To Whom It May Concern

For ISO 15189:2012 and ISO 15189:2014 accredited Laboratories — requirements regarding "Calibration & Verification Procedures" [1]

All In vitro Diagnostics Products which are manufactured and distributed by Roche Diagnostics GmbH and for which a Free-Sales-Certificate is issued, are CE-marked.

The In-Vitro-Diagnostics Directive of the European Union [2A.] which is currently switching to IVD Regulation 2017/746/EU (final timeline: May 26, 2022) [2B.] requires for all CE marked products that the manufacturer assures compliance of the products with the requirements of the mentioned directive or regulation. This means that all processes in development and manufacturing of Roche Diagnostics GmbH products are guided by a Quality Management System. Our Quality Management System is in compliance with the requirements from ISO 13485:2016 [3] and 21 CFR Part 820 [4].
The mentioned regulations and standards require that the production systems and measuring devices used are qualified and the manufacturing and test procedures are validated. This status has to be assured by scheduled maintenance and by regular qualification resp. validation reviews and updates.

All physical quantities, calibrators and controls used in Roche Diagnostic systems are fully traceable to certified standards or reference materials. The performance of all In-vitro diagnostics systems of Roche Diagnostics GmbH at the customer site is assured if regular Quality Control measurements, cleaning and maintenance procedures as described in the instructions for use or service documentation are performed. By having controlled internal procedures and by running the tasks required in the respective user documentation, all In-vitro diagnostics systems of Roche Diagnostics GmbH will be performed as specified during their defined lifetime.

Additional calibration or verification procedures are NOT required by the user in order to assure the specified performance of every system of Roche Diagnostics GmbH. Only if a user deviates from these manufacturer's recommendations, the user have to establish site-specific calibration and verification procedures as part of his accreditation process.

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

[1] ISO 15189:2012/ ISO 15189:2014 Medical laboratories — Requirements for quality and competence

[2] A. Directive 98/79/EC of the European Parliament and of the Council of the 27 October 1998 on vitro diagnostics medical devices;
B. IVD Regulation 2017/746/EU of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

[3] EN ISO 13485:2016 Medical devices — Quality management systems-Requirements for regulatory purposes

[4] CFR Part 820, Quality System regulations 21 Regulations on medical devices

Mannheim, 10. August 2021

Sincerely,

Roche Diagnostics GmbH

i.V./*on behalf of the company*

DocuSigned by:
ECA5294AC4E94AF...

Andrea Weber
Manager Global Regulatory Affairs
Centralised and Point of Care Solutions

ppa/*on behalf of the company*

DocuSigned by:
Ralf Zielenski
A7F0BA9FE91A46A...

Ralf Zielenski
Head Q&R Compliance, PRRC RDG
Centralised and Point of Care Solutions

Roche Diagnostics GmbH
Sandhofer Straße 116
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A3 HORMONE LAB
Assured Accurate Affordable

