

H.No. 32, Near Pavakkulam Temple, LFC Road, Kaloor.P.O, Kochi-682017, Ph : +91 484 4038304 (Off. ) : +91 97467 44304, +91 934 9349304

E-mail : inznabiomedicals@gmail.com, Web : www.insigniabiomedical.com

**MANJERI CLINICAL LABORATORY & IDEAL X-RAYS, MANJERI**  
PPM CHECKLIST FOR ELECTROLYTE ANALYZER

<u>CBS 300 ELECTROLITE ANALYZER</u>		<u>SERIAL NO: BE010802</u>	
<b>I. SPECIAL PRECAUTIONS</b>			
<p>If there is evidence of blood or serum contamination, submit the device for cleaning and decontamination before inspecting it.</p> <p>Wear appropriate Personnel Protection Equipment (PPE) during work.</p> <p>Refer to the Safety procedure for additional precautions and guidance.</p>			
<b>II. TEST APPARATUS REQUIRED</b>			
1. ELECTROLYTE ANALYZER		Model: CBS 300	Serial: BE010314
Description	status	Description	status
1. AC Plug	Passed	8. Rotary Valve	Passed
2. Line Cord	Passed	9. Fluid Flow	Passed
3. Fuse	Passed	10. Indicator	Passed
4. Tubes	Passed	11. Display	Passed
5. Connectors	Passed	12. User Calibration	Passed
6. Electrode Value	Passed	13. Pump Tube	Passed
7. Controls	Passed	14. Pinch Valve	Passed
		15. Air Sensor	Passed
<b>III. PREVENTIVE MAINTENANCE TASKS</b>			
Description	status	Description	status
1. Clean the whole tubings	Done	3. Replace Deteriorated components	Done
2. Clean the rotary valve	Done	4. Lubricate	Done



IV. QUALITY CONTROL DATA

Quality Control	Na+			K+			Cl-		
	Target	Measured Value	Range	Target	Measured Value	Range	Target	Measured Value	Range
Level -1	118.0	118.2	1.87	2.12	2.28	0.17	81.5	81.6	1.53
Level -2	140.6	140.6	1.89	3.97	4.05	0.17	102.1	101.5	1.49
Level -3	160.2	161	1.89	6.05	6.03	0.17	120	119.5	1.5

V. SUMMARY

NOTES

Calibrated the instrument. Analyzed the Tri Level Quality Controls. Instrument is working perfectly.  
 Next calibration is due on 16-09-2022

Completed by  
**MOHAMMED RASHID CM**

Verified by:



Customer Signature: **M. ALI KOYA**

Date :

17-09-2021

Time:

4.30 PM

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**INSTALLATION QUALIFICATION**

MODEL NO. : CBS 300 ELECTROLYTE ANALYZER  
SERIAL NO. : BE010802  
IMPORTED & MARKETED BY : B&E DIAGNOSTICS INDIA PVT LTD  
DISTRIBUTOR : INSIGNIA BIOMEDICAL  
LFC ROAD, NEAR PAVAKKULAM TEMPLE  
KALOOR , ERNAKULAM - 682017  
CUSTOMER NAME : MANJERI CLINICAL LABORATORY & IDEAL X- RAYS  
MANJERI, MALAPPURAM DIST  
DATE OF INSTALLATION : 15-09-2021

ENGINEER (INSIGNIA BIOMEDICAL)

SIGNATURE :



NAME : MUHAMMED RASHID  
DESIGNATION : SERVICE MANAGER  
COMPANY : INSIGNIA BIOMEDICAL

CUSTOMER (MANJERI CLINICAL LABORATORY & IDEAL X- RAYS)

SIGNATURE :



NAME : M. ALIKOYA  
DESIGNATION : MANAGER

**OPERATIONAL QUALIFICATION**

ANALYSER OPERATIONAL CHECK POINT	REMARK
❖ PROBE	OK
❖ AIR SENSOR	OK
❖ PINCH VALVE	OK
❖ PROBE CUP	OK
❖ PUMP CALIBRATION	OK
❖ Power SWITCH	OK
❖ FUSE	OK
❖ CODE WIRE	OK

