

PrCr URINE DIPSTICK TEST

A Protein/Creatinine rapid test for determining proteinuria status as onset indicator of Preeclampsia/Eclampsia

BACKGROUND

Preeclampsia (PE) is a leading cause of maternal death worldwide. Prevention of severe clinical complications due to PE requires accurate, timely identification of women at high risk and linking them to proper medical care. Proteinuria remains one of the primary indicators to identify women at high risk for PE. Proteinuria is a cardinal manifestation of preeclampsia, together with blood pressure, and its quantitation is important not only for making the diagnosis but also in predicting the prognosis of mother and baby. Measurement of these indicators is recommended in routine antenatal care visits for pregnant women as part of many national antenatal care programs. However, current tools for proteinuria determination have significant limitations in accuracy or accessibility. In the case of the widely-used protein-only dipstick, test results can be unreliable as the test cannot adjust for daily fluctuation of body hydration which can lead to protein measurements that are either too low or too high depending on the level of urine dilution. More accurate tests, such as the 24-hour urine test, are only available for confirmatory testing in tertiary-level clinical settings due to their high cost and technical complexity. A need exists therefore, for a simple to use, accessible, accurate and point of care urine dipstick proteinuria determination test.

TECHNOLOGY DESCRIPTION

Life Assay Diagnostics and its partners have developed a simple to use Protein-to-Creatinine (PrCr) radiometric urine dipstick test. The PrCr urine dipstick test consists of two detection pads that have been specifically formulated to detect protein and creatinine in urine with specific concentrations. The chemical formulation of the pads reacts in such a way resulting in a colour change, which then corresponds to a particular colour block provided on the product label. A woman's proteinuria result is then determined by using an easy-to-use colorimetric chart which corresponds to the specific protein-creatinine ratios. The colorimetric chart has already undergone initial refinement based on feedback received from target users in Ghana during PATH's previous usability evaluation study. The PrCr test is intended for use by health care providers across the health care system in developing countries including at the community level where the majority of women receive routine antenatal care.

VALUE PROPOSITION

The PrCr radiometric urine dipstick test is a low-cost, highly sensitive and specific screening test that is intended to improve antenatal care decisions related to PE in low and middle-income countries (LMICs). The characteristics of the PrCr dipstick test are aligned with the WHO-standards and those of the current protein-only dipstick test, which makes it easier for market adoption. The test will provide access to more accurate proteinuria screening across antenatal care settings, which will help identify more women at risk and provide proper

interventions to ensure that those that are vulnerable receive proper health care.

CURRENT STATUS

Life Assay Diagnostics has been working with PATH and clinical partners in the USA, Canada, South Africa, and Ghana to advance the development of the beta prototype of the PrCr radiometric urine dipstick test.

- Initial laboratory verification tests using urine biorepository samples from pregnant women to determine the correct disease classification have been completed.
- Usability testing in Kintampo Ghana showed that the PrCr test was easy to use and identified the need for other materials to provide additional user support to link the test result to clinical decision-making and further care.
- Pilot thermal stability tests have shown that the PrCr prototype remains stable up to at least four months at various temperatures.

INTELLECTUAL PROPERTY STATUS & PUBLICATIONS

Know-how (manufacturing and operation of the designed product).

OPPORTUNITIES

The project is seeking additional funding and partnerships to introduce PrCr test into Sub-Saharan Africa and other markets. Specific areas where support is still needed include:

- Evidence Generation: Demonstrate PrCr performance in clinical setting.
- Support in commercialisation of the test by Life Assay Diagnostics (Pty) Ltd.
- Advocacy in countries to support and increase product adoption.



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