

Performance Evaluation of the CareSTART S1 Analyzer for Quantitative Point-Of-Care Measurement of Glucose-6-Phosphate Dehydrogenase Activity

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Abstract : Background & Objective: Glucose-6-phosphate dehydrogenase (G6PD) deficiency is a genetic abnormality that results in an inadequate amount of G6PD, leading to increased susceptibility of red blood cells to reactive oxygen species and hemolysis. The present study aimed to evaluate the careSTARTTM S1 analyzer for measuring G6PD activity to hemoglobin (Hb) ratio. Methods: Precision for G6PD activity and hemoglobin measurement was evaluated using control materials with two levels on five repeated runs per day for five days. The analytic performance of the careSTARTTM S1 analyzer was compared with spectrophotometry in 40 patient samples. Reference ranges suggested by the manufacturer were validated in 20 healthy males and females each. Results: The careSTARTTM S1 analyzer demonstrated precision of 6.0% for low-level (14~45 U/dL) and 2.7% for high-level (60~90 U/dL) control in G6PD activity, and 1.4% in hemoglobin (7.9~16.3 u/g Hb). A comparison study of G6PD to Hb ratio between the careSTARTTM S1 analyzer and spectrophotometry showed an average difference of 29.1% with a positive bias of the careSTARTTM S1 analyzer. All normal samples from the healthy population were validated for the suggested reference range for males (≥ 2.19 U/g Hb) and females (≥ 5.83 U/g Hb). Conclusion: The careSTARTTM S1 analyzer demonstrated good analytical performance and can replace the current spectrophotometric measurement of G6PD enzyme activity. In the aspect of the management of clinical laboratories, it can be a reasonable option as a point-of-care analyzer with minimal handling of samples and reagents, in addition to the automatic calculation of the ratio of measured G6PD activity and Hb concentration, to minimize any clerical errors involved with manual calculation.

Keywords : POCT, G6PD, performance evaluation, careSTART

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