volume? (Yes/No)	Remarks
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 volume in test programmes.

Pipettor Calibration Data using distilled Water				
Measured Volume taken in sample cup ( $\mu\text{L}$ ) (A)	Water to be aspirated by syringe ( $\mu\text{L}$ ) (B)	Water that should be remaining in cup after aspiration ( $\mu\text{L}$ ) (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 $\mu\text{L}$	300 $\mu\text{L}$ X 3 test = 900 $\mu\text{L}$	4100 $\mu\text{L}$	Yes	OK

## ➤ 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
35°C	<b>37 °C ± 2 °C</b>	35.6°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: 15-02-2024**

  
Signature & Stamp of Issuing Authority

Place: LUCKNOW  
Date: 16/02/2024







Control name: E AVE  
 Batch number: Check 3  
 Entry date:   
 Measurement date: Control  
 Sample type: RE ADY  
 Spike: A1

Test name: Value: 0.000 Alu  
 Check 3



Check 3 2.000 Alu  
**COMPLETED**

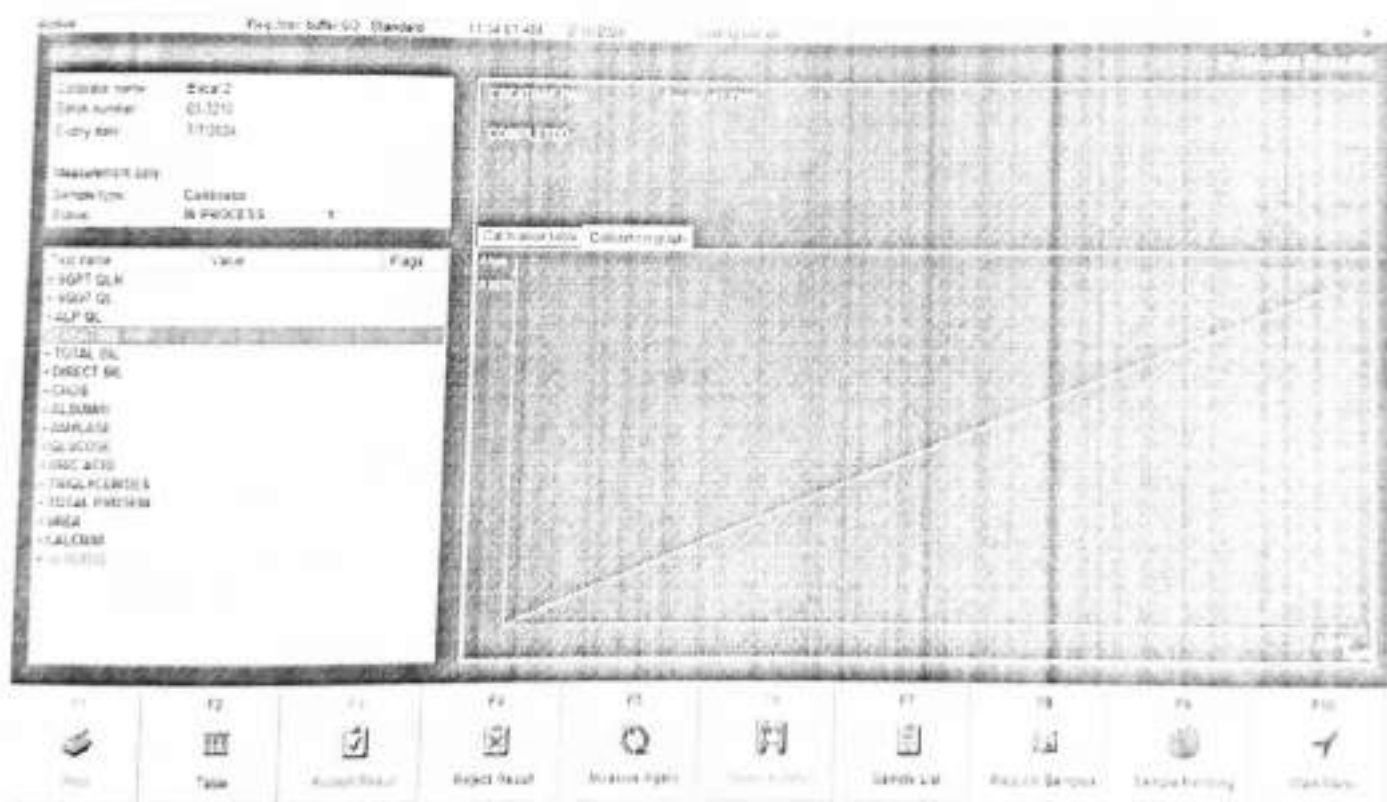
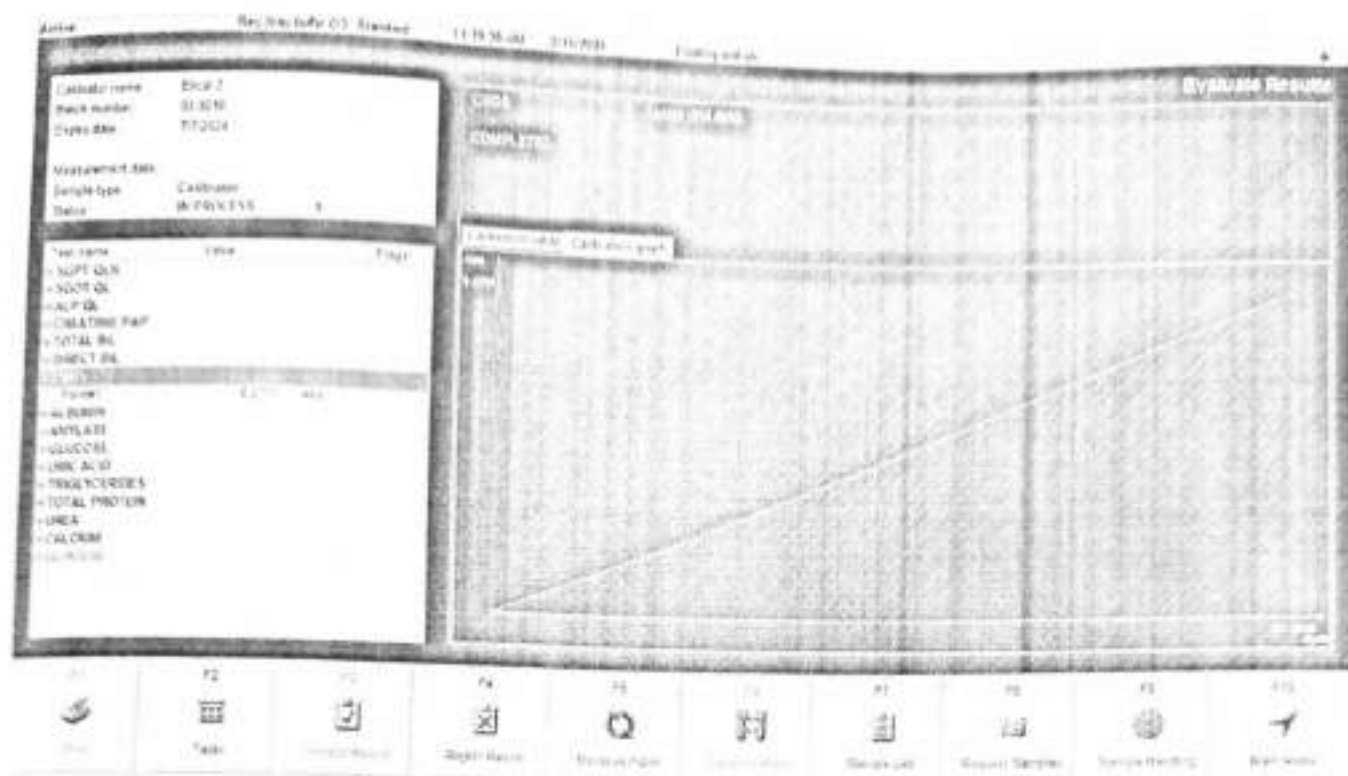
Max value: 2.007 Alu  
 Min value: 0.000 Alu  
 Max diff: 0.007 Alu  
 SD: 0.001 Alu  
 CV: 0.459 %  
 All: 0.004 Alu  
 Target: 2.000 Alu  
 Low limit: 2.000 Alu  
 High limit: 2.100 Alu

