

Instructions for Use – FemLab[®] Vaginitis Test Kit

Intended use

FemLab is a biochemical assay intended for use as a screening test for nitrites, blood, protein, leukocytes, and proline-iminopeptidase in vaginal fluid samples, and also to measure vaginal fluid pH. It is indicated for use as an aid in the presumptive diagnosis of vaginitis or urethritis and should be used in conjunction with other laboratory tests such as Gram stain, microscopic examination, culture and KOH test. The FemLab Vaginitis Test Kit is for professional and laboratory use only.

The diagnosis of any vaginitis condition will depend on the careful analysis of the FemLab results, and the performance of the additional diagnostic tests mentioned above. 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 be referred to a medical professional for further evaluation and testing prior to diagnosis and treatment.

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 (parasites), Urethritis, Cervicitis and Inflammation. 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.

The FemLab test kit is an easy to use product that can screen for biochemical analytes that may be present with the common types of vaginitis within a few minutes. The test kit is intended to be used by a trained medical professional. The test kit is easy to use and only minimal training is necessary for staff level technicians to become proficient in the use of the kit. 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 interpreted by comparing the color change results for each of the six test zones to the colors on the test cassette, and then consulting the interpretation protocol described later in this document. The major forms of Vaginitis have biochemical characteristics that can be detected using this assay methodology. However these assays can not be used to diagnosis vaginitis or rule out the absence or presences of an infection.

FemLab results must be confirmed by culture, microscopic examination, gram stain and KOH test and treatment or recommended treatment regimens require the consultation of a medical professional. FemLab is not to be used for self-diagnosis and self-treatment.

Principles of the Test

The FemLab test kit has a total of seven sample application zones on a small plastic test cassette or tray. 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 biochemical tests that detect specific chemical or biological aspects of the vaginal fluid samples. Correct interpretation of the color changes in the test zones can assist the medical professional to presumptively screen for the various vaginitis 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. An interpretation protocol to presumptively determine the condition causing the vaginitis will be described in this document. The interpretative protocol detailed below, and the sample collection and application instructions must be followed closely. 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. A pH zone change to a light blue-green color – an abnormally high pH - is a positive finding, consistent with vaginitis caused by microorganisms that impair the growth of the normal vaginal lactobacilli, which keep pH low. Additional testing, such as microscopic evaluations and KOH testing will be necessary to identify the organism causing the low pH.

Zone 2a - 2b: PIP Zone

The proline iminopeptidase enzyme activity test is used in Zone 2. This test is indicative of the presence of certain strains of PIP producing bacteria in vaginal fluid specimens. The development of a visible peach-to-pink-to-red color on the test swab after

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application of the vaginal fluid sample onto the test zone is a positive PIP test result. No color change on the test swab indicates there is no PIP present in the specimen or the PIP is below the detection level.

Zone 3: Nitrite Zone

This test zone depends upon the chemical conversion of nitrate to nitrite by the action of most 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 nitrite producing organisms. If no color change is observed, this indicates no nitrites were detected or were below detection level.

Zone 4: Blood Zone

A vaginal infection may result in bleeding in the vaginal cavity. After application of the buffer diluted vaginal fluid sample onto the Blood Zone, a color change from yellow to dark green or blue is an indication of blood in the vaginal fluid. The presence of blood indicates the possibility of inflammation. A confounding factor can be the presence of menstrual blood in the sample, which may result in a false positive test. If menstrual blood may be present, this zone should be given less weight in the interpretative scheme.

Zone 5: Protein Zone

Application of the buffer diluted vaginal fluid sample onto the Protein Zone will result in a blue color if the protein concentration in the vaginal fluid exceeds normal levels. A blue color, a positive reaction, is consistent with the presence of inflammation, urethritis or other metabolic conditions. Some organisms cause the host to produce WBC's and Epithelial cells which will result in abnormal protein levels in the vaginal fluid..

