

Call 0471 - 2982488 / 9400 101 488 | Email labxmedicalsyste.ms@labx.in



SELECTRA PRO
CHEMISTRY SYSTEM



Instrument Calibration/Validation Certificate

Customer Name	Nirnaya Diagnostics Centre, Trivandrum	
Address	Main Road, Kunnathukal, Karakonam P O, Trivandrum	
Instrument	SELECTRA PRO S Lite	
Serial No.	18-4522	
Contract Type	WARANTY <input checked="" type="checkbox"/> AMC <input type="checkbox"/> RRC <input type="checkbox"/>	
Calibration	Comm. Date : 20-11-2021	Exp Date : 19-11-2022
Validation Date	20-11-2021	
Next due date	20-11-2022	

Instrument Condition:

- Room is Air Conditioned Yes No
- Power Supply Earthing less than 5 V Yes No
- Room Working Environment is Good Yes No

Initial check

- Switch On the instrument with Analyser Software Yes No
- Instrument is Initialising properly Yes No
- Display is showing all Characters Yes No
- Syringes movement is smooth during aspiration Yes No
- Bellows pump is moving to Home position Yes No
- The Needle is coming to Wash Position Yes No
- Lamp is Glowing Yes No
- Temperature of Peltier is showing 37 degrees Yes No

Validation

Performing Filter Check:

Test	Range in Abs	AbsValue
Filter 340nm	1.7 to 3.5	2.1
Filter 405nm	1.2 to 2.6	1.5
Filter 505nm	0.8 to 2.6	1.1
Filter 546nm	0.8 to 2.6	1.7
Filter 578nm	0.6 to 2.6	2.0
Filter 620nm	0.6 to 2.6	1.1
Filter 660nm	0.6 to 2.6	1.8
Filter 700nm	0.6 to 2.6	1.9

Performance Check

- Reagent syringe Dispensing Volume: 1000UI Yes
- Sample syringe Dispensing Volume: 100UI Yes
- Blanking is proper during test: Yes
- Results are Satisfactory Yes
- Run 20 x Check-S and 20 x Check-R as QC samples

Test	Target value	Target CV%	Mean result	CV %
Check-S (left)	0.08 (0.060-0.100)	< 1%	0.08	0.88
Check-R (left)	1.75 (1.500-2.000)	< 1%	1.88	0.90

Chemical Installation

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

(a few enzymes, a few substrate tests and if applicable ISE tests and fill in the results in the table below)

Test	QC Range Level 1	Test result	QC Range Level 2	Test result
Glucose	73.5-102	86	240-303	272
Cholesterol	225-272	244	89-114	99
TGL	160-206	181	83-117	103
Albumin	3.72-4.65	4.2	2.5-3.2	2.9
SGPT	22-35	27	85-111	99
Uric Acid	5.43-7.63	6.66	8.21-9.9	9.1
SGOT	31.8 - 46.8	40	172-220	190

Remarks:

- Instrument is calibrated and working in good condition
- Tested Samples and found results are satisfactory

This Calibration is valid from 20-11-2021 to 19-11-2022.

Next Calibration is due on : 20-11-2022.

