



The AmniScreen™ Home Detection Liner Kit contains 3 Testing Panty-Liners (TPL) and 3 Drying Trays. The TPL comprises a regular panty-liner and an indicator strip assembled into the panty-liner, covered with two layers of one-way perforated film.

Carefully read the entire insert before using this product.

AmniScreen™ requires a prescription and is to be used according to your healthcare provider's instructions.

Indications for Use

The AmniScreen™ Home Detection Liner Kit is intended to detect possible leakage of amniotic fluid when vaginal wetness is experienced during pregnancy by indicating pH level. pH levels greater than or equal to 5.2 produce a blue-green color. Patients are instructed to report or show test results to their healthcare provider for interpretation and medical care.

Conditions for Use

To ensure accurate results:

1. Always contact your healthcare provider if the test is positive (shows a blue-green color) or if you are unsure or have any questions about the test results.
2. Do not use the test if it has been less than 12 hours since you had sexual intercourse or used a vaginal douche, or used 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 healthcare provider.
3. 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 healthcare provider immediately.
4. Talk to your healthcare provider before using the test if you are on any special diets, since some diets may alter your vaginal pH level and interfere with the test results.
5. A single AmniScreen™ test may be worn for up to 12 hours. If you still think that you may be leaking amniotic fluid, you should remove the testing panty liner after 12 hours and replace it with a new testing panty liner.
6. Before using the test, contact your healthcare provider if you have been diagnosed with a vaginal infection (such as bacterial vaginosis or Trichomoniasis infections), within the last 3 days. Vaginal infections may interfere with the test results.
7. Before using the test, notify your healthcare provider if you are being treated with an antibiotic. When you are on an antibiotic the results of the test may be misleading.
8. Do not use AmniScreen™ while sweating (e.g., during or immediately after exercise).

Instructions for Use

1. Remove the foil pouch from the box.
2. Tear open the pouch at notch and pull out the panty liner.
3. Pull off the paper backing from the testing panty liner to reveal the adhesive.
4. Attach the adhesive side of the testing panty liner to the inside of your underwear (Figure 1). The pale yellow side of the testing panty liner should sit directly against the outside of your vagina.
5. Wear the testing panty liner as you would a normal panty liner. One testing panty liner can be worn for up to 12 hours. If you still think that you may be leaking amniotic fluid, you should remove the testing panty liner after 12 hours and replace it with a new testing panty liner.



Figure 1

At the first sense of vaginal wetness, or when replacing with a new testing panty liner, take the clear plastic tray out of the box. Remove the testing panty liner from your underwear. Remove the yellow indicator strip from inside the testing panty liner by gently pulling on the tab at the pale yellow end of the testing panty liner (Figure 2).

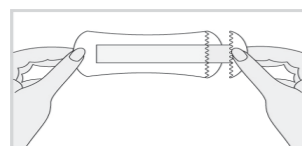


Figure 2



Lay the yellow indicator strip on the white cloth in the plastic drying tray (Figure 3). Close the tray by bending the open side over the strip and pressing closed. Dispose of the testing panty liner.

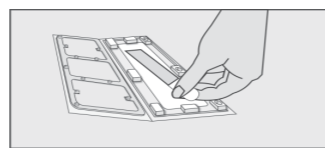


Figure 3

If the indicator strip is completely yellow when removed there is no need to wait 30 minutes for the strip to dry, as the test results are negative. If the indicator strip is stained blue-green wait and check the color of the indicator strip again after 30 minutes. A color change to blue-green after 30 minutes is a positive test result and may mean that you are leaking amniotic fluid. It is important that you report or show test results to your healthcare provider for interpretation or medical care.

Reading your Results

After 30 minutes in the plastic drying tray, look at the color of the indicator strip (Figure 4).

If you observe any signs of vaginal bleeding disregard the results of the test, and contact your healthcare provider immediately.

- If the indicator strip is stained blue-green (after 30 minutes of drying), you may be leaking amniotic fluid, and you should contact your healthcare provider without delay.
- If the indicator strip is stained blue-green at first, but the color changed back to yellow during the 30 minute waiting period, the indicator strip has probably not been in contact with amniotic fluid. You should report or show test results to your healthcare provider. If you continue to experience vaginal wetness, apply a new testing panty liner and repeat the test or contact your healthcare provider.
- If the indicator strip did not change color (remained yellow), the vaginal wetness was probably not caused by amniotic fluid. You should report or show test results to your healthcare provider. If you continue to experience vaginal wetness, apply a new testing panty liner and repeat the test or contact your healthcare provider.
- Report the results (positive or negative) to your healthcare provider according to his/her instructions. Contact your healthcare provider if you are unsure about your test results.

