

Femlab® Vaginitis Test Kit ■ ■ ■ ■ ■ ■ ■ ■ ■ ■

The FemLab Vaginitis test kit is a screening device for use in the detection of the major forms of vaginitis in vaginal fluid specimens from women concerned about their vaginal health.

Summary and Explanation of the FemLab® Vaginitis Test Kit

Vaginitis is defined as irritation of the vagina, a troublesome condition that affects millions of women of all ages in all parts of the world. The most common types of vaginitis are Bacterial vaginitis, Candida yeast infections, Trichomoniasis, and Chlamydia trachomatis. These common forms of vaginitis can usually be treated effectively with prescription or over-the-counter medication if correctly diagnosed. However, if left untreated, misdiagnosed or incorrectly treated, vaginitis can produce serious consequences such as sterility or miscarriage, and it can be a precursor to cancer.

The various types of vaginitis will be discussed in detail in a later section of this package insert.

The FemLab® test kit is an easy to use product that can accurately diagnose common types of vaginitis within a few minutes. The test kit is intended to be used by or under the direction of a trained medical professional. The test kit is very easy to use and only minimal training is necessary for staff level technicians to become proficient in the accurate diagnosis of vaginitis in any particular case. Such trained professionals can also easily instruct or assist patients with the use of the kit on their own. To use the kit, samples of vaginal fluids are taken on sterile swabs, and are either applied to test zones on the test kit platform, or diluted in a specially designed buffer delivery system for application to the remaining test zones. The test results are evaluated by comparing the color change results for each of the six test zones to the colors on the test cassette, and then consulting the diagnosis protocol described later in this document. Each major form of Vaginitis may be accurately diagnosed by following this methodology. Treatment or recommended treatment regimens require the consultation of a medical professional. FemLab is not to be used for self-diagnosis and self-treatment.

Intended use

This test kit is intended for use in professional medical facilities by trained technicians to diagnose the common forms of vaginitis; or, in certain circumstances, under a physician's or trained medical professional's supervision, the kit may be prescribed for home use by any woman concerned about her vaginal health.

The FemLab vaginitis diagnostic test kit requires careful collection and application of several vaginal fluid samples. Each vaginal fluid sample must be collected as described in the sample collection directions below.

As the FemLab test kit is to be used as a screening tool, the diagnosis of any vaginitis condition will depend on the careful analysis of the FemLab results as described in this document. All final diagnostic conclusions, including medical decisions regarding patient treatments, are the responsibility of the treating medical professional. The FemLab test kit is primarily a screening tool, and any positive results should always be referred to a clinician for further evaluation and for treatment.

Principles of the Test

The FemLab Pro test kit has a total of seven sample application zones on the small plastic test platform. Each test zone and the color changes for each positive and negative result are described in detail in this document. The seven test zones are individual chemical and biological tests that screen for specific chemical or biological aspects of the vaginal fluid samples. These test zones can accurately differentiate between the various disease states (see Interpretation of Results later in this document). Vaginal fluid samples are collected in a three-step collection procedure; two samples are used directly on test zones, and the third is diluted in a custom designed buffer dilution and delivery system. The test results are determined by observing color changes on each test zone following sample application. The colors are compared to a color chart on the test cassette to draw conclusions as to the results of each test. A diagnostic protocol to accurately determine the condition causing the vaginitis will be described in this document. The diagnostic protocol detailed below, and the sample collection and application instructions must be followed closely to achieve an accurate diagnosis. Descriptions of each test zone, drawings of the test cassette and recommended methods of use are shown below:

Zone 1: pH Zone

The normal pH of vaginal fluid is in the range 3.8 – 4.2. After application of the test fluid sample, if the pH test zone (zone 1) turns from pink to light blue-green within 3 minutes, the pH is above 4.7, which indicates a positive result. If the vaginal fluid is below pH 4.7, the color remains pink, indicating normal vaginal pH. The pH zone change to a light blue-green color – an abnormally high pH - is a positive finding, consistent with bacterial vaginitis and/or trichomoniasis, microorganisms that impair the growth of the normal vaginal lactobacilli, which keep pH low.

