

## AL SENSE™ Package Insert

# AL-SENSE™

Amniotic Fluid Detector Panty Liner

CLIA-Waived as AmniScreen

### Healthcare provider information section

The AL-SENSE™ package contains 50 testing panty liners (with a yellow pH indicating band), which allow to monitor leakage of amniotic fluid when vaginal wetness is experienced during pregnancy.

Carefully read the entire insert before using this product. This product is to be used in a hospital/clinic, requires a prescription for use at home, and is to be used according to the healthcare provider's instructions.

#### INDICATIONS FOR USE:

The AL-SENSE™ Panty Liner 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 6.5 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. AL-SENSE™ Panty Liner detects elevated pH by changing colors upon contact with vaginal discharge at pH levels of 6.5 units or greater. Amniotic fluid normally has pH levels of 6.7 or greater. AL-SENSE™ Panty Liner 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 AL-SENSE™ Panty Liner is a test to be used as an aid for screening pregnant women experiencing unexplained vaginal wetness in detecting amniotic fluid leakage. The AL-SENSE™ Panty Liner is comprised of a regular panty liner 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 6.5 units and above), the user observes a light blue-green stain (any stain, shape, size or location) on the yellow background. Amniotic fluid always has a pH level above 6.0 (normally varying between 6.5 and 7.5 units), and will stain the AL-SENSE™ Panty Liner whenever it comes in contact. Stains caused by amniotic fluid leakage are stable for at least 2 hours.

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 AL-SENSE™, 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 final clinical diagnosis was positive for amniotic fluid leakage in 161 patients. Pivotal trial results demonstrated that in 154 of these 161 cases using the AL-SENSE™ 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 final clinical diagnosis was negative for amniotic fluid leakage in 148 patients. Pivotal trial results demonstrated that in 125 cases using the AL-SENSE™ 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 AL-SENSE™ test match. Pivotal trial results show AL-SENSE™ to have 97.4% overall agreement ((128 yellow + 172 blue-green)/308 total). In some cases, the AL-SENSE™ indicator strip will show a blue-green stain when the user has a bacterial vaginosis or Trichomoniasis infection.

#### Important:

- AL-SENSE™ 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.
- AL-SENSE™ 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 AL-SENSE™ 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 advise her healthcare provider when the test results are positive (indicator strip stains blue-green).
- Yellow indicates a negative test (indicator strip remains yellow), however the patient should be advised to contact her healthcare provider if she has any questions about her results.
- 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 the area of an amniotic fluid leak stain completely causing the blue-green stain to reverse back to yellow, and 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 TPL testing panty liner promptly after the first sign of wetness to decrease the possibility of large amounts of urine interfering with the test results.

#### AL-SENSE™ Panty Liner for the Detection of Intermittent Amniotic Fluid Leakages

In some patients, leakage of amniotic fluid is not continuous, but occurs intermittently. Wearing AL-SENSE™ Panty Liner until vaginal wetness is sensed gives the amniotic fluid leakage, even if intermittent, a chance to come into contact with the indicator. Continuous exposure of vaginal fluid to the AL-SENSE™ 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 AL-SENSE™ Panty Liner may be worn for up to 12 hours and replaced by an AL-SENSE™ Panty Liner at that time. The AL-SENSE™ Panty Liner is recommended for use, by 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

#### INSTRUCT YOUR PATIENT:

- Patients should be advised to report or show the test results to their healthcare provider according to instructions and should always advise their healthcare provider when the test results are positive (indicator strip stains blue-green).
- Yellow indicates a negative test (indicator strip remains yellow), however the patient should be advised to contact her healthcare provider if she has any questions about her results.
- 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.
- AL-SENSE™ should not be used if it has been less than 12 hours since the patient had sexual intercourse, vaginal douching or used 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 AL-SENSE™, she should contact her healthcare provider.
- AL-SENSE™ should not be used when a patient is experiencing vaginal bleeding or spotting, as test results may be obscured. Patients experiencing vaginal spotting/bleeding should advise 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:

The following instructions should be given to patient by the healthcare provider:

1. Attach the AL-SENSE™ Panty Liner to your underwear.
  2. The AL-SENSE™ Panty Liner is to be worn up to 12 hours or until vaginal wetness is experienced.
  3. When vaginal wetness occurs, remove the panty liner from the underwear, and check for a stain on the yellow background.
- Immediately after removal of the test from the panties, look at the result for a change in color (if positive, yellow panty liner stain blue-green).