Zone 6: Leukocyte Zone

Application of the buffer diluted vaginal fluid sample onto the leukocyte zone will result in a color change to pink or light purple if white blood cells are present. Light purple indicates a positive result, consistent with inflammation or infection. If there is no color change, this indicates no leukocytes or leukocytes below the detection limit.

Package Contents and Instructions for Use

Warnings and Precautions

- Check the expiration date printed on foil pouch and carton box. Do not use the test kit after the expiration date.
- Do not use the test kit if the foil pouch is not sealed, or if the pouch is broken.
- Do not remove the test from foil pouch until ready to use. Once the foil pouch has been opened, the test must be used within 60 minutes.
- To obtain accurate results, the Package Insert Instructions for Use must be read before using the test kit, and followed closely.
- Do not use the vaginal fluid collection container if it is broken or the buffer is leaking out.
- This product is intended only for vaginal fluid use. Do not touch or collect vaginal fluid near the cervix. Do not use vaginal fluid specimens that contain blood.
- Only use the sterile tri-pack swabs included with the test kit. Do not use sterile swabs if the package is not sealed or if the seal has been broken.
- Patient vaginal swabs are not appropriate for any other purpose, including bacterial culture, after performing the test.
- Dispose of patient samples in biological sample disposal containers
- FemLab is a screening test kit only. Any positive results should be referred to a medical professional for further evaluation.

Test Tray and Supplies

This package contains the following items:

- Vaginal fluid specimen container with buffer solution
- Tri-pack Sterile Swab
- Instructions for Use (Package Insert)
- Test Tray

Instructions for Use

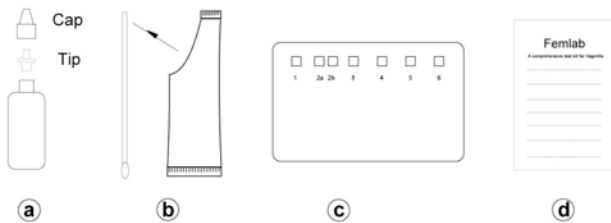
Femlab[®] Vaginitis Test Kit ■ ■ ■ ■ ■ ■ ■ ■

This test kit is intended for use by a trained medical technician, nurse, nurse practitioner, physician's assistant, or physician. The instructions for use shown below should be studied carefully and followed exactly to ensure accurate sample collection and application, and therefore reliable and accurate results.

The FemLab test kit may be used only on site in physician's offices, clinics, and hospital or professional laboratories – point of care sites - where women will visit in person to have the test performed. The test kit procedures may be performed only by trained medical professionals who have carefully read, and understand, the Instructions for Use. Samples must be tested on site, and may not be transported for testing in remote locations. The FemLab test kit may not be used at a pharmacy, unless the pharmacy is also a professional laboratory or other point of care site, where women visit in person to have the test performed by a medical professional who has been trained in the use of the test kit.

Drawing 1 – Contents of Package

Package Contents



- (a)** Vaginal Fluid Specimen Container with Buffer Solution
- (b)** Sterile Swab with Sterilized Handle in Sterile Packet
- (c)** Test Tray
- (d)** Package Insert

The package also contains this package insert and instructions for use. Patient records are recorded on the FemLab cassette by circling each positive or negative finding on the cassette label.

Collection of Vaginal Fluid Sample

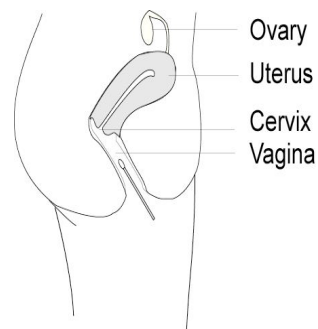
Open the package and identify the vaginal fluid specimen container with buffer (a), the tri-pack of three sterile swabs (b), the test tray (c) and the Instructions for Use package insert (d).

Wash hands thoroughly, and observe sterile technique while taking and testing vaginal fluid samples.

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. Gently open the vaginal opening, and insert the three swabs about two to three inches into the vagina. Do not insert near the cervix, as pH results would be inaccurate. Use extreme care if the patient is pregnant.

