

AccuPreg-Screen[®] Ref. 3066-1000/GB

A self-test to check the outcome of first trimester Termination of Pregnancy (ToP) or miscarriage For the measurement of hCG above 1000mIU/mL



INTRODUCTION

AccuPreg-Screen[®] is not a classical pregnancy test. AccuPreg-Screen[®] is a manual qualitative rapid immunochromatographic screening test for the detection of hCG (human chorionic gonadotropin) level above 1000 mIU/mL in women's urine samples. It can be used at home by lay users for self-testing to determine the outcome of first trimester previously confirmed Termination of Pregnancy (ToP) or miscarriage.

Your Health Care Professional will explain to you when and how to use this test.

PRESENTATION

The box contains:

- 1 hermetically sealed aluminium pouch containing:
1 AccuPreg-Screen[®] test and 1 desiccant bag.
- 1 Instruction for use.

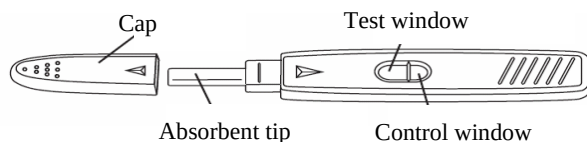
Material required but not provided:

- Timer
- Gloves

PRINCIPLE OF THE TEST

AccuPreg-Screen[®] is a rapid qualitative test for the presence of hCG in urine. In 5 to 10 minutes, it will detect an hCG level of 1000 mIU/mL or more.

When hCG level is below 1000 mIU/mL, only one coloured line appears in the control window but no coloured band appears in the test window. When hCG level is above 1000 mIU/mL two coloured lines appear, one in each window.



PRECAUTION

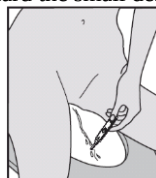
1. This test is exclusively intended for external use only (*in vitro* diagnostic use). Do not swallow.
2. Carefully read the instructions before carrying out the test. The test is not reliable unless the instructions are strictly followed.
3. Store at +4°C to +30°C. **Do not freeze.**
4. Use the device within 30 minutes after pouch opening.
5. Do not use after the expiry date printed on the aluminium pouch and on the external package or if the aluminium pouch has been damaged.
6. Do not reuse AccuPreg-Screen[®].
7. Keep out of reach of children.
8. After use, please dispose of all kit components into domestic waste.
9. WARNINGS:
 - AccuPreg-Screen[®] cannot be used for pregnancies where the initial hCG was lower than 1000mIU/mL.
 - Use AccuPreg-Screen[®] only within a medical treatment ordered by your treating doctor. The clinical interpretation of the test has to be done with or according to the medical staff managing you.
 - AccuPreg-Screen[®] cannot be used for the assessment of ectopic pregnancies or other abnormal pregnancy profiles.
 - Very high level of hCG commonly seen in cases of multiple gestation and molar pregnancies may give a false negative result as a result of the high dose hook effect.

ASSAY PROCEDURE

The test must be performed after Termination of Pregnancy at a time indicated by your gynaecologist, usually between 10 to 20 days after:

- miscarriage
- the first drug intake in Medical ToP

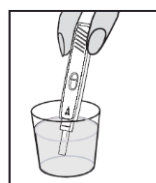
1. Remove the AccuPreg-Screen[®] test device from the foil pouch. Discard the small desiccant bag.



2. Remove the cap and either:

- hold the absorbent tip directly in your urine stream for 5-10 seconds.

Take care no urine enters the test window.



- or collect your urine in a clean and dry container (not provided) and dip the absorbent tip into the urine for at least 5 to 10 seconds in order for it to be completely soaked.

3. **Replace the cap** on the test device.

4. Lay the test device on a dry flat surface with the two windows facing up. Results will be shown in the windows and can be read between 5 to 10 minutes. Do not read the test after 10 minutes.

RESULT INTERPRETATION

Wait between 5 to 10 minutes to read the test results.

Within between 5 to 10 minutes, a line will appear in the control window (the smaller window).

Important: Do not read before 5 minutes or after 10 minutes.

Positive test result



If two pink coloured lines appear within 10 minutes: one line in the test window and one in the control window, the test is positive. Your hCG level may be above 1000 mIU/mL. This could mean that the treatment for termination of pregnancy may not have worked or is not complete, or that the miscarriage has not occurred. **In any case you should consult your gynaecologist.**

Note: One line can be darker than the other. The two lines can be any shade of pink-purple and the test line can be lighter or darker than the control line. However, you should see two clear parallel lines.

