



Can We Trust a Compact Bacteriological Screening Test to Identify the Common Vaginal Pathogens?

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Abstract

Objectives: The objective of this study was to evaluate the performance of the A.F. Genital System® in the detection of vaginal pathogens in patients with obstetrical and gynecological pathologies.

Materials and Methods: A total of 197 vaginal swab samples were collected from patients presenting with various obstetrical and gynecological pathologies. The A.F. Genital System® and vaginal culture/traditional methods were used for pathogen detection.

Results: The A.F. Genital System® demonstrated a detection rate of 68% for single vaginal infectious agents, outperforming the vaginal culture/traditional methods (52.8%). However, differences in detection rates were observed for specific pathogens, such as *E. coli*, *Gardnerella vaginalis*, *Staphylococcus aureus*, and *Pseudomonas* spp.

Conclusions: Despite lower sensitivity for specific pathogens, the A.F. Genital System® showed a high correlation with reference tests, suggesting its potential utility as a diagnostic tool for identifying common vaginal pathogens in clinical settings.

Keywords: Culture, Vaginitis, Diagnostic tests, Routine

Introduction

In cases of suspected vaginitis, the tests that may be performed to differentiate between pathogens include pH testing, saline wet mount, the so-called whiff test, culture, nucleic acid amplification testing, staining (Giemsa, Papanicolaou, Schiff), and several other second-line tests such as latex agglutination test and gas-liquid chromatography (1). Since a single test is insufficient to detect every pathogen, combination tests that combine multiple pathogens in a single assay have been developed to facilitate these molecular tests to be implemented in routine microbiology (2). A.F. Genital System® (Liofilchem Bacteriology Products, Roseto degli Abruzzi, Teramo, Italy), which is one of these compact bacteriological screening tests, was developed to provide a complete ecological profile in a patients' genital system and diagnose the infections of pathogenic microorganisms within a short time. The test contains 24 wells in which antibiotics and dry biochemical substratum is included. By this test, the organisms in urethral secretions, seminal fluid, or vaginal swabs may be detected, identified, and tested for susceptibility within 24-48 hours (3).

Although it has been in clinical use for a long time, there is insufficient research in the literature evaluating this assay's performance in the detection of vaginal pathogens (2). In the current study, it was aimed to assess the utility

and accuracy of A.F. Genital System® via comparing it with conventional methods and reference tests in the identification of clinical samples analyzed in a hospital-derived cohort of obstetric and gynecological patients who have high risk for vaginal infections.

Materials and Methods

Study Design

This prospective observational diagnostic cohort study was conducted at the outpatient clinics and wards of the obstetrics and gynecology department. Participants for this study were recruited among consecutive women presenting with various obstetrical and gynecological pathologies associated with abnormal vaginal discharge. Patients fulfilling the inclusion criteria but unwilling to participate or not giving informed consent were not included in the study. As calculated by Lev-Sagie et al(4) based on Hajian-Tilaki (5), a minimum sample size of 139 patients was needed for such a study to reach an accuracy level of at least 90% with a confidence interval half-width of 5%. To obtain a reasonable representation of each of the vaginal pathogens, the recruitment continued to a larger sample size. After obtaining the Institutional Ethics Committee approval, the study population consisted of 200 patients (aged 19-73) diagnosed with vaginitis (n=50), pelvic inflammatory disease (n=50), preterm labor

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Key Messages

- ▶ As a compact bacteriological screening test, the A.F. Genital System® is highly reliable to identify the common vaginal pathogens with lower sensitivities for *E. coli*, *S. aureus*, and urogenital mycoplasmas.

(n=50), or preterm premature rupture of membranes (n=50). It was carried out in compliance with relevant laws and guidelines, and with the ethical standards of the Declaration of Helsinki. Since three samples (one from a patient with preterm labor and two from patients with the diagnosis of pelvic inflammatory disease) were excluded due to inadequate quality, 197 subjects in total were analyzed in the current study. Patients who were menstruating; those who had taken antibiotics, antifungals, or vaginal preparations for at least one week before the enrolment; and those who had coitus within the last 24 hours were excluded from the study.

Sample Collection

The samples were collected from a single center (Yuzuncu Yil University Hospital, Department of Obstetrics and Gynecology) between March 2013 and July 2013. Sterile speculums were used only once for each patient, while three cervicovaginal swabs were collected from the ectocervix and posterior fornix of the vagina, concurrently. One of the swabs inoculated into Stuart's transport medium was used for culture and Gram staining, while another was used for wet prep. The third swab was subjected to the A.F. Genital System® and an additional cervicovaginal swab for Mycoplasma IES testing was obtained in a subgroup of randomly selected patients in whom urogenital mycoplasmas were also tested. All specimens were quickly transported to the laboratory.

