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Can mailed swab samples be dry-shipped for the detection of *Chlamydia trachomatis, Neisseria gonorrhoeae*, and *Trichomonas vaginalis* by nucleic acid amplification tests?

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Abstract

Background—Dry-shipped and mailed vaginal swabs collected at home have been used in research studies for the detection of *C. trachomatis* (CT), *N. gonorrhoeae* (GC), and *Trichomonas vaginalis* (TV) by nucleic acid amplification tests (NAATs) in screening programs. A verification study was performed to compare the limit of detection of CT, GC, and TV on swabs that were dry-shipped to paired swabs that were wet-shipped in transport media through the U.S. mail.

Methods—The Centers for Disease Control and Prevention prepared inocula in sterile water to mock simulated urogenital swabs with high to low concentrations of CT and GC. Replicate swabs were inoculated with 100μl of dilutions, were dry transported or placed into commercial transport media ("wet") for mailing for NAAT testing. The University of Alabama prepared replicate concentrations of TV, which were similarly shipped and tested by NAAT.

Results—All paired dry and wet swabs were detectable for CT. For GC, all paired dry and wet swabs were detectable for GC at concentrations 10^3. At 10^2 and 10 CFU/ml, the 10 replicate GC results were variably positive. For TV, wet and dry shipped concentrations $> 10^2$ TV/ml tested positive, while results at 10 TV/ml were negative for dry swabs. Holding replicate dry swabs at 55°C 5 days before testing did not affect results.

Conclusion—NAATs were able to detect CT, GC, and TV on dry transported swabs. Using NAATs for testing home-collected, urogenital swabs mailed in a dry state to a laboratory may be useful for outreach screening programs.

Keywords

Dry-shipped simulated swabs; chlamydia; gonorrhea; trichomonas; NAAT testing

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Introduction

Chlamydia trachomatis (CT) is the most commonly reported communicable disease in the U.S., occurring most often among adolescent and young adult females. The Centers for Disease Control and Prevention (CDC) estimates there are approximately 3 million new cases each year (Centers for Disease Control and Prevention, 2010a). Acute chlamydia infections often have no symptoms, leaving many cases untreated. Serious sequelae such as pelvic inflammatory infections (PID) can be associated with untreated CT infections. The U.S. Preventive Services Task Force and major medical professional organizations recommend an annual *screening test* for chlamydia for all sexually active adolescents and young women 25 years of age and under, for all pregnant women, and for women at high risk (U.S.Preventive Services Task Force, 2007). Yet chlamydia screening remains an underutilized clinical preventive service with less that 50 percent of eligible women in commercial or Medicaid health plans being screened annually (National committee for Quality Assurance, 2010).

Likewise, *Neisseria gonorrhoeae* (GC) infections are highly prevalent with over 700,000 new infections every year in the U.S. and are also associated with the serious sequelae as CT (Centers for Disease Control and Prevention, 2010a). *Trichomonas vaginalis* (TV) infections are highly prevalent with estimates of 7–8 million infections annually in the United States and 180 million globally (WHO, 2010) representing the most common curable STI in sexually active women (Van Der Pol et al., 2005; Weinstock et al., 2004). Trichomonas infections have been associated with poor reproductive outcomes such as low birth weight and premature birth (Cotch et al., 1997; Schwebke and Burgess, 2004). Screening for all of these infections in women of reproductive age can impact these epidemics but many barriers exist, which could be overcome by offering home collection of urogenital samples to women.

Despite national screening recommendations and concerted efforts at control, rates of CT and GC among young women remain high, particularly amongst young minority women. Expanded outreach screening programs, beyond traditional clinics, are needed to reach young sexually active persons at risk. The advent of non-invasive specimens for CT and GC detection using NAAT technology has enabled the expansion of screening to non-clinical settings such as schools, mobile vans, and other settings outside the clinic. Because of the increasing prevalences of CT and GC, public health programs are needed that can implement novel screening programs to improve access to testing. Although there are no national surveillance data available for TV, because these infections are not reportable to CDC by law, research studies have demonstrated high prevalences in both young and older populations, as well as in minority groups (Van Der Pol et al., 2005; Weinstock et al., 2004).

