A HealthTech Historical Profile

HIV Dipstick

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HealthTech Historical Profile: HIV Dipstick

Identification of Problems or Needs

The ability of developing countries to perform HIV testing at multiple levels of the health care system is crucial to implementation of HIV/AIDS prevention strategies and maintenance of safe blood. In sub-Saharan Africa, for example, five to ten percent of HIV transmission is still thought to result from transfused blood because freshly donated blood may be used to treat women and children with life-threatening anemia in malaria endemic areas. The lack of routine blood testing has interfered with efforts to prevent the spread of HIV/AIDS. HIV tests available in the mid-to-late 1980s were too technically complex to be performed outside reference centers; the few commercial rapid tests were restricted in availability, very expensive, and their optimal uses had not been established.

The standard of practice for screening of blood in blood banks for HIV back in the late 1980s, and still today, was the enzyme immunoassay (EIA). EIA methods are highly accurate, relatively inexpensive per test, and suitable for high-volume testing; but it requires expensive equipment and considerable technical expertise to perform and sustain. As Dr. Don de Savigny of the International Development Research Centre (IDRC, Ottawa, Canada) related in 1991: "The [current] tests are so costly and require so much equipment and technical expertise that only the urban and regional hospitals can use them." At the district hospital level and at the community centers it is impossible to do the ELISA test.

When recognized by HealthTech

In the late 1980s PATH recognized that the larger blood banks already had access to EIA equipment and reagents, but that EIA testing was not practical in the smaller, lower-volume blood banks on the periphery of the health care system. Since the use of EIA was limited to larger blood banks, donated blood was not adequately screened for HIV in smaller facilities. The possibility that patients were being exposed to HIV through blood transfusions was extremely high. Innovative, simpler-to-use, yet highly accurate tests were acutely needed for these testing situations. In addition, PATH realized that for patient testing, EIA results are typically available only after two to four days, but with a simple/rapid HIV test, a preliminary result could be available on the same day. If the test result was accurate and comparable in clinical significance to the EIA, patients could be counseled immediately or on the same day after the results are known and would be less likely to be lost to follow-up.

When recognized by international agencies

PATH recognized the immediate need to develop and provide additional tools in the form of rapid and relatively simple, affordable tests that could be used to supplement existing tests for blood screening, as well as for rapid clinical diagnosis of patients, and for epidemiological surveillance. International agencies agreed. Initial funding for development of the HIV-1 dipstick was provided through co-funding from the IDRC and the Rockefeller Foundation in the late

1980s. In the early 1990s, USAID funding through HealthTech provided the basic development team infrastructure, supplemented the cost of technology transfers, and allowed for continued technical support to the recipients.

Technology Solutions/Strategies

Initial discovery/vision

PATH's field evaluation of the few rapid HIV tests available in the late 1980s, just as the HealthTech program was starting, revealed that the tests were expensive, limited in availability, sometimes too complex to be performed reliably in the field, and their optimal uses had not been established. These findings were subsequently published in *The Lancet*[1]. As a result of these findings, PATH decided to undertake product development of a simple, rapid, HIV test for peripheral blood banks in developing countries. This was an innovative project for its time, with the primary goal of the PATH HIV dipstick to provide a simple, yet dependable test at the lowest possible cost that could be reliably manufactured in developing countries closer to the epicenters of the rising HIV/AIDS epidemic.

Design/development of test applications

In the PATH laboratory, HealthTech staff proceeded with what was, at that time, an innovative concept, namely to develop and produce a test designed for rapid, manual detection of HIV-1 and HIV-2 at the lowest possible cost. To do so, the following design criteria were established:

- High sensitivity and specificity (>98% to 99%).
- Rapid return of results (30 minutes or less).
- Moderate- to low-cost (less than US$1 per test).
- Detects both HIV-1 and HIV-2 equally.
- Can be performed with no additional supplies or equipment.
- Uses an easily obtained specimen such as peripheral blood, serum, or plasma.
- Simple and easy interpretation of results.
- Minimal technical training required to perform testing.
- Robust (stable for 6–12 months at ambient temperature).

The dipstick format, consisting of a plastic comb and standard 96-well microtest plate, was selected as the most promising, easy to use, and affordable approach at that time. After several years of work, PATH successfully developed the test in the Seattle laboratory to the specifications above, with one exception. As is normal in product development, tradeoffs may have to be made. One compromise was the ambient temperature stability. The signal reagent is less heat-stable than the other kit components, resulting in the recommendation that it be refrigerated to achieve maximum shelf life of the kit.

