Drop News™

One Step hCG Rapid Pregnancy Test Device

SPECIFICATION:-

1. **Purpose :**
Drop News – One-Step hCG-Pregnancy Rapid Test is an immunoassay for the rapid qualitative detection of human chorionic gonadotropin (hCG) in urine specimens for the early detection of pregnancy. This test uses a monoclonal antibody specific to the beta subunit of hCG to accurately detect hCG.

Human chorionic gonadotropin is not normally detected in the urine of non-pregnant women. hCG is a hormone produced by the developing placenta during pregnancy.
In normal pregnancy, 25 mIU/ml of hCG may be present in the urine as early as 2 to 3 days before the first missed menstrual period, Drop News – One-Step hCG-Pregnancy Rapid Test will detect urine hCG.

Urine is added to the sample well on the test cassette. If hCG is present in the specimen at concentrations of 25mIU/ml or greater, a pink-to-red test (T) line will appear along with a pink procedural control (C) line in the result window. If hCG is present at very low levels, or not present in the specimen, only a pink procedural control line will appear in the result window.

2. **Specimen :**
   A. Urine specimens should be collected in a clean, dry container such as a urine collection cup.
   B. Specimens may be collected at any time of the day. First morning urine samples will normally contain the highest levels of hCG.
   C. If not tested immediately, urine may be stored at room temperature (15-30°C) for up to 8 hours or refrigerated at 2-8°C for up to 72 hours. Samples may be frozen once at -20°C or below. If frozen, mix after thawing. Do not refreeze. Samples must be brought to room temperature before testing.
   D. Specimen rejection criteria: Samples of unknown age or in unapproved containers should be rejected, and a fresh sample collected.

SAFETY WARNING : Human specimens may harbor infectious agents. Use standard (universal precautions) when working with these materials, including gloves and eye protection.

3. **Materials :**
   A. Test Kit (Drop News – One-Step hCG-Pregnancy Rapid Test). Materials supplied with kit:
      1. Test cassettes (50/100 units per package) containing a membrane coated with beta-hCG monoclonal antibody and conjugated alpha-hCG monoclonal antibody.
      2. Disposable droppers (50/100 units per package).
   B. Materials not supplied with kit :
      1. Watch or clock that measures minutes.
      2. Specimen collection containers.

4. **Storage and Stability :**
The test kit is to be stored at room temperature (4-30°C) out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box carton.

5. **Quality Control :**
   A. External Controls are used to assure that the reagents are performing properly and that the analyst is correctly performing the test procedure. Some commercial controls may contain interfering additives and are not recommended for use in Drop News –One-Step hCG-Pregnancy Rapid Test.
      1. External positive and negative controls are to be performed on a monthly basis.
      2. External positive and negative controls are to be performed on each new lot of test kits.
      3. If the controls do not yield the expected results, the kit must be removed from service and the action noted in the corrective action section of the QC log sheet.
      4. The responsibility for performance of external controls must be rotated among all staff performing testing. The designation of a specific individual to perform all QC activities in the clinic is not permitted.

   B. Procedural Control. Drop News-One-Step hCG-Pregnancy Rapid Test provides several levels of internal procedural controls with each test run. For daily quality control, the results of these controls must be documented for each sample tested.
      1. The appearance of a pinkish procedural control line is an internal positive control. This indicates that sufficient sample fluid was added for capillary flow to occur and the correct procedural technique was used. If this line does not develop, the test result is considered invalid.
      2. A clear background in the test result window is an internal background negative control. If the test has been performed correctly, the background should be white to light pink within 3 minutes and not interfere with the reading of the test result.
      3. The results of this procedural control must be documented for the external positive control, the external negative control, and all patient results.

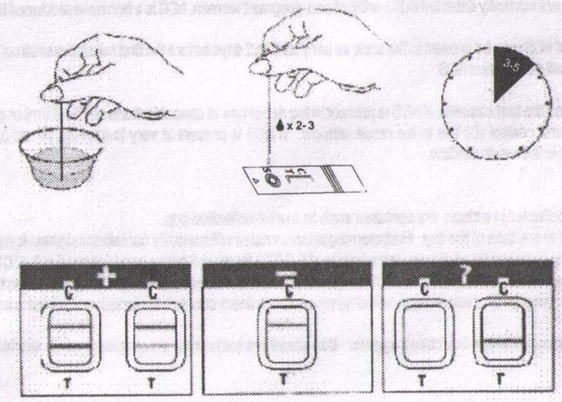
   C. Prior to using a new shipment or lot number of Drop News-One-Step hCG-Pregnancy Rapid Test, the Positive Control and Negative Control must be tested and shown to yield the expected results. Upon observing the expected results, the kit is ready for use with patient specimens.

