

## CALIBRATION REPORT

**Customer Name** : Primus Pathology & Diagnostics LLP  
**Address** : Shop No 14, 15, And 16 On Ground Floor,  
Sheetal Darshan Chs Ltd, Mira Road, Thane- 401107.  
**Instrument Model** : ST-200 CL Plus Electrolyte Analyzer  
**Serial no** : STCLP -0086  
**Calibration Date** : 18.10.2022  
**Calibration Due Date:** 17.10.2023

As per the Standard Operating procedure of ST-200 CL Plus Electrolyte Analyzer, the instrument has been calibrated.

As per method mentioned into manuals/sop, the Known Value Sample/Control run on the analyzer for five times for the Electrolyte parameters. All obtained values are in the range and CV values were checked. CV values were within a normal range as mentioned in performance certificate. This indicated that an instrument is performing accurately and precisely.

Hence, we certified that ST-200 CL Plus Electrolyte Analyzer is calibrated.

  
  
(Service Engineer)

**INSTALLATION QUALIFICATION – IQ**

**OPERATIONAL QUALIFICATION – OQ**

**&**

**PERFORMANCE QUALIFICATION - PQ**



**ST-200 CL PLUS  
Electrolyte Analyzer**

**INSTALLATION QUALIFICATON**

**FOR**

**Primus Pathology & Diagnostics LLP**

Shop No 14, 15, And 16 On Ground Floor,  
Sheetal Darshan Chs Ltd,  
Mira Road, Thane- 401107.

**BY**

**NIRMAAN BIOMEDICALS**

**CERTIFICATION OF INSTALLATION**



**INSTRUMENT NAME** : ST-200 CL PLUS Electrolyte Analyzer  
**SERIAL NUMBER** : STCLP -0086  
**CUSTOMER NAME** : Primus Pathology & Diagnostics LLP  
**ADDRESS** : Shop No 14, 15, And 16 On Ground Floor,  
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Mira Road, Thane- 401107.

THE UNDESIGNED PERFORMERS CERTIFY THAT THE INSTALLATION QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR THE INSTRUMENT STATED ABOVE.

**SERVICE DIVISION :**

**Signature** :   
**Name** :   
**Designation** : (Service Engineer)  
**Distributor** :

**QUALITY DIVISION :**

**Signature** :   
**Name** :   
**Designation** : (QC Engineer)  
**Distributor** :

**INSTALLATION REPORT**

**CUSTOMER NAME** : Primus Pathology & Diagnostics LLP  
**PLACE** : Mira Road  
**DEPARTMENT** : DIAGNOSTICS CENTER.  
**CONTACT PERSON** :  
**INSTRUMENT NAME** : ST-200 CL PLUS Electrolyte Analyzer  
**SERIAL NUMBER** : STCLP -0086  
**INSTALLATION DATE** : 18.10.2023

THE ELECTROLYTE ANALYZER WAS INSTALLED ALONG WITH THE NECESSARY STANDARD ACCESSORIES, ALL BASIC REQUIREMENTS AND ADJUSTMENTS WERE CHECKED AND FOUND TO BE SATISFACTORY. THE PRELIMINARY STANDARDIZATION OF THE ELECTROLYTE ANALYZER AND THE TRAINING WERE PROVIDED TO THE COMPLETE SATISFACTION OF THE CUSTOMER. THE ELECTROLYTE ANALYZER IS FOUND TO BE WORKING SATISFACTORILY.

For Nirmaan Biomedicals



(Service Engineer)

INSTRUMENT SETUP

S No	ITEM DESCRIPTION	STATUS
1	SOFTWARE VERSION Up to date	INSTALLED
2	REAGENT PACK	INSTALLED
3	QUALITY CONTROL	TESTED

OPERATION INSPECTION

- POWER SUPPLY CHECKED.
- NO UNUSUAL NOISE PRODUCED IN THE SYSTEM.

For Nirmaan Biomedicals



(Service Engineer)



**INSTALLATION QUALIFICATION**

**INSTRUMENT NAME** : ST-200 CL PLUS Electrolyte Analyzer  
**SERIAL NUMBER** : STCLP -0086  
**CUSTOMER NAME** : Primus Pathology & Diagnostics LLP  
**ADDRESS** : Shop No 14, 15, And 16 On Ground Floor,  
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**INSTALLATION REQUIREMENTS FOR THE INSTRUMENT:**

REQUIREMENTS	ACCEPTABLE RANGE	OBSERVED RANGE
Input Voltage	220±10AC	217±5V AC
Line Frequency	50/60 HZ	50HZ
Ambient Temperature	15-45 degree	37 degree

For Nirmaan Biomedicals



(Service Engineer)



**ST-200 CL PLUS  
Electrolyte Analyzer**

**OPERATIONAL QUALIFICATION**

**For  
Primus Pathology & Diagnostics LLP**

Shop No 14, 15, And 16 On Ground Floor,  
Sheetal Darshan Chs Ltd,  
Mira Road, Thane- 401107.

**BY  
NIRMAAN BIOMEDICALS**



CERTIFICATION OF OPERATION



**INSTRUMENT NAME** : ST-200 CL PLUS Electrolyte Analyzer  
**SERIAL NUMBER** : STCLP -0086  
**CUSTOMER NAME** : Primus Pathology & Diagnostics LLP  
**ADDRESS** : Shop No 14, 15, And 16 On Ground Floor,  
Sheetal Darshan Chs Ltd,  
Mira Road, Thane- 401107.

THE UNDESIGNED PERFORMERS CERTIFY THAT THE OPERATIONAL QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR THE INSTRUMENT STATED ABOVE.

SERVICE DIVISION :

**Signature** :   
**Name** :   
**Designation** : (Service Engineer)  
**Distributor** : Nirmaan Biomedicals

QUALITY DIVISION :

**Signature** :   
**Name** :   
**Designation** : (QC Engineer)  
**Distributor** : Nirmaan Biomedicals

**PERFORMANCE ANALYSIS**



The performance of the system has been verified by the following process.

Three replicates of the control Level 1 & Level 2 & Level 3 have been run and the statistical analysis of the data is performed. The results should be within control range with following precision limits.



**THE UNDERSIGNED PERFORMERS CERTIFY THAT THE PERFORMANCE QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR THE INSTRUMENT STATED ABOVE.**

A separate annexure has been attached along with this document

**SERVICE DIVISION :**

Signature :   
Name :   
Designation : (Service Engineer)  
Distributor : Nirmaan Biomedicals

**QUALITY DIVISION :**

Signature :   
Name :   
Designation : ( QC Engineer)  
Distributor : Nirmaan Biomedicals

OPERATIONAL QUALIFICATION OF THE INSTRUMENT:

DESCRIPTION	STATUS	REMARKS
POWER SUPPLY	SELF CHECK	PASSED
ELECTRONICS	SELF CHECK	PASSED
REAGENT PACK	SELF CHECK	PASSED
HARDWARE	SELF CHECK	PASSED
FLOW PATH	SELF CHECK	PASSED

For Nirmaan Biomedicals



(Service Engineer)