

Intended Use

The HCG URINE CARD 20 mIU/mL is an immunoassay designed for the qualitative determination of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy. It is intended for professional or laboratory use.

Summary and Explanation of the Test

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the placenta during pregnancy. The appearance and rapid increase in the concentration of hCG in the mother's urine makes it a good marker for confirming pregnancy. The concentration of hCG in urine increases steadily to a circulation peak of as much as 50,000 mIU/ml between the eighth and eleventh weeks of pregnancy (1,2,3). The HCG URINE CARD 20 mIU/mL is a chromatographic immunoassay which uses specific antibodies to selectively identify hCG in urine with a high degree of sensitivity. Elevated levels of hCG as low as 20 mIU/ml can be detected within 5 minutes.

Principles of the Test

Urine is added to the test kit and allowed to migrate through the absorbent device. 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 test zone and produces a purple color band when the hCG concentration is equal to or greater than 20 mIU/ml. In the absence of hCG, no band is formed in the test zone. The reaction mixture continues flowing through the absorbent device past the test and control zones. Unbound conjugate binds to the reagents in the control zone, producing a purple color band, demonstrating that the reagents and the test kit are functioning correctly.

Reagents Used

The test kit contains combination of goat/rabbit polyclonal antibodies and mouse monoclonal antibodies in a protein buffer containing sodium azide.

Precautions

- (1) For in vitro diagnostic use only.
- (2) Do not use after the expiration date imprinted on the test kit package.
- (3) Dispose of all reaction devices in a proper biohazard container.
- (4) Patient specimens may contain infectious agents and should be handled as potential pathogens.

Test Kit Storage

The test kit may be stored at room temperature 4-30°C (40-86°F) for up to 18 months or until the expiration date. Optional Liquid control reagent may have different storage requirements. Refer to individual components for their specific requirements.

Urine Collection and Storage

- (1) The first morning urine typically contains the highest concentration of hCG and is therefore the best sample for performing the urine test. However, any urine specimen may be used.
- (2) Collect the urine specimen in a clean glass or plastic container. Do not use preservatives.
- (3) If the specimen is not used immediately following collection, but will be used within 48 hours, it should be refrigerated (2 to 8 °C), then brought back to room temperature (4 to 30 °C) before testing. If specimen is not going to be used within 48 hours, it should be frozen at -20 degrees C. A frozen specimen should not be used if stored longer than 2 weeks. Prior to testing, the frozen specimen must be completely thawed, thoroughly mixed, and brought to room temperature.

Assay Procedure

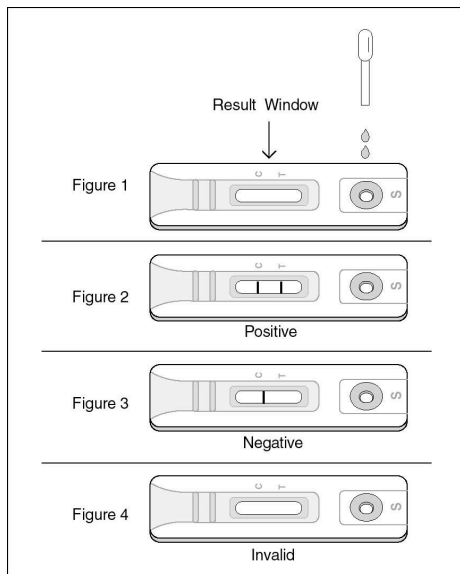
- (1) Take the test kit from the foil pouch.
- (2) Put the test kit on a flat and dry surface. Using the urine dropper to add 2 drops of urine into the sample well (Figure 1).
- (3) Read results at 3 to 5 minutes. Do not interpret results after 5 minutes.

Interpretation of Results

- (1) **POSITIVE:** If there are two purple color bands in the Result Window, this indicates that the specimen contains detectable levels of hCG and should be interpreted as a positive result. (Figure 2)
- (2) **NEGATIVE:** If there is only one purple color band in the Result Window, this indicates that there is not a detectable level of hCG in the specimen and should be interpreted as a negative result. (Figure 3)

(3) **INVALID:** If there are no purple color bands in the Result Window, the test result is invalid (Figure 4). The control band will not appear if an insufficient volume of specimen is added into the sample well. Proper procedures may not have been followed in performing the test or deterioration of the test kit may have occurred. Repeat the test procedure using a new test kit.

