

## Evaluation of Self-Collected Glans and Rectal Swabs from Men Who Have Sex with Men for Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Use of Nucleic Acid Amplification Tests<sup>∇</sup>

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Self-collected glans and rectal swab specimens from men who have sex with men (MSM) may be appropriate, convenient specimens for testing. We evaluated the use of self-collected swabs for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by a transcription-mediated amplification test (AC2; Aptima Combo 2; Gen-Probe Inc.) and a strand displacement amplification test (SDA; ProbeTec; Becton Dickinson Co.) in MSM seen at the city sexually transmitted disease clinic in San Francisco, CA. For the glans swab specimen, subjects enrolled early in the study rolled a Dacron swab across the meatus three times (method 1). A slightly more invasive procedure was performed later in the study: the subjects inserted the swab 1/4 in. into the urethra, rotated the swab, and then withdrew the swab (method 2). MSM self-collected a rectal swab specimen and also provided first-catch urine (FCU). Additional rectal swab samples were then obtained by the clinician. For the detection of *C. trachomatis* and *N. gonorrhoeae*, all swabs were evaluated by AC2 and SDA, FCU was tested by AC2, and the clinician-collected rectal swabs were cultured. A rectal true-positive (TP) result was defined as a culture-positive result for *C. trachomatis* or *N. gonorrhoeae*, two or more positive nucleic acid amplification test (NAAT) results, or a single NAAT-positive result confirmed by an alternate amplification method (the Aptima *C. trachomatis* or *N. gonorrhoeae* test). A glans TP result was defined as a positive result for FCU, positive results for both glans specimens (one tested by AC2 and one tested by SDA), or a positive result for a single glans specimen confirmed by an alternate amplification method. The prevalence rates of *C. trachomatis* and *N. gonorrhoeae* by testing of FCU were 6.8% (60/882 specimens) and 12.2% (108/882 specimens), respectively. Mixed results were obtained with the glans swab: *N. gonorrhoeae* detection by AC2 and SDA (method 1) had the best performance (sensitivities, >92%) with samples from a population with a higher prevalence of infection, but their performance for the detection of *C. trachomatis* was poor and varied by collection method (sensitivities, 56 to 68%). The prevalence rates of *C. trachomatis* and *N. gonorrhoeae* in the rectum were 7.3% (66/907 specimens) and 9.4% (83/882 specimens), respectively. The sensitivities of the tests with self-collected and clinician-collected rectal swab specimens were comparable (for *C. trachomatis*, 41% and 44%, respectively, by SDA and 82% and 71%, respectively, by AC2; for *N. gonorrhoeae*, 77% and 68%, respectively, by SDA and 84% and 78%, respectively, by AC2). AC2 and SDA were far superior to culture for the detection of *C. trachomatis* and *N. gonorrhoeae* in the rectum, with both tests detecting at least twice as many infections. While we found self-collected rectal swabs from MSM to be valid specimens for testing, the sensitivities of the tests with glans swab specimens were disappointing except for those from patients with symptomatic *N. gonorrhoeae* infections. Self-collected glans swab specimens may not be appropriate for the detection of *C. trachomatis* or for the detection of *N. gonorrhoeae* in low-risk or asymptomatic patients by AC2 and SDA, and we would not recommend their use on the basis of our results. Further studies are needed.

Nucleic acid amplification tests (NAATs) are highly sensitive and specific for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. Currently, in the United States, there are three commercially available NAATs: PCR (Amplacor CT/NG PCR; Roche Diagnostics Corp., Branchburg, NJ), the strand displacement amplification test (SDA; ProbeTec; Becton Dickinson Co., Sparks, MD), and the transcription-mediated amplification test (AC2; Aptima Combo 2 CT/GC; Gen-Probe Inc., San Diego, CA) (10, 16, 19, 29, 31). False-positive (FP) results for *N. gonorrhoeae* can occur with PCR and SDA, as their targets may cross-react with other *Neisseria*

spp. (6, 30). AC2 or the Aptima *Neisseria gonorrhoeae* test (Gen-Probe Inc.) has yet to report this type of FP result. Because of potential FP results and the relatively low specificities, the CDC recommends confirmatory testing of specimens positive for *C. trachomatis* and *N. gonorrhoeae* by NAATs when the positive predictive value is <90% (1). However, in two large-scale studies, we found that confirmatory testing by the use of NAATs is unwarranted for genital specimens (18, 24).