Home collection of urogenital samples has been promoted by public health officials (Hobbs et al., 2008). Submission of such self-obtained vaginal samples (SOVS) collected at home could compliment screening programs, as well as remove barriers that women and men face in getting tested for STIs (Gaydos C.A. et al., 2009; Gaydos and Rompalo A.M., 2002). Since neither home-collected nor dry-shipped urogenital swab samples are cleared by the Federal Drug Administration (FDA) for use with commercial nucleic acid amplification tests (NAATs), we performed a verification study to compare the limit of detection of CT, GC and TV titered concentrations of organisms on swabs that were dry-shipped versus matching swabs that were transport media (wet)-shipped through the U.S. mail to a laboratory for testing.

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Methods

Chlamydia and Gonorrhea Organisms

C. trachomatis genotype E was selected for this study based on genetic analysis of the outer membrane protein gene at the CDC and is a strain commonly found in genito-urinary tract infections among women (Millman et al., 2004). A single strain was tested since this was a pilot study and this strain is a very common serotype. The CT strain was grown in cultured buffalo green monkey kidney (BGMK) cells and harvested by differential centrifugation to remove cellular debris. The strains was serially diluted in sucrose-phosphate-glutamic acid (SPG) buffer and titrated for determination of the infectious end-point by calculation of inclusion-forming units (IFU). Inocula to spike simulated urogenital swabs were prepared in sterile water and represented dilutions ranging from 10^7 to 1 IFU per ml, which were estimated by CDC to be representative of most clinical infections. (Michel CE, et al. 2007)

A clinical isolate of *N. gonorrhoeae* was selected on the basis of biochemical reference testing at the CDC. A single clinical strain was selected as being representative of current circulating strains since this organism is always genetically changing. The *N. gonorrhoeae* strain was grown on Modified Thayer-Martin selective medium incubated at 35°C for 24 hours under an atmosphere containing 5% CO_2. The strain was serially diluted in Mueller-Hinton broth and titrated for determination of the infectious end-point by calculation of colony forming units (CFU). Inocula were prepared in sterile water and represented dilutions ranging from 10^7 to 10 CFU per ml.

Swabs

Becton Dickinson, BBL culture EZ, #220144 swabs were used. Presently, self sampling swabs collected at clinics are placed into manufacturers' liquid ("wet") transport media for shipment to the laboratory. We refer to these swabs for standard techniques as "wet". There many research studies that have successfully used shipment of urogenital swabs in the dry state without any transport media. (Gaydos CA et al. 2002, 2006, 2009, Masek BJ et al 2009). We refer to these as "dry" swabs. For CT, there were replicate (2) "dry" swabs and matching "wet" swabs of each of concentration (10^7, 10^5, and 10^3 IFU/ml, and 10 duplicates of 10 and 1 IFU/ml). For GC, there were replicate (2) "dry" and matching "wet" swabs each concentrations (10^7, 10^5, and 10^3 IFU/ml, and 10 duplicates of 10 IFU/ml). Replicate swabs were inoculated with 100 μl of appropriate CT and GC concentrations. Thus, 100 ul of the 10^7 /ml concentration yielded a swab representing 10^6 organisms/swab for that test. One replicate swab was placed in the holding tube for "dry" transport, one replicate swab was placed into the holding tube for "heated transport", and the matching swab made from the same concentration was placed into specimen transport media (STM) for wet transport, Aptima Combo 2 (Gen-Probe Inc., San Diego, CA). The replicate dry-shipped swabs were held at 55°C for 5 days before testing (see below). Also included were 8 swabs with only STM as negative controls.

Additionally, for GC, additional experiments with sets of the lower concentrations (10^2 and 10 CFU/ml) were repeated and transported two additional times.

Trichomonas organisms

Likewise, the University of Alabama at Birmingham (UAB) laboratory prepared concentrations of a clinical strain of TV, representing currently circulating strains, which was grown in Diamonds Media (Remel). TV organisms were counted in a hemocytometer counting chamber and dilutions were prepared to achieve various concentrations by serially diluting TV 10-fold in Diamonds Media and titrating for determination of the TV organisms/ml. Inocula were used to mock two simulated vaginal swabs from 10^7 to 10^2 organisms/ml.