Production costs and costs to the end user were drivers in the design decisions. To reduce materials costs, for example, buffers consisted of commonly available salts and detergents. Inexpensive food-grade polystyrene plastic sheeting was evaluated and used for the combs. The plastic was die-cut into "combs" having eight individual "teeth," each a separate test, spaced to fit into a standard 96-well microtest plate in which an assay is performed. A standard protocol for large-volume production of colloidal gold signal reagent was adapted and developed. Several antigens, both peptides and recombinant proteins, were screened in the initial development of the test. Three HIV-1 peptides derived from the *env* region and one HIV-2 peptide also from the *env* region were selected. The peptide concentrations were optimized for binding and combined into a single indicator spot, since it is initially not necessary to determine infection between types 1 and 2. Later versions of the HIV dipstick made by licensees have an additional procedural control spot on each test.

To perform the test, the user simply incubates the dipstick comb for ten minutes with diluted human serum or plasma suspected of containing antibodies to HIV and then washes it. Colloidal gold conjugated to protein-A is then used to visualize the binding of anti-HIV antibody to the dipstick. After another brief wash, the results can be immediately visualized under indirect lighting and read without use of any instrumentation, making it easy to use in any setting.

HIV dipstick in use

Validation–PATH's and third party

Once the HIV dipstick development efforts in Seattle were complete, the test was first evaluated in the field in January 1990. Independent field evaluations were subsequently initiated in several developing countries. A prospective design-stage field study in Thailand evaluated 1,162 specimens at low- to high-incidence sites. The object was to confirm assay sensitivity and specificity using local sera tested in parallel with reference ELISA and Western blot. PATH also wanted to determine the ease of training local technicians and how well assay performance could be sustained without constant supervision. Excellent results were obtained from the low- and intermediate-risk sites, while at the high-risk sites several technical problems arose, resulting in slightly lower sensitivity. These problems were identified and corrected.

In October 1990 a prospective field trial began in Kenya. Four hundred and fifteen high-risk sera from a sexually transmitted disease clinic were screened at the University of Nairobi and 2,000 lower-risk blood bank donors in Kisumu. The HIV dipstick identified all 188 positive samples in Nairobi for a sensitivity of 100 percent and a specificity of 96 percent.

In November 1990 the HIV dipstick was independently evaluated at the World Health Organization (WHO) Collaborating Center for AIDS in Antwerp, Belgium, on a panel of 261 African sera, 140 European sera, and 48 South American sera with an HIV seroprevalence of 44.5 percent. The resulting HIV dipstick test sensitivity was 99.5 percent and specificity was 98.2 percent. Results from these initial studies demonstrated that the test was highly accurate and the results were comparable and equivalent in performance to other rapid tests evaluated by

WHO at that time. In total, over twenty independent evaluations were performed on the HIV Dipstick test from 1990–1993, demonstrating favorable results. The test was eventually evaluated on over 10,000 sera retrospectively in the laboratory as well as prospectively in the field.

Since initial results demonstrated that the test was accurate and robust, and that high quality tests could be manufactured in developing countries, WHO officials were very helpful in subsequently accommodating the evaluations of test kits from the technology recipients.

Technology Transfer or Liceses

Collaboration through technology transfer or licensing

After product development, standard operating procedures and technology transfer manuals were drafted, validated, and completed. The test kit was then made available at low cost by transferring production technology to collaborative organizations in developing countries. To leverage its existing activities in helping to establish new nonprofit entities, PATH chose to license the HIV dipstick technology through the Concept Foundation (Bangkok, Thailand) as the prime licensee and ultimate manager of the HIV dipstick technology.

In seeking technology transfer collaborations to manufacture, distribute, and sell the HIV dipstick in developing countries, PATH and Concept followed the guiding principles below:

- Ensure access by requiring low prices and guaranteed supply to public-sector customers.
- Ensure product quality through established systems of quality control and periodic auditing.
- Ensure commercial viability by designating commercial markets and permitting reasonable profits from private-sector sales.
- Encourage local production where feasible.

HIV dipstick test performed in the laboratory

Ultimately, the HIV dipstick was licensed by Concept to eight commercial partners, four of which are still active. In order to give each collaborator opportunities to adequately develop their respective markets, specific territories were allocated. The following chart lists the current HIV dipstick manufacturers and their assigned territories.

