

NEW AND IMPROVED

PACKAGE INSERT



Amniotic Fluid Leak Detection Test

Carefully read the entire insert before using this product.

Indications for use

AmnioSense blue™ is an easy-to-use *in vitro* self-test that detects probable leakage of amniotic fluid during pregnancy by indicating the pH level of leaked fluid. A pH level greater than or equal to 6.5 produces a blue or green stain in any size, shape or location on the panty liner and may be indicative of amniotic fluid leakage. For further diagnosis and medical care, report or show test results to your physician.

If you think you may have a vaginal infection, contact your physician before performing the test.

Package contents

Three individually foil-wrapped AmnioSense blue™ test panty liners and one package insert.

Keep the AmnioSense blue™ tests sealed and use them immediately after opening.

Conditions for use

To ensure valid results:

- Always advise your physician if the test is positive (presence of a blue or green stain) or if you are unsure about the test results.
- Do not use the test if, during the last 12 hours, you have had sexual intercourse, have used a vaginal douche, or have applied any other product (creams, gels, etc.) in your vagina, since this may interfere with the test results. If you experience vaginal wetness and/or think that you may be leaking amniotic fluid but cannot use the test for any of these reasons, contact your physician.
- Do not use the test if you have had any recent vaginal bleeding or spotting. If you experience any vaginal bleeding or spotting, contact your physician immediately.
- Do not use the test if you are on a special diet, since some diets may alter your vaginal pH level and interfere with the test results.
- A single AmnioSense blue™ panty liner may be worn for up to 12 hours. If you still think that you may be leaking amniotic fluid, you should remove the panty liner after 12 hours and replace it with a new panty liner.

- Do not use the test if you have been diagnosed with a vaginal infection (such as bacterial vaginosis or trichomoniasis), within the last three days. Vaginal infections may interfere with the test results.
- Do not use the test if you are being treated with antibiotics. When you are on antibiotics, the results of the test may be misleading.
- Do not use AmnioSense blue™ while sweating (e.g., during or immediately after exercise).

Directions for use

- Tap water can interfere with the test: wash and dry your hands.
- Pull off the paper backing from the panty liner to reveal the adhesive. The panty liner contains a pale yellow indicator.
- Attach the adhesive side of the panty liner to the inside of your underwear (Figure 1). The pale yellow indicator strip should sit directly against your vagina. Wear the panty liner as you would a normal panty liner until you feel wetness (do not exceed 12 hours).



- At the first sign of vaginal wetness, or when replacing the panty liner, remove the panty liner from your underwear, wait 15 minutes, then check for a stain on the panty liner's yellow background.
- If the panty liner remains completely yellow after 15 minutes, but you are still experiencing wetness, consider using another test and continue monitoring or contact your physician.
- Dispose of the panty liner as you would dispose of other hygiene products.

It is important that you contact your physician when you have a positive result (yellow panty liner shows a blue or green colour change), or if you are unsure of your result.

Reading your results

15 minutes after removing the panty liner look at its colour (Figure 2):

- If you observe any signs of vaginal bleeding, disregard the results and contact your physician immediately.
- If the yellow panty liner is **stained blue or green**, there may be amniotic fluid leakage, in which case you should contact your physician without delay.
- If the yellow panty liner **did not change colour** (remained yellow), the vaginal wetness was probably not caused by amniotic fluid. If you continue to experience vaginal wetness, use a new panty liner and repeat the test or contact your physician.

Reading the results of the AmnioSense blue™ panty liner

Test Result	AmnioSense blue™ panty liner stain colour 15 minutes after removal
Positive	Blue or green
Negative	Yellow

- The presence of a blue or green stain (in any intensity, size, shape or location on the panty liner) is a positive result and may indicate amniotic fluid leakage. You should always advise/contact your physician when results are positive.
- If there is a possibility of remaining wetness from shower, bath etc., disregard the positive result and retest, as these conditions may interfere with the results.

Showing the results to your physician

When showing the results to your physician, bring the panty liner with this package insert to your physician (amniotic fluid stains stay visible for at least two hours).

Figure 2 **READING YOUR RESULTS**

15 minutes after removing the panty liner look at its colour:

BLUE/GREEN > High risk of amniotic fluid leak

Positive Results – Colour Stain Options

Positive

YELLOW > Urine leak

Negative Results – Colour Stain Options

Negative

Questions and answers

- Q:** Why is it important to know if I have amniotic fluid leakage?
- A:** Amniotic fluid leakage due to a ruptured membrane can increase the risk of infection to both you and your fetus because it provides a way for bacteria to enter the amniotic sac and potentially cause an infection.
- Q:** How does the AmnioSense blue™ panty liner work?
- A:** Upon any contact with amniotic fluid, the AmnioSense blue™ panty liner will present a blue or green stain on its pale yellow background.
- Q:** When should I not use the test?
- A:** You should not use the test if you have had sexual intercourse or used a vaginal douche or any other vaginal product (gels, creams, etc.) within the past 12 hours. Residual wetness from a shower, bath, sweat, or exercising may also interfere with the test results.
- If you think you may be leaking amniotic fluid, but cannot use the test for any of these reasons, contact your physician.
- If you are experiencing vaginal bleeding or spotting do not use the test as the results may be obscured. Contact your physician immediately.
- If you think you may have a vaginal infection, contact your physician before performing the test.
- Do not use the test if you are being treated with an antibiotic or if you are on a special diet.
- Q:** Can vaginal infections interfere with the test?
- A:** Yes, vaginal infections, such as bacterial vaginosis and trichomoniasis, can interfere with the test results and make the indicator strip turn blue or green even if there is no amniotic fluid leakage. If the indicator strip turns blue or green, contact your physician immediately.
- Q:** Can the test be performed if I am experiencing vaginal bleeding or spotting?
- A:** No, vaginal bleeding or spotting will interfere with the results of the test. If you are experiencing vaginal bleeding or spotting, you should contact your physician immediately.

Storage

Store in a dry place at room temperature. Keep the AmnioSense blue™ tests sealed until use to avoid contamination. Check the expiration date on the individual test package before using this product.

KEEP OUT OF REACH OF CHILDREN.

For more information visit www.amniosenseblue.com

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