Zone 2a - 2b: Gardnerella Zone

An enzyme activity test specifically designed to detect the presence of Gardnerella vaginalis bacteria and a few other infectious bacteria in vaginal fluid specimens is used in Zone 2. The development of a visible peach-to-pink-to-red color on the test swab after application of the vaginal fluid sample onto the test zone is a positive test result, indicating the presence of Gardnerella Bacterial vaginitis. No color change on the test swab indicates there is no Gardnerella infection.

Zone 3: Nitrite Zone

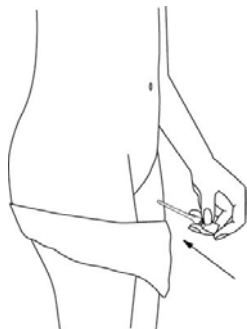
This test zone depends upon the chemical conversion of nitrate to nitrite by the action of gram-negative bacteria in the vaginal fluid. If the test procedure using the buffer diluted vaginal fluid sample turns the test zone from colorless to a pink color, this is a positive reaction consistent with the presence of a yeast infection. If no color change is observed, this indicates a lack of yeast.

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First, thoroughly swab the inner and outer labia of the patient with a sterile wipe to reduce the exterior bacterial count from the vaginal opening.

Open the sterile tri-pack of sample collection swabs, and gently open the vaginal opening, and insert the swabs about two to three inches into the vagina. Do not insert near the cervix, as pH results would be inaccurate.

Drawing 2 – Insertion of sterile swab tri-pack into vagina



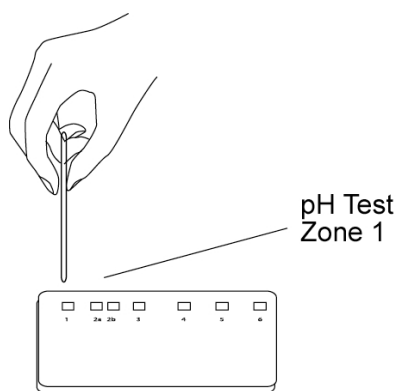
Gently stroke the inner walls of the vagina with the swabs, ensuring that the swabs are all moistened thoroughly. Leave the swabs in the vagina several minutes to ensure they are saturated with vaginal fluid.

Remove the Vaginal fluid specimen container with buffer solution and the test cassette tray from the foil pouch. Write the patient's name in the space provided on the FemLab test cassette

Remove **the three swabs** from the vagina.

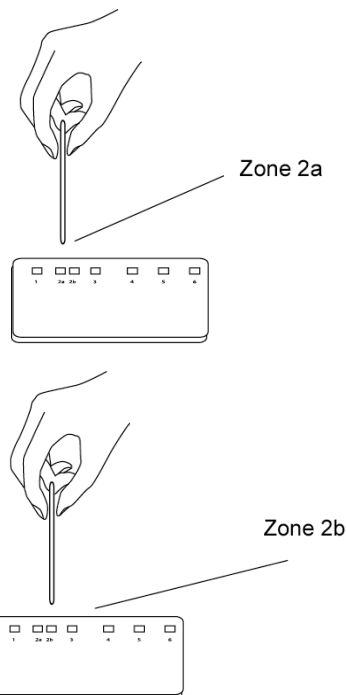
Rub one swab saturated with fluid sample onto Zone 1 - the pH zone – of the test tray. Discard the swab in a biological specimen container. Read the pH color after three minutes, and note the result on the Test cassette tray next to the pH Zone Result color comparison chart. Simply circle the color – either positive or negative – with an ink pen .

Drawing 3 – Application of swabs onto test Zone 1, pH Zone.



While the pH Zone color is developing, take a second swab and rub onto Zone 2a six or seven times. Then, immediately rub this same swab onto Zone 2b several times. Wait 1 - 5 minutes. If the swab itself becomes peach or pink within One minute, it is a positive reading for Gardnerella. Record the Gardnerella result on the test cassette near the Gardnerella Zone Result color comparison.

