JOURNAL OF CLINICAL MICROBIOLOGY, Aug. 2003, p. 3592–3596 Vol. 41, No. 8
0095-1137/03/$08.00+0 DOI: 10.1128/JCM.41.8.3592–3596.2003

Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Strand Displacement Amplification and Relevance of the Amplification Control for Use with Vaginal Swab Specimens

Lisa A. Cosentino,[1] Daniel V. Landers,[1,2]† and Sharon L. Hillier[1,2]*

Magee-Womens Research Institute[1] and Department of Obstetrics, Gynecology, and Reproductive Sciences, University of Pittsburgh,[2] Pittsburgh, Pennsylvania

Received 31 January 2003/Returned for modification 31 March 2003/Accepted 6 May 2003

Vaginal swab specimens may be preferable to cervical swab or urine specimens for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* because of the ease of specimen collection and transport. The purpose of this study was to evaluate whether vaginal swab specimens are equivalent to cervical swab specimens for the detection of *N. gonorrhoeae* and *C. trachomatis* by the Becton Dickinson strand displacement amplification assay (SDA) with the BDProbeTec ET instrument and then to evaluate the use of the amplification control in a clinical research setting. In the first phase, vaginal and cervical swab specimens were obtained from 455 symptomatic women aged 18 to 40 attending primary health care and sexually transmitted disease clinics. Thirty-nine specimens (8.6%) had true-positive results for *N. gonorrhoeae* and 37 specimens (8.1%) had true-positive results for *C. trachomatis*. The sensitivity of SDA was superior to that of culture for the detection of *N. gonorrhoeae* with vaginal swab specimens and equivalent to that of the Roche PCR for the detection of *C. trachomatis* with cervical swab specimens. In the second phase of the study, 1,411 consecutively collected vaginal swab specimens were evaluated, with 357 (25.3%) specimens giving indeterminate readings on the basis of the result for the amplification control. The prevalences of sexually transmitted pathogens in vaginal swab specimens with and without use of the amplification control were 6.0 and 5.8%, respectively, for *C. trachomatis* and 3.1 and 3.0%, respectively, for *N. gonorrhoeae*. Although, vaginal swab specimens were equivalent to cervical swab specimens for the detection of *N. gonorrhoeae* and *C. trachomatis* by SDA with respect to sensitivity, one in four vaginal swab specimens yielded an indeterminate result when the amplification control was used. The amplification control has limited value for use with vaginal swab specimens.

Nucleic acid amplification techniques are available for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. These methods have better sensitivities than culture and allow the detection of infection in individuals with a low number of infectious units (1). Recent studies have shown PCR (Roche Diagnostic Systems, Branchburg, N.J.) and ligase chain reaction (LCR; Abbott Laboratories, Chicago, Ill.) to be acceptable methods for the detection of *C. trachomatis* and *N. gonorrhoeae* with urine and urethral and endocervical swab specimens (2, 3, 9, 10, 11, 15). The amplified DNA assay with the BDProbeTec ET instrument (the strand displacement amplification assay [SDA]; Becton Dickinson, Sparks, Md.) for the detection of *C. trachomatis* and *N. gonorrhoeae* is based on simultaneous strand displacement amplification and real-time fluorescence detection (7, 16). Like other amplification methods, this system can detect the bacterial agents of both urethritis and cervicitis in one specimen. Some amplification systems, including SDA and PCR, also have an amplification control, which is designed to detect inhibitors of amplification in the specimen. Use of the amplification control is at the discretion of the user, but the amplification control is regarded as a useful tool that serves to minimize false-negative results resulting from inhibition of analyte nucleic acid amplification.