NAATs are cleared for use with urogenital specimens from men and women and with specimens that can be obtained by noninvasive means, such as first-catch urine (FCU) and vaginal swab specimens (8, 23, 27). Testing of the last two types of samples has made broad-scale screening programs and home-based sampling possible. For these reasons, the use of self-collected specimens is appealing. Although AC2 has FDA clearance for use only with vaginal swab specimens (23), laboratories can still com-

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ply with the regulations in the Clinical Laboratory Improvement Amendments and verify the use of this type of specimen for SDA or PCR.

Because the CDC guidelines recommend routine screening of urethral, oropharyngeal, and rectal swab specimens for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* for men who have sex with men (MSM), this population would benefit from the availability of specimens that do not require a medical procedure for collection (noninvasive specimens), as it will likely increase access to testing and the regularity of testing for sexually transmitted diseases (STDs) (1). While the use of sample types from MSM that can be obtained by noninvasive means (oral wash, glans swab, and rectal swab specimens) has been evaluated, none is yet recognized to be a reliable specimen for testing (2, 5, 7, 15, 20, 21, 28). Studies have been limited, and there is no consensus on the performance characteristics of NAATs with these sample types.

Currently, FCU is the only sample that can be obtained by noninvasive means used for the routine screening of MSM, but specimen-specific limitations do exist (9, 12, 26). Problems have been associated with the handling of FCU in the laboratory, and specimen transport can be messy. NAATs with FCU and urethral swab specimens have similar performance profiles for the detection of *C. trachomatis* and *N. gonorrhoeae*, but swabs are more easily processed (4). The replacement of FCU with a self-collected swab would be an improvement. It eliminates the centrifugation steps (which are required for SDA and PCR). A potential, specimen that can be obtained by noninvasive means is a self-collected glans swab. This alternate sample is easy to obtain, transport, and process. A recent study showed that patient-collected glans and coronal sulcus swab samples performed comparably to clinician-collected samples for the detection of human papillomavirus (11). There are a few evaluations of NAATs for the detection of *C. trachomatis* and *N. gonorrhoeae* by the use of self-collected glans and penile swab specimens; however, the results have not been conclusive. Three studies described in brief reports found that self-collected glans and penile swab specimens were suitable for the detection of either *C. trachomatis* or *N. gonorrhoeae* by AC2 and/or SDA (2, 7, 28). In contrast, de Barbeyrac et al. found that self-collected glans swab specimens from asymptomatic men had a poor performance for the detection of *C. trachomatis* compared to the performance of a Roche PCR with FCU (5). A study of men with urethritis also found that penile skin swab specimens were less sensitive than FCU or urethral swab specimens for the detection of *C. trachomatis* by PCR (21). Given the results of these small-scale studies, further assessment of the use of the glans swab specimen is still needed.

Another promising noninvasive specimen for MSM is the self-collected rectal swab. At present, none of the NAATs are cleared by FDA for use with rectal swabs, so the standard for testing is culture. Again, in-house NAAT verification studies will circumvent this limitation. The self-collected rectal swab sample has been shown to be suitable for cytological examination and screening for *C. trachomatis* and *N. gonorrhoeae* (14, 15). Lister et al. used self-collected rectal swab specimens for the detection of *C. trachomatis* and *N. gonorrhoeae* by NAATs but did not compare the results obtained with self-collected specimens to those obtained with clinician-collected rectal swab specimens (15). The self-collected rectal swab remains a

novel specimen, and thorough evaluations of this type of specimen are lacking. Additional studies of the use NAAT for the detection of *C. trachomatis* and *N. gonorrhoeae* would help determine whether these types of swab specimens are useful.

