CE

FERTICHECK® - LH

One step test for detecting human Luteinising hormone in urine

DEVICE

INTENDED USE

FERTICHECK®-LH is a rapid, semi-quantitative, two-site sandwich immunoassay for the detection of human Luteinising Hormone (hLH) concentration in urine. It is a 7-day ovulation test designed to predict the hLH-surge associated with ovulation time and the best probable time to plan conception.

SUMMARY

Human Luteinising hormone (hLH) is a glycoprotein hormone produced by anterior pituitary gland. hLH has a molecular weight of 30,000 Daltons. hLH is involved in regulating the ovulation and ovarian function during the menstrual cycle. Approximately 12 to 36 hours after the hLH surge, the enlarged follicle ruptures to release the mature ovum. Following ovulation, hLH returns to its basal level in 48 hours. The rapid change of hLH level in a short period during the menstrual cycle makes hLH an excellent predictor for ovulation. **FERTICHECK®-LH** is a one step test for the determination of hLH in human urine and can therefore be used as an aid to successful conception. Immunological methods such as **FERTICHECK®-LH** are superior to Basal Body Temperature (BBT) method for prediction of ovulation. BBT method indicates that ovulation has already occurred whereas **FERTICHECK®-LH** indicates that ovulation is about to take place.

PRINCIPLE

FERTICHECK®-LH utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. The conjugate pad contains two components - Agglutinating sera for hLH conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the highly specific Agglutinating sera for hLH -colloidal gold conjugate complexes with the hLH in the specimen and travels on the membrane due to capillary action along with the rabbit globulin - colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is immobilized by Agglutinating sera for alpha hCG coated on the membrane, leading to formation of a coloured band, if hLH level is equal to or greater than 40 mIU/ml, indicating hLH surge. Absence of this coloured band in the test region or if the colour intensity of this band is less than that of control band (hLH is in basal level, lower than 40 mIU/ml), it indicates a negative test result.

The rabbit globulin-colloidal gold conjugate and unbound complex , if any, move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region (C), forming a coloured band. This control band acts as a procedural control and serves to validate the results.

PATIENTS	hLH LEVEL, mIU/ml
Men	2 - 15
Postmenopausal women	10 - 200
Premenopausal women	Basal level : 5 – 20 Surge level : 40 - 100

REAGENTS AND MATERIALS SUPPLIED

FERTICHECK®-LH kit contains:

A. Individual pouches, each containing :
   1. DEVICE : Membrane assembly pre-dispensed with Agglutinating sera for hLH - colloidal gold conjugate, rabbit globulin - colloidal gold conjugate, Agglutinating sera for alpha hCG and Agglutinating sera for rabbit globulin coated at the respective regions.
   2. PIPETTE : Disposable Plastic Sample Applicator.
   3. Desiccant Pouch.

B. Package Insert.

REF	505010001	505010005	505010010	505010025
Σ	1	5	10	25

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 4°C to 30°C for the duration of shelf life as indicated on the pouch/carton. DO NOT FREEZE.

NOTES

1. Read the instructions carefully before performing the test.
2. For *in vitro* diagnostic use only. NOT FOR MEDICINAL USE. For professional use only.

Size : 137 x 218 mm

3. Do not use beyond expiry date.
4. Do not re-use the test device.
5. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.
6. Handle all specimens as if potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
7. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.

SPECIMEN COLLECTION AND PREPARATION

1. **FERTICHECK®-LH** uses human urine as specimen.
2. Urine specimens can be collected at anytime of the day. However, urine collected between 10 am to 8 pm is preferred as LH is synthesized during this time. It is also recommended that on each day of testing, the specimen may be collected at the same time of the day.
3. Collect the urine specimen in a clean, dry plastic or glass container.
4. Though fresh specimen is preferable, it may be **stored at 2°C to 8°C for maximum of 24 hours**, in case of delay in testing.
5. Sodium azide can be added as a preservative up to 0.1% without affecting the test results.
6. Refrigerated specimens must be brought to room temperature prior to testing.
7. Do not use turbid or contaminated specimens.
8. It is preferable to restrict fluid intake 2 hrs before the test to prevent dilution of urine sample.

TEST SCHEDULE

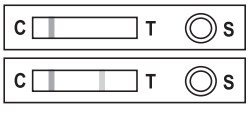
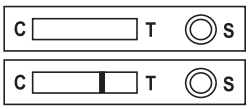
To start testing for the hLH surge, it is necessary to determine a woman's Menstrual Cycle Length. The Menstrual Cycle Length is the number of days from the first day of the woman's period (menstrual bleeding) to the last day before her next period begins. The following table shows the menstrual cycle length and the corresponding days to begin testing for hLH surge.