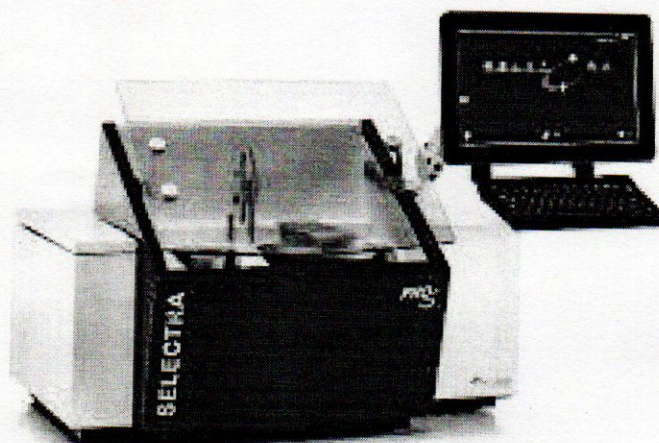
Technical Acceptance By,



Amal V K
Service Engineer
Thiruvananthapuram



BOSE E. K, DMLT
Lab Technician
Nirnaya Laboratory



SELECTRA PRO_S

CHEMISTRY SYSTEM

INSTALLATION QUALIFICATION

CUSTOMER NAME	Nirnaya Diagnostics Centre
CUSTOMER ADDRESS	Main Road, Kunnathukal, Karakonam P.O, Thiruvananthapuram
INSTRUMENT NAME	Selectra Pro S
INSTRUMENT SERIAL NUMBER	18-4522
INSTALLATION DATE	01-12-2019

Transport damages

- Package damaged Yes No
- Parts damaged Yes No

If yes, please specify:

Initial check:

Parts missing?

(Check against packing list)

- Yes → Please specify parts
- No

Part Number	Part Description

* Please return parts, including a malfunction report.

Installation

Perform the next steps



- Install PC (Main unit, monitor, printer, keyboard and mouse)
- Install Cooling unit. Add cooling solution (1:4) (if applicable)
- Install water and waste containers (add sufficient amount of system liquid to the water)
- Install cuvette rotor(s)
- Install syringes (be aware the 1000 ul is on the rear-side)
- Install the ISE unit (if applicable)
- Power Up the PC, Analyser, Cooling unit and ISE unit.
- Start Up the analyser software.
- Set system parameters
- Run "Fill system"
- Install Acid Solution (on the reagent rotor) and Needle Rinse solution (System Cleaning Solution) (on reagent rotor and sample rotor)
- Run "Rotor Blank"
- Run 20 x Check-S and 20 x Check-R as QC samples (for XL instruments left and right)

INSTALLATION, OPERATIONAL AND PERFORMANCE QUALIFICATION

Fill in the results in the table below

Test	Target value	Target CV%	Mean result	CV %
Check-S	0.08 (0.060-0.100)	< 1%	0.07	
Check-R	1.75 (1.500-2.000)	< 1%	1.65	

-----END OF QUALIFICATION-----


The customer confirms that the conditions required to ensure the proper functioning of the device according to the supplier's recommendations have been inspected and qualified.			
<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO			
Customer's comments		Installer's comments	
		Successfully verified all installation criteria as per manufacturer recommendation.	
Customer (Name and Position)	Signature	Installer (Name and Position)	Signature
BOSE E. K. DMIT Lab. Technician Nimaya Laboratory		Amal V K Field Service Engineer LabX Medical Systems	
This document is prepared and signed in duplicate. Each page must be initialled by the installer.			

CHEMICAL INSTALLATION

- Run Reagent Blank
- Run Calibrations
- Run QC material for several clinical chemistry applications
(a few enzymes, a few substrate tests and if applicable ISE tests and fill in the results in the table below)

Test 3	QC range level 1	Test result	QC range level 2	Test result
Glu	73.5-102	86	240-303	272
CHO	225-272	244	89-114	99
TGL	160-206	181	83-117	103
Creatinine	1.54-2.55	1.99	4.95-6.14	5.7
SGOT	31.8-46.8	40	172-220	192
SGPT	22-35	27	85-111	99
Uric acid	5.43-7.63	6.6	8.21-9.9	9.1
Total Protein	6-7.22	6.4	3.96-4.79	4.44
Albumin	3.72-4.65	4.2	2.5-3.2	2.9
ALKP	112-207	167	457-646	556

-----END OF QUALIFICATION-----

The customer confirms that the conditions required to ensure the proper functioning of the device according to the supplier's recommendations have been inspected and qualified.			
<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO			
Customer's comments		Installer's comments	
		Successfully verified all operational criteria as per manufacturer recommendation.	
Customer (Name and Position)	Signature	Installer (Name and Position)	Signature
BOSE E. K, DMLT Lab Technician Nimaya Laboratory		Amal V K Field Service Engineer LabX Medical Systems	