Be Sure Early HCG Pregnancy Test (Midstream)
Ultra Sensitive

CE 0197

medical device
For Self-testing Use
Specimen: Urine
Format: Midstream

(A) INTEDED USE

HCG Pregnancy Test Midstream is a self-testing immunoassay made for the rapid, visual and qualitative determination of human chorionic gonadotropin (HCG) in urine specimen to aid in the early detection of pregnancy.

(B) SUMMARY

Human chorionic gonadotropin (HCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. In normal pregnancy, HCG can be detected in serum as early as 7 days following conception. The concentration of HCG continues to rise rapidly, frequently exceeding 100mIU/ml by the first missed menstrual period and peaking in the 100,000–200,000mIU/ml range by 10–12 weeks into pregnancy. The appearance of HCG soon after conception and its subsequent rise in concentration during early gestational growth make it an excellent marker for the early detection of pregnancy.

(C) PRINCIPLE

HCG Pregnancy Test Midstream is a chromatographic immunoassay (CIA) for the rapid qualitative determination of HCG in urine. The membrane is pre-coated with anti-alpha HCG capture antibody in the test line region and goat anti-mouse in the control line region. During testing, the urine specimen is allowed to react with the colored conjugate (mouse anti-beta HCG monoclonal antibody-colloidal gold conjugate), which has been pre-dried on the test strip.The mixture then moves upward on the membrane chromatographically by capillary action. For a positive result, a pink-colored line with the specific antibody-HCG-colored conjugate complex will form in the test line region of the membrane. Absence of this pink-colored line in the test line region indicates a negative result. Regardless of the presence or absence of HCG, as the mixture continues to move across the membrane to the immobilized goat anti-mouse, a pink-colored line in the control line region will always appear. The presence of this pink-colored line serves as: 1) verification that sufficient volume is added, 2) that proper flow is obtained, and 3) as a control for the reagents.

(D) COMPOSITION

HCG Pregnancy Test Midstream contains anti-β HCG on a colloid gold particles and a combination of anti-α HCG coated on the membrane.

REAGENTS AND MATERIALS PROVIDED

1. HCG Pregnancy Test Midstream
2. One desiccant
3. One Instruction

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Sample container

(E) WARNINGS AND PRECAUTIONS

1. Read the instruction carefully before performing this test. Pay attention to the position of the C and T line.
2. Do not use beyond the labeled expiration date.
3. HCG Pregnancy Test Midstream should remain in the sealed pouch until use. Do not use if pouch is damaged or opened.
4. Do not reuse the test kit. Discard it in the dustbin after single use.
5. Do not touch the membrane located within the windows.
6. Do not swallow the desiccant.

(F) STORAGE

HCG Pregnancy Test Midstream should be stored at temperature 2–30 ℃, the sealed pouch for the duration of the shelf time (36months). Do HCG Pregnancy Test Midstream in 1 hour when you open the pouch. **DO NOT FREEZE.**

(G) SAMPLE COLLECTION

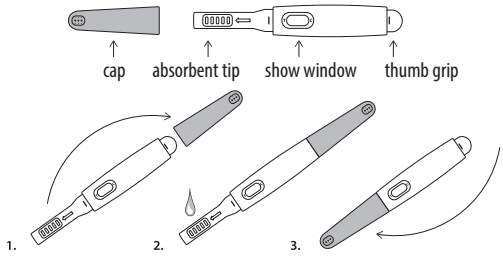
1. Collect fresh urine sample by using a disposable container which is clean and dry.
2. First morning specimens generally contain the highest concentration of HCG for early detection of pregnancy. However, any urine specimen is suitable for testing.
3. Specimens may be kept at room temperature for 8 hours. If the sample cannot be tested immediately, may store the sample at 2–8 ℃ for 48 hours or at -20 ℃ for a long time. Do not make the specimens repeat freeze and thaw.
4. Bring the urine sample to room temperature before testing.

(H) TEST PROCEDURE

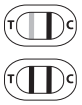
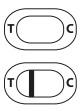
Allow the test midstream, urine specimen and/or controls to equilibrate to room temperature (15–30 ℃) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test midstream from the sealed pouch and use it as soon as possible.
2. Remove the cap to expose the absorbent tip.
3. Hold the midstream by the thumb grip with the exposed absorbent tip pointing downward. Urinate on the absorbent tip directly till it is thoroughly wet (at least 5 seconds).
   NOTE: Be careful do not urinate in the show window.
   If you wish, you can also catch some urine in a clean, dry container and hold the absorbent tip in the urine for 20 seconds.
4. Re-cap the test midstream and lay it on a flat surface with window on top.
5. Wait for pink-colored lines to appear. Read result within 5 minutes. Do not read result after 5 minutes.

test stick



(I) INTERPRETATION OF RESULTS

	PREGNANT	**Two distinct pink-colored lines appear, one in the test region (T) and the other one in the control region (C). NOTE:** The intensity of the pink color in the test region (T) may vary depending on the concentration of HCG present in the specimen. Therefore, any shade of pink color in the test region (T) should be considered positive.
	NOT PREGNANT	**Only one pink-colored line appears in the control region (C).** No apparent pink line appears in the test region (T).
	INVALID	**Control line fails to appear. NOTE:** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test midstream. If the problem persists, please contact your local distributor.

(J) QUALITY CONTROL

A procedural control is included in the test. A colored line appearing on the control region (C) is considered an internal positive procedural control, indicating proper performance and reactive reagents. A clear background in the membrane is considered as an internal negative procedural control. If the test has been performed correctly and reagents are working properly, the background will clear to give a discernible result.

