Transasia Bio - Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (E) Mumbai - 400 072
Tel: +91 22 4230 8200 Fax: +91 22 2857 3530 Email: transasia@transasia.co.in CIN: U33110MH1985PLC036198

TRANSASIA®

TRANSASIA
UNMATCHED SERVICE
SINCE 1979...

Certificate of Conformity and Calibration

TO WHOMSOEVER IT MAY CONCERN

ISO 15189:2012 REQUIREMENTS REGARDING,"CALIBRATION AND VERIFICATION PROCEDURE"

All Transasia Bio-Medicals Ltd diagnostics products which are distributed and for which a certificates is issued are CE Marked. Transasia Bio-Medicals Ltd , Mumbai ,manufacturers of diagnostic devices with company quality management system in compliance with standard ISO13485:2016 ;ISO9001:2015 .This means that all the processes in development and manufacturing of TBM products are guided by quality management system.

TBM declares and assure following

- The mentioned regulations require that production system and measuring devices are qualified and manufacturing and test procedures are validated as per ISO 13485:2016 and ISO 9001:2015 standard and it is assured through schedule maintenance and by regular qualification.
- TBM declares to have established procedure and to maintain it in order to assure the post marketing surveillance according to directive of 98/79/EC.
- All physical quantities, calibrators and controls used in TBM system are fully traceable to certified standards or reference materials.
- All TBM products are factory calibrated and final qc passed at the time of release.
- The performance of TBM system at customer site is assured if regular QC measurements, cleaning and maintenance procedure as described in the instruction for use or service documentation are performed
- Additional calibration or verification procedure is not required in order to assure the specified performances of every TBM system. Only if user deviates from the manufactures recommendation does he have to establish site specific calibration and verification procedure as part of his accreditation process.

Date:-26/04/2021

Manish Airan

Head Of Quality Department & Regulatory

Installation Certificate for Easylyte Expand (Na/K/Cl/Ca)

This is to certify that the Easylyte Expand Instrument Serial No. 64821CXPA is successfully Installed and Commissioned at Vyas Super Speciality Hospital, Jodhpur as per Installation Protocol / checklist has been successfully completed for the above instrument.

TRANSASIA BIOMEDICALS LTD,

Name : Mr. Girdhari Sharma

Designation : Service Engineer

Date : 25-02-2023

Installation Qualification for Easylyte Plus

Customer Name : Vyas Super Speciality Hospital

Address : Pali Road, Jodhpur

Instrument Name : Easylyte Expand Na/K/Cl/Ca

Serial Number : 64821CXPA

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 placed it on solid work surface. Visually inspected EasyLyte for any damage sustained during shipment.

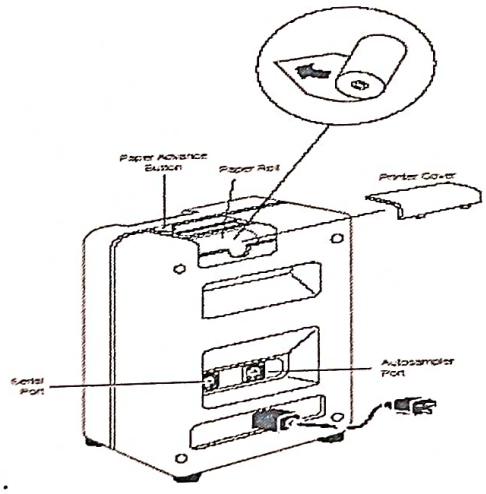
External Requirements for Installation:

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 and installation manual on the rear of the analyzer.
2. Checked the mains supply and found the Earth, neutral voltage at 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

12. Printer Paper/Accessories Installation

To install roll the paper into the printer, Cut the new edge to a point in the center of the paper, forming a V. Gently pushed was the leading edge of the paper into the slot behind the printer until the paper tip reached the plastic tear bar. The paper was Pulled 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: **Mr. Girdhari Sharma**