#	Concentration [mg]	Response [Au]
#1	0.006	0.0052
#2	0.006	0.0061
#3	0.007	0.0067
#4	0.007	0.0073
#5	0.006	0.0059
#6	0.005	0.0045
#7	0.005	0.0057
#8	0.004	0.0042
#9	REJECT	A 22307E0012

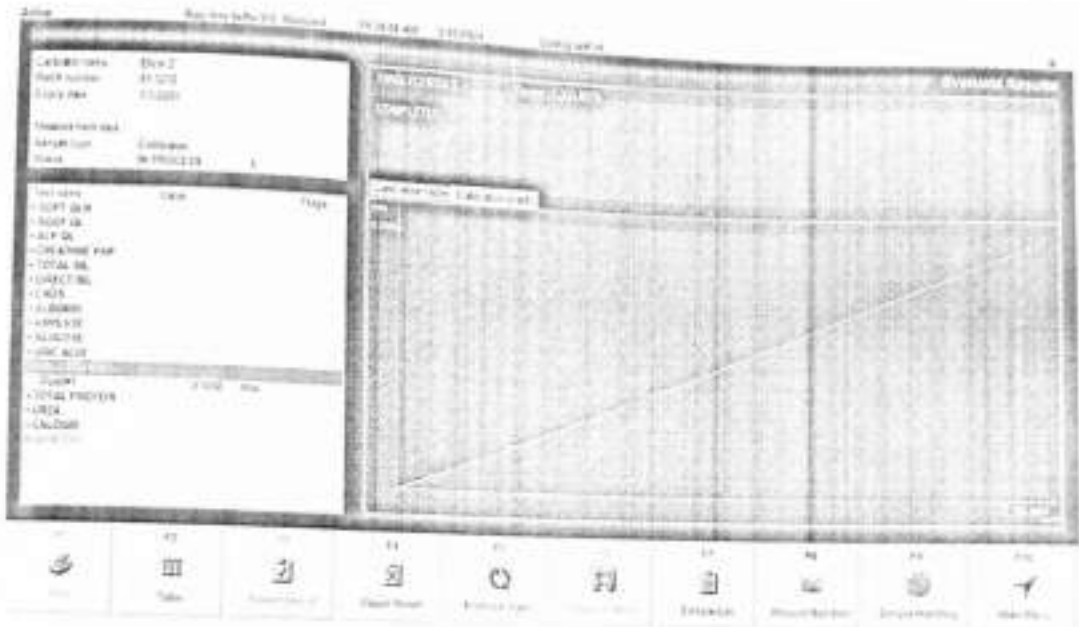
- F1 Home
- F2 Graph Mode
- F3 Accept Result
- F4 Reject Result
- F5 Monitor Alarm
- F6 Measure Flow
- F7 Sample List
- F8 Request Samples
- F9 Sample Handling
- F10 Main Menu

