

Rapid Strip Test for Malaria

Health need

Despite intensive public health efforts, more than 300 million new cases of malaria occur each year, resulting in more than a million deaths worldwide. Microscopy is still the standard method for diagnosis in many parts of the developing world, but it is time consuming, labor intensive, and can only be performed by expert microscopists in specialty clinics or higher levels of the health care system. It is impractical whenever large numbers of samples must be examined. An alternative test method was urgently needed for the rapid and accurate identification of falciparum malaria infection in smaller clinics and rural hospitals.

Technology solution

The malaria immunochromatographic strip (ICS) test developed by PATH under HealthTech utilizes relatively inexpensive, off-the-shelf components and is formatted to identify *Plasmodium falciparum* in whole blood. A test can be completed in less than 20 minutes using a single drop of finger-stick blood. It can be performed and the results interpreted by technicians with minimal training. The strips are stable for months at ambient temperatures when appropriately sealed in foil pouches, and built-in procedural controls indicate whether each strip performs correctly.

Current status and results

The malaria ICS test has been evaluated in the laboratory as well as under field conditions in the developing world in collaboration with the Centers for Disease Control and Prevention and USAID in Peru and Malawi. The evaluations demonstrated a sensitivity of over 96 percent, and a specificity of 93 percent or more. Ease-of-use studies have also concluded that the test is extremely easy to interpret. PATH then licensed the manufacturing know-how to two companies, one in Germany and one in India. Reported sales of the test by spring 2005 were 300,000 tests. PATH has also provided technical assistance to two other commercial manufacturers for development of their own falciparum malaria ICS tests; sales have been in the range of 10,500,000 worldwide.

The simple, rapid ICS technologies allow testing for falciparum malaria in rural or small clinics or hospitals in the developing world so that accurate results can be returned the same day, allowing effective patient follow-up and prescription of appropriate therapeutic drugs. This is especially important since WHO now recommends artemisinin combined therapy, a relatively expensive treatment, because the falciparum malaria organism is resistant to chloroquine. Epidemiological surveillance teams can also use the test to gather baseline data or to assess the effect of public health interventions. The tests can supplement or confirm infection in conjunction with microscopic diagnosis of malaria at central reference facilities. In lower-volume blood banks or transfusion centers, the test can be used to rapidly test donated blood before storage and subsequent transfusion.



A rapid, easy-to-read, low-cost test for malaria.

A study of the PATH-developed rapid test for malaria diagnosis found that in areas where microscopy expertise is lacking and laboratory capacity limited, the rapid test is considered useful.

Parkes R, et al. Comparison of a nested polymerase chain reaction–restriction fragment length polymorphism method, the PATH antigen detection method, and microscopy for the detection and identification of malaria parasites. *Canadian Journal of Microbiology*. 2001;47(10):903–907.

Availability

The test has been transferred to companies in India and Germany and is available from: Human GmbH, tel: 49-6122-9988-275, fax: 49-6122-9988-100 or Span Diagnostics, tel: 91-261-8677211, fax: 91-261-8679319.

Donor support

Funding for this project was provided by the **United States Agency for International Development** under PATH's HealthTech program.