Drawing 4 – Application of swabs onto test Zone 2, Gardnerella zone



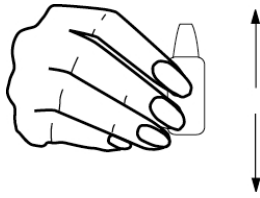
Finally, take the third swab, open the vaginal fluid specimen container with buffer solution, and thoroughly mix the swab into the buffer in the container. Swirl the swab vigorously for 15 seconds, and then expunge as much liquid as possible from the swab by pressing and rotating the fiber portion against the wall of the specimen collector. Discard the swab. Insert the dropper tip securely into the specimen container opening, and then screw the cap onto both the dropper tip and the specimen container.

Drawing 5 – Screw the Tip and Cap onto the Specimen Container.



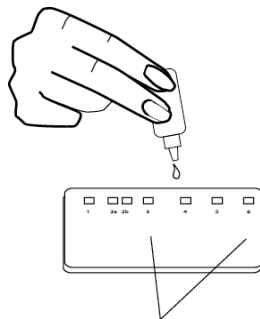
After the specimen container is tightened securely, shake vigorously up and down ten (10) times.

Drawing 6 – Shake vigorously up and down ten (10) times.



Remove the cap. Hold the vaginal fluid collection container above each of test zones 3 through 6, and carefully squeeze one drop onto each of test zones 3 through 6.

Drawing 7 - Squeeze buffer solution container and place one drop into each of zones 3 - 6.



Zones 3-6

Wait about two minutes, and then read the color results for each of the test zones 3 through 6.

Promptly circle the square that most closely matches the test zone color.

Note: It is important to read the test results within two (2) to three (3) minutes after placing the droplets of specimen onto the test zones.

Discard the specimen collection container with the second and third swabs in a biological specimen container.

Important Issues to Obtain Best Results

- The specimen used for pH testing must be an undiluted vaginal fluid sample.
- The specimen used for Gardnerella testing must be a separate undiluted sample.
- The specimen used for the remaining tests must be diluted in the buffer solution container as directed.
- The collection of the vaginal fluid sample should be performed in a single step.
- Ensure that nothing remains inside of vagina after collection.
- Read the colors on the test cassette within the prescribed time of application of the sample, and circle the color result with a pen on the cassette to record the results.

Kit Storage

Store the FemLab test kit at 2-30 degrees C (35 – 86 degrees F), out of direct sunlight.

Quality Control

Each production lot of FemLab cassettes is tested rigorously at the factory before packaging and shipping, with both positive and negative control reagents. Positive and negative control reagent kits are available from the Manufacturer if a clinic or pharmacy wishes to conduct in house control procedures. The positive and negative control reagents are designed to produce the color changes expected for positive or negative results on the FemLab test cassette.

Limitations of the test kit

- The FemLab test kit is to be used as a screening device. Final diagnostic results should be rendered by medical professionals, who may recommend additional laboratory or medical testing to confirm any diagnosis.
- The absence of any positive results with the FemLab test kit does not rule out the presence of vaginitis.
- Test results may be affected by improper specimen collection, handling and procedure.
- Mixed infections may occur. Therefore, a test result indicating one positive result does not rule out the presence of other infectious organisms.

FemLab Test Kit - Diagnostic Protocol and Interpretation of Results

The major forms of Vaginitis can be determined fairly accurately by a careful analysis of the FemLab test results as recorded on the test cassette color chart. The following diagnostic protocol will provide guidance in this process.

It cannot be emphasized enough that accurate results require that the vaginal fluid sample collection methodology and test application methodology be performed according to the instructions in this document. The diagnostic protocol will be described below in three sections: (1) Test Zone Color Interpretation – will describe generally what the color result for each test zone means; (2) Identification of Infectious Organisms – will describe the combinations of test zone results that identify a particular organism; and (3) performance characteristics of FemLab in a controlled clinical trial.

