Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
Tel: +91 22 4030 9000 Fax: +91 22 2857 3030 Email : transasia@transasia.co.in CIN : U33110MH1985PLC036198

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SINCE 1979...

December 01, 2023

Calibration Certificate for Electrolyte Analyzer
Model: Easylyte Plus (Sl. No. 60625CNKC)

This is to certify that the Electrolyte Analyzer, Model: Easylyte Plus (Na/K/Cl) installed at Unity Gastrocare and Diagnostic Centre, Agartala, Tripura has been calibrated. All parameters have been checked and found well within the limit.

This calibration is valid till November 30, 2024.

For Transasia Bio-Medicals Ltd.

Tarakanath Chakraborty,
Regional Service Manager

Transasia Bio-Medicals LTD

Installation Certificate for Easylyte:

This is to certify that the Easylyte Instrument Serial No. 60625 CNKC is successfully Installed and Commissioned at Unity Gastrocare & Diagnostic Center and the Installation Protocol / checklist has been successfully completed for the above instrument.

TRANSASIA BIOMEDICALS LTD, MUMBAI.

Name : **Prasenjit Das**

Designation : ASM

Date : 24-3-20

Installation Qualification for Easylyte Plus

Customer Name: Unity Gastrocare & Diagnostic Center

Address : Kadamtali, Krishna Nagar, Agartala, Tripura-799001

Instrument Name : Easylyte **Plus**

Serial Number : 60625 CNKC

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report:
Removed the EasyLyte and accessories from shipping containers and place on solid work surface. Visually inspected EasyLyte for any damage sustained during shipment.

External Requirements for Installation:

1.The power cord of the EasyLyte was connected to a matching grounded outlet Supply of 220 VAC, 50/60 Hz, as indicated on the label on the rear of the analyzer.
2. Checked the mains supply and found the Earth, neutral voltage 0 V
3. The environment is free from dust, mechanical vibrations, and electrical interference.
4. Ambient Conditions Maintained : 15-32 degree Celsius(60-90F),< 85% Humidity

UNPACKING

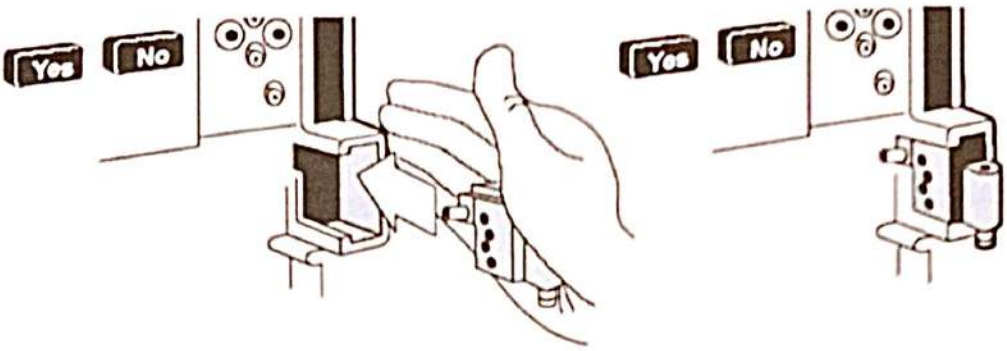
Removed the EasyLyte and accessories from shipping containers and placed on solid work surface. Visually inspected EasyLyte for any damage sustained during shipment.

INSTALLATION/REPLACEMENT

For installation or replacement instructions of EasyLyte components, followed the procedures in this section.

1.Solutions Valve

Installed the SOLUTIONS VALVE into the EasyLyte by pushing firmly on the rounded front of the valve.



