Comparison of Flocked and Aptima Swabs and Two Specimen Transport Media in the Aptima Combo 2 Assay

Jenny Li, Dan Jang, Jodi Gilchrist, Marek Smieja, Ruth Ewert, Cindy MacRitchie, Max Chernesky

St. Joseph’s Healthcare, McMaster University, Hamilton, Ontario, Canada; Evergreen Health Centre, Toronto, Ontario, Canada; Hamilton Community Health Centre, Hamilton, Ontario, Canada

Self-collected vaginal Aptima swabs and flocked swabs in Aptima specimen transport medium and ESwabs in ESwab medium detected all 37 Chlamydia trachomatis-infected patients from 287 women tested by the Aptima Combo assay. Prevalence rates of C. trachomatis, Neisseria gonorrhoeae, and dual infection were 12.8%, 3.1%, and 2.4%, respectively.

The Aptima Combo 2 (AC2) transcription-mediated amplification assay (Hologic Gen-Probe, San Diego, CA) has been shown to be effective for testing first-void urine samples and vaginal swabs (1, 2). A novel nylon flocked swab has been developed by Copan Italia and was shown to enhance the analytical sensitivity of AC2, Amplicor (Roche, Basel, Switzerland), and ProbeTec (Becton Dickinson, Franklin Lakes, NJ) nucleic acid amplification tests (NAATs) for Chlamydia trachomatis and Neisseria gonorrhoeae in mock samples (3). It is thought that enhancement is accomplished by stripping more cells during collection and releasing more analyte into the transport medium for testing (4). As diagnostic laboratories expand their testing menus for microorganism recovery by growth, antigen detection, NAATs, and sequencing, the ability to universally collect, transport, and test with crossover compatibility of assays becomes desirable (5–7).

The study objectives were to compare AC2 testing of combinations of vaginal swabs and transportation media and first-void urine samples.

A total of 287 women signed consent forms for self-collection of a first-void urine sample (first 10 to 20 ml) and the collection of randomized vaginal swabs collected as follows: (i) Aptima vaginal swab (Hologic Gen-Probe; catalog no. 301162) in Aptima specimen transport medium, (ii) a regular flocked swab (Copan Italia, Brescia, Italy; catalog no. 519CS01) transported in Aptima specimen transport medium, and (iii) Copan ESwab collection kit (Copan Italia; catalog no. 480CE) containing a regular flocked ESwab transported in ESwab medium. The Aptima swab has Dacron fibers wrapped around the end of a plastic shaft and is cleared for use in the AC2 assay following transportation in Aptima specimen transport medium. The flocked swab has short nylon fibers glued to the end of a plastic shaft and is cleared for use in the AC2 assay following transportation in Aptima specimen transport medium. The flocked swab has short nylon fibers glued to the end of a plastic shaft and has been used as a collection device for the diagnosis of many infections by using NAAT (8, 9). The ESwab is a flocked swab used with ESwab medium for subsequent recovery of organisms by culture (5, 6).

For self-collection of vaginal swabs, the plastic container was opened to take out a swab and vial. The swab was held at a mark on the shaft and inserted, so the fingertips were just inside the vulva. The swab was rotated in a circular fashion to brush against the vaginal wall. After 5 turns, the swab was placed into the transport tube, the shaft was broken, and the tube was capped and then sent to the laboratory. The Aptima and flocked swabs were kept in the Aptima specimen tubes and tested by AC2 as recommended in the manufacturer’s package insert. The ESwabs were removed without agitation from the ESwab medium and placed into an Aptima tube for testing. The first-void urine sample (1 ml) was aliquoted from the specimen containers into Aptima urine transport tubes. All three swabs and the first-void urine sample were simultaneously tested within 24 h with the AC2 test on the Tigris system (Hologic Gen-Probe).

Calculations of sensitivity, specificity, and predictive values with confidence intervals were made with 2-by-2 tables. Women were considered infected if 2 or more of the samples were positive.