Company	Exclusive Territory	Nonexclusive Territory
SPAN Diagnostics Ltd., India	Private sector in India, Bangladesh, Nepal, Sri Lanka.	Public sector in India, Nepal, Sri Lanka, and all international agencies.
Yayasan Hati Sehat (YHS), Indonesia	Private and public sector in Indonesia.	All international agencies.
Wiener Laboratorios, Argentina	Private sector in Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay, Venezuela.	Private sector in Angola, Bahrain, Egypt, Jordan, Nigeria, Pakistan, Saudi Arabia, Turkey, United Arab Emirates. Nonexclusive rights for sales to public sector in all countries listed in private-sector distribution.
Bangkok R.I.A. (BRIA), Thailand	Private sector in Thailand, Viet Nam, Cambodia, Laos, Malaysia, Myanmar.	Private sector in Botswana, Malawi, Swaziland, Uganda, Zambia, Zimbabwe. Public sector in Botswana, Cambodia, Laos, Malawi, Malaysia, Myanmar, Swaziland, Thailand, Uganda, Viet Nam, Zambia, Zimbabwe, and all international agencies.

Technology transfers for production of the HIV dipstick commenced in 1992. Technical and managerial staff from each licensee traveled to Seattle for a one- to two-week orientation and training session in production of the tests. This was followed by one or more visits by PATH staff to manufacturing facilities in their countries.

Policy Environment

Involvement of international agencies

In the early 1990s the HIV EIA was the reference standard, and existing rapid/simple tests were, in general, thought to lack sufficient sensitivity and dependability for use in the field. Today, the situation is very different. There is ample support by national AIDS programs and international groups for the use of rapid tests in developing countries wherever standard EIA testing methods cannot be performed or sustained. In addition, rapid tests are supported in developed countries for specific use niches. PATH, through its pioneering work and early introduction of the HIV Dipstick test, advocacy of rapid testing, collaboration with developing-world manufacturers, national AIDS programs, and international agencies such as WHO, has played a significant role in changing policy to include simple/rapid assays in standard testing protocols.

WHO's HIV evaluation program at the Institute for Tropical Medicine in Antwerp, Belgium, has evaluated the HIV dipstick test from PATH and its collaborators as well as other rapid/simple tests. These data can be found in a series of publications on the operational characteristics of HIV tests available on WHOs web site.[2] In comparative evaluations on standard panels of sera, this WHO-sponsored program has provided ample data indicating that quality simple/rapid tests are similar in performance to EIAs. As a result, WHO policy has evolved[3] to include the use of rapid tests for diagnosis of HIV, although many simple/rapid assays may detect seroconversion slightly later than the most sensitive EIAs, but these differences are not always significant. The actual performance of simple/rapid tests in the field has shown that they are able to provide results at least equivalent to EIAs.

In addition, PATH's seminal publication[4] presented data from a field study indicating that two rapid tests could be used together for screening and confirmation to produce results as accurately as standard EIA and Western blot. This pioneering concept was embraced and extended in an official WHO publication.[5]

Changes in policy needed and completed

One example of national policy that includes the use of rapid/simple HIV testing is from Australia. Their policy supports use of rapid tests in laboratory settings for rapid identification of HIV-infected individuals to guide clinical decision-making in the management of occupational exposure, screening potential organ donors, and other situations where the need for an urgent result is indicated. Similar policies exist in European countries. In addition, the United States FDA has approved a number of rapid/simple tests and supports their use to augment reference-level testing and their use with individuals to rapidly determine their serological status and prevent their loss to follow-up and counseling.

Introduction Phase

There were numerous follow-up visits to the licensees to inspect facilities, provide Good Manufacturing Procedures (GMPs) and quality control/quality assurance training, and to offer technical assistance to improve for production improvements. Some of these companies were initially inexperienced in manufacturing diagnostic tests. For example, BRIA had previously only imported a number of diagnostic products or components for repackaging or reassembling for sales in Thailand but had not completely manufactured any diagnostic test kits, SPAN was an established diagnostics manufacturer but did was not have experienced in EIA or rapid test production, and YHS had only limited experience manufacturing a rapid hepatitis B test in a relatively simple agglutination format. Of the licensees, Wiener Laboratories had the most experience in manufacturing diagnostic test kits.

