

ONE STEP PREGNANCY MIDSTREAM TEST

(Urine)

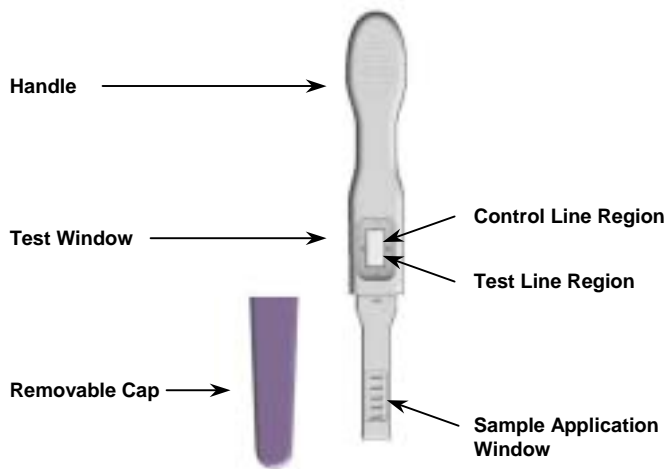
FOR IN VITRO DIAGNOSTIC USE ONLY

INTENDED USE

THE PREGNANCY TESTS ARE USED TO OBTAIN QUICK VISUAL, QUALITATIVE RESULTS FOR EARLY DETECTION OF PREGNANCY HCG (HUMAN CHORIONIC GONADOTROPIN) HORMONE IN URINE SAMPLES.

INTRODUCTION

Human Chorionic Gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after egg fertilization. hCG can be detected in the urine (also blood and serum) of a patient as early as 6 to 15 days after conception. The intended use of these tests is to screen for early beta hCG development which occurs between 5-50 mIU/mL. The hCG is released by the pituitary gland and peaks at 100,000-200,000 mIU/mL the end of the first trimester.



TEST PROCEDURES

1. Remove the plastic cap to expose the sample application window as the illustration above.
2. Point the absorbent tip (with 5 small openings) directly in urine stream for at least 7-10 seconds to allow the sample into the testing device. See the illustration below.



Note: Do not urinate on the Test and Control windows. Another technique is to collect urine into a clean container and dip the sample application window for at least 10 seconds.

3. After removing the midstream test from your urine, immediately replace the Cap over the Absorbent Tip, lay the midstream test on a flat surface with the Test and Control windows facing upwards, and then begin timing.
4. As the test begins to work, you may notice a light red flow moving across the Test and Control windows. Wait at least 3 minutes for the red line(s) to appear. If no red line appears, wait one minute longer. Some positive results may be observed in 1 minute or less depending on the concentration of hCG. Do not read the result after 10 minutes.

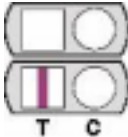
INTERPRETATION OF RESULTS



PREGNANT: The presence of two red lines in both the test window (T) and control window (C) means you are probably pregnant. One line may be lighter than the other, they do not have to match.



NOT PREGNANT: The presence of one red line in the control window (C) means you are probably not pregnant.



INVALID RESULT: The result is invalid if no red line appears in the control window (C), even if a line appears in the test window (T). You should repeat the test with a new midstream test.

PERFORMANCE CHARACTERISTICS

Sensitivity:

25 mIU/mL hCG detection limit

Specificity:

> 99% correlation was determined from cross reaction studies with known amounts of Luteinizing Hormone (300 mIU hLH/mL), Follicle Stimulating Hormone (1,000 mIU hFSH/mL), and Thyroid Stimulating Hormone (1,000 mIU hTSH/mL).

Reagents:

Containing membrane coated with goat anti-hCG colored colloidal gold - monoclonal mouse anti-hCG conjugated predried in pad.

Interference Testing

None of the substances at concentration tested interfered in the assay.

Acetaminophen	20 mg/mL
Acetylsalicylic acid	20 mg/mL
Ascorbic acid	20 mg/mL
Atropine	20 mg/mL
Caffeine	20 mg/mL
Gentecic acid	20 mg/mL
Glucose	2 g/dL
Haemoglobin	1 mg/dL

Built in Quality Control

The procedural control is built in to the test. A color band appearing on the control region of the strip indicates proper test performance.

The test will yield a positive result on the first day of missed menstrual period providing the beta hCG concentration is in detectable range (25 mIU/mL).

Urine from healthy men and non-pregnant women will normally show undetectable levels of hCG when tested with pregnancy tests. If unexpected results occur it is strongly recommended to consult with a qualified specialist.

TEST LIMITATIONS

1. The urine pregnancy test is designed for in vitro diagnostic use only.

2. a. Elevated levels of hCG may be produced in rare conditions other than pregnancy (such as trophoblastic disease and certain nontrophoblastic neoplasms).
- b. A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone.
- c. A spontaneous miscarriage may cause confusion in interpreting the test results.
- d. Test results may vary between different individuals.

If you obtain unexpected or inconsistent results please consult with your physician.

3. As with all pre screening devices, a definitive diagnosis should not be based on the results of a single test, and should always be confirmed with a qualified specialist.

STORAGE AND STABILITY

The test devices should be kept from prolonged exposure to direct sunlight, moisture, heat, and other related conditions. The test kit can be stored at normal room temperature (2 to 30) in the sealed pouch up to the expiration date of 2 years, which is indicated on the package.

DISPOSAL

Urine samples and used test devices are potentially infectious so please keep them away for direct contact with objects. Proper handling, hands washing, and immediate disposal is recommended.

WARNING AND PRECAUTION

1. Keep away from children and prolonged exposure to extreme storage conditions.
2. This test is designed for single in vitro diagnostic use only.
3. Do not use test kit beyond expiry date printed on package.
4. Tests results may vary for different individuals.
5. Confirm all test results with a qualified specialist.

PRIORITY ASSISTANCE

Our customer service team will be glad to offer assistance so please feel free to contact us with your detailed inquiry.

TECHNICAL REFERENCES

1. Batzer FR, Fertility & Sterility, Vol. 34, 1, 1980.
2. Braunstein GD, Rasor J, Alder D, Danzer H, Wade ME. Am.J. Obstet. Gynecol., Vol 126, 678, 1976.
3. Braunstein GD, et al. Ann. Inter. Med. Vol. 78, pp 39-45, 1973.
4. Catt KJ, Dufan ML & Vaitukaitis JL. J. Clin. Endocrinol. Metab., Vol 40, 537, 1975. 5.