The increased sensitivities of nucleic acid amplification techniques have led to the evaluation of less invasive procedures for screening for sexually transmitted pathogens. The vaginal introitus (17) and vulva (12) have been shown to be acceptable sites for noninvasive sampling with swabs for the detection of *C. trachomatis*. It has been shown that patient-obtained vaginal swab specimens can be used to accurately detect *N. gonorrhoeae* infections (4). Noninvasive collection methods allow women to be screened without the need for a speculum examination. Vulvar swabbing (13) and vaginal flushing (8) have been used to collect specimens that were mailed to a laboratory. The self-collection of vaginal swab specimens at home may be more acceptable for the screening of young people who have limited contact with health services (8, 13).

SDA has already been shown to be an acceptable method for the detection of *C. trachomatis* and *N. gonorrhoeae* with urine and endocervical swab specimens (14). The purpose of the present study was to compare vaginal swab specimens to endocervical swab specimens for the detection of *C. trachomatis* and *N. gonorrhoeae*. The swabs used for SDA are transported medium-free and are therefore less prone to spillage during transport than urine samples. A second goal of this study was

* Corresponding author. Mailing address: Department of Obstetrics, Gynecology and Reproductive Sciences, University of Pittsburgh, Magee-Womens Hospital, 300 Halket St., Pittsburgh, PA 15213-3180. Phone: (412) 641-6435. Fax: (412) 641-1133. E-mail: slh6+@pitt.edu.
† Present address: University of Minnesota, Minneapolis, MN 55455.

TABLE 1. Performance of vaginal swab specimens for detection of *C. trachomatis* and *N. gonorrhoeae*

Organism and test	Swab specimen	No. of specimens with positive result	No. of specimens with false-positive results	Sensitivity[a]	Specificity[b]	Positive predictive value[a]	Negative predictive value[d]
C. trachomatis[e]							
PCR	Endocervical	33	2	33/37 (89.2)	416/418 (99.5)	33/35 (94.3)	416/420 (99.0)
SDA	Vaginal	34	1	34/37 (91.9)	417/418 (99.8)	34/35 (97.1)	417/420 (99.3)
SDA	Endocervical	34	2	34/37 (91.9)	416/418 (99.5)	34/36 (94.4)	416/419 (99.3)
N. gonorrhoeae[f]							
Culture	Endocervical	30	0	30/39 (76.9)	416/416 (100)	30/30 (100)	416/425 (97.9)
SDA	Vaginal	39	1	39/39 (100)	415/416 (99.8)	39/40 (97.5)	416/416 (100)
SDA	Endocervical	39	0	39/39 (100)	416/416 (100)	39/39 (100)	415/415 (100)

[a] The data represent the number of specimens with a positive result/total number of true-positive specimens (percent).
[b] The data represent the number of specimens with a negative result/total number of negative specimens (percent).
[c] The data represent the number of specimens with a correct positive result/total number of positive specimens tested (percent).
[d] The data represent the number of specimens with a correct negative result/total number of negative specimens tested (percent).
[e] A true-positive result was defined as positive results by two molecular tests (PCR and SDA, PCR and LCR, or LCR and SDA).
[f] A true-positive result was defined as a positive result by culture or positive results by two molecular tests (SDA and LCR).

to evaluate the utility of the amplification control for vaginal swab specimens in a clinical research setting.

(This study was presented in part at the 101st General Meeting of the American Society for Microbiology, Orlando, Fla., 20 to 24 May 2001.)

MATERIALS AND METHODS

The evaluation phase of the study included 455 women visiting reproductive health clinics in Pittsburgh, Pa., between January 1997 and May 2000. After the women provided written informed consent, three cervical swab specimens and two vaginal swab specimens were obtained. For SDA, one endocervical swab specimen and one vaginal swab specimen were collected by using the Culturette Direct specimen collection and dry transport kit (Becton Dickinson). One vaginal swab specimen was collected for PCR by using the STD swab specimen collection and transport kit (Roche Diagnostic Systems). The specimen used for *N. gonorrhoeae* culture was collected from the cervix by using BBL Culture Swab Plus (Becton Dickinson). One endocervical swab specimen was collected by using the LCR collection kit (Abbott Laboratories). The collection order for the swabs was rotated in order to reduce the potential for sampling bias to influence the results. Samples were transported to the laboratory within 24 h. Once at the laboratory, the specimens were processed as recommended by the package insert for each product.