Test Zone Color Interpretation

Zone 1: pH Test Zone: A light blue-green color indicates a positive result, a pH above 4.7. This may indicate a bacterial infection and will also be present with most cases of Trichomonal vaginitis if Leukocytes, Zone 6, are also present. No color change indicates a pH below 4.7, which is normal for the vagina. This indicates the absence or very low level of bacterial infection or Trichomoniasis.

Zone 2: Gardnerella Test Zone: A peach-pink color indicates a positive result. The Gardnerella test zone (2b) and the test swab used on Zone 2 will turn peach-pink within five minutes if a

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Gardnerella bacterial infection is present. A positive result specifically indicates the presence of Gardnerella bacteria. A negative result means that Gardnerella is not present, but infections from other bacteria are not ruled out by a negative result.

Zone 3: Nitrite Test Zone: A pink color indicates a positive result. The nitrite test zone will turn to pink if the conversion of nitrate to nitrite by the action of gram-negative bacteria in the vaginal fluid occurs. This result reliably indicates the presence of Yeast infections.

Zone 4: Blood Test Zone: A dark green or blue color indicates a positive result. The blood test zone turns from yellow to dark green if red blood cells are present in the buffer diluted vaginal sample. This is generally indicative of the presence of Chlamydia bacteria, if Leukocytes are also present, but may also be present with other bacterial or yeast infections. If both zone 4 and zone 6 are positive (blood and leukocytes), this is indicative of a Chlamydia infection, caused by the bacterium Chlamydia. Menstrual blood in the sample may result in a false positive test. If menstrual blood is suspected, less weight should be given to the blood zone. .

Zone 5: Protein Test Zone: A blue color indicates a positive result. The protein test zone will turn to blue if the buffer diluted vaginal fluid sample contains protein in excess of normal values. A positive result is associated with bacterial, yeast, Chlamydia and Trichomonal infections. Serious occurrences of these infections will produce pus which shows up as positive protein in the protein test zone. A negative protein zone result is associated with the absence or low levels of these infectious organisms.

Zone 6: Leukocytes Test Zone: A light purple color indicates a positive result. The Leukocyte test zone, initially colorless, turns to light purple with application of the diluted vaginal fluid specimen if

white blood cells are present in the sample. A positive result indicates the presence of Trichomonas parasites or Chlamydia infection. If both leukocyte and blood tests are positive (zones 4 and 6), it is likely that Chlamydia is present. If both leukocyte and pH tests are positive (zones 1 and 6), it is likely that Trichomonas is present. A negative leukocyte zone result indicates the absence or very low levels of Trichomonas or Chlamydia.

Identification of Infectious Organisms

The following two tables (**Table I** and **Table II**) summarize the interpretation method for the FemLab test kit.

To use the Diagnostic Protocol in **Table I** and **Table II** below, compare the test zone color results on the FemLab Test Kit to the test zones on the Tables.

The cells in **Table I** indicate the general positive and negative interpretations for each Zone color result. Use this information to evaluate the possible disease states diagnosed by the FemLab cassette results

Table II shows the expected result for the four main pathogenic organisms that are causes of vaginitis. **Compare the actual FemLab test cassette color results to the positive and negative cells on Table II.** If a specific combination of zones on the test kit match those in **Table II**, the corresponding disease organism is correctly identified. If specific test zones on the FemLab cassette are negative and the corresponding cells in **Table II** are positive, then that disease organism is not present. If the zones for a particular organism match, and other zones also match another organism, then this is a multiple diagnosis, and multiple organisms are present.

