

ABSTRACT

The Pap smear is the most widely used early detection method for HPV caused cervical cancer. Many women in rural Ethiopia do not have access to this procedure, which allows developing cervical cancer to go undiagnosed. This device is an at-home, self-collected urine sample test for the presence of cervical cancer markers E6 and E7. Positive results are indicated by a color change using a lateral flow assay. This device allows women to have more autonomy surrounding their health and provides a low-cost alternative to invasive testing methods.

BACKGROUND RESEARCH

- HPV is the most common sexually transmitted infection [1]
 - 200 different types, but only 40 can infect the genital areas
- Persisting infection of certain strains of HPV can lead to cervical cancer [2]
 - HPV 16 is linked to approximately 50% of cervical cancers worldwide
 - HPV 18 is the second most prominent
- Cervical cancer is one of the most common cancers in women [1]
- Pap smears [3]
 - Provider inserts speculum to visualize cervix
 - Provider then uses a wooden or plastic scraper and/or cervical brush to collect cell sample
 - A cytopathologist then examines the cell sample under a microscope
- OncoE6 Cervical Test [4]
 - Uses Pap smear samples to test for E6
- Pregnancy tests [5]
 - Uses a sandwich assay on nitrocellulose strips
 - Blue latex particles for the dye

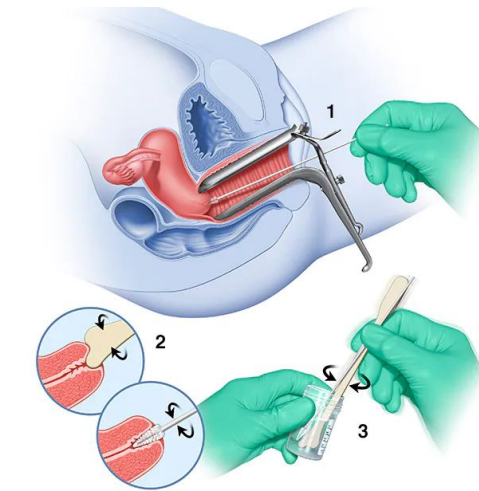


Figure 1. Step-by-step illustration of a Pap Smear Test [3]

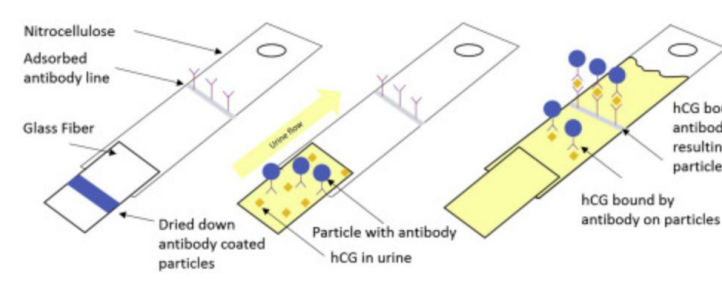


Figure 2. Illustration of a lateral flow test strip for pregnancy tests [5]

PROBLEM STATEMENT

Cervical cancer is one of the most common cancers in women and is one of the most treatable cancers when diagnosed early. Current cervical cancer screenings include routine Pap smears and occasional HPV (human papillomavirus) oncoprotein tests using laboratory techniques. A Pap smear must be performed by a medical professional, as it requires cells to be collected from the surface of the cervix and vagina. While these tests are successful at detecting cervical cancer, they are uncomfortable and not easily accessible for people in developing countries. The development of a self-collected urine sample test would increase accessibility and allow more cervical cancer screenings to be performed worldwide, which in turn would prevent many cervical cancer-related deaths.

DESIGN SPECIFICATIONS

- Client Requirements
 - Sale price between \$3-5 USD
 - Accessible to demographic
 - Easy to use
 - Provides clear results
- Test should provide at least 70% accurate results
- Biocompatible and non toxic
- Should not be biodegradable
- Product should be single use

FINAL DESIGN

COMPONENTS

Lateral Flow Immunochromatographic Assay

- Sandwich Assay
- Nitrocellulose Paper
- Blue Latex particles for control and E6/E7 lines
- Control line antibodies: Goat-anti rabbit IgG and Rabbit IgG (↑)
- E6 (→): E6AP antibody (↓) and p53 antibody
- E7 (←): pRb antibody(↓) and anti-E7 antibody

User Components

- 3D printed rigid resin material testing device
- Urine collection cup
- Sample deposit dropper

TEST HOUSING AND USER MECHANISM

Rigid plastic device to house test strip and increase usability

- Thin lid with viewing hole to allow user to read results on strip and funnel bubble for ease of sample deposit
- Hollow base piece attached to lid
- 3.0" x 1.5" outside dimensions allow device to easily fit in user's hand

