**Vaginal Health Test**

**Package Contents**
The MONISTAT® CARE Vaginal Health Test contains two individually foil-wrapped swab testing units and 1 package insert.

**Indication/Intended Use**
The MONISTAT® CARE Vaginal Health Test is a home test kit, to be used by women of menstruating age, to test the acidity of vaginal discharge. It is intended for women who have any of the following symptoms; vaginal itching, vaginal burning or an abnormal color, odor, or excessive amount of vaginal discharge. The test may help determine if your symptoms are caused by an infection that may require follow-up by a healthcare provider.

**Pregnancy Warning**
Note: Vaginal infections can be very risky for pregnant women and dangerous to the mother and her fetus. Bacterial vaginosis and other infections may cause complications in pregnant women including premature birth. Please consult your healthcare provider before using the MONISTAT® CARE Vaginal Health Test.

**Understanding Vaginal Infections**
Vaginal infections are quite common and can be a recurring problem for some women. Abnormal vaginal discharge, unpleasant odor and the itching or burning associated with it can be a sign of a vaginal infection, inflammation or irritation of the vagina is called vaginitis. Vaginitis can be due to an imbalance of healthy bacteria in the vagina and is one of the most frequent reasons women visit their gynecologist. Bacterial vaginosis (BV) causes 40–50% of vaginal infections in women aged 10–30–35% of cases in pregnant women. Candidiasis (commonly known as yeast infection) accounts for 70–75% of vaginitis cases in all women, and Trichomoniasis, a parasitic infection, causes 15–20% of cases. While yeast infections may be treated by over-the-counter antifungal medications, other vaginal infections may require evaluation by a healthcare provider and prescription medication for treatment.

**How does the MONISTAT® CARE Vaginal Health Test Work?**
The test swab changes color when the acidity of the vaginal discharge is abnormal (pH level is elevated or the discharge is “watery”). “Watery” discharge is abnormal in 10–20% of cases. Other factors are known to accompany bacterial and parasitic infections, as well as some non-infectious causes (including estrogen deficiency). Determining if your vaginal discharge acidity is abnormal can help you assess whether your vaginal symptoms are likely caused by an infection that may require follow-up with your healthcare provider.

The discharge associated with a healthy vagina will normally have a pH value up to 4.5. Yeast (fungus) infections do not usually have an elevated vaginal pH level. If the test indicates that your discharge has a normal acidity, you are experiencing symptoms of an infection, as described above, you may have a yeast infection. Some vaginal infections known to be associated with abnormal vaginal acidity (including BV and Trichomoniasis), may cause the vaginal pH to be 5.0 or higher. These infections must be treated by your healthcare provider. Some cases of abnormal discharge with abnormal acidity may be caused by a combination of infections. For accurate infection diagnosis, you should visit your healthcare provider who may use various assessment methods to determine your specific condition.

This test assesses your vaginal discharge and indicates whether your vaginal acidity is normal or abnormal. It does not indicate a specific vaginal infection. For any positive test (abnormal vaginal acidity), discuss your symptoms and results with your healthcare provider; do not treat yourself with OTC (over-the-counter) antifungal creams.

**Precautions**
• This product is not a test for diseases such as HIV, chlamydia, herpes, gonorrhea or syphilis, or for Group B Streptococcus.
• Other factors may affect vaginal acidity (pH) levels. These include blood, semen, menstrual and perineal/perineum (erv estrogen), bacteria and Trichomoniasis.

• If you are pregnant, consult your healthcare provider before use, as interpreting test results during pregnancy requires professional knowledge.
• Do not use with test if you have any signs of menstruation or any vaginal bleeding.
• Do not use the test if it is less than 1 day before, or 5 days after your period.
• Do not perform the test if you have any signs of menopause or any vaginal bleeding.
• Do not use the test if it is less than 48 hours after sexual intercourse or vaginal douching.
• Do not use the test if you are perimenopausal or menopausal and are not on hormonal therapy.
• Other factors may affect vaginal acidity (pH) levels. These include blood, semen, menstrual and perineal/perineum (erv estrogen), bacteria and Trichomoniasis.