Our laboratory has validated the use of clinician-collected swab specimens from the oropharynx and rectum of MSM for the detection of *C. trachomatis* and *N. gonorrhoeae* by NAATs. We found that AC2 and SDA were far superior to culture for the detection of *C. trachomatis* or *N. gonorrhoeae* in the oropharynx and rectum, with AC2 detecting twice as many infections as culture (25). The present study evaluated the use of self-collected glans and rectal swab specimens from MSM for the detection of *C. trachomatis* and *N. gonorrhoeae* by AC2 and SDA. The results obtained with the glans swab specimens were compared to those obtained by AC2 with an FCU specimen; and the results obtained with self-collected rectal swab specimens were compared to those obtained by AC2, SDA, and culture with clinician-collected rectal swabs.

#### MATERIALS AND METHODS

**Patient population.** MSM attending the city STD clinic in San Francisco, CA, were enrolled in the study. Subjects who had urinated within the previous 1 h or who had received antibiotic therapy within the previous 21 days were excluded from participation. The Committee on Human Research at the University of California, San Francisco (UCSF), granted approval to conduct this evaluation, and verbal consent was obtained from all patients.

**Specimen collection.** Each patient provided self-collected glans swab, rectal swab, and FCU specimens; and clinician-collected rectal swab specimens were also obtained from each patient. Patients were given both oral and written instructions on specimen self-collection and were specifically directed to wash their hands after each collection procedure. Initially, the MSM self-sampled the glans by rolling the tip of a Dacron type 1 swab across the opening of the penis three times (method 1). Later in the study, a slightly more invasive sampling method was used in which the swab was inserted 1/4 in. into the urethra and rotated once (method 2). After glans swab specimen collection, the MSM provided approximately 25 ml of FCU in a sterile cup. The subjects then self-collected a rectal swab specimen by inserting a Dacron type 1 swab 1.5 in. into the anus and rotating it once. After sample self-collection was completed, the clinician examined the patient and obtained, in randomized order, a rectal swab specimen for culture and the NAATs.

The self-collected glans swab was placed in 3.0 ml of M4 medium (Remel Inc., Lenexa, KS) for NAAT. The inoculated tubes containing M4 medium were held at 4°C and transported in the cold within 24 h of collection to the UCSF Chlamydia Laboratory, where the NAATs (AC2 and SDA) were performed.

The self- and clinician-collected rectal swab specimens were also placed in 3.0 ml of M4 medium for the isolation of *C. trachomatis* and the NAATs, and cotton swabs for *N. gonorrhoeae* culture were streaked onto Thayer-Martin plates (Remel Inc.). The specimens in M4 medium were kept at 4°C and transported in the cold within 24 h of collection to the UCSF Chlamydia Laboratory, where *C. trachomatis* culture and the NAATs (AC2 and SDA) were performed. The plates used for the detection of *N. gonorrhoeae* were immediately placed in candle jars, and the jars were incubated at 36°C. At the end of each day, *N. gonorrhoeae* cultures and FCU (for AC2 testing) were transported to the San Francisco Public Health laboratory for final identification of the organism present.

***C. trachomatis* tissue culture.** We used a modification of the procedure of Ripa and Mardh for the isolation of *C. trachomatis* (22). Tubes containing M4 medium were vortexed for 2 min, and aliquots were removed for use in the NAATs. In order to reduce the possibility of bacterial contamination in the tissue culture, the rectal swab specimens were diluted 1:2 and 1:10 in medium containing antibiotics. McCoy cells seeded in 1-dram shell vials were inoculated by centrifugation of the diluted samples at 3,000 × g for 1 h and were incubated with medium containing cycloheximide for 72 h at 36°C in 5% CO<sub>2</sub>. The cell monolayers were stained with the MicroTrak *C. trachomatis* culture confirmation reagent (Trinity Biotech Plc., Wicklow, Ireland), a species-specific fluorescent antibody that detects chlamydial inclusion bodies. At 4 days postinoculation, we performed a blind passage and read the coverslips from the second passage in 72 h.