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There were 4 replicate swabs for concentrations of 10^1 and 10 replicates of 1 TV/ml. Amount placed on each swab was 100μl of each concentration. Negative control swabs containing STM transport media (Gen-Probe) were included for testing. The replicate dry-shipped swabs were held at 55°C for 5 days before testing, as for the CT and GC experiments.

Shipping Conditions

Matching swabs containing the various concentrations of organisms (two “dry” and one “wet” swab of each dilution) were placed in sealed biohazard bags and then into individual mailing envelopes at the CDC in Atlanta (CT and GC) or UAB (TV) and sent via United States Postal Service, first class, to The International STD Research Laboratory, Johns Hopkins University, Baltimore, MD.

Testing

Upon receipt, one of the “dry” swabs were placed into Aptima Combo 2 transport media for testing. These simulated urogenital swabs were (“wet” and one “dry” transported) were tested for CT and GC at the same time according to the routine Aptima Combo2 (Gen-Probe, Inc. San Diego, CA) protocol. Similarly, the same algorithm was followed for the TV swabs, which were tested by the ASR (Analyte Specific Reagents) Aptima TV assay (Gen-Probe).

High temperature environment

Upon receipt, for all three organisms, the replicate set of identical dry-shipped swabs with the various organism concentrations were heated at 55°C in an incubator for 5 days before being placed into transport media and tested, in order to simulate environmental transport conditions during higher ambient shipping temperatures (Papp et al., 2007).

Results

C. trachomatis

All concentrations of paired dry and wet swabs and heated dry swabs were detectable as positive for CT, except for one equivocal result for a 1 IFU/ml dry heated swab (Table 1).

N. gonorrhoeae

All paired dry and wet swabs were detectable for GC at all concentrations at and above 10 CFU/ml. For dry heated swabs, one 10^3/ml was negative and at 10 CFU/ml results varied (5 positives, 3 equivocal, and 2 negatives) (Table 2).

Two different repeat experiments, which were conducted later for GC for dry heated swabs at 10^2 and 10 CFU/ml concentrations [concentration per swab corresponded to 10 and 1 CFU/swab each] demonstrated some variability. For the GC concentration for dry heated swabs at 10^2 CFU/ml [10 CFU/swab] for the first repeat experiment (Set A), there were 8 negative and 2 equivocal results. For the second repeat experiment at 10^2 CFU/ml [10 CFU/swab] (Set B), there were 3 positive results, 2 equivocal results, and 5 negative results.

For the GC concentration for dry heated swabs at 10^1 CFU/ml [1 CFU/swab] for the first repeat experiment (Set A), there were 5 positive, 3 equivocal results and 2 negative result. For the second repeat experiment at 10^1 CFU/ml [1 CFU/swab] (Set B) there were 10/10 negative results.

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T. vaginalis

All concentrations from 10^7 to 10^3 TV/ml were positive in the wet, dry, and dry/heated swabs (Table 3). For 10^2 TV/ml, 2/2 were positive for wet transported swabs and 1 of 2 each were positive for both dry and dry/heated transported swabs. For the 4 replicates of TV at 10/ml, 4 were positive for the wet transported swabs and none were positive for dry or dry/heated transported swabs. This concentration corresponded to 1 TV per swab. For the 10 replicates at 1 TV/ml (corresponding to 0.1 TV per swab), 2/10 were positive in wet transported swabs and none were positive in dry or dry/heated swabs.

Discussion

The results of this series of experiments demonstrated that shipping simulated swabs with differing organism concentrations in a dry state provided identical results for chlamydia and similar results for gonorrhea and trichomonas. It was only at the very lowest concentrations which corresponded to 10 and 1 CFU/dry heated swabs for gonorrhea and 1 and 0.1 trichomonas/swab that variability was observed. In all likelihood, these levels were close to the lowest level of the limit of detection for the assays tested, since only 2/10 wet transport swabs at the 1 organism/ml [0.1 organism/swab] tested positive for trichomonas.

Vaginal swabs have been shown to perform as well as or better than endocervical specimens and better than urine specimens when screening for chlamydia and gonorrhea (Schachter et al., 2003; Shafer et al., 2003). Self-collected vaginal swabs can save significant clinician time, if the patient does not require a pelvic exam because of symptoms.

