

A Comparative Performance Evaluation of Flocked Swabs Versus Dacron® Swabs for Use with an Immunodiagnostic STI Assay in a Population of High Risk Women in Bolivia

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Introduction

Many immunodiagnostic rapid tests for sexually transmitted infections (STI) are plagued by poor sensitivity. To improve performance, one can either change the biochemistry of the platform to improve visualization of results or level of detection, or optimize the collection and concentration of target analyte(s), or both. For the purpose of this work, we assessed the impact of a new sampling device on the performance of a rapid immunochromatographic strip (ICS) test under development at PATH.

Dacron® swabs are the current standard device for collecting vaginal or endocervical specimens for use with these tests. Their organic polyester spun weave matrix makes them simple and inexpensive to manufacture. However, it is unclear how efficient they are at collecting and, most importantly, releasing analyte for diagnostic testing.



Newly designed flocked swabs are manufactured by electrostatically attaching nylon fibers to the swab shaft at right angles. The flocking process creates a hydrophilic layer along with a consistent structure to efficiently collect and remove cellular matter. Preliminary laboratory-based evaluations of flocked swabs at PATH showed a dramatic increase in the number of cells collected and released by these devices when compared to standard Dacron® swabs.

Aims

1. Evaluate the sensitivity and specificity of the PATH Chlamydia immunochromatographic strip (CT ICS) tests using provider-obtained endocervical swab specimens collected from women who are at high risk for *Chlamydia trachomatis* infection.
2. Evaluate the effect of using flocked swabs compared to Dacron® swabs on assay performance.



Photo: PATH/Blake Wang

Methods

In 2005, 1,762 adult women at high risk for STI were recruited at four STI surveillance center clinics in Bolivia in the departments of El Alto, La Paz, Cochabamba, and Santa Cruz.

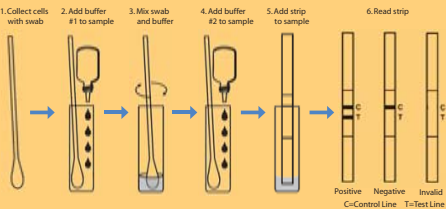
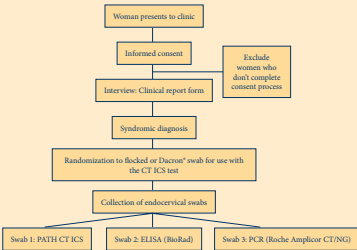


After a written informed consent process, participants were interviewed about recent sexual history and any symptoms related to their clinic visit. The attending physician then made a diagnosis based on standard syndromic protocols for women who have vaginal symptoms common to STI.

Study participants were randomized to either have a flocked or Dacron® endocervical swab collected for use with the CT ICS test. A health care provider then collected three endocervical swabs: the randomized flocked or Dacron® swab for use with the PATH CT ICS test, a Dacron® swab for use with an ELISA for Chlamydia (BioRad Chlamydia EIA), and an additional Dacron® swab for use with a reference PCR test for Chlamydia (Roche Amplicor CT/NG).

The sensitivity and specificity of the PATH CT ICS test were calculated by comparing the results with those of the PCR Roche Amplicor CT/NG test.

Testing with the PATH CT ICS and ELISA was performed at the STI surveillance center clinics. Reference testing for CT, using the Roche Amplicor CT/NG test, was carried out at the National Reference Laboratory (INLASA) in La Paz.



The PATH CT ICS Test is a rapid, qualitative, in-vitro immunoassay which utilizes a monoclonal antibody specific for the lipopolysaccharides (LPS) portion of *Chlamydia trachomatis*. The test is used with direct endocervical swab specimens. After the specimen is collected the result can be available within 20 minutes, which allows for immediate appropriate treatment as indicated. The test requires minimal technical training to perform and interpret the results.

Results

Study population

Variable	% or Value	Minimum and Maximum if applicable or (95% CI)
Median Age	25	18, 66
>3 Sexual Partners in Last 24 Hours	39.9%	
Self-Reported 100% Condom use in last 5 sexual episodes	47.5%	
Ever Diagnosed with an STI	33.1%	
Chlamydia Prevalence (by PCR)		
Santa Cruz	13.8% (81/443)	(10.6-17.0)
Cochabamba	12.1% (51/423)	(9.0-16.2)
El Alto	14.1% (51/433)	(10.1-17.4)
La Paz	11.0% (51/463)	(8.2-13.9)

Effect of flocked versus Dacron® swabs on performance of the PATH CT ICS test

Swab Type	Location	Sensitivity	Specificity	PPV	NPV
Flocked	Santa Cruz	29.0% (9/31)	97.4% (186/190)	64.3%	89.3%
	Cochabamba	23.1% (6/26)	94.1% (175/186)	33.3%	89.7%
	El Alto	20.6% (7/34)	93.3% (166/178)	36.8%	86.0%
	La Paz	26.9% (7/26)	99.0% (203/205)	77.8%	91.4%
Dacron	Santa Cruz	0.0% (0/30)	97.4% (186/190)	0.0%	86.2%
	Cochabamba	12.0% (5/25)	99.5% (185/186)	75.0%	89.4%
	El Alto	18.5% (5/27)	96.4% (187/194)	41.7%	89.5%
	La Paz	16.0% (4/25)	98.1% (203/207)	50.0%	90.6%
Flocked	Total	24.8% (29/117)	96.0% (736/766)	53.5%	89.1%
Dacron	Total	11.2% (12/107)	97.8% (736/760)	41.7%	88.9%

Conclusions

This is the first large evaluation employing a randomized design to assess the effect of an alternative swab collection device on the performance of an STI immunodiagnostic.

Although the performance of the PATH CT ICS was poor overall, the use of flocked swabs improved the sensitivity of this test and should be considered for use with other immunodiagnostic tests.

Further research is necessary to better understand the potential utility of flocked swabs or other swab devices with nucleic acid amplification tests.



Photo: PATH/Roger Peck

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