In the implementation phase of the study, vaginal swab specimens were obtained consecutively from 2,973 women at five different geographic locations. Written informed consent approved by each institutional review board was obtained from all participants prior to the initiation of study procedures. Clinician- or patient-obtained vaginal swab specimens for SDA were collected by using the Culturette Direct specimen collection and dry transport kit (Becton Dickinson), delivered to the laboratory, and processed within 6 days according to the guidelines of the manufacturer.

For SDA, the swab contents were expressed into tubes containing 2 ml of sample diluent. The tube was then placed into a lysing rack and heated at 114°C for 30 min. The samples were then removed from the heater and cooled for 15 min at room temperature. The samples were transferred to the priming microwells and incubated at room temperature for 20 min. The priming microwell plate and the amplification microwell plate were then placed in the priming heater for 10 min at 72.5 and 54°C, respectively. At the end of the 10 min, 100 μl was transferred from the priming microwells to the amplification microwells. The amplification microwell plate was then sealed with an amplification sealer and placed in the BDProbeTec ET instrument. The run was initiated for 60 min at 52.5°C. The presence or absence of *C. trachomatis* and *N. gonorrhoeae* was determined by relating the BDProbeTec ET method-other-than-acceleration scores for the specimen to predetermined cutoff values (7).

Amplicor PCR (Roche Diagnostic Systems) analysis was performed according to the instructions in the manufacturer's package insert. PCR amplification was conducted with a Thermocycler TC 9600 instrument (Perkin-Elmer Cetus, Norwalk, Conn.). After the amplification, the amplified nucleotide sequences were detected by using target-specific DNA probes. The resulting enzyme reaction was measured with a spectrophotometer (Molecular Devices, Sunnyvale, Calif.). Specimens with an A_{450} of ≥0.500 were considered positive (1).

The endocervical swab specimen for the culture detection of *N. gonorrhoeae* was stored at ambient temperature and inoculated onto modified Thayer-Martin medium and chocolate agar (PML Microbiologicals, Tualatin, Oreg.) within 24 h of collection. The plates were placed in 5 to 7% CO_2 at 36°C for up to 48 h (6), after which they were examined for the presence of *N. gonorrhoeae.* Identification was based on Gram staining, the oxidase test, and the Gonochek II identification system (EY Laboratories, Inc., San Mateo, Calif.).

In the case of a disagreement between the results of SDA and PCR or the results of SDA and culture, samples with discrepant results were evaluated by the LCR assay. The samples to be tested by LCR were stored at −20°C until they were transferred to the Clinical Microbiology Laboratory at Magee-Womens Hospital. The LCR assay was performed according to the instructions in the manufacturer's package insert (1).

For *C. trachomatis*, a sample was considered to have a true-positive result if it was positive by two molecular tests (PCR and SDA, PCR and LCR, or LCR and SDA). For *N. gonorrhoeae*, a sample was considered to have a true-positive result if it was positive by culture or positive by two molecular tests (SDA and LCR).

RESULTS

Of the specimens from 455 women tested during the evaluation phase of the study, 37 (8.1%) were positive for *C. trachomatis* and 39 (8.6%) were positive for *N. gonorrhoeae* (Table 1). The sensitivity and specificity of SDA for the detection of *C. trachomatis* were similar to those of PCR. Furthermore, the sensitivity and specificity of SDA with vaginal swab specimens were equivalent to those of SDA and PCR with cervical swab specimens. For the detection of *N. gonorrhoeae*, SDA was more sensitive than culture. Additionally, tests with vaginal and cervical swab specimens exhibited similar sensitivities and specificities. Of the 455 vaginal swab specimens from women tested, 29 (6.4%) specimens yielded indeterminate results on the basis of the results for the amplification control. The results for all 29 specimens with indeterminate results were resolved by repeat testing, and all specimens were subsequently found to be negative for both pathogens by all methods. This may have been because the specimens were stored at −80°C before they were retested, and therefore, the inhibitory effect was eliminated.