2.Probe Wiper-

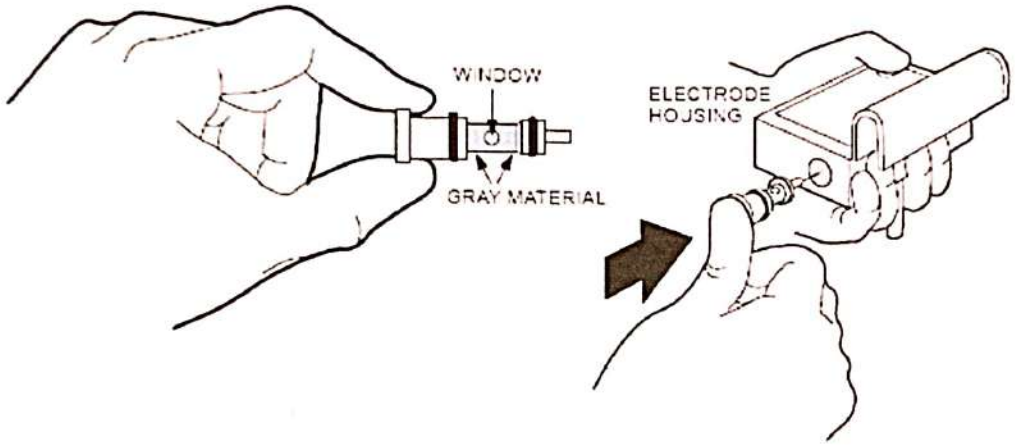
Installed the PROBE WIPER by pushing it firmly onto the mounting post on the bottom of the SOLUTIONS VALVE.

3.Sample Probe

Rotated the SAMPLE PROBE until the side PROBE HOLE (near the rounded tip) faced forward. Then, gently inserted the rounded tip of the SAMPLE PROBE downward into the top of the SOLUTIONS VALVE. Aligned the probe collar ring with the white notch on the PROBE ARM.

Membrane Assembly

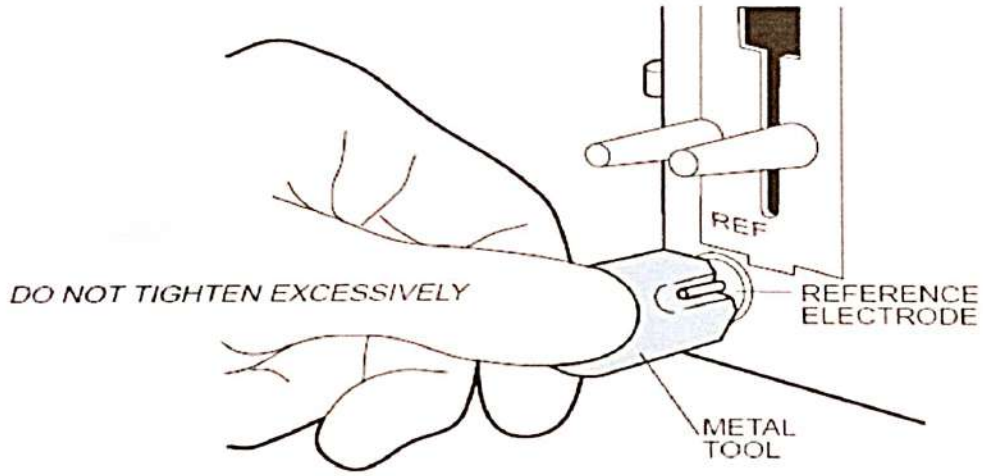
Removed the MEMBRANE ASSEMBLY from holding it by the large end. Note the small, Installed the membrane assembly with round window visible to the operator in the electrode housing.