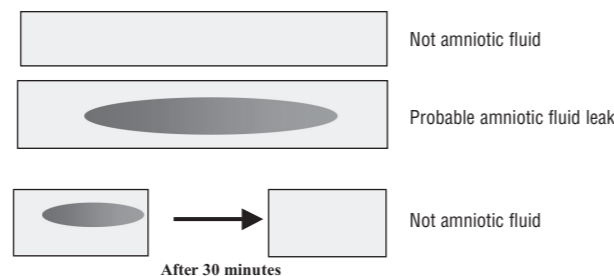


Figure 4

Reading Results for AmniScreen™ Home Detection Liner

Test Results	AmniScreen™ indicator strip color when removed from Panty Liner	AmniScreen™ Indicator strip color after 30 minutes in Drying Tray
Positive	Blue-green	Blue-green
Negative	Blue-green	Yellow
	Yellow	No need to place in drying tray or check results in 30 minutes.

- The presence of a blue-green color after 30 minutes of drying time is a positive test result and may indicate amniotic fluid leakage. Always contact your healthcare provider when test results are positive.

Showing the Indicator Strip to your Healthcare Provider

If you plan on showing the indicator strip result to your healthcare provider, bring the indicator strip in the drying tray with this package insert to your healthcare provider (amniotic fluid stains stay visible for at least one week).

Storage

Store in a dry place and at room temperature. Keep the testing panty liner pouch sealed until ready to use to avoid contamination. Keep out of reach of children.



Questions and Answers

Q: Why it is important to know if I have amniotic fluid leakage?

A: Leakage of amniotic fluid may be risky for both the baby and the mother. Amniotic fluid leakage (ruptured membranes) can increase the risk of infection to both you and your baby because it provides a way for bacteria to enter the amniotic sac and potentially cause an infection.

Q: How does the AmniScreen™ Home Detection Liner work?

A: The AmniScreen™ yellow indicator strip stains with a blue-green color upon any contact with amniotic fluid. This stain remains stable after 30 minutes of drying time. The positive blue-green color stain is dark and easily observed over the yellow background.

Q: Can the test tell when unexplained wetness is caused by amniotic fluid?

A: Yes. AmniScreen™ detects elevated pH levels, which may or may not be due to amniotic fluid leakage. When the indicator strip, which is yellow before use, comes into contact with fluids having a high pH level (from 5.2 units and above), you will observe a blue-green stain on the yellow background. Amniotic fluid always has a pH level above 5.5 (normally varying between 6.5 and 7.5 units).

Q: Do I have to wait the full 30 minute drying period before I can read the results?

A: If the color of the strip changed back to yellow before the end of the 30 minute drying period, the wetness was probably not caused by amniotic fluid and you can stop waiting.

Q: When shouldn't I use the test?

A: You should not use the test if you have had sexual intercourse, used a vaginal douche, or used any other vaginal product (gels, creams, etc) within the past 12 hours, since this may interfere with the test results. If you think you may be leaking amniotic fluid, but cannot use the test for any of these reasons, you should contact your healthcare provider. If you are experiencing vaginal bleeding or spotting do not use the test as the results may be obscured. Contact your healthcare provider immediately. If you think you may have a vaginal infection, contact your healthcare provider before performing the test.

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-green even if there is no amniotic fluid leakage. If the indicator strip turns blue-green, contact your healthcare provider.

Q: Can the test be performed if I am having vaginal bleeding or spotting?

A: No, vaginal bleeding or spotting will interfere with the results of the test. If you are having vaginal bleeding or spotting you should contact your healthcare provider immediately.

Q: If I go to the bathroom and the indicator strip becomes wet due to contact with urine, do I need to replace with a new liner?

A: If after going to the bathroom you see that the testing panty liner has changed color from yellow to blue-green, open the drying tray, remove the indicator strip from the testing panty liner and place the strip inside the tray to dry. If after 30 minutes the strip changes back to yellow, a new testing panty liner will need to be used. If the strip remains blue-green, please contact your healthcare provider.

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DURAMED
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For more information, please call: 1-877-Amni-Kit (1-877-266-4548) or visit www.amniscreen.com.
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AmniScreen™ Home Detection Liner Kit

INFORMATION FOR THE HEALTHCARE PROVIDER

The AmniScreen™ Home Detection Liner Kit contains 3 Testing Panty-Liners (TPL) and 3 Drying Trays. The TPL comprises a regular panty-liner and an indicator strip assembled into the panty-liner, covered with two layers of one-way perforated film.

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This product requires a prescription and is to be used according to the healthcare provider's instructions.