In the implementation phase of the study, the use of vaginal swab specimens was instituted and expanded to all clinical research sites. Of the subsequent 685 vaginal swab specimens

evaluated, the results for 134 (19.6%) were found to be indeterminate. When these specimens were retested undiluted, as recommended in the manufacturer's package insert, the results for only 43 (32%) were resolved, leaving 91 specimens with indeterminate results. Following dilution of the specimen 1:10 with the sample diluent provided by the manufacturer, all of the samples with indeterminate results were negative for both pathogens. Of the next 413 specimens, 165 (40%) had indeterminate results, with the results for all specimens being resolved after dilution 1:10. However, it was recognized that routine 1:10 dilution of all samples could decrease the sensitivity of the assay. To evaluate this possibility, 228 specimens were concurrently evaluated by using a 1:10 dilution of the specimen and an undiluted specimen. Of these, the results for 76 (33.3%) were indeterminate for both *C. trachomatis* and *N. gonorrhoeae* when the specimens were tested undiluted, but the results were negative for both pathogens when the specimens were tested diluted 1:10. However, five samples that were initially positive for *C. trachomatis* and two that were initially positive for *N. gonorrhoeae* became negative when they were diluted 1:10. These studies suggest that routine 1:10 dilution of vaginal swab specimens effectively eliminated indeterminate results but also resulted in an unacceptable loss of assay sensitivity.

Indeterminate assay results with vaginal swab specimens continued to present a challenge with respect to having to recall patients for retesting. Therefore, another series of vaginal swab samples was concurrently evaluated by using a 1:1 dilution of the specimen and an undiluted specimen. Of the 236 specimens evaluated in this manner, 56 (23.7%) were found to have indeterminate results for one or both analytes. Overall, when the results for the undiluted specimens were compared to those for the specimens diluted 1:1, 49 of the 56 specimens (88%) with indeterminate results were negative. The remaining seven samples, which had indeterminate results for *C. trachomatis* by SDA, were tested by PCR, and six were confirmed to be negative for *C. trachomatis* and one sample was also found to inhibit the PCR assay. Among the 236 specimens evaluated in this series, routine 1:1 dilution yielded 4 specimens newly positive for *N. gonorrhoeae*, but the results for 2 specimens initially positive for *C. trachomatis* became indeterminate with repeat testing of the sample diluted 1:1, and 1 specimen initially positive for *N. gonorrhoeae* became negative. This series of evaluations revealed that retesting of samples indeterminate by SDA by repeating SDA or PCR usually yielded negative results. To confirm this, an additional 1,411 vaginal swab specimens were evaluated by SDA with the amplification control. All specimens whose results were indeterminate by SDA and for which the results were not resolved by repeat testing were evaluated by PCR. Of 357 specimens with indeterminate results by SDA, the results for 316 (89%) were resolved after repeat testing by SDA. The remaining 41 specimens were retested by PCR; and 36 specimens were negative for *C. trachomatis*, 3 specimens were inhibitory, and 2 specimens yielded equivocal results. Of the 41 vaginal swab samples tested by PCR, only 7% inhibited the PCR, even though all specimens inhibited SDA, suggesting that the two assays are inhibited by different factors.