261, Krishnammal Nagar,
Fairlands, Salem-636016.
Tamil Nadu, INDIA.
Phone : 0427-4042601
Mobile : +91 99945 27758, 96005 13336, 95008 99918
E-mail : a3hormonelabs@gmail.com

```
-     9180     -
ELECTROLYTE ISE
-   NA-K-CL    -
 22OCT22  07:28
*CALIBR. REPORT*

DailyMaintenance
Performed Last:
 22OCT22  02:16

Standard A
Na = -1278mV (3)
K  = -1198mV (4)
Cl =  -284mV (5)

Difference A-B
Na =   403mV ( )
K  =   595mV ( )
Cl =  -629mV ( )

Temp. = 29.2°C
SnapPak:
00% Remaining

Corr. Factors:
Na Offs.=    0.0
Na Slope=  1.000
K  Offs.=   0.00
K  Slope=  1.000
Cl Offs.=    0.0
Cl Slope=  1.000
Bicarb. Factors:
Na Offs.=    0.0
Na Slope=  1.000
K  Offs.=   0.00
K  Slope=  1.000
Cl Offs.=    0.0
Cl Slope=  1.000
Acetate Factors:
Na Offs.=    0.0
Na Slope=  1.000
K  Offs.=   0.00
K  Slope=  1.000
Cl Offs.=    0.0
Cl Slope=  1.000
Urine Factors:
Na Offs.=    0.0
Na Slope=  1.000
K  Offs.=   0.00
K  Slope=  1.000
Cl Offs.=    0.0
Cl Slope=  1.000
```

```
Normal Ranges:
Units: [mmol/L]
Na:  136 -   145
K :  3.5 -   5.1
Cl:   97 -   111


QC Ranges:
Units: [mmol/L]

*** Level 1  ***
Lot Number:0000
Na:   40 -   205
K :  1.5 -  15.0
Cl:   50 -   200

*** Level 2  ***
Lot Number:0000
Na:   40 -   205
K :  1.5 -  15.0
Cl:   50 -   200

*** Level 3  ***
Lot Number:0000
Na:   40 -   205
K :  1.5 -  15.0
Cl:   50 -   200

Service Codes:
   ,   ,   ,
   ,   ,   ,
   ,   ,   ,
```

Roche 9180 calibration report

A3 HORMONE LAB
D.No.261, Krishnammal Nagar,
Fairlands, SALEM-636016.
Phone: 0427-4042601

Roche Diagnostics

ISE 9180 Analyzer

Electrolyte Analyzer

INSTALLATION QUALIFICATION

For

A3 HORMONE LAB

Salem

Ph: 04274042601

MARKETED BY:

Roche Diagnostics India Pvt. Ltd,

Roche House, Plot No. 114 Road No. 15, MIDC, Andheri (E) , Mumbai - 400 093

Validation Protocol — Installation **Qualification**

System/ Equipment: **ISE 9180 Analyzer**
Electrolyte analyzer

Protocol written by: **Roche Diagnostics Pvt Ltd.**

Approval by: Thamaraiselvan.S *Sign:*

Departmental Approval by: Dr. Gandhi *Sign :*
Designation: Chief of the laboratory

Objective

To ensure that the system/equipment installed confirms to the purchase specifications and the manufacturers literature, and to document the information that the equipment meets specifications.

Scope

To be performed at time of installation, modification, or relocation.

Responsibility

Person overseeing the installation will perform the qualification and record the information. The responsible engineer will review the records and write the report.

The Department head/supervisor will supervise the study, verify the completion of the records.

Quality Assurance will review and approve the IQ Protocol and Report.

Procedure

Prepare a checklist for all components and parts, including spare parts according to the purchase order and manufacturers specifications.

Record the information for each actual part, component, auxiliary equipment, supporting facilities, and compare to the manufacturer's specifications.

Record any deviations to the system/equipment.

Prepare a Deviation Report including the justification of acceptance and impact on the function.

Prepare an Installation Qualification Report:

This should include date study initiated; date completed;
Results of any tests;
Deviation report;
Justification for acceptance;
Impact on operation;
other information relevant to the study;
and conclusions on the validity of the installation.

Submit the report to QA for review and approval.

System/Equipment ISE 9180 Analyzer Instrument ID:28608

Results:

a.) **Description of the System/Equipment being installed:** The 9180 electrolyte analyzer for measuring Electrolytes, in whole blood, serum, plasma, dialysate, aqueous standards and QC materials.

b.) List of the main components

The ISE 9180 Analyzer consists of several major components.

1) Printer ☑
2) Pump ☑
3) Roller ☑
4) Measuring chamber ☑
5) Flap ☑
6) Power Supply ☑
7) Accessory Kit ☑
8) Manual ☑

Results:

c.) Description of any required supporting utilities.

The standard Accessories that accompany the ISE 9180 Analyzer.

