INTENDED USE

The DRG® hCG Combo Rapid Test is intened for detecting the presence of hCG in both urine and serum specimens in a qualitative format sensitive to 20 mIU/ml. This test is for in vitro screenning use in obtaining a visual qualitative result for the early detection of pregnancy.
For the rapid detection of human chronic gonadotropin (hCG) in urine or serum specimens.
For *In Vitro* Diagnostic Use.

INTRODUCTION

The human chronic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. The hCG soon appears after conception and only during early stages of pregnancy. The DRG® hCG Combo Rapid Test is a qualitative, two site sandwich immunoassay for the determination of hCG antigen. The assay employs a combination of hCG monoclonal antibodies to selectively detect elevated level of hCG in urine or serum specimens. The immunological specificity of the test kit virtually eliminates cross reactivity in interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at physiological levels.

PRINCIPLE

The DRG® hCG Combo Test is a chromatographic immunoassay for the rapid qualitative determination of hCG in specimens. The membrane is precoated with hCG specific antibodies on the test region. During the test, the specimen is allowed to react with the hCG monoclonal antibody-colloid gold conjugate which was pre-dried on the test strip. The mixture then moves upward on the membrane chromato-graphically by the capillary action. For a positive specimen, the conjugate binds to the hCG forming an antibody-antigen complex. This complex binds to the hCG antibody as a capture regents on the test region and produces a colored band when hCG concentration is equal to or greater than 20 mIU/ml. Absence of this colored band in the test region suggests a negative result. To serve as a procedural control, a colored band at control region will always appeared regardless the presence of hCG.

STORAGE AND STABILITY

The DRG® hCG Combo Rapid Test can be store refrigerated or at room temperature (2-28ºC) in sealed pouch. Avoid freezing.

PRECAUTIONS

1. For in vitro diagnostic use.
2. Do not use after expiration date.
3. Test device should remain sealed until ready for use.
4. The reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide build up. Specimens should be considered hazardous and handled appropriately.

SPECIMEN COLLECTION

A. For the serum collection

Collect and centrifuge blood specimens following standard clinical procedures.
1. Remove serum as soon as possibel to avoid hemolysis, Lipernic, icteric or hemolyzed specimens that may give inconsistent test results. Specimens containing a precipitate should be clarified prior to testing.
2. If specimens cannot be tested immediately, they should be refrigerrated at 2-8 ºC. Also, if storage period is anticipated more than three days, the specimens should be frozen. Avoid repeated freezing and thawing

B. For the urine collection

The urine specimen must be collected in a clean dry container either plastic or glass without preservative. No centrifugation or filtration of urine is required.
Specimens collected at any time may be used. However the early morning urine generally contains the highest concentration of hormone.
If specimens cannot be tested after collection, they should be stored refrigerated at 2-8 ºC .

ASSAY PROCEDURE

A. For Dipstick Test

1. Remove the strip from pouch and label the device with specimen identification.
2. Carefully place the white end (sample pad) of the reaction strip into the specimen vial. Make sure that the absorbent patch (white end of the strip) is underneath the surface of the sample liquid. A 10 to 30 second dip into the sample is sufficient.
3. Remove end of the test strip from the reaction vial and start the watch or timer.
4. Within 5 minutes, a colored band will appear at the top of the test region, indicating the reaction is completed.

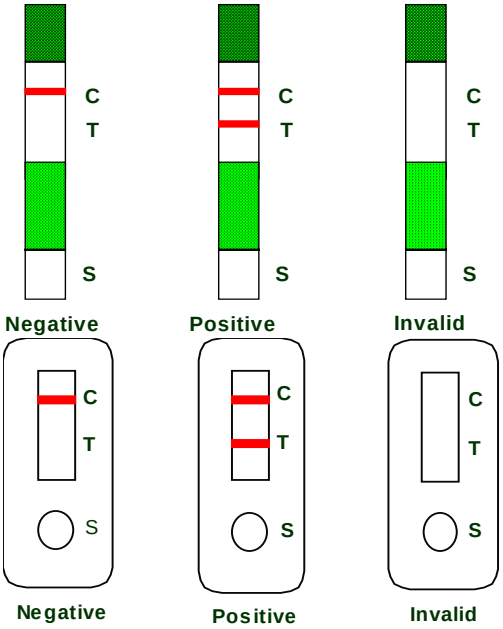
B. For Card Test

1. Remove the device from pouch and label the device with specimen identification.
2. Add 3 drops (150 µl) of urine or serum to the sample well (S).
3. Observe the result within 5 minutes, no longer than 10 minutes.

INTERPRETATION OF RESULTS

Negative: Only one colored band appears on the control region (C). No colored band in the test region (T).
Positive: In addition to the control band, a distinct colored band also appears in the test region (T).
Invalid: If no bands appear after 10 minute, the result is invalid. The protocol may not have been performed correctly, or the test is deteroirated. The assay should be repeated using a new test device.

Note: *Do not interpret result after 10 minutes.*



PROCEDURAL NOTE

If the flow of the specimen is not observed through the test area, this is due to an insufficient amount of specimen dispensed into the sample well. The test performer should re-read the instructions thoroughly prior to performing the test again.

EXPECTED VALUE

Healthy non-pregnant women do not have detectable hCG by this Rapid Combo Test. On the day of the first missed menstrual period, hCG concentration will be reached to 100 mIU/ml after 8-10 weeks and then decline to lower values for the remainder of the pregnancy.

LIMITATION

1. If a urine specimen is too diluted (i.e. low specific gravity), it may not contain representative levels of hCG. If pregnancy is still suspected a first morning urine should be obtained from the patient and tested. If hCG concentrations less than 20 mIU/ml will be detected as negative.
2. A number of conditions other than pregnancy including trophoblastic disease, proteinuria, hematuria, choriocarcinoma, ovarian and testicular teratomas cause elevated levels of hCG. These diagnosis should be considered if appropriate to the clinical evidnece.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE AND CHARACTERISTICS

Sensitivity
The analytical sensitivity of the LiveSureTM hCG Combo Test has been set at 20 mIU/ml. The 40 mIU/ml Positive Control (calibrated to the 2nd International Standard) was designed as the cutoff for the test because hCG concentrations in this ranges are usually achieved the 2nd week post conception. The test will yield a positive result on the first day of missed menstrual period.

Specificity
The specificity 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, 1000mIU/ml hFSH and 1000 mIU/ml hTSH all gave negative results.

Accuracy
A study was performed using a total of 251 randomly selected urine specimens. These specimens were assayed with HCG Combo Test and a similar commercially available qualitative visual pregnancy test. The results indicated a complete agreement (99 positive specimens and 152 negative specimens).

Interference Testing:
The following substances at certain concentrations do not interfere with the hCG rapid test in the assay:

Acetaminophen	**20 mg/dl**
Acetysalicylic Acid	**20 mg/dl**
Ascorbic Acid	**20 mg/dl**
Atropine	**20 mg/dl**
Caffeine	**20 mg/dl**
Gentesic Acid	**20 mg/dl**
Glucose	**2.0 g/dl**
Hemoglobin	**1.0 mg/dl**

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