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



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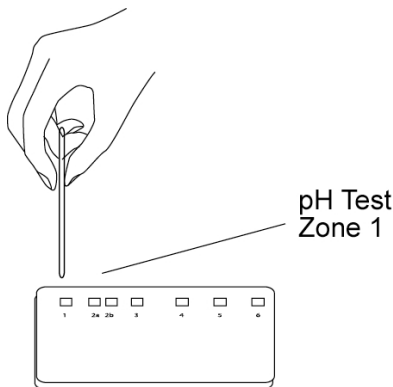
Gently stroke the inner walls of the vagina with the swabs, ensuring that the swabs are all moistened thoroughly. Leave the swabs in the vagina 3 to 5 minutes to ensure they are saturated with vaginal fluid.

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.

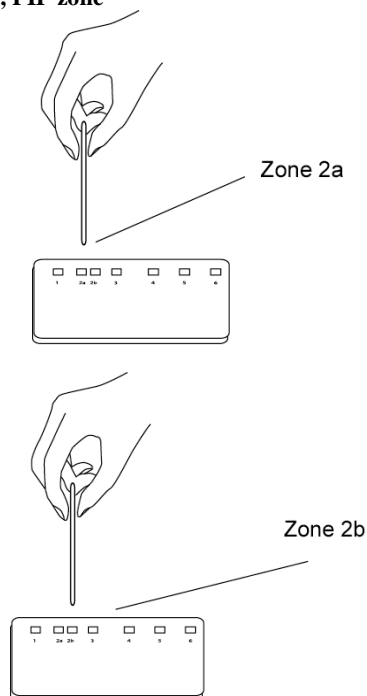
Rub one swab saturated with fluid sample onto Zone 1 - the pH zone – of the test tray. Discard the swab in a biological specimen container. Read the pH color after three minutes, and note the result on the Test tray next to the pH Zone Result color comparison chart. Simply circle the color – either positive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

Drawing 2b – 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 one minute. If the swab itself becomes peach or pink within one minute, it is a positive reading for PIP producing organisms. Record the PIP result on the test cassette near the PIP Zone Result color comparison.

Drawing 3 – Application of swabs onto test Zone 2, PIP zone



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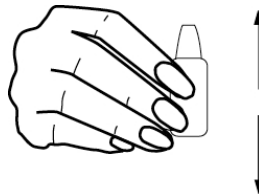
Finally, take the third swab, open the vaginal fluid specimen container with buffer solution, and thoroughly mix the swab into the buffer in the container. Swirl the swab vigorously for 15 seconds, and then expunge as much liquid as possible from the swab by pressing and rotating the fiber portion against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

Drawing 4 – Screw the Tip and Cap onto the Specimen Container.



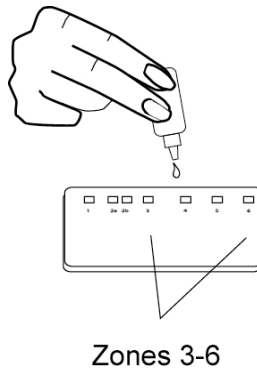
After the specimen container (a) is tightened securely, shake vigorously up and down ten (10) times.

Drawing 5– Shake vigorously up and down ten (10) times.



Squeeze the vaginal fluid collection container device above each of test zones 3 through 6. Use one drop on each of test zones 3 through 6.

Drawing 6 - Squeeze buffer solution and place the droplets into 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.

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Important Issues to Obtain Best Results

- a) The specimen used for pH testing must be an undiluted vaginal fluid sample.
- b) The specimen used for PIP testing must be a separate undiluted sample.
- c) The specimen used for the remaining tests must be diluted in the buffer solution container as directed.
- d) The collection of the vaginal fluid samples on the three swabs should be performed in a single step.
- e) Ensure that nothing remains inside of vagina after collection.
- f) 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.

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 laboratory 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. The Catalogue number is V02-NC for the negative control kit, and V02-PC for the positive control kit.

