

ST-200 Plus CALIBRATION CERTIFICATE

CUSTOMERS NAME: Likhitha's Diagnostics & Speciality Lab, ZenRise
.....

ADDRESS: Plot No. 201, Mythrinagar, Madinaguda, Hyderabad - 500049
.....

CONTACT NO:

SERIAL NO OF THE INSTRUMENT: ST - 6826
.....

CALIBRATION DATE: 16/08/2021
.....

VALID TILL: 15/08/2022
.....

CALIBRATION DONE BY: Mr. KIRAN DATE
.....

Calibration Slopes:				
S.No.	Na ⁺	K ⁺	iCa	Cl ⁻
1	65.13	63.79	34.12	50.93
2	64.88	63.40	35.01	51.06
3	64.78	63.42	35.12	51.02
Mean	64.93	63.53	34.75	51.00
Ranges	35-100mV/dec	35-100 mV/dec	15 - 50 mV/dec	30 - 100 mV/dec
Status	O.K	O.K	O.K	O.K

Sensa Core Medical Instrumentation Pvt. Ltd.

Plot, No: 3, Export Promotion Industrial Park, Pashamylaram, Medak (Dist), 502307, T.S. INDIA. Tel: +08455 - 223400, www.sensacore.com

Quality Control 1:		Lot:- UQC2006A-L1			Exp: Dec 2021
S.No.	Na+	K+	iCa	Cl ⁻	
1	122.7	1.96	1.88	83.6	
2	122.0	1.97	1.87	83.7	
3	121.8	1.99	1.89	83.0	
Mean	122.1	1.97	1.88	83.4	
Ranges	113-128 mmol/L	1.5-2.5mmol/L	1.25-2.25mmol/L	76-90mmol/L	
Status	O.K	O.K	O.K	O.K	
Quality Control 2:		Lot:- UQC2006A-L2			Exp: Dec 2021
S.No.	Na+	K+	iCa	Cl ⁻	
1	141.4	3.91	1.24	103.5	
2	141.6	3.91	1.20	103.4	
3	141.5	3.93	1.25	102.9	
Mean	141.5	3.91	1.23	103.2	
Ranges	132-153mmol/L	3.5-4.7mmol/L	0.62-1.62mmol/L	95-111mmol/L	
Status	O.K	O.K	O.K	O.K	
Quality Control 3:		Lot:- UQC2006A-L3			Exp: Dec 2021
S.No.	Na+	K+	iCa	Cl ⁻	
1	159.3	5.89	0.70	120.8	
2	160.1	5.85	0.73	121.0	
3	160.5	5.91	0.71	121.5	
Mean	159.9	5.88	0.71	121.1	
Ranges	152-164mmol/L	5.4-6.8mmol/L	0.75-1.15mmol/L	116-128mmol/L	
Status	O.K	O.K	O.K	O.K	



Signature of Engineer

DATE: 16/08/2021

Signature of Doctor

DATE: 16.08.2021

Sensa Core Medical Instrumentation Pvt. Ltd.

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INSTALLATION QUALIFICATION – IQ
OPERATIONAL QUALIFICATION – OQ
&
PERFORMANCE QUALIFICATION - PQ

**ST-200 Pro
Electrolyte Analyzer**

INSTALLATION QUALIFICATION

FOR

Likhitha's Diagnostics & Speciality Lab

ZenRise, Plot No. 201, Mythinagar,
NH – 65, Madinaguda, Miyapur
Hyderabad, 500049

BY

SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

CERTIFICATION OF OPERATION

INSTRUMENT NAME : ST-200Pro
SERIAL NUMBER : ST - 6826
CUSTOMER NAME : Likhitha's Diagnostic s and Speciality Lab.
ADDRESS : ZenRise, Plot No. 201, Mythrinagar,
NH – 65, Madinaguda, Miyapur, Hyderabad, 500049


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

ENGINEER



Signature :
Name : MR. KIRAN DATE
Designation : NATIONAL SERVICE MANAGER
Company : SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

QUALITY MANAGER

Signature : 
Name : MR. POSI BABU V
Designation : QA/QC TEAM LEADER
Company : SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

Sensa Core Medical Instrumentation Pvt. Ltd.

Plot, No: 3, Export Promotion Industrial Park, Pashamylaram, Medak (Dist), 502307, T.S. INDIA.
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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 SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.



KIRAN DATTA
(National Manager-Service)

Sensa Core Medical Instrumentation Pvt. Ltd.

