



EARLY DETECTION PREGNANCY TEST

Rapid Immunochromatographic manual self-test for the qualitative detection of the chorionic gonadotropin hormone (hCG) in human urine as an aid to the early identification of the pregnancy status in women



POSITIVE



NEGATIVE



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 6 days before the period is due. So in this way it is possible to early identify a pregnancy.

TEST PRINCIPLE

EARLY DETECTION 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

SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
>99%	>99%	>99%

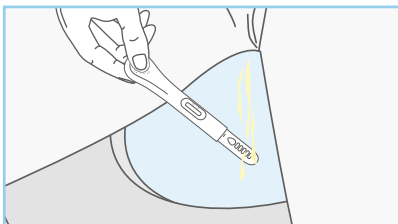
clinical study with 111 clinical samples

CLINICAL EVIDENCES

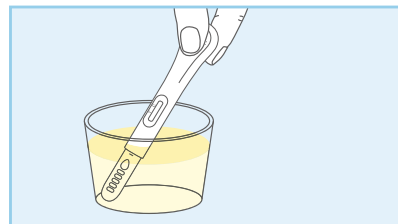
1. BLarsen, John, Philip Buchanan, Sarah Johnson, Sonya Godbert, and Michael Zinaman. "Human Chorionic Gonadotropin as a Measure of Pregnancy Duration." *International Journal of Gynaecology and Obstetrics: The Official Organ of the International Federation of Gynaecology and Obstetrics* 123, no. 3 (December 2013): 189-95. <https://doi.org/10.1016/j.ijgo.2013.05.028>.
2. Cole, Laurence A., Stephen DuToit, and Trefor N. Higgins. "Total HCG Tests." *Clinica Chimica Acta; International Journal of Clinical Chemistry* 412, no. 23-24 (November 20, 2011): 2216-22. <https://doi.org/10.1016/j.cca.2011.08.006>.
3. Pike, Joanna, Sonya Godbert, and Sarah Johnson. "Comparison of Volunteers' Experience of Using, and Accuracy of Reading, Different Types of Home Pregnancy Test Formats." *Expert Opinion on Medical Diagnostics* 7, no. 5 (September 2013): 435-41. <https://doi.org/10.1517/17530059.2013.830103>.
4. Gnoth, C., e S. Johnson. 2014. "Strips of Hope: Accuracy of Home Pregnancy Tests and New Developments". *Geburtshilfe und Frauenheilkunde* 74 (7): 661-69. <https://doi.org/10.1055/s-0034-1368589>.
5. Moghazy, Dalia, Omar Al-Hendy, and Ayman Al-Hendy. "Krukenberg tumor presenting as back pain and a positive urine pregnancy test: a case report and literature review." *Journal of Ovarian Research* 7.1 (2014): 36.
6. El Hage, Lea, and Betül Hatipoğlu. "Elevated hCG can be a benign finding in perimenopausal and postmenopausal women." *Cleveland Clinic Journal of Medicine* 88.11 (2021): 635-639.

HOW TO USE IT

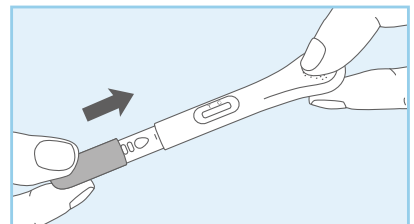
1) Remove the protective cap and place the absorbing tip right under the flow of urine for at least 10 seconds.



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.



VIDEO
TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
HGEH88000KIT02E5	EARLY DETECTION PREGNANCY TEST	1-2 TEST	36 MONTHS

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