***N. gonorrhoeae* isolation.** The inoculated Thayer-Martin plates were incubated at 36°C in 5% CO<sub>2</sub> for 48 h. Presumptive *N. gonorrhoeae* colonies were Gram stained, tested for oxidase production, and subcultured onto chocolate agar. The presence of pure cultures was confirmed by use of either the MicroTrak *N. gonorrhoeae* culture confirmation reagent fluorescent antibody (Trinity Biotech Plc.) or the API NH carbohydrate reaction test (bioMérieux, Inc., Marcy l'Etoile, France).

**Standard NAATs.** Prior to the study, the M4 medium was validated for in-house use with each of the NAATs. For SDA, we inoculated 100 µl of the specimen in M4 medium into a ProbeTec collection tube and then processed the culture. For AC2, we inoculated 100 µl of the specimen in M4 medium into a Combo 2 swab transport tube, and ~2.5 ml of FCU was transferred into a Combo 2 urine transport tube. The protocols described in the individual AC2 and SDA package inserts were followed. The technologists performing the tests were blinded to the results of any of the other tests.

**Alternate NAATs for resolution.** Specimens (glans or rectal swabs) that were uniquely positive by one NAAT (negative by culture and the other NAAT) received additional testing by another NAAT targeting alternate primers (3). For specimens with apparent FP results for *N. gonorrhoeae*, the Aptima *N. gonorrhoeae* assay (Gen-Probe Inc.), which detects a region of the 16S rRNA different from that which AC2 detects, was performed. For specimens with apparent FP results for *C. trachomatis*, the Aptima *C. trachomatis* assay (Gen-Probe Inc.), which detects the 16S rRNA, was performed. This in-house testing was performed blinded.

**Definition of a true-positive result.** For *C. trachomatis*, a true-positive result was defined as a positive result by AC2 with FCU, positive results by two or more NAATs with glans swab specimens, a positive result by rectal swab culture, positive results by two or more NAATs with rectal swab specimens, or a positive result by a single NAAT with a glans or rectal swab specimen that was confirmed by an alternate NAAT for *C. trachomatis*. For *N. gonorrhoeae*, true-positive results were defined as a positive result by AC2 with FCU, positive results by the two NAATs with glans swab specimens, a positive result by rectal swab culture, positive results by two or more NAATs with rectal swab specimens, or a positive result by a single NAAT with a glans or rectal swab specimen that was confirmed by an alternate NAAT for *N. gonorrhoeae*.

**Statistical methods.** Differences in proportions were evaluated by the chi-square and Fisher's exact tests.

## RESULTS

A total of 907 men were enrolled in the study; 469 (51.7%) were symptomatic, and 438 (48.3%) were asymptomatic. There were 280 (30.9%) MSM who reported dysuria or urethral discharge, 14 (1.5%) had rectal ulcers, 21 (2.3%) had rectal discharge, 16 (1.8%) had rectal warts, and 41 (4.5%) had a sore throat. The remaining 97 (10.7%) had other symptoms or findings (rash, abdominal pain, genital irritation, etc.).

Overall, the prevalence rates of *C. trachomatis* and *N. gonorrhoeae* in the urethra were 6.8% (60/882) and 12.2% (108/882), respectively. Table 1 shows the results for the detection of *N. gonorrhoeae* and *C. trachomatis* by NAATs with self-collected glans swab specimens. Our initial findings with specimens collected by method 1 found a poor performance of the tests for the detection of *C. trachomatis* but a good performance of the tests for the detection of *N. gonorrhoeae* compared to the results obtained with the FCU specimens. AC2 and SDA had comparable results when glans swab specimens were used; both tests were significantly less sensitive than AC2 with FCU specimens (*P* values, 0.0005 for SDA and 0.001 for AC2). By the use of method 1 for specimen collection, the prevalence rates of *C. trachomatis* and *N. gonorrhoeae* were 6.5% (32/492) and 16.3% (80/492), respectively. However, mixed results were obtained when the method 2 collection procedure (the more invasive collection procedure) was used. We found that the sensitivities for the detection of *C. tracho-*

