



INSTALLATION QUALIFICATION

Customer Name : Care Diagnostics
3rd cross, Neeladri Nagar,
Electronic City Phase I, opposite to ICICI Bank,
Bengaluru, Karnataka 560100

Instrument Model : DIESTRO ELECTROLYTE INSTRUMENT

Instrument Serial No. : 2157

THE FOLLOWING CHECKS AND SETUPS ARE CARRIED OUT FOR **DIESTRO ISE ELECTROLYTE INSTRUMENT** FOR INSTALLATION QUALIFICATION.

- | | |
|---|----------------------------------|
| 1. INSPECT SHIPPER FOR PHYSICAL DAMAGE
Found any damage | <input type="text" value="NO"/> |
| 2. INSPECT THE INSTALLATION SITE
Clean
Dust free
Air- conditioned | <input type="text" value="YES"/> |
| 3. INSTALLATION WORK BENCH
Stable
Capable of supporting 20 kg | <input type="text" value="YES"/> |
| 4. BENCH SPACE TO ACCOMMODATE THE
Following instrument dimensions
(W x D x H) 430 x 300 x 330mm, | <input type="text" value="YES"/> |
| 5. CLEARANCE FOR THE SYSTEM
Minimum should be 30 cms al sides | <input type="text" value="YES"/> |
| 6. OPERATIONAL ROOM ENVIRONMENT
Temperature (12 -32 deg.C) | <input type="text" value="YES"/> |

- | | |
|---|--------------------------|
| 7. POWER REQUIREMENTS
Operating voltage: 110-230 V
Electrical grounded outlets | <input type="checkbox"/> |
| 8. Verify all contents as per instrument kit list | <input type="checkbox"/> |
| 9. Install the all three chambers | <input type="checkbox"/> |
| 10. Install the 2.5A/230 V fuse & memory card | <input type="checkbox"/> |
| 11. Install reagent pack | <input type="checkbox"/> |
| 12. Install the printer paper roll | <input type="checkbox"/> |

The above mentioned check has been carried out and the installation qualifications for the instrument found satisfactory.

Protocol performed by: JK Biomed

Name : KALAIARASAN TR

Signature : 

Designation: SERVICE MANAGER

Date : **06/03/2020**



PERFORMANCE QULIFICATION

Customer Name : **Care Diagnostics**
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Instrument Model : **DIESTRO ELECTROLYTE INSTRUMENT**

Instrument Serial No. : **2157**

Calibration Done on : **06/03/2020**

Calibration Due on : **05/03/2021**

THE FOLLOWING CHECKS AND SETUPS ARE CARRIED OUT FOR **DIESTRO ELECTROLYTE INSTRUMENT** FOR PERFORMANCE QUALIFICATION.

TRI LEVEL **QC** **Exp Date 2021/10** **Level -1**

PARAMETER	MEASURED (MMOL/L)	RANGE (MMOL/L)
Na+	121.1	110 – 122 MEAN (116)
K+	2.01	1.85- 2.16 MEAN(2.00)
Cl-	83.0	71 – 85 MEAN (77)

TRI LEVEL **QC** **Exp Date 2021/10** **Level -2**

PARAMETER	MEASURED (MMOL/L)	RANGE (MMOL/L)
Na+	140.6	132 – 147 MEAN (140)
K+	3.98	4.13 – 4.51 MEAN(4.47)
Cl-	100.2	89 – 104 MEAN(99)

TRILEVEL QC

Exp Date 2021/10

Level -3

PARAMETER	MEASURED (MMOL/L)	RANGE (MMOL/L)
Na+	157.3	153– 160 MEAN (161)
K+	8.03	6.61 – 7.70 MEAN (7.15)
Cl-	120.1	107 – 125 MEAN(116)

TWO POINT CALIBRATION FOR ELECTRODES

PARAMETER	CAL VALUES (MMOL/L)	SLOPE (MMOL/L)
Na+	57.61	50 – 64
	57.30	
K+	61.04	50 – 64
	60.63	
Cl-	50.86	40 – 64
	49.19	

REPEATABILITY TEST FOR SAMPLE


PARAMETER	CAL VALUES (MMOL/L)	RANGES (MMOL/L)
Na+	134.5	135 – 148
	134.4	
K+	4.87	3.50 – 5.30
	4.80	
Cl-	99.8	99 – 107
	98.8	

REMARKS: ALL MEASURED VALUE IS WITHIN THE TARGET RANGE FOR ALL THREE LEVELS OF CONTROLS AND CALIBRATION.

Protocol performed by: JK Biomed

Name : KALAIARASAN TR
Signature : 
Designation: SERVICE MANAGER
Date : 06/03/2020

Customer Authorization:

Name : SUDHARSAAN M
Designation: LAB MANAGER
Signature : 
Date : 06/03/2020.



OPERATIONAL QUALIFICATION

Customer Name : Care Diagnostics

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THE FOLLOWING CHECKS AND SETUPS ARE CARRIED OUT FOR **DIESTRO ISE ELECTROLYTE INSTRUMENT** FOR OPERATIONAL QUALIFICATION.


- | | |
|---|----------------------------------|
| 1. DEFINE SETUP AS PER LABORATORY REQUIREMENTS | |
| a) Q.C | <input type="text" value="YES"/> |
| b) SAMPLE | |
| c) SYSTEM OPTIONS | |
| d) PRINTER AND MEMORY | |
| e) Fill Port Cleaner | |
| 2. PERFORM DIAGNOSTIC (SLOW SPEED & HIGH SPEED) | |
| Check for Roller Pump | <input type="text" value="YES"/> |
| 3. PERFORM DIAGNOSTIC CHECK FOR TUBINGS & VALVE | <input type="text" value="YES"/> |
| 4. PERFORM SAMPLE DETECTOR TEST FOR ELECTRODES CHAMBER | <input type="text" value="YES"/> |
| 5. PERFORM 2 POINT CALIBRATION | <input type="text" value="YES"/> |
| 6. PERFORM CONDITIONING BY USING FRESH SERUM/WHOLE BLOOD | <input type="text" value="YES"/> |
| 7. PERFORM SAMPLE ASPIRATION IN MANUAL MODE | <input type="text" value="YES"/> |

- 8. **PERFORM FULL TWO POINT CALIBRATION**
(CALIBRATION PERFORMED BY THE INSTRUMENT ITSELF FOR REGULAR USAGE) YES

- 9. **HANDING OVER AND USER TRAINING** YES

- 10. **CHECKED FOR TRUE VALUE CHECK (Q.C)**
(REFER PERFORMANCE QUALIFICATION FOR DETAILS) YES

- 11. **THE SYSTEM IS READY FOR SPECIFIC USAGE.** YES

Protocol performed by : JK Biomed
Name : KALAIARASAN TR
Designation: SERVICE MANAGER
Signature : 
Date : 06/03/2020

Customer Authorization:
Name: SUDHARSAN. M
Designation: LAB MANAGER
Signature: 
Date: 06/3/2020



CALIBRATION CERTIFICATE

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Name : SUDHARSAN M
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Signature : 
Date : 06/03/2020