


## Evaluation Report on the Accuracy of hCG Rapid Test Dipstick Verified by Multi-Center Clinical Comparison Experiment

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### Abstract

**Background:** In 1976, the first home pregnancy test was introduced, and since then, it has become the most commonly used diagnostic assay for home use. These tests use antibodies to detect human chorionic gonadotropin (hCG), which is an ideal marker of pregnancy. This is because hCG levels rise consistently and rapidly in early pregnancy and can be detected in urine [5].

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 or plasma as early as 7 to 10 days after conception. [1-4] hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period [2-4] and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG 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.

hCG Pregnancy Rapid Test Dipstick 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. At the level of claimed sensitivity, hCG Pregnancy Rapid Test Dipstick shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

**Objective:** The main significance of this paper is to verify the accuracy, specificity, and sensitivity of the hCG Pregnancy Rapid Test Dipstick manufactured by ACRO Biotech, Inc. through comparative experiments, in order to explore the significance of high-precision hCG rapid detection products in early pregnancy testing.

**Method:** The hCG Pregnancy Rapid Test Dipstick is a fast and efficient way to detect human chorionic gonadotropin (hCG) in urine to aid in the detection of pregnancy. The test uses a combination of monoclonal hCG antibodies and goat polyclonal antibodies to selectively detect elevated levels of hCG in the urine specimen. The test is conducted by immersing the test dipstick in the urine specimen and observing the formation of colored lines. The presence of two colored lines, one in the test line region and one in the control line region, indicates a positive result, while the absence of the test line suggests a negative result. A colored line in the control line region always appears to confirm that the proper volume of specimen has been added and membrane wicking has occurred. This test is a rapid chromatographic immunoassay, which provides accurate results quickly and easily.

**Result:** The hCG Pregnancy Rapid Test Dipstick is a highly accurate and sensitive product for detecting pregnancy. Its sensitivity is greater than 99.9% and its specificity is greater than 99.9%, with an accuracy of over 99.9%.

**Conclusion:** The hCG Pregnancy Rapid Test Dipstick manufactured by ACRO Biotech, Inc. is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

According to the results of a multi-centre clinical comparative experiment, this product is user-friendly, provides rapid results, and readings can be obtained within 3 minutes of testing the sample. When compared to 608 samples, the product demonstrated a high accuracy rate of 99.9% and excellent specificity of 99.9%.

Furthermore, this test dipstick is a reliable option for women who want to obtain accurate results and determine early in their pregnancy whether they are pregnant or not. With its high accuracy and convenience, this test kit can provide women with peace of mind and help them take the necessary steps to ensure a healthy pregnancy.

**Keywords:** HCG; Rapid Test; Early Pregnancy

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## Introduction

### About hCG

Human chorionic gonadotropin (hCG) is a hormone produced by the placenta after implantation of a fertilized egg in the uterus. Its main role is to support the development of the fertilized egg and to maintain the production of progesterone, which is important for the on-going pregnancy. hCG is also the hormone that is detected in most pregnancy tests.

hCG levels rise rapidly in the early stages of pregnancy, peaking at around 8-11 weeks, and then gradually decline. The level of hCG in the blood or urine can be used to confirm pregnancy, monitor fetal development, and diagnose certain medical conditions, such as ectopic pregnancy, miscarriage, and trophoblastic disease.

While hCG is primarily associated with pregnancy, it is also produced by some types of cancer, such as testicular, ovarian, and bladder cancer. In these cases, measuring hCG levels can help with diagnosis and monitoring of the disease.

### Detection Methods of hCG

When it comes to pregnancy testing, there are two main options available: serum testing and urine testing.

Serum hCG testing is performed using immunometric assays, which involve two antibodies that bind to the hCG molecule. One antibody is fixed, while the other is radiolabeled and adheres to a different site on the molecule, sandwiching and immobilizing the molecule to make it detectable [6]. The excess serum components are washed away, and the remaining labelled hCG is measured to provide a quantitative result.

Urine testing is similar, but many detect total hCG levels greater than 20 mIU/m [7]. However, many over-the-counter urine pregnancy tests do not detect Hyperglycosylated hCG, which accounts for most of the hCG in early pregnancy, resulting in a wide range of sensitivities for these tests.