• Do not use the test while sweating (e.g., during or immediately after exercise).
• Do not use this test until 72 hours after the application of vaginal preparations like contraceptive creams. Antifungal treatments do not interfere with test results.

**Directions for Use**
1. Keep the protective foil package containing the test swab sealed until use for use to avoid contamination.
2. Wash and dry your hands.
3. Unwrap the individual swab testing unit. If the swab is damaged or the tip is stained, dispose of the test and use a new one.
4. Make sure that the swab tip is clear and free of dirt, before inserting into the vaginal entrance.
5. Hold the test swab with your fingers on the handle of the swab.
6. Gently insert the yellow tip of the swab until your fingers reach the outer skin of the vagina approximately 2 inches (5 cm) into the mid vagina and very slowly rotate the swab several times. Do not touch the vaginal entrance.
7. Gently rotate the swab from your vagina. Carefully avoid wiping the tip making contact with anything, and check that it has collected a visible amount of secretion.
8. Wash your hands after you finish handling the MONISTAT® CARE Vaginal Health Test.
9. Dispose of the swab after usage as you would any other feminine hygiene product.
10. Do not perform the test if you have any signs of menstruation or any vaginal bleeding.

**Reading Your Results**
- Check the tip of the swab for color changes from yellow to blue or green.
- If the tip is stained (including partially stained) blue or green, your vaginal acidity (pH) is abnormal, and you may have a vaginal infection. You should see your healthcare provider for further testing and treatment. Do not self treat with an over-the-counter antifungal.
- Important: If you are pregnant and the tip is stained blue or green, the color may indicate an amniotic fluid leak. It is important to consult your healthcare provider as soon as possible.
- If the test does not change color, your vaginal acidity (pH) is normal. However, if you are experiencing symptoms of an infection (i.e., abnormal discharge, itching, irritation, or burning) you may have a yeast infection. If this is your first yeast infection, see your healthcare provider.

**Repeating the Test**
If you are not certain that vaginal discharge was collected on the test, perform a second sampling. If the tip is stained blue or green on either test, your vaginal acidity is abnormal, and you should consult your healthcare provider.

**Storage**
Store in a dry place at room temperature 59°F to 86°F (15°C to 30°C). Keep the protective foil package containing the test swab sealed until use to avoid need for contamination.

**Frequently Asked Questions**

1. Why is vaginal acidity important?
- Normal vaginal bacteria produce factors that keep the vaginal environment slightly acidic. The acidic environment helps suppress the overgrowth of abnormal bacteria. When abnormal bacteria overgrow or parasitic infections like Trichomoniasis become established, this results in abnormal vaginal acidity. Not all vaginal infections are associated with a change in vaginal acidity—yeast infections usually do not result in a change in vaginal acidity.

2. Are all vaginal infections yeast infections?
- No. In fact, the most common vaginal infection is bacterial vaginosis (BV), which is an infection caused by an imbalance of bacteria in the vagina. Bacterial vaginosis is distinguished by a fishy odor and a thin, grayish-white discharge and a drop in vaginal acidity. BV is caused by an abnormal growth of bacteria and must be treated with prescription antibiotics. By contrast, yeast infections do not usually cause an odor, and the discharge will often be thick, white, and clumpy associated vaginal itching and irritation. If left untreated, BV may lead to a serious infection of the reproductive organs called pelvic inflammatory disease, including premature birth. You should see your doctor if you are experiencing symptoms like a fishy odor, change in discharge, or sudden irritation within 48 hours after a new sex partner to make sure you do not have a sexually transmitted disease.

Another common vaginal infection is Trichomoniasis (Trich) which is a parasitic infection. Symptoms of Trichomoniasis may include: itching, burning, redness or soreness of the genitals, discomfort with urination, or a thin discharge with an unusual smell. The discharge can be clear white, yellowish, or greenish. Like BV, Trichomoniasis must be treated by a healthcare provider.

