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LH Ovulation Rapid Test Cassette (Urine) Plays an Important role in Preparing Pregnant

Abstract

Background: Luteinizing hormone (LH) plays a vital role in induced ovulation and controlled ovarian hyperstimulation in human assisted reproduction. This evaluation has a brief review of the roles of LH in supporting follicular development and function of LH Ovulation Rapid Test Cassette in preparing pregnancy.

A rapid increase in LH plasma, called an LH surge, induces ovulation within 2-3 days. The surge can be detected by the observation of LH in serum or urine with ovulation predictor kits (OPKs). If a woman knows the duration of her menstrual cycle, she can plan the timing of testing. The average length of the menstrual cycle is 28 days, but a regular cycle lasting anywhere between 24 and 38 days is considered normal. The cycle length is determined by follicular growth and by the lifespan of the corpus luteum [1]. Many women experience varying cycle lengths with back and forth shifts in the day of ovulation, which may pose a problem especially for infertility patients. To detect ovulation, patients are required to determine LH levels in urine with an OPK daily until getting a positive result, which causes undue stress in addition to the financial burden.

To optimize the probability of conception in a menstrual cycle, the appropriate timing of intercourse is of utmost importance. Randomized controlled trials show evidence that ovulation predictor kits (OPKs) may increase pregnancy rates. In ovulatory cycles, ovulation usually occurs about 14 days before the onset of the next period. The length of the normal ovulatory cycle may vary considerably (26-35 days, mean 28 days), and extensive variations both in follicular (10-23 days) and luteal phases (7-19 days) [2]. Thus, making the prediction of ovulation and appropriate timing for intercourse or natural cycle intrauterine insemination is rather challenging.

Objective: The main purpose of this evaluation report was to explore the reliability and performance of the Citest LH Ovulation Rapid Test Cassette for the qualitative detection of of luteinizing hormone (LH) in urine to aid in the detection of ovulation.

Method: Run a rapid chromatographic immunoassay for the qualitative detection of LH in urine to aid in the detection of ovulation, containing the anti-LH particles and anti-LH antibody coated on the membrane.

Result: The results show that the overall relative sensitivity for the detection of LH Ovulation Rapid Test Cassette (Urine) is 40mIU/ml, and the accuracy is 99.0%.

Conclusion: Citest LH ovulation Rapid Test Cassette (Urine) is a rapid test that utilizes a rapid chromatographic immunoassay for the qualitative detection of luteinizing hormone (LH) in urine to aid in the detection of ovulation.

The product is simple to operate, gives results within 5 minutes of the sample being tested and has high accuracy. Women can use this test kit to obtain accurate results and to determine the ideal time to get pregnant.

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Introduction

Luteinizing hormone is secreted by basophils in the anterior lobe of the pituitary gland. It acts on mature eggs and can cause

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ovulation and luteal formation. It can also promote the secretion of oestrogen by luteal, inner capsule and interstitial cells. In male animals, it acts on the interstitial cells of the testes to promote the secretion of androgens. Due to the role of androgens, sperm

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development is completed during the development of the second sex character. LH promotes steroid hormone synthesis, which is believed to be mediated by the generation of cAMP as the second information. LH is a glycoprotein with a molecular weight of about 30,000. In acidic solution, it can be dissociated into two different monobasic compounds (subunits) with molecular weight of about 15,000 [3]. The amino acid arrangement of the two polypeptide chains (single base) of the LH of sheep has been determined. One of its single bases has a common or similar structure with one of the single bases of follicle stimulating hormone (FSH) and thyroid stimulating hormone (TSH) [4]. The LH secreted by the pituitary gland is promoted by the luteinizing hormone releasing factor generated in the hypothalamus.

Human reproduction is a complex process, tightly linked to a chronological timeframe. Human sperm cells survive up to 6 days in the female vaginal tract, whereas the oocyte can only be fertilized within 12-24 hours after ovulation. The "fertile window", when intercourse can result in pregnancy, comprises a time frame of 5 days before ovulation and the day of ovulation itself. Consequently, the timing for sexual intercourse plays a major role in achieving pregnancy in natural menstrual cycles.

Follicular stimulating hormone (FSH) induces the growth of follicles inside the female ovary and one dominant follicle is selected and induced to grow. The high level of estrogen produced by the dominant follicle induces the release of LH, which triggers ovulation. The abrupt secretion of LH into the bloodstream is induced by serum estradiol (produced from the dominant follicle) through a positive feedback mechanism impacting the anterior pituitary gland. With a mean duration of 3 days, the LH surge is defined as an abrupt onset resulting in a peak, followed by a gradual descent until baseline. 35-44 hours prior to ovulation the LH surge starts and reaches its peak 10-12 hours before ovulation. Recent literature provides evidence that LH peak is best described as a wave with different surge variants rather than a peak. While measurement of serum LH levels is invasive and impractical, urinary LH levels have been proven accurate and are used as inexpensive way to detect the fertile window. The general recommendation to start LH testing with the best predictive value for ovulation within 24 hours is day 7 of the cycle. Due to its easy handling, the LH surge measurement has become popular within the last several years [5]. Despite positive correlations between urinary LH tests and ovulation, LH surges are very variable in configuration, amplitude and duration. Furthermore, urinary LH assessments are mostly qualitative based on the respective threshold of the used test. Crossing this threshold (= test positivity), indicates the approaching ovulation and does not provide information about the onset of the rise and how long the level already persists.

