

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> | |
| I. SPECIAL PRECAUTIONS | | | |
| <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> | | | |
| II. TEST APPARATUS REQUIRED | | | |
| 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 |
| III. PREVENTIVE MAINTENANCE TASKS | | | |
| Description | status | Description | status |
| 1. Clean the whole tubings | Done | 3. Replace Deteriorated components | Done |
| 2. Clean the rotary valave | Done | 4. Lubricate | Done |



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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 |

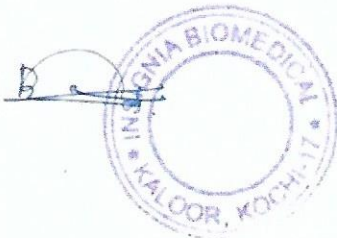
FUNCTIONAL CHECK

| | |
|--------------------------|----|
| ❖ 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
QC DATA REPORT

 MODEL : CBS 300
 S/N : BE010802
 QC LOT NO : 10059
 EXP : 10-11-2022

DATE : 15-09-2021

INSTRUMENT PERFORMANCE:

 SLOPE VALUES: K = 35 - 80
 : Na = 35 - 80
 : CI = -80 - -35

 AIR SENSOR : LIQUID: 839(NR> 700)
 AIR : 460 (NR<540)
 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 ^{1.67} | 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 | | |
|--------------|----------------------|--------|--------|
| | LOW | NORMAL | HIGH |
| QC LEVEL | | | |
| 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 |

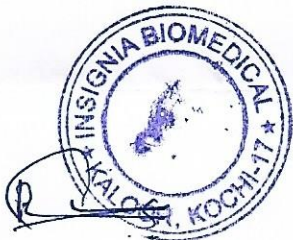
HERE I'm VERIFYING THAT THE CONTROL RESULT OF THE EXECUTED PARAMETERS ARE WITHIN THE RANGE.

VERIFIED BY : Mr. MUHAMMED RASHID

REVIWED BY:
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