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Good Performance of Rapid Prostate-Specific Antigen Test for Detection of Semen Exposure in Women: Implications for Qualitative Research

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Abstract

Background—Prostate-specific antigen (PSA) is a valid biomarker of semen exposure in women and has been used to assess reliability of self-reported sexual behavior as well as serve as a proxy measure for condom efficacy. Quantitative PSA tests are expensive and require specialized equipment. A simple, rapid, and inexpensive test for PSA would facilitate semen biomarker evaluation in a variety of research settings. This study evaluated the performance of a rapid PSA test compared with a quantitative assay to identify semen in vaginal swab specimens.

Methods—We tested 581 vaginal swabs collected from 492 women participating in 2 separate research studies in Bangladesh and Zimbabwe. PSA in vaginal secretions was detected using the quantitative IMx (Abbott Laboratories) assay and the ABAcard p30 (Abacus Diagnostics) rapid immunochromatographic strip test.

Results—The ABAcard test was 100% sensitive (95% confidence interval [CI], 98%–100%) and 96% specific (95% CI, 93%–97%) compared with the quantitative test in detecting >1.0 ng PSA/mL vaginal swab eluate. Rapid PSA results were semiquantitative and correlated well with PSA concentrations ($\kappa = 0.88$; 95% CI, 0.85–0.90).

Conclusion—Rapid PSA detection requires no instrumentation and can be performed easily and economically. Having rapid PSA results available immediately following interview provides opportunities to explore discrepancies between the objective marker of recent semen exposure and self-reported behaviors.

Research evaluating clinical or behavioral interventions, barrier methods, or microbicides for the prevention of HIV and other sexually transmitted infections frequently relies on self-reports of sexual behavior, which may be inaccurate. The validity of self-reported data relating to coitus is threatened by social desirability bias, leading to concerns that study subjects may frequently fail to report unprotected sex.[1] The detection of seminal biomarkers in vaginal fluid provides objective evidence of a woman's recent exposure to semen. Results

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from recent studies comparing detection of prostate-specific antigen (PSA) in vaginal swabs with self-reported condom use among female sex workers suggest that concerns about misreported semen exposure may be well-founded; substantial proportions of women who reported no sex or protected sex only within the past 48 hours, tested positive for PSA.[2,3]

PSA (also known as p30) has been validated as a reliable marker of semen exposure in studies of vaginal specimens obtained after unprotected intercourse, or after vaginal insemination with different volumes of semen.[4–6] High PSA concentrations (100–10000 ng PSA/mL vaginal swab eluate) are detectable immediately after exposure, and levels return to baseline (<1.0 ng/mL) within 24 to 48 hours.[5] PSA concentrations in vaginal fluid have also been correlated with intensity of semen exposure in condom efficacy studies, and PSA levels corresponding to a range of likely semen exposure categories that may result from incorrect condom use or mechanical failure have been described.[4,7,8] However, quantitative PSA tests are expensive and require specialized equipment usually restricted to central laboratories, and their use is limited in resource-constrained or field settings where complex testing is not possible.

Rapid, immunochromatographic strip tests for detection of PSA are available commercially, and have been used in the forensic detection of semen.[9,10] The strip tests are completely portable, require no instrumentation, and are easy to use and relatively inexpensive (~US $4.50 for rapid test vs. ~$20.00 for quantitative test). Having semen marker test results available immediately after an interview provides opportunities for qualitative researchers to explore discrepancies between the objective marker and respondents' reports of sexual activity. In this study, we evaluated the performance of the ABAcard p30 test from Abacus Diagnostics compared with a quantitative PSA assay to identify semen in vaginal swab specimens.

