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Comparison Analysis and the Bias Assessment of the Results between Celercare M1 and Beckman DXC800 Analyzer

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Abstract To investigate the comparability of conventional biochemical assay results between Celercare M1 and Beckman DXC800 analyzer, and provide the basis for clinical laboratory accreditation and mutual recognition of test results in different laboratories, Beckman DXC800 detection system (comparison method) and Celercare M1 detection system (test method) were used respectively to make a determination for conventional biochemical items with fresh serum according to the EP9-A2 document of CLSI. We calculated the system bias of each item between test method and comparison method at the level of medical decision and judged the comparability of test results according to the half of CLIA'88 standard. It is shown that the correlation coefficient and the linear equation between Celercare M1 and Beckman DXC800 analyzer are excellent ($R \geq 0.975$, $P < 0.01$), the result biases for each item in medical decision levels are lower than 1/2 CLIA'88 acceptance standard. It is demonstrated that the measurement results between Celercare M1 detection system and Beckman DXC800 detection system have excellent comparability.

Keywords method comparison; Celercare M1 analysis system; bias