In July 2006, the NIH conducted a workshop to review published data and practices supporting the use of self-obtained vaginal swabs (SOVS) as specimens for the diagnosis of sexually transmitted infections (Hobbs et al., 2008). The expert panel concluded that such specimens were well accepted performed as well as or better than other specimen types for *C. trachomatis* and *N. gonorrhoeae* detection. In addition, citing successful studies of home collected, mailed SOVS (Cook et al., 2007; Gaydos et al., 2006), the panel stated that the validation of these specimens for home use was “urgently needed”. Home collection of urogenital samples sent by postal mail has been successfully used in many other prior research studies. (Gaydos C.A. et al., 2009; Grasek et al., 2010; Novak and Karlsson, 2006; Ostergaard et al., 2000; Ostergaard et al., 1998; van den Broek et al., 2010).

Dry shipped swabs for the detection of chlamydia and gonorrhea have been used previously in a STD clinic in a military population. There was no statistical difference in the sensitivity between wet or dry shipped swabs (Gaydos et al., 2002). Additionally, the strand displacement amplification assay (ProbeTec, Becton Dickinson, Sparks, MD) has achieved FDA clearance for dry-transported cervical swabs (Van Der Pol et al., 2001). Because of the earlier FDA clearance of dry-transported swabs, we have used dry-shipped vaginal swabs, collected at home after Internet recruitment, for home-collection kits in a research program (Gaydos C.A. et al., 2009; Gaydos C.A. et al., 2011; Masek et al., 2009). Pilot studies before the initiation of this program were performed in our laboratory to demonstrate the stability of chlamydia on dry swabs at room temperature (Hardick et al., 2005).

This method of shipping samples collected at home in a dry state offers an easy way to accomplish screening, while affording convenience, confidentiality, and privacy. For women for whom re-screening is desired, women clearly preferred home collection (75.5%) (Grasek et al., 2010). Since CDC recommends rescreening at 3 months after treatment for chlamydia or gonorrhea infection, the home collection with ry transport method has much appeal (Centers for Disease Control and Prevention, 2010b).

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Despite national screening recommendations and concerted efforts at control, rates of CT among young women remain high, particularly amongst young minority women. Expanded outreach screening programs, beyond traditional clinics, are needed to reach young sexually active persons at risk. The advent of non-invasive specimens for CT and GC detection using NAAT technology has enabled the expansion of screening to non-clinical settings. Although there are no national surveillance data available for TV, because these infections are not reportable, research studies have demonstrated high prevalences in both young and older populations. (Gaydos C.A. et al., 2011; Weinstock et al., 2004). Because of the increasing prevalences of CT, GC, and TV, public health programs such as home collection sampling are needed that can complement novel screening programs to improve access to testing.

Since chlamydia screening has been identified as one of the top seven priorities in preventive health, based on health impact, cost effectiveness, and low current uptake, it seems reasonable to explore more home collection methods in order to facilitate asymptomatic screening methods for chlamydia, as well as for gonorrhea and trichomonas (Maciosek et al., 2006). Home collection of vaginal swabs with dry transport may well facilitate screening efforts for several sexually transmitted infections (STI) among women and help expand services to high-risk populations who have less access or inclination to utilize healthcare clinics. Also needed are more cost-effectiveness or comparative effectiveness research studies to determine the effectiveness of home-based STI screening compared to clinic screening (Huang et al., 2011; Smith et al., 2007). Consideration must be given to both the direct and indirect costs of screening, treatment, and potential STI complications, as well as partner notification programs.

This study was a pilot "proof of concept" phase one study and has limitations. We acknowledge that low numbers of strains and low numbers of replicates for the most part were tested. This precluded a statistical analysis of the comparability between wet and dry shipped swabs. A larger carefully designed phase 2 validation study is being performed. Other limitations of our study are that actual clinical samples were not used, but rather simulated swabs were employed. Clinical trials will be necessary to determine whether this slight difference in sensitivity has any clinical significance in screening programs, but one study using duplicate clinical samples did not detect significant difference between wet and dry transported samples for PCR for chlamydia and gonorrhea (Gaydos et al., 2002).

