



SELECTRA PRO S  
CHEMISTRY SYSTEM

### Instrument Calibration/Validation Certificate

|   |   |                             |
|---|---|-----------------------------|
| <b>Customer Name</b>                              | Nirnaya Diagnostics Centre, Trivandrum  |                             |
| <b>Address</b>                                    | Main Road, Kunnathukal, Karakonam P O, Trivandrum   |                             |
| <b>Instrument</b>                                 | SELECTRA PRO S Lite   |                             |
| <b>Serial No.</b>                                 | 18-4522   |                             |
| <b>Contract Type</b>                              | WARRANTY <input type="checkbox"/> AMC <input type="checkbox"/> RRC <input type="checkbox"/> |                             |
| <b>Calibration</b>                                | Comm. Date : 20-11-2021   | Exp Date : 19-11-2022       |
| <b>Validation Date</b>                            | 20-11-2021  |                             |
| <b>Next due date</b>                              | 20-11-2022  |                             |
| <b><u>Instrument Condition:</u></b>               |   |                             |
| Room is Air Conditioned                           | <input checked="" type="checkbox"/> Yes   | <input type="checkbox"/> No |
| Power Supply Earthing less than 5 V               | <input checked="" type="checkbox"/> Yes   | <input type="checkbox"/> No |
| Room Working Environment is Good                  | <input checked="" type="checkbox"/> Yes   | <input type="checkbox"/> No |
| <b><u>Initial check</u></b>                       |   |                             |
| • Switch On the Instrument with Analyser Software | <input checked="" type="checkbox"/> Yes   | <input type="checkbox"/> No |
| • Instrument is Initialising properly             | <input checked="" type="checkbox"/> Yes   | <input type="checkbox"/> No |
| • Display is showing all Characters               | <input checked="" type="checkbox"/> Yes   | <input type="checkbox"/> No |
| • Syringes movement is smooth during aspiration   | <input checked="" type="checkbox"/> Yes   | <input type="checkbox"/> No |
| • Bellows pump is moving to Home position         | <input checked="" type="checkbox"/> Yes   | <input type="checkbox"/> No |
| • The Needle is coming to Wash Position           | <input checked="" type="checkbox"/> Yes   | <input type="checkbox"/> No |
| • Lamp is Glowing                                 | <input checked="" type="checkbox"/> Yes   | <input type="checkbox"/> No |
| • Temperature of Peltier is showing 37 degrees    | <input checked="" type="checkbox"/> Yes   | <input type="checkbox"/> No |



SELECTRA PRO S  
CLINICAL SYSTEMS

### Instrument Calibration/Validation Certificate

|                        |   |                              |                              |
|------------------------|---|------------------------------|------------------------------|
| <b>Customer Name</b>   | Niraya Diagnostics Centre, Trivandrum             |                              |                              |
| <b>Address</b>         | Main Road, Kunnathukal, Karakonam P O, Trivandrum |                              |                              |
| <b>Instrument</b>      | SELECTRA PRO S Lite                               |                              |                              |
| <b>Serial No.</b>      | 18-4522   |                              |                              |
| <b>Contract Type</b>   | WARANTY <input type="checkbox"/>                  | AMC <input type="checkbox"/> | RRC <input type="checkbox"/> |
| <b>Calibration</b>     | Comm. Date : 20-11-2021                           |                              | Exp Date : 19-11-2022        |
| <b>Validation Date</b> | 20-11-2021  |                              |                              |
| <b>Next due date</b>   | 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   |          |
| Filter 405nm | 1.2 to 2.6   |          |
| Filter 505nm | 0.8 to 2.6   |          |
| Filter 546nm | 0.8 to 2.6   |          |
| Filter 578nm | 0.6 to 2.6   |          |
| Filter 620nm | 0.6 to 2.6   |          |
| Filter 660nm | 0.6 to 2.6   |          |
| Filter 700nm | 0.6 to 2.6   |          |

### 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%       |             |      |
| Check-R (left) | 1.75 (1.500-2.000) | < 1%       |             |      |

### 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      |                  |             |                  |             |
| Cholesterol  |                  |             |                  |             |
| LDL          |                  |             |                  |             |
| Microalbumin |                  |             |                  |             |
| CRP          |                  |             |                  |             |
| RF           |                  |             |                  |             |
| ASO          |                  |             |                  |             |
| IGE          |                  |             |                  |             |

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**



**INSTALLATION QUALIFICATION**

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

## INSTALLATION, OPERATIONAL AND PERFORMANCE QUALIFICATION

### Transport damages

Package damaged             Yes                             No

Parts damaged                 Yes                             No

If yes, please specify:

### Initial check:

Parts missing?

| Part Number | Part Description |
|-------------|------------------|
|             |                  |
|             |                  |
|             |                  |
|             |                  |

(Check against packing list)

Yes → Please specify parts

No

\* 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”

**INSTALLATION, OPERATIONAL AND PERFORMANCE QUALIFICATION**

Run 20 x Check-S and 20 x Check-R as QC samples (for XL instruments left and right)

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%       |             |      |
| Check-R | 1.75 (1.500-2.000) | < 1%       |             |      |

-----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  |                  |   |                  |
| <b>Customer's comments</b>   |                  | <b>Installer's comments</b>   |                  |
|  |                  | Successfully verified all installation criteria as per manufacturer recommendation. |                  |
| <b>Customer<br/>(Name and Position)</b>  | <b>Signature</b> | <b>Installer<br/>(Name and Position)</b>  | <b>Signature</b> |
| Gautham Hospital -<br>Panayapally  |                  | Amal V K<br>Field Service Engineer<br>LabX Medical Systems                          |                  |
| This document is prepared and signed in duplicate. Each page must be initialled by the installer.  |                  |   |                  |

**INSTALLATION, OPERATIONAL AND PERFORMANCE QUALIFICATION**

**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 |
|--------|------------------|-------------|------------------|-------------|
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|        |                  |             |                  |             |
|        |                  |             |                  |             |

-----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  |                  |  |                  |
| <b>Customer's comments</b>   |                  | <b>Installer's comments</b>  |                  |
|  |                  | Successfully verified all operational criteria as per manufacturer recommendation. |                  |
| <b>Customer<br/>(Name and Position)</b>  | <b>Signature</b> | <b>Installer<br/>(Name and Position)</b>   | <b>Signature</b> |
| Gautham Hospital -<br>Panayapally  |                  | Amal V K<br>Field Service Engineer<br>LabX Medical Systems                         |                  |
|  |                  |  |                  |