



Clinical science

7 A new, low-cost protein-to-creatinine strip dipstick to improve proteinuria screening for preeclampsia: Preeclampsia in low and middle income countries

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<https://doi.org/10.1016/j.preghy.2016.08.089>

Introduction

Accurate and timely diagnosis of women at high risk for preeclampsia (PE) is key to accessing proper interventions and improving clinical outcomes. In collaboration with LifeAssay Diagnostics (LAD; South Africa), we have developed a new low-cost protein-to-creatinine (Pr/Cr) ratiometric strip test that improves the accuracy of [proteinuria](#) screening over the commonly-used protein-only dipstick by adjusting for urine dilution.

Objectives

Developmental efforts by PATH and its partners have focused on optimizing and evaluating the PrCr test characteristics to advance the prototype to downstream field validation and early introduction.

Methods

Performance evaluation: PATH and Magee Women's Research Institute (USA) performed a laboratory-based evaluation of the LAD Pr/Cr test and the Siemens Multistix PRO LS, a commercial urinary dipstick that measures protein and [creatinine](#) but costs about US \$7 per test. Each test was evaluated using 137 repository [urine samples](#). Samples were selected across the capable dynamic range of the Pr/Cr test, based on protein and creatinine levels determined using a reference clinical laboratory analyzer.

Usability: PATH, in collaboration with Kintampo Health Research Center (Ghana), conducted a field usability study with community [antenatal care](#) (ANC) providers. Data was collected through observation and interviews of 25 participants, including midwives and community health [nurses](#), who performed and interpreted the test using urine control samples and multiple versions of prototype instructions.

Thermal stability: A six-month longitudinal study is being conducted to evaluate both shelf-life stability of unopened product and in-use stability where the same product is repetitively opened over time. Three lots stored at 25 °C, 37 °C, and 45 °C were used for shelf-life evaluations, while the in-use stability study examined test performance on two manufacturing lots at either 25 °C or 45 °C.

Results

Performance evaluation: Compared to the reference standard assay, the LAD Pr/Cr dipstick demonstrated performance of 85% sensitivity and 71% specificity (95%CI) for proteinuria determination using a normal to abnormal cutoff of 0.19 Pr-to-Cr ratio. The Siemens Multistix demonstrated a 82% sensitivity and 79% specificity (95%CI).

Usability: Participants found the test to be simple and easy to use. All participants accurately matched the color of the protein marker on the strip to the instructions, while 80% of participants correctly matched colors for the creatinine marker. Participants overwhelmingly preferred a linear test interpretation chart that outlines each possible permutation of Pr and Cr.

Thermal stability: After four months, the Pr/Cr test strips demonstrated stable performance across all temperatures and manufacturing lots in both shelf-life and in-use stability testing.

Conclusions

The LAD Pr/Cr test provides a similar performance to the Siemens product as compared to the reference test at much lower cost comparable to the protein-only dipstick commonly used in low-resource countries. Other evaluation results indicate the test characteristics are compatible for field use. Additionally, the Pr/Cr test may offer additional advantages to the current protein-only dipstick in providing clearer interpretation to inform proper care.

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