

One step rapid CardTest for the qualitative detection of human chorionic gonadotropin (hCG) in urine

Store at 2-30°C. DO NOT FREEZE.  
For In-Vitro Diagnostic Use only

#### ORDER INFORMATION

Pack Size	REF
10 Tests	HCGC 10
25 Tests	HCGC 25
50 Tests	HCGC 50

#### CLINICAL SIGNIFICANCE

Human chorionic gonadotropin (HCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, HCG can be detected in both urine and serum as early as 7 to 10 days after conception. HCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed Menstrual period, and peaking in the 100 to 200 IU/mL range about 10-12 weeks into pregnancy. The appearance of HCG in both urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

The **ACCUCARE® ONE STEP PREGNANCY (hCG) RAPID TEST (Urine)** is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HCG in urine.

#### PRINCIPLE

The **ACCUCARE® ONE STEP PREGNANCY (hCG) RAPID TEST** is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (HCG) in urine to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal HCG antibody to selectively detect elevated levels of HCG. The assay is conducted by applying urine sample in the sample well and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific antibody-hCG colored conjugate to form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

#### CONTENTS

Test Device  
Instruction for Use (IFU)  
Disposable (Dropper) 25 µl sampling device  
Desiccant

#### STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device, if the pouch is damaged or seal is broken.

#### PRECAUTIONS

1. For professional In-vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

#### LIMITATIONS

Very dilute urine specimens as indicated by low specific gravity may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine sample should be obtained 48-72 hours later and tested. Very low levels of HCG (less than 50m IU/ml) are present in urine shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be interpreted in conjunction with other clinical and laboratory data. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG in urine as determined by using hCG One Step Pregnancy Test should not be used to diagnose pregnancy unless these conditions have been ruled out. As with all diagnostic tests, a confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

#### SPECIMEN COLLECTION & PREPARATION

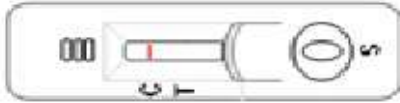
The urine specimen must be collected in a clean, dry plastic or glass container. The first morning urine is preferred since it generally contains the highest concentration of HCG. However, urine collected at any time of day may be used. Urine samples exhibiting visible precipitates should be centrifuged, or allowed to settle to obtain clear supernatant for testing. Urine specimens may be stored at 2-8 °C for up to 48 hours prior to assay. Urine containing excessive bacterial contamination should not be used as this may cause spurious results.

#### PROCEDURE

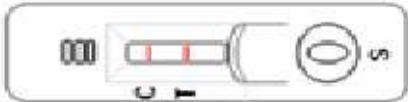
1. Allow test device and specimen equilibrates to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and flat surface. Carefully dispense 2drops (50 µl) of urine specimen in the sample well "S" using the dropper provided.
4. Allow reaction to occur and read the results at 5 minutes. Do not interpret the results after 10 minutes.
5. It is significant that the background is clear before reading the test, especially when samples have low HCG concentration, and only a weak line appears in the test band region (T).

**INTERPRETATION OF RESULTS**

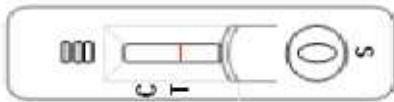
**NEGATIVE:** If only one color line appear at control region 'C' as the specimen is Negative for Pregnancy (hCG).



**POSITIVE:** If two color lines appear, one at control region 'C' and other at test region 'T', the specimen is positive for Pregnancy (hCG).



**INVALID:** If no color line appear, at control line 'C' within the stipulated time then result is invalid. Repeat the test using a fresh Test Device.



**PERFORMANCE CHARACTERISTICS**

The ACCUCARE® ONE STEP PREGNANCY (hCG) RAPID TEST has been evaluated with positive and negative urine samples and Sensitivity & Specificity data are as below:

Method		Other hCG Rapid Test		Total Results
hCG Pregnancy Rapid Test	Results	Positive	Negative	
	Positive	231	0	231
	Negative	0	377	377
<b>Total Results</b>		231	377	608

**Relative Sensitivity:** >99.9% (98.7%~100%)\*

**Relative Specificity:** >99.9% (99.2%~100%)\*

**Overall Accuracy:** >99.9% (99.5%~100%)\*

\* 95% Confidence Intervals













No interference and cross-reactivity in the ACCUCARE™ ONE STEP PREGNANCY (hCG) RAPID TEST was evident when tested with Luteinizing Hormone (LH) up to 500 mIU/ml, Follicle Stimulating Hormone (FSH) up to 1000 mIU/ml and Thyroid Stimulating Hormone (hTSH) up to 1000 mIU/ml.

**BIBLIOGRAPHY**

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**GLOSSARY OF SYMBOL**

	Consult Instruction for Use		Lot Number
	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
	For <i>in vitro</i> Diagnostic use only		Keep Dry
	Tests per Kit		Do Not Use if Damaged