

Vitam[®]

cassette

SINGLE USE PREGNANCY TEST FOR HOME USE WITH A SENSITIVITY OF 25 mIU/mL.

For in vitro self-testing use only. For external use only.
Device for self-testing.

PLEASE READ THE INSTRUCTION MANUAL CAREFULLY BEFORE PERFORMING THE TEST.

Vitam[®] is an easy and rapid pregnancy test. The test result appears within 3-5 minutes. Vitam[®] may be used for up to 10 days after intercourse. If the first day of expected your period does not happen, a morning urine specimen is appropriate for pregnancy testing. If the first day of your expected period passes, any urine specimen is appropriate for pregnancy testing.

INSTRUCTION MANUAL

BEFORE STARTING THE TEST:

- Carefully read the following instructions before use. If you have any questions about the method of performing the test or its results, please contact us at a toll-free number: 800 70 30 11, from 8 a.m. to 4 p.m. (Monday to Friday).
- Do not open the sealed pouch if you are not ready for testing.
- Do not use the kit if the pouch is punctured or not well sealed
- Do not use beyond the expiration date (expiration date printed on the box and label)
- Store at a temperature of between 4°C - 30°C, and keep away from sunlight.
- Do not freeze the test.
- If it is not possible to do the test right after collection of the urine specimen, it may be stored at 2-8°C (e.g. in a refrigerator) for up to 3 days prior to testing.
- Allow the urine specimens to reach room temperature for approx. 30 minutes before testing.
- Keep away from children.
- **Do not take any decision of any medical relevance without first consulting a medical practitioner after and/or before performing the test.**

HOW DOES IT WORK?

Human chorionic gonadotropin (hCG) is a hormone produced by the developing placenta shortly after fertilisation. Vitam[®] can detect the presence of hCG in urine specimens at very low concentrations, which can determine pregnancy or lack of pregnancy. Vitam[®] detects the presence of hCG in the urine specimen at a sensitivity of 25 mIU/mL.

KIT CONTENTS

The kit of Vitam[®] includes:

- Test panel.
- Droppers.
- Instruction manual.
- Desiccant sachet

NOTE: Throw away the desiccant sachet when you open the sealed pouch.

MATERIALS REQUIRED

BUT NOT PROVIDED:

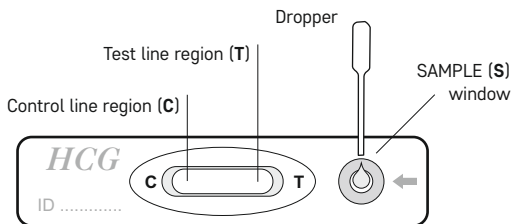
A clean, dry, plastic or glass specimen collection container, timer.

DIRECTION FOR USE

1. The urine specimen must be collected in the clean, dry plastic or glass container prior to testing.
2. Remove the sealed pouch from the box
3. Remove the test panel and Droppers from the sealed pouch
4. Immerse a Dropper into the urine specimen.
5. Fill the Dropper with the sample.
6. Hold the Dropper vertically above the SAMPLE (S) window and transfer 3-4 drops of urine. Avoid trapping any air bubbles in the droppers.
7. Positive results may be observed in as soon as 1 minute. However, to confirm negative results, the complete reaction time of 3 minutes is required.

DO NOT INTERPRET RESULTS after 5 minutes.

NOTE: If the colour line appears in the control test line C (not pregnant), do not interpret results after more than 5 minutes, as the chemical reaction occurring in the test can affect the observed test results.



INTERPRETATION OF THE RESULTS



POSITIVE (PREGNANT)

The result is considered **POSITIVE** if one line appears in the **control line region (C)** and another in the **test line region (T)** it means that you are pregnant.

The intensity of the colour of lines may vary.

Consult your physician. He should confirm your pregnancy after evaluating all clinical and laboratory findings. Indeed, in certain conditions, the test may give a false positive result. He will also give you further information and advise on your pregnancy.



NEGATIVE (NOT PREGNANT)

The result is considered **NEGATIVE** if the line occurs in the **control line region (C)** it means that you are not pregnant.

If you have reasons to believe that you are pregnant (e.g. no menstrual bleeding), you can repeat the test a few days later. If the test is still negative, consult your physician.



INVALID

The result is considered **INVALID** if within 5 minutes:

1. Line in the **test line region (T)** appears but line in the **control line region (C)** fails to appear.
2. Lines in the **control line region (C)** and in the **test line region (T)** fail to appear

In both situations, the result shall be considered invalid. Repeat the test using a new test panel.

NOTE: if the colour in the test zone is weak, it is recommended that the test be repeated in 48 hours.

QUESTIONS & ANSWERS

1. There is much difference between the control lines of two tests. Is this a concern?

No. Variations in the colour of the control band will not affect the test result.

2. Can test results be interpreted after more than five minutes?

No. Test results must be read in 5 minutes. Though a positive result should not change for several days, a negative result may change to a false positive within minutes after the end of the testing period, which would not be an accurate reading. It is always best to read the results at the 5 minute testing period and then discard the test to avoid confusion.

3. A pink background colour and vertical streaking appeared in the result area during the testing period. Is this a concern?

No. Each urine sample will vary in its chemical composition, as will the humidity of the air in testing room. Such variations in physical conditions can cause the vertical streaking and/or the pink-rose background colour but will not affect the test results. As long as the control band appears within five minutes, the test is working properly.

LIMITATIONS

1. As it is with any diagnostic procedure, a confirmed pregnancy diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
2. If a urine sample is too diluted (i.e., low specific gravity) it may not contain a representative level of hCG. If pregnancy is still suspected, another urine specimen should be collected 48 hours later and tested.
3. Elevated levels of hCG can be caused by a few conditions other than pregnancy. Therefore, the presence of hCG in the urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out. Consult your physician.
4. A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results. Consult your physician.
5. Sterility treatments, based on hCG, may cause false results. Consult your physician.

ALL COMPONENTS OF THE USED TEST SHOULD BE PUT INTO THE ORIGINAL PACKAGE AND DISPOSED OF IN DOMESTIC WASTE. NONE OF THE TEST COMPONENTS IS REUSABLE.



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	Storage temperature		Read the insert
	Lot number		Do not reuse
	Expiry date		For in vitro diagnostic use - not to be taken internally
	Number of tests per kit		Reference number
	Producer/Manufacturer		Revision date
	Do not use if package is damaged		Keep away from moisture
	Keep away from sunlight		

Store at 4-30°C. See the package and the label for the lot number and expiry date.

Diagnosis S.A.
ul. Gen. W. Andersa 38A
15-113 Białystok, Poland
www.diagnosis.pl

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