Table I
FemLab Test Kit - Test Zone Interpretation Table

Test Result	Positive Color	Negative Color	Positive Result Interpretation	Negative Result Interpretation
<u>pH Zone 1</u>	Blue-green	Pink	Bacterial Vaginitis and/or Trichomonas	No or low level bacterial infection. Trichomonas still possible
<u>Gardnerella Zone 2</u>	Pink	No color	Bacterial Vaginitis and/or Gardnerella	No Gardnerella infection
<u>Nitrite Zone 3</u>	Pink	No color	Yeast infection.	No or low level yeast or bacterial infection
<u>Blood Zone 4</u>	Blue	Yellow	Chlamydia infection if Leukocyte (Zone 6) also positive. Bacterial infection if pH (Zone 1) also positive	No Chlamydia Infection
<u>Protein Zone 5</u>	Blue	Light Yellow-green	Bacterial, Chlamydia, Yeast or Trichomonas infections, associated with severity	No color change suggests only moderate infections of any types
<u>Leukocytes Zone 6</u>	Pink-purple	No color	Trichomonas infection if pH (Zone 1) also positive. Chlamydia infection if blood (Zone 4) also positive.	No color change indicates patient has no Trichomonal or Chlamydia infection.

Table II - FemLab Test Kit Diagnostic Conclusions

Test Zone	Zone 1 pH	Zone 2 Gardnerella	Zone 3 Nitrite	Zone 4 Blood	Zone 5 Protein	Zone 6 Leukocytes
<u>Bacterial Vaginitis</u>	Positive	Positive or Negative	Negative	Negative (or Positive, severe Bacterial Vaginitis)	Negative (or Positive, severe Bacterial Vaginitis)	Negative
<u>Chlamydia Vaginitis</u>	Negative	Negative	Negative	Positive	Positive or Negative	Positive
<u>Yeast Vaginitis</u>	Negative	Negative	Positive	Negative or Positive (severe Yeast Vaginitis)	Negative	Negative
<u>Trichomonal Vaginitis</u>	Positive (or Negative, light Trichomonal Vaginitis)	Negative	Negative	Negative	Positive or Negative	Positive
<u>Healthy</u>	Negative	Negative	Negative	Negative or Positive (during menstrual period)	Negative	Negative

**Performance Characteristics
FemLab Clinical Trial Results**

The performance of the FemLab test kit to detect Bacterial, yeast, Chlamydia and Trichomonas vaginitis in vaginal fluid specimens collected from symptomatic and asymptomatic patients, was determined in a multi-center study conducted at three geographically separate clinical sites. A total of 300 women were enrolled and tested. Study site personnel performed the FemLab test according to a specific protocol, and also performed traditional tests for comparison to the FemLab results. The study personnel performed control tests on each patient, and reported diagnoses of the most important vaginitis disease entities: Bacterial Vaginitis, Gardnerella, Yeast Vaginitis, Trichomonas vaginitis, and Chlamydia Vaginitis. In addition, clinical evaluations of the severity of symptoms in the presenting patients were recorded.

The traditional tests used as control methods included commercially available pH and Gardnerella tests, wet mount microscopic evaluation of samples for Trichomonas parasites, and culture systems for detection of Chlamydia and yeast. A pelvic exam was performed on each patient to determine overall level of vaginal health.

The clinical trial results are discussed below, first with a general comparison between results, and then specific comparisons of the ability of each method to diagnose infectious organisms. The results for each diagnosis as found by the FemLab Test Kit are compared to the results found by the control methods, and are reported in a 2 by 2 chart from which the statistical model may be calculated.

The terms positive (+) and negative (-) are used to refer to the presence or absence of the condition of interest, the presence of an infectious diagnosis. Thus there are true positives and true negatives, where both methods of diagnosis agree. There are also two cells on each chart where the diagnoses disagree. These proportions are described with the following terms:

Sensitivity is the proportion of true positives that are correctly identified by the test, compared to the control method.

Specificity is the proportion of true negatives that are correctly identified by the test, compared to the control method.

Sensitivity and specificity are one approach to quantifying the diagnostic ability of a diagnostic test. In clinical practice, however, the test result is all

that is known, so we want to know how good the test is at predicting the abnormal condition. The comparison of sensitivity and specificity provide this means.

