CLINICAL TEST FOR HPV INDUCED CANCER IN LOW RESOURCE SETTINGS VIA DIRECT DETECTION OF ELEVATED HPV E6 ONCOPROTEIN

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Challenge

The high mortality caused by cervical cancer in the developing world (figure 1) calls for screening technology that allows for widespread implementation while minimizing unnecessary over treatment. The Onco***E6***™ Cervical Test has been developedto meet these requirements (figure 2).

Technology

The Onco***E6***™ Cervical Test features lateral flow format is void of cold chain requirements for storage and for sample collection. Various sample types can be applied, including self collected samples. The time from sample collection to result is 2.5 hours, allowing for immediate action upon a positive result. The test only requires low complexity equipment resulting thus in a low capital investment for laboratory setup (figure 2). The current test detects E6 oncoprotein of HPV types 16 and 18 on two distinct test lines (figure 2). HPV types 16 and 18 account for about 83% of cervical cancer in India (ICO report India “Human Papillomavirus and Related Diseases”).

Clinical Performance

Direct detection of elevated levels of the cancer causing HPV viral oncoprotein E6 results in high clinical specificity and high positive predictive value (figure 3). A Positive test outcome in women with normal pathology informs a high risk of future disease (Figure 4), and the test has detected micro-invasive cancer where the matching cytology outcome was negative (ACCESSING study, Ghana).

Figure 1

Cervical Cancer Worldwide

Onco*E6*™ Cervical Test: Key Features

- High clinical specificity and positive predictive value
- Reduces unnecessary referral to follow-up, while a positive test indicates high disease risk
- Easy to perform, no complex equipment needed, no cold chain required
- Lab set-up cost is low (~US $ 1,000)
- 2.5 hours from sample collection to result – suitable for use screen-and-treat settings
- Compatible with physician and self collected specimens, “dry” collection device or PresrvCyt collected specimens

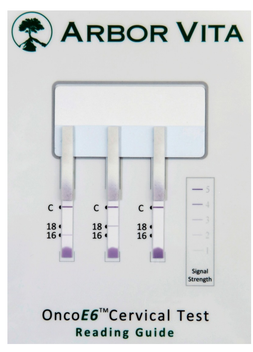
Figure 2

Onco*E6*™ Cervical Test

Test Unit

Complete Workstation Setup

Read of Result



Lateral Flow Principle and Work Flow

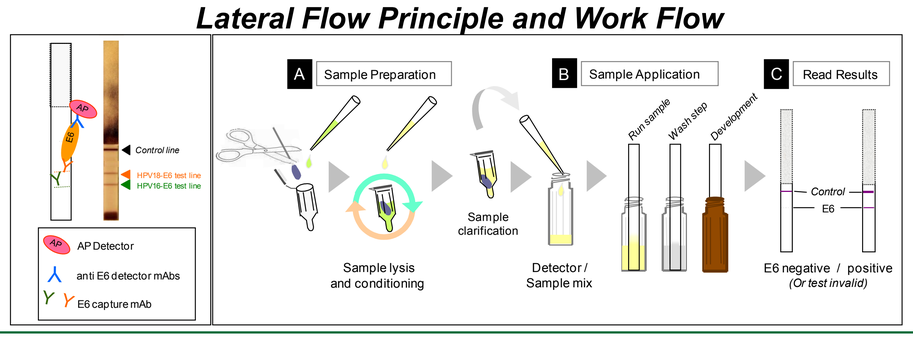
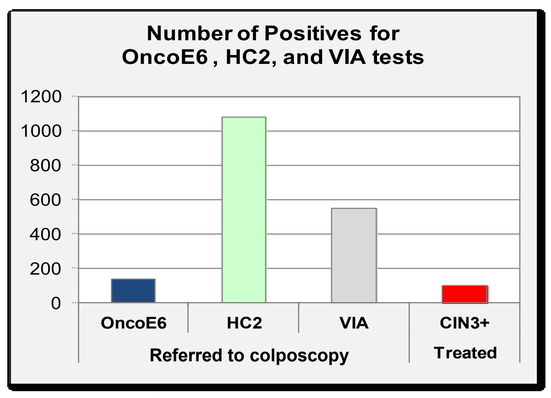


Figure 3

Clinical Performance START-UP Study, China



Positivity by Test

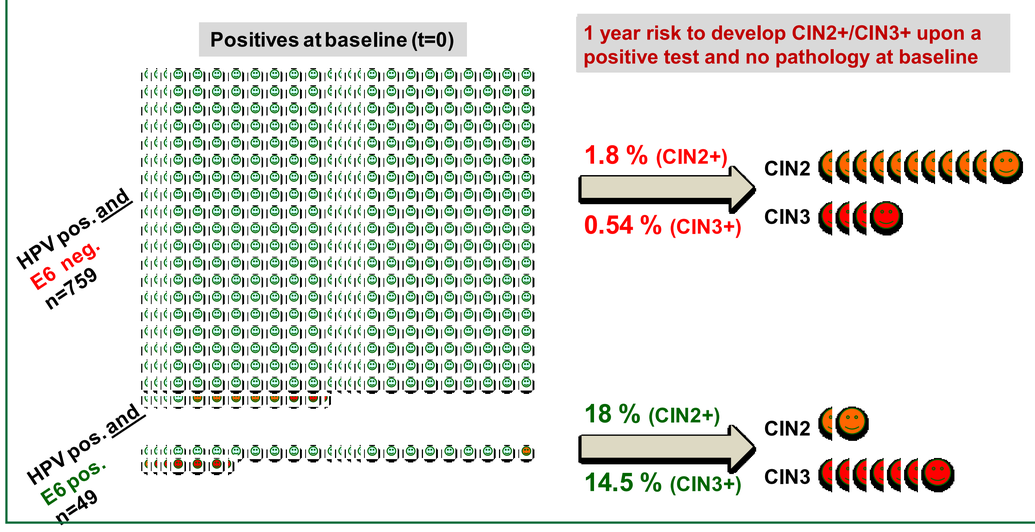
Positivity by Disease State*

*Data based on screening of 3058 subjects from study site 1

Figure 4

Onco*E6*™ Positive Test Describes High Risk for Future Disease

Prediction of Risk: Year 1 Follow-Up Study



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NIH SBIR 2 R44AI068160-03 “Development of an E6 based Rapid Strip Test Commercial Prototype for Cervical Cancer”
NIH BRIDGE 9R44CA182927-05 “Commercialization of the OncoE6TM Cervical Test for detection of HPV induced malignancies”

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