

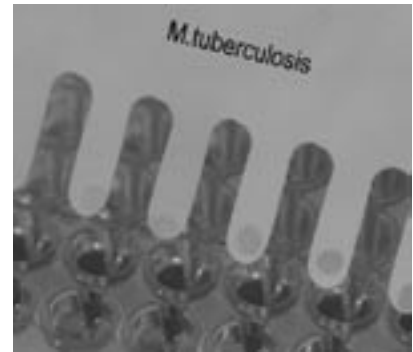
Health Need: Tuberculosis (TB), a bacterial disease caused by *Mycobacterium tuberculosis*, is a major health problem in the developing world, as well as a disease that is re-emerging as a major health threat in the developed world. High prevalence in some developing countries is associated with HIV infection and AIDS. World Health Organization statistics indicate there are 20 million cases of active TB worldwide, and approximately 8 million new cases occur each year. TB has the highest mortality rate of any infectious disease in the world and results in approximately 3 million deaths annually. TB is a highly contagious disease that can be difficult to identify and diagnose accurately. Since it is curable with a course of antibiotic therapy, early diagnosis and treatment can curtail the spread of the disease within the general population.

Technology: HealthTech, in collaboration with DynaGen, Inc., in the United States, developed the MycoDot™ serological assay, which detects anti-mycobacterial antibodies in serum. The test is based upon PATH's HIV-dipstick core technology, and utilizes purified lipoarabinomannan as antigen. The assay procedure, which can be performed using a blood, plasma, or serum sample obtained from a finger prick, takes 20 minutes to perform and requires no special equipment. Used in conjunction with clinical signs and symptoms, the results of the MycoDot serological assay can identify and diagnose suspected cases of pulmonary and extrapulmonary TB.

Specific Applications: The format of the MycoDot test is equipment-independent and can easily be employed at primary health care and higher levels, such as reference laboratories. It can be used prior to the culture method, which is time-consuming. A positive result from a rapid test can indicate infection so that treatment can immediately be prescribed, thus reducing risk of transmission. The test can differentiate between infection and vaccination. Other applications of the test include epidemiological studies, tracking transmission patterns, and determination of vaccine efficacy. The test also has potential use wherever TB is on the rise in HIV-positive individuals and in medically underserved populations.

Current Status: The MycoDot test was developed at PATH in collaboration with DynaGen, whose marketing rights have recently been transferred to Mossman Associates. In preliminary testing of 1,733 reference serum samples collected in Bolivia, India, Romania, and the United States, a sensitivity of 70% and a specificity of 95% were reported. To ensure efficient, large-scale, and low-cost production, the technology was transferred to a developing-world manufacturing site in India, where it was successfully scaled up for production. The MycoDot test was recently approved by the Japanese Ministry of Health.

MycoDot™ is a registered trademark of Mossman Associates



Tuberculosis Dipstick

**A rapid, easy-to-read,
low-cost screening test for
tuberculosis**

Availability of the Test:

For more information contact Mr. Don Mossman at Mossman Associates, 30 Liberty Hill Road, Blackstone, MA 01504 (telephone 508-883-4722, fax 508-883-4993, e-mail donmossman@hotmail.com, web site <http://www.mossmanassociates.com>).

About HealthTech:

Technologies to meet the health care needs of women and children in developing countries are developed, adapted, or assisted by Program for Appropriate Technology in Health (PATH) with support from the United States Agency for International Development (USAID) under the Technologies for Health (HealthTech) Project.

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>