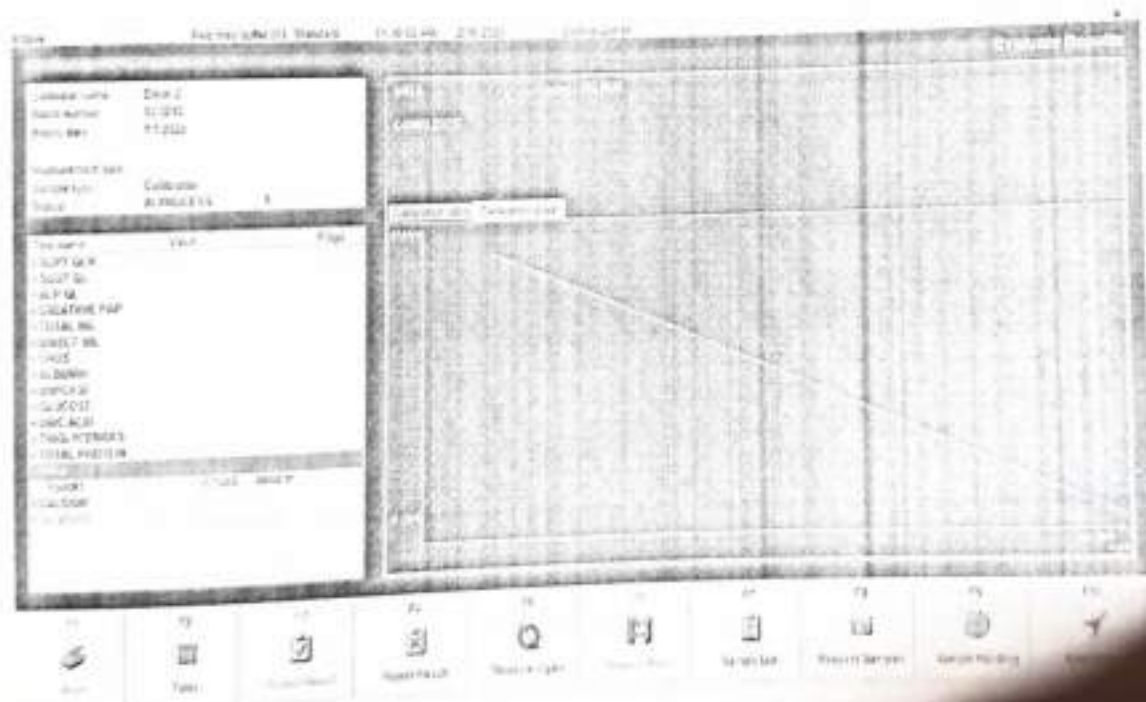
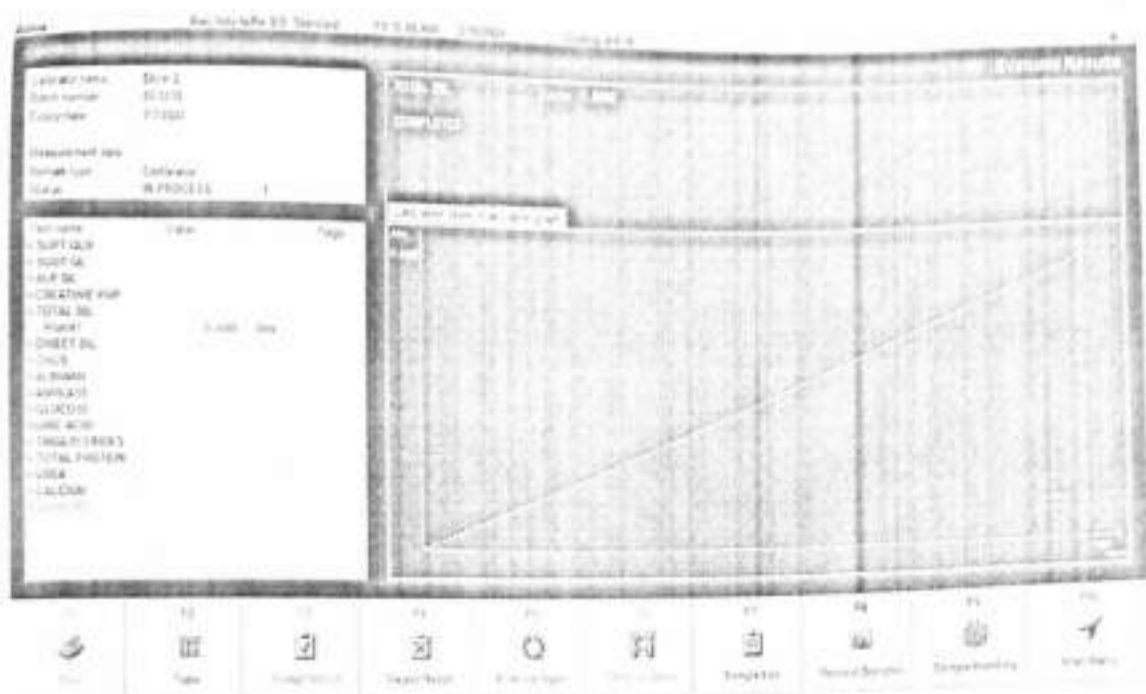














Patient Name: 87001  
 Birth Date: 05/12/00  
 Study No: 435801  
 Measurement Date: 01/02/04 11:00 AM  
 Sample Type: Control  
 Tube: 8L204 2