Microbiological Evaluation

The vaginal smears were prepared on heat-fixed glass slides by rolling the swabs from the Stuart's transport media. They were stained per the standard gram staining procedures (6). The examination was performed under a light microscope's 1000× magnification (oil immersion) objective to identify microbial morphology, epithelial cells, and neutrophils. According to Nugent's criteria (7), each morphotype (small Gram-negative and Gram-variable rods for *Bacteroides*, and *Gardnerella* morphotypes, rods for *Lactobacillus* morphotypes, and curved gram-variable rods for *Mobiluncus* morphotypes) was quantified on a scale (0–4) and weighted to yield a score (0–10) that defined the result of a vaginal smear with a score of 0–6 and one with a score of 7–10 as normal and bacterial vaginosis, respectively.

For culture, the clinical specimens were inoculated onto chocolate agar (Oxoid, Basingstoke, United Kingdom), eosin-methylene-blue sucrose (EMB) agar, and 5% sheep blood agar. While the chocolate agar plate was incubated

with 10% CO₂ to optimize the growth of *Neisseria gonorrhoeae* at 37 °C for 18–24 hours (8), EMB agar and 5% sheep blood agar plates were incubated with 5% carbon dioxide (CO₂) (9,10), before they were evaluated. Isolate identification was performed using a BD PhoenixSpec™ nephelometer (Becton Dickinson, MD, USA) automated system and by conventional methods (Gram stain, catalase, coagulase tests, and colonial morphology). Lastly, the presence of amines was evaluated by whiff test (sniffing a drop of KOH on a vaginal swab) (11).

The presence of motile trichomonads was investigated on direct preparations under a microscope. One drop of physiological water was dropped onto clean glass slides. The sample was mixed with this drop, and a suspension was prepared. After being covered with a cover slip, the examination was performed under a light microscope at 400× magnification and screened for *Trichomonas vaginalis* trophozoites based on their typical appearance and movements.

The third swab was immersed into the vial of physiological solution contained in the kit of the A.F. Genital System® and left for 5 minutes. For the clinical material to be dispersed homogeneously in the physiological solution, the swab was carefully squeezed against the vial wall and dipped in a nutritive broth until the test concluded. Then, a system was taken from its wrapper and brought to room temperature. The patient's name, the type of clinical material, and the date of the start of the examination were written down. Next, 0.2 mL of clinical sample suspension was added to each well of the system and the tray was inoculated according to the manufacturer's instructions. All the wells, except for wells 6, 16, 17, 18, 20, 21, 22, and 23, were covered with one drop of Vaseline oil for microbiological use. After being covered with the lid provided, the system was incubated for 18–24 hours at 36 ± 1 °C. If the presence of *Mycoplasma hominis* was suspected, the incubation was extended for a further 24 hours. After incubation, a drop of culture liquid taken from well 6 was deposited on a glass slide and examined under the microscope (40×) with a cover slip on top for identification of *T. vaginalis* by assessing the presence of ciliated mobile trophozoites and/or for identification of *Candida* spp. by determining the presence of hyphae and chlamyospores. From well 22, a drop of liquid was also taken, deposited on an Oxidase Test Stick, and observed for oxidase test positivity for *N. gonorrhoeae* by the immediate development of a blue color within 10 seconds. The test results for detection of *Escherichia coli*, *Proteus* spp./*Providencia* spp., *Pseudomonas* spp., *Gardnerella vaginalis*, *Staphylococcus aureus*, *Enterococcus faecalis*, *Streptococcus agalactiae* (Group B), and *Candida* spp. were interpreted after color changes in different wells (wells 16, 17, 18, 19, 20, 21, 23, and 24, respectively). *Ureaplasma urealyticum* and *M. hominis* were shown to be present by the urea test in well 5, and the yellow to red color changes of the arginine test in well 4, respectively. Their

semiquantitative counts in colony forming units (CFU) provided by similar color changes in wells 1 ($10^2 < \text{titer} < 10^4$ CFU/mL), 2 ($10^4 < \text{titer} < 10^5$ CFU/mL), and 3 (titer $> 10^5$ CFU/mL) were also available with this test, but they were not taken into account during interpretation of the results. Although it was possible to test the susceptibility of these urogenital mycoplasmas for tetracycline, pefloxacin, ofloxacin, doxycycline, erythromycin, clarithromycin, minocycline, and clindamycin by observing the change of color in wells 7 to 15, respectively, this was not assessed in the current study.