Menstrual Cycle Length	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
Day to start testing	5	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23

Example: A woman has a menstrual cycle of 28 days, the first day of testing for the hLH surge should be the 11th day after the beginning of her current menstrual cycle. If a woman is not sure about her cycle length, she should use her shortest cycle length. In this case, the test might be needed for more than 5 days.
The test can be stopped once the hLH surge has been detected.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the sealed aluminium foil pouch of **FERTICHECK®-LH** device to room temperature, prior to testing.
2. Open foil pouch by tearing along the "notch".
3. Remove the test device and the sample applicator. ***Once opened, the test must be used immediately.***
4. Label the test device with patient's identity.
5. Place the testing device on a flat horizontal surface.
6. Holding the sample applicator vertically, carefully dispense exactly **two drops** of urine into the specimen port.
7. Observe the development of visible coloured band at Test region (T).
8. Positive results may be observed within 5 minutes, depending on the concentration of hLH in the tested specimen.
9. Do not read and interpret test results after 5 minutes.

	**Negative Result** (1) If there is no test band (T) i.e. only control band (C) appears or (2) If the colour intensity of the test band (T) that appears is less than that of control band (C).
	**Positive Result** If the colour of test band (T) is equal to or stronger than that of control band (C), it indicates a hLH surge, i.e., the hLH concentration is ≥ 40 mIU/ml.
	**Invalid Result** The test is invalid if no band is visible at 5 minutes. The test should also be considered invalid if only the test band appears and no control band appears. Verify the test procedure and repeat the test with a new **FERTICHECK®-LH** device.

Size : 137 x 218 mm

PERFORMANCE CHARACTERISTICS

Sensitivity

FERTICHECK®-LH Ovulation Test can detect hLH in urine with concentration of 40 mIU/ml or greater.

Specificity

The specificity of **FERTICHECK®-LH** Ovulation Test was determined from cross-reaction with known amounts of human Follicle Stimulating Hormone (hFSH) and human Thyroid Stimulating Hormone (hTSH). Samples containing 500 mIU/ml hFSH and 1000 IU/ml hTSH all gave negative results.

Interference Testing

The following substances were added to hCG free and 40 mIU/ml hLH spiked urine samples. No interference was found with any of the substances at the following concentrations:

Acetaminophen	20 mg/dl
Acetylsalicylic acid	20 mg/dl
Ampicillin	40 mg/dl
Ascorbic acid	40 mg/dl
Atropine	40 mg/dl
Caffeine	40 mg/dl
Gentisic acid	40 mg/dl
Glucose	2000 mg/dl
Human albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/dl

LIMITATIONS OF THE TEST

1. Testing with **FERTICHECK®-LH** device should be continued with the remaining devices in the kit everyday at the same time till a positive result is obtained.
2. Once the result is positive with **FERTICHECK®-LH**, it means ovulation is likely to occur within 24-36 hours. This is the most fertile time in the woman's cycle. Sexual intercourse within this time frame is advised to improve chances of conception.
3. Urine should be collected at about the same time every day. Do not use first morning urine; for best results, use urine collected between 10 am to 8 pm as LH is synthesized during this time.
4. Postmenopausal women usually have an elevated hLH level.
5. Women suffering from polycystic ovary syndrome may have elevated hLH concentration.
6. Due to the cross-reactivity with hCG , the test is intended for the analysis of hLH in hCG free samples only.
7. Consumption of drugs containing tetracycline or oxytetracycline may cause misleading results.
8. Inaccurate results are likely to occur in lactating mothers and women attaining menopause.
9. The test will not work for women who are pregnant, in menopause or consuming birth control pills. The results of this test should not be used as an aid for contraception.
10. The test should be interpreted in caution in Pre Menstrual Syndrome.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Clinical Laboratory Diagnostics, Use and Assessment of Clinical Laboratory results, Edited by Lothar Thomas, First Edition, TH Books Verlagsgesellschaft mBH, Frankfurt, Germany, 1998: 1091-1095.
2. Teitz Book of Clinical Chemistry, Second Edition, WB Saunders Publishing, 1994: 1679-1681.
3. Data on file: Zephyr Biomedicals.

Size : 137 x 218 mm

SYMBOL KEYS

Temperature Limitation	Consult Instructions for use	Date of Manufacture	Do not reuse
Manufacturer	IVD — *In vitro* Diagnostic Medical Device	This side up	EC REP — Authorised Representative in the European Community
Use by	REF — Catalogue Number	DEVICE — Device	
Σ — Contains sufficient for <n> tests	LOT — Batch Number / Lot Number	PIPETTE — Disposable Plastic Sample Applicator	

Manufactured by:

Zephyr Biomedicals

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EC REP

CMC Medical Devices & Drugs S.L., Spain.

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