

Protein-to-creatinine ratiometric urinalysis dipstick test for improved diagnoses of PE/E

Paving the way for improved proteinuria diagnosis

The Test-it® PrCr test, an innovative urine dipstick test that improves the accuracy of proteinuria diagnosis for management of pregnant women with hypertensive disorders, transitioned from a late-stage prototype to a fully commercialized test with market authorizations in two key countries — Ghana and Kenya — as well as in seven countries in Southern Africa and the Philippines.

To advance the product in these key markets, we developed the target product profiles using a human centered design approach and making it publicly available for other product developers and procurers of PrCr tests, and formalized a partnership with LifeAssay Diagnostics, the manufacturer of the Test-it® PrCr test, for closer collaboration.

Preeclampsia (PE) remains one of the leading causes of maternal death worldwide. Accurate and timely diagnosis of PE risk is key to increasing prevention of severe clinical complications and linking women to proper care to prevent death. Current diagnostic tools vary in accuracy and affordability.



Antenatal care provider persona

Rukaya
Midwife

DEMOGRAPHICS

Gender: Female
Age: 36 years old
Education:
• High school certificate
• 2 years of specialized nursing training (DNR)
• 2 years of midwifery training
Experience: 5 years

WORKLOAD

Patients seen per day: 15
Time spent with clients during that ANC visit: 30 to 45 minutes
Time spent with clients during subsequent ANC visits: 15 to 20 minutes
Deliveries per month: 25

GOAL

Rukaya wants her clients to be happy and healthy. She tries to reduce maternal and neonatal mortality through ANC and safe deliveries.

MOTIVATOR

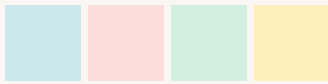
"I just need that passion to guide midwifery as that I will be able to empower these women to know more about themselves, pregnancies, and how to care for themselves."

Check vital signs
Perform physical exam (maternal and fetal development monitoring)
Provide health education (e.g., maternal development, preparation for delivery)
Prescribe lab tests (including one dipstick test to report albuminuria)
Prescribe routine drugs (e.g., low dose aspirin, hypertension medication)
Provide referrals (as needed)
Refer hypertension and complex cases
Prescribe drugs (antihypertensives, PDE-5V treatment)
Provide postnatal care
Discharge the health center
Provide to service training of CHWs and junior midwives
Other responsibilities of midwives in antenatal care

Digital solutions defined by users

We used personas to understand the context and experiences of midwives and community health nurses providing antenatal care in Ghana and specific challenges related to use of routine diagnostics during antenatal care. We found that digital solutions could address their needs for data management and access, automated test interpretation and linkage to care. Digital applications must be able to be used offline, compatible with android devices, offer optional instructional videos and include alerts and timers to address next steps.





PrCr PROTEINURIA DIAGNOSTIC STRIP TEST PIPELINE STATUS

Research ► Translation ► Development ► Implementation

Exited from the portfolio to discontinuation of product

PATH and country partners defined the need and product requirements for the PrCr Test and collaborated to validate the clinical performance of the product and usability among target end-users to support LMIC market entry.

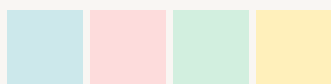
In Kenya, we refined and validated the value proposition of the Test-it® PrCr test by interviewing clinicians at 31 health facilities and disseminating the results at the stakeholder workshop held in June 2021 with attendees from Ministry of Health, Country Health Management Team in Kisumu and Siaya, United Nations Population Fund, and non-government organizations. Hesitancy to task shift from laboratory technicians to providers and difficulty of switching from multiparameter to two-parameter tests emerged as significant issues. Their feedback was used to reshape the value proposition of the Test-it® PrCr test as a tool to effectively monitor high-risk women especially in countries where multi-parameter dipstick tests are the standard of care. Hesitancy to task shift from laboratory technicians to providers and difficulty of switching from multiparameter to two-parameter tests emerged as significant issues.

In Ghana, we assessed the operational and performance characteristics of the LifeAssay Diagnostic (LAD) Test-it PrCr Urinalysis Dipstick test in a representative antenatal care setting. We learned that although the PrCr test offers the potential for improved detection of proteinuria over the standard of care tests currently used in antenatal care, this test and the others evaluated in our study demonstrate limited performance overall, particularly among samples with low levels of proteinuria. We also evaluated the PrCr test in three referral hospital facilities in Ghana when used by healthcare workers with a population of pregnant women at high-risk of hypertensive disorders of pregnancy, alongside the standard-of-care urine dipstick products. While the study demonstrated that the test had good usability and was well accepted by end-users and key stakeholders, results highlighted challenges with implementation such as that the test strip does not include other parameters in addition to protein and creatinine (for example, glucose), which limits its clinical utility in a screening use-case beyond the detection of proteinuria and therefore its ability to replace current products, even among high-risk populations.