Performance Characteristics- Symptomatic vs. Asymptomatic Patients

As part of the clinical trial, pelvic exams were performed by gynecologists on each of the 300 patients enrolled, and the results were reported on a scale of 1 to 4. The pelvic examination reported the general condition of vaginal cavity, the color, amount and any odor of discharge, and other visible observations. The results were reported as the following:

- I+: Slight discharge with no color and odor
- II+: Slight discharge with redness and no odor
- III+: White discharge with redness, slight odor and itching
- IV+: White discharge with pus, redness, strong odor, burning and itching

Thirty eight women were found to be asymptomatic (I+). Of these women, however, 23 were also diagnosed by the hospital as having some form of vaginitis. Fifteen were found to be completely free from any form of vaginitis. FemLab results on these asymptomatic women agreed: 21 women were found to have some form of vaginitis, and 17 were healthy. The remainder of the trial population (262 cases) had clinical symptoms of vaginal disease, with pelvic exam reports of II+, III+ or IV+. Upon testing, only 10 of these cases were diagnosed as healthy with no form of infectious vaginitis by the hospital control methods, and by the FemLab test, and these cases were in the II+ pelvic exam category. Thus, 96.2% of symptomatic patients had at least one, and sometimes more, diagnosis of Bacterial Vaginitis, Yeast Vaginitis, trichomoniasis, or chlamydia infections. The conclusion that can be drawn from this analysis of the pelvic exam data is that pelvic exams are generally very accurate at predicting the presence of vaginitis, but that some forms of vaginitis are asymptomatic, and may not be diagnosed by this method alone. This suggests that pelvic exams are not sufficient in themselves in the final determination of vaginitis.

Performance Characteristics – Healthy vs. Diseased Patients

The ability of the FemLab test kit to detect any of the various forms of vaginitis in vaginal fluid specimens collected in the multi-center study was compared to the results of the traditional tests for diagnosing any form of vaginitis.

Out of the 300 patients tested for any of the various forms of vaginitis, the FemLab and hospital control diagnoses agreed in 284 cases, resulting in an overall agreement of 94.7%. In 18 cases (6% of the total), both FemLab and reference methods concluded with a “Healthy” vaginal diagnosis. However, FemLab found 7 cases with some form of vaginitis that the

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83.1%; positive predictive value =80.1%; negative predictive value = 92.9%; and overall agreement = 86.7%.

Performance Characteristics – Trichomonas Infections

The traditional method of diagnosing trichomonal infections is a wet mount microscopic examination of vaginal secretions in saline. Careful examination may show moving organisms - trophozoites are about the size of a white blood cell with 3 flagella that cause the movement. Compared to DNA testing, which can pick up about 87% of positive Trichomonal cases, wet mount microscopy usually identifies only about half of cases. Symptoms can be similar to a yeast infection vaginitis. pH measurement of vaginal discharge for both is usually greater than 4.5.

Trichomonal Vaginitis is often asymptomatic, and even when symptoms are present, they correlate poorly with a clinical diagnosis of vaginitis. The relative lack of specificity of symptoms precludes a differential diagnosis based on symptoms. In the clinical study, Bacterial Vaginitis, Yeast infections, and Trichomoniasis were diagnosed on the basis of reference tests and the FemLab test results. The overlap of the various diagnoses from both test methods shown on Table VII below shows the results of different test methods in patients stratified by clinical diagnosis.

The ability of the FemLab test kit to diagnose Trichomonal infections was compared to the traditional method of wet mount microscopy used by the control laboratory.

In the trial population of 300 patients analyzed for Trichomonal Vaginitis, the FemLab diagnosis agreed with the reference control method in 264 cases (88.0% overall agreement). In the 85 cases where the hospital control methods produced positive tests for Trichomonal Vaginitis, the FemLab test also showed positive in 72 cases (84.7% sensitivity). (Sensitivity is the proportion of true positives that are correctly identified by the test. Specificity is the proportion of true negatives that are correctly identified by the test). In contrast, in the 215 cases where the hospital reference methods produced negative test results for Trichomonal Vaginitis, the FemLab results were positive in 23 cases (89.3% specificity).

