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ONE-STEP PREGNANCY CARD TEST

INTENDED USE
For the rapid determination of human chorionic gonadotropin (hCG) in human urine. This test kit is for professional use in obtaining a visual qualitative result for the detection of pregnancy.

INTRODUCTION
Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. From the onset of pregnancy hCG concentrations in a woman's serum and urine increase rapidly making the hormone a good marker for pregnancy testing. Seven to ten days after conception the hCG concentration reaches 25 mIU/ml and then increases steadily to reach its maximum between the eighth and eleventh week of pregnancy[1,2,3].

One-Step Pregnancy Test is a qualitative, sandwich dye conjugate immunoassay for the determination of human hCG in urine.[4,5] The method employs a combination of monoclonal and polyclonal antibodies to selectively identify hCG in test samples with a high degree of sensitivity. In less than 5 minutes, elevated levels of HCG equal to or greater than 25 mIU/mL can be detected.

PRINCIPLE
As the test sample diffuses through the absorbent reaction pack, the labeled antibody-dye conjugate binds to the hCG in the specimen forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the positive reaction zone and produces a pink-rose color band when hCG concentration is equal to or greater than 25 mIU/mL. In the absence of hCG, there is no line in the positive reaction zone. The reaction mixture continues flowing through the absorbent device past the positive reaction zone and negative zone. Unbound conjugate binds to the reagents in the negative control zone, producing a pink-rose color band, demonstrating that the reagents and reaction pack are functioning correctly.

MATERIALS AND REAGENTS PROVIDED
1. One-Step Pregnancy Test and Disposable Plastic Dropper:
   Test pack containing goat polyclonal antibody coated membrane and a pad containing mouse monoclonal IgG (antibody) dye conjugate in protein matrix with 0.1% sodium azide.
2. Reaction Pack and Disposable Plastic Dropper:
   Each pouch contains one "reaction pack" and one disposable plastic dropper.

MATERIALS REQUIRED BUT NOT PROVIDED
Specimen collection containers and a clock or timer.

STORAGE AND STABILITY
One-Step Pregnancy reaction pack can be stored at 4 -30°C. Avoid freezing

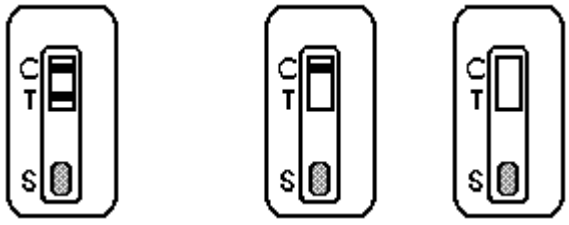
WARNINGS AND PRECAUTIONS
1. For *in vitro* diagnostic use only.
2. Warning: the reagents in this kit contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build up. Urine specimens should be considered hazardous and handled appropriately.

SPECIMEN COLLECTION
The urine specimen must be collected in a clean dry container either plastic or glass, without preservative. Specimens collected at any time may be used, however the first morning urine generally contains the highest concentration of hormone.

Urine specimens may be refrigerated (2 - 8°C) and stored up to 48 hours prior to assay. If samples are refrigerated, they must be equilibrated to room temperature (15-30°C) for 10 minutes before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle and clear aliquots obtained for testing.

PROCEDURE
1. Equilibrate all materials and reagents to room temperature (15-30°C).
2. Remove the "reaction pack" from its foil wrapper by tearing along the "splice".
3. Fill the urine dropper with urine and hold the dropper vertically and add four (4) full drops (160 µl), without bubbles, of urine onto the sample (S) well.
4. Read results at 5 minutes. Strong positive results may be observed in 2-3 minutes. **Do not interpret results after 5 minutes.**

INTERPRETATION OF RESULTS
Positive: At 5 minutes, two pink colored bands appear, one in the control region (C) and one in the test region (T), indicate a positive result and that the specimen contains hCG level of 25 mIU/ml or greater.
Negative: At 5 minutes, only one pink colored band appears in the control region (C) indicating a negative result and that the specimen contains hCG level of less than 25 mIU/ml.
Invalid: At 5 minutes, if no bands appear, or a test band appears without a control band, the result is invalid and the test should be repeated using a new device.