Designation: Service Engineer

Signature: Gd

Date: 25-02-2023

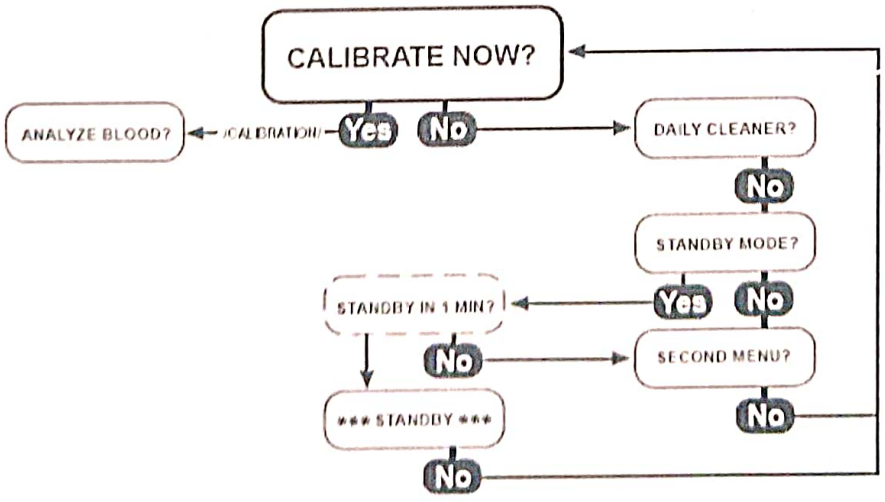
Customer Authorization:

Name	:	Mr. Sharwan
Designation	:	**Lab Technician**
Signature	:	
Date	:	**25-02-2023**

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.



Proper installation was Verified, and the display characteristics were as per manual instructions, showed **CALIBRATE NOW?**.

After Successful calibration of the instrument it displayed **ANALYZE BLOOD?**. The instrument also printed every step as per the manual instructions and the results were found within range.

Summary: Operation of the instrument is as per expectations. It was checked and found ok.

Protocol Performed By: **Mr. Girdhari Sharma**

Designation: Service Engineer

Signature:

Date: 25-02-2023

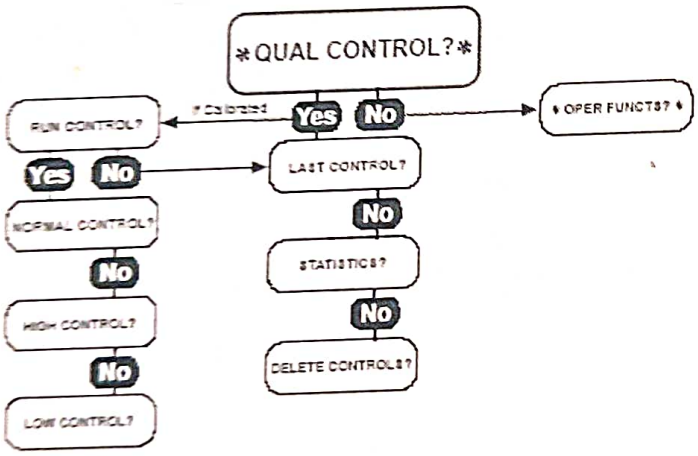
Customer Authorization:

Name	:	Mr. Sharwan
Designation	:	**Lab Technician**
Signature	:	
Date	:	**25-02-2023**

Performance Qualification:

QUALITY CONTROL

After calibrating the instrument, checked with Quality Control (Level 1,Level 2 and Level3) and found the results and precision within specified ranges.



Quality Control was used to verify the accuracy and precision of the Easylyte 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: **Mr. Girdhari Sharma**

