LIMITATIONS OF THE TEST

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.

If you suspect you have a vaginal infection, consult your doctor.

PERFORMANCE DATA

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

References:
INTENDED USE
Vision® Amniotic Leak Detector (ALD) is an in vitro self-test, easy-to-use kit that is intended to detect probable leaking amniotic fluid and identify the cause of wetness during pregnancy.

INTRODUCTION
If your doctor suspects you may be in a higher risk than normal of amniotic fluid leak then Vision® ALD can be used to monitor this. Risk of amniotic fluid leak is higher than normal during the 48 hours after amniocentesis tests, or when encountering unidentified wetness, or among women with a history of premature membrane rupture.

Vision® ALD changes colour when it comes in contact with fluid which has a pH level greater than 5. Amniotic fluid has a pH level greater than 6.5.

TEST PRINCIPLE
Simply attach the special Vision® ALD panty liner to your underwear as you would a normal panty liner. If you feel a fluid leak, remove the indicator strip from the panty liner and check for a change in colour.

If the indicator strip is stained blue or green, amniotic fluid maybe leaking from your uterus, or you may have a vaginal infection. You should consult your doctor 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 doctor.

The Vision® ALD is recommended for both high-risk and normal pregnancies. It can be used after amniocentesis, or from week 36 onwards or whenever encountering unidentified wetness. 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

CONTENTS AND STORAGE
20 individually foil wrapped Vision® ALD Test Panty Liners (TPL), 20 plastic drying boxes and 20 instruction for use leaflets.

Please note this pack does not contain a device for the measurement of time. The user must use their own watch to determine the wearing time and drying time.

Keep the TPL sealed to avoid contamination and use it immediately after opening.
Store in a dry place at room temperature 8°C - 40°C. Do not use after the expiry date.

PRECAUTIONS
1. Do not open the foil until ready to use.
2. Do not use the device if it has become wet or damaged.
3. Properly dispose of all contaminated waste such as used tests.
4. Do not use test beyond the expiry date printed on the foil wrapper.
5. To ensure valid results, do not use Vision® ALD monitoring device if the answer to any of the following questions is YES:
   (a) Is it less than 12 hours after sexual intercourse?
   (b) Is it less than 12 hours after vaginal douching?

During bleeding, results reading may need professional assistance. Report all bleeding situations to your doctor. In case of sensitisation or irritation of the skin at the application site, stop use and contact your doctor.

INSTRUCTIONS FOR USE
1. Tap water can interfere with the test - wash and dry your hands first.
2. Where there is a nick on the foil edge, tear open the foil to remove the Test Panty Liner (TPL).
3. Attach the TPL to your underwear, as you would a normal panty liner (Figure 1). The TPL contains a removable pale yellow indicator strip, this should remain in place and sit directly against your vagina. Wear the TPL until you feel wetness but do not exceed 12 hours.
4. When the TPL is wet or when you replace the TPL, you need to have the plastic drying box to hand.
5. Remove the indicator strip from the TPL by gently pulling the loose tail of the indicator strip (Figure 1).
6. Lay the indicator strip on the white cloth in the open plastic drying box (Figure 3). Close the box and dispose of the TPL.
7. If you feel wetness and the indicator strip is stained blue or green, wait 30 minutes and check the colour of the indicator strip again.

INTERPRETATION OF RESULTS
After 30 minutes of drying, look at the colour of the indicator strip (Figure 4).
- If the indicator strip stained blue or green, the fluid leak is probably amniotic fluid. Consult your doctor or go to the hospital without delay.
- If the indicator strip stained blue or green but the colour 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 colour, consider using another test. If the indicator strip is stained blue or green, wait 30 minutes and check the colour of the indicator strip again.

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 doctor.

SHOWING THE INDICATOR STRIP TO YOUR DOCTOR
Positive results should be reported to a doctor as soon as possible. Some doctors may request to observe the results (i.e. the stained strip). The colour change in cases of amniotic fluid leak is stable for more than 2 hours. If you intend to show the indicating result to your doctor, bring the closed plastic drying box containing the indicator strip to your doctor within 2 hours.
LIMITATIONS OF THE TEST
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