5. Reference Electrode

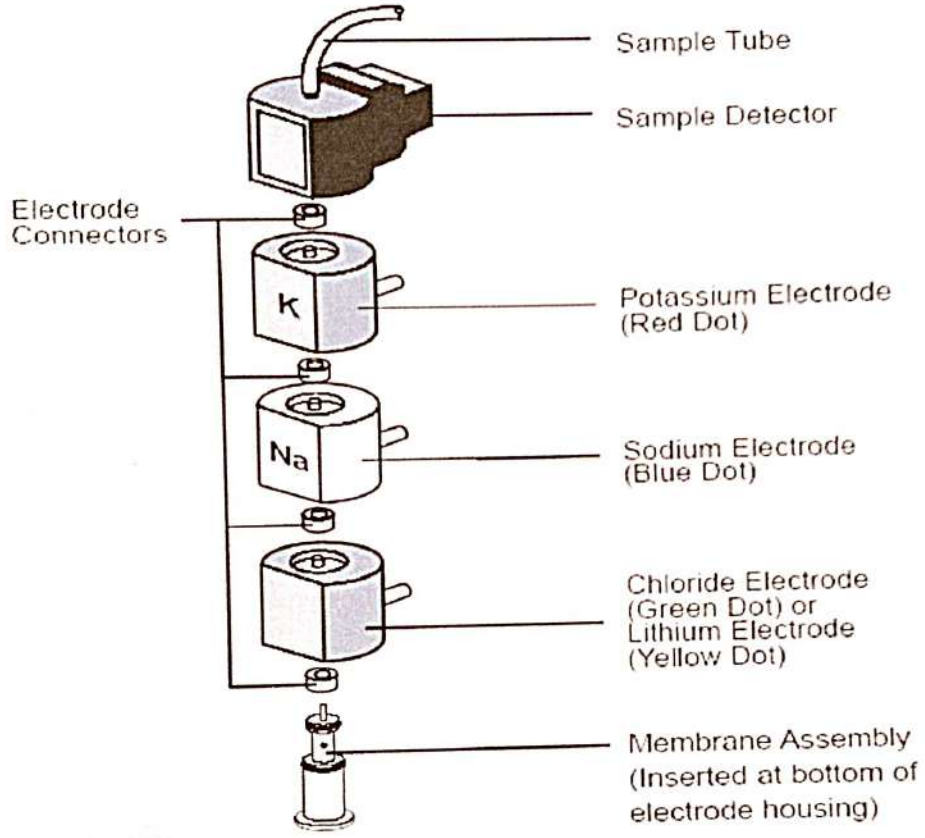
Removed the REFERENCE ELECTRODE from its package. Remove and discard the red vinyl cap and packaging.

Screwed the new REFERENCE ELECTRODE into the ELECTRODE HOUSING using the METAL TOOL.



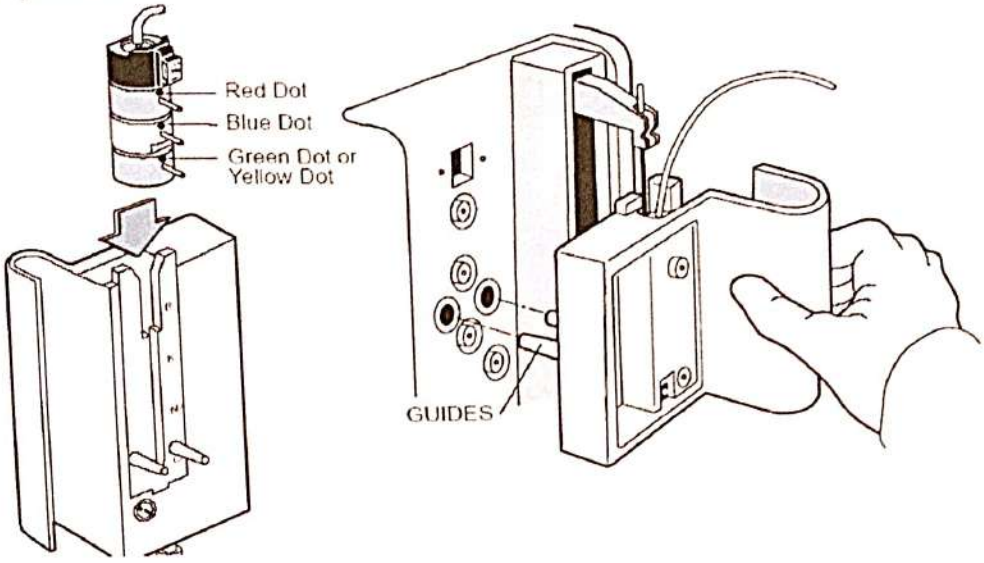
6.Building Electrode Stack

Assemble the ELECTRODE CONNECTORS, ELECTRODES, and SAMPLE DETECTOR. Made sure each component is clean and dry, and the electrode symbols,"Na", "K", "Cl" or "Li", are right-side up. Connected the SAMPLE TUBE to the metal connector on the SAMPLE DETECTOR at the top of the ELECTRODE STACK.



7.Loading Electrode Stack

Slided the ELECTRODE STACK into the ELECTRODE HOUSING. PUSHED DOWN firmly until the SAMPLE DETECTOR snaps into position.

