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Clinical Application of High Accuracy hCG Pregnancy Rapid Test Cassette (Urine) in Gynaecology

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Abstract

Background: Human chorionic gonadotropin (hCG) is a glycoprotein hormone that is essential for the maintenance of pregnancy. Glycosylation of hCG is known to be essential for its biological activity. "Hyperglycosylated" variants secreted during early pregnancy have been proposed to be involved in initial implantation of the embryo and as a potential diagnostic marker for gestational diseases [1]. Therefore, the hCG Pregnancy Rapid Test Cassette (Urine) can detect the gestational diseases during early pregnancy which plays an important role in gynaecology.

Human chorionic gonadotropin (hCG) is an essential pregnancy-associated glycoprotein that is a member of the same family that includes luteinizing hormone, follicle stimulating hormone and thyroid stimulating hormone. Each member is a heterodimer consisting of shared α-subunits in non-covalent association with distinct β-subunits that confer their specific physiological activities. Pregnancy associated hCG is mainly secreted by the syncytiotrophoblast (ST) associated with the embryo and is excreted in urine.

hCG levels in maternal blood increase progressively during early pregnancy, reaching maximal levels between the 8-11th week of gestation. Thereafter, the level of hCG declines until around twenty weeks and then remains comparatively low for the remainder of the pregnancy. The functional roles of hCG throughout pregnancy have been extensively studied and are thought to be necessary for the maintenance of pregnancy by mediating multiple placental, uterine and fetal functions. hCG may play a part in implantation through its receptors on the endometrium and is thought to aid smooth muscle relaxation, maintain quiescence of the myometrium in pregnancy and promote myometrial vasodilatation. hCG induces relaxin secretion by the corpus luteum during the luteal phase and in early pregnancy. Both relaxin and progesterone play an important role in the maintenance of early pregnancy. hCG may also contribute to maternal immune tolerance but as pregnancy progresses into the second and third trimester, the role of this hormone becomes less apparent. hCG is also expressed in several trophoblastic diseases and is often used as a sensitive biomarker for malignancy. This hormone is expressed in both gonadal and non-gonadal tumors.

Objective: The main purpose of this evaluation report was to explore the reliability and performance of the Citest hCG pregnancy Rapid Test Cassette for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

Method: Run a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine.

Result: The results show that the overall relative sensitivity for the detection of the Citest hCG Pregnancy Rapid Test Cassette (Urine) is >99.9% (98.7%~100%), the relative specificity is >99.9% (99.2%~100%), and the relative accuracy is >99.9% (99.5%~100%).

Conclusion: The Citest hCG Pregnancy Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

The product is simple to operate, and results can be read within 3 minutes of the sample being tested. A comparison of 608 samples showed an accuracy of 99.9% and an excellent specificity of 99.9%. Women can use this test kit to obtain accurate results and to determine whether they are pregnant or not in an early time.

Keywords: hCG; Early Pregnancy; Rapid Test

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Introduction

About hCG

Human chorionic gonadotropin (hCG) is produced primarily by differentiated syncytiotrophoblasts and represents a key embryonic signal that is essential for the maintenance of pregnancy. hCG can activate various signaling cascades including mothers against decapentaplegic homolog 2 (Smad2), protein kinase C (PKC), and/or protein kinase A (PKA) in several cells types by binding to luteinizing hormone/chorionic gonadotropin receptor (LHCGR) or potentially by direct/indirect interaction with transforming growth factor beta receptor (TGFβR) The molecule displays specialized roles in promoting angiogenesis in the uterine endothelium, maintaining myometrial quiescence, as well as fostering immunomodulation at the maternal-fetal interface [2]. It is a member of the glycoprotein hormone family that includes luteinizing hormone (LH), thyroid-stimulating hormone (TSH), and follicle-stimulating hormone (FSH). The α-subunit of hCG displays homologies with TSH, LH, and FSH, whereas the β subunit is 80–85% homologous to LH. The hCG molecule is produced by a variety of organs, exists in various forms, exerts vital biological functions, and has various clinical roles ranging from diagnosis and monitoring of pregnancy and pregnancy-related disorders to cancer surveillance.