In summary, we demonstrated that dry-shipped simulated swabs appeared to perform as well as transport media wet-shipped swabs for all concentrations of chlamydia tested and for gonorrhea and trichomonas organisms at low, moderate, and high concentrations. The loss of sensitivity for gonorrhea (dry heated swabs) and trichomonas (dry and dry heated swabs) at the very low levels of organisms in the range of 10-0.1 organisms per swab may or may not be clinically significant. Dry shipped diagnostic urogenital swabs collected outside a clinic appear to be useful and may assist outreach STI screening programs.

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Reference List

Centers for Disease Control and Prevention. Sexually transmitted disease surveillance 2009. Atlanta, GA: U.S. Department of Health and Human Services; 2010a. 2010. CDC

Centers for Disease Control and Prevention. Sexually transmitted disease treatment guidelines (2010). MMWR Dec 17, 2010; at www.cdc.gov/std/treatment/2010. CDC. 2010b; 59:1–110.

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Cook RL, Ostergaard L, Hillier SL, Murray PJ, Chang CC, Comer DM, et al. Home screening for sexually transmitted diseases in high risk young women: randomized controlled trial. Sex Transm Inf. 2007; 83:285–291.

Cotch MF, Pastorek JG, Nugent RP, Hillier SL, Gibbs RS, Martin DH, Eschenbach DA, Edelman R, Carey JC, Regan JA, Krohn MA, Klebanoff MA, Rao AV, Rhodes GG. *Trichomonas vaginalis* associated with low birth weight and preterm delivery. Sex Tansmit Dis. 1997; 24:353–360.

Gaydos CA, Barnes M, Aumakham B, Quinn N, Agreda P, Whittle P, Hogan T. Can Etechnology through the Internet be used as a new tool to address the *Chlamydia trachomatis* epidemic by home samplng and vaginal swabs? Sex Tansmit Dis. 2009; 36:577–580.

Gaydos CA, Hsieh Y-H, Barnes M, Quinn N, Jett-Goheen M, Whittle P, Hogan T. *Trichomonas vaginalis* infection in women who submit self-collected vaginal samples after Internet recruitment. Sex Transm Dis. 2011; 38:828–832. [PubMed: 21844738]

Gaydos CA, Crotchfield KA, Shah N, Tennant M, Quinn TC, Gaydos JC, MeKee KT Jr, Rompalo AM. Evaluation of dry and wet transported intravaginal swabs in detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in female soldiers by PCR. J Clin Micro. 2002; 40:758–761.

Gaydos CA, Dwyer K, Barnes M, Rizzo-Price PA, Wood BJ, Flemming T, Hogan MT. Internet based screening for *Chlamydia trachomatis* to reach non-clinic populations with mailed selfadministered vaginal swabs. Sex Tansmit Dis. 2006; 33:451–457.

Gaydos CA, Rompalo AM. The use of urine and self-obtained vaginal swabs for the diagnosis of sexually transmitted diseases. Current Infect. Dis. Reports. 2002; 4:148–157.

Grasek AA, Secura GM, Allsworth JE, Madden T, Peipert JF. Home-screening compared with clinic-based screening for sexually transmitted infections. Obstet. Gynecol. 2010; 115:745–752. [PubMed: 20308834]

Hardick, A.; Wood, BJ.; Holden, J.; Agreda, P.; Gaydos, CA. Comparison of Sensitivity for Detection of *Chlamydia trachomatis* Serial Dilutions in Dry Swabs by GEN-PROBE APTIMA COMBO 2®, ROCHE AMPLICOR PCR, Becton Dickinson ProbeTec™ ET Tests. 105th ASM Annual Meet; June 5–9; Atlanta, GA. 2005. p. 46C-068

Hobbs MM, Van Der Pol B, Totten P, Gaydos CA, Wald A, Warren T, Winer RL, Cook RL, Deal CD, Rogers E, Schachter J, Holmes KK, Martin DH. From the NIH: Proceedings of a workshop on the importance of self-obtained vaginal specimens for detection of sexually transmitted infections. Sex Tansmit Dis. 2008; 35:8–13.

