a PerkinElmer company

CIN: U85195GA1988PTC005717

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Coralyzer Series Fully Automatic Biochemistry Analyzer,Inspection/calibration Report

Test QC refer to: <<Coralyzer Series Fully Automatic Analyser>> Registered Standard Model: Coralyzer Junior, S/N: AES2KOKH12052

SRI SAMRAJ LAB'S , TIRUVARUR

| | / | leter Number:TU/INST/ | Criterion of QC test | | Result | Conclusion | |
|----|-------------------------------|---|-------------------------------|-----------------|------------|------------|--|
| | Inspection Item | | | Conclusion | | | |
| | | a) Analytical method m | OK | | | | |
| | | b) Programming item | | | OK | | |
| | | | spect of emergency sample. | OK OK | - | | |
| | | d) Calibration linearity/non-linearity multi point calibration. | | | | | |
| | | e) QC at may operate n | OK | | | | |
| | | g)Storage | OK | | | | |
| | | OK | PASS | | | | |
| | | h) Printer multiple repo | OK | | | | |
| | - | j) Sample rerun/rechec | OK | | | | |
| | | k) Sample /reagent pro | OK | | | | |
| | | I) Mixing function. | OK | | | | |
| | | m)Results storage,quer | OK | | | | |
| | | n) cuvette condetion. | OK | | | | |
| | | o) Crash gard function | | | ОК | | |
| 2 | Dark Abs | Absorbance >= 3.400 A | | | 5.2 | ОК | |
| 3 | Linearity range of | | nce should be not less than 3 | 700A within the | 340nm: 5.1 | OK | |
| | | relative range of ± 5% | 505nm: 4.8 | OK | | | |
| | Accuracy of absorbance | Less than ± 0.040A at 1 | .00A | | 0.012 | OK | |
| 4 | | Less than ± 0.060A at 1 | 0.027 | OK | | | |
| | | Less than ± 0.020A with | 0.048 | OK | | | |
| | | | 340nm: 0.003A | OK | | | |
| 5 | Accuracy | Absorbance change sh | 505nm: 0.002A | OK | | | |
| 6 | Reproducibility of absorbance | cofficient of variation of | 2.73% | ОК | | | |
| | Temperature of | Accuracy less than tha | | 37°C | OK | | |
| 7 | reaction cuvette 37 | Fluctuate of temperatu | 0.005°C | OK | | | |
| 8 | Teperature of reagent storage | Under normal work co | 6.0 °C | ОК | | | |
| 9 | Carryover | Sample carryover less | than 0.05% | | PASS | | |
| | Accuracy of parameter | Items | Concentration | CV | | | |
| | | UREA | 76.3-109.9 | ≦ 3% | 1.30% | OK | |
| 10 | | GLUC | 81.0-116.6 | ≦ 3% | 1.20% | OK | |
| | | SGOT | 55-87 | ≦ 3% | 2.70% | OK | |
| | | a) Whole appearance of | | 1 | | | |
| 11 | Apperance | corrosion and surface | PASS | | | | |
| | | b) All connections are | | | | | |
| | | c) Moving parts runnin | | | | | |
| 12 | Protect ground | The impedance betwe | PASS | | | | |
| | connect | protected touchable m | FASS | | | | |
| - | Power grid, power | Basic insulation:50Hz t | PASS | | | | |
| 13 | supply, circuit | brakdown or occur ele | FASS | | | | |

Inspection/Calibration date: 25.06.22

Check: S Nishanth

re-check: S Nishanth

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First Line
Second Line

| QC(Name-Lot) | Test | Target Valu | ue SD Value | QC Range | Result | Test Date | State |
|--------------|--------|-------------|-------------|---------------------|--------|------------|-------|
| RANDOX | GLUC | 279 | 21 | 238 ~ 320 | 307 | 06-07-2022 | |
| RANDOX | CREAT | 4.80 | 0.48 | $3.84 \sim 5.76$ | 4.05 | 06-07-2022 | |
| RANDOX | CHO SR | 284 | 19 | $247 \sim 321$ | 314 | 06-07-2022 | |
| RANDOX | TGL SR | 252 | 20 | $212 \sim 292$ | 251 | 06-07-2022 | |
| RANDOX | HDL-D | 94.65 | 7.18 | $80.30 \sim 109.00$ | 87.15 | 06-07-2022 | |
| RANDOX | SGOT | 155 | 16 | $124 \sim 186$ | 142 | 06-07-2022 | |
| RANDOX | SGPT | 151 | 15 | $121 \sim 181$ | 130 | 06-07-2022 | |
| RANDOX | TP | 4.45 | 0.44 | $3.56 \sim 5.34$ | 4.12 | 06-07-2022 | |
| RANDOX | ALB | 2.82 | 0.21 | $2.40 \sim 3.24$ | 3.16 | 06-07-2022 | |
| RANDOX | CALA3 | 12.2 | 0.6 | $11.0 \sim 13.4$ | 12.2 | 06-07-2022 | |
| RANDOX | TBIL | 5.85 | 0.61 | $4.62 \sim 7.08$ | 6.30 | 06-07-2022 | |
| RANDOX | ALP | 325 | 25 | $276 \sim 374$ | 282 | 06-07-2022 | |