To compare A.F. Genital System[®] results to detect *M. hominis* and *U. urealyticum*, the Mycoplasma IES kit[®] (Autobio, Zhengzhou, China), which is based on the cultural method and biochemical identification, was used as a diagnostic standard method. This new commercially available diagnostic assay is a simpler alternative to conventional culture to identify *U. urealyticum* and *M. hominis* from genital specimens and determine their antimicrobial susceptibility profiles within 24 hours. By performing Mycoplasma IES testing, 300 μ L from the seeded suspension was put in a reconstituted medium within the manufacturer's collection kits. Then, 100 μ L from the suspension was inoculated in the gallery's wells. After adding one drop of mineral oil into each well, the strips were incubated for 24 hours at 37 °C. While urea can be cleaved by urease for *U. urealyticum* and arginine can be decomposed by arginase for *M. hominis* by releasing NH_3 in both, the pH value of the liquid medium is increased, and the indicator's corresponding color change is used to read the result (12). According to the study by D'Inzeo et al, the Mycoplasma IES assay identifies *M. hominis* and *U. urealyticum* accurately and rapidly with sensitivities of 92.8% and 100%, respectively (12).

The researchers examining the wet preparations, Gram-stained slides, culture, and the test results of the Mycoplasma IES kit[®] (HG and AO) were blinded to the test results of A.F. Genital System[®].

Statistical Analysis

The Z-test or Fisher's exact test was used to analyze of categorical variables. The statistical significance was considered when $P < 0.05$. Statistical Package for the Social Sciences (SPSS) 18.0 (IBM Corporation, Armonk, NY, USA) was used for the statistical analysis. To evaluate the performance of A.F. Genital System[®], statistical parameters of sensitivity, specificity, negative and positive predictive values (NPV and PPV, respectively), and accuracy were calculated.

Results

When mixed infections were assigned to discrete diagnostic categories, for single vaginal infectious agents other than urogenital mycoplasmas, 134 (68%) and 104 (52.8%) positive samples out of 197 vaginal swab samples were detected by the A.F. Genital System[®] and vaginal

culture/traditional methods, respectively. With the same categorization, 21 (41%) and 29 (56.8%) positive samples out of fifty-one randomly selected subgroup vaginal samples were found for urogenital mycoplasmas by the A.F. Genital System[®] and Mycoplasma IES kit[®], respectively.

The rates of detection achieved by each method of detection used in comparison (culture/traditional methods or Mycoplasma IES kit[®]) differed from those of the A.F. Genital System[®] only for *E. coli*, *G. vaginalis*, *S. aureus*, and *Pseudomonas* spp., the detection of which was higher with the A.F. Genital System[®] ($P < 0.05$). The details are given in Tables 1 and 2.

The sensitivity, specificity, PPV, NPV, and accuracy rate of A.F. Genital System[®] in the detection of *Candida* spp., *E. faecalis*, *E. coli*, *S. aureus*, *M. hominis*, and *U. urealyticum* are given in Table 3. While the numbers of samples positive for *G. vaginalis*, *Pseudomonas* spp., *T. vaginalis*, *Proteus* spp./*Providencia* spp., *N. gonorrhoeae*, and *S. agalactiae* with either the A.F. Genital System[®] or conventional culture/traditional methods were too small to calculate the sensitivity, specificity, PPV, or NPV of A.F. Genital System[®] for identification of these vaginal pathogens, its accuracy rates for the detection of these microorganisms were 91.9%, 94.4%, 98%, 99.5% and 100%, respectively.

The overall correlation of A.F. Genital System[®] with vaginal culture/traditional methods and the Mycoplasma IES assay was 95.4% and 84.3%, respectively.

Discussion

In the English literature, there is a need for studies evaluating the accuracy of compact bacteriological screening tests in the identification of all significant vaginal pathogens in patients presenting with various disorders related to obstetrics and gynecology.