The manufacturer recommends that when a technician or other medical professional is being trained to use the test kit, the control solutions be applied to a test kit until the technician is familiar with the color changes to be expected. Thereafter, the controls should be used at the beginning of every quarter, or when a technician has not used the test kit for at least one month. Quality control should be performed following local state or federal regulations.

Kit Storage

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

Limitations of the test kit

- The FemLab test kit is to be used as a screening device by medical professionals only. Final diagnostic results should be rendered by medical professionals, who may recommend additional laboratory or medical testing to confirm any FemLab result.
- 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.

Interpretation of Results from the FemLab Test Kit

The major forms of Vaginitis can be presumptively determined by a careful analysis of the FemLab test results as recorded on the test cassette color chart. The results should be interpreted in conjunction with other laboratory tests such as Gram Stain, Microscopic exam, culture, and KOH. The following interpretative 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 interpretative 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 and indications of inflammation or urethritis – will describe the combinations of test zone results associated with a particular organism; and (3) issues of interpretation important to accurate results.

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 or inflammation. 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 inflammation.

Zone 2: PIP Test Zone: A peach-pink color indicates a positive result. The PIP test zone (2b) and the test swab used on Zone 2 will turn peach-pink within five minutes if PIP producers are present. A positive result indicates the presence of PIP activity. A negative result means that PIP enzyme is not present.

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. A positive reaction is consistent with the presence of nitrite producing organisms..

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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 inflammation if Leukocytes are also present, but may also be present with inflammation. If both zone 4 and zone 6 are positive (blood and leukocytes), this is indicative of inflammation. 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 inflammation. Serious occurrences of these infections cause the host to produce WBC's and epithelial cells which shows up as a positive result which is consistent with the presence of inflammation, urethritis or other metabolic conditions. A negative protein zone result is associated with the absence or low level of inflammation.

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 leukocytes, and is associated with inflammation. Positive leukocyte and blood results (zones 4 and 6) is also consistent with inflammation. A negative leukocyte zone result indicates the absence of leukocytes.

Identification of Infectious Organisms

The following Table I summarizes the interpretation method for the FemLab test kit.

To use the Interpretative Protocol in Table I, compare the test zone color results on the FemLab Test Kit to the test zones on the Table.

The cells in Table I indicate the general positive and negative interpretations for each Zone color result. Use this information to evaluate the presence of vaginitis as detected by the FemLab test kit results.

Caution: the results of the FemLab test kit are to be used for screening purposes only. Any positive result should be confirmed with Gram stain, culture, microscopic exam, and a KOH test, and referred to a medical professional for further evaluation and recommendations for additional testing prior to any diagnosis and treatment decisions.

Table I

FemLab Test Kit Test Zone Interpretation Table

Test Result	Positive Color	Negative Color	Positive Result Interpretation	Presumptive	Negative Result Interpretation
<u>pH Zone 1</u>	Blue-green	Pink	Inflammation or Abnormal pH		Normal pH.
<u>PIP Zone 2</u>	Pink	No color	PIP		No PIP
<u>Nitrite Zone 3</u>	Pink	No color	Nitrite		No or low level of Nitrite
<u>Blood Zone 4</u>	Blue	Yellow	Inflammation or Cervicitis		No inflammation
<u>Protein Zone 5</u>	Blue	Light Yellow-green	Inflammation,		No inflammation
<u>Leukocytes Zone 6</u>	Pink-purple	No color	Leukocytes, inflammation		No leukocytes or inflammation

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The performance of the FemLab test kit to detect pH, nitrites, protein, blood, and Leukocytes 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 (Asian population base) 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, Parasite vaginitis, and inflammation or Cervicitis. 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 PIP tests, wet mount microscopic evaluation of samples for parasites, and culture systems for detection of inflammation or Cervicitis. A pelvic exam was performed on each patient to determine overall level of vaginal health.

The terms positive (+) and negative (-) are used to refer to the presence or absence of the condition of interest, the presence or absence of an infectious organism. 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:

Percent Agreement Positive is the proportion of presumed positives that are correctly identified by the test, compared to the control method.