TABLE 1. Detection of *N. gonorrhoeae* and *C. trachomatis* by NAATs with self-collected glans swab specimens<sup>a</sup>

Test	Specimen	Sensitivity (%)			
		<i>N. gonorrhoeae</i>		<i>C. trachomatis</i>	
		Method 1	Method 2	Method 1	Method 2
SDA	Glans swab	92.5 (74/80) <sup>b</sup>	75.0 (21/28)	56.3 (18/32) <sup>c</sup>	60.7 (17/28)
AC2	Glans swab	96.3 (77/80)	82.1 (23/28)	59.4 (19/32) <sup>d</sup>	67.9 (19/28)
AC2	FCU	97.5 (78/80)	96.4 (27/28)	93.8 (30/32)	82.1 (23/28)

<sup>a</sup> True-positive results are defined as a positive result by AC2 with FCU, positive results for glans swab specimens by both NAATs, or a positive result by a single NAAT with glans swab specimens confirmed by an alternate amplification method. The specificities of all assays were ≥99.7%. For specimen collection by methods 1 and 2, the prevalence rates of *N. gonorrhoeae* were 16.3 (80/492) and 7.2 (28/390), respectively, and those of *C. trachomatis* were 6.5 (32/492) and 7.2 (28/390), respectively.

<sup>b</sup> The values in parentheses are the number of MSM positive/total number of MSM tested.

<sup>c</sup> *P* = 0.0005 by comparison with the results of AC2 with FCU.

<sup>d</sup> *P* = 0.001 by comparison with the results of AC2 with FCU.

*matis* increased slightly (~4 to 8%) but that the sensitivities for the detection of *N. gonorrhoeae* decreased moderately (~14 to 17%). AC2 had better performance characteristics than SDA for the detection of both *C. trachomatis* and *N. gonorrhoeae*. The prevalence of *C. trachomatis* (7.2% [28/390 specimens]) was slightly higher and that of *N. gonorrhoeae* was much lower (7.2% [28/390 specimens]) in the method 2 collection group than in the method 1 collection group. The specificities of all NAATs were ≥99.7%.

Of the 280 men with urethral symptoms, 45 had discharge only, 104 had dysuria only, and 131 reported both discharge and dysuria. For MSM presenting with only urethral symptoms, the prevalence rates of *N. gonorrhoeae* and *C. trachomatis* were 33.6% (94/280) and 13.6% (38/280), respectively. Although the number of positive asymptomatic MSM (22 positive for *C. trachomatis* and 14 positive for *N. gonorrhoeae*) was small, we found that the NAATs for the detection of *N. gonorrhoeae* performed better with samples from symptomatic MSM (Table 2). The opposite was seen for AC2, by which the test for *C. trachomatis* performed better with samples from asymptomatic MSM. Table 3 shows that circumcision status did not affect the performance of the NAATs for the detection of *C. trachomatis* or *N. gonorrhoeae* (*P* > 0.10).

By tests with rectal swab specimens, the overall prevalence rates of *C. trachomatis* and *N. gonorrhoeae* were 7.3% (66/907) and 9.4% (83/882), respectively. More rectal chlamydial infections was seen in asymptomatic MSM (9.8%) than symptomatic MSM (4.9%). The opposite was seen for *N. gonorrhoeae*, with more symptomatic MSM than asymptomatic MSM having *N. gonorrhoeae* infections (10.7% and 8.0%, respectively). Table 4 shows that the performance profiles of the NAATs performed with self-collected swab specimens were either similar (*C. trachomatis* by SDA) or marginally better than those of the NAATs performed with clinician-collected swabs. SDA and AC2 were significantly more sensitive than culture with either clinician- or self-collected rectal swab specimens (all *P* values were <0.005 by comparison of the results of SDA and AC2 with those of culture). The specificities of the NAATs were ≥99.3%. Only 51 MSM presented with rectal symptoms; thus, the performance characteristics of the NAATs were not analyzed on the basis of this symptomatology. As expected, culture