In the present study, 17.8% of the specimens were positive for *E. coli* with culture: 15.1% were from pregnant women, and 20.4% were those without. In the literature, it has been reported that *E. coli* is identified in the female reproductive system of 9-28% and 24-31% of the women who are not pregnant and the women who are pregnant, respectively (13). In the report by Guiral et al, *E. coli* was positive in 13% of the samples (15% from the women who were pregnant and 12% from the women who were not pregnant) (14). In the present study, the A.F. Genital System[®] identified *E. coli* with similar but half rates in nonpregnant (10.2%) and pregnant women (10.1%). Despite its low (54.3%) sensitivity rate, the A.F. Genital System[®] showed a relatively high accuracy (91.4%) for identifying *E. coli*.

In the current study, *E. faecalis* was isolated from 10.7% of the samples cultured and 14.7% of the samples tested with A.F. Genital System[®]. It has already been reported that *Enterococcus/Enterobacteriaceae* spp. were identified in 9.6% of male patients with acute urethritis by multiplex real-time polymerase chain reaction (RT-PCR), while *E.*

Table 1. Detection Rates of Vaginal Pathogens in Vaginal Swabs With the A.F. Genital System® and Vaginal Culture/Traditional Methods (n=197)

	A.F. Genital System®	Vaginal Culture and Traditional Methods	P Value
<i>Candida</i> spp.	41 (20.8%)	44 (22.3%)	0.713 ^a
<i>E. faecalis</i>	29 (14.7%)	21 (10.7%)	0.225 ^a
<i>E. coli</i>	20 (10.1%)	35 (17.8%) ^c	0.028 ^a
<i>G. vaginalis</i>	16 (8.1%)	0 (0%)	0.001 ^b
<i>S. aureus</i>	12 (6.1%)	3 (1.5%)	0.032 ^b
<i>Pseudomonas</i> spp.	11 (5.6%)	0 (0%)	0.001 ^b
<i>T. vaginalis</i>	4 (2%)	0 (0%)	0.123 ^b
<i>Proteus</i> spp./ <i>Providencia</i> spp.	1 (0.5%)	0 (0%)	1.000 ^b
<i>N. gonorrhoeae</i>	0 (0%)	0 (0%)	1.000 ^b
<i>S. agalactiae</i>	0 (0%)	1 (0.5%)	1.000 ^b

Results are expressed as the number (detection rate) of detected vaginal pathogens.

^a Z test.

^b Fisher's exact test.

^c 15 (15.1%) from the women who are pregnant and 20 (20.4%) from those who are not.

Table 2. Detection Rates of Urogenital Mycoplasmas in Vaginal Swabs With the A.F. Genital System® and Mycoplasma IES kit® (n=51)

	A.F. Genital System®	Mycoplasma IES kit®	P Value
<i>U. urealyticum</i>	19 (37.2%)	25 (49%)	0.227 ^a
<i>M. hominis</i>	2 (3.9%)	4 (7.8%)	0.678 ^b

Results are expressed as the number (detection rate) of detected vaginal pathogens.

^a Z test.

^b Fisher's exact test.

Table 3. Accuracy of the A.F. Genital System® Compared to Culture/Traditional Tests or Reference Vaginitis Tests (n=51 for Genital Mycoplasmas, n = 197 for Others)

	Accurate		Inaccurate		Accuracy Indices				
	(+/+)	(-/-)	(+/-)	(-/+)	Accuracy	Sensitivity	Specificity	PPV	NPV
<i>Candida</i> spp.	36	148	5	8	93.4%	81.8%	96.7%	87.8%	94.6%
<i>E. faecalis</i>	18	165	11	3	92.9%	85.7%	93.7%	62.1%	98.2%
<i>E. coli</i>	19	161	1	16	91.4%	54.3%	99.4%	95%	91%
<i>S. aureus</i>	1	183	11	2	93.4%	33.3%	94.3%	8.3%	98.9%
<i>M. hominis</i>	1	46	1	3	92.2%	25%	97.9%	50%	93.9%
<i>U. urealyticum</i>	16	23	3	9	76.5%	64%	88.5%	76%	71.9%

PPV: Positive predictive value; NPV: Negative predictive value.

Results are expressed as numbers and percentages.

(+/+): positive both in the A.F. Genital System and the comparison test.

(-/-): negative both in the A.F. Genital System and the comparison test.

(+/-): positive in the A.F. Genital System but negative in the comparison test.

(-/+): negative in the A.F. Genital System but positive in the comparison test.

Accuracy: Number of accurate reference or traditional vaginitis test results divided by the total number of reference or traditional vaginitis test results (accurate and inaccurate).

faecalis was identified with A.F. Genital System® in 3.6% of them, with low sensitivity (37.5%) and high specificity (100%) (2).