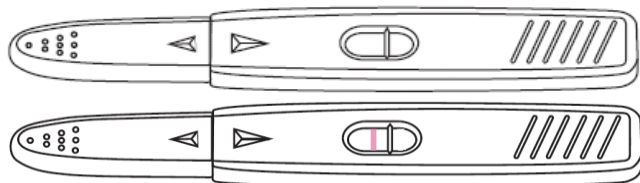
Negative test result



If only one pink coloured line appears in the Control window (the smaller window) and no line appears in the Test window (the largest window), the test is negative. **Miscarriage or Termination of Pregnancy is confirmed.**

Note: A ghostline which can appear for hCG concentration lower than 1000 mIU/mL is to be interpreted as a negative result.

Invalid test result



The test is invalid if there is no coloured line in the control window of the test. It is recommended that the test be repeated with a new **AccuPreg-Screen®** and tested using a fresh urine sample.

QUESTIONS AND ANSWERS

How does the AccuPreg-Screen® test work?

When a woman becomes pregnant, her body begins to produce a hormone, human Chorionic Gonadotropin (hCG), which is excreted in the urine where its concentration rises over time. The **AccuPreg-Screen®** test uses a pair of antibodies specifically detecting the hCG hormone in urine to check whether the hormone level is 1000 mIU/mL (determined against W.H.O.* reference) or greater. If treatment for Termination of Pregnancy or miscarriage has been successful then the hCG level should drop below 1000 mIU/mL within 10 to 20 days. **AccuPreg-Screen®** will not detect hCG levels lower than 1000 mIU/mL while classical pregnancy tests will be positive.

*World Health Organisation

Should I test at a certain time of day?

Yes, we recommend testing **AccuPreg-Screen®** on the first morning urine that should be more concentrated.

Will the quantity of fluids I have drunk affect the results?

Yes, a high fluids intake may dilute the urine and make the hCG detection more difficult. Abnormal fluids intake is therefore not recommended.

What if I am unsure about the result of the test?

If you are unable to determine whether or not a line is present in the oval test window, repeat the test after 1 day with a new **AccuPreg-Screen®** test.

If you follow the instructions, you should get accurate results.

Certain drugs and medical conditions such as cancer or uterine malignancies inducing high level of hCG or LH secretion may lead to a false positive result.

I left the absorbent tip in my urine for more than 10 seconds. Will I still obtain a correct result?

Yes. A few extra seconds will not affect the results.

I left the absorbent tip in my urine for less than 5 seconds. Will I still obtain a correct result?

No, because the urine sample volume may not be sufficient in order for the test to perform well.

What if the line in the Test window is darker than the line in the Control window or the line in the Test window is lighter than the line in the Control window?

As long as you see a line in each window, the test result is positive.

What should I do when I have the result?

You must follow the advice given by the medical staff managing you.

What if I don't wait the full 5 minutes before reading the test?

If you read the test before 5 minutes, you may not give the test enough time of work, and the test result may not be accurate.

DO NOT INTERPRET the results if 10 minutes have elapsed after having brought the absorbent tip into contact with urine.

How accurate is the test?

The **AccuPreg-Screen®** is very accurate and has been used by health care professionals to confirm the success of medical Termination of Pregnancy up to 9 weeks amenorrhea (hospitals and laboratories).

Evaluation reports show that **AccuPreg-Screen®** overall correlation is 99%* (CI** 95% [94.21 - 100.0]), the diagnostic sensitivity of **AccuPreg-Screen®** test is 100% (CI 95% [92.45 - 100.0]) and the diagnostic specificity is 98.0% (CI 95% [88.78 - 100.0]) when compared to reference method. Even if the test is negative, you should still contact your health care provider if you have symptoms of pregnancy such as scanty bleeding, no period, tender breasts, feeling sick, and a growing tummy.

* Claimed accuracy is with regard to testing performed on or after the day prescribed by the gynaecologist.

** CI 95%: 95% Confidence Interval.

Can I use AccuPreg-Screen® to diagnose a pregnancy?

Yes, but **AccuPreg-Screen®** is not able to detect very early pregnancies and only shows positive if the hCG hormone concentration is over 1000 mIU/mL. Other urine pregnancy tests are usually more sensitive and show a positive result starting from 25 mIU/mL.

Information on pregnancy and termination of pregnancy:

1. Web information: <https://www.health.harvard.edu/topics/womens-health/>
2. Web Information: <https://www.nhs.uk/conditions/abortion/what-happens/>



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	Read the instructions before use	IVD IVD	For <i>in vitro</i> diagnostic use		Do not reuse
 +30°C +4°C 4°C...30°C	Store between +4°C and +30°C	LOT LOT	Batch number	 EXP	Expiration date
	Manufacturer				

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CHANGES DESCRIPTION

Changes type:

- N/A Not Applicable (creation)
- Technical change Addition, revision and/or removal of information related to the product.
- Administrative Implementation of non-technical changes noticeable to the end-user.

Changes type	Changes description
Technical	Addition of diagnostic sensitivity and specificity; precaution n°4, information in Precaution n°9; note in negative result
Administrative	Addition of gloves as not provided material, Modification of symbol table

Note: Minor typographical, grammar, spelling and formatting changes are not reported in the change details.