Plot, No: 3, Export Promotion Industrial Park, Pashamylaram, Medak (Dist), 502307, T.S. INDIA.
Tel: +08455 - 223400, www.sensacore.com

**ST-200 PRO
Electrolyte Analyzer**

**OPERATIONAL QUALIFICATION
FOR**

Likhitha's Diagnostics & Speciality Lab

ZenRise, Plot No. 201, Mythrinagar,
NH – 65, Madinaguda, Miyapur
Hyderabad, 500049

**BY
SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.**

CERTIFICATION OF INSTALLATION

INSTRUMENT NAME : ST-200 Pro
SERIAL NUMBER : ST - 6826
CUSTOMER NAME : Likhitha's Diagnostic s and Speciality Lab.
ADDRESS : ZenRise, Plot No. 201, Mythrinagar,
NH – 65, Madinaguda, Miyapur, Hyderabad, 500049

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

ENGINEER



Signature :
Name : MR. KIRAN DATE
Designation : NATIONAL SERVICE MANAGER
Company : SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

QUALITY MANAGER

Signature : V. POSI BABU
Name : MR. POSI BABU V
Designation : QA/QC TEAM LEADER
Company : SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

Sensa Core Medical Instrumentation Pvt. Ltd.

Plot, No: 3, Export Promotion Industrial Park, Pashamylaram, Medak (Dist), 502307, T.S. INDIA.
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INSTALLATION REPORT

CUSTOMER NAME : Likhitha's Diagnostic s and Speciality Lab.
PLACE : Zenrise, Miyapur, Hyderabad – 49
DEPARTMENT : Pathology Laboratory
INSTRUMENT NAME : ST 200 Pro
SERIAL NUMBER : ST - 6826
INSTALLATION DATE : 16.08.2021
WARRANTY EXPIRY : 15.08.2022

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 SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.



KIRAN DATTA
(National Manager-Service)

Sensa Core Medical Instrumentation Pvt. Ltd.

Plot, No: 3, Export Promotion Industrial Park, Pashamylaram, Medak (Dist), 502307, T.S. INDIA.
Tel: +08455 - 223400, www.sensacore.com

INSTRUMENT SETUP

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

OPERATION INSPECTION

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

FOR SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.


KIRAN DATE
(National Manager-Service)

INSTALLATION QUALIFICATION

INSTRUMENT NAME : ST-200PRO
SERIAL NUMBER : ST 6826
CUSTOMER NAME : Likhitha's Diagnostic s and Speciality Lab.
ADDRESS : ZenRise, Miyapur, Hyderabad – 49

INSTALLATION REQUIREMENTS FOR THE INSTRUMENT:

REQUIREMENTS	ACCEPTABLE RANGE	OBSERVED RANGE
Input Voltage	220 \pm 10AC	217 \pm 5V AC
Line Frequency	50/60 HZ	50HZ
Ambient Temperature	10-35 degree	24 degree

FOR SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.


KIRAN DATTA
(National Manager-Service)

**ST-200Pro
Electrolyte Analyzer**

PERFORMANCE QUALIFICATION

FOR

Likhitha's Diagnostics & Speciality Lab

ZenRise, Plot No. 201, Mythrinagar,
NH – 65, Madinaguda, Miyapur
Hyderabad, 500049

BY

SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

PERFORMANCE ANALYSIS

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

Ten 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

ENGINEER



Signature :
Name : MR. KIRAN DATE
Designation : NATIONAL SERVICE MANAGER
Company : SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

QUALITY MANAGER

Signature : *V. Posi Babu*
Name : MR. POSI BABU V
Designation : QA/QC TEAM LEADER
Company : SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

Likhitha's Diagnostics and Speciality Lab, ZenRise, Madinaguda, Hyderabad

Precision Study - Sodium (mmol/L)

Equipment Name : Sensacore ST200 Plus

Equip S.N. - ST - 6826

Control Lot No. : UQCA2103A

Expiry Date : 28.02.2023

Date of Processing : 16.08.2021

TEa = ± 4 mmol/L

S.N.	Control L1	Control L2	Control L3
1	120.3	139.9	159.7
2	120.1	139.6	160.1
3	119.8	139.7	159.9
4	119.7	139.8	159.9
5	119.9	139.4	159.8
Mean	119.96	139.68	159.88
SD	0.24	0.19	0.15
%CV	0.20	0.14	0.09

Processed By : Mr. Shiva

Date : 16.08.2021

Verified By: DR Ashoka Varshini

Date : 16.08.2021

Likhitha's Diagnostics and Speciality Lab, ZenRise, Madinaguda, Hyderabad

Precision Study - Potassium (mmol/L)