TABLE 2. Sensitivities of NAATs for detection of *N. gonorrhoeae* and *C. trachomatis* with self-collected glans swab specimens from asymptomatic and symptomatic MSM<sup>a</sup>

Collection method and specimen	Test	Sensitivity (%)			
		<i>N. gonorrhoeae</i>		<i>C. trachomatis</i>	
		Asymptomatic MSM	Symptomatic MSM <sup>b</sup>	Asymptomatic MSM	Symptomatic MSM
<b>Method 1<sup>c</sup></b>					
Glans swab	SDA	100 (7/7) <sup>d</sup>	91.8 (67/73) <sup>e</sup>	55.6 (5/9)	56.5 (13/23) <sup>f</sup>
Glans swab	AC2	100 (7/7)	95.9 (70/73)	66.7 (6/9)	56.5 (13/23) <sup>f</sup>
FCU	AC2	71.4 (5/7)	100 (73/73)	77.8 (7/9)	100 (23/23)
<b>Method 2<sup>g</sup></b>					
Glans swab	SDA	42.9 (3/7)	85.7 (18/21)	53.8 (7/13)	66.7 (10/15)
Glans swab	AC2	42.9 (3/7)	95.2 (20/21)	84.6 (11/13)	53.3 (8/15)
FCU	AC2	85.7 (6/7)	100 (21/21)	76.9 (10/13)	86.7 (13/15)

<sup>a</sup> True-positive results are defined as a positive result by AC2 with FCU, positive results for glans swab specimens by both NAATs, or a positive result by a single NAAT with glans swab specimens confirmed by an alternate amplification method. Overall, the prevalence rates of *C. trachomatis* infection were 3.7% (22/602) for asymptomatic MSM and 13.6% (38/280) for symptomatic MSM. Overall, the prevalence rates of *N. gonorrhoeae* were 2.3% (14/602) for asymptomatic MSM and 33.6% (94/280) for symptomatic MSM.

<sup>b</sup> Urethral symptoms only.

<sup>c</sup> For specimen collection by method 1, the prevalence rates of *N. gonorrhoeae* and *C. trachomatis* among asymptomatic MSM were 2.5 (7/279) and 3.2 (9/279), respectively, and those among symptomatic MSM were 34.3 (73/213) and 10.8 (23/213), respectively.

<sup>d</sup> The values in parentheses are the number of MSM positive/total number of MSM tested.

<sup>e</sup>  $P = 0.04$  by comparison with the results of AC2 with FCU.

<sup>f</sup>  $P < 0.001$  by comparison with the results of AC2 with FCU.

<sup>g</sup> For specimen collection by method 2, the prevalence rates of *N. gonorrhoeae* and *C. trachomatis* among asymptomatic MSM were 2.2 (7/323) and 4.0 (13/323), respectively, and those among symptomatic MSM were 31.3 (21/67) and 22.4 (15/67), respectively.

performed poorly with rectal swab specimens; the NAATs detected two to three times more *C. trachomatis* and *N. gonorrhoeae* infections than culture.

## DISCUSSION

We evaluated self-collected glans and rectal swab specimens as potential specimens that can be collected by noninvasive means for use for the detection of *C. trachomatis* and *N. gonorrhoeae* in MSM by NAATs. Our study showed that AC2 and SDA are far superior to culture for the detection of *C. trachomatis* and *N. gonorrhoeae* in samples from the rectum collected by either the patient or the clinician. These findings were significant (all  $P$  values were  $<0.005$ ); the NAATs detected two to three times more infected patients than culture. The overall prevalence rates of rectal *C. trachomatis* and *N. gonorrhoeae* were 7.3% (66/907) and 9.4% (83/882), respectively. We found that 4.9% of symptomatic MSM and 9.8% of asymptomatic