Percent Agreement Negative is the proportion of presumed negatives that are correctly identified by the test, compared to the control method.

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 than one, diagnosis of Bacterial Vaginitis, Yeast Vaginitis, Parasite vaginitis, inflammation or Cervicitis. 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

Table IV - 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 (described above) for diagnosing any form of vaginitis. The traditional tests used as control methods included commercially available pH and Gardnerella tests, wet mount microscopic evaluation of samples for parasites, and culture systems for detection of inflammation and yeast. A pelvic exam was performed on each patient to determine overall level of vaginal health.

Out of the 300 patients in the trial, the FemLab and Control diagnoses agreed in 266 cases that some form of vaginitis existed, resulting in an overall agreement of 94.7%. In 18 cases (6% of the total), both FemLab and Control methods concluded with a “Healthy” vaginal diagnosis. However, FemLab found 7 cases with some form of vaginitis that the Control methods interpreted as negative, while the Control methods found 9 cases with some form of vaginitis that were interpreted “Healthy” by FemLab. These results are shown in Table IV below.

Table IV
Healthy or Vaginitis Finding
Comparison between FemLab and Control Methods

				Control	Methods				

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				Diagnosis			
		Healthy	(%)	Vaginitis	(%)	Total	
FemLab	Healthy	18	6%	9	3%	27	9%
Result	Vaginitis	7	2%	266	89%	273	91%
	Total	25	8%	275	92%	300	100%

Analytical Sensitivity

The FemLab test kit reliably detects the required minimum concentrations of standard solutions with a positive test result. Analytical sensitivity studies performed by the manufacturer show that the desired analytical sensitivity levels for a positive FemLab result, as listed below, were met. The analytical sensitivity level was also stable between multiple production lots tested.

- pH Above 4.7
- PIP 20 pm/m
- Nitrite 0.06- 0.1 mg/dl
- Blood 0.015 - 0.062 mg/dl
- Protein 1.5 - 30 mg/dl
- Leukocytes 5 - 15 cells/h

Analytical Specificity

Samples of FemLab test kits were removed at random from three separate lots of finished product inventory for analytical testing. From these, three samples of the test kit from each of the three lots were analyzed with standard solutions prepared in the the Manufacturer laboratories at various concentration levels. Samples were then spiked with different levels of glucose, bilirubin and triglycerides. The concentrations of the standard solutions were adjusted in order to bracket and exceed the possible concentration levels of the potential interfering substances. The three compounds were chosen because human urine may contain glucose, bilirubin and triglycerides that could inadvertently mix with vaginal fluid during sampling. In these tests, the FemLab test produced only negative results, even after 10 minutes of reaction time, showing that these substance are unable to produce false positive FemLab results, even at high concentrations.

Interference Analysis

Potentially interfering drugs and other substances such as Acetaminophen, Atropine, Caffeine, Glucose, Penicillin, Sodium Chloride, Rite Aid Brand Decolorized Iodine Tincture, disposable douches, and spermicides were added to positive and negative control samples for interference studies. Normal (negative) vaginal fluid specimens as well as positive control samples were analyzed in parallel with samples containing a specific concentration of one of the potentially interfering substance listed above. The results of the interference study show that none of the substances interfered with the ability of FemLab to correctly analyze both positive and negative control samples. Both the normal (negative) sample and the positive control test solution were correctly diagnosed with FemLab irrespective of the presence of the potentially interfering substances. This test does not reflect any metabolic changes that might occur after a patient ingests a drug.

It may be concluded from this analysis that none of the potentially interfering substances interfered with the ability of FemLab to correctly analyze both positive and negative control samples. Both the negative and positive control samples were correctly interpreted by the FemLab test kit irrespective of the presence of the potentially interfering substances. However, it is not known if these agents can significantly affect pH, nitrites, or proteins, leukocytes or PIP, since no studies were done using patients ingesting these substances.

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

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