During the technology transfer phase, an issue arose regarding adequate supply of HIV antigen. The HIV dipstick was originally developed with antigens supplied by Genetic Systems/Sanofi; but after numerous attempts at negotiating a license, PATH was unable to gain commercial access to this antigen. A supply of antigen was initially arranged from Diagnostic Biotechnology (later Genelabs Diagnostics) in Singapore for two years, but this company discontinued the supply of the antigen due to licensing conditions imposed by Diagnostics Pasteur. Another

supplier, American Peptide, located in the United States, was then able to produce the peptide and supply all of the licensees. These supply arrangements remain intact to date.

Another production issue related to supply of the plastic for the HIV dipstick combs. This is a food-grade plastic commonly used for the manufacturing of individual, small-volume containers. It is made from virgin-grade raw materials, as opposed to recycled plastic, and ordinarily is available only in bulk (multi-ton) quantities. This plastic is relatively difficult to locate in the countries where the HIV dipstick is produced, and PATH has as a result continued to source the licensees with this plastic.

The HIV dipstick is now largely used in the markets for which it was intended: in public- and private-sector laboratories that perform a low volume of HIV testing and that cannot afford or sustain the use of more sophisticated or higher volume EIA equipment. It is also used in small-scale, public-sector blood banks in Indonesia and public- and private-sector blood banks in India. PATH continues to get reports of the sales by the four companies which demonstrate the widespread dissemination of the product:

Years Sold	Manufacturer	Unit Sales
1995-2004	Wiener Labs	3,333,840
1995-2004	SPAN Diagnostics	8,243,544
1997-2004	Yayasan Hati Sehat	1,957,605
1993-2004	BRIA	1,842,629

Mainstreaming/General Acceptance

One of the major goals of the HIV Dipstick project was to produce a test that would cost the end user less than $0.50 per test. This goal has been achieved. In 2003, for example, SPAN's average public- and private-sector cost per test was $0.31 and $0.45, respectively. In addition, the introduction of this test into these markets also stimulated not only sales competition but also competition in product development. Companies in developed countries that had not previously serviced these markets began to make their own products for these low-cost niches and introduced rapid, low cost HIV tests of their own. Now, 15 years later, there are many more choices of high-quality HIV tests, often at a relatively low cost.

A 2000 review of the status of the HIV Dipstick project concluded that the primary design goals of the HIV dipstick were largely met:

- The HIV dipstick remains the lowest priced HIV test for HIV-1 and HIV-2 on the market in India, Thailand, and Indonesia.
- The HIV dipstick remains the only locally manufactured HIV test in Thailand and Indonesia, and was the first locally produced HIV test in India.

Although the HIV Dipstick test was originally developed to screen the blood supply, it has also been a useful and affordable test for individual case management and surveillance, and is currently sold and used for these purposes as well.

Hurdles/Constraints

In marketing the HIV dipstick test kit, the inherent biases of purchasers and decision-makers needed to be overcome. For example, a perception was that if a test were made in a developing country, attributes such as quality, customer support, and accuracy would be lower. Furthermore, price was sometimes equated with quality. Since the HIV dipstick kit was designed for the lowest cost niche, it was often difficult to convince users that the accuracy and quality of the test were high. Another constraint was in marketing. Because the licensing conditions for the HIV dipstick demanded that it be sold at low cost, manufacturers were not able to promote the kit aggressively because of the low return on investment.

A constraint of rapid tests in general is that if they are used clinically as a screening test for individual patients, they always need to be evaluated with a second confirmatory test. In a small percentage of cases the first test result will be positive when the person is really not infected. Because the results of rapid tests are available immediately, care providers may inform patients based on the single result of a screening test that has not been verified through confirmatory testing. Although this is contrary to best practices and the repeated recommendations of international agencies such as WHO, this still occurs, often because of lack of adequate resources and inadequate training of health workers.

Evidence of impact

Impact of a specific diagnostic test on disease control is often difficult to measure directly and quantitatively in terms of the number of lives saved or a reduction of disease incidence or prevalence. This is difficult in HIV/AIDS prevention and control programs since a combination of technologies or interventions such as the introduction of condoms, education, diagnostic testing, epidemiological surveillance, identification of risk groups, behavior modification, improved counseling, and other methods all contribute to an overall impact. Also, impact cannot be measured on the basis of selling millions of units of a product, since results may not be highly accurate or the tests may not be effectively used or applied.