MSM had rectal chlamydial infections. These results are similar to those of Kent et al. (13); lower rates of *C. trachomatis* infection were also seen in MSM with symptoms. The results obtained with self-collected rectal swab specimens were at least as good or better than those obtained with clinician-collected swab specimens. Compared to the results obtained with the clinician-collected swabs, the sensitivities of the NAATs with self-collected swab specimens for the detection of *N. gonorrhoeae* were 6 to 10% higher and the sensitivities of the NAATs with self-collected swab specimens for the detection of *C. trachomatis* were either comparable (41% and 44%, respectively, for SDA) or slightly higher (10% for AC2). The performance profiles of our tests confirm that rectal swab specimens self-collected by MSM are valid specimens for use in NAATs for the detection of *C. trachomatis* and *N. gonorrhoeae*.

Although we have shown that the self-collection of rectal swab specimens is feasible and that the results obtained with those specimens are accurate, most laboratories will find the process of verifying the results for the specimens to be somewhat complicated. Because rectal swabs are not cleared for use by the FDA with *C. trachomatis*- or *N. gonorrhoeae*-specific NAATs, a more extensive verification method is required. Laboratories might have to perform two verifications: one for the use of clinician-collected rectal swabs and the other for the use of self-collected rectal swabs. The moderate prevalence rates of *C. trachomatis* and *N. gonorrhoeae* in asymptomatic MSM (Table 4) show that there is clearly a need to screen this population, and self-collected rectal swabs would be ideal specimens for use for screening. The fact that the sensitivities of none of the swab-test combinations approached 100% shows that we must still improve either the specimen collection or the processing method. It is possible that the dilution caused by the relatively large volume of our collection medium, which was required for the number of tests that we performed, had a

TABLE 3. Circumcision status of MSM who self-collected glans swabs for detection of *N. gonorrhoeae* and *C. trachomatis*<sup>a</sup>

Test and circumcision status	Sensitivity (%)	
	<i>N. gonorrhoeae</i> (n = 108)	<i>C. trachomatis</i> Sensitivity (n = 60)
SDA		
Yes	92 (76/88) <sup>b</sup>	58 (29/50)
No	95 (19/20)	60 (6/10)
AC2		
Yes	86 (81/88)	64 (32/50)
No	95 (19/20)	60 (6/10)

<sup>a</sup> All  $P$  values were  $>0.10$  for the comparison of sensitivity by circumcision status.

<sup>b</sup> The values in parentheses are the number of MSM positive/total number of MSM tested.

TABLE 4. Detection of *N. gonorrhoeae* and *C. trachomatis* by NAATs with rectal swab specimens<sup>a</sup>

Rectal swab specimen collector	Test	<i>N. gonorrhoeae</i> (n = 882)		<i>C. trachomatis</i> (n = 907)	
		Sensitivity <sup>a</sup> (%)	Specificity (%)	Sensitivity (%)	Specificity (%)
Self	SDA	77.1 (64/83) <sup>b,c</sup>	99.3 (793/799)	40.9 (27/66) <sup>c</sup>	100 (841/841)
Clinician	SDA	67.5 (56/83) <sup>c</sup>	100 (799/799)	43.9 (29/66) <sup>c</sup>	99.9 (840/841)
Self	AC2	84.3 (70/83) <sup>c</sup>	100 (799/799)	81.8 (54/66) <sup>c</sup>	100 (841/841)
Clinician	AC2	78.3 (65/83) <sup>c</sup>	99.8 (797/799)	71.2 (47/66) <sup>c</sup>	99.6 (838/841)
Clinician	Culture	34.9 (29/83)	100 (799/799)	18.2 (12/66)	100 (837/837)

<sup>a</sup> True-positive results were defined as positivity by culture, positive results by two or more NAATs, or a positive result by a single NAAT confirmed by an alternate amplification method. The overall prevalence rates of *C. trachomatis* were 9.8% (43/438) for asymptomatic MSM and 4.9% (23/469) for symptomatic MSM. The overall prevalence rates of *N. gonorrhoeae* were 8.0% (33/413) for asymptomatic MSM and 10.7% (50/469) for symptomatic MSM.