INDICATIONS FOR USE

The AmniScreen™ Home Detection Liner Kit is intended to detect possible leakage of amniotic fluid when vaginal wetness is experienced during pregnancy by indicating pH level. pH levels greater than or equal to 5.2 produce a blue-green color. Patients are instructed to report or show test results to their healthcare provider for interpretation and medical care.

SUMMARY AND EXPLANATION OF THE TEST

Rupture of the membranes can result in small and intermittent volumes of amniotic fluid leakage into the vagina. AmniScreen™ detects elevated pH by changing colors upon contact with vaginal discharge at pH levels of 5.2 units or greater. Amniotic fluid normally has pH levels of 6.7 or greater. AmniScreen™ should be used by pregnant women who sense unexplained vaginal wetness, to give them an initial indication whether the wetness may be caused by amniotic fluid.

PRINCIPLES OF THE TEST

The AmniScreen™ Home Detection Liner is an at-home test to be used as an aid for screening pregnant women experiencing unexplained vaginal wetness in detecting amniotic fluid leakage.

The AmniScreen™ Home Detection Liner is comprised of a regular panty liner and strip coated with an innovative proprietary polymer containing the colorimetric pH indicator Nitrazine Yellow. When the polymer, which is yellow before use, comes into contact with fluids having a high pH level (from 5.2 units and above), the user observes a blue-green stain on the yellow background. Amniotic fluid always has a pH level above 5.5 (normally varying between 6.5 and 7.5 units). Stains caused by amniotic fluid leakage are stable for at least a week.

Stains caused by fluids with concentrations of ammonia exceeding 6mM (such as urine), will reverse any color change and turn back to yellow within 30 minutes. The ammonia concentration of urine is normally between 40-175 mM and the pH is normally between 5 and 7 units. Therefore, whenever the blue-green stain is caused by urine with a pH level up to 7 units, it should reverse back to yellow within 30 minutes, and the user will observe no stains on the indicator strip after the required drying period.

The following data refer to a pivotal clinical study where the Standard Clinical Diagnosis was determined by performing the pooling test, ferning test and pH test with nitrazine paper. A positive pooling test or positive result in both the pH test and the ferning test was defined as a positive Standard Clinical Diagnosis. The Final Clinical Diagnosis was defined as positive when the Standard Clinical Diagnosis was positive either initially or when testing was repeated within 48 hours.

Sensitivity

During the pivotal trial of AmniScreen™, the results that were observed by the patient were read by a clinician who was non-biased, and by the principal investigator who made the clinical diagnosis. The sensitivity of the test, or the percentage of true positive amniotic fluid leaks, was calculated. The Standard Clinical Diagnosis was positive for amniotic fluid leakage in 161 patients. Pivotal trial results demonstrated that in 154 of these 161 cases using the AmniScreen™ test the presence of a blue-green stain on a yellow background was observed by the patient (95.65% sensitivity).

Specificity

The specificity of the test, or the percentage of true negative results, was also calculated. The Standard Clinical Diagnosis was negative for amniotic fluid leakage in 148 patients. Pivotal trial results demonstrated that in 125 cases using the AmniScreen™ test the absence of a blue-green stain on a yellow background was observed by the patient (84.46% specificity).

Overall Agreement

Overall agreement is the percentage of time the patient-read results and the clinician-read results of the AmniScreen™ test match. Pivotal trial results show AmniScreen™ to have 97.4% overall agreement ((128 yellow + 172 blue-green)/308 total).

In some cases, the AmniScreen™ indicator strip will show a blue-green stain when the user has a bacterial vaginosis or Trichomoniasis infection.

Important

- AmniScreen™ should not be used in women who:
 - have used vaginal products such as douches in the past 12 hours
 - have had sexual intercourse within the last 12 hours



- are experiencing vaginal bleeding or spotting

- AmniScreen™ should not be used in patients with vaginal bleeding or spotting because the test results may be obscured. Patients experiencing vaginal bleeding or spotting should contact their healthcare provider immediately.
- In cases where the AmniScreen™ test shows positive results but the clinical assessment results are negative, the possibility of a vaginal infection (such as bacterial vaginosis or Trichomoniasis) should be evaluated using standard diagnostic procedures.
- Confirm that the patient is not practicing a diet that may alter the vaginal pH level.
- The patient should be advised to **always** contact her healthcare provider when the test results are positive (indicator strip stains blue-green after 30 minutes of drying time).
- Yellow indicates a negative test (indicator strip remains or becomes yellow after 30 minutes of drying time), however the patient should be advised to report or show results to her healthcare provider.
- A testing panty liner should not be worn for longer than 12 hours. If the patient still experiences vaginal wetness, the testing panty liner should be removed after 12 hours and replaced with a new testing panty liner.
- Large quantities of urine on the indicator strip may completely cover an area with amniotic fluid leakage stain causing the blue-green stain to reverse back to yellow, yielding a false-negative test result. Clinical studies demonstrate that this occurs less than 5% of the time. Patients should be directed to remove the test panty liner promptly after the first sign of wetness to decrease the possibility of large amounts of urine interfering with the test results.

