AmnioSense™

FOR IN-HOME DETECTION OF AMNIOTIC FLUID

The **only** non-invasive monitoring test for **amniotic fluid leaks**

www.amniosense.co.uk

The facts

- ✓ 30-40% of women experience some degree of urinary leakage during pregnancy.[1]
- ✓ Premature Rupture of Membranes (PROM), occurs in 5-10% of pregnancies.[2]
- ✓ Amniotic fluid leakage is a major stress to pre-term pregnant women.
- ✓ Over 20% of pregnant women report to hospital because of wetness. 50% are sent home as the wetness was due to urine.
- ✓ AmnioSense™ is already marketed in Australia, South Africa and Asia.

What is AmnioSense™

- ✓ AmnioSense™ is the only non-invasive monitoring test for amniotic fluid leaks.
- ✓ AmnioSense™ diagnostic panty liner is designed to detect small volumes of amniotic fluid when wetness is sensed and differentiate it from urine (one diagnostic liner can be worn for up to 12 hours).
- ✓ AmnioSense™ is targeted at pregnancies in the last trimester, especially for first time pregnancies, high risk pregnancies with a history of miscarriage and post amniocentesis.

AmnioSense™ mode of action

How

- ✓ Simple to use identification tool which uses colour for interpretation of the results.

BLUE/GREEN
Indicates probable amniotic fluid leakage & directs patient to midwife/hospital.

YELLOW
Indicates probable urine presence and requires no referral.

Science

Step 1:

- ✓ Test strip acts as a pH indicator and changes colour on contact with fluid of pH > 6.5. Amniotic fluid has a high pH of more than 6.5.

Step 2:

- ✓ If ammonia present test strip remains yellow or reverses colour back to yellow.

References: 1. "Sangsawang B, Sangsawang n. Stress urinary incontinence in pregnant women: a review of prevalence, pathophysiology, and treatment. Int Urogyneocol J. 2013 Jun;24(6):901-12. **2.** Bornstein J, Geva A, Sdt I et al. Non intrusive Diagnosis of Premature Ruptured Amniotic Membranes Using a Novel Polymer. Am J Perinatol 2006;23:1-4. **3.** Bornstein J, Gonen Ohel, Sorokin Y et al. Effectiveness of a novel home-based testing device for the detection of rupture of membranes. Am J Perinatol. 2009 Jan;26(1):45-50. (AmnioSense is referred to as AL-Sense within this study). **4.** Caughey A, Robinson J, Norwitz E. Contemporary Diagnosis and Management of Preterm Premature Rupture of Membranes. Rev Obstet. Gynaecol., 2008;1(1):11-22 **5.** NICE report; Vision Amniotic Leak Detector to assess unexplained vaginal wetness in pregnancy. Medical technologies guidance (MTG15) July 2013.

Advantages of prolonged monitoring with AmnioSense™

The ability of AmnioSense™ to **detect even a small volume of amniotic fluid**, over a **prolonged period of time**, may assist in avoiding mis-diagnosis of amniotic fluid leakage and sending a woman with amniotic fluid leakage home.

AmnioSense™ Pivotal Clinical Study

OBJECTIVE: Evaluate the effectiveness of AmnioSense™ panty-liner in diagnosing Amniotic Fluid Leaks.[3]

The AmnioSense™ results reading were compared to the "Standard Clinical Diagnosis" results:

1. Sterile speculum examination in cases of clear membrane rupture.
2. Microscopic Ferning Test.
3. pH test by pH paper.

Sensitivity and Specificity of AmnioSense™ Vs. the Standard Clinical Diagnosis (n=309)

	Sensitivity	Specificity
Overall	**95.76%**	**86.81%**

Study conclusions

AmnioSense™ is a highly sensitive, nonintrusive method to detect the presence of amniotic fluid.

False-positive results may occur in women with baterial vaginosis or Trichomonas Vaginalis; however, that information may be useful for the management of the pregnancy.

AmnioSense™ is suitable for use in the outpatient setting, as the results are easy for the subject to read and understand.

Limitation of the device

Antibiotic therapy or vaginal infections (such as BV or TV) can lead to an elevated vaginal pH level, which may result in a false-positive test result for the presence of amniotic fluid.

Tap water can interfere with the test and may give a false-positive result.

AmnioSense™ Safety

- ✓ AmnioSense™ has undergone cyto-toxicity, skin irritation, and sensitisation tests and complies with the U.S.P. guidelines.
- ✓ There is no leaching of chemical components.
- ✓ The product can be used for up to 12 hours.
- ✓ No direct physical contact between the woman's body and chemicals in the diagnostic component.

Why AmnioSense™?

	AmnioSense™[2,3]	Nitrazine[4]	Ferning[4]
Method	Panty line	Smear + pH paper	Smear + Microscope
Usage	Non-Invasive	Invasive	Invasive
Easy to Use	Very Easy	Easy	Moderately Complex
Momentary/ Continuous Monitoring	Continuous	Momentary	Momentary
Sensitivity	95.76-100%	90-97%	51-98%
Specificity	86.81%	16-70%	70-88%
PPV/NPV*	89.3%/94.7%	63-75%/80-93%	84-93%/87-97%
Stability of Results	Stain will remain for at least 2 hours	After colour change, compare to chart	Smear is read after drying on glass
Price	£	£	££
User	Pregnant Woman	Point of Care	Point of Care

*PPV = Positive Predictive Value, NPV = Negative Predictive Value

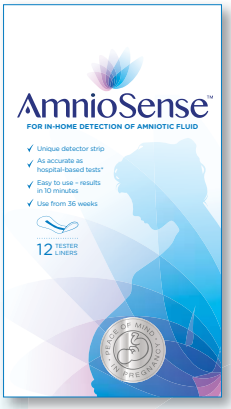
AmnioSense™ Key Benefits

AmnioSense™ is reliable, cost effective and easy to use, offering rapid and continual reassurance against amniotic fluid leaks.

It is:

- ✓ Non-invasive – comfortable at-home monitoring
- ✓ Accurate – high sensitivity and specificity
- ✓ Prolonged monitoring – up to 12 hours
- ✓ Rapid – results in 10 minutes

"Using (AmnioSense™) in the community could prevent unnecessary referrals ... for speculum examinations, releasing clinical time" NICE National Institute for Health and Care Excellence



Available in packs of 12.

For more information visit www.anmiosense.co.uk or call 0344 243661 or email enquiries@ceutahealthcare.com

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F-3-AL1-CEUB6 Revised on 22 February 2017