Equipment Name : Sensacore ST200 Plus

Equip S.N. - ST - 6826

Control Lot No. : UQCA2103A

Expiry Date : 28.02.2023

Date of Processing : 16.08.2021

TEa = ± 0.3 mmol/L

S.N.	Control L1	Control L2	Control L3
1	1.7	3.78	6.07
2	1.69	3.77	6.09
3	1.69	3.77	6.08
4	1.69	3.77	6.08
5	1.68	3.76	6.07
Mean	1.69	3.77	6.08
SD	0.01	0.01	0.01
%CV	0.42	0.19	0.14

Processed By : Mr. Shiva

Date : 16.08.2021

Verified By: DR Ashoka Varshini

Date : 16.08.2021

Likhitha's Diagnostics and Speciality Lab, ZenRise, Madinaguda, Hyderabad

Precision Study - Chloride (mmol/L)

Equipment Name : Sensacore ST200 Plus

Equip S.N. - ST - 6826

Control Lot No. : UQCA2103A

Expiry Date : 28.02.2023

Date of Processing : 16.08.2021

TEa = ± 5.0 %

S.N.	Control L1	Control L2	Control L3
1	78.00	99.9	122.9
2	78.00	100.6	122.7
3	78.30	100.5	122.9
4	78.40	100.6	122.7
5	78.10	100.8	123.0
Mean	78.16	100.48	122.84
SD	0.18	0.34	0.13
%CV	0.23	0.34	0.11

Processed By : Mr. Shiva

Date : 16.08.2021

Verified By: DR Ashoka Varshini

Date : 16.08.2021

Likhitha's Diagnostics and Speciality Lab, ZenRise, Madinaguda, Hyderabad

Precision Study (Patient Samples)

Equipment Name : Sensacore ST200 Plus

Control Lot No. : UQCA2103A

Date of Processing : 16.08.2021

Equip S.N. - ST - 6826

Expiry Date : 28.02.2023

S.N.	Sample ID	Sodium	Potassium	Chloride
1	Pooled Patient Serum Sample	132.1	8.33	104.1
2		137.0	8.80	100.0
3		136.9	8.75	100.0
4		136.4	8.76	99.9
5		137.2	8.73	100.0
6		137	8.79	100.0
7		136.7	8.79	100.0
8		136.7	8.75	100.1
9		137.5	8.77	100.0
10		137.0	8.82	100.2
Mean		136.45	8.73	100.43
SD		1.56	0.14	1.29
%CV		1.14	1.64	1.29
TEa		± 4 mmol/L	± 0.3 mmol/L	± 4 mmol/L

Processed By : Mr. Shiva *Shiva*

Date : 16.08.2021

P. Ashoka Varshini
Verified By: Dr Ashoka Varshini

Date : 16.08.2021

ANALYZE TYPE: QUALITY CONTROL
Aug-16-21 10:55:34

SENSACORE
LEVEL 1

ANALYZE QC

Na = 120.3 mmol/L LOW
K = 1.70 mmol/L
iCa = 1.86 mmol/L
Cl = 78.0 mmol/L HIGH

Aug-16-21 10:57:08

SENSACORE
LEVEL 1

ANALYZE QC

Na = 120.1 mmol/L
K = 1.69 mmol/L LOW
iCa = 1.85 mmol/L
Cl = 78.0 mmol/L HIGH

Aug-16-21 10:58:29

SENSACORE
LEVEL 1

ANALYZE QC

Na = 119.8 mmol/L
K = 1.69 mmol/L LOW
iCa = 1.85 mmol/L
Cl = 78.3 mmol/L HIGH

Aug-16-21 10:59:54

SENSACORE
LEVEL 1

ANALYZE QC

Na = 119.7 mmol/L
K = 1.69 mmol/L LOW
iCa = 1.85 mmol/L
Cl = 78.4 mmol/L HIGH

Aug-16-21 11:01:17

SENSACORE
LEVEL 1

ANALYZE QC

Na = 119.9 mmol/L
K = 1.68 mmol/L LOW
iCa = 1.85 mmol/L
Cl = 78.1 mmol/L HIGH

Aug-16-21 11:02:40

SENSACORE
LEVEL 2

ANALYZE QC

Na = 139.9 mmol/L HIGH
K = 3.78 mmol/L LOW
iCa = 1.25 mmol/L LOW
Cl = 99.9 mmol/L HIGH

Aug-16-21 11:04:24

SENSACORE
LEVEL 2

ANALYZE QC

Na = 139.6 mmol/L HIGH
K = 3.77 mmol/L LOW
iCa = 1.24 mmol/L LOW
Cl = 100.6 mmol/L HIGH

Aug-16-21 11:05:50

SENSACORE
LEVEL 2

ANALYZE QC

Na = 139.7 mmol/L HIGH
K = 3.77 mmol/L LOW
iCa = 1.24 mmol/L LOW
Cl = 100.5 mmol/L HIGH

