



Date: 04-03-2020

## CALIBRATION CERTIFICATE

TO WHOMSOEVER IT MAY CONCERN

We hereby certify that the Electrolyte Analyzer Model NuLYTE SMART, which belong to Arpan Diagnostics Centre, Rajkot and is installed in Laboratory is Standardized and tested on 04<sup>th</sup> March, 2020.

Measured mV Values are:-

S.N.	Electrode	Calibration Slope (mV)	Calibration Ranges (mV)
01	Na <sup>+</sup>	58.51 mV/dec	35-100 mV/dec 35-100 mV/dec 15- 35 mV/dec
02	K <sup>+</sup>	60.67 mV/dec	
03	iCa <sup>++</sup>	34.26 mV/dec	

QC Measurement ( QC LEVEL LOT NO:-UQC19F Exp: May. 2021)

S.N	Parameter	Expected Values (mmol/L)
		LEVEL 2
01	Na <sup>+</sup>	133 - 147
02	K <sup>+</sup>	3.46 - 4.46
03	iCa <sup>++</sup>	1.10-1.35

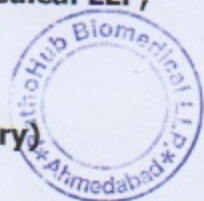
Measured Values are:-

S.N	Parameter	Measured Values (mmol/L)
		LEVEL 2
01	Na <sup>+</sup>	138
02	K <sup>+</sup>	3.96
03	iCa <sup>++</sup>	1.22

Successful completion of the preceding activities and checks indicates that this instrument has been satisfactorily installed. The instrument has passed the Installation Qualification procedure. This Calibration Certificate is valid for one year.

For PathoHub Biomedical LLP,

(Authorized Signatory)



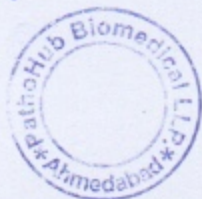


Date: 04/03/2020

**Installation / Qualification Report**

Customer Name	Arpan disgnostic Centre, Rajkot	
Address	150ft. Ring Road, Indra Circle, Rajkot – 360005	
Equipment	Electrolyte Analyzer	
Model	NuLYTE SMART	
Serial No.	1507	
Supplier Name	Pathohub Biomedical LLP G-43, Sumel Business Park -6, Jupiter Mill Compound, Dudheshwar Cross Road, Shahibaug, Ahmedabad. 382004	
Installation Date	29/08/2017	
Power Supply	220 V	O.K
Daily Maintenance	O.K	
Calibration Report	O.K	

*Handwritten signature*





**Basic Conditions:**

Power Input	Ground-Neutral	02 to 05 V
	Neutral -Phase	180 to 240 V
	Phase-Ground	180 to 240 V
UPS	3KVA pure sine wave output with 180 to 240 V	

**Location Specifications:**

1. Keep Away from or shielded from any centrifuges, X-Ray sources, Ultrasound, Nuclear and Magnetic Equipment.
2. Also keep away from direct sunlight, A.C. vent, heat vent and other heat producing equipments
3. Stable Level, Non-porous and Non-absorbing work surface.
4. 15<sup>o</sup>-32<sup>o</sup> C, Room Temperature (60<sup>o</sup>-90<sup>o</sup>F) < 85% Humidity

The location for Installation and the Equipment were checked as per specifications and the equipment was installed.

**For, PathoHub Biomedical LLP.**

**(Authorized Signatory)**





## PERFORMANCE QUALIFICATION

The performance of the equipment was checked for the following:

Na<sup>+</sup>/K<sup>+</sup>/iCa<sup>++</sup> Electrode voltage verification.

Calibration Time verification.

The results are well within the acceptable range.

Operational Status - Working

Equipment has been validated to perform desired parameters.

Performance for parameters (Na<sup>+</sup>/K<sup>+</sup>/Cl<sup>-</sup>) verified with commercial control.

Run Level-2, Level-3 control and results are within acceptable range.

Calibration Date 04/03/2020

Calibration Validity One Year

Next Calibration due 03/03/2021

**For, Pathohub Biomedical LLP.**

**Authorized Signatory**





## **OPERATION QUALIFICATION**

This is for operational verification of NuLYTE SMART ELCTROLYTE ANALYZER at **Arpan Diagnostic Centre, Rajkot.**

Purchase Order Date	25/08/2017
Equipment Received as per order	Yes
Equipment Accessories	O.K.
Equipment Safety and Control Provisions	O.K.

This instrument operates within specified set of parameters under normal operational condition.

Equipment was checked and found to be operating satisfactorily as per the specifications (Refer Operator Manual)

All acceptance criteria are passed in the operational qualification.

**For, Pathohub Biomedical LLP.**

**Authorized Signatory**