In summary, a total of 1,647 vaginal swab specimens were tested for *C. trachomatis* and *N. gonorrhoeae* by SDA. Of the undiluted vaginal swab samples, 413 (25%) yielded indeterminate test results and required further testing. Following 1:1 dilution of the specimen and repeat testing, the prevalences of *C. trachomatis* and *N. gonorrhoeae* in the group of 1,647 specimens were 6.0 and 3.1%, respectively (Table 2). However, even after dilution and repeat testing, only 1.5% of the specimens that initially had indeterminate results and whose results were resolved were found to be positive. If the original samples had been evaluated without the amplification control and all of the indeterminate results had been interpreted as negative, the prevalence rate for *C. trachomatis* would have been 5.8% (95 of 1,647) and that of *N. gonorrhoeae* would have been 3.0% (49 of 1,647). Thus, the repeat testing and resolution of the results by PCR for samples with indeterminate results had a limited overall impact on the prevalence of positivity in this population.

TABLE 2. Prevalence of *C. trachomatis* and *N. gonorrhoeae* determined with vaginal swab samples

Organism	No. (%) of specimens from women with:		
	Valid test results (n = 1,234)	Indeterminate test results who were retested[a] (n = 413)	Valid results and indeterminate results on retesting (n = 1,647)
C. trachomatis	95 (7.7)	4 (1.0)	99 (6.0)
N. gonorrhoeae	49 (4.0)	2 (0.5)	51 (3.1)

[a] All vaginal swab specimens yielding indeterminate results were diluted 1:1 and retested. For specimens that still had indeterminate results by SDA following 1:1 dilution, PCR testing of the undiluted specimen was performed.

DISCUSSION

Some investigators have described the vaginal swab to be a superior specimen type for the detection of *C. trachomatis* and *N. gonorrhoeae* because specimens can be collected by means less invasive than those required for the collection of cervical swab specimens and patients can self-collect clinical specimens (4, 12, 13). SDA of vaginal swab specimens allows the simultaneous testing for *C. trachomatis* and *N. gonorrhoeae* and has a sensitivity and a specificity equivalent to those of PCR for the detection of *C. trachomatis* and superior to those of culture for the detection of *N. gonorrhoeae*. The sensitivity of culture in this study was 77%, which is similar to that reported in a study evaluating LCR (5). However, it is possible that the transport time for swabs in Amies medium with charcoal, which could be up to 24 h, may have led to a loss of viability of this organism in some cases.

The amplified DNA assays with the BDProbeTec ET instrument were designed so that endocervical swab, urethral swab, or urine specimens could be evaluated for the detection of *C. trachomatis* and *N. gonorrhoeae*. However, other studies of amplified tests for the detection of these organisms have shown that vaginal swab specimens are an acceptable specimen type. For example, tests with vaginal swab specimens were found to be 100% sensitive and 99.6% specific for the detection of *N. gonorrhoeae* by LCR (4), while tests with vaginal swab specimens were reported to be 92% sensitive and 100% specific for the detection of *C. trachomatis* by PCR (17). The manufactur-

er's instructions for the collection of cervical swab specimens include the removal of excess mucus from the cervix with a large-tipped cleaning swab before insertion of the collection swab into the cervical os. In contrast, the vagina is a moist epithelium that does not secrete mucus. Nevertheless, cervical mucus is present in the vaginal fluid and may be present in the vaginal swab specimen, leading to the potential for sample inhibition by mucus or other vaginal fluid components.

Use of the amplification control during testing is an option. The amplification control is designed to identify samples that may contain inhibitors that could prevent the detection of *C. trachomatis* or *N. gonorrhoeae.* However, when test results are interpreted, a positive result may be interpreted for any amplification control value. An indeterminate result is interpreted only for samples with low scores for *C. trachomatis* or *N. gonorrhoeae* score, i.e., <2,000, which is also the lower limit for positive results. The present study suggests that most vaginal swab specimens with indeterminate results by SDA have true-negative results.