POSITIVE ***NEGATIVE*** ***INVALID***

NOTE: Avoid over flooding the device with sample. This will cause erroneous result. If this occurs, it is strongly recommended that the test be repeated. Also, if the flow of the sample is not observed through the viewing window, this is due to an insufficient amount of urine sample dispensed into the sample well.

QUALITY CONTROL

Each reaction device has its own built-in quality control indicator. After performing the test and no line in either the "T" or "C" region of the reaction device is visible, the urine has been added in the wrong window or the test device may have deteriorated. Repeat the assay using a new kit. It is strongly recommended that commercial controls should also be used with every new lot as part of the quality control.

PERFORMANCE CHARACTERISTICS

1. Sensitivity:
   One-Step Pregnancy Test detects Urinary HCG concentrations equal to or greater than 25 mlU/ml as indicated by the development of a line in the "T" region of the viewing window. Urine from healthy men and non-pregnant women will normally show undetectable levels of HCG when tested on One-Step Pregnancy Test. The test will yield a positive result on the first day of missed menstrual period.
2. Specificity:
   Specificity of the One-Step Pregnancy Test was determined from cross reaction studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH), and Thyroid Stimulating Hormone (hTSH), 300 mIU/ml hLH, 1,000 mIU/ml hFSH and 1,000 mIU/ml hTSH all gave negative results.
3. Menopausal Urines:
   A study was performed using urine specimens from 20 postmenopausal women. These specimens were chosen because urine from postmenopausal women frequently interferes with pregnancy tests due to cross reactivity with other gonadotropin hormones. All 20 urine specimens were negative when tested with One-Step Pregnancy Test. Potentially interfering substances were added to urine, which had HCG levels of 0 and 25 mIU/mL. In each case, no interference with the expected One-Step Pregnancy Test results was observed.
4. Standardization:
   One-Step Pregnancy test has been standardized to World Health Organization First International Reference Preparation (IRP 75 – 537).
5. Accuracy:
   A study was performed using a total of 70 positive and negative urine specimens. These specimens were assayed with One-Step Pregnancy Test and a similar commercially available pregnancy test and it showed identical results.
6. Interference Testing:
   The following substances were added in spiked urine samples containing 0, or 25 mIU/mL hCG. None of the substances at concentration tested interfered in the assay.

Chemical analytes:

DESCRIPTION	CONCENTRATION
Acetoacetic Acid	*2,000 mg/ml*
Acetaminophen	*20 mg/ml*
Acetylsalicylic Acid	*20 mg/ml*
Ascorbic Acid	*20 mg/ml*
Benzolecgonine	*10 mg/ml*
Caffeine	*20 mg/ml*
Cannabinol	*10 mg/ml*
DMSO	*5%*
EDTA	*80 mg/ml*
Ephedrine	*20 mg/ml*
Ethanol	*1%*
Gentisic Acid	*20 mg/ml*
Methadone	*10 mg/ml*
Methanol	*10%*
Phenothiazine	*20 mg/ml*
Phenylpropanalamine	*20 mg/ml*
Salicyclic Acid	*20 mg/ml*
β-hydroxybutyrate	*2,000 mg/ml*
Uric acid	*20 mg/ml*

Biological analytes:

DESCRIPTION	CONCENTRATION
Albumin (Serum)	*2,000 mg/ml*
Bilirubin	*1,000 mg/ml*
Hemoglobin	*1,000 mg/ml*
Glucose	*2,000 mg/ml*
pH	*5-9*

Bacteria:

DESCRIPTION	CONCENTRATION
E. Coli	*108 CFU/ML*
Group B streptococcus	*2.5x 108 CFU/ML*
Chlamydia trachomatis	*104 CFU/ML*

REFERENCES

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