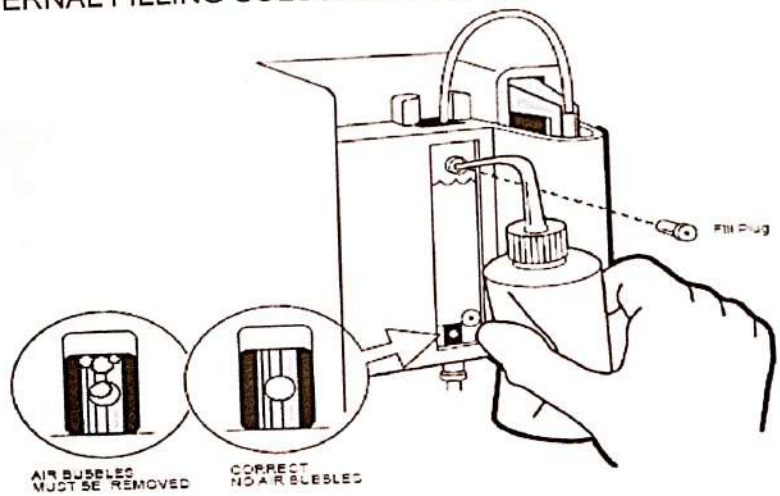


8.Installing the Tubing

Connected the SAMPLE TUBE to the top of the SAMPLE PROBE.

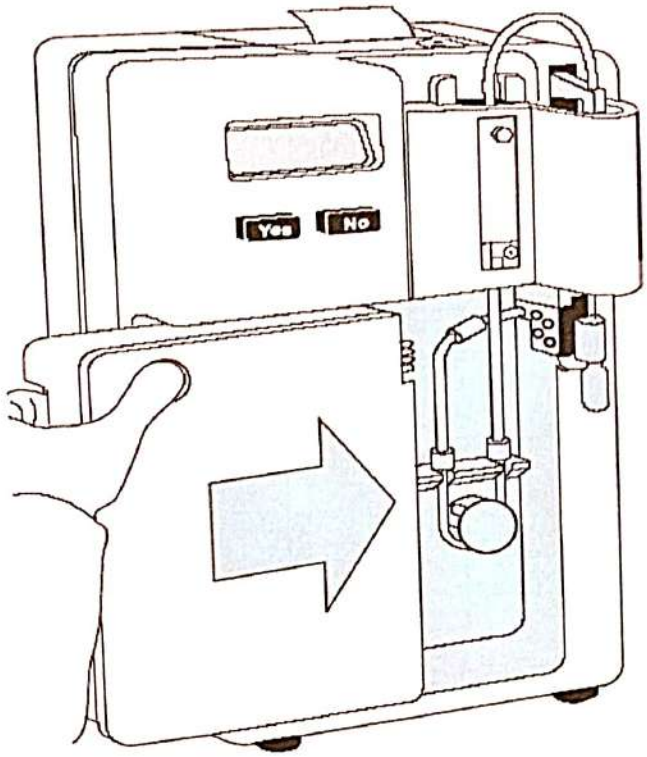
9.Internal Filling Solution

Removed the cap on the INTERNAL FILLING SOLUTION bottle. Place the spout cap on the bottle. Filled the ELECTRODE HOUSING through the fill plug hole until the INTERNAL FILLING SOLUTION reached the "fill line" on the window.