1) Fuse ☑
2) Dummy electrode ☑
3) 1 Pack printer paper (5 rolls) ☑
4) Valve Clips ☑
5) Probe cleaner ☑

6) Shutdown kit ☑
7) Electrode "O" rings ☐
8) Mannual ☑

Additional Accessories (not supplied)

-

-Power cord

-

Do the results meet the specified Acceptance criteria?

YES ☑ **NO** ☐

Performed by: Thamaraiselvan S *Signature :* _____
Roche Diagnostics India Pvt Ltd
Verified by: Dr.Gandhi *Signature :* _____
Designation: Chief of the Laboratory

System/ Equipment: ISE 9180 Analyzer
Instrument Name: ISE 9180 Analyzer
Serial No.: 28608

Results:

	Required/Ordered	Actual	Specs. met
Model	ISE 9180 Analyzer	ISE 9180 Analyzer	
System Description			
Precision	Long-life, maintenance free electrodes ensure high precision & reliability	Long-life, maintenance free electrodes ensure high precision & reliability	N/A
Robustness			
Software/data handling CPU- Operating System- Memory- Bus architecture- Data storage- Internal External Interfaces- Display- Printer-	 RS-232C(standard serial port) Dot matrix, 2lines,16characters wide Built-in, thermal roll printer,16characters wide	 RS-232C(standard serial port) Dot matrix, 2lines,16characters wide Built-in, thermal roll printer,16characters wide	N/A
Samples Sample handling- Throughput- Incubation time- Incubation cycle time-	 Whole blood,serum, Plasma,urine,dialysate Aqueous standards, QC 60 samples/hour without printout, 50 samples/hour with printout	 Whole blood,serum, Plasma,urine,dialysate Aqueous standards, QC 60 samples/hour without printout, 50 samples/hour with printout	N/A

System/ Equipment: ISE 9180 Analyzer

Results:

	Required/Ordered	Actual	Specs Met
Calibration	Fully automatic, 1-point with every sample. 2-point every 4 hours	Fully automatic, 1-point with every sample. 2-point every 4 hours	N/A
Measuring unit	mmol/L	mmol/L	
Physical Dimensions (max): Height- Depth- Width- Weight-	 33.5cm 29.5cm 31.5cm 6kg	 33.5cm 29.5cm 31.5cm 6kg	N/A
Power requirements Line Voltage- Line frequency- Power consumption- Insulation coordination- Fuse-	 110-240v 50/60Hz 50W	 110-240v 50/60Hz 50W	N/A
Environment Condition Temperature: -Running condition- -Transport/storage- Humidity- Pollution- Altitude-	 +15 °C to +32 °C 5%-95%,non condens		N/A
Installation Manual/Booklet			**N/A**
Spare parts list, part numbers and supplier			**N/A**
Other			**N/A**

Performed by: Mr.Thamaraiselvan. *Signature:*
Service Engineer – Roche Diagnostics India Pvt Ltd
Verified by: Dr.Gandhi *Signature:*
Designation: Chief of the Laboratory

Deviation Report

Deviation(s): No Deviations observed

Justification for acceptance: Instrument has demonstrated satisfactory performance

Report Written by: Thamaraiselvan S *Signature :*
Designation:Service Engineer - Roche Diagnostics Pvt Ltd

Installation Qualification Report

Date study initiated:	26.12.2019
Date study completed:	26.12.2019
Observations made:	None
Problems encountered:	None
Completeness of information collected:	Yes
Results of the tests:	Passed
Conclusions:	Instrument is in Good working Condition

Report Written by: Thamaraiselvan S *Signature:*
Service Engineer– Roche Diagnostics India Pvt. Ltd
Verified by: Dr.Gandhi *Signature:*
Designation: Chief of the Laboratory

Roche Diagnostics

ISE 9180 Analyzer

Electrolyte Analyzer

OPERATIONAL QUALIFICATION

For

A3 HORMONE LAB

Salem

Ph: 04274042601

MARKETED BY:

Roche Diagnostics India Pvt. Ltd,

Roche House, Plot No. 114 Road No. 15, MIDC, Andheri (E) , Mumbai - 400 093

Roche

Materials, SOPs, Documents

Following are the topics course needed to perform the Operational Qualification

1.) Basic Operational Procedures
- -Startup
- -Preparing samples
- -Analyzing samples
- -Working with results and
- -Shut down.

