

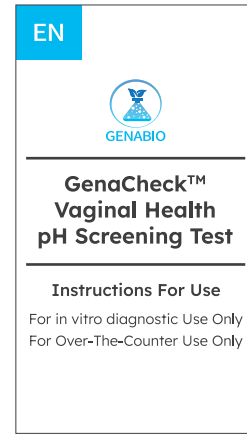
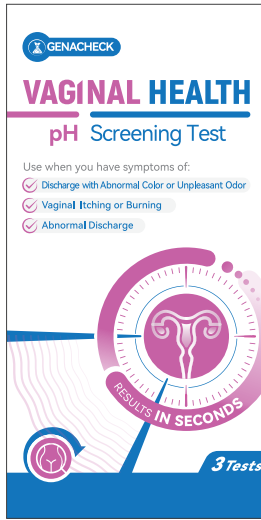


VAGINAL HEALTH pH SCREENING TEST



- ✓ FDA Cleared for At-Home Use
- ✓ Results in Seconds
- ✓ CLIA-Waived
- ✓ Easy-to-Read



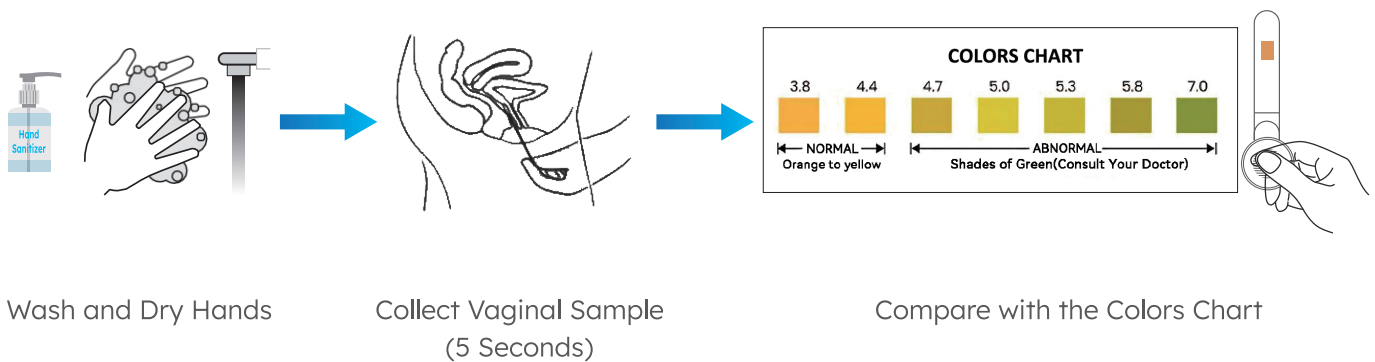


PRODUCT FEATURES

Quick: Results in Less than 30 Seconds

Easy: One-Step - No additional Sampling Cotton Swab Needed

Convenient: Stored at Room Temperature




ORDER INFORMATION

Name	Item No.		Package	
GenaCheck™ Vaginal Health pH Screening Test	RA9-E02303		3 Tests per Box	
	Dimension	Pack Size	Gross Weight	Quantity
Carton	L: 37cm w: 25cm H: 33cm	102 (boxes per carton)	4kg	306 (tests per carton)
Pallet	L: 112cm w: 100cm H: 111cm	36 (cartons per pallet)	184kg	11016 (tests per pallet)


SUGGESTED GUIDANCE ON pH RESULT AND INFECTION TYPE

Vaginal Infection	Yeast Infection	Bacterial Vaginosis	Trichomoniasis
Associated Symptoms	Likely	Sometimes	Sometimes
Itching, Burning, Irritation			
Discharge	Thick, cottage cheese-like	Thin, milky	Frothy, yellow-green
pH Results	4.5	> 5.0	> 5.0
Next Steps	Vaginal Antifungal	Consult Healthcare Provider	Consult Healthcare Provider

FREQUENTLY ASKED QUESTIONS (FAQ)

What does this test do?

This is a Home-Use test kit which measures the pH value of the vagina.

What does the pH value indicate?

A pH value represents how acidic or basic a substance is, in this case, vaginal discharge.

The standard pH scale runs 1 to 14, where acids have low values (≤ 7), and bases have high values (≥ 7).

The pH of your vagina fluctuates throughout your cycle and is generally acidic, an acidic environment prevents bacteria, yeast and other microorganisms from overgrowing.

Your vaginal pH can change if you have an infection.

Why Should You Take this Test?

This test helps to evaluate if your vaginal symptoms (i.e., itching, burning, unpleasant odor, or unusual discharge) are caused by an infection that would require medical attention.

How Accurate is the Test?