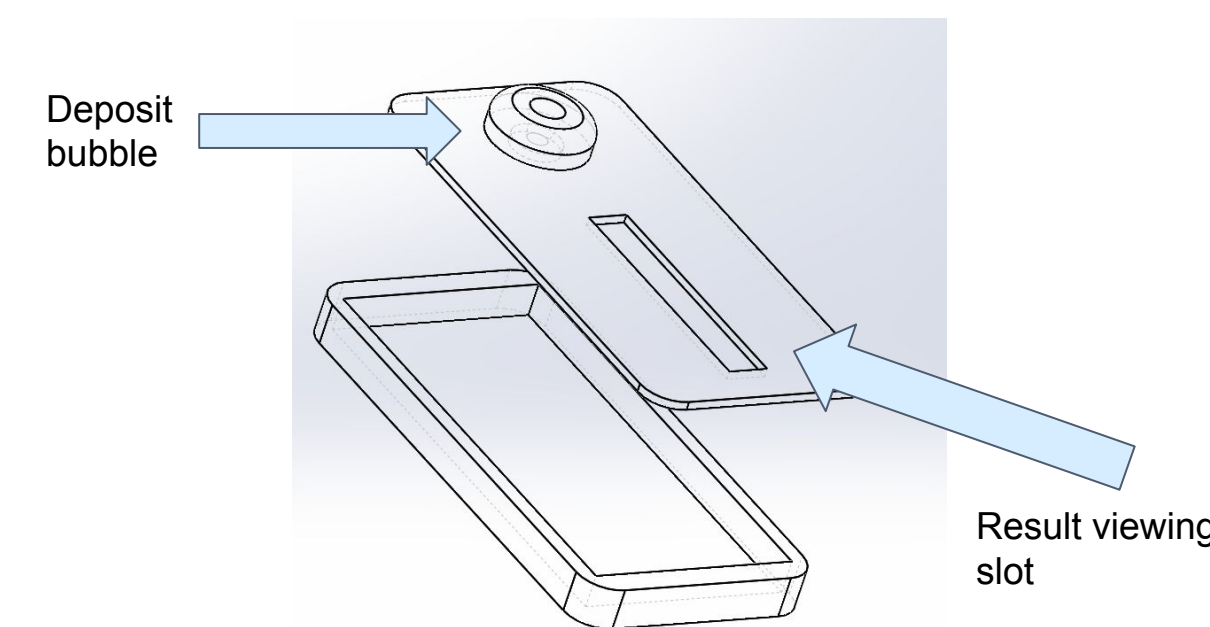


Figure 4. Exploded view of testing device

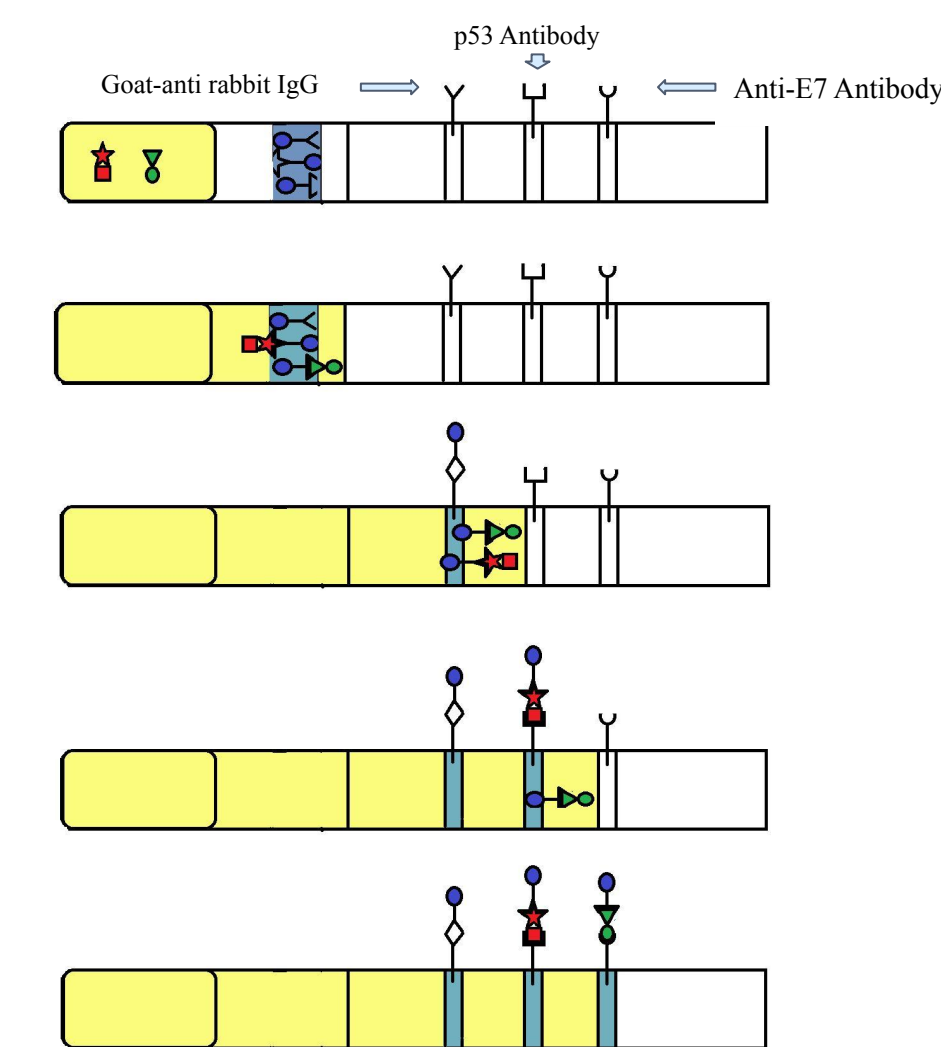


Figure 3. Schematic of function of lateral flow assay

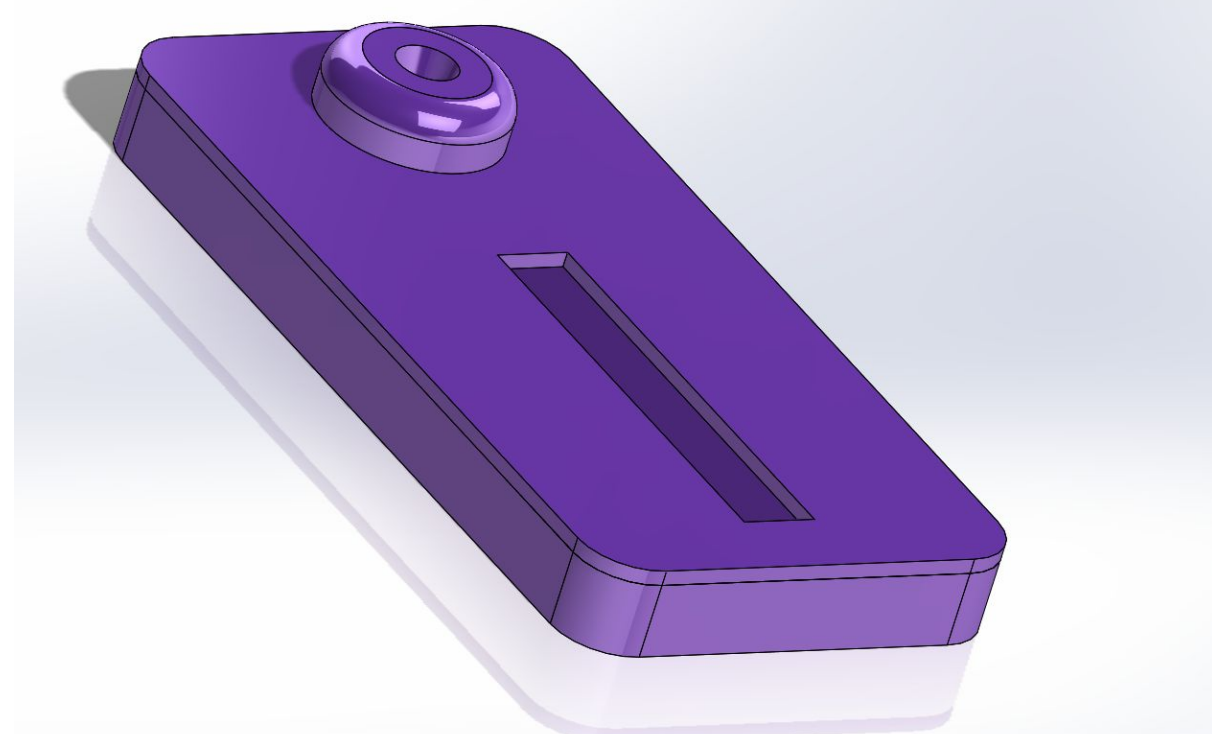


Figure 5. Complete user testing device

TESTING

MECHANICAL TESTS

- Durability Test - test to determine the durability of the prototype design and material
 - Using estimated pressure from typical use, any mechanical failures of the housing were observed
- Leakage Test - a test to determine if the housing will securely hold enough liquid to complete the test without leaking
 - Recommended amount of liquid to complete a test (0.5mL) was deposited into the device through the insertion bubble to test for leakage under proper use or ideal conditions
 - Maximum amount of liquid able to be held by included pipette (3mL) deposited into device to observe potential leakage under improper use, or worst case scenario