Test Name	Value	Flag
WPT GLU	40.8	HI
WPT GL	48.4	HI
ALP GL	103	HI
CREATINE TAP	1.20	mg/dL
TOTAL BIL	1.30	mg/dL
DIRECT BIL	1.12	mg/dL
CHOL	194.7	mg/dL
ZINCUM	1.17	g/dL
AMYLASE	91	U/L
ALCOHOL	91.5	mg/dL
UREA ACID	4.74	mg/dL
FRUCTOSAMIN	162.4	mg/dL
TOTAL PROTEIN	4.10	g/dL
UREA	42.5	mg/dL
CALCIUM	9.01	mg/dL

Type: Series 01  
 Patient Name: 87001  
 A: 87001  
 B: 87001  
 C: 87001  
 D: 87001

Home | Download | Total Reading | Home | Quality Control | Result Details | Report Details | Sample Handling | Main Menu

Patient Name: 87001  
 Birth Date: 05/12/00  
 Study No: 435801  
 Measurement Date: 01/02/04 10:00 AM  
 Sample Type: Control  
 Tube: 8L204 2

Test Name	Value	Flag
WPT GLU	114.0	HI
WPT GL	114.0	HI
ALP GL	101	HI
CREATINE TAP	1.06	mg/dL
TOTAL BIL	0.57	mg/dL
DIRECT BIL	0.48	mg/dL
CHOL	117.7	mg/dL
ZINCUM	1.05	g/dL
AMYLASE	210.0	mg/dL
ALCOHOL	12.42	mg/dL
UREA ACID	29.9	mg/dL
FRUCTOSAMIN	2.10	g/dL
TOTAL PROTEIN	117.8	mg/dL
UREA	10.40	mg/dL
CALCIUM	10.40	mg/dL

Type: Series 01  
 Patient Name: 87001  
 A: 87001  
 B: 87001  
 C: 87001  
 D: 87001

Home | Download | Total Reading | Home | Quality Control | Result Details | Report Details | Sample Handling | Main Menu



## Installation Qualification

### Fully Automatic Instrument Series

Company (Name & Add) : POCT SERVICES  
TRANSPORT NAGAR, LUCKNOW U.PCustomer (Name & Add) : SANJIVINI HOSPITAL & RESEARCH CENTER

VIRAJ KHAND, GOMTI NAGAR, LUCKNOW, U.P

Contact Person: RITESH  
BHATNAGARContact Person : SANJIVINI HOSPITAL & RESEARCH CENTER

Telephone No. : 7607886655

Telephone No. : .....

Name of instrument : Selectra Pro XS / PRO S / PRO M / PRO XL / ISE (Select by  $\checkmark$ )Serial no. : 20-4520Installation Date : 20-02-2021

### Initial check

Parts missing?

(check against packing list)

 Yes (please specify parts) No

Part number

Part description

.....

.....

.....

.....

.....

.....

### Installation

Perform the Following steps

 Check Power Supply 230 V ( $\pm 10V$ ) Check Earth ..... 0.1 ..... V ( $< 5.0 V$ ) Room Temperature ..... 28 ..... ( $15^{\circ}C$  to  $30^{\circ}C$ ) Install Instrument on Flat & Dry Surface by leaving a space of 24" between instrument & back wall Install (PC, Main unit, monitor, printer, keyboard & mouse) Install Cooling Unit Install Water & Waste Containers (add sufficient amount of System liquid in the water) Install Cuvette Rotor(s) Install Syringes (be aware the 1000 $\mu$ L is on the rear side). Install the ISE unit (If Applicable) Start up the PC, Analyzer, Cooling Unit and ISE Unit. Set up the Analyzer Software

Set the System Parameters

Contd.....

## Installation Qualification



### Fully Automatic Instrument Series

- Run the function "Fill System".
- Install HCL 0.1N(on the reagent rotor(s)) and Needle Rinse solution(on the reagent & sample rotor)
- Run the function "Rotor Blank".
- Rotor blank should be acceptable ( $SD \leq 0.020$  Abs)
- Check for any leakage in the syringes, tighten screws if required

### Technical acceptance

Date (dd-mm-yyyy) : 20-02-2021

Service Engineer Name : ... RITESH BHATNAGAR      Customer Name : SANJIVINI HOSPITAL & RESEARCH CENTER

Signature & Stamp : 

Signature & Stamp : .....





