



ONE STEP HCG PREGNANCY TEST STRIP

(HUMAN CHORIONIC GONADOTROPIN)

For self-testing and in vitro diagnostic use only

for Urine Samples

REF ABT-FT-A1

INTENDED USE

Accu-Tell® One Step hCG Pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid for the early detection of pregnancy.

WARNING AND PRECAUTIONS

1. Read directions for use 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. The test device should remain in the sealed pouch until use. Do not use if pouch is damaged or opened.
4. Do not reuse the test devices. Discard it in the dustbin after single use.
5. Do not touch the membrane located within the windows.

SUMMARY

The pregnancy hormone human Chorionic Gonadotrophin (hCG) starts to be produced the developing placenta shortly after fertilization. The role of HCG is to stimulate production of the hormones progesterone and oestrogen. These in turn maintain the uterine lining and prevent menstruation, so allowing the pregnancy to continue. The appearance of hCG in both urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy. The level of hCG increases rapidly during early pregnancy. The level of HCG increases rapidly during early pregnancy, doubling every 1.3-2 days, soon reaching a level that can be detected in blood or in urine. While the level of HCG can vary between pregnant women, published literature has shown that the level of HCG reaches at least 50 mIU/ml on the day the period is due. Accu-Tell® One Step hCG Pregnancy Test is sensitive enough to detect HCG at this level.

PRINCIPLE

Accu-Tell® One Step hCG Pregnancy Test is a rapid qualitative one step assay for the detection of HCG in urine. The test utilizes a 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. The specimen migrates via capillary action along the membrane to react with the colored conjugate and observe the formation of colored lines. 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.

COMPOSITION

The test strip contains anti- β hCG on a colloidal gold particles and a combination of anti- α hCG coated on the membrane.

MATERIALS PROVIDED

Each Strip test kit individually sealed in a foil pouch. Each test kit contains:

1. One Accu-Tell® One Step hCG Pregnancy Test strip
2. One Desiccant

3. One Instruction

MATERIALS REQUIRED BUT NOT PROVIDED

Timer, sample container and disposable gloves. No other equipment or reagents are needed.

SPECIMEN COLLECTION AND PREPARATION

COLLECTION

A urine specimen must be collected in clean dry container.

Collect urine specimens in clean containers.

First morning specimens generally contain the highest concentrations of hCG and are recommended for early detection of pregnancy. However, any urine specimen is suitable for testing.

PREPARATION

Specimens may be kept at room temperature for 8 hours or stored at 2-8°C for up to 3 days. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

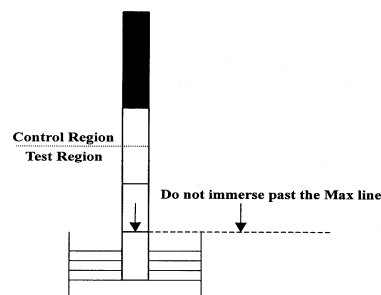
TEST PROCEDURE

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

(1) Remove the test device from the sealed pouch and use it as soon as possible.

(2) With arrows pointing toward the urine specimen, immerse the Strip test vertically in the urine specimen, for at least 5 seconds. Do not pass the maximum line (max) on the Strip test when immersing the strip.

(3) Lay the strip flatly on a non-absorbent clean surface. Start the timer and wait for the red line (s) to appear. Read result within 5 minutes but no longer than 15 minutes.

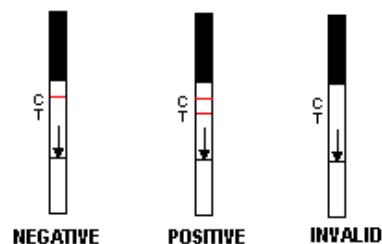


INTERPRETATION OF RESULTS

NEGATIVE one red-purple colored line in the control region(C). No apparent red or pink line appears in the test region (T).