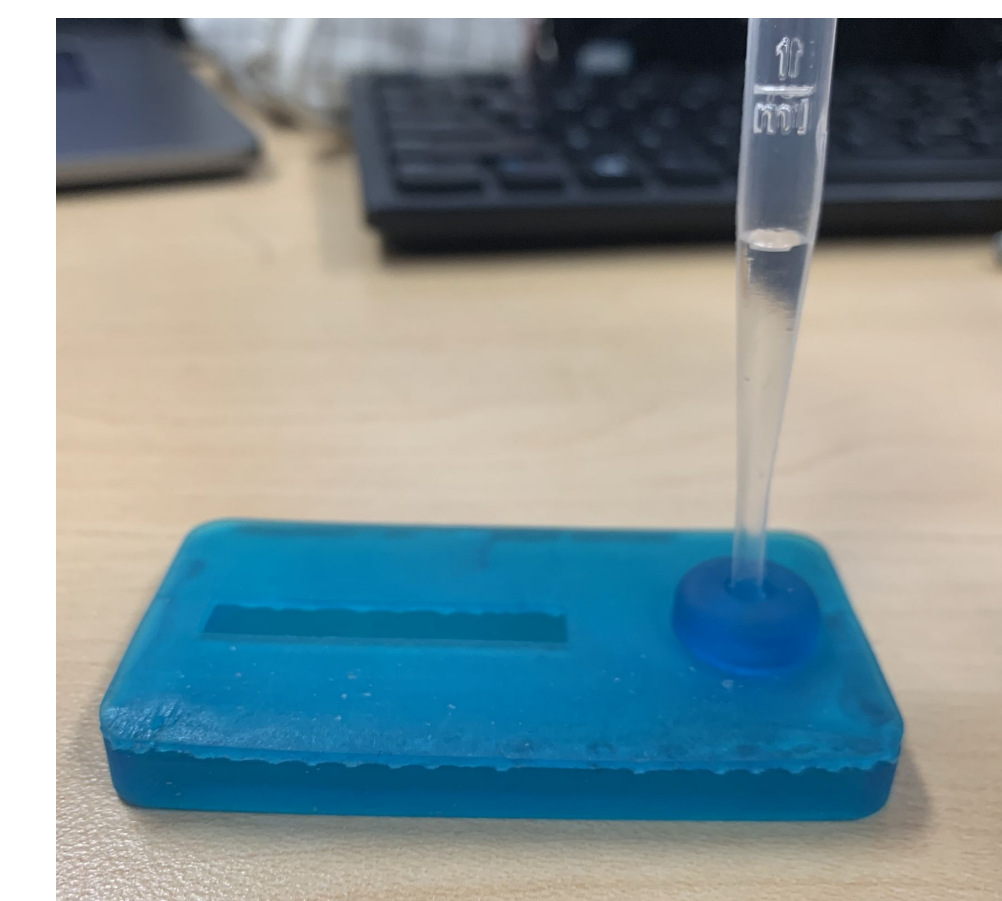


Figure 6. Sample deposit for leakage testing

RESULTS

DURABILITY TEST

- Initial prototype printed from PLA material failed durability test
 - Deposit bubble collapsed with small amount of force from handling the device
- Final prototype made of "TOUGH" resin material passed the durability test
 - Redesigned bubble with larger base and material switch increased rigidity

LEAKAGE TEST

- Final prototype passed leakage test
 - No water leaked from device after 2 minutes

DISCUSSION/FUTURE WORK

DISCUSSION

- The current prototype is theoretically operational but has not been tested for accuracy or fully assembled due to cost and testing limitations.

FUTURE WORK

- Further Device Testing
 - Absorbent Pad Testing and Improvement
 - Concentration of E6/E7 in Urine
 - 200 nmol/L levels in plasma [6]
 - 882.53 copies/ml in cervical scrape[7]
 - Positive Line Visibility
 - Potential difference in line visibility based on cancer progression
 - Multiple HPV Strain Testing
 - More commonly oncogenic strains such as HPV16 and HPV18 versus more commonly benign strains
 - Determine if Testing for Both E6 and E7 is Necessary
 - Positive lines more consistently visible for E6 or E7?
 - Are positive lines visible for both oncoproteins?

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