



EARLY PREGNANCY TEST

Rapid self-test for the early detection of the hCG in human urine samples (10 mIU/mL)



PREGNANCY AND hCG

In the very early stages of pregnancy, the fertilized egg is transported from the tubes to the uterus where, around seven days later, it lurks. Precisely at this stage, the tissue that will form the placenta begins to produce the human Chorionic Gonadotropin, also called hCG hormone, essential for the correct development of pregnancy. The quick appearance and rapid increase in the concentration of the hCG hormone in the urine make it an excellent indicator for the early confirmation of pregnancy.

WHO ARE THE INTENDED USERS

Women who want to identify early stages of pregnancy.

WHY - BENEFITS

The test detects the hCG hormone in urine at a concentration of 10 mIU/mL, therefore the test can be performed 3 days before the period is due. So in this way it is possible to early identify a pregnancy.

TEST PRINCIPLE

EARLY PREGNANCY TEST is an immunochromatographic assay for the early detection of hCG hormone in urine by using a combination of one monoclonal-dye conjugate and another one monoclonal-solid phase antibody to selectively identify hCG in test samples.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
10 mIU/mL	100%	100%	100%

Performance data obtained by clinical study with 47 participant enrolled. Clearblue Test Early Pregnancy has been used as reference method.

CLINICAL EVIDENCES

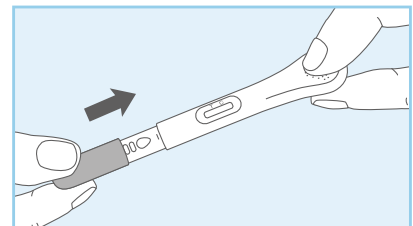
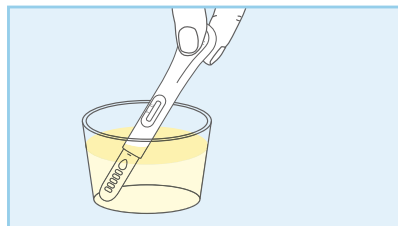
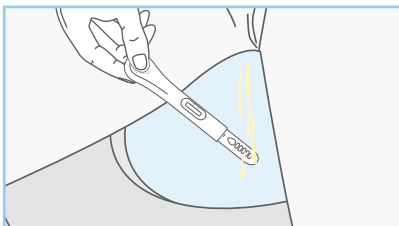
1. Batzer FR. "Hormonal evaluation of early pregnancy", *Fertil. Steril.* 1980; 34(1): 1-13 2.
2. Snjder J.A., Haymonth F., Parvin C.A. et al. "Diagnostic considerations in the measurement of Human Chorionic Gonadotrophin in aging women" *Clin Chem* 2005; 51: 1830 – 1835
3. Gnoth C., Johnson S.: "Strips of hope: accuracy of home pregnancy tests and new development"

HOW TO USE IT

1) Remove the protective cap and place the absorbing tip right under the flow of urine for at least 10 seconds.

2) If easier, collect the urine in a clean, dry, residue-free container and dip the absorbing tip into the urine for 10 seconds.

3) Place the protective cap back onto the absorbing tip. Wait 5 minutes before reading the result.



CONTENT: 1 or 2 sealed aluminium pouches containing each: 1 spoon device and 1 desiccant bag; 1 instructions for use leaflet.



REF	DESCRIPTION	NUMBER OF TESTS	SHelf LIFE
820010-1	EARLY PREGNANCY TEST	1 TEST	30 MONTHS
820010-2	EARLY PREGNANCY TEST	2 TESTS	