

Vaginal pH Rapid Test Cassette (Vaginal Secretions)



- 25 Test cassettes
- 1 Package insert

Materials Required But Not Provided

- Timer

INTENDED USE

Vaginal pH Rapid Test Cassette (Vaginal Secretions) is a pH rapid test for the determination of vaginal fluid acidity in human vaginal fluid specimens. The vaginal determination of the pH is a very useful screening parameter as it is an indication for most clinical and subclinical vaginal infections. This kit is intended for use as an aid

1. in the diagnosis or prevention of possible vaginal infections in both pregnant and not pregnant women and
 2. to provide the physician for a clinical reference and increase chances of a successful pregnancy.
- The test is designed for professional in vitro diagnostic use. The assay should not be used without proper supervision and is not intended for over the counter sale to lay persons.

SUMMARY

An acidic vaginal pH value of 3.8 to 4.5 is a basic requirement for the optimal functioning of the body's own system of protecting the vagina. This system can effectively avoid colonization by pathogenic germs and the occurrence of vaginal infections. The most important and most natural protection against vaginal problems is therefore a healthy vaginal flora. There are many factors that regulate the composition and dynamics of the vaginal microbial ecosystem and that maintain the natural protective functions of the vagina. One important factor is lactobacilli. Under the influence of lactobacilli, the glycogen released from the upper vaginal epithelium degrades to form the glucose and then lactic acid. This results in an acid environment forming in the vagina, with a pH value that is usually 3.8 to 4.5. This acidic vaginal environment forms effective protection against infections, because the vast majority of pathogenic bacteria cannot settle and proliferate under such conditions. The physiological vaginal pH level is therefore dependent on the quantitative presence of the lactic acid.

In pregnant women it may decide to prevent the pathogenic bacteria from migrating to the uterus where they may cause complications like early contractions or a premature rupture of the amniotic membrane. The growth of the germs in the vagina mostly goes unnoticed. The earlier this disorder is detected by a regular testing of the vaginal pH, the earlier appropriate action can be taken to reduce the risk of a premature birth. A determination of vaginal pH is also significant in not pregnant women to prevent proliferation of bacteria which may lead to many gynecological complaints and complications including sterility. A routine testing may help determine potential infections.

The pH level in the vagina is subject to fluctuations, possible causes for a high pH level are bacterial infections, sexually transmitted diseases, a PROM event, estrogen deficiency or excessive intimate care.

PRINCIPLE

Vaginal pH Rapid Test Cassette (Vaginal Secretions) consists of two components: an applicator and a color chart. The test applicator is packed separately to assure hygienic and dry conditions. The applicator includes a dry chemical pad to determine the pH value in vaginal fluid specimens. The pH color development is adjusted to the range of vaginal acidity and allows for an interpretation of small changes in vaginal acidity. Vaginal pH Rapid Test Cassette (Vaginal Secretions) is a reliable, hygienic, pain-free method of determining the vaginal pH level. As soon as the convex pH measurement area on the applicator comes into contact with vaginal secretion, a color change occurs that is to be assigned to a value on the color scale. This value is the test result. Vaginal pH Rapid Test Cassette (Vaginal Secretions) is a vaginal applicator of approx. 3 inch in length with an integrated pH measurement pad. The vaginal applicator consists of a round handle area and an insertion tube of approx. 2 inch in length. On one side at the tip of the insertion tube is a window, where the indicator area of the pH strip is located (pH measurement area). The round handle makes it safe to touch the vaginal applicators. The vaginal applicator is inserted approx. one inch into the vagina and the pH measurement area is pressed gently against the back wall of the vagina.

When collecting the vaginal fluid with the applicator the reactive pad is moistened with vaginal fluid specimen, the pH value of the specimen will change its color and the vaginal applicator is then removed from the vagina. By comparing the color of reagent pad with the standard color chart on the package foil, the detail result will be obtained.

