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ESwab as an Optional Collection Device for Use with the Affirm VPIII Microbial Test System

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The ESwab collection device was compared to the collection swab provided as part of the Affirm VPIII microbial identification test kit for testing vaginal specimens with the Affirm test system. There was excellent agreement between the two sampling devices for Candida spp., Gardnerella vaginalis, and Trichomonas vaginalis.

The workup of potential infections in patients often includes multiple diagnostic possibilities requiring the use of various platforms and specimen collection devices to arrive at an accurate diagnosis. The use of multiple collection and transport devices has the inherent risk of added cost, increased opportunities for labeling errors and use of the incorrect transport device, increased patient discomfort, and increased risk of inadequate specimen quality. Thus, the ability to use a single collection device for multiple applications is desirable. The BD Affirm VPIII microbial identification test system (BD, Franklin Lakes, NJ) is widely used by many clinical laboratories and as an office-based test for gynecologists to diagnose vaginal infections (1). The Affirm system provides its own collection device specific to that test. However, clinicians often order additional tests for patient care. For example, the ESwab has been validated for use in testing for sexually transmitted diseases (STD), including gonorrhea, chlamydia, and trichomoniasis (2–5). Thus, it is possible that the ESwab could be used as a universal transport medium in women's health care settings. The purpose of the present study was to validate the use of the ESwab collection device (Copan Diagnostics, Murrieta, CA) as an optional collection device for use with the Affirm system.

Women attending the Jefferson County Department of Health STD clinic in Birmingham, AL, were invited to join the study. The patient population of the clinic is mainly a young adult age group and is >90% African-American. All women seen at the clinic are evaluated for vaginitis using one vaginal swab collection for an evaluation of vaginal pH and wet mount microscopy. The University of Alabama at Birmingham institutional review board approved the study. Participants were asked to join if they were ≥19 years of age and were able to provide informed consent. The exclusion criteria were <19 years of age, previous participation in the study, inability to provide informed consent, or inability to provide the specimen required for the study. After the collection of the usual single vaginal swab used for routine care, two additional vaginal swabs were collected: an Affirm swab (part of the Affirm VPIII microbial identification test kit) and an ESwab. The order in which the swabs were collected was randomized. The Affirm swab was processed for long-term transport using the Affirm VPIII ambient temperature transport system (BD, Franklin Lakes, NJ); this system contains a preservative that stabilizes the nucleic acids for up to 72 h at room temperature (RT) (15°C to 30°C), which is required for testing. The ESwab was processed according to the instructions in the package insert. Both specimens were stored at RT before and during testing.

The Affirm testing result at 24 h postcollection was established as the nonreference standard for this matched-pair study design. For each patient, a matched specimen collected by the ESwab system was tested in parallel with the Affirm specimen at 24 h using the Affirm VPIII microbial test for Candida spp., Gardnerella vaginalis, and Trichomonas vaginalis on the BD MicroProbe processor system (BD, Franklin Lakes, NJ), with the appropriate reagents. The Affirm testing of the ESwab specimen was repeated at 48 h for any ESwab specimen initially positive (n = 377) at 24 h to evaluate concordance across time. The Affirm specimen was not repeated at 48 h, as it is consumed in its entirety during testing.

The Affirm swab specimens were tested according to the instructions in the product insert. Briefly, a specimen on the Affirm swab was lysed and neutralized directly, i.e., the swab remained in the tube during the lysis and neutralization steps. The swab was then removed, and the testing proceeded. In contrast, the ESwab tube was vortexed for 15 s to elute the specimen from the swab into the transport medium. An aliquot of 200 µl (20% of the total volume) was removed from the ESwab tube and transferred to an Affirm test processing tube for the lysis and neutralization steps of the protocol.

The mean and standard deviation were calculated according to hours postcollection to testing. The prevalence rates for Trichomonas vaginalis, G. vaginalis, and Candida spp. at 24 h postcollection, based on the Affirm specimen results, are presented in Table 1. An estimate of agreement, Cohen's kappa (κ), comparing the Affirm and ESwab specimen results, was calculated with 95% confidence intervals (CI) (6). P values were calculated using McNemar's chi-square test.

A total of 460 participants was recruited into the study. The Affirm specimens were collected first in 46.7% of the specimens.
TABLE 1 Prevalences and estimates of agreement comparing ESwab to Affirm collection systems at 24 and 48 h

<table>
<thead>
<tr>
<th>Organism</th>
<th>Time (h)</th>
<th>Prevalence based on Affirm collection kit (% [range])</th>
<th>n</th>
<th>No. with Affirm/ESwab results of:</th>
<th>Cohen’s k (κ % [95% CI])</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>+/+</td>
<td>-/+</td>
<td>-/-</td>
</tr>
<tr>
<td>Trichomonas</td>
<td>24</td>
<td>10.9 (8.2–14.1)</td>
<td>460</td>
<td>44 6 2</td>
<td>408</td>
<td>94.0</td>
</tr>
<tr>
<td>Trichomonas</td>
<td>48</td>
<td></td>
<td>377</td>
<td>40 8 1</td>
<td>328</td>
<td>92.6</td>
</tr>
<tr>
<td>Gardnerella</td>
<td>24</td>
<td>77.2 (73.1–80.9)</td>
<td>460</td>
<td>348 7 3</td>
<td>102</td>
<td>96.0</td>
</tr>
<tr>
<td>Gardnerella</td>
<td>48</td>
<td></td>
<td>377</td>
<td>348 3 3</td>
<td>23</td>
<td>92.0</td>
</tr>
<tr>
<td>Candida</td>
<td>24</td>
<td>17.2 (13.8–20.9)</td>
<td>460</td>
<td>77 2 7</td>
<td>374</td>
<td>95.6</td>
</tr>
<tr>
<td>Candida</td>
<td>48</td>
<td></td>
<td>377</td>
<td>78 1 14</td>
<td>284</td>
<td>92.6</td>
</tr>
</tbody>
</table>