(K) EXPECTED VALUES

Negative result will be found in the urine of healthy men and healthy non-pregnant women. However, healthy pregnant women have HCG present in their urine and serum specimens. The amount of HCG will vary greatly with gestational age and between individuals. HCG Pregnancy Test Midstream has an analytical sensitivity of 10mIU/ml, and is capable of detecting pregnancy as early as 5–6 days before the day of the missed menses.

(L) PERFORMANCE CHARACTERISTICS

1. ANALYTICAL SENSITIVITY
   No less than 10 mIU/ml
2. ANALYTICAL SPECIFICITY
   The test results show negative for the 500 mIU/ml hLH, 1000 mIU/ml hFSH and 1000 µIU/ml hTSH specimens.
3. DIAGNOSTIC SENSITIVITY AND DIAGNOSTIC SPECIFICY
   This HCG Pregnancy Test Midstream detects HCG at a concentration of 10mIU/ml or greater. 900 known negative urine samples were equally divided into 6 groups. Each group of samples (150) were spiked with HCG to the concentration of 0mIU/ml, 2.5mIU/ml, 5mIU/ml, 10mIU/ml, 20mIU/ml and 5IU/ml separately, calibrated against WHO 4th international standard. Each group of sample was tested with HCG Pregnancy Test Midstream. The results from this study gave >99% agreement with the expected results.

Result	0 mIU/ml	2.5 mIU/ml	5 mIU/ml	10 mIU/ml	20 mIU/ml	5 IU/ml	Total
Positive	0	0	0	150	150	150	450
Negative	150	150	150	0	0	0	450
Total	150	150	150	150	150	150	900

Diagnostic sensitivity = 100% (450/450)
Diagnostic specificity = 100% (450/450)
Interference Testing: The following substances were added in HCG free and HCG spiked urine samples. None of the substances at concentration tested interfered in the assay. For example:

Acetaminophen	0.2 mg/ml
Acetylsalicylic acid	0.2 mg/ml
Ascorbic Acid	0.2 mg/ml
Atropine	0.2 mg/ml

Caffeine	0.2 mg/ml
Gentesic Acid	0.2 mg/ml
Glucose	20 mg/ml
Hemoglobin	10 µg/ml

Tetracycline	0.2 mg/ml

(M) LIMITATION

1. Although it is not necessary to test with an early morning urine sample, excessive fluid intake should be avoided before testing. A "Not Pregnancy" result may be obtained if the urine sample is too dilute.
2. The contents of this kit are for use in the qualitative detection of HCG in urine only.
3. A specimen with a low level of HCG may show color development over time. If a negative result is obtained but pregnancy is suspected, another specimen should be collected after 48–72 hours and tested.
4. Fertility drugs containing HCG can give misleading results (these fertility drugs are usually given by injection and testing too soon after administration may give a false "pregnancy" result).
5. Other fertility therapies (such as clomiphene citrate), painkillers and hormonal contraceptives (e.g. contraceptive pill) should not affect the result.
6. HCG may remain detectable for a few days to several weeks after delivery, spontaneous abortion, or HCG injections.
7. Ectopic pregnancy, ovarian cysts, menopause, and some very rare medical conditions can give misleading results.
8. While pregnancy is the most likely reason for the presence of HCG in serum and urine, elevated HCG concentrations unrelated to pregnancy have been reported in some patients, for example, trophoblastic disease and certain nontrophoblastic neoplasms.
9. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
10. Alcohol may interfere the test result. It is not recommended using the test after drinking.
11. The user with eye diseases such as color blindness or color weakness may interpret the result wrongly.

(N) QUESTIONS & ANSWERS

1. **Q:** How soon after I suspect that I am pregnant can I take the test?
   A: You can test your urine as early as the first day you miss your period.
2. **Q:** Do I have to test with first morning urine?
   A: You can perform the test at any time of the day. However, your first morning urine is usually the most concentrated of the day and would have the most HCG in it.
3. **Q:** How do I know that the test was run properly?
   A: The appearance of a colored line in the control region tells you that you followed the test procedure properly and proper amount of urine was absorbed.
4. **Q:** Can test results be interpreted after more than five minutes?
   A: No. Test results must be read within 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.

(O) REFERENCES:

[1] Robert D. Nerenz, Haowei Song, and Ann M. Gronowski. Screening Method to Evaluate Point-of-Care Human Chorionic Gonadotropin (hCG) Devices for Susceptibility to the Hook Effect by hCG βCore Fragment: Evaluation of 1 1 Devices. Clinical Chemistry 60:4.667-674 (2014)

[2] Berger P, Paus E, Hemken PM, Sturgeon C, Stewart WW, Skinner JP, Harwick LC, Saldana SC, Ramsay CS, Rupprecht KR, Olsen KH, Bidart JM,Stenman UH. Candidate epitopes for measurement of hCG and related molecules: the second ISOBM TD-7workshop.Tumor Biol. (2013) 34:4033-4057

INDEX OF SYMBOLS

PRODUCT NAME Be Sure Early HCG Pregnancy Test (Midstream) Ultra Sensitive / PZN 10043884

	Manufacturer	EC REP	Authorized representative in the European Community/ European Union		Date of manufacture		Use-by date
LOT	Batch code	CN	Country of manufacture „CHINA"		EU Importer		Distributor
	Do not re-use		Consult instruction for use or consult electronic instruc-tions for use	MD	Medical device	CE 0197	CE mark
UDI	Unique device identifier	Σ	Contains suffficient for >1< tests	IVD	In-vitro disagnostic medical device	+30°C +2°C	Store at 2°C – 30°C

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