2.) Special Operation
- -Calibration
- -Control

3.) Maintenance
- -General Maintenance.

Procedure

Provide SOPs and datasheets for normal operations of the system.

Providing basic operational training and documenting that operators have been trained.

Ensure adequate practice with general Maintenance and some tips to trouble shooting.

Test and record calibration data with QC reports.

Test and record other outputs.

Record any deviations to the procedures performed.

Prepare an Operational Qualification Report:

This should include date study initiated; date completed; observations made; Deviation report; justification of acceptance and impact on the operation. Results of control/alarm tests; other information and Conclusions on the validity of the equipment/system operations.

Submit to QA for review and approval

Results:

Preparation: System/Equipment -**ISE 9180 Analyzer** Instrument ID: **28608**

Document check:

SOP Title & Number	File Location	QA/QC approval date
Basic Operational Procedures Special Operation Maintenance Procedures	LAB	26-12.2019

Training Records

Staff name	*Designation*
1. *Dr.M.Gandhi*	*Biochemist*
2. *Mrs.Jayam*	*Lab Technician*
3. *Mr.Ramesh*	*Lab Technician*
4. *Mr.Mani*	*Lab Technician*

**For training certificates and reports refer to the attachment.*

Equipment Make and Model
Roche ISE 9180 Analyzer

Manual Available
Y [yes] N [ ]

Conclusion: *Do the results meet the specified Acceptance Criteria?*

Yes: ☑ *No:* ☐ *Signature & Date:*

Performed by: Mr.Thamaraiselvan *Signature :*

Verified by: Dr.Gandhi *Signature :*

Designation: Chief of the Laboratory

Results:

Calibration Data: 26-12-2019

Expected Millivolt Values

Electrode	Standard- A milli volts	Standard B milli volts	Standard C milli volts	Difference A-B milli volts	Difference A-C milli volts
Na	-600 to 2400	-1600 to 2000	-600 to 2400	250 to 680	-50 to 50
K	-700 to 1000	-2500 to 500	-700 to 1000	470 to 1200	-40 to 40
Cl-	-3100 to -100	-1000 to 3000	-3100 to -100	-370 to -860	N/A
Ca+	-3100 to 1000	-2300 to 2300	-3100 to 1000	-350 to -650	-550 to 150
Li+	-3100 to 1900	-3600 to 1400	-2600 to 3400	1 to 760	-1730 to -285

Measured Calibration Millivolt Values

Electrode	Electrode Serial Numbers	Standard A Solution mv	Difference A-B mv	Difference A-C mv
Na	32622744947	637	566	N/A
K	40529744747	-167	1073	N/A
Cl	2032044247	-168	-660	N/A
iCa	N/A	N/A	N/A	N/A
Li	N/A	N/A	N/A	N/A
Reference	N/A	N/A	N/A	N/A

For Calibration and Quality Control Results data, refer to the attachment.

Performed by: Mr. Thamaraiselvanar *Signature :*

Deviations: Nil

Verified by: Dr. Gandhi *Signature:*

Designation: Chief of the Laboratory

Results: Date performed:

Quality Control Material: Bio-Rad

Control	Test	Result	Acceptable Range	Acceptable Yes/No
BIO-RAD Level-1 Lot-26461 Exp date: 31-07-2022	Na+	144	138-144	YES
	K+	4.0	3.5-4.1	YES
	Cl-	96	77-115	YES
	iCa2+	N/A	N/A	N/A
	Li	N/A	N/A	N/A
BIO-RAD Level-2 Lot-26462 Exp date: 31-07-2022	Na+	131	98-148	YES
	K+	6.8	4.84-7.24	YES
	Cl-	88	65-98	YES
	iCa2+	N/A	N/A	N/A
	Li	N/A	N/A	N/A

Performed by: Mr.Thamaraiselvan.s Signature :

Deviations: ___Nil_____

Verified by: Dr.Gandhi Signature : _

Designation: Chief of the Laboratory

Maintenance procedures of the equipment or system

Test in normal conditions:

List and protocols for 'Maintenance under Normal Conditions' attached.