Serum testing is much more sensitive and specific than urine testing. However, urine testing is more convenient, affordable, and comfortable for patients. It also has the advantages of a short detection time, good privacy, relatively high accuracy, and does

not require a medical prescription.

### Evaluation of ACRO hCG Pregnancy Rapid Test Dipstick (Urine)

#### Materials and hCG for Use

To ensure accurate results, it is recommended to bring the test dipstick to room temperature before opening the pouch or canister. For canister packaging, close the canister tightly after removing the required number of test dipsticks and record the initial opening date.

The test dipstick should be immersed vertically in the urine specimen with arrows pointing towards it for at least 15 seconds without passing the maximum line (MAX). Afterward, the dipstick should be placed on a non-absorbent flat surface, and the timer should be started.

The result should be read at 3 minutes, and it is not recommended to interpret the result after 10 minutes. Note that a low hCG concentration might result in a weak line appearing in the test line region (T) after an extended period of time.

#### Urine Assay

To ensure accurate results, a urine specimen for hCG testing should be collected in a clean and dry container. Although a first morning urine specimen is preferred as it typically contains the highest concentration of hCG, urine collected at any time of the day can be used.

In cases where the urine specimen exhibits visible precipitates, it is recommended to either centrifuge, filter, or allow the specimen to settle in order to obtain a clear specimen for testing. This will help to ensure that the test accurately measures the hCG concentration in the urine, as any visible precipitates may interfere with the accuracy of the results.

### Specimen Maintenance Criterion

Urine specimens for hCG testing may be stored at a temperature of 2-8°C for up to 48 hours prior to testing. If longer storage is necessary, specimens may be frozen and stored below -20°C.

It is important to note that frozen specimens should be thawed and mixed thoroughly before testing to ensure accurate results.

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Additionally, repeated freezing and thawing of specimens should be avoided as this can degrade the quality of the specimen and potentially affect the accuracy of the test.

### Performance Characteristics

The hCG Rapid Test Cassette (Urine) has been evaluated with specimens obtained from a population of pregnant and non-pregnant individuals.

A multi-centre clinical evaluation was conducted comparing the results obtained using the hCG Pregnancy Rapid Test Dipstick to another commercially available urine hCG Rapid test. The study included 608 urine specimens, and both assays identified 231 positive and 377 negative results. The results demonstrated >99% overall accuracy of hCG Pregnancy Rapid Test Dipstick when compared to the other hCG Rapid Test (**Table 1**).

**Table 1.** Performance of ACRO hCG Pregnancy Rapid Test Dipstick (Urine).

Method		Other hCG Rapid Test		Total Results
hCG Pregnancy Rapid Test Dipstick	Results	Positive	Negative	
	Positive	231	0	231
	Negative	0	377	377
Total Results		231	377	608

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

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

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

\* 95% Confidence Intervals

### Expect Value

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. hCG

### Summary

High accuracy hCG rapid test products play a significant role in early pregnancy detection because they provide reliable and quick results, allowing women to confirm their pregnancy status with greater certainty. Human Chorionic Gonadotropin (hCG) is a hormone that is produced by the placenta during pregnancy, and its presence in a woman's urine or blood can indicate that she is pregnant.

Early pregnancy detection is important for several reasons. Firstly, it allows women to start receiving prenatal care as early as possible, which can help identify and manage any potential health risks to both the mother and the fetus. This is particularly important for women who have pre-existing medical conditions or who have had complications in previous pregnancies.

Secondly, early detection also helps women make informed decisions about their pregnancy, including whether or not to continue with the pregnancy, and if so, how to prepare for the arrival of their baby. Knowing that they are pregnant early on can also help women make lifestyle changes, such as avoiding alcohol and tobacco, which can have a positive impact on the health of the developing fetus.

High accuracy hCG rapid test products are designed to detect even very low levels of hCG in a woman's urine or blood, making them highly effective at detecting pregnancy in its earliest stages. These tests are also easy to use and provide results quickly, often within minutes, which make them convenient for women to use at home or in a clinical setting.

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