MATERIALS AND METHODS

Vaginal Swab Specimens

Specimens were from women participating in 2 different studies: 1 in Bangladesh and the other in Zimbabwe. We tested 402 provider-collected vaginal swabs from 313 women obtained during a speculum exam at baseline and/or 9-month follow-up visits as part of a study comparing 2 methods of STI prevention and control among sex workers in Dhaka, Bangladesh, conducted from February 2005 through September 2006 (manuscript in preparation). Women provided written informed consent, and the study was approved by the Biomedical Institutional Review Board (IRB) of the University of North Carolina at Chapel Hill and the IRB of the International Center for Diarrhoeal Disease Research, Bangladesh. We also tested self-obtained vaginal swabs from 179 women collected at a single visit as part of a study comparing 2 interviewing techniques to obtain reports of sexual behaviors among sexually active women in Zimbabwe from November 2006 through January 2007 (manuscript in preparation). The women in the Zimbabwe study had participated in the Methods for Improving Reproductive Health in Africa (MIRA) trial,[11] a median of 8.8 months (range, 2.5–20.5 months) previously. Women provided written informed consent for the study, which was approved by the IRBs of Family Health International, the University of North Carolina at Chapel Hill, the University of California at San Francisco, and by the ethics review committees of the Medical Research Council of Zimbabwe and the Medicines Control Authority of Zimbabwe. In both studies, vaginal specimens were collected on cotton-tipped swabs (Falcon Screw Cap Single SWUBE applicator, Becton Dickinson and Co., Sparks, MD). Immediately after collection, swabs were air-dried, stored in screw-capped tubes and shipped at ambient temperatures to the research laboratory at the University of North Carolina at Chapel Hill.

For recovery of vaginal secretions, each swab was placed into 3.0 mL phosphate-buffered saline (PBS), incubated at room temperature for 15 to 30 minutes, agitated, and pressed against the side of the tube to elute the sample. These details are the same as those used for PSA detection in vaginal swabs using the quantitative IMx assay in earlier studies.[5,7,8] However, these methods differ somewhat from the manufacturer's instructions for vaginal swab processing for PSA detection using the rapid ABAcard test, which suggest extraction in a smaller volume of buffered saline (0.75 mL) for a longer time (2 hours). Thus, the concentrations of PSA in the specimens prepared as reported here may not reflect the maximum extractable amount of PSA on the vaginal swabs.

To assess the adequacy of self-obtained specimens from the Zimbabwe study, we examined eluates from these vaginal swabs for the presence of epithelial cells. A small volume of specimen (0.01 mL) was loaded into the chamber of a hema-cytometer and examined at 200 × magnification in a Nikon Labphot 2 light microscope. Epithelial cells were present in all self-obtained vaginal swab eluates, suggesting that swabs were indeed inserted into the vagina and sampling was adequate. A priori, we had high confidence in the quality of vaginal swabs obtained by providers in the Bangladesh study, and epithelial cells were not assessed in those specimens. Vaginal specimens were centrifuged at 250 × *g* for 10 minutes, supernatants were removed from cell pellets and stored at −80°C until testing.

Quantitative PSA Testing

Supernatants (0.20 mL) from vaginal swab eluates were tested using the IMx PSA assay (Abbott Laboratories, Abbott Park, IL.). The enzyme immunoassay measures PSA concentrations from 0.04 to 50 ng/mL; samples with initial test results >50 ng/mL were diluted 1:100 with PBS and retested to obtain PSA concentrations. Using the same assay with vaginal swabs prepared as described, Macaluso et al. established that samples containing >1.0 ng PSA/mL indicate exposure to semen within the past 48 hours.[5]

Rapid PSA Testing

For testing with ABAcard p30 (Abacus Diagnostics, West Hills, CA.), 0.20 mL of vaginal swab eluate was loaded directly into the sample well of the immuno-chromatographic strip test cassette according to the manufacturer's instructions. After a 10-minute incubation at room temperature to allow sample migration throughout the test strip, a positive result was indicated by pink lines in both the test and the control areas. A negative result was indicated by a line in the control area only, and tests without a visible pink control line would have been considered invalid. A control line was visible in all tests with vaginal swab eluates, documenting valid ABAcard results.

According to the manufacturer, the lower limit of detection for the ABAcard is 4 ng PSA/mL. Like all immunoassays that depend on antigen-antibody interactions, the ABAcard test is subject to potential interference in the presence of excess antigen, which impairs immune complex formation. As a result of this so-called "high-dose hook effect," high concentrations of PSA can give false negative results. The threshold concentration at which ABAcard results may be subject to the high-dose hook effect has not been established by the manufacturer. However, our unpublished observations suggest that this threshold may be between 2000 and 5000 ng PSA/mL. Dilutions of purified human PSA with final concentrations ranging from 1 to 50 ng/mL made from the calibrator solutions of the IMx PSA assay (Abbott Laboratories) and a negative control of PBS without PSA were included with each batch of specimens tested to provide a guide for semiquantitative assessment of PSA concentration. The standard solution containing 1 ng PSA/mL produced a faint, but consistently visible line in the test area. Standards containing 25 or 50 ng PSA/mL produced consistently strong lines in the test area, and the standard solution containing 5 ng PSA/mL

produced a line in the test area with intensity intermediate between the 1 and 25 ng/mL standards.

