



Coral Clinical Systems
A Division of Tulip Diagnostics (P) Ltd.

a Perkin Elmer company

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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: Cralyzer Smart, S/N: AES2K1KH051664

Meter used for calibration: TULIP/01/2021/FLU/179/265/8003, Cal Date:- 01/06/2023, Due Date:- 01/06/2024

Sr. No.	Inspection Item	Criterion of QC test	Result	Conclusion												
1	Software functions	CRITERIA OF QC TEST a) Analytical method may analyse 40 pos at the same time. b) Programming item c) Automatic priority inspect of emergency sample. d) Calibration linearity/non-linearity multi point calibration. e) QC at may operate most of QC at same item. f) Data processing calculation parameters, balk value correction, the defination of normal range, g)Storage h) Printer multiple report formats available, user can self edit report formats. i) STAT j) Sample dilute/recheck. k) Sample /reagent probe liquid check. l) Mixing function. m)Results storage,query,quality control chart,the whole process of monitoring the responce curve. n) Crash gard function.	OK OK OK OK OK OK OK OK OK OK OK OK	PASS												
2	Dark Abs	Absorbance >= 3.400 A	5.2	OK												
3	Linearity range of absorbance.	The maximum absorbance should be not less than 3.700A within the relative range of ± 5%	340nm: 4.9 505nm: 4.8	OK OK												
4	Accuracy of absorbance	Less than ± 0.040A at 1.00A Less than ± 0.060A at 1500A Less than ± 0.020A within 0.500A	0.012 0.027 0.048	OK OK OK												
5	Accuracy of absorbance	Absorbance change should be less than 0.005A/min	340nm: 0.003A 505nm: 0.002A	OK OK												
6	Reproducibility of absorbance	cofficient of variation cv ≤ 3%	2.73%	OK												
7	Temperature of reaction cuvette 37	accuracy less than than ± 0.1° C Fluctuate of temperature less than ± 0.1° C	37° C 0.005° C	OK OK												
8	Teperature of reagent storage	Under normal work condition, reagent storage should be 2-8° C	6.0° C	OK												
9	Carryover	0.05% Sample carryover less than 0.05%	PASS													
10	Accuracy of parameter	<table border="1"> <thead> <tr> <th>Items</th> <th>Concentration</th> <th>CV</th> </tr> </thead> <tbody> <tr> <td>UREA</td> <td>76.3-109.9</td> <td>IA 3%</td> </tr> <tr> <td>GLUC</td> <td>81.0-116.6</td> <td>IA 3%</td> </tr> <tr> <td>SGOT</td> <td>55-87</td> <td>IA 3%</td> </tr> </tbody> </table>	Items	Concentration	CV	UREA	76.3-109.9	IA 3%	GLUC	81.0-116.6	IA 3%	SGOT	55-87	IA 3%	1.30% 1.20% 1.70%	OK OK OK
Items	Concentration	CV														
UREA	76.3-109.9	IA 3%														
GLUC	81.0-116.6	IA 3%														
SGOT	55-87	IA 3%														
11	Apperance	a) Whole appearance of the surface should not have obvious mechanical abrasion, corrosion and surface coating spalling. b) All connections are stable and fixed well. c) Moving parts running smooth and keypad works well	PASS	PASS												
12	Protect ground connect	The impedance between ground outlet from power supply net and ground protected touchable metal should not more than 0.1 Ω	PASS	PASS												
13	Power grid, power supply, circuit	Basic insulation:50Hz the sine 230V alternating voltage test, continue 2s. should not apper brakdown or occur electric arcing	PASS	PASS												

Inspection/Calibration date: 01/06/2023

Check: DINIL



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