Huang W, Gaydos CA, Barnes M, Jett-Goheen M, Blake DR. Cost-effectiveness analysis of *Chlamydia trachomatis* screening via Internet-based self-collected swabs compared to clinicbased sample collection. Sex Transm Dis. 2011; 38:815–820. [PubMed: 21844736]

Maciosek MV, Coffield AB, Edwards NM, Flottemesch JT, Goodman MJ, Solberg LI. Priorities among effective clinical preventive services: results of a systematic review and analysis. Am J Prev Med. 2006; 31:52–61. [PubMed: 16777543]

Masek BJ, Arora N, Quinn N, Aumakham B, Holden J, Hardick A, Agreda P, Barnes M, Gaydos CA. Performance of three nucleic acid amplification tests for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by use of self-cllected vaginal swabs obtained via an Internet-based screening program. J Clin Microbiol. 2009; 47:1663–1667. [PubMed: 19386838]

Michel CE, Sonnex C, Carne CA, Michel CE, Sonnex C, Carne CA, White JA, Magbanua JPVM, Nadala ECB, et al. *Chlamydia trachomatis* load at matched anatomic sites:implications for screening strategies. J Clin Microbiol. 2007; 45:1395–1402. [PubMed: 17376879]

Millman K, Black CM, Johnson RE, Stamm WE, Jones RB, Hook EW 3rd, Martin DH, Bolan G, Tavare S, Dean D. Population-Based Genetic and Evolutionary Analysis of *Chlamydia trachomatis* Urogenital Strain Variation in the United States. J Bacteriol. 2004; 186:2457–2465. [PubMed: 15060049]

National committee for Quality Assurance. The State of Health Care Quality 2010: HEDIS Measures of Care. Washington, DC: 2010. p. 43-44.http://www.ncqa.org/portals/0/state%20of%20health%20care/2010/SOHC%202010%20-%20Full2.pdf

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Novak DP, Karlsson RB. Simplifying chlamydia testing: an innovative *Chlamydia trachomatis* testing approach using the internet and a home sampling strategy: population based study. Sex Transm Infect. 2006; 82:142–147. [PubMed: 16581742]

Ostergaard L, Andersen B, Moller JK, Olesen F. Home sampling versus conventional swab sampling for screening of *Chlamydia trachomatis* in women: A cluster-randomized 1- year follow- up study. Clin Inf Dis. 2000; 31:951–957.

Ostergaard L, Anderson B, Olesen F, et al. Efficacy of home sampling for screening of *Chalmydia trachomatis*: randomized study. BMJ. 1998; 317:26–27. [PubMed: 9651263]

Papp, J.; Taylor, S.; Knaup, R.; McGloster, N.; Steece, R.; Phillips, C.; Farshy, C.; Xu, F.; Stoner, B.; Martin, D. Effect of Specimen Transport Temperatures Encountered during Postal Shipping on Detection of *Chlamydia trachomatis* (CT) using GenProbe Aptima Combo 2. International Society for Sexually Transmitted Disease Research Meet; July 29 - August 1; Seattle, Washington. 2007.

Schachter J, Chernesky MA, Willis DE, Fine PM, Martin DH, Fuller D, Jordan JA, Janda WM, Hook EW III. Vaginal swabs are the specimens of choice when screening for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*: Results from a multicenter evaluation of the APTIMA assays for both infections. Sex Transmit Dis. 2005; 32:725–728.

Schachter J, McCormick WM, Chernesky MA, Martin DH, Van Der Pol B, Rice P, Hook EW III, Stamm WE, Quinn TC, Chow JM. Vaginal swabs are appropriate specimens for diagnosis of genital tract infection with *Chalmydia trachomatis*. J Clin Microbiol. 2003; 41:3784–3789. [PubMed: 12904390]

Schwebke JR, Burgess D. Trichomoniasis. Clin Microbiol Review. 2004; 17:794–803.

Shafer MA, Moncada J, Boyer CB, Betsinger K, Flinn SD, Schachter J. Comparing first-void urine specimens, self-collected vaginal swabs, and endocervical specimens to detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by a nucleic acid amplification test. J Clin Microbiol. 2003; 41:4395–4399. [PubMed: 12958275]

Smith KJ, Cook RL, Ness RB. Cost compariaons between home- and clinic-based testing for sexually trnamitted diseases in hig-risk young women. Infect Dis Obstet Gynecol. 2007 Article ID 62467, doi: 10.1155/2007/62467.