Daily Maintenance: 1) Perform Deprotinizer (Cleaning Sloution)

2) Perform Conditioner (Na+ conditioning solution)

Monthly: Check needle & fillport. Clean reference electrode housing

As required: - Changing Snap pack, changing fill port holder, Clean Probe and wash port, Replacing electrode and p p tubing, Cleaning Measuring chamber, Decontamination tube path.

For Protocols refer to ISE 9180 Analyzer Operator manual > Maintenance Chapter.

Conclusion: *Do the results meet the specified Acceptance Criteria?*

☑ *Yes:* ☐ *No:* *Signature :*

Performed by: .Mr. Thamaraiselvan.s *Signature:*

Deviations: _____N/A_____

Verified by: Dr.Gandhi *Signature:*

Deviation Report

Deviation(s): None

Justification for acceptance: Instrument has demonstrated satisfactory performance

Impact on operation, function or process: None

Report Written by: Mr.Thamaraiselvan.s *Signature:*

Designation: Service Engineer

Operational Qualification Report

Date study initiated:

Date study completed:

Observations made:	Mechanical function, Measurement, Display, Result Reporting-No Error encountered
Problems encountered:	None
Completeness of information collected:	Yes
Results of the tests:	Passed
Conclusions:	All function passed without Error

Written by: Mr.Thamaraiselvan.s *Signature :*

Verified by: Dr.Gandhi *Signature :*
Designation: Chief of the Laboratory

Roche Diagnostics

ISE 9180 Analyzer

Electrolyte Analyzer

PERFORMANCE QUALIFICATION

Form

A3 HORMONE LAB

Salem

Ph: 04274042601

MARKETED BY:

Roche Diagnostics India Pvt. Ltd.

Roche House, Plot No. 114 Road No. 15, MIDC, Andheri (E) , Mumbai - 400 093

Validation Protocol **Performance Qualification**

System/ Equipment: **ISE 9180 Analyzer**
Electrolyte analyzer

Protocol written by: **Roche Diagnostics Pvt Ltd.**

Departmental Approval by: Dr. Gandhi *Sign :*__

Designation: Chief of the Laboratory

Objective

To determine that the systems/equipment perform as intended by repeatedly running the system on its intended schedules and recording all relevant information and data. Results must demonstrate that performance consistently meets pre-determined specifications under normal conditions, and where appropriate for worst case situations.

Scope

To be performed after the Installation and Operational Qualification have been completed and approved. To be performed after installation, modification or relocation and for re-validation at appropriate intervals. The performance Qualification protocol includes: Precision study, Control recovery study, Linearity study, Method Correlation study, & Ref range Study.

Responsibility

Person responsible for operating the system or equipment will perform the qualification and record the information. The supervisor will supervise the study, verify the completion of the records and write the Deviation Report and the Performance

Validation Report

Equipment Name: AVL -9180 (ISE)

Serial No:28608

Validated during: Dec 20219

Analyzer Type: Ion-Selective Electrolyte Analyzer

Manufacturer: Roche Diagnostics India Pvt. Ltd.