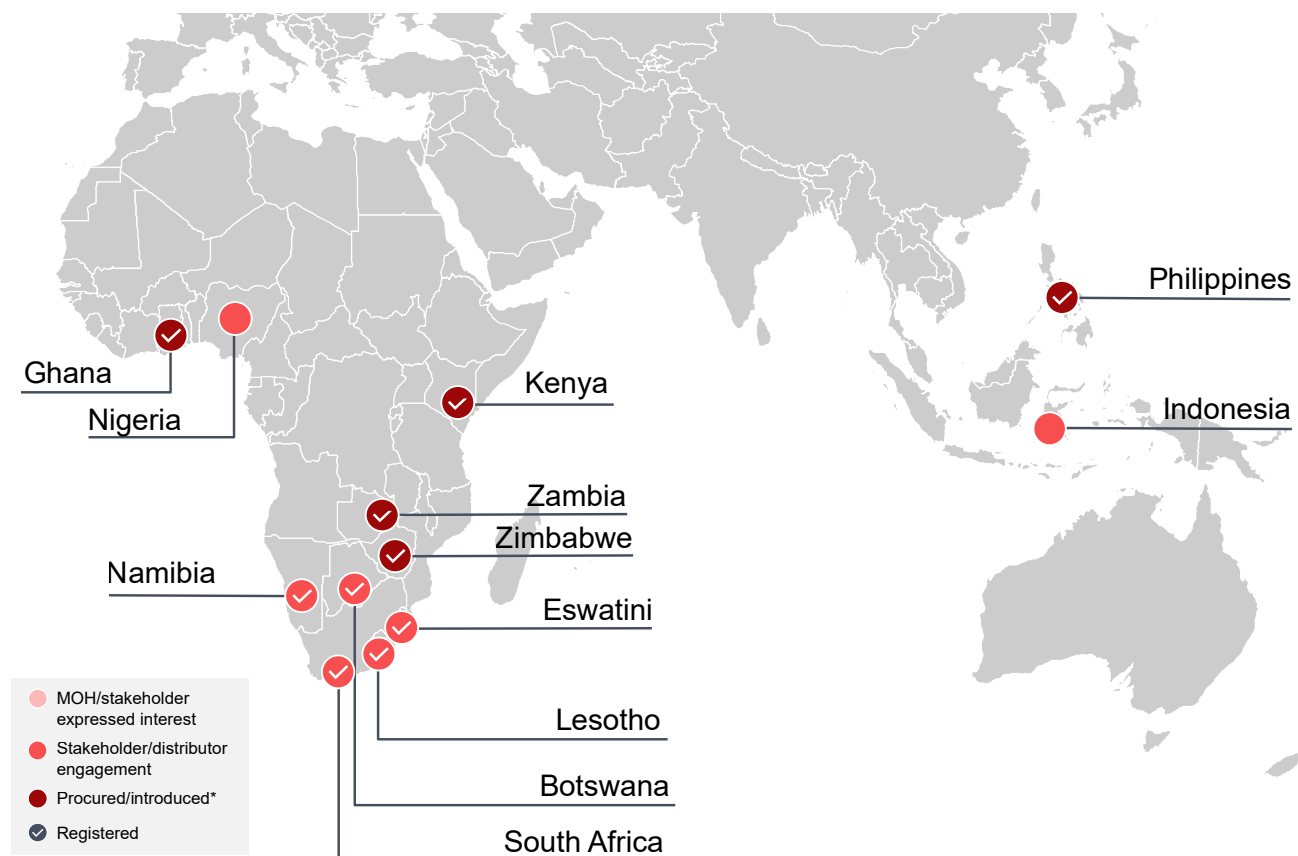


Training of antenatal care providers with the Test-It PrCr test in Ghana.

LifeAssay continues to promote the Test-it® PrCr test to the government and to the not-for-profit sector. Although new biomarker tests are currently in the pipeline, they will likely take some time to be commercialized. In the meantime, the Test-it® PrCr test provides a more accurate option for users to identify and monitor high-risk women with hypertensive disorders during their pregnancy.



Status of introduction for Test-it® PrCr Dipstick Test as of August 2022



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otherwise indicated

