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PERFORMANCE EVALUATION OF STATSTRIP® GLU/KET HOSPITAL METERS ACCORDING TO CLSI-EP STANDARDS

C. Lhermerout[1], G. Musso[1], E. Cavalier[1], R. Gadisseur[1]

[1]CHU de Liège, Liege, Belgium

Objectives: This study evaluated the performance of 169 StatStrip®Glu/Ket Hospital Meters before use across seventy rooms in seven hospital sites, where 216 000 blood glucose tests are performed annually.

Material and Methods: We evaluated 169 StatStrip®Glu/Ket Hospital Meters (Gen 2.0) (Nova Biomedical Corporation®), using an enzymatic electrochemical assay for whole blood glucose, following CLSI-EP standards with a total allowable error of 11% (RiliBÄK guidelines). Precision was assessed using three control levels (59, 115, and 300 mg/dL), tested twice daily for 5 days. Bias was calculated against the method's mean for each control level. For method comparisons, we first compared StatStrip®(Gen 1.0) (A.Menarini Diagnostics) and StatStrip®(Gen 2.0) in 20 patients' whole blood. Then, we compared StatStrip®(Gen 2.0) using heparinized whole blood and the Alinity (Abbott) with the centrifuged plasma hexokinase method in 40 patients. Results were analyzed using Bland-Altman plots and Passing-Bablok regression. Sciensano's external quality control was evaluated in duplicate over 5 days. Two biases were calculated: one using Sciensano's hexokinase target value and a second using the mean of the peer group with StatStrip®(Gen 1.0).

Results: Mean inter- and total imprecision was 2.4% and 2.9%, respectively. Eight devices exceeded the desirable bias (2.33%) for level-1, two for level-2, and five for level-3. Comparison between the Alinity and StatStrip®(Gen 2.0) showed a non-significant bias of 2.5%, with a slope of 1.04 (95%CI: 0.981–1.08) and an intercept of -0.367 (95%CI: -3.82–3.20). StatStrip®(Gen 1.0) and (Gen 2.0) indicated good agreement, with a slope of 1.03 (95%CI: 0.960–1.09), an intercept of -1.24 (95%CI: -6.67–3.92), and a non-significant bias of 0.6%. Bias using Sciensano's target value was -7.4% and bias using peer's target value was 1.36%.

Conclusions: StatStrip®(Gen 2.0) results were comparable to peer group. However, they showed lower results than Sciensano's target value when using artificial matrix, while non-significant bias was observed in patient samples. This might be due to non-human sample commutability issues. CV and bias were within minimal biological ranges (2.3–3.45% and 2.33-3.49%, respectively), the total error remained within the 11% limit, validating the method according to CLSI-EP standards.