Name of the Laboratory:A3 Hormone Lab

Lab Location: Salem

Validated Protocol:

1) 1 Serum specimen was analyzed 20 times in a single run- **Intra assay variations.**
2) Non-Roche (Bio-Rad) has been run both the levels 10 time each –**Accuracy.**
3) 1 High concentration sample has been diluted and examined in **replicate – Linearity.**

Test Validated:

1. Sodium (Na)
2. Potassium (K)
3. Chloride (CL)

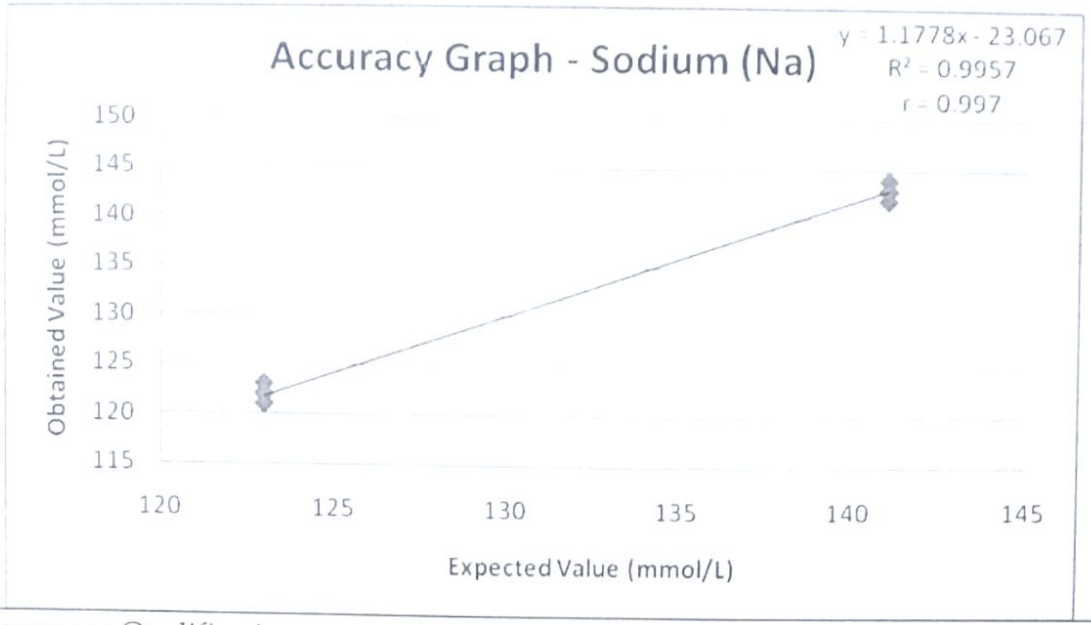
1) **Intra-assay precision data:**

Sr.No:	Sodium	Potassium	Chloride
Unit	**mmol/L**	**mmol/L**	**mmol/L**
Run 1	135	4.1	101
Run 2	135	4.1	104
Run 3	135	4.0	103
Run 4	135	4.0	103
Run 5	135	4.1	103
Run 6	135	4.2	103
Run 7	134	4.1	104
Run 8	135	4.1	102
Run 9	135	4.1	102
Run 10	135	4.1	102
Run 11	135	4.1	102
Run 12	135	4.1	102
Run 13	136	4.1	102
Run 14	136	4.1	102
Run 15	135	4.1	102
Run 16	135	4.1	102
Run 17	135	4.1	102
Run 18	136	4.1	102
Run 19	136	4.1	102
Run 20	135	4.1	102
Mean	**135.2**	**4.1**	**102.4**
S.D	**0.49**	**0.04**	**0.75**
% C.V	**0.36**	**0.96**	**0.73**

2a) Accuracy check – Sodium

Sr.No:	Biorad Levels	Target Mean Value (mmol/L)	Obtained Value (mmol/L)
1	Lot No: 26461	141	144
2		141	143
3		141	143
4		141	144
5		141	143
6		141	142
7		141	143
8		141	143
9		141	143
10		141	142
11	Lot No: 26462	123	121
12		123	121
13		123	122
14		123	122
15		123	121
16		123	123
17		123	122
18		123	121
19		123	122
20		123	123