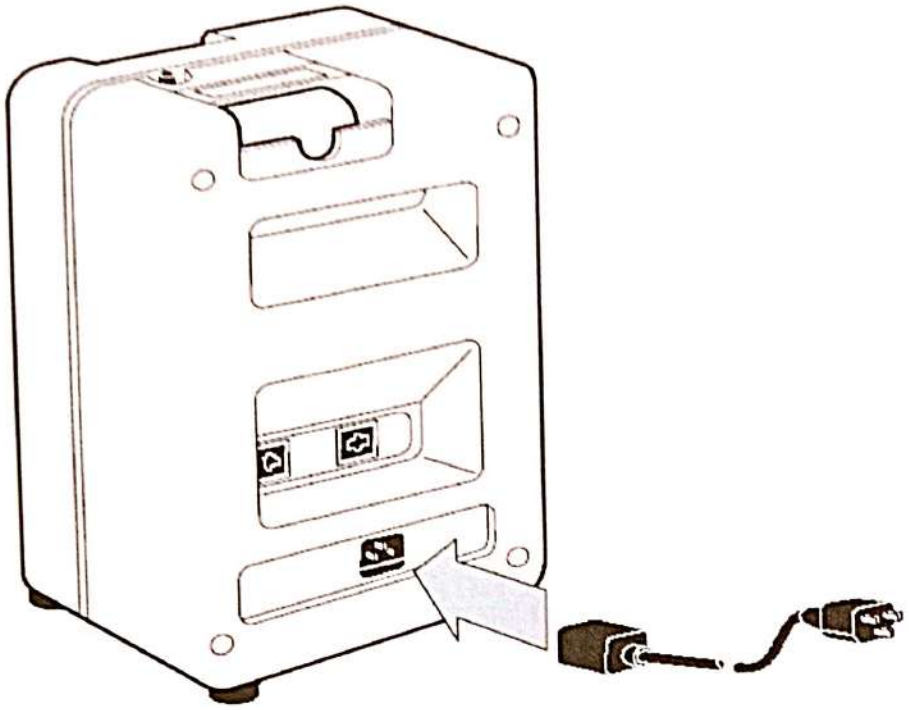
10.Solutions Pack Installation

Placed SOLUTIONS PACK into the front of the analyzer, and slided the SOLUTIONS PACK firmly to the right, plugging it into the SOLUTIONS VALVE.



11.Power Up

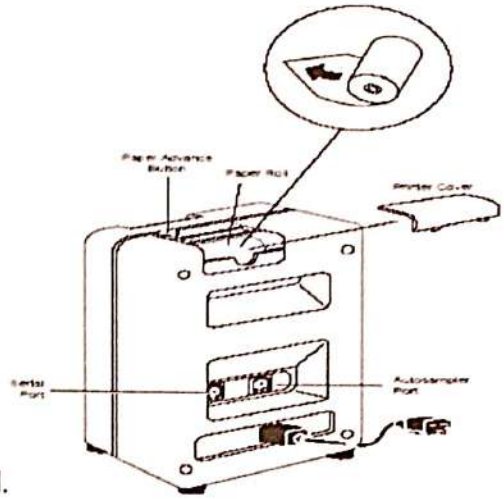
After assembling all the components, plugged the EasyLyte into a GROUNDED outlet. A beep sound along with with, ****Na/K**** or****Na/K/Cl**** or ****Na/K/Li**** appeared on the display. The EasyLyte displayed **CALIBRATE NOW?** installation is completed.



12.Printer Paper/Accessories Installation

To install the roll of paper into the printer, Cut the new edge to a point in the center of the paper, forming a V. Gently pushed this leading edge of the paper into the slot behind the printer until the paper tip reached the plastic tear bar. Pull the paper by hand until the full width appears at the tear bar.

After installing the paper, replaced the small cover on top of the



housing to protect the printer paper roll.

Protocol Performed By: Prasenjit Das

Designation: ASM

Signature:

Date:

Customer Authorization:

Name : Dr. Devleena Dev Barman.
Designation : MD Pathology

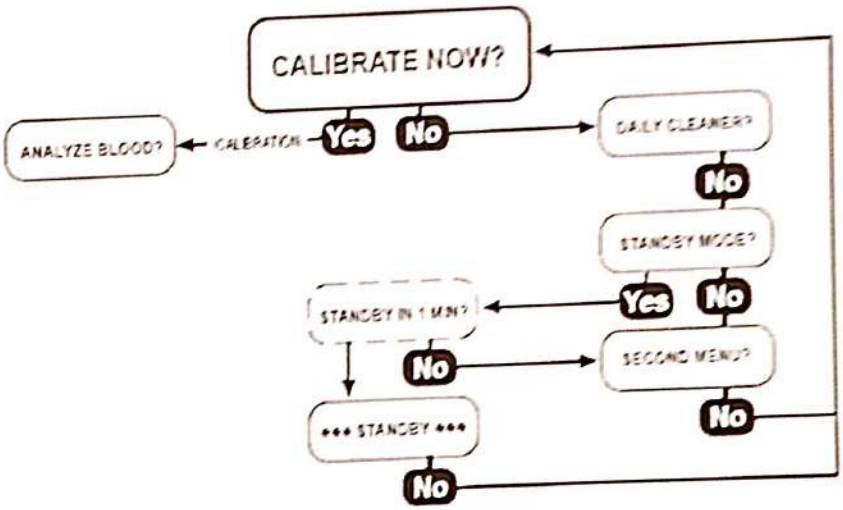
Signature :
Date: 24-03-20

Operational Qualification:

1.SOLUTION PURGE.

