

Poor sensitivity of field rapid HIV testing: implications for mother-to-child transmission programme (PMTCT)

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BACKGROUND

Only pregnant women with known HIV-positive status can access PMTCT interventions. South Africa's PMTCT programme utilises on-site rapid HIV tests. If the result of the first test is negative, the person is considered HIV uninfected. If the test is positive, a confirmatory second test is performed. A second positive test result is indicative of a true positive result. It is recommended that HIV rapid tests should have a sensitivity of at least 99% and a specificity of 98%.¹ South Africa reviews its tender for rapid test kits every two years. Prior to the introduction of these kits, tests are validated in a laboratory.

Between January 2006 and September 2007 the First Response 1,2,3 test (PMC Medical Pty. Ltd, Daman, India) was used as the first screening test and the Pareekshak test (Bhat Bio-Tech India Private Limited) was used as the confirmatory test. After September 2007 the First Response 1,2,3 was replaced by the Standard Diagnostic test (Standard Diagnostic, Inc, Korea). These tests underwent laboratory validation using specimens obtained from South African National Blood Bank Services. Sensitivities were > 99% and specificity were 100% for all rapid tests.

METHOD

Pregnant women attending their first antenatal visit between March and November 2007 were invited to participate in this study. HIV pre- and post-test counselling was conducted by HIV counsellors in accordance with local guidelines. Rapid HIV tests were carried out by two trained research nurses and specimens of whole blood were collected by finger prick and venesection. Testing was performed using the First Response or Standard Diagnostic test and Pareekshak test in parallel. All rapid test results were confirmed using an automated HIV 3rd generation ELISA test (Abbott AxSYM, Abbott Laboratories, Germany). Indeterminate ELISA results and any discordant results were retested using PCR RNA HIV tests (COBAS AmpliPrep/COBAS AmpliCor HIV-1 Monitor version 1.5, Roche Diagnostics, Branchburg NJ, USA) and an automated HIV 4th generation ELISA (Abbott AxSYM, Abbott Laboratories, Germany). All negative rapid tests were subjected to PCR RNA HIV viral load testing using a pooling strategy to identify acute HIV.² The combination of the ELISA and the PCR results determined the HIV status of participants in this study. (See figure 1)

Statistical evaluation was performed using MS Excel and Vassar stats clinical calculator and confirmed using STATA (STATA version 10; Stata Corp, College Station, TX).

Ethical clearance was obtained from the Human Research Ethics Committee of the University of the Witwatersrand (protocol M051017).

OBJECTIVE

Validate the field performance of these rapid HIV tests among pregnant women.

Figure 2: Rapid HIV tests used in field validation.



RESULTS

A total of 313 women were recruited into the study with a mean age of 29 (CI:28.4 – 29.7). Among these 81 (25.9%) were HIV infected. For 69 women the median CD4 count was 418 cells/ μ L (IQR 256-517cells/ μ L).

Figure 1: Flow diagram for field validation study

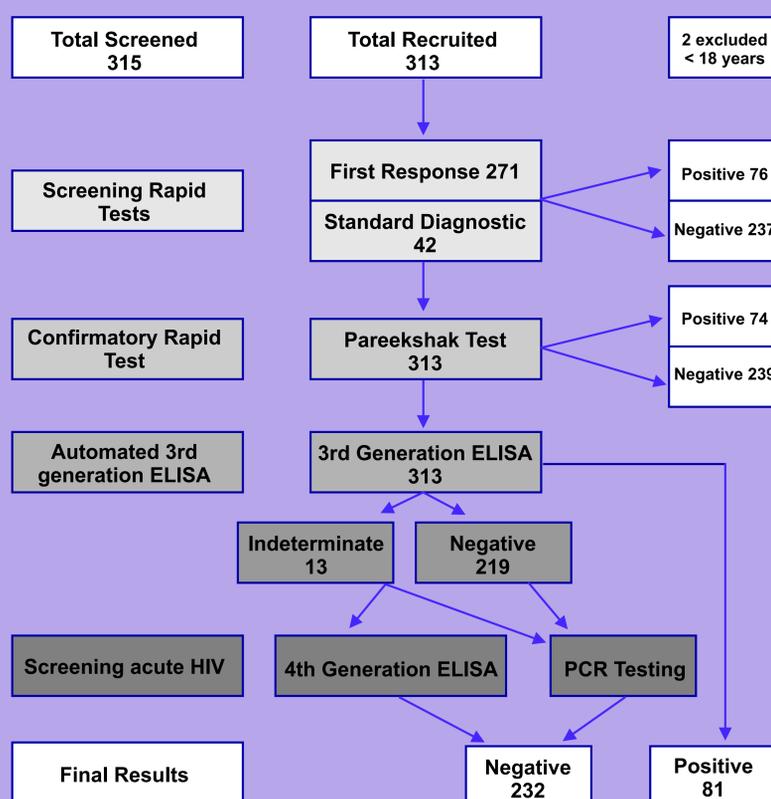


Table 1: Field validation of rapid HIV tests among pregnant women

CATEGORY	FIRST RESPONSE	STANDARD DIAGNOSTIC	PAREEKSHAK
Number	271	42	313
Positive	69	7	74
False negative	4	0	7
Sensitivity	94.5 (CI:85.8-98.2)	87.5 (CI:46.7-99.3)	90.2 (CI:81.2-95.4)
Specificity	100 (CI:97.6-100)	100 (CI:87.7-100)	100 (CI:98-100)

DISCUSSION

This study suggests that South Africa's current testing strategy may misdiagnose 5% of HIV infected pregnant women as negative due to poor performance of routinely-used rapid HIV tests in the field. Based on 2007 birth statistics this would translate into 11101 women. These women will not receive appropriate PMTCT interventions and consequently, with 20% transmission, between 2 220 and 3 956 infants may have become HIV infected. Systems to improve and standardize quality of on-site testing should be implemented widely in South Africa to reduce additional MTCT cases.

REFERENCES

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