



LH CARD TEST

Single Step Detection of Luteinizing Hormone in Urine



For Professional Use



READ THIS PACK INSERT CAREFULLY BEFORE PERFORMING THE TEST

INTENDED USE

BHAT BIO-SCAN[®], One Step Ovulation Test is a rapid chromatographic immunoassay for the detection of luteinizing hormone (LH) in urine, as an aid for the early detection of ovulation

SUMMARY

Ovulation is the release of an egg from the ovary. The egg then passes into the fallopian tube where it is ready to be fertilized. In order for pregnancy to occur, the egg must be fertilized by sperm within 24 hours after its release.

When a woman is about to ovulate, the body produces a large amount of luteinizing hormone (LH) which triggers the release of a ripened egg from her ovary. This "LH Surge" usually takes place in the middle of her cycle.

BHAT BIO-SCAN[®] LH Surge (Ovulation) Test Kit is a complete system to help a woman to predict the time of ovulation, the time when she is most fertile. It is during this fertile time that pregnancy is most likely to occur.

BHAT BIO-SCAN[®], LH Surge (Ovulation) Test Kit detects the LH Surge in her urine, telling her that ovulation is likely to occur in the next 24-48 hours.

Important : The LH Surge and ovulation may not occur in all cycles

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The Kit is stable within the expiration date printed on the label. DO NOT FREEZE or use beyond the expiration date.

MATERIALS PROVIDED : OVU-SCAN Test Device, Disposable Dropper & Instruction Literature.

MATERIALS REQUIRED BUT NOT PROVIDED : Specimen collection container and Timer

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WHEN TO START TESTING

First Determine the Length of the Menstrual Cycle. The Menstrual Cycle Length is the number of days from the first day of her period (menstrual bleeding) to the last day before her next period starts. Think back over the last few months to decide what is the usual cycle length has been.

Circle the usual cycle length on the "WHEN TO START CHART" Then look down to the number directly below. Count ahead that number of days from the first day of the last period. This will be the day to begin testing.

WHEN TO START CHART

Circle The Usual Cycle Length

21	22	23	24	25	26	27	28	29	30	31
06	06	07	07	08	09	10	11	12	13	14

Count ahead this many days STARTING WITH THE FIRST DAY of her LAST Period

Note :

If she is unsure about her cycle length, she may want to use her shortest cycle length when reading the chart. If she does this, she may need to test for more than 5 days.

Example :

"My usual cycle length is 28 days. My last period started on the third. The "When to Start Chart" shows that I will count ahead on the calendar, I find that I will collect and test my urine starting on the 13th (see "Sample Calendar")

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SAMPLE CALENDAR

SUN	MON	TUE	WED	THU	FRI	SAT
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

()-First day of your last period

..... testing with OVU-SCAN-LH Surge (Ovulation) Test

URINE COLLECTION

Decide when to start collecting her urine. For best results, collect her urine at about the same time each day between 10.00 AM and 8.00 PM. Some women have found that their best sample is after 12 noon

Do not collect the first urine waking up.

Reduce the liquid in take for about 2 hours before collecting her urine. Be sure to write down the date, cycle day and time that she collected her urine in the "Test Results Chart" below.

You can store the urine if you want to do the test later. The urine can be stored at room temperature for upto 8 hours or in the refrigerator for upto 24 hours. Do not freeze it. For best results, test the urine on the day that it is collected. If you refrigerate the urine, let it reach room temperature before testing (about 30 minutes). Do not shake the container. If a sediment forms at the bottom of the collection container, allow the sediment to settle.

Use urine only from the top of the container.

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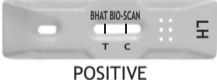
PRECAUTIONS

1. Patient Samples should be handled in the same manner as any potentially infective biological material.
2. Read this Pack Insert Carefully
3. Do not store the kit in freezer.
4. DO NOT USE AFTER THE EXPIRATION DATE.
5. Carefully observe the prescribed number of drops to be added 2-3 DROPS ONLY
6. The BHAT BIO-SCAN[®] LH Kit if refrigerated should be brought back to room temperature before testing.
7. Use only urine specimens.
8. Use the Kit Soon after removing from the aluminium pouch.

PROCEDURE

1. Determine your First Testing Day (see Section "WHEN TO START TESTING").
2. Open one foil pouch and remove the test device. Place the device on a flat clean surface.
3. Using the Urine Dropper, add 2-3 drops of urine into the round window.
4. Read the results between 3-5 minutes.
5. DO NOT READ AFTER 10 MINUTES

POSITIVE RESULT : If two lines are visible and the line in T Band is equal or darker than the one in C band, you will probably ovulate in 24-48 hours.



POSITIVE

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NEGATIVE RESULT : If two lines are visible and the line in T band is lighter than the one in C band, or there is no line in T band, no LH surge has been detected.



NEGATIVE

NEGATIVE

INVALID RESULT : If there is no line in C band the result is invalid and a new test should be performed.



INVALID RETEST

INTERPRETING YOUR RESULTS

A positive result means that the urine contains a high level of LH, a hormone body makes all of the time but which reaches very high levels just before ovulation. You can assume that she will ovulate in 24 -48 hours.

A negative result means that no LH Surge has been detected and she should continue daily testing.

Not every woman ovulates mid-cycle, and you may therefore not see a positive result during the first 5 days of testing. Continue testing with OVU-SCAN Ovulation Test Device.

TEST LIMITS

The test works only when instructions are precisely followed. Do not reuse the Test Device. For in Vitro Diagnostic Use (Not for internal use). This test not be used as a form of birth control. Test results should not be affected by pain relievers, antibiotics and other common drugs. Medication containing hCG or LH may affect the test and should not be taken while using OVU-SCAN LH Surge (Ovulation) Test Kit. In addition, the test will not work properly if you are pregnant, in menopause, or are taking birth control pills

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INTERFERENCE TESTING

OVU-SCAN-LH Surge (Ovulation) Test Kit was tested with commonly known drugs and hormones including FSH (700mIU/ml), TSH (500mIU/ml) and hCG (1000mIU/ml). At the levels tested, none of these substances interfered with the expected test results

TEST RESULTS CHART

TEST	COLLECTION	RESULT
Day 1		
Day 2		
Day 3		
Day 4		
Day 5		

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EN 980:2008 (E) MEDICAL DEVICES SYMBOL

2°C-30°C	Temperature Limitation	2001-06	Date of Manufacture	IVD	In vitro Diagnostic Device
LOT	Batch Code		Company name & address		Refer Operating Instructions
	Use by		Company Name		Authorised Representative in European Community
	Do Not Reuse		Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY		NON-STERILE		NEGATIVE CONTROL
	POSITIVE CONTROL	Authorised Representative in EC _____			

Mfg. In India by
BHAT BIO-TECH INDIA (P)LTD.

No.11-A, 4th Cross, Veerasandra, Industrial Area, Electronics City, Bangalore - 560 100, Karnataka. Tel.: +91-804351 4000 (30 Lines) Fax :+91-80-4351 4001
E-mail : bhatbiotech@vsnl.net Visit us at :www.bhatbiotech.com



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