Comparative analysis of blood glucose test results between portable Celercare M1 analyzer and Beckman DxC800 analyzer

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【Abstract】Objective: To compare and analyze the blood glucose test results of the portable Celercare M1 analyzer and the Beckman DxC800 analyzer. Methods: Refer to the Clinical and Laboratory Standards Institute (CLSI) EP9-A2 method test protocol. Collect serum from 100 patients with different blood glucose concentrations. Blood glucose was measured using a Celercare M1 analyzer and a Beckman DxC800 analyzer. Compare the differences between the two methods of blood glucose measurement results.

Results: The Celercare M1 analyzer, the intra assay precision and inter assay (within day) precision coefficient of variation (CV) of median blood glucose values was 1.41%, 1.88%, respectively. The intra assay precision and inter assay (within day) precision coefficient of variation (CV) for high blood glucose values was 0.78% and 0.97%, respectively. The blood glucose measurement result of the analyzer was linear in the range of 1.0 mmol/L to 30.0 mmol/L, and the regression equation was y=0.9799x+0.0598 (R²=0.999).

The regression equations for the Celercare M1 analyzer (y) and Beckman DxC800 (x) blood glucose measurements are y=0.974x+0.139, R²=0.999 (P<0.001). The relative bias at the level of blood glucose medical decision-making (2.8 mmol/L, 7.0 mmol/L, 11.1 mmol/L) was 2.4%, 0.6%, and 13%, respectively, which were lower than the allowable error range of the US Clinical Laboratory Improvement Amendments (CLIA'88).

Conclusions: The precision and linear range of the blood glucose measurement results of the portable Celercare M1 analyzer meets clinical requirements and is
comparable to the Beckman DxC800 analyzer blood glucose measurement results.

【Key words】Celercare M1 analyzer; blood glucose; comparative analysis