Instant-View® LH Ovulation Predicting Cassette Test CE

One Step Assay
Rapid Visual Results
For Qualitative In Vitro Diagnostic Use

INTENDED USE
The LH Ovulation Predicting Cassette Test is a qualitative Immunoassay for the detection of human Luteinizing Hormone (hLH) in human urine to predict the occurrence of ovulation. It is for health care professional use only and not for self testing.

SUMMARY AND EXPLANATION OF TEST
Ovulation is regulated by the elevation of human luteinizing hormone (hLH). In a menstrual cycle, hLH remains at a basal level (usually below 20 mIU/ml, WHO 1st International Reference Preparation 68/40) most of the time. Usually, around 14 days before period starts, hLH has a brief, significant rapid increase. That is called "LH surge". The hLH surge triggers the release of an egg or eggs from the ovary. Statistics have shown that conception is most likely to happen within thirty-six hours following the LH surge. The hLH level returns to its basal line 2 to 3 days after ovulation. The hLH surge is an ideal indicator for predicting ovulation. Detecting hLH surge has been used successfully as an aid in ovulation predicting and would similarly assist in timing of artificial insemination.

PRINCIPLE OF THE PROCEDURE
This Ovulation Predicting Test is a lateral flow chromatographic immunoassay. The test strip in the device includes: 1) a conjugate pad containing anti-hLH antibody coupled to colloidal gold, and 2) nitrocellulose membrane containing a test line (T line) and a control line (C line).

When an adequate amount of urine specimen is applied to the sample well of the device, hLH in the specimen binds to sites on the anti-hLH antibody-gold conjugate in the conjugate pad to form a complex and migrates along the membrane strip. If the specimen contains hLH at a level close to or higher than 20 mIU/ml, the complex will bind to the capture antibody coated on the T line to develop a burgundy colored band.

The C line, a burgundy colored band in the control region of the test, which should always appear regardless of the presence of hLH, serves as an internal control of the test system.

REAGENTS AND MATERIALS SUPPLIED
- 25 test devices, each sealed in a pouch with a dropper pipette.
- 1 package insert

MATERIAL REQUIRED BUT NOT PROVIDED
- Timer
- Specimen Container

STORAGE AND STABILITY

Store the kit at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch.

Do not freeze and/or expose the kit to temperatures over 30°C (86°F). **15°C**  **30°C**

PRECAUTION
1. **The instructions must be followed to obtain accurate results.**
2. This test is for professional in vitro diagnostic use only.
3. Do not open the sealed pouch, unless ready to conduct the assay.
4. Do not use expired devices.
5. Dispose of all specimens and used assay materials as potentially biohazardous.

SPECIMEN COLLECTION
1. Use a clean container to collect specimens at any time convenient during the day, but consistently at the same time of day in the same menstrual cycle.
2. Use the cycle chart below as a reference to start testing.

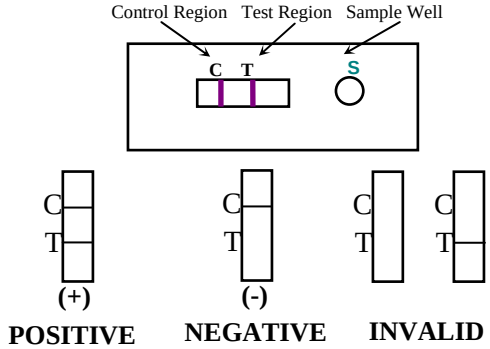
Cycle length (days)	Day of cycle to start testing
21	5
22	6
23	7
24	8
25	9
26	10
27	11
28	12
29	13
30	14
31	15
32	16
33	17
34	18
35	19
36	20
37	21
38	22
39	23
Consult doctor, if cycle length is more than 40 days	

3. Urine specimens can be kept at room temperature for 8 hours, at 2-8°C for one week, and at -20°C or lower for prolonged storage.

ASSAY PROCEDURE
1. Refrigerated specimens and other test materials including devices, **must be equilibrated to room temperature before testing**.
2. Remove the device from pouch and place it on a flat surface.
3. Holding the dropper vertically, add four drops of the specimen to the sample well.
4. Read the test result between four (4) to seven (7) minutes after adding the specimen.

INTERPRETATION OF RESULTS

***IMPORTANT*: Do not interpret the results after 7 minutes. The T Line should always be interpreted independently of the C Line.**



Positive:
If both **C line** and **T line** appear, indicating that "LH surge" is detected in the specimen at a level close to or higher than 20mIU/ml.