Publications

There has been a considerable international response to the HIV dipstick test. Evidence of widespread awareness of the HIV dipstick test and its value as a breakthrough product to developing world AIDS control programs is indicated by an extensive list of publications and abstracts throughout the 1990s, including both those from PATH staff and independent evaluations. There have also been many references to the HIV dipstick in publications about the field of rapid HIV testing. Many of these publications and abstracts are listed below:

Tam MR. The search for an appropriate, affordable HIV test for Africa. *Africa Health*. 1990;12:18-19.

Van Kerckhoven I, Vercauteren G, Piot P, van der Groen G. Comparative evaluation of 36 commercial assays for detecting antibodies to HIV. *Bulletin of the World Health Organization*. 1991;69(6):753-760.

Charbonneau R. New test for AIDS. *International Development Research Center Report*. 1991;19(2):22-23.

Schaeffler BA, Tam MR, Maitha GM, Ndinya-Achola JO. Field Evaluation of a simple test for HIV-1 Infection in both high- and low-risk sites in Kenya. *Program and Abstracts from VIth International Conference on AIDS in Africa.* December 16-19,1991; Senegal.

Bansal J, Constantine N, Zhang X, Kataaha P. Evaluation of the PATH HIV-1/2 dipstick assay on serum specimens from Uganda. *Program and Abstracts from VIIth International Conference on AIDS in Africa.* December 8-11, 1992; Cameroon. p. 29.

Tam MR. Manufacture and transfer of technology. In: *Issues of HIV Testing in Developing Countries.* London, UK: UK AIDS NGO Consortium; 1992:30-32.

Koffi K, Gershy-Damet GM, Schaeffler B, Buchanan I, Tam M. Retrospective evaluation of the PATH HIV-1/2 dipstick assay on serum specimens from Cote d'Ivoire. *Program and Abstracts from VIIth International Conference on AIDS in Africa.* December 8-11, 1992; Cameroon.

Cayemittes M, Hankins C, Tam MR. An AIDS test that travels well. *International Development Research Center Report.* 1993;21(2):27-28.

Tamashiro H, Heymann D. Reducing the cost of HIV antibody testing. *The Lancet*. 1993; 342(8875):866.

Sato PA, Maskill WJ, Tamashiro H, Heymann DL. Strategies for laboratory HIV testing: an examination of alternative approaches not requiring Western blot. *Bulletin of the World Health Organization*. 1994;72(1):129-134.

Beristain CN, Rojkin LF, Lorenzo LE. Evaluation of a dipstick method for the detection of human immunodeficiency virus infection. *Journal of Clinical Laboratory Analysis*. 1995;9(6):347-350.

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Ray CS, Mason PR, Smith H, Rogers L, Tobaiwa O, Katzenstein DA. An evaluation of dipstick-dot immunoassay in the detection of antibodies to HIV-1 and 2 in Zimbabwe. *Tropical Medicine and International Health*. 1997;2(1):83-88.

McKenna SL, Muyinda GK, Roth D, et al. Rapid HIV testing and counseling for voluntary testing centers in Africa. *AIDS*. 1997;11 Suppl 1:S103-110.

Plourde PJ, Mphuka S, Muyinda GK, et al. Accuracy and costs of rapid human immunodeficiency virus testing technologies in rural hospitals in Zambia. *Sexually Transmitted Diseases*. 1998;25(5):254-259.

Third Party Comments about the test

The following comments can be found in a report by the IDRC on their website.[6]

- **Lowest price**–The dipstick has consistently been one of the lowest-priced tests of its kind available for detecting HIV-1 and HIV-2 infection. It is one of the few rapid, instrument-free screening tests often available for less than US$1 per test. In some markets, the price is closer to US$0.50. The introduction of the dipstick has also led to a rapid lowering of

prices for similar tests now on the market. This, in turn, increases the potential for HIV testing.