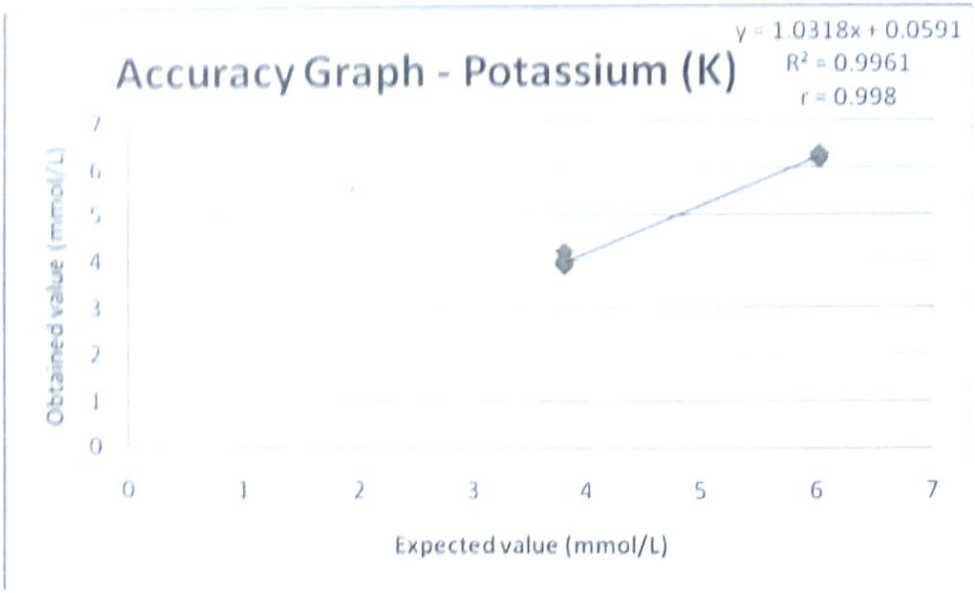
STEYX: 0.73



2b) Accuracy check – Potassium

Sr.No:	Biorad Levels	Target Mean Value (mmol/L)	Obtained Value (mmol/L)
1	Lot No: 26461	3.8	3.9
2		3.8	3.9
3		3.8	3.9
4		3.8	4.2
5		3.8	4.0
6		3.8	3.9
7		3.8	4.0
8		3.8	4.0
9		3.8	4.0
10		3.8	4.0
11	Lot No: 26462	6.0	6.3
12		6.0	6.3
13		6.0	6.2
14		6.0	6.2
15		6.0	6.3
16		6.0	6.3
17		6.0	6.2
18		6.0	6.3
19		6.0	6.2
20		6.0	6.2

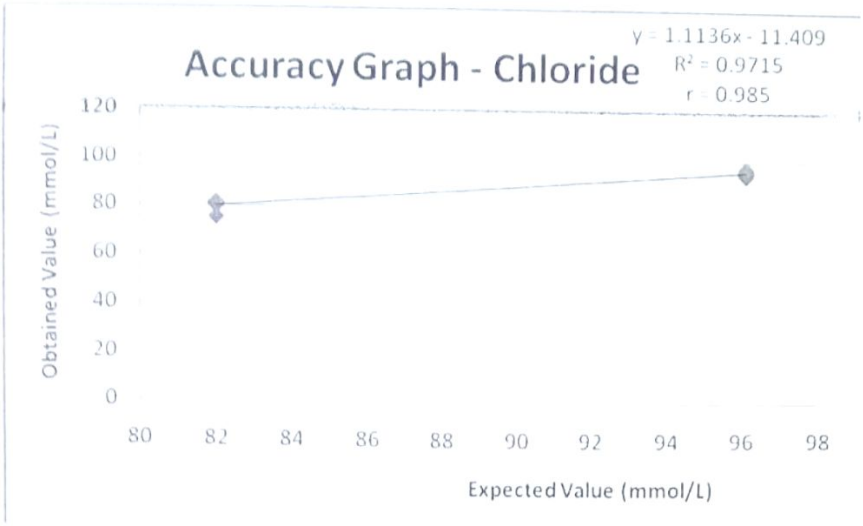
STEYX: 0.07



2c) Accuracy check – Chloride

Sr.No:	Biorad Levels	Target Mean Value (mmol/L)	Obtained Value (mmol/L)
1	Lot No: 26461	96	95
2		96	96
3		96	96
4		96	97
5		96	96
6		96	96
7		96	95
8		96	95
9		96	95
10		96	94
11	Lot No:— 26462	82	81
12		82	81
13		82	80
14		82	81
15		82	81
16		82	81
17		82	80
18		82	80
19		82	80
20		82	75