Aug-16-21 11:07:13

SENSACORE
LEVEL 2

ANALYZE QC

Na = 139.8 mmol/L HIGH
K = 3.77 mmol/L LOW
iCa = 1.24 mmol/L LOW
Cl = 100.6 mmol/L HIGH

Aug-16-21 11:08:38

SENSACORE
LEVEL 2

ANALYZE QC

Na = 139.4 mmol/L HIGH
K = 3.76 mmol/L LOW
iCa = 1.24 mmol/L LOW
Cl = 100.8 mmol/L HIGH

Aug-16-21 11:10:15

SENSACORE
LEVEL 3

ANALYZE QC

Na = 159.7 mmol/L HIGH
K = 6.07 mmol/L
iCa = 0.77 mmol/L HIGH
Cl = 122.9 mmol/L HIGH

Aug-16-21 11:12:25

SENSACORE
LEVEL 3

ANALYZE QC

Na = 160.1 mmol/L HIGH
K = 6.09 mmol/L
iCa = 0.76 mmol/L HIGH
Cl = 122.7 mmol/L HIGH

Aug-16-21 11:13:59

SENSACORE
LEVEL 3

ANALYZE QC

Na = 159.9 mmol/L HIGH
K = 6.08 mmol/L
iCa = 0.75 mmol/L HIGH
Cl = 122.9 mmol/L HIGH

Aug-16-21 11:15:24

SENSACORE
LEVEL 3

ANALYZE QC

Na = 159.9 mmol/L HIGH
K = 6.08 mmol/L
iCa = 0.77 mmol/L HIGH
Cl = 122.7 mmol/L HIGH

Aug-16-21 11:16:45

SENSACORE
LEVEL 3

ANALYZE QC

Na = 159.8 mmol/L HIGH
K = 6.07 mmol/L
iCa = 0.76 mmol/L HIGH
Cl = 123.0 mmol/L HIGH

Aug-16-21 11:18:09

ANALYZE TYPE : SERUM/PLASMA
Aug-16-21 11:19:29

PATIENT ID:000001
SENSACORE

ANALYZE SAMPLE

Na = 132.1 mmol/L LOW
K = 8.33 mmol/L HIGH
iCa = 1.07 mmol/L LOW
Cl = 104.1 mmol/L

Aug-16-21 11:20:55

PATIENT ID:000002
SENSACORE

ANALYZE SAMPLE

Na = 137.0 mmol/L
K = 8.80 mmol/L HIGH
iCa = 1.14 mmol/L
Cl = 100.0 mmol/L

Aug-16-21 11:22:18

PATIENT ID:000003
SENSACORE

ANALYZE SAMPLE

Na = 136.9 mmol/L
K = 8.75 mmol/L HIGH
iCa = 1.16 mmol/L
Cl = 100.0 mmol/L

Aug-16-21 11:23:47

PATIENT ID:000004
SENSACORE

ANALYZE SAMPLE

Na = 136.4 mmol/L
K = 8.76 mmol/L HIGH
iCa = 1.15 mmol/L
Cl = 99.9 mmol/L

Aug-16-21 11:25:06

PATIENT ID:000005
SENSACORE

ANALYZE SAMPLE

Na = 137.2 mmol/L
K = 8.73 mmol/L HIGH
iCa = 1.17 mmol/L
Cl = 100.0 mmol/L

Aug-16-21 11:26:34

PATIENT ID:000006
SENSACORE

ANALYZE SAMPLE

Na = 137.0 mmol/L
K = 8.79 mmol/L HIGH
iCa = 1.16 mmol/L
Cl = 100.0 mmol/L

Aug-16-21 11:28:11

PATIENT ID:000007
SENSACORE

ANALYZE SAMPLE

Na = 136.7 mmol/L
K = 8.79 mmol/L HIGH
iCa = 1.16 mmol/L
Cl = 100.0 mmol/L

Aug-16-21 11:29:36

PATIENT ID:000008
SENSACORE

ANALYZE SAMPLE

Na = 136.7 mmol/L
K = 8.75 mmol/L HIGH
iCa = 1.16 mmol/L
Cl = 100.1 mmol/L

Aug-16-21 11:30:57

PATIENT ID:000009
SENSACORE

ANALYZE SAMPLE

Na = 137.5 mmol/L
K = 8.77 mmol/L HIGH
iCa = 1.17 mmol/L
Cl = 100.0 mmol/L

Aug-16-21 11:32:19

PATIENT ID:000010
SENSACORE

ANALYZE SAMPLE

Na = 137.0 mmol/L
K = 8.82 mmol/L HIGH
iCa = 1.16 mmol/L
Cl = 100.2 mmol/L

Aug-16-21 11:33:44