Table VII - Trichomonas Vaginitis (Tv) Diagnosis Comparison between FemLab and Control Methods

		Control	Diagnosis	Method				
		Ty+	%	Ty-	%	Total	%	
Femlab Diagnosis	Ty+	72	24%	23	8%	95	32%	
	Ty-	13	4%	192	64%	205	68%	
	Total	85	28%	215	72%	300	100%	

Comparison To Control Methods: The FemLab test produced the following results for diagnosis of Trichomonal Vaginitis: sensitivity = 84.7%; specificity = 89.3%; positive predictive value 75.8= %; negative predictive value = 93.7%; and overall agreement = 88.0%.

Performance Characteristics – Other Vaginal Diseases

Sexually transmitted diseases such as syphilis, gonorrhea, HPV or Herpes are not detected directly by the FemLab test kit. In some cases of such diseases, such as an aggressive Herpes infection, the FemLab test may report pH, blood, or protein as positive due to the symptoms of the Herpes. In such cases, pelvic exams will clearly reveal the cause of the symptoms, and additional tests are widely available to confirm diagnoses. In cases of syphilis or gonorrhea also, symptoms will often be very specific for the disease state. Thus, even though FemLab may reveal no positive results when sexually transmitted diseases are causal factors of symptomology, an accurate diagnosis of the disease state can result from additional test procedures specific for such diseases.

Performance Characteristics – Multiple Diagnoses

Significant numbers of patients in the clinical trial were diagnosed with multiple forms of vaginitis. Eleven cases were diagnosed with 3 forms of vaginitis by FemLab – Bacterial, Chlamydia, and Trichomonal Vaginitis. An additional two cases also had yeast infections as well as the prior three. These diagnoses were confirmed by the control methods of testing. The

two cases with four diagnoses found by FemLab also had four diagnoses by control methods. Of the remaining eleven FemLab cases with three or more diagnoses, eight were picked up by the control methods as showing two or three diagnoses. In 11 of the 13 cases, the pelvic exam reported a IV+ result, showing severe symptoms.

Performance Characteristics – Summary

In Table VIII below, the statistical results of the comparisons between FemLab diagnoses and control method diagnoses for the four major infectious organisms responsible for vaginitis are shown.

**Table VIII
Statistical Measures of the Sensitivity, Specificity and Overall Agreement of the FemLab Test kit Compared to Control Methods**

Vaginitis	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Overall Agreement	Prevalence in trial population
Bacterial Vaginitis	89.4%	78.6%	68.9%	93.3%	82.3%	31%
Chlamydia Vaginitis	92.0%	92.0%	92.0%	99.3%	98.7%	8%
Trichomonal Vaginitis	84.7%	89.3%	75.8%	93.7%	88.0%	24%
Yeast Vaginitis	91.4%	83.1%	80.1%	92.9%	86.7%	39%

The Sensitivity and Specificity for each infectious organism are the key factors for evaluation of the efficacy of FemLab. The Sensitivity of the FemLab test kit – the agreement with the control methods for the positive diagnosis of the four various disease states - ranges between 84.7% and 92.0%. This means that FemLab can be considered very effective in the identification of the infectious organisms; a clinician can have a high degree of confidence in the results. Indeed, given the known uncertainties in the control methods of diagnosis, this level of agreement is excellent. In addition, the Specificity – the ability to obtain negative diagnosis agreement – is also very good, ranging between 78.6% and 92.0%. From the perspective of the FemLab test kit, many of these cases can be considered misdiagnosed by the control methods, giving a clinician additional confidence in the FemLab accuracy.

In addition, many cases of FemLab “misdiagnosis” compared to the control method for one particular disease state are in fact correctly diagnosed for another disease. For instance, many cases diagnosed with both Bacterial Vaginitis and Trichomoniasis by FemLab, only were diagnosed with Bacterial Vaginitis by the control methods. It is very possible that in fact these women did have Trichomonal infections as well, since the control method of diagnosis of Trichomoniasis – microscopic evaluation – is well known to be sensitive to technician error.

These results can be interpreted as providing a high level of confidence to a clinician for use of the FemLab test kit as a screening method. Only a very small proportion of patients are misdiagnosed compared to the control method, and many of these are diagnosed correctly for another infection. In summary, the clinical data show clearly that FemLab is very effective in diagnosing the major forms of vaginitis.