This procedure was required, as SOLUTIONS PACK was newly installed.
After purging, the display returned to CALIBRATE NOW?

2.CALIBRATION.



Verified proper installation, and the display showed **CALIBRATE NOW?**

Successfully calibrated the instrument and it displayed **ANALYZE BLOOD?**

Protocol Performed By: Prasenjit Das

Designation: ASM

Signature:

Date:

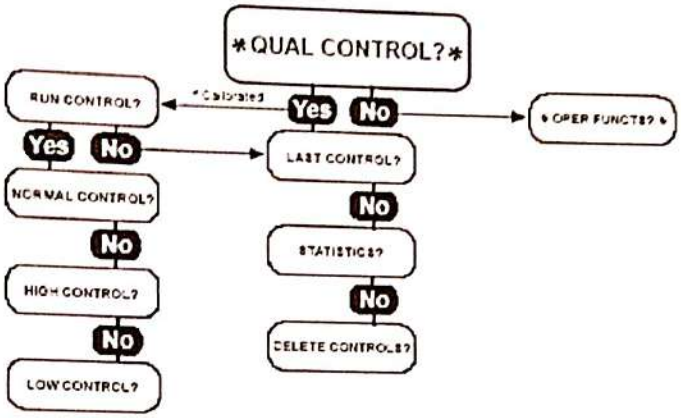
Customer Authorization:

Name	:	Dr. Devleena Der Barman.
Designation	:	MD Pathology
Signature	:	
Date:		24-03-20

Performance Qualification:

QUALITY CONTROL

After calibrating the instrument, checked with Quality Control (Level 1) and found the results and precision within specified ranges.



Used Medica's Quality Control to verify the accuracy and precision of your Analyzer. Results are attached.

System Certification:

Study data has determined that the System described in this document either meets all criteria outlined in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

The System is ready for specific usage.

Protocol Performed By: Prasenjit Das

Designation: ASM

Signature:

Date:

Customer Authorization:

Name	:	Dr. Devleena Dev Barman.
Designation	:	MD Pathology.
Signature	:	
Date:		24-03-20

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TRANSASIA

Ref. No TBM/EZ3/23-24/0047

Date: 13.01.2024

Precision worksheet : UNITYGASTROCARE AND DIAGNOSTICS CENTRE

Instrument Id: Medica Na/K/CL
Name of Technical person: PRASENJIT DAS
Supervisor review: Dr. DEVLEENA DEV BURMAN
Date performed: 13-1-2024

Run sequence	Sodium	Potassium	Chloride
1	101.4	3.70	242
2	101.6	3.68	240
3	101.1	3.71	240
4	101.6	3.73	237
5	101.3	3.64	234
6	102.2	3.70	236
7	100.8	3.69	241
8	101.4	3.69	237
9	102.4	3.72	243
10	103.2	3.68	238
Mean	101.9	3.69	239
SD	0.61	0.02	2.19
CV%	0.60	0.76	0.91
Allowable Limit	Pass	Pass	Pass