STEYX: 1.42



3) Linearity Data:

a) Sodium Electrolyte

Sr.No:	Target Value	Replicate 1	Replicate 2	Lower Tolerance Limit	Upper Tolerance Limit	Assay Mean value	S.D Value	Recovery (%)	% C.V
1	178	178	178	160.2	195.8	178	0.00	100.0	0.00
2	91	90	91	81.9	100.1	90.5	0.71	99.5	0.78

Note: Undiluted and 1:2 dilution

b) Chloride Electrolyte

Sr.No:	Target Value	Replicate 1	Replicate 2	Lower Tolerance Limit	Upper Tolerance Limit	Assay Mean value	S.D Value	Recovery (%)	% C.V
1	163	162	162	146.7	179.3	162	0.00	99.4	0.00
2	67	67	67	60.3	73.7	67	0.00	100.0	0.00

Note: Undiluted and 1:2 dilution

Manufacture Linearity Limit:

	specified for	specified range
Sodium	B/S/A/D/Q U	40 - 205 mmol/L 1 - 300 mmol/L
Potassium	B/S/Q A/D U U*	1.5 - 15 mmol/L 0.8 - 15 mmol/L 4.5 - 120 mmol/L 60 - 120 mmol/L
Chloride	B/S/A/D/Q U	50 - 200 mmol/L 1 - 300 mmol/L
Calcium	B/S/A/D/Q	0.2 - 5.0 mmol/L
Lithium	B/S/Q	0.1 - 6.0 mmol/L

B -whole blood
S -serum or plasma
A -dialysis solutions containing acetate
D -dialysis solutions containing bicarbonate
Q -aqueous QC material
U -urine samples (dilution required)
U*- urine samples (second dilution required)

DILUTION PROCEDURE:

Before measuring urine, accurately dilute the sample with Urine Diluent in the ratio

of 1 part urine to 2 parts diluent (e.g., 1 mL urine and 2 mL urine diluent). Thoroughly mix the sample and analyze in the urine mode.

As soon as **[READY]** will be displayed, the analyzer is ready for measurements. Urine samples, diluted with urine diluent, are analyzed in the urine mode. To enter this mode:

- Press **NO**, until **[QC/STD/DIALYSATE/URINE SAMPLE?]** is displayed. Press **YES**
- Press **NO**, until **[Urine Sample?]** is displayed. Press **YES** and follow the instructions.
- Upon completion of measurement, the analyzer will display and print the results.

Summary:

The AVL 9180 Electrolyte validation has been done. Upon Intra-assay precision check the obtained % C.V is < 1.0 % which is valid and acceptable. The accuracy study with Non-Roche Quality Control (Biorad) material the obtained co-efficient correlation value $r \geq 0.95$, which is valid and acceptable. The Standard Error (STEYX) has been calculated of the accuracy data (T.Mean Vs the obtained Q.C results). The Linearity study has been done with high concentration sample for sodium and chloride electrolytes, in which dilution for lower concentration analytes such as potassium is not applicable. The obtained % recovery (90- 120 %) and % C.V (< 1 %) is valid and acceptable for linearity study.

Performance Qualification Report

Date study initiated:

Date study completed:

Observations made: None

Problems encountered: None

Completeness of information collected: Yes

Results of the tests: Acceptable

Conclusions:

Study demonstrates acceptable performance of precision & accuracy.

Written : Mr.Thamaraiselvan.s *Signature & Date:*

Verified by: Dr.Gandhi *Signature :*

Designation: Chief of the Laboratory