**PERFORMANCE QUALIFICATION****Fully Automatic Instrument Series**

- Run Reagent Blank
- Run Calibrations
- Run QC material for several clinical chemistry applications

( a few enzymes, a few substrate tests using customer's reagent)

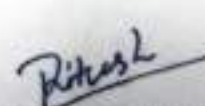
Test	QC Range Level 1	Test Result	QC Range Level 2	Test Result
GLUCOSE	77.8-91.3-103.2	89.35	187-220-253	218
CHOL	99-118-133	103	151-178-205	160
TRIG	85-101-117	102.9	170-202-234	211
ALT/GPT	29.3-48.2-56.0	47.2	116-142-167	145
AST/GOT	38-47-55	48.5	126-153-181	160
ALKP	130-158-186	121	259-316-375	260
CREAT	77-94-1.11	0.89	3.01-3.67-4.33	3.16
UREA	34.2-40.2-46.2	40.96	69-98-127	113
URIC ACID	5.18-6.09-7.00	6.7	10.45-12.29-14.13	11.8

 Remarks:

We hereby certify that Instrument standardization / calibrations have been carried out under the Warranty/ AMC. Verified by evaluating controls before processing patients Samples and obtained results are satisfactory. Instrument is ready for regular use.

**Technical acceptance**

Date (dd-mm-yyyy) :20-02-2021

Service Engineer Name :RITESH BHATNAGAR  
CENTERCustomer Name : SANJIVINI HOSPITAL & RESEARCHSignature & Stamp : 

Signature &amp; Stamp

Evaluate Results

Control name    B-Abs  
 Batch number    Check 5  
 Expiry date  
 Measurement date  
 Sample type  
 Status            **READY**            A1

Check 5            **0.095 Abs**  
**COMPLETED**

Test name	Value	Flags
← Check 5	0.095 Abs	

Graph Info

Max value:    **0.096 Abs**  
 Min value:    **0.095 Abs**  
 Max diff:     **0.001 Abs**  
 SD:            **0.000 Abs**  
 CV:            **0.408 %**  
 Avg:            **0.095 Abs**  
 Target:        **0.090 Abs**  
 Low limit:    **0.060 Abs**  
 High limit:   **0.100 Abs**

	Concentration [Abs]	Absorbance [Abs]
#1	0.095	0.0952
#2	0.095	0.0948
#3	0.095	0.0953
#4	0.095	0.0956
#5	0.095	0.0957
#6	0.095	0.0958
#7	0.095	0.0951
#8	0.095	0.0949
#9	0.095	0.0949

- F1  
  
 Home
- F2  
  
 Graph Mode
- F3  
  
 Accept Result
- F4  
  
 Reject Result
- F5  
  
 Measure Again
- F6  
  
 Measure Weight
- F7  
  
 Sample List
- F8  
  
 Request Samples
- F9  
  
 Sample Handling
- F10  
  
 Main Menu

# QC DATA LEVEL 1 & LEVEL 2

Archived Results

Type: Serum U  
 Batch: 2  
 Patient name: 2001

Control  
 URIC OXALIC

Test name	Value	Units	Flags
SCPT Q.M	43.2	UA	
SCPT CR	48.5	UA	
SCPT CR	121	UA	
ALP CL	0.89	mg/dl	
CREATININE PHA	1.80	mg/dl	
TOTAL BIL	1.06	mg/dl	
BUN CL CR	103.0	mg/dl	
CHOL	3.01	g/dl	
ALBUMIN	91	UA	
ALBUMIN	89.25	mg/dl	
ALBUMIN	6.7	mg/dl	
GLUCOSE	75.0	mg/dl	
UREA ACID	402.9	mg/dl	
UREA	4.4	g/dl	
TOTAL PROTEIN	40.96	mg/dl	
UREA	9.94	mg/dl	
ALBUMIN	17.41	mg/dl	
ACTIVITY			

Home  
 Biochem info  
 Research Handling  
 Assay request  
 Quality Control  
 Result Details  
 Request Samples  
 Sample Handling  
 User View

