

## Rapid Tests for Cervical Cancer

### Health need

Cervical cancer is a preventable disease that strikes 470,000 women and kills more than 270,000 women each year, about 85 percent of which are in developing countries. In most developing countries, cervical cancer is the leading cause of cancer deaths among women. The lack of effective cervical cancer prevention programs in poorer countries, including the lack of accurate and affordable tests giving rapid results, is the cause of this inequity between developed and developing countries.

### Technology solution

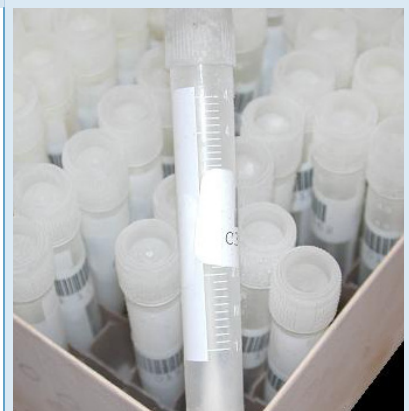
In 2003, PATH began assessing the scientific and economic feasibility of new biochemical tests for the types of human papillomavirus (HPV) that cause most cervical cancers. PATH entered into collaborations with private-sector partners—Digene Corporation and Arbor Vita Corporation—to develop two different rapid tests that will be safe, accurate, affordable, simple, portable, and acceptable to women. As a result, women will have more alternatives to Pap smears and be able to get accurate test results while they wait. If testing reveals that a woman has been infected with a high-risk type of HPV, she could receive medical management on the same day as screening and greatly decrease her risk of developing cervical cancer.

To ensure acceptability, PATH completed an in-depth assessment of users' needs and perceptions and evaluated test characteristics that influence acceptability in low-resource settings (LRS). Prior research has shown that the need for a pelvic exam is a barrier to screening participation in many settings; thus the possibility of a vaginal swab—obtained by the woman or a provider—is also being explored.

### Current status and results

Research and development of the two rapid biochemical tests are nearing completion. Digene is in pilot project phase (in four LRS countries) of a new rapid batch test that detects the presence of DNA from the most common oncogenic types of HPV using hybrid capture technology. This test processes dozens of samples in about 2.5 hours and meets the parameters set for sensitivity, ease of use, and cost. For the second biochemical test, Arbor Vita and PATH are jointly researching the feasibility of a rapid strip test that will process one or more samples within 15 minutes. This test detects the presence of a protein produced by an HPV-infected cell, indicating some loss of control over cell reproduction.

Field testing of the prototype rapid strip test occurred in 2007, with field testing of a revised version of the product planned for 2009. Once the tests are validated, demonstration projects will introduce the Digene test in several low-resource settings worldwide, and the predictive validity of the Arbor Vita test will be determined.



PATH

**Rapid diagnostic tests for cervical cancer prevention.**

**Safe, simple, accurate, and affordable biochemical screening tests for cervical cancer are the breakthrough needed to reduce the great burden of suffering due to cervical cancer in low-resource settings.**

### Availability

For more information regarding this project contact [start@path.org](mailto:start@path.org).

### Donor support

Funding for this project has been provided by the **Bill & Melinda Gates Foundation**.