We compared 2 semiquantitative scoring systems for ABAcard results. In the first scoring system, we used a 4-category scale: specimens were scored as negative if no line was visible in the test area, low positive if the signal was visually similar to the 1 ng/mL PSA standard, medium positive if the signal was similar to the 5 ng/mL standard, and high positive if the signal was equivalent to the 25 ng/mL standard. In the second system, we used a 3-category scale: specimens with no line or a faint line were scored as negative, those with a signal visually similar to the 5 ng/mL standard were scored as low positives, and those with a signal equivalent to the 25 ng/mL standard were scored as high positives.

To assess interreader variability, rapid tests with specimens from the Bangladesh study were evaluated by 4 independent observers without knowledge of quantitative PSA results or one another's scores. Readers scored ABAcard results as negative or positive (low, medium, or high). For dichotomous results, considered as negative or positive, interreader reliability was high with a κ score of 0.97 (SE, 0.02). Using semiquantitative scores to distinguish low, medium, and high positives, interreader reliability was lower with a κ score of 0.82 (SE, 0.01). Most of the discordant semiquantitative results occurred among specimens with low PSA concentrations (0.4–2.0 ng PSA/mL). For comparisons between rapid and quantitative PSA tests, scores from a single representative reader were used. Different ABAcard lots were tested with specimens from the Zimbabwe study. Reproducibility was high with a linear weighted κ score of 0.92 (SE, 0.03) for scores from the same reader using cards from different lots.

Statistical Analyses

The κ statistic for multiple raters was calculated using the MAGREE macro from SAS/STAT Software (Release 6.11 TS020). Ninety-five percent confidence intervals (CIs) for proportions were calculated according to Wilson.[12] Differences between groups were assessed by χ^2 or Mann-Whitney rank sum test using Sigma Stat for Windows version 3.0.1 (Systat Software, Inc.); $P < 0.05$ were considered statistically significant.

RESULTS

Baseline characteristic of study participants are shown in Table 1. Using the cutoff of >1.0 ng PSA/mL previously established to define exposure to semen within the last 48 hours,[5] a higher proportion of specimens from women in the Bangladesh study were positive, and the range of PSA values was greater than that observed among specimens from women in the Zimbabwe study (Table 2). However, median PSA concentrations were similar among positive vaginal swabs from the 2 studies (Table 2). Figure 1 shows the distribution of PSA concentrations in vaginal swabs from the 2 study groups.

Rapid Test Performance

We compared the performance of the rapid PSA test with the IMx PSA assay to detect semen in vaginal swab specimens from the Bangladesh and Zimbabwe studies (Table 3). Rapid test performance was similar with specimens from the 2 study populations. Among specimens with ≤1.0 ng PSA/mL, 5% in the Bangladesh study and 3% in the Zimbabwe study were positive, and all specimens containing >1.0 ng PSA/mL were positive with the rapid test (Table 3). Overall, ABAcard sensitivity was 100% (95% CI, 98%–100%) and specificity was 96% (95% CI, 93%–97%) for detection of >1.0 ng PSA/mL of vaginal swab eluate.

Calibration of the ABAcard for Semiquantitative PSA Detection

In the comparisons of the rapid and quantitative PSA tests described above, ABAcard results were considered as positive or negative. Using any visible test line to define a positive, the ABAcard was slightly less specific for detection of PSA than the 1.0 ng/mL cutoff; 4% of negative samples tested positive with the rapid test (Fig. 2A; Table 3). The 16 specimens with false positive rapid tests had low PSA concentrations ranging from 0.1 to 1.0 ng/ml. To see if we could calibrate the ABAcard to more closely align its performance with the 1.0 ng PSA/mL cutoff, we evaluated specimens from the Zimbabwe study using 3- and 4-category scoring scales as described under “Materials and Methods” (Fig. 2). With the 3-category scale, the rapid test was 88% sensitive (95% CI, 73%–96%) and 100% specific (95% CI, 97%–100%) for detection of >1.0 ng PSA/mL of vaginal swab eluate. There were no ABAcard positives among specimens with ≤1.0 ng PSA/mL; however, 13% of PSA-positives (5/40) were misclassified as negative (Fig. 2B). The missed positives had low PSA concentrations ranging from 1.1 to 2.8 ng/ml. All the remaining PSA-positives, with concentrations ranging from 1.7 to 450.5 ng/ml, were detected by the ABAcard test using the less sensitive scoring system. Thus, ABAcard results may be used as a semiquantitative measure of PSA concentration in vaginal swab eluates; however, the rapid test will likely identify slightly more or fewer positive specimens compared with the >1.0 ng PSA/mL definition using a quantitative assay, depending on the scoring system employed.