Candida spp. were the microorganisms isolated most in the present study (22.3% with culture and 20.8% with A.F. Genital System®). *Candida* spp. was in two isolates in which A.F. Genital System® obtained a high accuracy rate (93.4%) with relatively high sensitivity and specificity rates (81.8% and 96.7%, respectively). In a cross-sectional study conducted on 1000 women from 12 health centers, the prevalence of candidiasis was found to be 25.2%, consistent with our culture results (15). In our study, the culture did not confirm the results of A.F. Genital System®

in identifying *Candida* spp. in 2.5% of the samples. In comparison, 4.1% of the samples were isolated only by the culture. In male urethral swab samples, Sarier et al reported that *Candida* spp. was detected in only 1 out of 83 patients (1.2%) with multiplex rt-PCR, but that case could not be identified with A.F. Genital System® (2).

In our study, *G. vaginalis* was identified only via A.F. Genital System® in 8.1% of the samples. In contradiction to our findings, in the investigation of Sarier et al, which was conducted on the urethral swab samples from male patients with acute urethritis, rt-PCR identified *G. vaginalis* in 12% of the patients (10 out of 83). In comparison, only one of these patients (1.2%) was determined by A.F.

Genital System[®] with a very low sensitivity (10%) (2).

Although *S. aureus* was detected in a relatively small number of samples (1.5% in conventional culture and 6.1% in A.F. Genital System[®]), it was one of 2 isolates in which A.F. Genital System[®] obtained a high accuracy rate (93.4%), resulting mainly due to agreement in the negative results. For this microorganism, A.F. Genital System[®]'s sensitivity was relatively low (33%) compared to a high specificity rate (94.3%).

In our study, while *Pseudomonas* spp., *T. vaginalis*, and *Proteus* spp./*Providencia* spp. were detected in none of the samples by culture and conventional methods, only 5.6%, 2%, and 0.5% of the samples were positive for these microorganisms in the A.F. Genital System[®], respectively. In contrast to our findings, in the study by Sarier et al, *T. vaginalis* was identified in 3 out of 83 patients (3.6%) with multiplex rt-PCR and none of them could be identified via A.F. Genital System[®] from the urethral swab samples of male patients (2).

S. agalactiae (Group B) was not identified in any specimen by A.F. Genital System[®] and was isolated from only one sample (0.5%) with culture, yielding a 99.5% accuracy rate, originating primarily from the negative results.

With a 100% agreement for negative results, none of the samples of our study yielded positivity for *N. gonorrhoeae* with A.F. Genital System[®] and conventional culture. The investigation by Sarier et al conducted on urethral swab samples from male patients, identified it with multiplex rt-PCR and A.F. Genital System[®] in 18% and 3.6% of the patients, respectively (2). In that study, for diagnosing gonococcal urethritis, A.F. Genital System[®] had a low (20%) sensitivity and a high (100%) specificity, respectively (2).

In the literature, the prevalence of genital mycoplasma has been reported to be 30-40% among symptomatic patients (16, 17). In the study by Mardaneh et al, 40.4 %, 12.8 %, and 11.7% of the cases were single positive for *U. urealyticum*, single positive for *M. hominis*, and dually positive for *U. urealyticum* and *M. hominis*, respectively (18). In our study, 19 out of 51 women (37.2%) and 26 out of 51 women (51%) were found to be positive for *U. urealyticum*, *M. hominis*, or for both in A.F. Genital System[®] and the reference Mycoplasma IES assay, respectively. According to the reference test results, genital mycoplasmas were detected in higher numbers in our study population compared to the prevalence documented in the literature (16, 17) and some other recent studies, e.g., 35.6% by D'Inzeo et al (12), 43.5% by Leli et al. (19), and 18.6% by De Francesco et al (20). The difference may be related to the different populations of the studies and the methodologies used to detect them. In a recent study by Tjoa et al, the prevalences of *U. urealyticum* and *M. hominis* in vaginal specimens were 10.2% and 6.8% by using PCR versus 10.2% and 15.9%, by using culture methods, respectively (21). In their study,