During the evaluation phase of the study, the rate of indeterminate results was 0.7% in tests with cervical swab specimens and 6.4% in tests with vaginal swab specimens. This phase of the study was conducted at a single site, and only three clinicians collected the specimens. However, in the research implementation phase of the study, about 25% of the vaginal swab specimens gave indeterminate results. It is unknown why the rate of indeterminate results increased. However, during the implementation phase of the study, five different clinical sites were involved, and a large number of different people collected samples. A first strategy to resolve indeterminate results was to repeat the test with undiluted specimens. However, repeat testing in this fashion resolved the results for only a third of the samples. Indeterminate results by the repeat test led to clinician notification that the patient should be recalled for collection and testing of another specimen. The need to recall patients for repeat testing was costly and caused the patients concern.

Our goal was to determine whether samples could be diluted routinely to reduce the number of samples with indeterminate results without the expense of retesting or a loss of test sensitivity. We found that routine dilution of the specimens resolved the indeterminate results, but at the cost of decreased sensitivity. Repeat testing was also very costly. The cost for the testing of the 2,973 samples evaluated during the second phase of this study and repeat testing to resolve the results for samples with indeterminate results was $13,000 for supplies alone. Tests for the detection of six additional positive specimens cost $2,166 in additional supplies per infection detected. By excluding use of the amplification control, there is a minimal difference in supply costs ($0.11/sample) and there is no basis for repeat testing. Data included in the BDProbeTec ET package insert note that use of the amplification control increased the sensitivity of the *C. trachomatis* test from 92.0 to 92.8% and decreased the specificity slightly, from 96.6 to 96.1%. When the amplification control was used for the testing of *N. gonorrhoeae*, the sensitivity increased from 96.4 to 97.6% and the specificity remained 99%. Thus, our findings with vaginal swab specimens are similar to those cited by the manufacturer in the package insert, in that the use of the amplification control had a minimal impact on test performance. The Food and Drug Administration does not require the use of the amplification control for the evaluation of cervical and urine specimens, and our data collected in a clinical research setting suggest that this control has limited value when vaginal swab specimens are tested.

From this study, we have concluded that vaginal swab specimens are an acceptable alternative to cervical swab specimens for the detection of *N. gonorrhoeae* and *C. trachomatis* by SDA with the BDProbeTec ET system. Furthermore, we have determined that use of the amplification control with this specimen type increases costs and can result in delay in test reporting due to the high frequency of indeterminate results.

ACKNOWLEDGMENTS

We thank Becton-Dickinson for supplying some of the test reagents used for this study.

This study was supported in part by a grant (grant DAMD 17-96-1-6298) from the U.S. Department of Defense.