Using the 4-category ABAcard scoring scale to maximize the combination of sensitivity and specificity, we compared rapid PSA test scores for all 581 vaginal swab specimens from both study populations with PSA concentration ranges determined using the quantitative IMx assay. The linear-weighted κ was 0.88 (95% CI, 0.85–0.90), indicating substantial agreement between the rapid and quantitative tests. Results were concordant for 510/581 samples (87.8%) (Table 4). For 5 of the 71 vaginal swab specimens with discordant scores, the ABAcard score was higher than the corresponding category indicated by the PSA concentration. Four samples with PSA concentrations ranging from 25.2 to 44.0 ng PSA/mL were scored as medium positives. One sample containing >5000 ng PSA/mL was scored as a low positive with the ABAcard; this was likely an artifact resulting from the high-dose hook effect with the rapid test.

DISCUSSION

In specimens from 2 independent and substantially different populations of sexually active women, the rapid ABAcard test performed very well compared with a quantitative PSA assay for detection of semen in vaginal swabs. The Bangladesh study population consisted entirely of sex workers with very high reported partner numbers (Table 1). In contrast, participants in the Zimbabwe study were sexually active women recruited from family planning, well baby and general health clinics, and community-based organizations.[11] The distribution of PSA concentrations in specimens from the 2 studies (Fig. 1) was consistent with higher risk of recent exposure to semen in the Bangladesh study compared with the Zimbabwe study. Furthermore, although the specimen collection methods differed in the 2 study populations (vaginal swabs from women in the Bangladesh study were obtained by a clinician during a pelvic examination, whereas vaginal swabs were self-collected in the Zimbabwe study), the findings were nevertheless quite comparable. A recent comparative study conducted in Brazil found good agreement in PSA detection between self-collected and nurse-collected samples.[13] Good performance characteristics of the rapid ABAcard test in both specimen sets, including high sensitivity, specificity, and interreader consistency, indicate that the test may be robust and reliable for the detection of semen in vaginal secretions in a variety of research settings, including those in which a pelvic examination is not feasible and laboratory facilities are not available.

The goal of the current study was to evaluate the performance of the ABAcard test for rapid PSA detection in vaginal swabs compared with the quantitative IMx assay and not to verify self-reported sexual activity or condom use. Previous studies have demonstrated substantial disagreement between self-reports and PSA detection[2,3] indicating that self-reports of sexual behavior cannot be assumed to be valid measures.

Using PSA as a marker of semen exposure capitalizes on previous studies that characterized the kinetics of PSA clearance from vaginal swab specimens prepared in the same way that was used in our study. Macaluso et al. showed that 24 hours after exposure to 1.0 mL of semen, vaginal swabs from 71% of women contained ≤1.0 ng PSA/mL and 97% of specimens were below the cutoff by 48 hours after insemination,[5] providing relevant time periods to frame questions about recent sexual activity and condom use. In condom efficacy studies, correlation of PSA concentrations in post coital vaginal swabs with reported problems with condom use (e.g., breakage, slippage, incorrect donning) established relevant semen exposure categories.[7,8] In the current study, the rapid PSA test was slightly less specific or less sensitive than the quantitative 1.0 ng PSA/mL cutoff to define a positive result, depending on the scoring system employed. The use of commercially available purified human PSA reference standards as convenient visual scoring guides allows rapid test results to be interpreted semi-quantitatively to approximate different levels of likely semen exposure.

The ABAcard test performed well, but not perfectly (Table 4), in comparison with the quantitative PSA test. Depending on individual study objectives, researchers may choose to maximize rapid test sensitivity or specificity by selecting the appropriate scoring system. It is important that researchers who use the ABAcard understand the potential for misclassification of PSA results and carefully consider the implications for false positive and false negative test results in individual study settings.

The ABAcard for rapid PSA detection is a simple and relatively inexpensive test that can be used to identify a marker of recent semen exposure in vaginal swabs. Currently, this rapid PSA test is planned for use in a forthcoming randomized trial of female STD clinic attendees undergoing treatment for bacterial infection to assess compliance with recommendations for avoiding unprotected sex during the short-term treatment period. With information about discordant self-reported behavior and semen test results available in real time, qualitative researchers will have the opportunity for in-depth probing during the interview visit, potentially increasing the accuracy of information obtained. In general, obtaining accurate data regarding recent semen exposure among women will improve assessment of interventions that have been historically difficult to evaluate, including those designed to increase consistent and correct condom use or evaluate condom or microbicide efficacy, for which accurate knowledge of recent sexual behaviors is essential.

