Cenogenics

ACCUNATE™ ONE-STEP CASSETTE URINE PREGNANCY TEST

INTENDED USE
CENOGENICS' ACCUNATE™ ONE-STEP CASSETTE is a rapid lateral flow colloidal gold strip test for the qualitative determination of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy.

SUMMARY AND EXPLANATION
Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the trophoblast of the developing blastocyst and later by the chorion and the placenta in pregnant women. Normally hCG can be detected in the urine or serum as early as 7 days after conception.' At the time of the first missed menstrual period, the concentration of hCG is approximately 100mIU/ml.' Cenogenics' ACCUNATE™ ONE-STEP CASSETTE will detect hCG in urine at a concentration of 25mIU/ml. The test employs a highly specific monoclonal antibody bound to colloidal gold to selectively detect hCG in urine thus virtually eliminating any cross reaction from related hormones, hLH, hFSH and hTSH.

PRINCIPLES OF THE PROCEDURE
Urine placed in the sample well of the cassette is allowed to react with the test strip contained in the cassette. If hCG is present, it binds to the anti-beta hCG monoclonal antibody-gold conjugate. The antibody-gold conjugate and the hCG-antibody-gold complex migrate through the membrane to the hCG capture antibody test area and then to the anti-IgG control area. If hCG is present at a concentration of 25mIU/ml or greater, two pink bands will develop on the membrane, indicating a positive test result. If hCG is absent, only one colored band will appear indicating a negative result.

CLIA complexity: Waived test

REAGENTS
The ACCUNATE™ ONE-STEP CASSETTE contains a membrane coated with anti-hCG capture antibody in the test zone, anti-IgG in the control zone and monoclonal anti-beta hCG coated colloidal gold particles.

MATERIALS PROVIDED
The ACCUNATE™ ONE-STEP CASSETTE is packaged in a sealed foil pouch containing a desiccant and a dropper.
Product instructions

MATERIALS REQUIRED BUT NOT PROVIDED
Specimen collection container
Timer or stop-watch

STORAGE
Store cassette in its sealed pouch either at room temperature (20° - 25°C) out of direct sunlight or refrigerate (2° - 8°C).

PRECAUTIONS
1. Do not use test beyond the expiration date.
2. Keep the test strip in the sealed pouch until ready to use.
3. If the control band does not develop a pink color, the test is invalid.
4. For in vitro diagnostic use.

SPECIMEN COLLECTION

Collect urine into a clean glass, plastic or wax coated container. Urine voided at any time can be used in the test. However, a first morning specimen is recommended especially in early pregnancy since it contains the highest concentration of hCG.

Filtration or centrifugation is usually not necessary. However, grossly turbid urine should be centrifuged (5 minutes at 1000 - 2000 x g).

Unless used fresh, urine should be refrigerated for up to 24 hours until tested. For longer storage, store frozen. Frozen specimens should be thawed by placing in a 37°C water bath. If thawed urines are turbid or if a precipitate is visible, centrifuge or filter as described above.

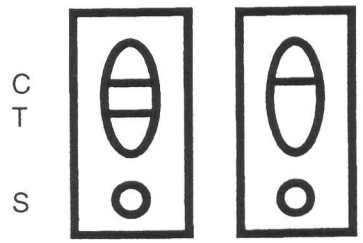
TEST PROCEDURE

1. Bring urine specimen and cassette to room temperature.
2. Remove the cassette from the foil pouch.
3. Using the dropper provided, add 2 - 4 drops of urine specimen to the well marked "S".
4. Reactions will appear within two minutes and will intensify over 5 minutes. Do not read after 5 minutes.

RESULTS

POSITIVE: A positive result is indicated by the presence of two (2) pink bands. The upper band (C) is the positive control and the lower band (T) is the specimen reaction. The bands may differ in color intensity from one another.

NEGATIVE: A negative result is indicated by the presence of only one (1) pink control band (upper band).



POSITIVE NEGATIVE

QUALITY CONTROL

The upper pink band is the positive control and is an indication that the test reagents are reactive and that the test was performed correctly. When two clearly visible bands develop, even if the color intensity is weaker in one band, the test is positive. If the positive control band is not present, the test is invalid and should be repeated with a fresh test cassette.

It is also recommended that a confirmed hCG positive (positive pregnancy) and a confirmed hCG negative (negative pregnancy) urine specimen be tested as external controls. Testing of the controls is performed as described above under Test Procedure.

LIMITATIONS OF THE PROCEDURE

1. Elevated levels of hCG may be seen in patients with trophoblastic and certain nontrophoblastic diseases.
2. A negative result may be seen in very early pregnancy if the level of hCG is below the detectability of the test (25mIU/ml) or if the urine specimen is dilute (low specific gravity).
3. If a negative result is obtained for a patient suspected to be pregnant, a fresh urine specimen should be obtained 48 hours later and retested.

EXPECTED VALUES

The levels of hCG in urine will reach 25mIU/ml approximately four days before the first missed menstrual period and will continue to rise until it reaches a maximum concentration over 200,000mIU/ml at the end of the first trimester.[5]

PERFORMANCE CHARACTERISTICS

Cenogenics ACCUNATE™ ONE-STEP CASSETTE can detect an hCG level of 25mIU/ml in urine. The sensitivity is calibrated against the World Health Organization (WHO) 3rd International Standard. No cross reactivity has been observed with hLH (300mIU/ml), hFSH (1000mIU/ml) or hTSH (1000μIU/ml).

ACCURACY

In a clinical study, the ACCUNATE™ ONE-STEP CASSETTE was directly compared to a similar commercially available pregnancy test. A total of 131 specimens (63 positives and 68 negatives) were tested. The correlation was 100%.

INTERFERING SUBSTANCES

The substances listed below, at the concentrations indicated, were added to urine specimens containing hCG at a level of 0mIU/ml and 25mIU/ml. None of the substances affected the assay results of the ACCUNATE™ ONE-STEP CASSETTE.

Acetaminophen	20mg/dL	Ethanol	200mg/dL
Acetylsalicylic acid	20mg/dL	Gentisic acid	20mg/dL
Ampicillin	20mg/dL	Glucose	2,000mg/dL
Ascorbic acid	20mg/dL	Hemoglobin	25mg/dL
Atropine	20mg/dL	Human serum albumin	2,000mg/dL
Caffeine	20mg/dL	Phenothiazine	2mg/dL
Estradiol	25ng/mL	Progesterone	40ng/dL
Estriol	25ng/mL	Tetracycline	20mg/dL

REFERENCES

1. Braunstein, G.D., Rasor, J., Adler, D., Danzer, H. and Wade, M.E., Am. J. Obstet. Gynecol., 126, 678-681 (1976).
2. Morgan, F.J., Canfield, R.E., Vaitukaitis, J.L. and Ross, G.T., Ann Intern. Med., 94, 1601- 1606 (1974).
3. Braunstein, G.D., Vaitukaitis, J.L. Carbone, P.P. and Ross, G.T., Ann. Intern. Med., 78, 39- 45 (1973).
4. Edmunds, D.K., Lindsay, K.S., Miller, J.F., Williamson, E. and Wood, R.J., Fertility and Sterility, 38, 447-453, (1982).
5. Lenton, E.A., Neal, L.M. and Sulaiman, R., Fertility and Sterility, 37, 773-778 (1982).