

Health Need: There is a rising global need for simple and accurate pregnancy tests for use in a variety of rural or small clinics or hospitals in developing countries. Currently, there are many high-volume manufacturers of human chorionic gonadotropin (hCG) strip tests which supply developing-world markets. As a result, the competitive forces have driven the cost of tests down to an affordable level. However, despite the availability and affordability of the tests, additional local manufacturers are still needed. The diagnostic tests produced for North American and European markets are not always appropriate or available for use in developing countries and may have a limited market because of their cost. Other commercial companies have developed more basic tests for developing-world markets but have had difficulties with quality control and availability. There is still a need for consistently high-quality tests which are produced for local markets and sold at an affordable price.

Technology: The immunochromatographic (IC) strip test for pregnancy utilizes relatively inexpensive and off-the-shelf components, and is formatted to identify hCG in urine or blood. A test can be completed in 5-10 minutes and can be performed by nurses or technicians with a minimum of training. The sensitivity limit of the test is < 30 mIU of hCG. The IC strip test is a true one-step, "walk-away" test. The strips are stable at ambient temperatures if packaged appropriately.

Specific Applications: This simple, rapid IC strip test allows pregnancy testing in a variety of rural or smaller clinics or hospitals in the developing world so that accurate results can be returned in a few minutes, thereby allowing effective patient follow-up and consultation as required.

Current Status: The assay and product development have been completed, and the technology has been transferred to commercial manufacturers. Initial evaluations using clinical specimens have indicated a sensitivity level matching or exceeding the results of other available commercial IC strip tests.



IC Strip Test for Pregnancy

A rapid, easy-to-read, low-cost pregnancy test

Availability of the Test:

For more information, contact Program for Appropriate Technology in Health (PATH), Seattle, WA, USA (Dr. Milton Tam, telephone 206-285-3500, fax 206-285-6619, e-mail mtam@path.org).

About PATH:

PATH is a nonprofit, nongovernmental, international organization. PATH's mission is to improve health, especially of women and children in developing countries. To achieve these goals, PATH works with public-sector agencies and with private companies. For more information on PATH and its programs, as well as links to other development agencies and private voluntary organizations, visit the World Wide Web at: <http://www.path.org>