U.S. Preventive Services Task Force. Screening for chlamydial infection: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2007; 147:128–134. [PubMed: 17576996]

van den Broek IVF, Hoebe CJPA, van Bergen JEAM, Brouwers EEHG, Feijter EM, Fennema JSA, Gotz HM, Koekenbier RK, van Ravesteijn SM, Op de Coul ELM. Evaluation design of a systemic selective internet-based *Chalmydia trachomatis* screening implementation in the Netherlands, 2008–2010: implications of first results for the analydis. BMC Infectious Diseases. 2010; 10:89. [PubMed: 20374635]

Van Der Pol B, Ferrero D, Buck-Barrington L, Hook E III, Lenderman C, Quinn TC, Gaydos CA, Moncada J, Hall G, Tuohy MJ, Jones BR. Multicenter evaluation of the BDProbeTec ET system for the detection of *Chalmydia trachomatis and Neisseria gonorrhoeae* in urine specimens, female endocervical swabs, and male urethral swabs. J Clin Microbiol. 2001; 39:1008–1016. [PubMed: 11230419]

Van Der Pol B, Williams JA, Orr DP, Batteiger BE, Fortenberry JD. Prevalence, incidence, natural history, and response to treatment of *Trichomonas vaginalis* infection among adolescent women. J Infect Dis. 2005; 192:2039–2044. [PubMed: 16288365]

Weinstock H, Berman S, Cates W. Sexually transmitted disease among American youth: Incidence and prevalence estimates. Perspect Sex Repro Health. 2004; 36:6–10.

World Health Organization (WHO). Trichomonas. 2010. http://search.who.int/search?ie=utf8&site=default_collection&client=WHO&proxystylesheet=WHO&output=xml_no_dtd&oe=utf8&query=trichomonas

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Table 1

Comparison of *C. trachomatis* (CT) concentrations from simulated swabs that were shipped in a dry or wet state and after heating the swab at 55°C for 5 days.

CT Concentration IFU/ml	CT wet	RLU[a] (×1000)	CT dry	RLU[a] (×1000)	CT dry heated[b]	RLU[a] (×1000)
10^7	**POS**	801	**POS**	1306	**POS**	1373
10^7	**POS**	1328	**POS**	1272	**POS**	1338
10^5	**POS**	1303	**POS**	1244	**POS**	1329
10^5	**POS**	1307	**POS**	1273	**POS**	1325
10^3	**POS**	1248	**POS**	1148	**POS**	1320
10^3	**POS**	1190	**POS**	1168	**POS**	1328
10	**POS**	1161	**POS**	1128	**POS**	941
10	**POS**	1188	**POS**	566	**POS**	1318
10	**POS**	1178	**POS**	1154	**POS**	1049
10	**POS**	1271	**POS**	1229	**POS**	1173
10	**POS**	1081	**POS**	1145	**POS**	1005
10	**POS**	722	**POS**	756	**POS**	986
10	**POS**	1147	**POS**	1117	**POS**	1112
10	**POS**	1129	**POS**	1159	**POS**	1146
10	**POS**	1131	**POS**	1106	**POS**	1133
10	**POS**	1133	**POS**	1159	**POS**	921
1	**POS**	837	**POS**	507	**POS**	1169
1	**POS**	1026	**POS**	1023	**POS**	1093
1	**POS**	1111	**POS**	975	**POS**	1009
1	**POS**	1039	**POS**	938	**POS**	1171
1	**POS**	1007	**POS**	896	**POS**	1091
1	**POS**	1091	**POS**	1056	EQUIV	59
1	**POS**	1154	**POS**	1054	**POS**	1009
1	**POS**	1111	**POS**	981	**POS**	949
1	**POS**	1005	**POS**	935	**POS**	1056
1	**POS**	1058	**POS**	1000	**POS**	1133

[a]RLU = Relative Light Unit measure for the Gen-Probe APTIMA test. Positive *C. trachomatis* specimens have RLU's >100 thousands.

[b]Heated test was conducted after the specimen was maintained at 55°C for 5 days.

Negative controls (16) tested were all negative.

