

# AL-SENSE™ kit

## Amniotic Leak Self-Test Detector

Carefully read the entire insert before using this product.

### The Amniotic Leak Self-Test Detector Kit

The AL-SENSE detector is an in vitro self-test, easy-to-use home test kit that allows you to detect probable leakage of amniotic fluid whenever your physician suspects you may be in a higher risk than normal of amniotic fluid leak. Risk of amniotic fluid leak are higher than normal during 48 hours after amniocentesis tests, or when encountering **unidentified wetness**, or among women with **history of premature membrane rupture**.

The AL-SENSE changes colors when it comes in contact with fluid of pH level greater than 5. Amniotic fluid pH levels are greater than 6.5.

### Principle of Operation

Simply attach the special AL-SENSE panty liner to your underwear and get on with your day. Wait until you feel a fluid leak, remove the indicator strip from the panty liner, and check for a change in color.

If the indicator strip is stained blue or green, amniotic fluid may be leaking from your uterus, or you may have a vaginal infection. You should consult your physician or go to the hospital without delay.

If the indicator strip stains blue or green and then fades back to yellow, the fluid leak is probably urine, which is common during pregnancy.

Any minimal amounts of amniotic fluid leakage which can be sensed as wetness, by the user will create a visible stain.

For further diagnosis and medical care, report or show the results to your physician.

The AL-SENSE Test is recommended for both high-risk and normal pregnancies. Leaking amniotic fluid increases the risk of infection to both mother and baby and early detection can help to:

- Prevent complications or premature birth.
- Identify a possible membrane rupture, especially after amniocentesis.
- Confirm that your water has broken so that you arrive at the hospital in time for a safe delivery.

### Performance Data:

A total of 412 pregnant women were enrolled in 2 different clinical studies of the AL-SENSE Test Kit (103 and 309 pregnant women). The AL-SENSE, as a continuance test, demonstrated a sensitivity ranging from 95.7% to 100%<sup>(1,2)</sup>. The clinical diagnosis of amniotic leak that was done in the hospitals reached a sensitivity of 97.6%<sup>(2)</sup>.

1) Bornstein J, Geva A, Salt I, Fait V, Schoenfeld A, Shoham HK, Sobel J. Noninvasive diagnosis of premature ruptured amniotic membranes using a novel polymer. Am J Perinatol. 2006 Aug; 23(6):351-4.

2) Bornstein J, Ohel G, Sorokin Y, Reape KZ, Shnaider O, Kessary-Shoham H, Ophir E. Effectiveness of a novel home-based testing device for the detection of rupture of membranes. Am J Perinatol. 2009 Jan;26(1):45-50.

As you wait to meet your baby, the AL-SENSE Test gives you a little extra peace of mind — when you need it most.

### Indications for Use

This product is intended to detect leaking amniotic fluid and identify cause of wetness during pregnancy. For further diagnosis and medical care, report or show test results to your physician.

If you suspect you have a vaginal infection, consult your physician!

### Limitation of the device

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.

### Package Contents

The AL-SENSE Kit contains XX test panty liners, XX plastic drying boxes, and instructions for use.

### Keep the TPL sealed and use it immediately after opening

Time watch is not supplied, the user will use her own watch to measure the wearing time and the drying time.

### Conditions for Use

To ensure valid results, do not use the AL-SENSE monitoring device if the answer to any of the following questions is **YES**: (1) is it less than 12 hours after sexual intercourse? (2) is it less than 12 hours after vaginal douching?

During bleeding results reading may need professional assistance. Report all bleeding situations to your physician.

In case of sensitization or irritation of skin, at the application site, stop use and contact your physician.

### Directions for Use

1. Tap water can interfere with the test — wash and dry your hands.
2. Unwrap the Test Panty Liner (TPL). The TPL contains a removable pale yellow indicator strip.
3. Attach the TPL to your underwear (Figure 1). The pale yellow indicator strip should sit directly against your vagina. Wear the TPL as you would a normal panty liner till you feel wetness (do not exceed 12 hours).



Figure 1

4. When the TPL is wet or when you replace the TPL, prepare the enclosed plastic box.
5. Remove the indicator strip from the TPL by gently pulling the loose tail of the indicator strip (Figure 2).

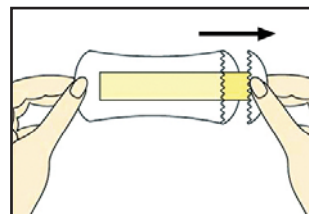


Figure 2

6. Lay the indicator strip on the white cloth in the open plastic box (Figure 3). Close the box. Dispose of the TPL.



Figure 3

7. If you feel wetness and the indicator strip is completely yellow, consider using another test. If the indicator strip is stained blue or green, wait 30 minutes and check the color of the indicator strip.

### Reading your Results

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

- If the indicator strip stained blue or green, the fluid leak is probably amniotic fluid. Consult your physician or go to the hospital without delay.

Important: The indicator strip may also turn blue or green if a serious infectious vaginal disease is detected. If the indicator strip turns blue or green, always consult your physician.

- If the indicator strip stained blue or green but the color faded back to yellow during the 30 minute waiting period, the indicator strip has been in contact with urine.
- If you feel wetness and the indicator strip did not change color, consider using another TPL or report the situation to your physician.

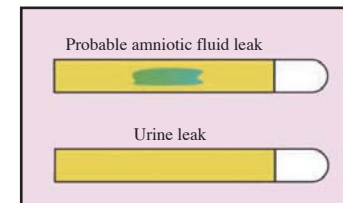


Figure 4

### Showing the Indicator Strip to your Physician

Positive results should be reported to the physician. Some physicians may request to observe the results (the stained strip). The color change in cases of amniotic fluid leak is stable for more than 2 hours. If you intend to show the indicating result to your physician, bring the closed plastic box containing the indicator strip to your physician within 2 hours.

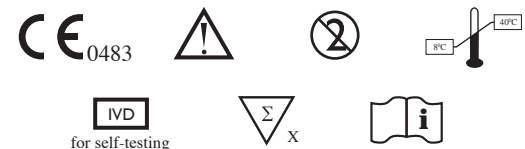
### Storage

Store in a dry place at room temperature. Keep the TPL sealed until use to avoid contamination. Please note the expiration date stated on the TPL. If in doubt, consult with the dispensing pharmacist. Keep out of reach of children.

### User Assistance Information and Distribution Details

#### Info of distributor

F-02-04-CS4  
Issue date: 12/2009



CS Common Sense