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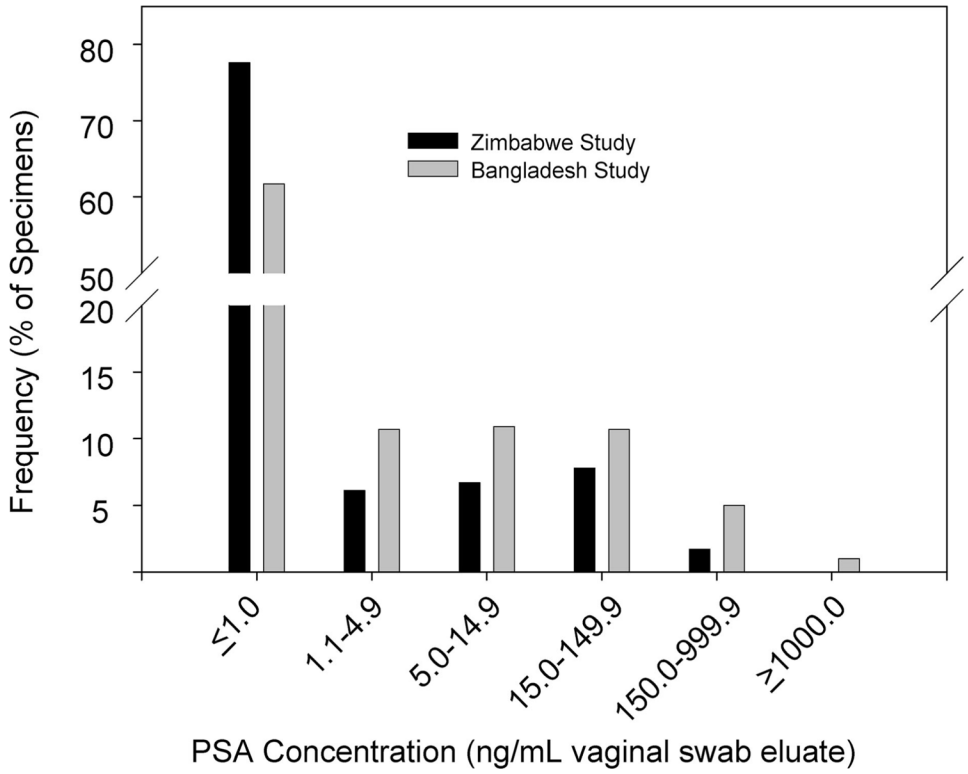

Figure 1.

Distribution of PSA concentrations among vaginal swab specimens from sexually active women in Zimbabwe (black bars, n = 179) and from sex workers in Bangladesh (gray bars, n = 402). Specimens with ≤1.0 ng PSA/mL were considered negative; those with >1.0 ng/mL were considered positive for semen.

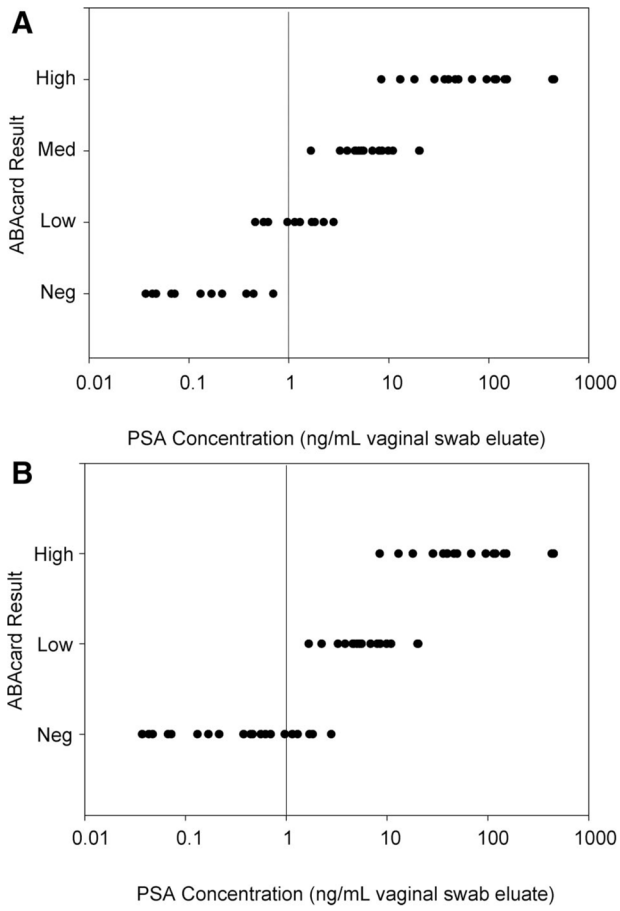

Figure 2.