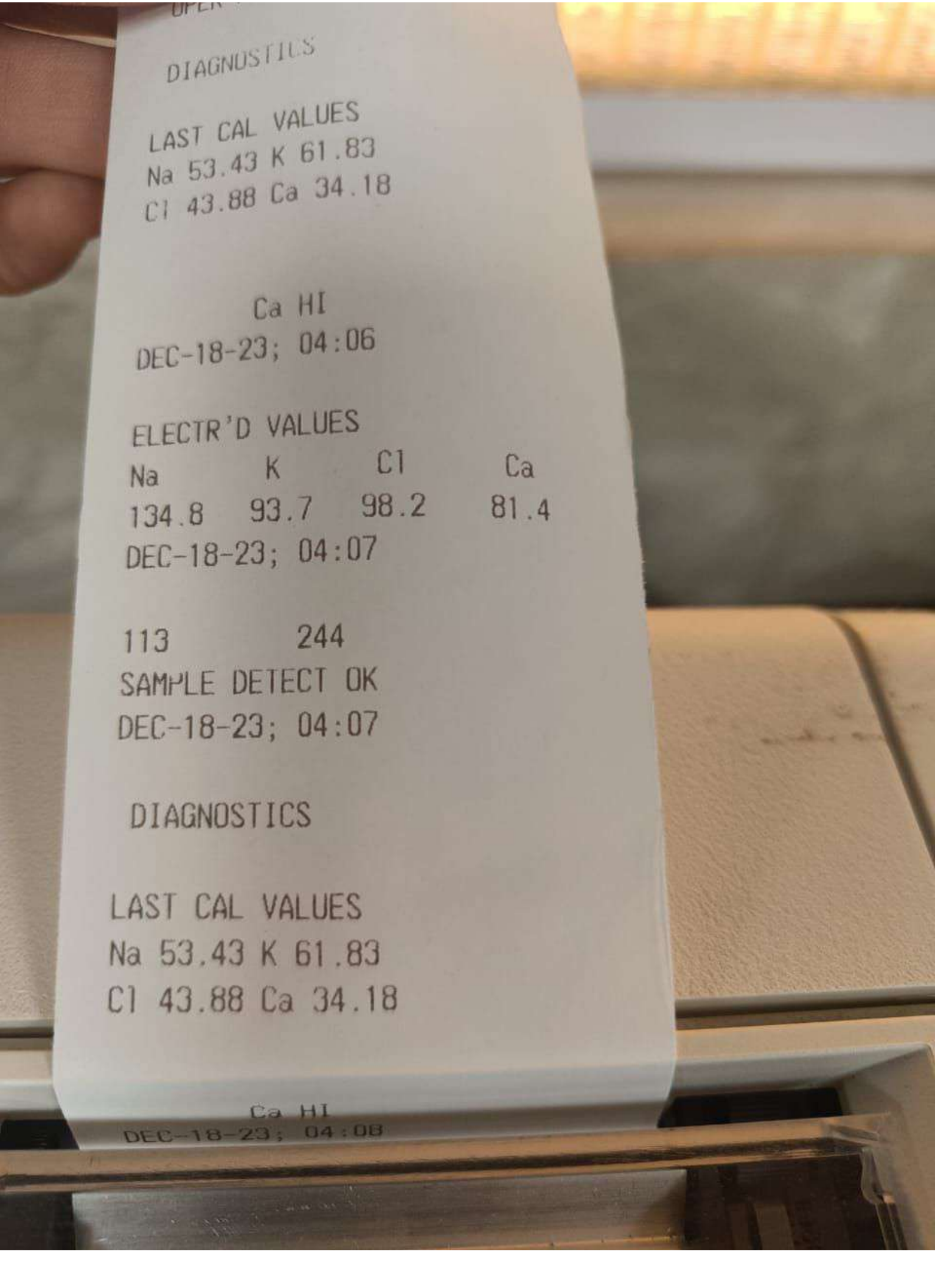
Designation: Service Engineer

Signature:

Date: 25-02-2023

Customer Authorization:

Name	:	Mr. Sharwan
Designation	:	**Lab Technician**
Signature	:	


DIAGNOSTICS
LAST CAL VALUES
Na 53.43 K 61.83
Cl 43.88 Ca 34.18
Ca HI
DEC-18-23; 04:06
ELECTR'D VALUES
Na K Cl Ca
134.8 93.7 98.2 81.4
DEC-18-23; 04:07
113 244
SAMPLE DETECT OK
DEC-18-23; 04:07
DIAGNOSTICS
LAST CAL VALUES
Na 53.43 K 61.83
Cl 43.88 Ca 34.18
Ca HI
DEC-18-23; 04:08