



CERTIFICATE OF COMPLIANCE

Beckman Coulter Chemistry Analyzer

Model Name	Item Number	Serial Number
Beckman Coulter Chemistry Analyzer M271-OPF	B23281	1053415

Manufacturing Date: (yyyy-mm-dd) 2021-05-25

Item	Description and/or Specification	Pass/Fail
1. Electrical safety	1. Insulation resistance Dielectric strength voltage Protective earth resistance Leakage current	Pass
2. Mechanical safety	2. Cover open / close status checking, etc.	Pass
3. Physical safety	3. Emergency shutdown system operation checking, etc.	Pass
4. Operation checking	4. Each unit(probe, nozzle operation etc.,) operation is smooth. The system does not produce an error.	Pass
5. Thermal property checking	5. DI water temp. in the cuvette : 36.9~37.5°C	Pass
6. Photometry performance checking	6. No errors.	Pass
7. Communication functional checking	7. No communication error.	Pass
8. Barcode reader functional checking	8. No communication error.	Pass
9. Appearance/Labeling	9. The space and the difference between covers are 3mm or less - same as reference.	Pass
10. Dispensing performance checking	10. Reagent R100 : CV \leq 0.8% Reagent R150 : CV \leq 1.5% Sample 1.0 μ l : CV \leq 1.5% Sample 1.6 μ l : CV \leq 1.3% Sample 2.0 μ l : CV \leq 0.9% Sample 5.0 μ l : CV \leq 0.7%	Pass
11. Within-run reproducibility	11. GLU : CV \leq 1.5% Mean = 85 \pm 6mg/dl	Pass
12. Software control	12. Verification checking result is not " FAILED".	Pass

AUTHORIZED SIGNATURE:

AKIHIKO OKAMOTO

Quality Assurance Group
Beckman Coulter Mishima K.K.

ISSUED DATE: (yyyy-mm-dd)

2021-05-25