PRECAUTIONS

- For professional in vitro diagnostic use only
- Test applicator is for single use only
- Do not freeze any components of the test kit
- Do not use components after stated expiration date (see pouch and box label)
- Do not use test if pouch is damaged
- Do not eat, drink or smoke in the area where the specimens or kits are handled
- Handle all specimens as if they contained infectious agents
- Observe established precautions for microbiological risks throughout all procedures and standard guidelines for appropriate disposal of specimens
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested
- Used testing materials should be discarded according to local regulations
- Humidity and high temperature can adversely affect results
- Bring all reagents to room temperature (15-30°C) before use
- Do not touch the reaction area of the applicator to avoid contamination
- The test applicator should remain in the sealed pouch until use
- Interpret results immediately after removing the applicator from vagina
- Store and transport the test device always at 10-30°C
- The potentially hazardous components of the test (chemicals) do not constitute any danger if test device is used according to instructions
- Do not use urine as liquid. Urine may cause a false test results
- Use test immediately after unwrapping
- It is recommended to make sure that the person interpreting the results of the applicator is tested for color blindness
- Please take the specificity and cross reactivity into account for evaluation
- Do not wash or shower the area immediately before starting the determination
- Certain events may temporarily affect the vaginal pH level and lead to false results. Therefore, the test should only be performed:
 - after more than 12 hours after last sexual activity or use of vaginal medical products (suppositories, creams, gels, etc.)
 - after more than 15 minutes after urinate
- Make sure to not test the first 3-4 days after the end of the last period

STORAGE AND STABILITY

The kit should be stored at 10-30°C. The test is stable through the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze! Do not expose to direct sunlight.

MATERIALS

Materials Provided

- Wait 15 minutes after last urine flow to perform the test. Patient should make sure (by wiping) that no urine is left at the vaginal entrance, if she just has used the toilet, as urine may change the acidity and interfere the test result.
- It is important not to perform the test within 12 hours after having sexual intercourse 12 hours after introducing the patient's vagina any substances like spray, cream, gel etc.
- Vaginal pH Rapid Test Cassette (Vaginal Secretions) cannot be used during menstruation and should be performed at least 3-4 days after the end of monthly period.
- Vaginal pH Rapid Test Cassette (Vaginal Secretions) cannot be used when the patient is taking antibiotics. These factors may change the vaginal pH and yield invalid results.
- Before using the test the patient should not have any bath or shower.
- Patient should not wash or rinse vagina before test as this will affect her vaginal pH value.

DIRECTIONS FOR USE

Bring tests and/or external controls to room temperature (15-30°C) before testing. Review instructions for Specimen collection. Do not open package foil until ready to perform the assay.

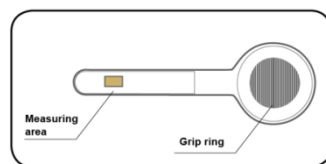


Fig. 1

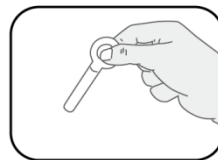


Fig. 2

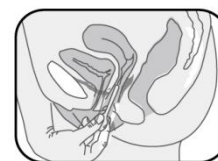


Fig. 3

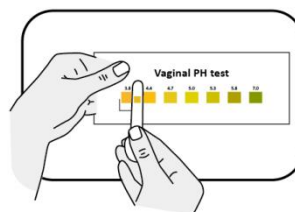
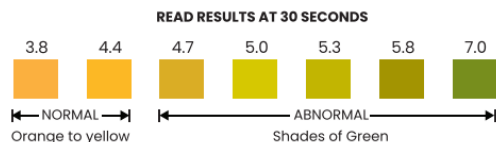


Fig. 4

1. Remove the test applicator from its sealed pouch, and use it as soon as possible. For best results, the assay should be performed immediately after opening the sealed pouch. Make sure that the pH area does not come in contact with other liquids.
2. Insert the applicator into the vagina no deeper than 2-3 cm (1 inch), but not beyond the round handle area. It is necessary to leave the applicator in the vagina to soak the applicator for approximately 10 seconds. Make sure the pH area is well moistened.
3. Withdraw the applicator. Do not touch the applicator with fingers after withdrawing it from vagina.
4. Read the result **immediately** after removing the applicator from the vagina by comparing the color of the reagent pad with the color chart printed on the pouch (the value on the color scale that is most similar to the pH level you have determined). Changes in color after more than 1 minute are of no diagnostic value.
5. Dispose of the used applicator.

INTERPRETATION OF RESULTS

Semi-quantitative results are obtained by visually comparing the color of pad with the corresponding test color block displayed on the pouch printing. No further equipment is required.



