First Sign ®

One-Step Urine Pregnancy Test Cassette Package Insert

For Professional and *In Vitro* Diagnostic Use Only

A Qualitative Test for Detection of Human Chorionic Gonadotropin (hCG) in Human Urine for Early Detection of Pregnancy

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INTENDED USE

First Sign® One-Step Urine Pregnancy Test is a rapid chromatographic immunoassay designed for the qualitative determination of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.

SUMMARY AND EXPLANATION

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. During normal pregnancy, hCG can be detected in urine as early as 7 days following conception. hCG levels continue to rise very rapidly, frequently exceeding 100mIU/mL by the first missed menstrual period, and peaking in the 100,000 to 200,00mIU/mL range about 10 to 12 weeks into pregnancy. The presence of hCG soon after conception during early gestational growth make it an ideal marker for the detection of pregnancy.

PRINCIPLE

The **First Sign® One-Step Urine Pregnancy Test** is rapid qualitative one step assay for the detection of hCG in urine. The method employs a unique combination of monoclonal dye conjugate and polyclonal-solid phase antibodies to selectively identify the hCG in the test samples with an extremely high degree of sensitivity. As early as 5 minutes, level of hCG as low as 25mIU/mL can be detected.

As the test sample flows through the absorbent device, the labeled antibody-dye conjugate binds to the hCG forming an antibody-antigen complex. This complex binds to anti-hCG antibody in the positive reaction zone ("T" area) and produces a pink-purple colored band when the hCG concentration is greater than 25mIU/mL. In the absence of hCG, there is no line in the positive reaction zone. Unbound conjugate binds to the reagents in the control zone ("C" area), producing a pink-purple band, demonstrating the reagents are functioning properly.

REAGENTS AND MATERIALS

Ingredients: contains a combination of mouse monoclonal antibodies and polyclonal antibodies (sheep or goat) directed against human gonadotropin.
Mouse monoclonal antibodies and polyclonal antibody on colloidal gold particle.

Material Provided:
Each **First Sign® One-Step Urine Pregnancy Test** cassette individually sealed in a foil pouch.
Each pouch contains:
1. One **First Sign® One-Step Urine Pregnancy Test** cassette
2. One disposable specimen dropper
3. Desiccant

Material Required But Not Provided:
1. Timer
2. Sample container
3. Disposable gloves

No other equipment or reagents are needed.

STORAGE AND STABILITY

Store test device at 4°C to 30°C (40°F to 86°F). The test device is stable until the date imprinted on the pouch label.

PRECAUTIONS

1. For professional and *in vitro* diagnostic use only.
2. Read directions for use carefully before performing this test.
3. Do not use the test beyond the expiration date indicated on the pouch label.
4. Handle all specimens for testing as if potentially infectious. Proper precautions in handling should be maintained according to good laboratory practice.
5. The test device should be discarded in a proper biohazard container after testing.
6. The test cassette should remain in the sealed pouch until use.

URINE SPECIMEN COLLECTION AND PREPARATION

A first morning urine specimen is preferred since it contains the highest concentration of hCG. However, randomly collected urine specimens may be used. Collect the urine specimen in a clean dry container. If testing is not immediate performed, the specimen should be stored refrigerated at 2°C to 8°C for 48 hours. In such cases bring the sample to room temperature prior to testing.

SPECIMEN STORAGE

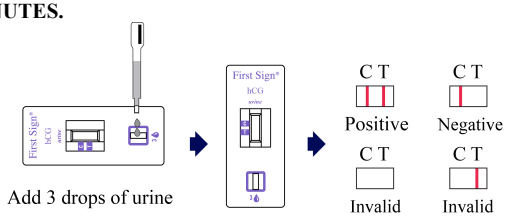
Urine specimen may be stored at 2°C to 8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

DIRECTION FOR USE

Allow the test cassette, urine specimen and/or controls to equilibrate to room temperature (15°C to 30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Using the sample dropper, withdraw the urine sample from the specimen container and slowly dispense 3 drops (approximately 100uL) into the circular sample well, being careful not to overfill the absorbent pad.
3. Wait for the pink-purple line(s) to appear**. Read the result at 5 minutes**. It is important that the background is clear before the result is read.

Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, **DO NOT INTERPRET RESULT AFTER 10 MINUTES.**



INTERPRETATION OF RESULTS

1. **Negative:**
   Only one pink-purple colored band appears in the control area (C).

Negative

2. **Positive:**
   In addition to the control band a clearly distinguishable pink-purple colored band also appears in the test area (T).

Positive

3. **Invalid:**
   As long as there is no distinct pink-purple colored band visible in control area, the test is invalid. It is recommended that in this case the test be repeated or fresh specimen be obtained and tested 48 hours later.

Invalid Invalid

QUALITY CONTROL

Built in Quality Control Features:
After addition of the sample, these colored bands migrate along the membrane at the leading edge of the dye conjugate and are "removed" from the test device completely.

When the test is complete, you will see a pink-purple colored band in the "C" area of the test device on negative samples and a pink-purple colored band in the "T" and "C" area on positive samples. The appearance of the CONTROL band indicates that the test device is performing properly and serves as procedural control.

PERFORMANCE CHARACTERISTICS

Sensitivity:
First Sign® One-Step Urine Pregnancy Test device is a rapid test used to detect the presence of hCG in urine qualitatively at levels as low as 25mIU/mL.

Accuracy:
Test accuracy was assessed by comparing 99 patient urine samples that were tested comparing the results of the **First Sign® One-Step Urine Pregnancy Test** to an equivalent product. **First Sign® One-Step Urine Pregnancy Test** demonstrated 100% correlation with the equivalent product (Fisher Sure Vue).

Specificity:
Potentially interfering substances were added to urine that had hCG levels of 0 and 25mIU/mL. No interference was observed with the **First Sign® One-Step Urine Pregnancy Test**.

Acetaminophen	20mg/dL
Acetysalicylic Acid	20mg/dL
Ascorbic Acid	20mg/dL
Atropine	20mg/dL
Caffeine	20mg/dL
Gentesic Acid	20mg/dL
Glucose	2mg/dL
Hemoglobin	1mg/mL
Ampicillin	20mg/dL
Tetracycline	20mg/dL
Bilirubin	2mg/dL

The following hormones were tested for cross reactivity and did not affect the performance of the **First Sign® One-Step Urine Pregnancy Test**

hTSH	1000μIU/mL	WHO 68/38
hLH	500mIU/mL	WHO 2nd IRP HMG
hFSH	2000mIU/mL	WHO 2nd IRP HMB

LIMITATION

1. Occasionally specimens containing less than 25mIU/mL for urine also yield positive results.
2. In addition to pregnancy, hCG has been found in patients with both gestational and non-gestational trophoblastic disease. Since the hCG has been found in patients with both gestational and non-gestational neoplasms is similar to that found pregnancy, these conditions, which include choriocarcinoma and hydatichiform mole, should be ruled out before a diagnosis of pregnancy is reached.
3. A normal pregnancy can not be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results.
4. A very early pregnancy containing an extremely low concentration of hCG can give a negative result. In this case, another specimen should be obtained at least 48 hours later and tested.
5. hCG levels may remain detectable for several weeks after normal delivery, delivery by cesarean section, spontaneous abortion or therapeutic abortion.

REFERENCE

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