Measurement Methods for LH Ovulation

Folded enzyme-linked immunoassay technology

An enzyme-linked immunoassay combining monoclonal and polyclonal antibodies was used to detect the peak secretion of urinary luteinizing hormone in fertile women to predict the time of ovulation. This is a newer method of detecting ovulation.

Folded immunoenzyme

Immunoenzyme technology refers to using the catalytic effect of enzymes to transform substances in a certain bioreactor. This method has good reproducibility, high specificity, high accuracy and reliability, good correlation with RIA, and no radioactive contamination, which is recommended. This method showed that with alkaline phosphatase as the marker and phosphophenolphthalein as the matrix, phenolphthalein was color-stable and had good repeatability.

Folded colloidal gold technology

With the principle of double antibody sandwich method to qualitatively detect the level of LH in women's urine, most people can buy LH test strips in pharmacies, such as the LH detection reagent produced by Citest. Women can self-tested at home and help women grasp the timing of pregnancy, or for the implementation of safe contraception.

Evaluation of Citest LH ovulation Rapid Test Cassette

Materials and Directions for Use

Materials provided include test cassettes, droppers and package inserts.

The LH Ovulation Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the qualitative detection of luteinizing hormone (LH) in urine to aid in the detection of ovulation.

Before testing, the person self-testing should determine the day started to detect.

First, determine the subject's menstrual cycle length. The menstrual cycle length is the number of days from the first day of the subject's period (menstrual bleeding) to the last day before the next period starts. Next, determine the days to count ahead after the period to start testing. Find the subject's menstrual cycle length on the first row of the chart below, and read the corresponding days to count ahead in the second row. This is the number of days after the period to begin testing. Finally, determine the day to start testing. Starting from and including the first day of the last period, count ahead the number of days indicated in the previous step. This is the day on which testing should begin. As a basic guideline, it is recommended to test once a day for five days (Table 1).

Allow the test cassette, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.

Table 1. Menstrual Cycle Length.

21	22	23	24	25	26	27	28	29
6	6	7	7	8	9	10	11	12
30	31	32	33	34	35	36	37	38
13	14	15	16	17	17	19	20	21

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For Urine specimen

Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour and then place the test cassette on a clean and level surface. Hold the sample dropper vertically and transfer 3 drops of urine (approx.120ul) to the specimen well of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well.

Performance Characteristics

The LH Ovulation Rapid Test Cassette (Urine) has been evaluated with specimens obtained from a population of female individuals. Laboratory studies show that the sensitivity of the LH Ovulation Rapid Test Cassette (Urine) is 40mIU/ml and the accuracy is 99.0%.

Summary

Luteinizing hormone is very important for women's ovulation and maintenance of luteal function. If the hormone is too high and follicle stimulating hormone is low, it may be a polycystic ovary syndrome. It is better to conduct a blood sampling test. The blood sampling test is performed on the 2-5th day of the coming menstrual period, and the results are relatively accurate. At the peak of LH, it means that women will enter an important ovulation stage. Egg cells discharge from the body within 24-48 hours [6, 7]. At this time, the leucorrhea will become more transparent and show a wiredrawing state. The ovulation test paper mainly measures the value of LH. After ovulation, the LH will drop. Women then enter the luteal phase, which is generally about 14 days. If a high peak of LH is found after the examination, it means that women have entered the ovulation stage and will ovulate within 24-48 hours. Women who are preparing for pregnancy can choose to have intercourse at this time, so the probability of pregnancy is very high. However, if there is no LH peak in the ovulation period, it means that women may have ovulation disorder, and it is necessary to find out the cause in time and explore relevant treatment to recover normal ovulation as soon as possible.

The clinical significance of LH determination is mainly to understand the specific conditions of female ovulation and luteal function because there may be abnormal ovarian function in the case of high LH. It is common that women with polycystic ovary syndrome are often in a high state of LH.

The LH Ovulation Rapid Test Cassette in this evaluation performed satisfactorily in standard experimental conditions. The tests showed both excellent accuracy and sensitivity.

The results of tested samples demonstrate that the LH Ovulation Rapid Test Cassette (Urine) developed by Citest Diagnostics Inc. meets the requirements of professional in vitro diagnostic intended use. Thus, a conclusion can be drawn that Citest LH Ovulation Rapid Test Cassette is qualified to be used in the detection of LH in urine to aid in the detection of ovulation.

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