<sup>b</sup> The values in parentheses are the number of MSM positive/total number of MSM tested.

<sup>c</sup> All *P* values were <0.005 by comparison with the results of culture.

negative impact on sensitivity. Given that, our results by culture were dismal and clearly show that it is time to stop relying on culture for routine diagnosis. We encourage the manufacturers of NAATs to seek FDA clearance for the use of rectal swabs for testing for *C. trachomatis* and *N. gonorrhoeae*.

Our results with the self-collected glans swab specimens were not as promising. We initially evaluated 492 MSM by the use of specimen collection by method 1, in which only the glans area was swabbed. The sensitivities of the NAATs for *N. gonorrhoeae* (>93%) were comparable to those of the tests with FCU specimens (98%), but the sensitivities of the NAATs for *C. trachomatis* were significantly poorer (56% for SDA and 59% for AC2). These early results were a disappointment and contrary to the results of other studies, in which favorable NAAT performances with a slightly more invasive method of sampling of the glans were reported (2, 6, 25). Since we did not swab at or in the urethra, we speculated that our low sensitivities for *C. trachomatis* detection were due to inadequate specimen collection. The *C. trachomatis* organism load in FCU does not differ significantly from the load in the urethra, so swabbing at the urethra should improve the performance of the NAATs (17). Therefore, we altered our collection method to include direct sampling of the urethra. An additional 390 MSM were evaluated by this new collection method; the sensitivities for the detection of *C. trachomatis* and *N. gonorrhoeae* were 61 to 68% and 75 to 82%, respectively. A small increase in the rate of detection *C. trachomatis* was noted, but the sensitivities still remained low, despite the use of the aggressive swabbing method. We had decreases in sensitivities for the detection of *N. gonorrhoeae* (93% to 75% by SDA, 96% to 82% by AC2), which might reflect the lower prevalence of *N. gonorrhoeae* (7.2%) in the latter part of the study. Our results agree with those of two previous studies that also found a poor performance of NAATs for *C. trachomatis* with self-collected glans swab specimens (5, 21). Circumcision status did not have an effect on the performance of the NAATs (*P* > 0.10) for the detection of *N. gonorrhoeae* or *C. trachomatis* (Table 3).

The results were better with glans swab specimens from a population with a high prevalence of STDs. When the prevalence of *N. gonorrhoeae* was 16.3% (in the first half of the study), the NAATs had a good ability to detect *N. gonorrhoeae* by the use of glans swab specimens. As expected, the majority of our positive NAAT results were with specimens from symptomatic (urethritis, dysuria, etc.) MSM. While the number

of positive NAAT results with specimens from asymptomatic MSM was low, there were some notable differences. The glans swab specimens from symptomatic MSM performed better in the NAATs for *N. gonorrhoeae* than those from asymptomatic MSM did (Table 2). For the detection of *C. trachomatis* in symptomatic men, both NAATs were significantly less sensitive than the AC2 with FCU. Regardless of the presence of symptoms, SDA had generally lower sensitivities for the detection of *C. trachomatis*.

In conclusion, self-collected rectal swabs from MSM are valid specimens for the detection of *C. trachomatis* and *N. gonorrhoeae* by SDA and AC2. However, the self-collected glans swab specimen has limited application. The performances characteristics of the NAATs varied on the basis of the patient's symptoms, the prevalence, and the collection method used. We had poor sensitivities for the detection of *C. trachomatis* with the glans swab specimens and would not recommend their use on the basis of our results. The glans swab specimen may not be appropriate for use for the detection of *C. trachomatis*, but it may be a suitable specimen for the detection of *N. gonorrhoeae* by NAATs in high-risk, symptomatic populations. Clearly, further evaluations are needed before self-collected glans swab specimens can be accepted as specimens that can be obtained by noninvasive means for use in *C. trachomatis* and *N. gonorrhoeae* NAATs.

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