

## Developing rapid screening tests for human papillomavirus

Cervical cancer kills approximately 270,000 women each year, mostly in low- and middle-income countries. Although screening programs using Pap smears have been successful in high-income countries, these programs don't work well in low-income nations, where routine tests are difficult to perform because of insufficient laboratories, technicians, and financial resources.

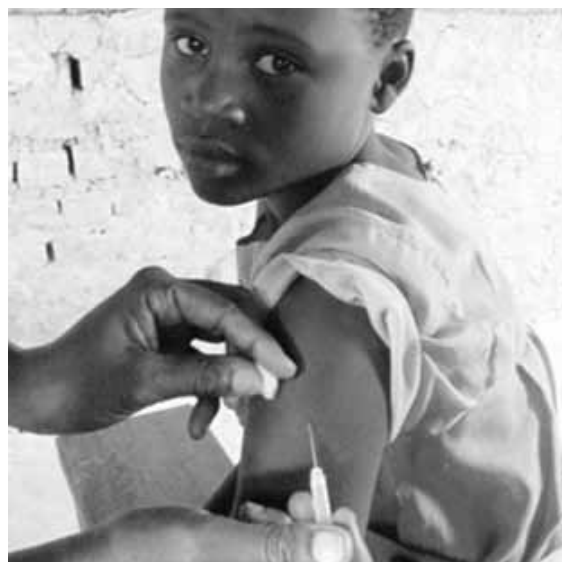
Because infection with human papillomavirus (HPV) is the primary cause of cervical cancer, HPV screening methods are highly sensitive for detecting cervical abnormalities. This technology, however, has previously been too expensive for low-resource settings.

In 2003, with funding from the Bill & Melinda Gates Foundation, PATH launched the Screening Technologies to Advance Rapid Testing (START) project. The goal was to facilitate development of rapid, affordable HPV-screening methods for low-income countries. PATH has partnered with QIAGEN, a large developer of assay technologies, for this work.

### Collaboration between PATH and QIAGEN

Because QIAGEN had already developed relevant commercial technologies and PATH had been leading cervical cancer prevention efforts in the public health arena, a public-private partnership was a logical choice. Under this partnership, QIAGEN

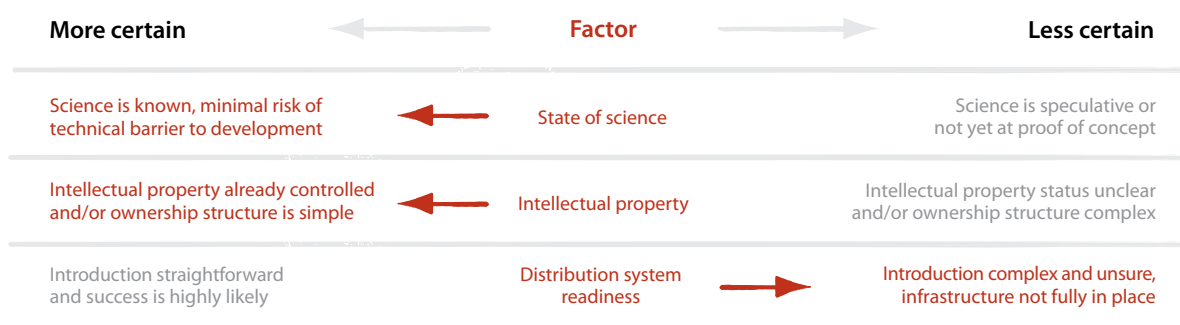
is responsible for developing an appropriate test for low-income countries, supplying the test for clinical studies, and finalizing it for registration and commercial supply. PATH, in turn, is responsible for providing high-quality tissue samples for product development, conducting marketing and industry assessments, conducting program and product cost-effectiveness studies, and developing an evaluation framework for public health programs. Both parties will join forces to drive public education and advocacy programs on cervical cancer prevention in low- and middle-income countries.



PATH/Robin Blelik

### Unique drivers of partnership diversity

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By 2008, QIAGEN and PATH had developed the careHPV™ test, which is accurate, safe, simple to use, and affordable for low- and middle-income country use. Clinical studies in China in 2007 yielded good results.

Following successful completion of research and development, as well as appropriate regulatory approval, QIAGEN will make the product available in select countries with preferential public-sector pricing. PATH will complete demonstration projects in three continents to generate operational data so health officials can compare the test to existing options for cancer detection. The new, rapid test will likely allow women to be both screened and treated in a single visit.

### Drivers of a unique partnership

Critical factors that make this partnership unique include:

- **State of science:** The careHPV™ test was developed based on QIAGEN's existing technologies. Because the underlying science was already known, the risk of product development failure was small.
- **Intellectual property:** QIAGEN controls the key intellectual property. This avoids the need to broker intellectual property for reagents from multiple parties.
- **Distribution system readiness:** Distribution system readiness is a major concern because cervical cancer screening has not been routinely done in low-income countries. The demonstration projects will help to decrease barriers to product uptake.



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