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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 $y=0.9799x+0.0598$ ($R^2=0.999$).

The regression equations for the Celercare M1 analyzer (y) and Beckman DxC800 (x) blood glucose measurements are $y=0.974x+0.139$, $R^2=0.999$ ($P<0.001$). 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

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comparable to the Beckman DxC800 analyzer blood glucose measurement results.

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