AmniScreen™ For the Detection of Intermittent Amniotic Fluid Leakages

In some patients, leakage of amniotic fluid is not continuous, but occurs intermittently. Wearing AmniScreen™ until vaginal wetness is sensed gives the amniotic fluid leakage, even if intermittent, a chance to come into contact with the indicator strip. Continuous exposure of vaginal fluid to the testing panty liner can detect intermittent amniotic fluid leakage that may be missed by one-time spot-checking, (as is the case with most in-office tests used for the diagnosis of ruptured membranes). A single AmniScreen™ testing panty liner may be worn for up to 12 hours and may be replaced by a new testing panty liner at that time, if necessary. The AmniScreen™ Home Detection Liner is recommended for use in women experiencing vaginal wetness during pregnancy. Reporting the occurrence of potential amniotic fluid leakage to healthcare providers may help reduce the risk of:

- Infection to the fetus/neonate, which might lead to premature birth or peri-natal morbidity
- Infection to the mother, which might lead to complications of pregnancy or maternal morbidity



PRESCRIBER INFORMATION FOR THE PATIENT

The AmniScreen™ Home Detection Liner Kit contains 3 Testing Panty-Liners (TPL) and 3 Drying Trays. The TPL comprises a regular panty-liner and an indicator strip assembled into the panty-liner, covered with two layers of one-way perforated film.

- Patients should be instructed to report or show the test results to their healthcare provider according to instructions and should **always** contact their healthcare provider when the test results are positive (indicator strip stain remains blue-green after 30 minutes of drying time).
- Yellow indicates a negative test (indicator strip remains or becomes yellow after 30 minutes of drying time), however the patient should be advised to report or show results to her healthcare provider.
- A single testing panty liner should not be worn for longer than 12 hours. If the patient still experiences vaginal wetness, the testing panty liner should be removed after 12 hours and replaced with a new testing panty liner.
- AmniScreen™ should not be used if it has been less than 12 hours since having sexual intercourse, vaginal douching or using any vaginal products (creams, gels, etc), as this may interfere with the test results. If leakage of amniotic fluid is suspected and the patient cannot use AmniScreen™, she should contact her healthcare provider.
- AmniScreen™ should not be used when a patient is experiencing vaginal bleeding or spotting, as test results may be obscured. Patients experiencing vaginal bleeding or spotting should contact their healthcare provider immediately.
- Any of the following conditions may interfere with test results and should be reported to the healthcare provider: vaginal bleeding or spotting, vaginal infections (such as bacterial vaginosis or Trichomoniasis) within the last 3 days; treatments with antibiotics; and diets that may alter vaginal pH.

PROCEDURE

- Open the foil pouch, remove the testing panty liner and discard the paper backing from the testing panty liner.
- Attach the testing panty liner to the inside of your underwear.
- The testing panty liner is to be worn up to 12 hours or until vaginal wetness is experienced.
- When vaginal wetness occurs, remove the testing panty liner from the underwear, and remove the indicator strip from the liner.
- Place the indicator strip in the plastic drying tray.

Wait 30 minutes and then check the indicator strip for a change in color (if positive, strip will have a blue-green stain).

Interpretation of Results

Test Result	AmniScreen™ indicator strip stain color when removed from Panty Liner	AmniScreen™ Indicator strip stain color after 30 minutes in Drying Tray
Positive	Blue-green	Blue-green
Negative	Blue-green	Yellow
	Yellow	No need to place in drying tray or check results in 30 minutes.

- The presence of a blue-green color after 30 minutes of drying time is a **positive** test result and may indicate amniotic fluid leakage. Patients should **always** contact their healthcare provider when test results are positive.

LIMITATIONS OF THE DEVICE

- AmniScreen™ can only detect a difference in pH levels and should be used only as indicated according to the test procedure described above.
- Antibiotic therapy or vaginal infections (such as bacterial vaginosis or Trichomoniasis) can lead to an elevated vaginal pH level, which may result in a false-positive test result for the presence of amniotic fluid. The possibility of a vaginal infection may be evaluated using standard diagnostic procedures.
- Do not use the AmniScreen™ while sweating (e.g., during or immediately after exercise).

(over)

Information for the Patient on reverse side