Note: The instructions provided must be strictly followed in order to achieve optimal test reactivity with the urine specimens.



Limitations of the Procedure

1. The Urine hCG Pregnancy Test is for in vitro diagnostic use only.
2. In addition to pregnancy, hCG has been found in patients with both gestation and non-gestation trophoblastic diseases. These conditions should be ruled out when interpreting hCG levels to establish a pregnancy diagnosis.
3. Although the test is very accurate in detecting pregnancy a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. Consult with a physician if unexpected or inconsistent results are obtained.
4. A normal pregnancy cannot be distinguished from an ectopic pregnancy based solely on hCG levels. Also, a spontaneous miscarriage may cause confusion in interpreting test results.
5. 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.
6. A negative result obtained from a urine specimen collected from a woman in very early pregnancy may be due to an extremely low concentration of hCG. In such cases, the test should be repeated on a fresh specimen obtained two days later.
7. If a urine sample is too dilute (i.e. low specific gravity), it may not contain a representative urinary hCG concentration. If a negative result is obtained with a low specific gravity specimen and pregnancy is still suspected, obtain a first morning urine specimen and retest.

Expected Normal Values

Urine hCG levels during pregnancy are estimated to be (1,2,3):

1. 10-30 mIU/ml 7-10 days post conception
2. 37,000-50,000 mIU/ml 8-11 weeks after last menstrual period
3. <5 mIU/ml Healthy men or non-pregnant women

Standardization

The Urine hCG Pregnancy Test will detect hCG concentrations of 20 mIU/ml or greater (referenced to the World Health Organization First International Standard).

Performance Characteristics

Sensitivity

The hCG Pregnancy Urine Test will detect hCG in urine at concentrations of 20IU/ml or greater. This sensitivity level has been confirmed with internal hCG standards in urine, calibrated against the World Health Organization First International Standard.

Specificity

The ability of the Urine hCG Pregnancy Test to specifically detect hCG was challenged through cross-reaction studies on urine samples containing known quantities of structurally and physiologically related hormones. Urine samples spiked with 500 mIU/ml LH (human Luteinizing Hormone), 1000 mIU/ml FSH (Follicle Stimulating Hormone) and 1000 µIU/ml TSH (Thyroid Stimulating Hormone) showed negative results only.

Interference Data

Potentially interfering drugs, protein and glucose were supplemented to normal urine specimens devoid of hCG. Baseline urine levels, as well as 20 mIU/ml hCG standards were then analyzed and compared with all samples containing a specific concentration of an interfering substance.

Substances

Acetaminophen, 20 mg/dl
Acetylsalicylic acid, 20 mg/dl
Ascorbic acid, 20 mg/dl
Atropine, 20 mg/dl
Caffeine, 20 mg/dl
Gentistic acid, 20 mg/dl
Glucose, 2000 mg/dl
Hemoglobin, 500 mg/dl
Mestranol, 3 mg/dl
Penicillin, 40,000U/dl
Tetracycline, 20 mg/dl

Conclusion: All of the above substances do not interfere with the results of the "urine test kits.

Accuracy

The hCG Urine test compared with a commercially available urine test (Table).

		A commercial hCG urine test		
		Negative	Positive	Total
urine test	Negative	50	0	50
	Positive	0	50	50
	Total	50	50	100

The conclusion is the hCG Urine disk format is in 100% agreement with commercially available hCG urine tests

References

1. E.A. Lenton, L.M. 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.
- (Revised 05-07-2007)

SYMBOLS

IVD	For in-vitro diagnostic use only		For single use only
	Content		Expiry date
LOT	Lot number		Store at room temperature

Liofilchem s.r.l.
Via Scozia - Zona Industriale
64026, Roseto degli Abruzzi (TE) Italy
Tel +390858930745 Fax +390858930330
www.liofilchem.net
liofilchem@liofilchem.net