



## CERTIFICATE OF COMPLIANCE

### Beckman Coulter Chemistry Analyzer

Model Name	Item Number	Serial Number
Beckman Coulter Chemistry Analyzer AU480	B96693	2025031522
ISE Unit	B11803	5039672

Manufacturing Date: (yyyy-mm-dd) 2025-03-13

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/Labelling	9. The space and the difference between covers are 3mm or less - same as reference.	Pass
10. Dispensing performance checking	10. Reagent : CV $\leq$ 0.8% Sample 1.6 $\mu$ l : CV $\leq$ 1.3% (Sample 1 $\mu$ l : CV $\leq$ 1.5%) Sample 2 $\mu$ l : CV $\leq$ 0.9% Sample 5 $\mu$ l : CV $\leq$ 0.8%	Pass
11. Within-run reproducibility	11. GLU : CV $\leq$ 1.5% , Mean=85 $\pm$ 6mg/dl Applicable with ISE model Only Na : CV $\leq$ 0.6% K : CV $\leq$ 2.0% Cl : CV $\leq$ 0.7%	Pass
12. Software control	12. Verification checking result is not " FAILED".	Pass

AUTHORIZED SIGNATURE:

SHINJIRO OKURO

Quality Assurance Group  
Beckman Coulter Mishima K.K.

ISSUED DATE: (yyyy-mm-dd)

2025-03-13