when compared with culture methods and polymerase chain reaction, A.F. Genital System[®] had sensitivities of 57% and 66.6% and specificities of 86.5% and 82.9% for identifying *M. hominis*. In comparison, it had sensitivities of 55.5% and 77.8% and specificities of 82.3% and 84.8% for identifying of *U. urealyticum*, respectively. In the study of Sarier et al, *M. hominis* was identified in four out of eighty-three patients (4.8%) by rt-PCR and one patient (1.2%) by A.F. Genital System[®] with 25% sensitivity and 100% specificity. *U. urealyticum* was identified in eight out of eighty-three patients (9.6%) by RT-PCR and in seven out of eighty-three patients (8.4%) by A.F. Genital System[®] with 50% sensitivity and 57% specificity since only four of the seven cases with *U. urealyticum* identified with A.F. Genital System[®] were inside the ones identified with multiplex RT-PCR. In accordance with the results of these studies, the sensitivities of the A.F. Genital System[®] for the identification of *U. urealyticum* and *M. hominis* were also relatively low (64% and 25%, respectively) in our study, in contrast to the much higher specificity values (88.5% and 97.9%, respectively) (21); showing that A.F. Genital System[®] may detect *M. hominis* and *U. urealyticum* from vaginal specimens with a low sensitivity but a reasonably good specificity.

The lower sensitivity rates of the A.F. Genital System[®] for specific pathogens, such as *E. coli* and *S. aureus*, which could be a limitation of the diagnostic method, may be related to the microbiological technique used to detect these microorganisms. In this regard, A.F. Genital System[®] requires improvement, and its sensitivity must be increased, as also stated by Sarier et al. (2)

Limitations and Strengths of the Study

In the present study, to assess the accuracy of the A.F. Genital System[®] for the identification of *U. urealyticum* and *M. hominis* from vaginal specimens, another new diagnostic assay that is also based on the culture method and biochemistry identification, Mycoplasma IES, was used for comparison. However, although the "gold standard" to detect *M. hominis* and *U. urealyticum* in laboratories with low-moderate test volume is still culture on semisolid media, tests based on nucleic acid amplification are associated with higher sensitivity and specificity compared to culture. They are also the only means to detect *Mycoplasma genitalium* and to discriminate between *U. urealyticum* and *U. parvum*, and the tests can be completed in a few hours (22-24). However, due to the requirements of high-cost reagents and equipment and personnel trained in molecular diagnosis, we could not use this method to compare the results of the A.F. Genital System[®]. Since it has already been shown that Mycoplasma IES was highly specific and sensitive for the identification of mycoplasma in genital specimens with a sensitivity notably higher than that of 2 other available diagnostic kits, Mycoplasma IST 2 and Mycofast Revolution (EliTech Diagnostic, Puteaux,

France) (100% versus 95.3% and 96.2%, respectively) (12), we may trust the results of this assay. For future research in this field, gold standard tests to detect *M. hominis* and *U. urealyticum* are recommended while comparing the results of A.F. Genital System®.

Secondly, our study has some other limitations, such as being performed in a single clinic over a short time with a relatively low number of samples, especially in evaluating mycoplasma detection. Since it was not the purpose of the present study, susceptibility testing of microorganisms in genital specimens was not performed, and it may be evaluated in future studies.

On the other hand, the strength of our study is that it is a controlled study adding new results to the currently available literature about the accuracy of a compact bacteriological screening test, the A.F. Genital System®, in the identification of common vaginal pathogens in clinical vaginal samples.

Conclusions

Despite the lower sensitivity rates for *E. coli*, *S. aureus*, and urogenital mycoplasmas, the A.F. Genital System® is highly correlated with the reference tests for identification of most of the common vaginal pathogens in patients presenting with various obstetrical and gynecological pathologies. The identification of the opportunistic pathogens which are found in vaginal flora but considered pathogenic at microbial overload may help to guide the proper diagnosis and treatment. However, since the microorganisms detected by A.F. Genital System® cannot be quantified, the clinical presentations of the patients should also be considered to avoid overtreatment of clinically insignificant positive results. On the other hand, low sensitivities of A.F. Genital System® for specific vaginal pathogens may also lead the patients to be undetected for these microorganisms and treated inadequately or inappropriately.

As a result, A.F. Genital System® may have a potential utility as a quick diagnostic tool for identifying common vaginal pathogens in clinical settings, provided that its low sensitivities for specific pathogens are kept in mind during the interpretation of the test results. Further comparative studies using gold standard tests as references are warranted in this field due to the scarcity of literature data.

Authors' Contribution

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Conflict of Interests

Authors declare that they have no conflict of interests.

Ethical Issues

The study was approved by the Yüzüncü Yıl University Faculty of Medicine Non-drug Clinical Research Ethics Committee Ethics Committee (approval number: 4, date: 14.02.2013).

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