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Highly Sensitive Lateral Flow Strips for Cervical Cancer Screening

A rapid, user-friendly, point-of-care colorimetric test enables highly sensitive, affordable detection of cervical precancerous lesions using gold nanoparticles and enzyme-enhanced protein biomarker analysis.

Around the globe, cervical cancer is a potentially preventable and curable cancer when detected early. However, cervical cancer still claims many lives among young women living in low and middle income countries (LMICs). In 2008, it was estimated that 529,512 women were diagnosed with cervical cancer and about 274,967 women died of the disease, with the majority being in low-resource countries. Cervical cancer screening can greatly improve these numbers, but implementation of an organized, population-based, cervical cancer screening program has not been done in LMICs due to limited resources, scarcities in trained personnel, and the availability of the appropriate screening test. Two methods of detection have been developed to improve screening, such as visual inspection with acetic acid and high-risk human papilloma virus DNA test. The first screen is limited in that cervical cell aceto-whitening is not specific, and the second is limited because one positive HPV test does not justify medical intervention, but identifies women who have an elevated risk. There is a need for an easy, efficient test that accurately diagnoses a patient with cervical cancer without overdiagnosis leading to overtreatment.

To help improve cervical cancer screening in LMICs, researchers at Purdue University have developed a simple point-of-care colorimetric test, CERVBIO, for onsite cervical cancer screening and treatment. It is a single-use, user-friendly technology utilizing key protein biomarkers that are sensitive and specific to cervical precancerous lesions. From a previous lateral flow immunochromatography design and employing the use of gold nanoparticles with an enzyme (horseradish peroxidase) as a tracer, this is a highly enhanced, multiplex detection of cancer protein markers within 15 to 30 minutes. It enhances the signal by increasing the number of enzyme molecules around the detection site. In addition, further improvement in the limit of detection can be achieved by increasing the interaction time between the target of interest (cervical cancer antigens) and the antibodies. This

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Authors
Joseph Irudayaraj

Further information
Patrick Finnerty
pwfinnerty@prf.org

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innovation is advantageous in that it can detect at picogram levels, is colorimetry-based, easy to use (no need for highly trained personnel), rapid, highly sensitive, quantitative, highly affordable, and can be used independently or integrated into existing platforms, making this beneficial for use in LMICs for the screening of cervical cancer.

Advantages:

-User friendly point of care device

-Fast detection of biomarkers

-Enhanced detection at low levels

Potential Applications:

-Medical/Health

-Cervical cancer screening

TRL: 3

Intellectual Property:

Provisional-Patent, 2015-03-05, United States | Provisional-Patent, 2016-07-12, United States | PCT-Patent, 2017-07-12, WO | NATL-Patent, 2018-11-29, United States | DIV-Patent, 2023-09-18, United States | Utility Patent, N/A, United States

Keywords: cervical cancer screening, point-of-care test, colorimetric test, protein biomarkers, precancerous lesions, gold nanoparticles, enzyme tracer, lateral flow immunochromatography, multiplex detection, low resource countries