The prevalence was 12.9% (37/287) for C. trachomatis and 3.1% (9/287) for N. gonorrhoeae, and 7 women (2.4%) had dual infections. From study patient forms, 34.8% of the women reported symptoms of discharge, dysuria, or pelvic pain, with no rate differences in infected or uninfected women. Table 1 summarizes the sensitivity, specificity, and predictive values according to the self-collected vaginal swab and the transport system used and the first-void urine sample. All C. trachomatis-positive patients (37/37) were detected by the Aptima swab and flocked swab in Aptima specimen transport medium and the ESwab in ESwab medium. Five cases were positive only for C. trachomatis in a single swab type (3 Aptima swabs in Aptima specimen transport medium and two flocked swabs in Aptima specimen transport medium).

On repeat testing, one flocked swab and three Aptima swabs were again positive, suggesting that they may have been true positives. However, confirmatory testing with an additional assay, using alternative primers, was not performed due to insufficient sample volume. The sensitivity of C. trachomatis detection in first-void urine samples was 100% (34/34), which was higher than reported in previous studies (1, 2) and may have been due to increased accuracy in collecting first-void urine samples in this group of women or not having a cervical swab result to broaden the reference standard. Although the number of N. gonorrhoeae positives were few (n = 9), all of the sampling and transportation strategies identified 100% of the positives and negatives except for the ESwab in ESwab medium, which missed one positive. Shortcomings of the study were the limited number of N. gonorrhoeae-infected patients from 287 women tested by the Aptima Combo assay.
TABLE 1 Sensitivities, specificities and predictive values of swabs transported in ASTM or ESM compared to those of first-void urine samples by AC2 testing for C. trachomatisa

<table>
<thead>
<tr>
<th>Sample and transport medium</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Predictive value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of samples/total no. of samples (%)</td>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td>Aptima swab in ASTM</td>
<td>37/37 (100, 88.8–100)</td>
<td>247/250 (98.8, 96.4–99.8)</td>
<td>37/40 (92.5, 79.4–98.1)</td>
</tr>
<tr>
<td>Flocked swab in ASTM</td>
<td>37/37 (100, 88.8–100)</td>
<td>249/250 (99.6, 97.6–100)</td>
<td>37/38 (97.4, 84.1–100)</td>
</tr>
<tr>
<td>ESwab in ESM</td>
<td>37/37 (100, 88.8–100)</td>
<td>250/250 (100, 98.2–100)</td>
<td>37/37 (100, 88.8–100)</td>
</tr>
<tr>
<td>First-void urine sample</td>
<td>34/34 (100, 98.2–100)</td>
<td>220/220 (100, 98.2–100)</td>
<td>34/34 (100, 88.2–100)</td>
</tr>
</tbody>
</table>

apositives and our lack of attempting the ability to culture N. gonorrhoeae or C. trachomatis. Further studies of culturing N. gonorrhoeae NAAT positives from the transportation vial would facilitate antibiotic resistance studies. Van Horn et al. have shown successful recovery of Gram-positive and Gram-negative bacteria from the ESwab system (5, 6), but Indevuyst et al. (7) reported ESwabs to be toxic for cell cultures used to isolate viruses. More detailed controlled studies are required.

Specimens processed within 24 h of collection may have favored the ESwab medium to yield results equal to Aptima specimen transport medium. Longer periods of holding time need to be studied to determine whether ESwab medium provides enough stability for rRNA detection in AC2. Le Roy et al. used flocked swabs transported in culture medium to study agreement of C. trachomatis positivity between Cobas 4800 and Cobas TaqMan (10), but they did not compare the off-label use of the flocked swab with the Roche collection and transportation kit. Although information from these kinds of studies may facilitate diagnosis, off-label use may provide limitations and require appropriate validation.

A previous laboratory study with mocked samples (3) compared kit swabs to flocked swabs and showed an enhancement of the endpoint of detection (analytical sensitivity) by flocked swabs in AC2, Amplicor, and ProbeTec assays. The phenomenon was not observed on clinical specimens using AC2 in this study, as both swab types and transport media yielded maximum numbers of positives. Similar observations were made comparing vaginal Dacron swabs to flocked swabs put into Aptima specimen transport medium for detection of Trichomonas vaginalis using analyte-specific reagents for the Aptima assay (11). Ease of collection, performance, and cost efficiency should be considered when studies comparing collection and transportation of clinical samples are compared in other NAATs to determine universality.

ACKNOWLEDGMENTS

This study was funded by Copan Italia.

This publication is dedicated to the late Daniele Triva.

REFERENCES


Downloaded from http://jcm.asm.org on September 13, 2017 by guest