Semiquantitative scoring systems for PSA detection using the ABAcard can maximize rapid test sensitivity (A) or specificity (B). A, Vaginal swab specimens from the Zimbabwe study (n = 179) were scored as negative (Neg) if no line was visible in the test area, low positive (Low) if the signal was visually similar to the 1 ng/mL PSA standard, medium positive (Med) if the signal was similar to the 5 ng/mL standard, and high positive (High) if the signal was equivalent to the 25 ng/mL standard. B, Using the same specimens and test cards, those with no line or a faint line were scored as negative (Neg), those with a signal visually similar to the 5 ng/mL standard were scored as low positives (Low), and those with a signal equivalent to the 25 ng/mL standard were scored as high positives (High). PSA concentrations, shown on the *x* axis, were determined using the quantitative IMx assay. Vertical lines show the 1.0 ng PSA/mL cutoff; symbols to the right of the line were considered PSA-positive, and symbols on the line and to the left were considered PSA-negative.

TABLE 1

Baseline Characteristics of Women in Study Groups

	Bangladesh N = 313		Zimbabwe* N = 179	
	N	**%**	**n**	**%**
Age (yr)				
≤24	240	76.7	42	23.5
25–34	66	21.1	98	54.8
≥35	7	2.2	39	21.8
Married or cohabiting				
Yes	148	47.3	175	97.8
No	165	52.7	4	2.2
Education				
None	99	31.6	NA	
1–5 yr	110	35.1	NA	
6–12 yr	104	33.2	NA	
<High school	NA		103	57.5
≥High school	NA		76	42.5
No. sex partners, mean (range)				
Last session	6.9	0–28	NA	
Lifetime	NA		1.3	1–5

*Characteristics reported at the baseline visit of the MIRA trial.[11] NA, not applicable.

TABLE 2

Specimen Characteristics

	Study Population	
Vaginal Swab Characteristic	**Bangladesh (N = 402)**	**Zimbabwe (N = 179)**
Method of collection	Provider collected	Self-obtained
PSA positive [*], number (%)	154 (38.3) [†]	40 (22.3)
Median PSA concentration (range, ng/ml)	11.2 (1.1–>5000.0) [‡]	10.4 (1.1–450.5)

[*] Specimens containing >1.0 ng PSA/mL as determined by the quantitative IMx assay.

[†] $P < 0.001$, χ^2 test.

[‡] Among PSA-positive specimens, $P = 0.884$, Mann-Whitney rank sum test.

TABLE 3

Performance of Rapid PSA Test for Detection of Semen in Vaginal Swab Specimens

		Study Population			
		Bangladesh (N = 402)		Zimbabwe (N = 179)	
Qualitative Result	Concentration* (ng PSA/mL)	Total	Number Positive (%, 95% CI)	Total	Number Positive (%, 95% CI)
Negative	≤1.0	248	12 (5,3–8)	139	4 (3,1–7)
Positive	>1.0	154	154 (100,98–100)	40	40 (100,91–100)

*PSA concentrations determined using the quantitative IMx assay.

TABLE 4

Good Agreement* Between Rapid PSA Test Scores and Quantitative PSA Concentrations in Vaginal Swab Specimens

		No. Specimens With Rapid PSA Test Score‡			
Qualitative Result	**Concentration† (ng PSA/mL)**	**Negative**	**Low**	**Medium**	**High**
Negative	≤1.0	371	13	3	0
Low	1.1–4.9	0	29	25	0
Moderate	5.0–24.9	0	0	52	25
High	≥25	0	1	4	58

*κ score with linear weighting indicates 0.88 (95% CI, 0.85–0.90).

†PSA concentration determined using the quantitative IMx assay.

‡ABAcard results were scored as negative if no test line was visible, low positive if the signal was similar to the 1 ng PSA/mL standard, medium if the signal was similar to the 5 ng/mL standard or high if the signal was similar to the 25 ng/mL standard.