#### INTERPRETATION OF RESULTS:

Test Result	AL-SENSE™ Panty Liner stain color when removed
Positive	Blue-green
Negative	Yellow

- The presence of a blue-green stain (any intensity), in any size, shape or location, on the panty liner is a positive result and may indicate amniotic fluid leakage.
- Patient should disregard positive result and retest if she have had possibility of wetness/wetness remains from shower, bath etc, as these may interfere with the results.

#### LIMITATIONS OF THE DEVICE:

AL-SENSE™ Panty Liner 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 result for the presence of amniotic fluid. The possibility of a vaginal infection may be evaluated using standard diagnostic procedures. If your patient is sweating disregard positive results of the AL-SENSE™ Panty Liner, and use a new panty liner.

#### MATERIALS SUPPLIED:

Each AL-SENSE™ Panty Liner Kit contains 1 test panty liner and instructions for use.

# AL-SENSE™

## Amniotic Fluid Detector Panty Liner

### Patient information section

The AL-SENSE™ contains 50 Panty Liners. The panty liners comprise a regular panty liner and yellow indicator band.

Carefully read the entire insert before using this product.

AL-SENSE™ is to be used in a hospital/clinic, requires a prescription for use at home, and is to be used according to your healthcare provider's instructions.

#### Indications for Use

The AL-SENSE™ Panty Liner 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 6.5 produce a light blue-green color in any shape, size or location. Patients are instructed to report or show test results to their healthcare provider for interpretation and medical care.

#### Package Contents

The AL-SENSE™ Test Kit contains 50 test panty liners, and instructions for use.

#### Conditions for Use

##### To ensure accurate results:

1. Always contact/advise your healthcare provider if the test is positive (shows a blue or green color) or if you are unsure 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 AL-SENSE™ testing 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, advise/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 the AL-SENSE™ while sweating (e.g., during or immediately after exercise).

#### Directions for Use

1. Pull off the paper backing from the testing panty liner to reveal the adhesive.
2. Attach the adhesive side of the testing panty liner to the inside of your underwear (Figure 1).
3. Wear the testing panty liner as you would a normal panty liner. One 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 panty liner after 12 hours and replace it with a new panty liner.



Figure 1

At the first sense of vaginal wetness, or when replacing with a new panty liner, remove the panty liner from your underwear, and check for a stain on the background of the yellow panty liner.

It is important that you contact your healthcare provider when you have a positive result (yellow panty liner shows a blue or green color change after removing the panty liner), or if you are unsure of your result.

#### Reading your Results

Immediately after removing the panty liner look at the yellow panty liner: (Figure 2).

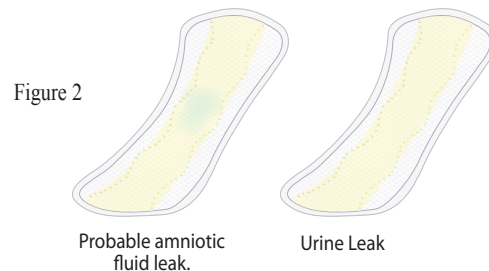


Figure 2

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

- If the yellow panty liner is stained blue or green, you may be leaking amniotic fluid, and you should advise/contact your healthcare provider without delay.
- If the yellow panty liner did not change color (remained yellow), the vaginal wetness was probably not caused by amniotic fluid. If you continue to experience vaginal wetness, apply a new 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.

#### Reading Results for AL-SENSE™ Panty Liner

Test Result	AL-SENSE™ Panty Liner stain color when removed
Positive	Blue-green
Negative	Yellow

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

#### Showing the results to your Healthcare Provider

When showing the result to your healthcare provider, bring the panty liner with this package insert to your healthcare provider (amniotic fluid stains stay visible for at least 2 hours).

#### Storage

Store in a dry place and at room temperature.  
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 fetus and the mother. Amniotic fluid leakage (ruptured membranes) 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 AL-SENSE™ Panty Liner work?

A: The AL-SENSE™ yellow panty liner stains with a blue-green color upon any contact with amniotic fluid. The positive blue/green color stain is observed over the pale yellow background.

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

A: Yes. If the panty liner remains yellow after using it, the wetness was probably not caused by amniotic fluid. If the yellow panty liner stains blue or green, the wetness is probably caused by amniotic fluid. You should contact your healthcare provider when the test results are positive (yellow panty liner is blue-green after removing the panty liner) or if you are unsure about your results.

##### 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 or there is a possibility of wetness/wetness remains from shower, bath etc, 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 or green even if there is no amniotic fluid leakage. If the indicator strip turns blue or 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.

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