



**Sens-E-Lyte  
Electrolyte Analyzer**

**INSTALLATION QUALIFICATION**

**FOR**

**Shruti Clinical Laboratory,  
203/204, Royal Chamber,  
N S Road No. 1,  
Opp. Club Millennium,  
Juhu, Mumbai-40049**



**CERTIFICATION OF INSTALLATION**

**INSTRUMENT NAME : Senselyte Electrolyte Analyzer**

**SERIAL NUMBER : ARK-870**

**CUSTOMER NAME : Shruti Clinical Laboratory, 203/204, Royal Chember,  
And ADDRESS N S Road No. 1, Opp. Clunb Millennium, Juhu, Mumbai-49**

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

**SERVICE DIVISION**



Signature :  
Name : MR. KIRAN DATE  
Designation : General Manager-Global Service  
Company : SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

**QUALITY DIVISION**



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



**INSTALLATION REPORT**

**CUSTOMER NAME** : Senselyte Electrolyte Analyzer  
**PLACE** : Mumbai  
**DEPARTMENT** : DIAGNOSTICS CENTER.  
**CONTACT PERSON** : Shruti Clinical Laboratory  
**INSTRUMENT NAME** : Senselyte Electrolyte Analyzer  
**SERIAL NUMBER** : ARK-870  
**INSTALLATION DATE** : 31/12/2021

THE ELECTROLYTE ANALYZER WAS INSTALLED ALONG WITH THE NECESSARY STANDARD ACCESSORIES, ALL BASIC REQUIREMENTS AND ADJUSTMENTS WERE CHECKED AND FOUND TO BE SATISFACTORY. THE EPRELIMINARY 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.



Mr. KIRAN DATE  
(General Manager-Global Service)



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 SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.



Mr. KIRAN DATE  
(General Manager-Global Service)



**INSTALLATION QUALIFICATION**

**INSTRUMENT NAME** : Senselyte Electrolyte Analyzer

**SERIAL NUMBER** : ARK-870

**CUSTOMER NAME** : Shruti Clinical Laboratory, 203/204, Royal Chember,  
**And ADDRESS** N S Road No. 1, Opp. Clunb Millennium, Juhu, Mumbai-49

**INSTALLATION REQUIREMENTS FOR THE INSTRUMENT:**

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

FOR SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.



**Mr.KIRAN DATE**  
(General Manager-Global Service)



**Sens-E-Lyte  
Electrolyte Analyzer**

**OPERATIONAL QUALIFICATION**

**FOR**

**Shruti Clinical Laboratory,  
203/204, Royal Chamber,  
N S Road No. 1,  
Opp. Club Millennium,  
Juhu, Mumbai-40049**





**CERTIFICATION OF OPERATION**

**INSTRUMENT NAME** : Senselyte Electrolyte Analyzer

**SERIAL NUMBER** : ARK-870

**CUSTOMER NAME** : Shruti Clinical Laboratory, 203/204, Royal Chember,  
**And ADDRESS** N S Road No. 1, Opp. Clunb Millennium, Juhu, Mumbai-49

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

**SERVICE DIVISION**



**Signature** :  
**Name** : Mr. KIRAN DATE  
**Designation** : General Manager-Global Service  
**Company** : SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

**QUALITY DIVISION**



**Signature** :  
**Name** : Mr. POSI BABU V  
**Designation** : QC TEAM LEAD  
**Company** : SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.



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.



Mr. KIRAN DATE  
(General Manager-Global Service)





**Sens-E-Lyte  
Electrolyte Analyzer**

**PERFORMANCE QUALIFICATION**

**FOR**

**Shruti Clinical Laboratory,  
203/204, Royal Chember,  
N S Road No. 1,  
Opp. Club Millennium,  
Juhu, Mumbai-40049**



**PERFORMANCE ANALYSIS**

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

The control Level 1 & Level 2 & Level 3 have been run and results are within control ranges.

**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 : MR. KIRAN DATE  
Designation : General Manager-Global Service  
Company : SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

**QUALITY MANAGER**



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



ARK Diagnostic System Pvt. Ltd.

### CALIBRATION REPORT

**Customer Name** : Shruti Clinical Laboratory  
**Address** : 203/204, Royal Chambers,  
N.S. Road No.1,  
Opp. Club Millennium,  
Mumbai - 400049  
**Instrument Model** : Sens-E-Lyte  
**Sr. No.** : Ark-870  
**Calibration date** : 31<sup>st</sup> Dec 2021

There is no due date for calibration. Since calibration is an automatic process and is done every 8 hourly.

Technical Service Dept.

*R. Kulkarni*



QC RUN

ARK Diagnostic System  
LEVEL 1

----- QC mV -----

Na = 14.31 mV  
K = 27.09 mV  
iCa = 31.73 mV  
Cl = 42.75 mV

-----CAL A mV-----

Na = 18.83 mV  
K = 44.11 mV  
iCa = 26.48 mV  
Cl = 34.26 mV

ANALYZE QC

Na = 121.2 mmol/L LOW  
K = 2.09 mmol/L LOW  
iCa = 1.98 mmol/L HIGH  
Cl = 83.3 mmol/L LOW

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ARK Diagnostic System  
LEVEL 2

----- QC mV -----

Na = 19.96 mV  
K = 45.84 mV  
iCa = 26.39 mV  
Cl = 38.01 mV

-----CAL A mV-----

Na = 18.82 mV  
K = 44.08 mV  
iCa = 26.42 mV  
Cl = 34.24 mV

ANALYZE QC

Na = 149.0 mmol/L HIGH  
K = 4.38 mmol/L  
iCa = 1.40 mmol/L HIGH  
Cl = 102.4 mmol/L HIGH

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ARK Diagnostic System  
LEVEL 3

----- QC mV -----

Na = 22.17 mV  
K = 54.65 mV  
iCa = 18.00 mV  
Cl = 34.63 mV

-----CAL A mV-----

Na = 18.72 mV  
K = 44.05 mV  
iCa = 26.27 mV  
Cl = 34.10 mV

ANALYZE QC

Na = 162.1 mmol/L HIGH  
K = 6.20 mmol/L HIGH  
iCa = 0.80 mmol/L HIGH  
Cl = 117.8 mmol/L HIGH

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PERFORMED BY : Radhika

CHECKED BY : Janday