* +/+ = Affirm positive/ESwab positive; -/+ = Affirm positive/ESwab negative; -/- = Affirm negative/ESwab positive; -/- = Affirm negative/ESwab negative.
* Cohen’s κ interpretation: 0% to 20%, poor; 20% to 40%, fair; 40% to 60%, moderate; 60% to 80%, good; >80%, very good.
* Eighty-three initially negative specimens were not retested; ESwab 48-h result compared to that of the Affirm collection kit 24-h result.

(conversely, 53.2% of the first specimens collected were the ESaw). The average time to testing postcollection was 24.2 ± 1.2 h. The average time to testing postcollection at the 48-h mark was 47.9 ± 1.1 h. The prevalences, based on Affirm testing, at 24 h for each of the collection types of T. vaginalis, G. vaginalis, and Candida spp. are presented in Table 1. At 24 h postcollection, 83 specimens (18%) were negative by Affirm and ESwab for all three organisms; in contrast, 8 specimens (1.7%) were positive for all three organisms by both Affirm and ESwab at 24 h.

The kappa (in percent) and concordance values are presented in Table 1. There was excellent agreement between the two collection devices at both 24 and 48 h for all three organisms tested. An analysis of the data stratified by the order of swab collection showed no significant difference between the Affirm and ESwab results at 24 and 48 h for Gardnerella. At 48 h, there was a statistically significant greater probability of observing a positive Candida spp. result with ESwab than with the Affirm kit. The reverse was true for T. vaginalis, in that there were more apparent false negatives with the ESwab than with the Affirm collection kit at 48 h.

Because the trend of the 48-h data for T. vaginalis suggested a loss in the detection of T. vaginalis over time, we stratified the analysis based on which swab was collected first. When the Affirm swab was collected first, no observable difference was observed between the 24-h and 48-h testing points (P = 0.180 and 0.103, respectively). If the ESwab was collected first, no significant difference was observed between the 24-h and 48-h testing points (P = 0.617 and 0.617, respectively). At 24 h, the ESwab had a marginally higher positive test rate for detecting T. vaginalis (12.7% versus 8.4%, respectively) when the ESwab specimen was collected first.

The BD Affirm VP III package insert (670160JA-2010/08) provides expected sensitivities and specificities, respectively, of 89.2% to 89.6% and 96.0% to 100% for T. vaginalis, 83.5% to 83.8% and 96.0% to 100% for G. vaginalis, 78.0% to 80.6% and 95.9% to 98.2% for Candida spp., respectively. The sensitivity and specificity values given are from the testing of the Affirm against the gold standards of T. vaginalis culture, G. vaginalis Gram stain, and Candida spp. culture. Although this study cannot make a direct comparison between the ESwab and the Affirm in terms of the original testing design against culture and Gram stain, the study does demonstrate that the use of ESwab is an acceptable option for collection. The kappa correlation demonstrates excellent agreement between the Affirm and ESwab results. The concordance of the results using McNemar’s chi-square test did show an increase in the detection of Candida spp. at 48 h. A significant difference between Affirm and ESwab for the detection of T. vaginalis was found not to be supported upon stratification of which swab type had been collected first; however, the percent positive test values at 24 h suggest that collection by ESwab may be preferable. The ESwab has been demonstrated to release a larger volume of specimen than a standard swab (7).

From a biological standpoint, the significant change from 24 to 48 h for the detection of Candida spp. is reflective of the difference in the composition of the two collection systems. The Affirm transport stabilizer kills all organisms while preserving their nucleic acids. In contrast, the ESwab medium is a minimal medium designed to keep organisms alive but with minimal to no replication. These results indicate that Candida spp. replicate to some extent when the ESwab medium is allowed to remain at room temperature for 48 h prior to testing. This small increase in the concentration of organisms then meets the threshold set for the detection of yeast by the Affirm system. As with any method testing for Candida spp. in the vagina, the clinician must consider the possibility of colonization versus infection and correlate the presence of Candida with the presenting symptoms of the patient.

The results of our study confirm that ESwab is a suitable collection device for use with the Affirm test system. Thus, it would be acceptable for a clinician to collect a single specimen to be sent to the laboratory for the detection of multiple pathogens of the female genitourinary tract, including vaginal infections and other sexually transmitted diseases, such as gonorrhea and chlamydia. Such streamlining of specimen collection enhances specimen quality and results in fewer labeling and transport errors, as well as decreases costs.

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