

# 1. Accuracy of Two Point-of-Care Devices in Detecting Elevated Serum Creatinine in Individuals at Risk for Mesoamerican Nephropathy

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## **Abstract:**

**Purpose:** The purpose of this analysis was to assess the accuracy of two point-of-care creatinine devices, the i-STAT handheld (Abbott, Princeton, NJ, USA) and the StatSensor Xpress (Nova Biomedical, Waltham, MA, USA) in comparison to venipuncture creatinine measures. Additionally, we explored how accurate a previously calculated correction factor for the StatSensor Xpress performed in two independent studies.

**Methods:** There were 213 paired i-STAT and venipuncture samples collected from a community study in Nicaragua in 2015-2016. An additional 267 paired StatSensor Xpress and venipuncture samples were collected, 158 from a community setting in Nicaragua and 109 from a Guatemala sugarcane worker cohort. Pearson correlation coefficients, Bland-Altman plots, and no intercept linear regression models were used to assess agreement between point-of-care devices and blood samples. The previously calculated correction factor of 0.78 was applied to the StatSensor Xpress data and was compared to the paired blood samples.

**Results:** The i-STAT performed the most accurately, overestimating creatinine by 0.07 mg/dL (95% CI: 0.02, 0.12) with no evidence of proportional bias. The StatSensor Xpress performed well at low levels of creatinine (Mean (SD): 0.87 (0.19)). Due to proportional bias, the StatSensor Xpress performed worse in the Nicaragua community setting where creatinine values ranged from 0.31 to 7.04, suggesting a correction factor of 0.66 was needed. The previously calculated correction factor of 0.78 performed well with the Nicaragua data when the data was restricted to creatinine  $\leq 2.59$  mg/dL (Adjusted difference: 0.06 mg/dL; 95% CI: 0.03, 0.09) .

**Conclusions:** These data suggest that the StatSensor Xpress is less accurate as the values of measured creatinine increase, a consideration when using the point-of-care device for screening individuals at risk for Mesoamerican Nephropathy. The i-STAT handheld is an accurate field alternative to lab tested serum; however, in low-resource settings other considerations such as cost and ease of use must be considered when conducting field research.

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