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REF VPH-502a

A healthy vagina has a pH lower than 4.4. The color of the indicator is yellowish to yellowish-grey

Vaginal pH levels over 4.4 are outside of the normal / healthy range. The color of the indicator is darker and becomes a brown-green-blue shade.

If the patient's pH value is outside the normal pH range on one occasion, perform a second test a few hours later or the next morning. If the second measurement still displays an elevated pH value a further investigation by a physician should be done. Please keep in mind, that stress or certain food may temporarily change vaginal pH value.

IMPORTANT: If the pH determination does not display a uniform color after the test has been performed, this is a warning that the test has not been performed properly. A possible cause is that the pH measurement area was not sufficiently moistened with vaginal secretion. If this is the case, you can perform the measurement again with the same vaginal applicator. However, you can also use a new test. Use the color scale on the foil packaging to evaluate the test

QUALITY CONTROL

External controls are not supplied with this kit. It is recommended to perform positive and negative controls for each kit as good laboratory practice to confirm the test procedure and to verify proper test performance and as deemed necessary by internal laboratory procedures.

LIMITATIONS

Comparison to the color chart is dependent on the interpretation of the individual. It is therefore, recommended that the person interpreting the results of these applicators be tested for color blindness. As with all diagnostic tests, a definite clinical diagnosis should not be based on the results of a single rapid test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Measurement range:

The measurement range of vaginal pH test was determined by testing three lots 10times at different pH from pH 3.0 up to pH 8.0. The pH of the solutions was adjusted by pH electrode. The interpretation of the vaginal pH test was done by comparison with the color chart.

In all three lots, the pH range from 3.8 to 7.0 was detected. The measurement range includes the physiological important pH value of 4.4 and has definite separations of the pH color of the pH indicator below and above pH 4.4.

Diagnostic specificity and Sensitivity:

Buffer solutions in the range of pH 3.8 to 7.0 were prepared and used as samples. The pH of these samples was determined by pH electrode and by Vaginal pH test. Both results were compared and evaluated regarding of their physiological evidence.

Specimens up to pH 4.4 are classified as positive samples. Above pH 4.4, specimens are classified as negative.

Results are showed in below table:

		pH electrode	
		+	-
pH test strip	+	63	7
	-	0	209

=> Sensitivity: 100%

=> Specificity: 96.8%

Interferences:

Following substances were added to buffer solutions with pH 3.8; 4.4; 4.7; 5.0; 5.3; 5.8 and 7.0. The pH was adjusted after adding the substances: Acetaminophen, Ascorbic Acid, Salicylic Acid, Atropine, Caffeine, Glucose, Hemoglobin, Ampicillin, EDTA, Ephedrine, Ibuprofen, Ethanol, Phenylpropylamine, Tetracycline, Human Albumin, Bilirubin, Creatinine, Estradiol, Estriol, 3-Hydroxybutyric Acid, Pregnanediol, Progesterone, Riboflavin, Uric Acid, Urea, Lactic acid, Glycerol, Acetic acid.

Expect of hemoglobin at higher concentration, none of the substances added showed any influence to the test result. Hemoglobin at concentrations form 2 mg/dl made a color shift to red. If there is only a small shift of the color, an interpretation is still possible as was shown at 1 mg hemoglobin / dl. Higher amounts of hemoglobin will appear in the vaginal fluid at the period of the women.

Specificity

Following actions and substances possibly interfere:

- Urine is left at the vaginal entrance, as urine may change the acidity and the test result.
- Performing the test within 12 hours after having sexual intercourse or 12 hours after introducing the patient's vagina any substances like spray, cream, gel etc.
- Performing the test during the patient's period.
- Antibiotics. This factor may change the bacterial environment of the vaginal tract. Thus, a change in the pH might occur and give invalid results.
- Having any bath or shower before using the test, as soaps and detergents may change the vaginal pH.
- Vaginal douche or rinse before testing because will change the vaginal pH.

The test is influenced by many detergents, soaps, disinfectants agents and alcohols if these substances are used at the vagina. In addition, antibiotics and some pharmaceuticals might influence the test indirectly by changing the bacterial environment. Foodstuffs or beverages have little influence on the vaginal pH.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Revision Date: 2022-02-21