POSITIVE Two red-purple colored lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

INVALID Control line fails to appear. Review the procedure and repeat the test with a new test strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



NOTES:

The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

**QUALITY CONTROL****Built-in Quality Control Features**

Internal procedural controls are included in the test. A red-purple line appearing in the control region (C) is the internal procedural control. The appearance of the C line indicates that the test has been performed correctly, including that the proper volume of specimen has been absorbed and the capillary flow has occurred. The C line should always appear regardless of the presence of hCG. If this line does not develop within 5 minutes, the result is invalid. In this case, review the whole procedure and repeat test with a new device.

LIMITATIONS

1. The content of this kit are for use in the qualitative detection of hCG in urine only.
2. 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.
3. Alcohol may interfere the test result. It is not recommended using the test after drinking.
4. Although it is not necessary to test with an early morning urine sample, excessive fluid intake should be avoided before testing. A 'Not Pregnant' result may be obtained if the urine sample is too dilute.
5. 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 'Pregnant' result.)
6. Other fertility therapies (such as clomiphene citrate) painkillers and hormonal contraceptives (e.g contraceptive pill) should not affect the result.
7. hCG may remain detectable for a few days to several weeks after delivery, spontaneous abortion, or hCG injections.
8. Ectopic pregnancy, ovarian cysts, menopause, and some very rare medical conditions can give misleading results.
9. 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.
10. 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.

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy men. 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. In normal pregnancy, hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/ml by the first missed menstrual period and peaking in the 100,000-200,000 mIU/ml range about 10-12 weeks into pregnancy.

PERFORMANCE CHARACTERISTICS**Sensitivity and Specificity**

The Accu-Tell® One Step hCG Pregnancy detects hCG at a concentration of 25mIU/mL or greater. 300 know negative urine samples were equally divided into 6 groups. Each group of samples(50) were spiked with HCG to the concentration of 0mIU/ml, 10 mIU/ml, 15 mIU/ml, 25 mIU/ml, 50 mIU/ml and 5 IU/ml separately, calibration against WHO 3rd international standard. Each group of sample of samples were tested with Accu-Tell® One Step hCG Pregnancy Test. The results from this study gave 100% agreement with the expected results.

Result	0mIU/ml	10mIU/ml	15mIU/ml	25mIU/ml	50mIU/ml	5IU/ml	Total
Positive	0	0	0	50	50	50	150
Negative	50	50	50	0	0	0	150
Total	50	50	50	50	50	50	300

Diagnostic sensitivity=100%(150/150)

Diagnostic specificity=100% (150/150)

Interference Testing

Accu-Tell® One Step hCG Pregnancy Test has been tested with commonly known drugs and hormones including LH(500mIU/ml),FSH(1,000mIU/ml),and TSH(1,000µIU/mL).At the levels tested, none of these substances interfered with the expected test results. For example: Acetaminophen 20mg/dl,Ace-tylsalicylic Acid 20mg/dl, Ascorbic Acid 20mg/dl,Atropine 20mg/dl,Caffeine 20mg/dl,Gentescic Acid 20mg/dl,Glucose2g/dl,Hemoglobin 20mg/dl, Ampicillin 20mg/dl,Tetracycline 20mg/dl.

Storage and Stability

The test kit can be Stored at 4-30°C in the sealed pouch. It is stable through the expiration date printed on the pouch label. Do not freeze.

REFERENCES

1. Dawood MY,BB Saxena, R Landesman "human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma",Obstet.Gynecol.1977 50(2),172-181
2. Braunstein GD,JL Vaitukaitis,PP Carbone,GT ROSS "Ectopic production of human chorionic gonadotropin by neoplasms ",Ann.intern Med.1973
3. Twenty-sixth Report of WHO Tech Report Series No.565,1975.
4. McCready J,Braunstein GD,Helm D, wade ME. Clin Chem 24; 1958-1961,(1978).
5. Lenton EA, Neal LM, Sulaiman R. Plasma concentrations of human Chorionic Gonadotrophin from the time of implantation until the second week of pregnancy,Fertil,Steril.1982,37(6): 773-8
6. Chard T Pregnancy test-a review, Hum Reprod,1992.7(5) :701-10

INTERPRETATION OF SYMBOLS ON PACKING BOX:

	Do not reuse		See instructions for use
	Temperature Limits		Lot Number
	Used by		For in vitro diagnostic use
	Manufacturer		European Representative



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