



AMNIOCHECK

Amniotic leak self-test detector



WHAT IS AMNIOCHECK

AMNIOCHECK is designed to detect any minute (100 microlitre) leak of amniotic fluid, differentiating it from urine by detecting the pH level.

WHO ARE THE INTENDED USERS

- Gynecologists' clinics or Delivery rooms: for amniotic fluid leakage screening or verification, especially for non-continuous leakage.
- Pregnant women at home: women with normal pregnancies experiencing unexplained wetness as well as by those at high risk of Premature Rupture of Membrane (PROM) and Preterm Premature Rupture of Membrane (PPROM).

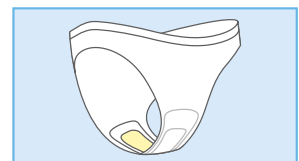
Available for home use and professional use.

WHY - BENEFITS

Non invasive method, easy to use; early diagnosis of PROM and PPRM; reduction of unnecessary speculum examination; reduction of time spent in hospital; reduced risk of infection from speculum examination (particularly if repeat examinations are required); incidental detection of possible vaginal infection; reduction in staff time and hospital bed use.

HOW TO USE IT

Attach the panty liner to the underwear; the panty liner has a central polymer-embedded strip that turns blue-green on contact with fluid. Wear the panty liner as a normal panty liner till feel wetness (do not exceed 12 hours). At the first sense of vaginal wetness, remove the panty liner and wait up to 15 minutes and check for a colour change on the panty liner. The detection panty liner is specific to vaginal fluid, and if contaminated with urine it will not give a positive result.



CONTENT: 5 aluminum pouches containing 1 panty liner each; 1 instructions for use leaflet.

TEST PRINCIPLE

AMNIOCHECK changes colours when it comes in contact with fluid of pH levels greater than or equal to 6,5 units. Amniotic fluid pH levels are greater than 6,5.

The panty liner is specific to vaginal fluid, and if contaminated with urine, in the range of pH 5,5-7,0, will not give a positive result (combination of the chemical formulation and panty liner composition reduces interference from urine and therefore increase specificity).

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
pH > 6,5	97,10%	96,90%	PPV 96,10% NPV 97,67%

Performance data obtained by clinical studies conducted in 2016-2017 (5 American centres and 1 Israeli centre) with 232 pregnant women enrolled. AMNIOCHECK has been compared to the standard clinical diagnosis protocol.

CLINICAL EVIDENCES

The National Institute for Health and Care Excellence (NICE, UK) has conducted evaluated this panty liner as "sufficiently accurate to exclude amniotic fluid leak as a cause of wetness in pregnancy, [...] the use of the panty liner could generate costs savings and avoid the discomfort of unnecessary speculum examinations, [...] its use should be encouraged."

Bibliography: 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.



REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
100088-5	AMNIOCHECK	5 TESTS	48 MONTHS