- **Quick results given**–The HIV dipstick gives results in 20 to 30 minutes, requires no special equipment, and is easy to use. In Africa, patients screened with more sophisticated tests often wait up to two weeks for results.
- **No refrigeration needed**–The test can be stored without refrigeration for up to six months, making it suitable for use in areas with few amenities.
- **Use spreading rapidly**–About 15 million HIV dipstick tests have been sold to date in more than 14 developing countries, including Thailand, Indonesia, Vietnam, Cambodia, China, the Philippines, Malaysia, Cameroon, Zimbabwe, Kenya, Argentina, Brazil, Mexico, and other Latin American countries. Steve Brooke of PATH "expects sales to increase rapidly as new dipstick production and distribution sites are established."
- **Manufacturing increasing**–The dipstick technology has been transferred to manufacturers in India, Thailand, Indonesia, and Argentina. Soon there will also be new partners in the Philippines, and there are distributors in Cameroon and Zimbabwe.
- **Technology transferable to other diseases**–Dipstick technology is now being used to diagnose other diseases. In Indonesia, the producers of the HIV dipstick have independently developed hepatitis B and hepatitis C virus tests using the same dipstick format. PATH has also codeveloped a dipstick to help diagnose tuberculosis, which is now being manufactured in India and sold in several Asian countries.
- **Collaboration between countries**–Another significant benefit has been the development of South-to-South interaction independent of PATH. The dipstick producers, none of whom knew each other before, now regularly collaborate on various projects. They share responsibility for bulk purchasing of raw materials for dipstick production and solve problems among themselves. Thus, the HIV dipstick project has strengthened the businesses of the producers in many ways, in addition to dipstick sales.

Sales Data

In 2005, Concept reported that over 15 million HIV dipstick tests have been sold from 1993-2004. From that data, one can presume that millions of people and/or their blood donations are being tested safely and accurately for HIV. Four licensees continue to manufacture and sell the test regionally and globally.

Stimulation of Competition

To stimulate competition, a major goal of the HIV Dipstick project was to produce a robust test at the lowest possible cost. When this test was introduced at that low cost it stimulated competition in sales as well as in product development. Companies in developed countries such as Abbott Diagnostics that had not previously targeted developing-country markets began to develop and introduce similar tests. Today there are many choices of quality rapid HIV tests at competitive costs.

Along with the transfer of technology to developing-country collaborators, a subsequent goal of PATH and Concept was to develop a regular communications network among the licensees so that they could provide assistance to each other in the production or procurement of dipstick test components. In March 1995 PATH staff arranged and conducted a meeting in Bangkok for the Asian licensees to discuss cooperation in purchasing and supplying each other with kit components and critical raw materials. The conclusions of this meeting were discussed at a later date with Wiener Diagnostics. This meeting proved very useful in establishing lasting relationships among the licensees, referred to as the **"family of companies."**

In 2000, HIV Dipstick kits made by two collaborators, Wiener Diagnostics and BRIA, were placed on WHO's Bulk Procurement list of "approved" test kits, a considerable achievement. In 2005, The Concept Foundation is sponsoring a technical development program to further improve the HIV dipstick test kit in terms of sensitivity and production efficiency, based on the projected extension of its product life, increasing the number of manufacturers, and expanding end-user acceptability.

The following are anecdotes concerning competitive forces stimulated by the HIV dipstick test:

- PATH envisioned the HIV Dipstick test as one of the least expensive test kits available, a position it still enjoys to this day. As such, it is a benchmark test that demonstrated the existence of a low-cost, developing world market; it still occupies the low-cost niche to this day, encouraging competitive prices.
- When the YHS HIV dipstick was first introduced in the market in Indonesia, Abbott immediately reacted by reducing the price of their standard HIV test by half.
- In response to the increasing number of lateral flow HIV tests coming into the market, SPAN improved their combs so that every test has an integral positive control, making it unnecessary to run a separate positive control. They also introduced a small amount of a recombinant protein to improve test sensitivity. Because there were high-volume sales, these improvements were implemented without appreciably increasing the cost of tests.
- In 2003 a competing dipstick-type test similar to PATH's HIV dipstick design was introduced by J. Mitra & Co. (New Delhi, India) at or below the cost of SPAN's dipstick test. The J. Mitra test was introduced as an attempt to capture the considerable market share in India (3.5 million tests in 2003) enjoyed by SPAN's HIV dipstick test, and the effect has been to keep the cost of both tests to a minimum.

Conclusion

After 18 years, PATH's early work as one of the first developers of a rapid, low-cost test for HIV has proven to be instrumental in the whole field of HIV testing, primarily through making the first efforts at bringing down the costs.

References

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[4] Spielberg F, Kabeya CM, Quinn TC, et al. Performance and cost-effectiveness of a dual rapid assay system for screening and confirmation of human immunodeficiency virus Type 1 seropositivity. *Journal of Clinical Microbiology.* 1990;28(2):303–306.

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