There are also non-infectious causes of vaginitis, vaginal inflammation and irritation. These are usually caused by an allergic reaction or irritation from vaginal sprays, douches, spermicidal products, soaps, detergents, or fabric softeners. Burning, itching, or vaginal discharge may be present even if there is no infection.

3. Are BV and Trichomoniasis treated the same way as a yeast infection?
- No. BV is caused by an abnormal growth of bacteria and must be treated with prescription antibiotics. Trichomoniasis is a parasitic infection and must be treated with prescription antibiotics. If you think you have a yeast infection and are familiar with the symptoms because you have been previously diagnosed with a yeast infection, you can try an over-the-counter antifungal remedy such as Monistat®. If this is your first yeast infection, see your healthcare provider.

4. Why should I be concerned about BV and Trichomoniasis?
- BV and Trichomoniasis may lead to complications in pregnant women, including serious infections and premature birth. Trich can also increase the risk of getting or spreading other sexually transmitted infections.

5. If I have a yeast infection, burning, and abnormal discharge, and I receive a result of abnormal acidity detected, what should I do?
- You should discuss your symptoms with your healthcare provider to help determine the best treatment for your vaginal discharge and symptoms.

6. If I have a yeast infection, burning, and/or abnormal discharge, and I receive a result of abnormal acidity detected, what should I do?
- You may have a yeast infection. If this is your first yeast infection, it is important that you talk to your doctor; however, if you are in good health, have been previously diagnosed with a yeast infection and are familiar with the symptoms, you may be treated with an over-the-counter antifungal remedy such as Monistat®. Monistat® can begin to relieve symptoms soon after the first dose, with a full cure after several days.

7. Can I have more than one type of infection at one time?
- Yes, in one study, 21.1% of the women with presumed yeast infection actually had mixed infection (a combination of yeast or bacterial infection and/or Trichomoniasis).

8. Can I take a shower before using the test?
- Yes. Showering before will not affect the results; however, make sure you are completely dry before using the test as excess water may affect the test result.

9. How accurate is the screening kit for vaginal Infections?
- In a clinical study of pre-menopausal women where the physicians used the test kit, the kit detected 91.8% of cases with an abnormal pH associated with a bacterial or Trichomoniasis infection. In 92.9% of cases of no bacterial infection, the kit indicated normal vaginal acidity. In another study where women used the test, there was a 92% agreement between the patient and physician reading of the results.

10. Are there any other factors that can affect my results?
- Yes. Besides infections such as BV and Trichomoniasis, other factors that may affect vaginal acidity (pH) levels include blood, semen, perimenopause and perineum (erv estrogen).
Prueba de salud vaginal

Contenido del paquete
La prueba de salud vaginal MONISTAT® CARE contiene dos unidades con hisopos para prueba con envoltorio de papel aluminio y 1 prospecto.

Indicaciones y uso previsto
La prueba de salud vaginal MONISTAT® CARE es un kit para que las mujeres que estén en edad menstruante analicen la acidez de las secreciones vaginales en el hogar. Se ha creado para el uso de las mujeres que tienen uno de los siguientes síntomas: picazón vaginal, ardor vaginal u olor vaginal anormal, más o menos asociados a estos pueden ser signos de una infección vaginal. A la infección o inflamación de la vagina se la denomina vaginitis. La vaginitis puede ser causada por un desequilibrio de las bacterias saludables de la vagina, y es una de las razones más comunes por las que las mujeres consultan a su ginecólogo. La vaginitis bacteriana (VB) causa el 40 al 50% de las infecciones en todas las mujeres y el 30 al 50% en las mujeres embarazadas. La candidiasis (causada por hongos) representa el 25 al 30% de las causas de vaginitis en todas las mujeres, y la tricomoniasis, que es una infección parasitaria, causa el 15 al 20% de los casos. Aunque las infecciones por hongos pueden ser tratadas con medicamentos antimicóticos de venta libre, otras infecciones vaginales requieren de la evaluación de un proveedor de atención médica y de medicamentos recetados para su tratamiento.

