

**ST-200 aQua CALIBRATION CERTIFICATE**

**CUSTOMERS NAME: Likhithas Diagnostics and Speciality Lab**  
.....

**ADDRESS: H. No. 1-8-65/A, North Kamalanagar, Above Andhra Bank, ECIL,  
Hyderabad -500062.**  
.....

**CONTACT NO: 8639830362**

**SERIAL NO OF THE INSTRUMENT: **ST-06221(F)****  
.....

**CALIBRATION DATE: **08.07.2021****  
.....

**VALID TILL: **07.07.2022****  
.....

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

<b>Calibration Slopes:</b>				
<b>S.No.</b>	<b>Na<sup>+</sup></b>	<b>K<sup>+</sup></b>	<b>iCa</b>	<b>Cl<sup>-</sup></b>
1	64.69	63.56	34.78	50.89
2	64.80	63.54	35.00	51.02
3	64.88	63.62	35.08	51.06
<b>Mean</b>	<b>64.79</b>	<b>63.57</b>	<b>34.95</b>	<b>50.99</b>
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

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223400, [www.sensacore.com](http://www.sensacore.com)

<b>Quality Control L1 :</b>		Lot:- UQCA2103A – L1			Exp: 28.02.2023
S.No.	Na+	K+	iCa	Cl <sup>-</sup>	
1	123.4	1.61	1.86	84.6	
2	122.7	1.65	1.85	84.9	
3	124.9	1.73	1.84	88.7	
Mean	123.67	1.66	1.85	86.07	
Ranges	110 - 128 mmol/L	1.46 - 2.46 mmol/L	1.34 - 2.34 mmol/L	72 - 90 mmol/L	
Status	O.K	O.K	O.K	O.K	
<b>Quality Control 2:</b>		Lot:- UQCA2103A –L2			Exp: 28.02.2023
S.No.	Na+	K+	iCa	Cl <sup>-</sup>	
1	143.2	4.09	1.32	104.6	
2	143.1	4.08	1.32	104.7	
3	143.1	4.08	1.32	104.7	
Mean	143.13	4.08	1.32	104.67	
Ranges	134 - 148 mmol/L	3.4 - 4.4 mmol/L	0.70 - 1.70 mmol/L	94 - 108 mmol/L	
Status	O.K	O.K	O.K	O.K	
<b>Quality Control 3:</b>		Lot:- UQCA2103A –L2			Exp: 28.02.2023
S.No.	Na+	K+	iCa	Cl <sup>-</sup>	
1	163.7	6.62	0.87	124.9	
2	164	6.64	0.87	125	
3	164.4	6.67	0.86	125.2	
Mean	164.03	6.64	0.87	125.03	
Ranges	150 - 168 mmol/L	5.40 - 6.80 mol/L	0.21 - 1.21 mmol/L	111 - 129 mmol/L	
Status	O.K	O.K	O.K	O.K	



Signature of Engineer

Date: 08.07.2021

Signature of Doctor

Date: 08.07.2021

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ANALYZE TYPE: QUALITY CONTROL  
Jul-08-21 10:46:07

SENSACORE  
LEVEL 1

ANALYZE QC

Na :123.4 mmol/L  
K :1.61 mmol/L  
iCa:1.86 mmol/L  
Cl :84.6 mmol/L HIGH

Jul-08-21 10:59:34

SENSACORE  
LEVEL 1

ANALYZE QC

Na :122.7 mmol/L  
K :1.65 mmol/L  
iCa:1.85 mmol/L  
Cl :84.9 mmol/L HIGH

Jul-08-21 11:01:25

SENSACORE  
LEVEL 1

ANALYZE QC

Na :124.9 mmol/L  
K :1.73 mmol/L  
iCa:1.84 mmol/L  
Cl :88.7 mmol/L HIGH

Jul-08-21 11:03:14

SENSACORE  
LEVEL 2

ANALYZE QC

Na :143.2 mmol/L HIGH  
K :4.09 mmol/L HIGH  
iCa:1.32 mmol/L HIGH  
Cl :104.6 mmol/L HIGH

Jul-08-21 11:05:09

SENSACORE  
LEVEL 2

ANALYZE QC

Na :143.1 mmol/L HIGH  
K :4.08 mmol/L HIGH  
iCa:1.32 mmol/L HIGH  
Cl :104.7 mmol/L HIGH

Jul-08-21 11:06:54

SENSACORE  
LEVEL 2

ANALYZE QC

Na :143.1 mmol/L HIGH  
K :4.08 mmol/L HIGH  
iCa:1.32 mmol/L HIGH  
Cl :104.7 mmol/L HIGH

Jul-08-21 11:09:13

SENSACORE  
LEVEL 3

ANALYZE QC

Na :163.7 mmol/L HIGH  
K :6.62 mmol/L HIGH  
iCa:0.87 mmol/L HIGH  
Cl :124.9 mmol/L HIGH

Jul-08-21 11:11:05

SENSACORE  
LEVEL 3

ANALYZE QC

Na :164.0 mmol/L HIGH  
K :6.64 mmol/L HIGH  
iCa:0.87 mmol/L HIGH  
Cl :125.0 mmol/L HIGH

Jul-08-21 11:14:06

SENSACORE  
LEVEL 3

ANALYZE QC

Na :164.4 mmol/L HIGH  
K :6.67 mmol/L HIGH  
iCa:0.86 mmol/L HIGH  
Cl :125.2 mmol/L HIGH

Jul-08-21 11:16:07

*[Handwritten signature]*  
8/7/2021.