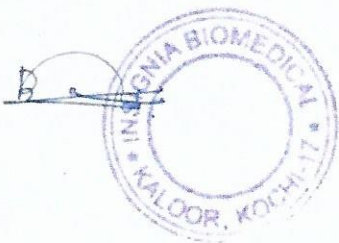
**FUNCTIONAL CHECK**

❖ SLOPE VALUES	OK
❖ SAMPLE	OK
❖ PUMP MOTOR	OK
❖ LIQUID LEVEL DETECTION	OK
❖ REAGENT STATUS	OK
❖ PRINTER TEST	OK
❖ COM PORTS	OK

VERIFIED BY : Mr. MUHAMMED RASHID

REVIWED BY:  
MANJERI CLINICAL LABORATORY & IDEAL X-RAYS  
M. ALIKOYA

SIGNATURE :



SIGNATURE :



**PERFORMANCE QUALIFICATION**

<b>QC DATA REPORT</b>		DATE : 15-09-2021
MODEL	: CBS 300	
S/N	: BE010802	
QC LOT NO	: 10059	
EXP	: 10-11-2022	

<b>INSTRUMENT PERFORMANCE:</b>		
SLOPE VALUES: K = 35 - 80	AIR SENSOR	: LIQUID: 839(NR> 700)
: Na = 35 - 80		AIR : 460 (NR<540)
: Cl = -80 - -35	PUMP CALIBRATION	: PUMP RATE : 1.002
		(0.9-1.1)

ACCURACY: Mean Must fall within low & high limit.  
Precision : CV must be equal to or less than the CV limit

K+	ACCURACY & PRECISION		
QC LEVEL	LOW	NORMAL	HIGH
TARGET VALUE	2.12	3.97	6.05
LOW LIMIT <sup>1.67</sup>	1.67	3.46	5.53
HIGH LIMIT	2.64	4.48	6.57
	2.13	3.94	5.99
	2.14	3.92	5.97
	2.11	3.95	5.99
MEAN	2.13	3.94	5.98
SD	0.02	0.02	0.01
CV	0.72	0.39	0.19
CV LIMIT	1.00	1.00	1.00
PRECISION	PASS	PASS	PASS
ACCURACY	PASS	PASS	PASS

CL -	ACCURACY & PRECISION		
QC LEVEL	LOW	NORMAL	HIGH
TARGET VALUE	81.50	102.10	120.30
LOW LIMIT	76.91	97.62	115.51
HIGH LIMIT	86.09	106.58	124.49
	82.50	102.80	121.10
	82.70	102.50	120.70
	81.90	101.80	120.70
MEAN	82.37	102.37	120.83
SD	0.42	0.51	0.23
CV	0.51	0.50	0.19
CV LIMIT	1.00	1.00	1.00
ACCURACY	PASS	PASS	PASS
PRECISION	PASS	PASS	PASS

NA+	ACCURACY & PRECISION		
QC LEVEL	LOW	NORMAL	HIGH
TARGET VALUE	118.00	140.60	160.20
LOW LIMIT	112.4	134.93	154.53
HIGH LIMIT	123.6	146.27	165.87
	118.70	141.60	161.80
	118.90	141.60	161.40
	118.70	141.60	161.40
MEAN	118.77	141.70	161.53
SD	0.12	0.17	0.23
CV	0.10	0.12	0.14
CV LIMIT	1.00	1.00	1.00
ACCURACY	PASS	PASS	PASS
PRECISION	PASS	PASS	PASS

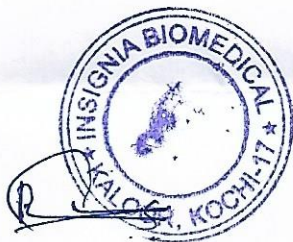
HERE I'm VERIFYING THAT THE CONTROL RESULT OF THE EXECUTED PARAMETERS ARE WITHIN THE RANGE.

VERIFIED BY : Mr. MUHAMMED RASHID

REVIWED BY:  
MANJERI CLINICAL LABORATORY & IDEAL X-RAYS

M. ALIKOYA

SIGNATURE :



SIGNATURE :