Comprisión de las infecciones vaginales
Las infecciones vaginales pueden ser un problema recurrente de algunas mujeres. Tener secreciones vaginales anormales, dolor difuso o dolor de la vagina, y el olor pueden ser signos de una infección vaginal. A la infección o inflamación de la vagina se la denomina vaginitis. La vaginitis puede ser causada por un desequilibrio de las bacterias saludables de la vagina, y es una de las razones más comunes por las que las mujeres consultan a su ginecólogo. La vaginitis bacteriana (VB) causa el 40 al 50% de las infecciones en todas las mujeres y el 30 al 50% en las mujeres embarazadas. La candidiasis (causada por hongos) representa el 25 al 30% de las causas de vaginitis en todas las mujeres, y la tricomoniasis, que es una infección parasitaria, causa el 15 al 20% de los casos. Aunque las infecciones por hongos pueden ser tratadas con medicamentos antimicóticos de venta libre, otras infecciones vaginales requieren de la evaluación de un proveedor de atención médica y de medicamentos recetados para su tratamiento.

Leyendo sus resultados
• Observe si el punta del hisopo cambia de color amarillo a azul o verde. Nota: si aparece una mancha de sangre en el hisopo, ignore los resultados.
• No se haga la prueba sin estar entre el 1º y 5º día de su periodo menstrual.14

Repita la prueba
Si no está segura de haber recibido un poco de secreción vaginal en la punta, recólela una segunda muestra. Si la punta se tiñe de un color azul o verde en cualquiera de las pruebas, su acidez vaginal es anormal, y debe consultar a su proveedor de atención médica.

Almacenamiento
Almacene la prueba en un lugar seco a temperatura ambiente de 59 °C a 86 °F (15 °C a 30 ºC). Mantenga sellado el paquete protector de papel aluminio que contiene el hisopo de prueba hasta que vaya a usarlo para evitar que se seque.

Preguntas frecuentes
1. ¿Por qué es importante la acidez vaginal? Las bacterias vaginales normales producen factores que mantienen el ambiente vaginal ligeramente ácido. El ambiente ácido ayuda a suprimir la proliferación de bacterias anormales. Cuando hay una proliferación de bacterias anormales o se establecen infecciones parasitarias como la tricomoniasis, esto conduce a una acidez vaginal anormal. Todas las infecciones vaginales están relacionadas con un cambio en la acidez vaginal; por lo general, las infecciones por hongos no tienen como resultado un cambio en la acidez vaginal.
2. ¿Son todas las infecciones vaginales infecciones por hongos? No. En las mujeres, la más común de las infecciones vaginales es la vaginitis bacteriana (VB), que es una infección causada por un desequilibrio de las bacterias de la vagina. La vaginitis bacteriana se caracteriza por un olor a pescado y una secreción blanca o grasa y una inflamación en la acidez vaginal. La VB es causada por un crecimiento anormal de bacterias y debe ser tratada con antibióticos recetados. En cambio, las infecciones por hongos por lo general no causan mal olor, y muchas veces las secreciones son ligeras, de color blanco y grasas y vienen acompañadas de picazón vaginal e inflamación. Si no se trata, la VB puede conllevar a una infección grave de las vías respiratorias superiores, incluyendo el hígado, el hígado, el estómago y el páncreas. Al igual que la VB, la tricomoniasis debe ser tratada por un proveedor de atención médica.

Para su proveedor de atención médica y de medicamentos recetados para su tratamiento.

Restricciones de uso
• Esta prueba se ha creado solamente para mujeres que tienen periodos menstruales normales (sangrado vaginal periódico).
• Si está embarazada, consulte a su proveedor de atención médica antes de usar este producto, debido a que la interpretación de los resultados de la prueba durante el embarazo requiere del conocimiento de un profesional.
• Para uso diagnóstico en otro modo.
• Este producto no es un tratamiento para enfermedades como el VIH, clamidia, herpes, gonarriosis o sífilis. Puede detectar indicios de infecciones que causan cambios en el pH vaginal, pero no es un tratamiento.