TestSure

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE USE

- **FDA Approved**
- **99% Accurate**
- **Independently Tested**
- **Scientifically Proven**

For more information visit www.testsure.com

ONE STEP HCG URINE TEST (MIDSTREAM)

The One Step HCG (human chorionic gonadotropin) Urine Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (HCG) in urine to aid int he early detection of pregnancy.
For professional in-vitro diagnostic use only.

HOW DOES IT WORK?

Human chorionic gonadotropin (HCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. The test utilizes a combination of antibodies including a monoclonal HCG antibody to selectively detect elevated levels of HCG. The assay is conducted by putting urine onto the test end of the applicator and observing the formation of colored lines. The specimens migrates via capillary action along the membrane to react with the colored conjugate.
Positive specimens react with the specific antibody-HCG-colored conjugate to form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

CONTENTS OF THE TEST KIT

- Pregnancy test
- Instructions

WHAT ELSE DO YOU NEED?

- Urine Cup
- Timer

PRECAUTIONS

For professional in-vitro diagnostic use only. Do not use after the expiration date.
The TestSure test device should remain in the sealed pouch until use.
All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
The test device should be discarded in a property biohazard container after testing.

STORAGE AND STABILITY

Store at 2 to 30 degrees in the sealed pouch up to the expiration date.
Keep away from direct sunlight, moisture and heat.

DO NOT FREEZE

Preferably open the pouch only shortly before testing.

WHEN TO DO THE TEST?

Any urine specimen is appropriate for Pregnancy Testing but the first morning urine specimens is optimal because of its highest concentration of HCG.

HOW TO DO THE TEST?

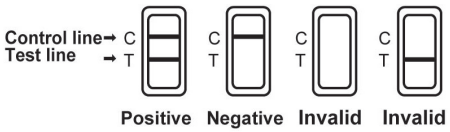
To begin testing, open the sealed pouch by tearing along the notch. Remove the test midstream from the pouch. Hold the round end of cover with one hand. Use the other hand to pull out the midstream cap and expose the absorbent.
Point the absorbent tip downward into the urine stream for at least three seconds to be thoroughly wet. Do not urinate past the arrow mark. Otherwise you can collect your urine into a clean cup and dip half of the absorbent paid into the urine for at least 3 seconds.
Re-cap the device and wait for color bands to appear. Read the result in ten minutes. Do not read results after more than 15 minutes.

HOW TO READ THE RESULTS

Negative (not pregnant):
Only one color band appears in the Control Zone. No apparent band in the Test Zone. This indicates that no pregnancy has been detected.

Positive (pregnant):
District color bands appear in the Control and Test Zones. This indicates that you are pregnant. The color inequity of the test bands may vary since different stages of pregnancy have differed concentrations of HCG hormone.

Invalid:
No visible band at all, or there is a visible band only in the test region. Repeat with a new test kit. If test still fails, please contact the distributor or the store, where you bought the product with the lot number.



NOTE: If the color in the Test Zone is weak, it is recommended that the test be repeated in 48 hours.

QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the results area should be white to light pink and not interfere with the ability to read the test results.
It is recommended that a positive HCG control (containing 25-250 mlU/mL HCG) and a negative HCG control (containing "0" mlU/mL HCG) be evaluated to verify property test performance. It is recommended that federal, state, and local guidelines be followed.

LIMITATIONS

1. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of HCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
2. False negative results may occur when the levels of HCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. Very low levels of HCG (less than 50 mlU/mL) are present in the urine specimen shortly after implantation. However, because a significant number of first trimester pregnancy terminate for natural reasons (5), a test results that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
4. As with any assay employed mouse antibodies, the interference possibility exists for human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.
5. This test provides a presumptive diagnosis for pregnancy. A pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.