Home vaginal pH tests show good agreement with the diagnosis of a Healthcare Provider.

Not all changes in vaginal pH indicate a vaginal infection.

Other than the pH test, a number of tests can be used by a Healthcare Provider to diagnose a vaginal infection (including testing of vaginal culture, gram staining and/or pap smear) in addition to examination of vaginal discharge using the microscope.

Does a Positive Test Surely Indicate a Vaginal Infection?

Not always. Sometimes, a positive test (elevated pH) can occur due to other causes.

See your Healthcare Provider for a consultation and treatment if you do test a high pH value.

Does a Negative Test Result Surely Indicate a Vaginal Infection?

Not always. Sometimes you may have an infection that is not detected.

If you have no symptoms, your negative test could suggest the possibility of a(n) chemical, allergic or other noninfectious irritation of the vagina.

A negative test with symptoms could also indicate a possible yeast infection.

You should see your Healthcare Provider if you find changes in your vaginal pH or if you continue to have symptoms.

Is This Same Test Used at the Medical Office?

The home vaginal pH test is practically identical to the ones sold to Healthcare Providers.

However, your Healthcare Provider can provide a more thorough assessment of your vaginal condition by evaluating your medical history, physical exam, and/or perform additional laboratory tests. These make Healthcare Provider assessments more comprehensive than using a single pH test to determine if you have an ongoing infection.

Establishment Registration & Device Listing

FDA Home Medical Devices Databases



New Search	Back To Search Results
Proprietary Name:	GenaCheck Vaginal Health pH Screening Test
Classification Name:	PAPER, OBSTETRIC PH
Product Code:	LNW
Device Class:	1
Regulation Number:	862.1550
Medical Specialty:	Clinical Chemistry
Registered Establishment Name:	GENABIO DIAGNOSTICS INC
Registered Establishment Number:	3016609999
Owner/Operator:	Genabio Diagnostics Inc.
Owner/Operator Number:	10063095
Establishment Operations:	Specification Developer

Page Last Updated: 03/11/2024

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [العربية](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [فارسی](#) | [English](#)



GenaCheck™ Vaginal Health pH Screening Test

Instructions For Use

For in vitro diagnostic Use Only
For Over-The-Counter Use Only

Product Description

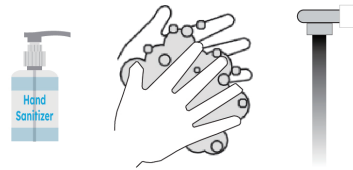
GenaCheck™ Vaginal Health pH Screening Test is a home-use, Over-The-Counter test strip to measure the pH in the vagina. Normal vaginal pH level is between 3.8-4.4. The normal pH environment is acidic and it creates a barrier that prevents the infections from unhealthy bacteria. Infections may cause an elevated vaginal pH level. The test range of this test kit is 3.8-7.0.

Intended Use

It is used to determine the pH level of the vaginal fluid.

Step By Step Instructions

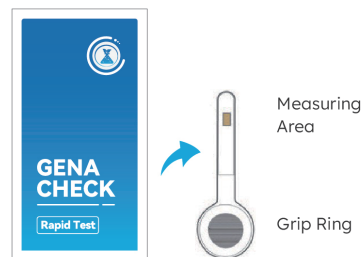
- 1 Wash and dry your hands.



- 2 Open the package and take out one pouch.

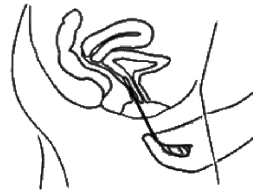
- 3 Take the Test Strip out of the pouch by holding the Grip Ring.

Note: Avoid the pH Measuring Area coming into contact with other liquids.

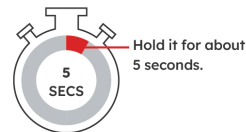


- 4 Sit down with the knees apart or stand with one foot on a stable surface, then spread apart your labia with your free hand.

- 5 Gently insert the Measuring Area into the vagina up to about 1-3 cm.



- 6 Press the strip against the vaginal wall gently. Hold it for about 5 seconds.

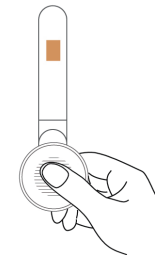
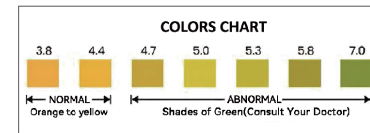


- 7 Remove the test strip from the vagina. Be careful not to touch the Measuring Area of the strip.

- 8 Compare the color of the Measuring Area immediately to the color chart below or on the pouch to determine the results.

How To Read The Results?

Compare your Measuring Area of the strip you used to the color chart below and find the best matching color.