REFERENCES

1. **Black, C. M.** 1997. Current methods of laboratory diagnosis of *Chlamydia trachomatis* infections. Clin. Microbiol. Rev. **10:**160–184.
2. **Crotchfelt, K. A., L. E. Welsh, D. DeBonville, M. Rosenstraus, and T. C. Quinn.** 1997. Detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in genitourinary specimens from men and women by a coamplification PCR assay. J. Clin. Microbiol. **35:**1536–1540.
3. **Goessens, W. H. F., J. W. Mouton, W. I. van der Meijden, S. Deelen, T. H. van Rijsoort-Vos, N. Lemmens-den Toom, H. A. Verbrugh, and R. P. Verkooyen.** 1997. Comparison of three commercially available amplification assays, AMP CT, LCx, and COBAS Amplicor, for detection of *Chlamydia trachomatis* in first-void urine. J. Clin. Microbiol. **35:**2628–2633.
4. **Hook, E. W., III, S. F. Ching, J. Stephens, K. F. Hardy, K. R. Smith, and H. H. Lee.** 1997. Diagnosis of *Neisseria gonorrhoeae* infections in women by using the ligase chain reaction on patient-obtained vaginal swabs. J. Clin. Microbiol. **35:**2129–2132.
5. **Kehl, S. C., K. Georgakas, G. R. Swain, G. Sedmak, S. Gradus, A. Singh, and S. Foldy.** 1998. Evaluation of the Abbott LCx assay for detection of *Neisseria gonorrhoeae* in endocervical swab specimens from females. J. Clin. Microbiol. **36:**3549–3551.
6. **Knapp, J. S., and K. K. Holmes.** 1975. Disseminated gonococcal infections caused by *Neisseria gonorrhoeae* with unique nutritional requirements. J. Infect. Dis. **132:**204–208.
7. **Little, M. C., J. Andrews, R. Moore, S. Bustos, L. Jones, C. Embres, G. Durmowicz, J. Harris, D. Berger, K. Yanson, C. Rostkowki, D. Yursis, J. Price, T. Fort, A. Walters, M. Collis, O. Llorin, J. Wood, F. Failing, C. O'Keefe, B. Scrivens, B. Pope, T. Hansen, K. Marino, K. Williams, and M. Boenisch.** 1999. Strand displacement amplification and homogeneous real-time detection incorporated in a second-generation DNA probe system, BDProbeTecET. Clin. Chem. **45:**777–784.
8. **Ostergaard, L., J. K. Moller, B. Andersen, and F. Olesen.** 1996. Diagnosis of urogenital *Chlamydia trachomatis* infection in women based on mailed samples obtained at home: multipractice comparative study. BMJ **313:**1186–1189.
9. **Quinn, T. C.** 1994. Recent advances in diagnosis of sexually transmitted diseases. Sex. Transm. Dis. **21:**S19–S27.
10. **Quinn, T. C., L. Welsh, A. Lentz, K. Crotchfelt, J. Zenilman, J. Newhall, and C. Gaydos.** 1996. Diagnosis by Amplicor PCR of *Chlamydia trachomatis* infection in urine samples from women and men attending sexually transmitted disease clinics. J. Clin. Microbiol. **34:**1401–1406.
11. **Schachter, J., W. E. Stamm, T. C. Quinn, W. W. Andrews, J. D. Burczak, and H. H. Lee.** 1994. Ligase chain reaction to detect *Chlamydia trachomatis* infection of the cervix. J. Clin. Microbiol. **32:**2540–2543.
12. **Stary, A., B. Najim, and H. H. Lee.** 1997. Vulval swabs as alternative specimens for ligase chain reaction detection of genital chlamydial infections in women. J. Clin. Microbiol. **35:**836–838.
13. **Stephenson, J., C. Carder, A. Copas, A. Robinson, and A. H. Ridgway.** 2000. Home screening for chlamydial genital infection: is it acceptable to young men and women? Sex. Transm. Infect. **76:**25–27.
14. **Van der Pol, B., D. V. Ferrero, L. Burk-Barrington, E. Hook, C. Lenderman, T. Quinn, C. A. Gaydos, J. Lovchik, J. Schacter, J. Moncada, G. Hall, M. J. Tuohy, and R. B. Jones.** 2001. Multicenter evaluation of the BDProbeTec ET system for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in urine specimens, female endocervical swabs, and male urethral swabs. J. Clin. Microbiol. **39:**1008–1016.

15. **van Doornum, G. J. J., L. M. Schouls, A. Pijl, I. Cairo, M. Buimer, and S. Bruisten.** 2001. Comparison between the LCx probe system and the COBAS Amplicor system for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in patients attending a clinic for treatment of sexually transmitted diseases in Amsterdam, The Netherlands. J. Clin. Microbiol. **39:**829–835.
16. **Walker, G. T., M. S. Fraiser, J. L. Schram, M. C. Little, J. G. Nadeau, and D. P. Malinowski.** 1992. Strand displacement amplification—an isothermal in vitro DNA amplification technique. Nucleic Acids Res. **20:**1691–1696.
17. **Wiesenfeld, H. C., R. P. Heine, A. Rideout, I. Macio, F. DiBiasi, and R. L. Sweet.** 1996. The vaginal introitus: a novel site for *Chlamydia trachomatis* testing in women. Am. J. Obstet. Gynecol. **174:**1542–1546.