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

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**ST-200 aQua  
Electrolyte Analyzer**

**INSTALLATION QUALIFICATION**

**FOR**

***Likhitha's Diagnostics & Speciality Lab***  
Kapra sainikpuri, Opp.Srikara Hospital,  
Bedside Andhra Bank, ECIL, North Kamala Nagar,  
Hyderabad, Telangana 500062

**BY**

**SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.**

**Sensa Core Medical Instrumentation Pvt. Ltd.**

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**CERTIFICATION OF OPERATION**

**INSTRUMENT NAME** : ST-200aQua  
**SERIAL NUMBER** : STAQW-06221  
**CUSTOMER NAME** : Likhitha's Diagnostic Lab.  
**ADDRESS** : ECIL , Hyderabad

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 : 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.**

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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 DATE  
(National Manager-Service)

**Sensa Core Medical Instrumentation Pvt. Ltd.**

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**ST-200 aQua  
Electrolyte Analyzer**

**OPERATIONAL QUALIFICATION**

**FOR**

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Kapra sainikpuri, Opp.Srikara Hospital,  
Bedside Andhra Bank, ECIL, North Kamala Nagar,  
Hyderabad, Telangana 500062

**BY**

**SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.**



**CERTIFICATION OF INSTALLATION**

**INSTRUMENT NAME** : ST-200 aQua  
**SERIAL NUMBER** : STAQW-6221  
**CUSTOMER NAME** : Likhitha's Diagnostic Lab.  
**ADDRESS** : ECIL, Hyderabad

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.**

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**INSTALLATION REPORT**

**CUSTOMER NAME** : Likhitha's Diagnostic  
**PLACE** : ECIL , Hyderabad  
**DEPARTMENT** : Pathology Laboratory  
**INSTRUMENT NAME** : ST 200 aQua  
**SERIAL NUMBER** : STAQW-06221  
**INSTALLATION DATE** : 09.07.2019  
**WARRANTY EXPIRY** : 08.07.2022

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 DATE  
(National Manager-Service)

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INSTRUMENT SETUP

<b>S No</b>	<b>ITEM DESCRIPTION</b>	<b>STATUS</b>
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  
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INSTALLATION QUALIFICATION

**INSTRUMENT NAME** : ST-200aQua  
**SERIAL NUMBER** : STAQW-06221  
**CUSTOMER NAME** : Likhitha's Diagnostic Lab.  
**ADDRESS** : ECIL , Hyderabad

INSTALLATION REQUIREMENTS FOR THE INSTRUMENT:

<b>REQUIREMENTS</b>	<b>ACCEPTABLE RANGE</b>	<b>OBSERVED RANGE</b>
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 DATE  
(National Manager-Service)

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**ST-200aQua  
Electrolyte Analyzer**

**PERFORMANCE QUALIFICATION**

**FOR**

***Likhitha's Diagnostics & Speciality Lab***  
Kapra sainikpuri, Opp.Srikara Hospital,  
Bedside Andhra Bank, ECIL, North Kamala Nagar,  
Hyderabad, Telangana 500062

**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**

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Name : MR. POSI BABU V  
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Likhithas Diagnostics and Speciality Lab, ECIL, Hyderabad

### Electrolytes Precision Study

Equipment : Sensa Core ST200 aQua

Equipment S.N. : STAQW - 06221

Date : 10.02.2022

Pooled Patient Serum Sample

S.N.	SODIUM	POTASSIUM	CHLORIDE
1	139.7	4.72	100.3
2	139.6	4.77	102.4
3	141.2	4.86	102.0
4	141.0	4.90	101.7
5	141.2	4.93	102.4
<b>Mean</b>	<b>140.5</b>	<b>4.84</b>	<b>101.8</b>
<b>SD</b>	<b>0.82</b>	<b>0.09</b>	<b>0.87</b>
<b>%CV</b>	<b>0.58</b>	<b>1.83</b>	<b>0.85</b>
<b>MU</b>	<b>1.14</b>	<b>3.59</b>	<b>1.67</b>
CLIA Specifications	± 4 mmol/L	± 0.3 mmol/L	± 5%

Processed By : Mr. Ch. Vamshi, Sr. Lab Technician

Verified By : Quality Manager



PATIENT ID:011111  
SENSACORE

01

ANALYZE SAMPLE

Na = 139.7 mmol/L  
K = 4.72 mmol/L  
iCa = 1.17 mmol/L  
Cl = 100.3 mmol/L

Feb-10-22 15:00:20

PATIENT ID:022222  
SENSACORE

02

ANALYZE SAMPLE

Na = 139.6 mmol/L  
K = 4.77 mmol/L  
iCa = 1.13 mmol/L  
Cl = 102.4 mmol/L

Feb-10-22 15:02:26

PATIENT ID:033333  
SENSACORE

03

ANALYZE SAMPLE

Na = 141.2 mmol/L  
K = 4.86 mmol/L  
iCa = 1.15 mmol/L  
Cl = 102.0 mmol/L

Feb-10-22 15:04:07

PATIENT ID:044444  
SENSACORE

04

ANALYZE SAMPLE

Na = 141.0 mmol/L  
K = 4.90 mmol/L  
iCa = 1.16 mmol/L  
Cl = 101.7 mmol/L

Feb-10-22 15:05:48

PATIENT ID:055555  
SENSACORE

05

ANALYZE SAMPLE

Na = 141.2 mmol/L  
K = 4.93 mmol/L  
iCa = 1.15 mmol/L  
Cl = 102.4 mmol/L

Feb-10-22 15:07:28