Normal: Your vaginal pH is normal if it is below 4.4. If you continue experiencing itching, burning, or abnormal discharge, consult with your doctor.

Abnormal: If your pH test falls into the "Abnormal" category per the color chart, please talk to your doctor about your symptoms and the results of this test.

Test Principle

The GenaCheck™ Vaginal Health pH Screening Test is a reliable, painless method to determine vaginal pH. As soon as the Measuring Area of the Test Strip comes into contact with the vaginal secretions, its color changes. The color obtained corresponds to a pH value on the measuring scale and gives the test result. Regular use of the self-test for vaginal infections test is a reliable way to detect vaginal flora disorders.

When Do I Need To Use The pH Screening Test?

Use the GenaCheck™ Vaginal Health pH Screening Test if you experience these symptoms:

- ✓ Unusual vaginal discharge
 - ✓ Unpleasant odor
 - ✓ Itching
 - ✓ Pain or burning during urination or sexual intercourse
- This is NOT a test for diseases such as HIV, chlamydia, herpes, gonorrhea or syphilis.

Storage

- Store at room temperature 2 -30°C (36-86°F) out of direct sunlight.
- DO NOT refrigerate.
- Keep out of reach of children.
- DO NOT open the pouch until ready to use.

Warnings And Precautions

- DO NOT reuse the test kit.
- DO NOT use if the product passes the expiry date.
- DO NOT use if the pouch is broken.
- DO NOT perform the test if you have signs of menstrual or vaginal bleeding.
- For testing of vaginal pH only.
- This is NOT a test for STDs, including HIV, chlamydia, herpes, gonorrhea, or syphilis.
- Used test strip(s) should be discarded after use.

Materials Provided

- 3 x Test strips
- 1 x Instructions for Use

Limitations Of Use

Comparison to the color chart is dependent on the user. Reading of the results may be affected if you have color blindness.

As with all rapid tests, major decisions about your health should not be based on any single test result. Consult with your physician if you have any questions or concerns.

Frequently Asked Questions

Q: Does a normal vaginal pH mean that I do NOT have an infection?

A: No. You can have a vaginal infection and still have a normal pH. If you have symptoms of a vaginal infection of any sort, see a healthcare provider or consult with your physician.













Q: Does an abnormal vaginal pH indicate an infection?

A: Abnormal vaginal pH frequently indicates the presence of a vaginal infection. However, not all vaginal infections cause changes to vaginal pH.

Q: What do I need to do if I have an abnormal vaginal pH result?

A: You should see your doctor if you find changes in your vaginal pH or if you continue to have symptoms.

Index Of Symbols

 Do Not Re-use	 Consult Instructions For Use
 Test Per Kit	 Store At 2-30°C (36-86°F)
 Batch Number	 Catalog #
 Unique Device Identifier	 For <i>in vitro</i> diagnostic Use Only
 Expiration Date	 Keep Away From Sunlight
 Keep Dry	 Manufacturer

Assistance

For questions or comments please call Genabio Customer Service at 1-800-614-3365 (9:00 - 17:00 EST).

Manufactured For Genabio Diagnostics Inc.

Address: 19 Crosby Dr., Ste 220, Bedford, MA 01730, USA
Phone: 1-800-614-3365
Hours of Operation: 9:00-17:00 EST
Email: info@genabio.com
Website: www.genabio.com

Document No.: RA9-U02303
Rev. 00
Effective Date: February 9, 2024

COMPANY INTRODUCTION

Genabio is a global leader in the production of over-the-counter self-testing products, with an impressive sales record of over \$100 million in the past three years. Our extensive customer base spans across the USA, Canada, the UK, Japan and India.

A significant aspect of our product range is the FDA approval, including the COVID-19 Rapid Self-Test Kit. These sought-after products can be found in thousands of locations, including renowned pharmacy chains like Walgreens, leading hospitals such as NYU Langone Health, accredited laboratories like SV Diagnostics Labs and Molecular Testing Labs, and various government departments.

In 2023, Genabio marked a pivotal moment in initiating our listing and financing efforts in Hong Kong. Simultaneously, we are focused on enhancing our brand identity and emphasizing clinical research within the United States. This commitment to research and development aligns with our expansion plans, which encompass increasing our production capacity in both the United States and China.

Our overarching vision is to be the world's foremost provider of self-testing solutions, offering precise, user-friendly, and cost-effective health diagnostics for individuals worldwide.

Our mission is to enhance global health awareness and accessibility, by delivering quality, FDA-approved self-test kits, by driving innovation, and by expanding our reach to ensure individual scan monitor their health with precision and convenience.



CONTACT US

Website: www.genabio.com

Email: info@genabio.com

Phone: 1-800-614-3365