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Table 2

Comparison of *N. gonorrhoeae* (GC) concentrations in Colony forming units (CFU)/ ml from simulated swabs that were shipped in a dry or wet state and after heating the swab at 55°C for 5 days.

GC Concentration CFU/ml	GC wet	RLU[a] (×1000)	GC dry	RLU[a] (×1000)	GC dry heated[b]	RLU[a] (×1000)
10^7	**POS**	1302	**POS**	1205	**POS**	1313
10^7	**POS**	1288	**POS**	1324	**POS**	1328
10^5	**POS**	1325	**POS**	1282	**POS**	1244
10^5	**POS**	1313	**POS**	1306	**POS**	1176
10^3	**POS**	1275	**POS**	1912	NEG	56
10^3	**POS**	1285	**POS**	553	**POS**	173
10	**POS**	1228	**POS**	896	**POS**	214
10	**POS**	1202	**POS**	578	**POS**	276
10	**POS**	1167	**POS**	1008	**POS**	293
10	**POS**	1233	**POS**	862	NEG	46
10	**POS**	1273	**POS**	824	**POS**	223
10	**POS**	1257	**POS**	864	EQU	116
10	**POS**	1247	**POS**	399	EQU	112
10	**POS**	1234	**POS**	559	EQU	82
10	**POS**	1196	**POS**	707	**POS**	166
10	**POS**	1230	**POS**	854	NEG	54

[a]RLU = Relative Light Unit measure for the Gen-Probe APTIMA test. Positive *N. gonorrhoeae* specimens have RLU's >150 thousands.

[b]Heated test was conducted after the specimen was maintained at 55°C for 5 days.

Repeat experiment data not in table. For 10^2 CFU/ml Dry heated, separate repeat experiments: Set A: 8 samples were negative, 2 were equivocal; Set B: 3 were positive, 2 were equivocal, and 5 were negative.

Repeat experiment data not in table. For 10^1 CFU/ml Dry heated, separate repeat experiments: Set A: 5 samples were positive, 3 were equivocal, and 2 were negative; Set B: 10/10 samples were negative.

Negative controls (16) tested were all negative.

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Table 3

Comparison of *T. vaginalis* (TV) concentrations from simulated swabs that were shipped in a dry or wet state and after heating the swab at 55°C for 5 days.

TV Concentration/ml	TV wet	RLU[a] (×1000)	TV dry	RLU[a] (×1000)	TV dry heated[b]	RLU[a] (×1000)
10^7	**POS**	1580	**POS**	1621	**POS**	4452
10^7	**POS**	1619	**POS**	1597	**POS**	4172
10^6	**POS**	1597	**POS**	1488	**POS**	3847
10^6	**POS**	1606	**POS**	1458	**POS**	2802
10^5	**POS**	1606	**POS**	1252	**POS**	2510
10^5	**POS**	1553	**POS**	1284	**POS**	2710
10^4	**POS**	1320	**POS**	908	**POS**	1436
10^4	**POS**	1370	**POS**	1002	**POS**	1427
10^3	**POS**	1076	**POS**	325	**POS**	349
10^3	**POS**	1099	**POS**	443	**POS**	520
10^2	**POS**	364	**POS**	71	**POS**	104
10^2	**POS**	718	NEG	11	NEG	36
10	**POS**	261	NEG	19	NEG	26
10	**POS**	257	NEG	25	NEG	2
10	**POS**	347	NEG	13	NEG	18
10	**POS**	410	NEG	32	NEG	9
1	**POS**	67	NEG	1	NEG	1
1	NEG	30	NEG	3	NEG	1
1	NEG	56	NEG	6	NEG	1
1	NEG	20	NEG	3	NEG	8
1	NEG	32	NEG	2	NEG	4
1	NEG	31	NEG	1	NEG	1
1	NEG	33	NEG	2	NEG	3
1	NEG	40	NEG	2	NEG	3
1	**POS**	115	NEG	1	NEG	1
1	NEG	23	NEG	2	NEG	1

[a]RLU = Relative Light Unit measure for the Gen-Probe TRIC APTIMA test. Positive *T. vaginalis* specimens have RLUs >60 thousands.

[b]Heated test was conducted after the specimen was maintained at 55°C for 5 days.

Negative controls (10) tested were all negative.