   D. The Quality Control Log Sheet should include:
      1. Device name and manufacturer
      2. Date package, or kit, opened
      3. Lot number and expiration date of pregnancy testing device
      4. Lot number and expiration date of each control reagent
      5. Results of:
      a. Positive Control
      b. Negative Control
      c. Procedural Control
      6. Initials of staff person conducting quality control tests. The site supervisor and laboratory incharge must review and sign all QC forms on a quarterly basis.

   E. Record the last number and expiration date of the pregnancy test device on the daily clinical worksheet.
   F. Store records for two years.

6. **Method :**
   A. When performing more than one test, ensure that the test cassettes are labeled correctly. Use a new dropper for each sample/test.
   B. Remove the Drop News-One-Step hCG-Pregnancy Rapid Test cassette from the foil pouch just before use and place it on a clean, dry, level surface.
   C. Using one of the disposable pipettes supplied in the test kit, collect the sample and add 2-3 drops (40-60µl) of urine to the round sample well on the test cassette. The test cassette should not be handled or moved until the test is complete and ready for testing.
   D. Wait 3-5 minutes and read. Some positive results may be seen sooner. Do not read results after 5 minutes.

7 **Interpretation of Results :**
   A. **Positive Test :** The appearance of any pink-to-purple line next to the letter "T" in the result window, along with a pink procedural control line next to the letter "C". Although the intensity of the bands may vary with different specimens, the appearance of 2 distinct bands should be interpreted as a positive test.
   B. **Negative Test :** The appearance of the pink procedural control line next to the letter "C" and no pink-to-purple line next to the letter "T" in 5 minutes.
   C. **Invalid Test :** The test is invalid if a pink control line (C) is not visible at 5 minutes. If this happens, retest a new sample and a new test cassette. Document the invalid test result using a corrective action form. If a second test is invalid, contact the site coordinator and Drop News Technical Support (01792-230156).



8. **Expected Values :**
   A. Specimens containing as low as 25 mIU/mL hCG will yield positive results when tested with Drop News-One-Step hCG-Pregnancy Rapid Test. In normal pregnancy, hCG can be detected as early as 6 days following conception with concentrations doubling every 32 to 48 hours, peaking in excess of 100,000 mIU/mL in approximately ten to twelve weeks. For some patients, an hCG of 25 mIU/mL can be detected as early as two to three days before expected menses.
   B. Healthy men and healthy non-pregnant women do not have detectable hCG in urine by this test.

9. **Limitations of Procedure :**
   A. The contents of this kit are for use in the qualitative detection of hCG in urine.
   B. Test results must always be evaluated with other data available to the clinician.
   C. In addition to the normal elevations of hCG produced in pregnancy, elevated values are also found in disease states related and unrelated to pregnancy. Conditions such as hCG-secreting neoplasms, hydatidiform mole, choriocarcinoma, testicular carcinoma, lung cancer, and diseases of the trophoblast are examples of this.
   D. Pathologic pregnancies cannot be differentiated from normal pregnancy by qualitative hCG measurements. Neither the quantitative value nor the rate of increase in hCG can be determined by a qualitative test.
   E. hCG levels may remain detectable for several weeks following delivery, abortion, natural termination, or hCG injections.
   F. Positive results from very early pregnancy may become negative later due to natural termination of pregnancy. Although this test is accurate-at determining early pregnancy, some false-positive results can occur.
   G. Early pregnancy associated with a low level of hCG may show color development after the 6-7 minute procedure time. If a negative result is obtained but pregnancy is suspected, hCG may be low or urine may be too dilute for detection. Another specimen should be collected after 48-72 hours and test. If waiting 48 hours is not medically advisable, the test result should be confirmed with a quantitative hCG test.
   H. If urine specimens have a low specific gravity (i.e. are very dilute), they may not have representative levels of hCG. The test should be repeated using a first morning urine sample.

References :

1. E.A. Lenton, LM. Neal, and Sulaiman. R. Fertil, Steril., Vol. 37 (1982), p773.
2. E. F. Batzer. Fertil, Steril., Vol. 34 (1980), p1.
3. N. W. Tietz. Clinical Guide to Lab. Tests, 2nd ed., p128, 1990.
4. Embree, L. (1985). Development of a High-Performance Liquid Chromatographic Assay for Human Chorionic Gonadotropin as an Alternative to the Official United States Pharmacopeial Animal Assay. Vancouver, BC: University of British Columbia.
5. Hussa, R.O. (1987). The Clinical Marker hCG. New York, NY: Praeger Publishers.

Diagnocure™ (India)

GMP CERTIFIED ISO COMPANY CE

Mfg. & Marketed by : **Diagnocure™** (India)
2, F/F, E. C., Chambaghat, Solan-173213 (H.P.) INDIA
Customer Care No. : + 91-1792 230156
E-mail : info.diagnocureindia@gmail.com