In early pregnancy, human chorionic gonadotropin (hCG) is produced primarily by differentiated syncytiotrophoblasts and represents a key embryonic signal essential for the maintenance of pregnancy. During the initial six weeks of pregnancy, hCG promotes secretion of progesterone, estradiol, and estrange via transformation of the post-ovulatory ovary into the gravid corpus luteum. Furthermore, hCG binds to its receptor to perform specialized roles in promoting angiogenesis in the uterine endothelium, maintaining myometrial quiescence, as well as fostering immunomodulation via alteration of activity of dendritic cells, the reduction of T-cell activation and cytokine production, promotion of T regulatory (Treg) cell recruitment, and an increase in proliferation of uterine natural killer (NK) cells at the maternal-fetal interface. Metabolism of hCG by the placenta, liver, blood, and kidney determines its steady-state levels. Measurements of serum or urine hCG levels provide important information in a variety of clinical situations, such as diagnosis and monitoring of pregnancy and pregnancy-related disorders, prenatal screening, and gynecological cancers.

hCG Measurements in Pregnancies

Both diagnosing and monitoring pregnancy can be achieved using assays that recognize either hCG alone, or together with hCG-β. While hCG-H is well documented as a marker of early pregnancy, it is also proposed to be a better predictor of a viable pregnancy compared to hCG because failing pregnancies have been shown to produce minimal hCG-H. A threatened abortion or a pregnancy of unknown location can be accurately monitored by serial measurements of serum hCG levels. Although an increase in serum hCG levels varies among pregnancies, its exponential increase predicts doubling of serum levels within 1.5–2 day intervals to confirm a viable pregnancy [2]. The hCG level can not only reflect the pregnancy but also helps the women to detect some gynecological diseases. Therefore, using the rapid test can detect the general value of hCG and know whether the result is normal or not.

hCG Detection Methods

Pregnant woman can detect the hCG level using different methods depends on cycles of pregnancy.

Venous Blood collection

The method of checking hCG requires intravenous blood collection and does not require fasting. If pregnant women want to dynamically observe fetal development, it is best to test the blood sample again after 48 hours. For normal pregnancies, the blood tested a second time should be twice the value of the first blood, so as to indicate that the fetal belly is better. If such conditions are not met, it means that the embryo development is not very good, or there is a possibility of ectopic pregnancy.

Urine Test

Pregnant women can use hCG Pregnancy Rapid Test Cassette (Urine) to detect the level of hCG and further know whether pregnant or not. Detecting pregnancy early can also help women to avoid many gynecological diseases.

Evaluation of CITEST hCG Pregnancy Rapid Test Cassette (Urine)

Materials and hCG for Use

Materials provided in the test cassette included one test cassette, dropper and package insert. The hCG Pregnancy Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy [3].

Urine Assay

A urine specimen must be collected in a clean, dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Maintenance Criterion

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and

stored below -20°C. Frozen specimens should be thawed and mixed before testing.

For Urine Specimens

Bring the pouch to room temperature (15-30°C) before opening it. Remove the cassette from the sealed pouch and use it within one hour. Then place the cassette on a clean and level surface and hold the dropper vertically and transfer 3 full drops of urine (approximately 120ul) to the specimen well of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. Wait for the colored line(s) to appear. The result should be read at 3 minutes.

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

Table 1. Performance of CITEST hCG Pregnancy Rapid Test Cassette.

Method		Other Rapid Test		Total Results
hCG Pregnancy Rapid Test Cassette	Result	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.

Expected Values

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine specimens. The amount of hCG will vary greatly with gestational age and between individuals. The hCG Pregnancy Rapid Test Cassette for Urine has a sensitivity of 25mIU/ml, and is capable of detecting pregnancy as early as 1 day after the first missed menses [4].

Summary

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancies, hCG can be detected in both urine and serum or plasma as early as 7 to 10 days after conception.

The hCG Pregnancy Rapid Test Cassette is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 25mIU/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, the hCG Pregnancy Rapid Test Cassette shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels. hCG Rapid Test Cassette (Urine) can help women to detect whether they are pregnant in an early time. If women can detect pregnancy in an early time, they can take action to prepare the pregnancy test or some other measures to protect themselves and their babies.

The hCG Rapid Test Cassette (Urine) in this evaluation performed satisfactorily in standard experimental conditions. The tests showed both excellent accuracy and specificity.

The results of tested samples demonstrate that the hCG Rapid Test Cassette (Urine) developed by CITEST Diagnostics Inc. meets the requirements of professional in vitro diagnostic intended use and is capable to be employed in the detection of pregnancy.

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