



# Asan EasyTest<sup>®</sup> hCG

Diagnostic Kit for hCG Detection

Immunochromatography

## EXPLANATION OF THE TEST

hCG(human chorionic gonadotropin) is an excellent marker for early detection of pregnancy as a glycoprotein hormone secreted by the developing placenta shortly after fertilization. The Asan EasyTest hCG is a chromatographic immunoassay for the rapid qualitative determination the presence of hCG in urine at the sensitivity of 25 mIU/mL. The membrane is pre-coated with goat anti-hCG on the test band region. During the test, the urine sample is allowed to react with monoclonal anti hCG-gold conjugate, which has been pre-dried on the test strip. The mixture then moves upward on the membrane by capillary action. For the positive result, a visible line with high sensitivity and specificity as forming goat anti hCG-monoclonal anti hCG-gold complex appears in the test band region of the membrane. Regardless of the presence of hCG antibodies, the mixture continuously moves across the membrane to pre-dried control line. Therefore, the control line will always appear and verify proper performance of the test.

## MATERIALS PROVIDED

The Asan EasyTest hCG contains following items to perform the assay.

1. Asan EasyTest hCG Device in aluminium pouch
2. Disposable specimen dropper
3. Instructions for use

## PRECAUTIONS

The Asan EasyTest hCG should be stored at room temperature 2-30°C. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing from the pouch. Do not use it beyond the expiration date.

## SPECIMEN COLLECTION AND STORAGE

1. Should be performed using human urine.
2. Should be stored refrigerated at 2~8°C or at room temperature up to 30°C. For prolonged storage, freezing is recommended.
3. Must be clarified prior to assay for the specimens containing precipitation. It may precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying

## WARNINGS

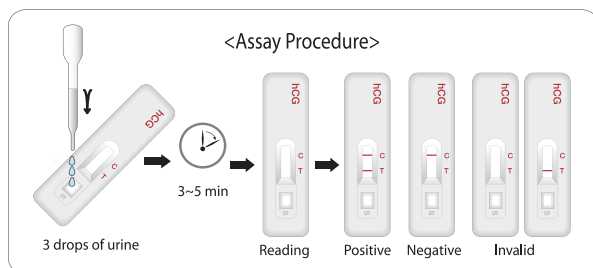
1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in biohazard container

## TEST PROCEDURE

1. Should be equilibrated refrigerated specimens or other materials to room temperature right before performing testing.
2. Remove the device from its protective pouch.
3. Apply 3 drops of urine (approx. 100µL) in the sample well.
4. Interpret test results at 3-5 minutes. It is important that the background is clear before the result is read.

**\*CAUTION :** The above interpretation time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, the interpretation time should be properly increased. A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.

5. See the illustration below.



## INTERPRETATION OF THE RESULTS

1. A color band will appear in the upper section("C" zone) of the window to show that the test is working properly. This band is the Control Band.
2. The down section("T" zone) of the window indicates the test results, test band. If another color band appears in the down section of the window, this band is the test band.

### A. POSITIVE RESULTS:

The presence of two color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result.



### B. NEGATIVE RESULTS:

The presence of only one purple color band(control band) within the window indicates a negative result.



### C. INVALID RESULTS:

If No band is visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.



## STORAGE & EXPIRATION

1. The EasyTest hCG-Kit should be stored at room temperature 2 - 30°C (36~86°F)
2. Expiration date of the kit is 20 months after its manufacture date.

## LIMITATIONS OF THE TEST

Other clinically available tests are required if questionable results are obtained. As all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but be made by the physician after all clinical and laboratory findings have been evaluated.

## EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals.

Asan Easy Test hCG has a sensitivity of 25 mIU/mL and is capable of detecting pregnancy as early as 1 day after the first missed menses.

## PERFORMANCE CHARACTERISTICS

### Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the Asan Easy Test hCG to another commercially available urine membrane hCG test. The study included 200 urine specimens: both assays identified 100 negative and 100 positive results. The results demonstrated a 100% overall agreement (for an accuracy of >99%) of the Asan Easy Test hCG when compared to the other urine membrane hCG test.

ASAN Method	Reference Method		
		Positive	Negative
		100	0
	Positive	100	0
	Negative	0	100

### Sensitivity and Specificity

The Asan EasyTest hCG detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 mIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

### Interfering Substances

The following potentially interfering substances were added to hCG negative and positive specimens.

Acetaminophen	20 mg/mL	Ascorbic Acid	20 mg/mL
Caffeine	20 mg/mL	Glucose	2 g/dL
Acetylsalicylic Acid	20 mg/mL	Atropine	20 mg/mL
Gentisic Acid	20 mg/mL	Hemoglobin	1 mg/dL
		Bilirubin	2 mg/dL

None of the substances at the concentration tested interfered in the assay.

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