

Rapid Strip Test for Gonorrhea

Health need

Despite long-standing global public health efforts to control sexually transmitted infections (STIs), *Neisseria gonorrhoeae* infections still occur in epidemic proportions in the developing world and in specific regions of the United States. For effective control of gonorrhea, STI-control programs must offer early and accurate diagnosis of symptomatic infection and identification of invasive, complicated, or asymptomatic infections. Control of STIs is also considered to be an essential component in control of HIV/AIDS transmission. However, in some regions of the world, point-of-care diagnosis of gonorrhea is currently inadequate because available tests are relatively expensive and/or complex, culture diagnosis is unavailable, and syndromic diagnostic protocols for women are often inaccurate.

Technology solution

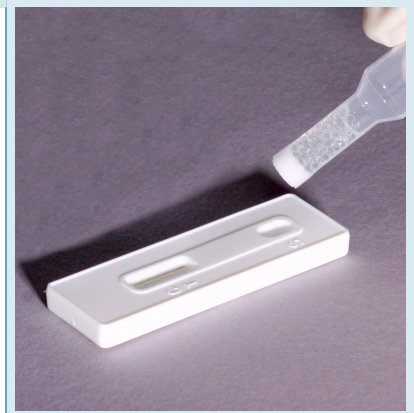
The immunochromatographic strip (ICS) test for gonorrhea being developed by PATH, uses relatively inexpensive, off-the-shelf components, and is formatted to identify specific gonococcal antigens obtained directly from clinical specimens. The test can be completed in 15 to 20 minutes and can be performed by technicians with minimal training. The strips are stable for months at ambient temperatures if packaged appropriately.

The simple, rapid ICS test for gonorrhea will allow testing to be performed on direct clinical specimens from patients in rural or smaller clinics or hospitals in the developing world or other resource-limited settings. Accurate results can be returned within the same hour or day, thereby allowing effective patient follow-up, additional counseling, and, if needed, prescription of therapeutic drugs. The tests may also be used by epidemiological surveillance teams in the field to gather baseline data or to assess the effect of public health interventions.

Current status and results

In a prospective field evaluation in South Africa, the sensitivity and specificity were 61.4% and 95.9% respectively using vaginal swab samples for women and 91.6% and 95.9% using urine samples from men when compared to the Ligase Chain Reaction (reference standard). The test was also used in a World Health Organization-sponsored multisite field evaluation of rapid tests for *Neisseria gonorrhoeae* in Benin. During this trial, the test performed well (70% sensitivity, 97% specificity).

We hope to license a critical antibody reagent and transfer the technical know-how to a commercial manufacturer in the developing world.



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

In a WHO-sponsored trial in Benin, the test performed quite satisfactorily (70% sensitivity, 97% specificity).

Alary M, Gbenafa-Agossa C, Aina G, Ndour M, Labbé A C, Fortin D, Steele M, Peeling R W. Evaluation of a rapid point-of-care test for the detection of gonococcal infection among female sex workers in Benin. *Sexually Transmitted Infections* 2006;82(5):v29-v32.

Availability

For more information regarding this project, contact Mutsumi Metzler at mmetzler@path.org.

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