Status : PASS

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TRANSASIA

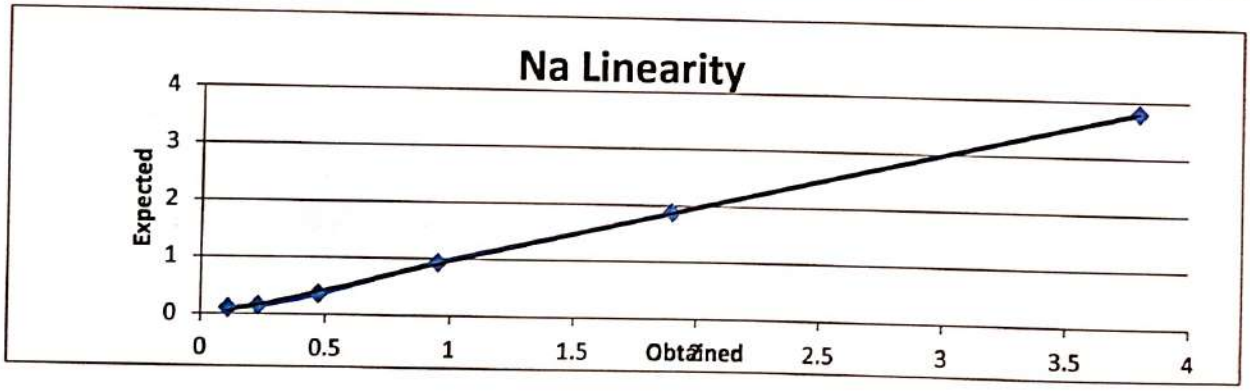
Ref. No TBM/EZ3/23-24/0044

Date: 13.01.2024

Linearity Study for Sodium (Na) Test

Institution: UNITY GASTROCARE & DIAGNOSTICS CENTRE
Name of the Technical person: PRASENJIT DAS
Date performed: 13.01.2024

Instrument Name : Sodium (Na)	SL No : 60625CNKC	Test Name : Sodium
Sodium	Expected	Obtained
Neat	154.6	154.6
1/2 DILUTION	77.3	82.5
1/4 DILUTION	38.65	47.5
1/8 DILUTION	19.32	29.5
1/16 DILUTION	9.66	20.0
1/32 DILUTION	4.83	16.2



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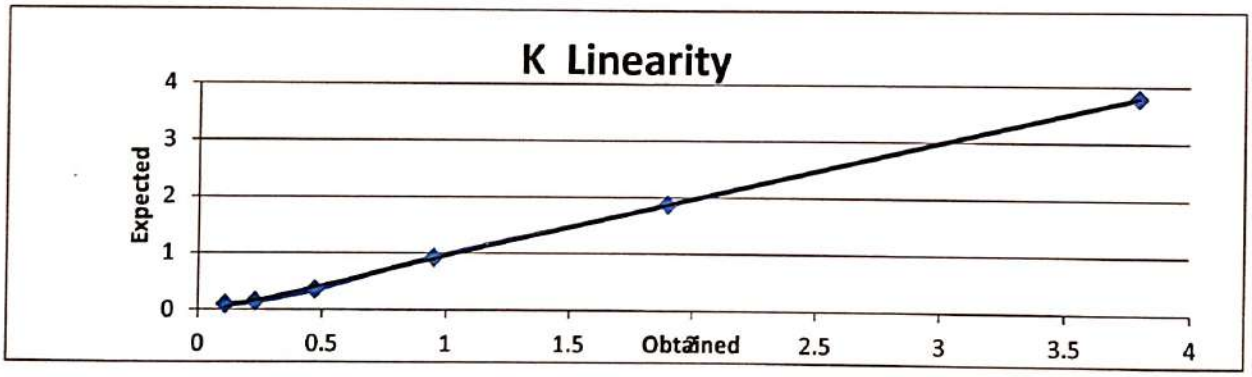
Ref. No TBM/EZ3/23-24/0045 **Date:** 13.01.2024

Institution: UNITY GASTROCARE & DIAGNOSTICS CENTRE
Name of the Technical person: PRASENJIT DAS
Date performed: 13.01.2024

Instrument Name : Potassium (K)	SL No : 60625CNKC	Test Name : Potassium
Potassium	Expected	Obtained
Neat	5.79	5.79
1/2 DILUTION	2.89	2.85
1/4 DILUTION	1.44	1.56
1/8 DILUTION	0.72	0.89
1/16 DILUTION	0.36	0.54
1/32 DILUTION	0.18	0.41



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TRANSASIA

Ref. No TBM/EZ3/23-24/0046

Date: 13.01.2024

Institution: UNITY GASTROCARE & DIAGNOSTICS CENTRE
Name of the Technical person: PRASENJIT DAS
Date performed: 13.01.2024

Instrument Name : Chloride (CL)	SL No : 60625CNKC	Test Name : Chloride
Chloride	Expected	Obtained
Neat	124.2	124.2
1/2 DILUTION	62.1	57.6
1/4 DILUTION	31.05	28.0
1/8 DILUTION	15.51	13.5
1/16 DILUTION	7.76	7.9
1/32 DILUTION	3.88	7.0