

CALIBRATION REPORT

To,
Gautam Iabdhhi Diagnostic Center,
Pune.

Date- 27/05/2024

As desired by you please find enclosed here with the report.

Name of System	<i>Microlyte Electrolytes Analyzer</i>
Sr. No.	EL19NV874
Calibration done on	27/05/2024
Next calibration Due on	26/05/2025
Calibrated By	Mr. Eknath Jadhav

Instrument calibration Values :-

Electrode	Na+	K+	Cl-
Results	132.8	4.2	97.1
Mean	139	3.96	97
Range	132-146	3.76-4.16	92.2-102
Cal. values	60.5	58.2	48.1

All value is within range.

Checked instrument all found ok.

With Regards



Crystal Diagnostivision
Service Engineer.

TRACEABILITY CERTIFICATE

Product Name : Standard CAL-A Reagent Pack

Product Code : ML-C-1001

Intended Use : To provide calibration points for Sodium, potassium, Ionized Calcium, Lithium, Chloride electrode with Electrolyte Analyzers.

Presentation : 1 Sealed Plastic pack containing 2 bags of Standard A (450ml x 2)

Storage : 18 – 25 ° C

Lot No : Mentioned on Pack

Handling : Exercise normal laboratory precautions.

Stability : Package stability (Expiration date) is listed on product pack label.

Notes : This product is intended to serve as a functional equivalent to pre-existing material distributed by the original equipment manufacturer. Micro Lab Instruments calibrators have defined electrolyte concentrations that provide internal calibration points against which samples are measured by direct Ion Selective Electrodes Methods.

Value Assignment : Each analyte is directly traceable to NIST Reference materials. Potassium (NIST 919c), Sodium (NIST 919b), Lithium (NIST 3129a), Calcium (NIST 915b) with Flame Photometry method and Chloride (NIST 919b) with Coulometric Titration method respectively.

This is to certify that the calibration standard solution used with Electrolyte Analyzer, Manufactured by Micro Lab Instruments is traceable to the National Institute of Standards and Technology (NIST) reference materials and methods which are listed above in value assignment.

TRACEABILITY CERTIFICATE

Product Name : Standard CAL-B Reagent Pack

Product Code : ML-C-1002

Intended Use : To provide calibration points for Sodium, potassium, Ionized Calcium, Lithium, Chloride electrode with Electrolyte Analyzers.

Presentation : 1 Sealed Plastic pack containing 1 bag of Standard A (280ml x 1).

Storage : 18 – 25 ° C

Lot No : Mentioned on Pack

Handling : Exercise normal laboratory precautions

Stability : Package stability (Expiration date) is listed on product pack label.

Notes : This product is intended to serve as a functional equivalent to pre-existing material distributed by the original equipment manufacturer. Micro Lab Instruments calibrators have defined electrolyte concentrations that provide internal calibration points against which samples are measured by direct Ion Selective Electrodes Methods.

Value Assignment : Each analyte is directly traceable to NIST Reference materials. Potassium (NIST 919c), Sodium (NIST 919b), Lithium (NIST 3129a), Calcium (NIST 915b) with Flame Photometry method and Chloride (NIST 919b) with Coulometric Titration method respectively.

This is to certify that the calibration standard solution used with Electrolyte Analyzer, Manufactured by Micro Lab Instruments is traceable to the National Institute of Standards and Technology (NIST) reference materials and methods which are listed above in value assignment.

Date- 27/05/2024

IQ (Installation Qualification)

Sr No	Utilities to be checked	Observation	Inference	Verified by & Date
1	Environmental condition as per requirement : Ambient Temp Range : <u>05 - 32 °C</u> Humidity Range: <u>Less Than 80 %</u>	Temp : <u>24 °C</u> Humidity : <u>52%</u>	YES	27/05/2024
2	Adequate space for installation : Minimum in FT. <u>3.0(W) X 2.5(D)</u>	OK FT.4.0(W)X2.6(D)	YES	27/05/2024
3	Electrical Outlets : Actual voltage on site : <u>140-250 V</u>	230 V AC Regular	YES	27/05/2024

The instrument has been verified for the following:

Sr No.	Verification		Verified by & Date
1	Equipment is identified	YES	27/05/2024
2	Manufacturer's specifications are included	YES	27/05/2024
3	Accessories / consumables are listed	YES	27/05/2024

Equipment Description:

Instrument Identification		Verified By	Date
Equipment Name	ISE based Electrolyte Analyser	Mr. Eknath Jadhav	27/05/2024
Model	Microlyte (Na/K/CL)	Mr. Eknath Jadhav	27/05/2024
Manufacturer	MICROLAB INSTRUMENTS	Mr. Eknath Jadhav	27/05/2024
Marketed By	CRYSTAL DIAGNOVISION	Mr. Eknath Jadhav	27/05/2024
Serial Number	EL21NV874	Mr. Eknath Jadhav	27/05/2024
SUPPLY	AC-220 V 50Hz POWER- 80VA	Mr. Eknath Jadhav	27/05/2024

Validation By:

Name: Mr. Eknath Jadhav

Designation: Service Engineer

Signature:

Date- 27/05/2024

OQ (Operational Qualification)

Equipment is working on ISE based maintenance free electrodes

Following is a list of tests to be performed and verified:

Test No	Test name	Test purpose	Verified by and Date
1	Self-checks	Initializing the instrument	27/05/2024
2	Mechanism operation Test	To test the mechanism of the instrument	27/05/2024
3	Printer	To test the working condition of the printer	27/05/2024
4	Calibration	For verification of the factory set calibration	27/05/2024
5	Quality control	For verification of calibration and validation of sample analysis	27/05/2024

Validation By :

Name: Mr. Eknath Jadhav

Designation: Service Engineer

Signature:

