

Clinical Evaluation of a handheld POC Creatinine device in a Sick Diabetes Patient Setting

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Background. Diabetic patients have an increased risk of developing chronic kidney disease which can often be undiagnosed. Diabetic patients are also at high risk of developing diabetic nephropathy particularly if nephrotoxic drugs have been prescribed such as ACE inhibitors, antibiotics, antifungals and anti-inflammatories or are exposed to radiocontrast agents. Early indication of renal impairment can improve patient management. The adoption of an easy to use handheld POCT creatinine device can aid the rapid identification of kidney function in diabetes outpatient clinics or even in the primary care setting. The aim of the present study was to assess the performance of a POCT creatinine (StatSensor Creatinine) for use in diabetes patients.

Methods.

The precision and accuracy (bias) of the new POCT creatinine meter (SSC) was compared to the central laboratory Dimension Vista Jaffe method routine (Siemens). An in laboratory analytical assessment was performed initially to assess the calibration (alignment) using venous whole blood samples spiked with creatinine. The clinical assessment was undertaken on capillary and venous samples collected from diabetes out-patients attending.

Results.

StatSensor Creatinine met CLSI EP05-A2 precision criteria and showed a good correlation to the central laboratory method ($r^2=0.995$; $y=0.923x+0.28$). The mean % bias of SSC compared to the laboratory method was 6.72%. The sensitivity and specificity was 100% when assessing concordance around creatinine levels of 1.2 and 2.0 mg/dL. .

Conclusions.

StatSensor Creatinine showed good analytical performance and correlated closely to the laboratory method. The routine use of the creatinine meter could greatly improve diabetes patient results turnaround time, and patient satisfaction and because of the immediate availability of the results (30 seconds). The application to capillary blood in comparison to venous blood in diabetes patients is ongoing and will be presented at the meeting.