Negative:
If only one line, the **C line**, appears in the control line region, indicating that the hLH surge is not detected or hLH level in the specimen is not detectable.

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Invalid:
If No C line is developed in the control region within 5 minutes. Repeat the assay with a new test device.

Note: For better results, establish a basal hLH level by running a test on the 7th days of the menstrual cycle.

QUALITY CONTROL

- **Built-in Control Features**
  This test contains a built-in control feature, the C line. The appearance of the burgundy C line indicates that an adequate volume of specimen has been absorbed and that capillary flow has occurred. The C line should always appear regardless of the presence of the chemicals being detected. If the control line does not develop within 5 minutes, review the whole procedure and repeat test with a new device.
- **External Quality Control**
  Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay.

LIMITATIONS

1. Some disorders are related to the elevated levels of hLH, such as polycystic ovary syndrome.
2. Negative results may be obtained when the specimen is diluted too much.

PERFORMANCE CHARACTERISTICS

1. Sensitivity
The LH Ovulation Predicting Cassette Test will detect hLH in human urine at the level higher than 20 mIU/ml.

2. Accuracy

- Comparison Studies
  100 urine specimens were tested with LH Ovulation Predicting Test and a legally marketed test in house and in a clinical Reference Laboratory. The correlation between LH Ovulation Predicting Test and marketed test was 99%.

		LH Test		
		* -	** +	Total
Marketed Test	-	37	1	38
	+	0	62	62
	Total	37	63	100

*** - = Negative, ** + = Positive**

- Physician's Office Laboratory (POL) Studies
  The LH Ovulation Predicting test was evaluated at three POL sites by persons with diverse education background and work experiences. The results from all three POL sites agreed 99%.

3. Specificity
The following high physiological concentration hormones were spiked in hLH negative urine specimens and hLH positive urine specimens (containing 20 mIU/ml hLH), and were tested separately with the LH Ovulation Predicting test. The results indicated that these hormones did not affect the expected results at the level tested.

Hormone	Conc.	Result Observed	
		hLH (0 mIU/ml)	hLH (20mIU/ml)
hCG	300 mIU/ml	-	+
hTSH	1,000 uIU/ml	-	+
hFSH	1,000 mIU/ml	-	+

4. Interference
The following analytes were spiked in hLH negative urine specimens and hLH positive urine specimens (containing hLH level of 20 mIU/ml), and were separately tested with the LH Ovulation Predicting Cassette test. The results indicated that these analytes did not affect the expected results at the level indicated in the table.

Chemical Analytes

Description	Concentration
Acetoacetic Acid	2,000 mg/dL
Acetaminophen	20 mg/ dL
Acetylsalicylic Acid	20 mg/ dL
Ascorbic Acid	20 mg/ dL
Benzoylecgonine	10 mg/ dL
Caffeine	20 mg/ dL
Cannabinol	10 mg/ dL
DMSO	5%
EDTA	80 mg/ dL
Ephedrine	20 mg/ dL
Ethanol	1%
Gentisic Acid	20 mg/ dL
Methadone	10 mg/ dL
Methanol	10%
Phenothiazine	20 mg/ dL
Phenylpropanalamine	20 mg/ dL
Salicylic Acid	20 mg/ dL
β-Hydroxybutyrate	2,000 mg/ dL
Uric Acid	20 mg/ dL

Biological Analytes

Description	Concentration
Albumin(serum)	2,000 mg/ dL
Bilirubin	1,000 ug/ dL
Hemoglobin	1,000 ug/ dL
Glucose	2,000 mg/ dL
pH	5-9

REFERENCES

- Elkind-Hirsch, K, et al., Obstetrics and Gynecology, 67 (3): 450-453, 1986
- Speroff, L., et al., Glass, R.H., Kase N.G. Clinical Gynecologic Endocrinology and infertility, 3rd ed., Williams and Wilkins, Baltimore, MD, 1983.
- France, J.T. In Recent Advances in Obstetrics and Gynecology Number 14, J. Bonner, ed., Churchill Livingstone, New York, NY, 1982. pp 215-239.
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30°C 15°C	Temperature limitation		Use by YYYY-MM
LOT	Batch/Lot code	IVD	*In vitro* diagnostic medical device
	Manufacturer	REF	Catalog number
Σ n	Contains sufficient for < n > tests		Consult instructions for use
2	Do not reuse	CE	CE Mark
	Caution, consult accompanying documents		

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