

GoldN™

GoldN™ Rapid Ovulation Test For Self-Testing

REF GN013ST

GoldN™ Rapid Ovulation Test Kit is a lateral flow immunoassay for the qualitative detection of human Luteinizing Hormone (LH) in urine to predict time of ovulation.



Read instructions carefully prior to taking the test.

For more information email us at: info@novo-dx.com

Scan the QR code to watch “How to Use Video” and for more information on how to use the test.



MATERIALS PROVIDED WITH KIT

COMPONENT	10 Test / box	25 Test / box
Test Device	10 Test Sticks (10 Sticks / pouch x 10 pouches)	25 Test Sticks (25 Sticks / pouch x 25 pouches)
Packing insert	1 Instructions for use	1 Instructions for use



Test Stick



Instructions for use

Required but not provided:



Timer

HOW TO PERFORM THE TEST

STEP 1 - Wash your hands prior to test



Wash your hands and make sure they are dry prior to starting the test. After washing your hands, open the box, and check the components for damage prior to use.

STEP 2 - Read Instructions for use



Read instructions for use thoroughly prior to using the test.

STEP 3 - Bring the pouch to room temperature



Allow pouch to come to room temperature (15-30°C) before opening it.

STEP 4 - Take out the strip



Carefully remove the Test Stick from the sealed pouch and use it within 5 minutes.



The test must be performed 5 minutes after opening.

5 min.

STEP 5 - Performing the test



Insert the Sample Tip into your urine stream for 15 seconds.



Do not urinate on the plastic portion of the Test Stick.

STEP 6 - Wait for result



Set timer and wait 5 minutes. Interpret results after 5 minutes.

STEP 7 - Read your results

See the Interpretation of Results section below.

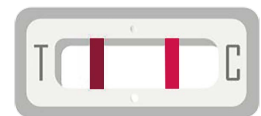
STEP 8 - Disposal after use

Please dispose of all parts of the test kits and place them in the household waste or rubbish bin if there are local regulations please follow them.

INTERPRETATION OF RESULTS

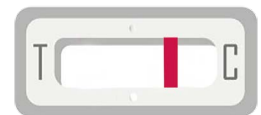
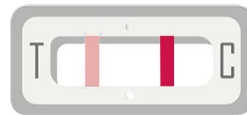
+ Positive Result

If two lines are present, and the test line (T) is equal to or darker than the control line (C), you will probably ovulate in the next 24-48 hours. If you are attempting to get pregnant, the best time to get lucky is after 24 but before 48 hours.



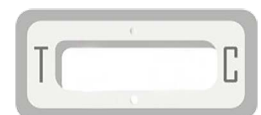
- Negative Result

If no test line is present or the test line is lighter than the control line. (Not in peak ovulation).



✗ Invalid

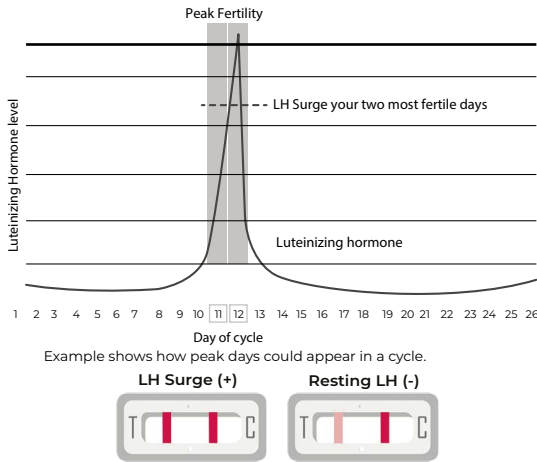
The result is invalid if no line appears in the control line region (C), even if a line appears in the test line region (T). Repeat the test with a new test stick.



GoldN™ RAPID OVULATION (LH) TEST KIT QUESTIONS & ANSWERS

1. How the test works

a. The GoldN™ Rapid Ovulation Test works by detecting an increase (spike) in production of a hormone called Luteinizing Hormone (LH) in your urine. LH in your urine will increase approximately 24-36 hours before an egg is released from the ovaries, this indicates ovulation is occurring. You are at your most fertile the day your LH increase is detected. The GoldN™ Rapid Ovulation Test can detect your 2 most fertile days, which begin from the time that the ovulation test detects your LH surge. Make love at any time in the next 48 hours to maximize your chance of becoming pregnant.



Note: Sperm can survive for several days and your LH spike may occur inside of the window between insemination and LH spike. Therefore, the GoldN™ Rapid Ovulation Test should not be used as a contraceptive.

2. When to take the tests

a. To find out when to begin testing, determine the length of your normal cycle. The length of your cycle is from the beginning of one period to the beginning of the next. Count the first day of bleeding or spotting as day 1. If your cycle length is irregular, that is, if it varies by more than a few days each month, take the average number of days for the last 3 months. Use the chart below to figure out the day you should begin testing. The day you begin testing is listed opposite the number of days in your cycle.

Length of Cycle (Days)	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
Using the first day of bleeding or spotting as Day 1, count forward the following number of days to begin testing.	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14	DAY 15	DAY 16	DAY 17	DAY 18	DAY 19	DAY 20	DAY 21	DAY 22	DAY 23

3. How accurate is the test result?

a. A clinical evaluation was conducted comparing the results obtained using the GoldN™ Rapid Ovulation Test to another commercially available urine LH test. The in-house clinical trial included 298 urine specimens. The results demonstrated 100% specificity and >99% sensitivity with an overall accuracy of >99%.

4. I have tested for several days and I did not see a surge. What do I do?

a. Since every woman does not always ovulate at mid-cycle, you may not detect the LH surge in the first seven days of testing. This could mean you have not ovulated yet and you should continue testing with an additional LH Test.

5. I have used the ovulation test for 3 months and have not become pregnant yet, is something wrong?

a. First, it is important to remember that it can take normal, healthy couples many months to become pregnant. There are many factors that can affect your ability to become pregnant even if you have been able to have intercourse during your most fertile days. If after several months you have no success, consult with your physician or health care provider.

6. What could interfere with my test result?

a. If you are already pregnant, have recently been pregnant, or have reached menopause you may get a misleading result. Some prescription drugs, such as menotropins for injection and Danazol may affect the results you see. Please consult your physician if you have any questions about prescription drug interactions.

7. Will oral contraceptives affect the result?

a. After using the pill your cycle may be irregular and may take some time to stabilize again. You may wish to wait until you have had two normal periods before starting to use the Test.

8. How sensitive is the GoldN™ Rapid Ovulation Test?

a. The GoldN™ Rapid Ovulation Test detects LH at a concentration of 25mIU/ml or greater. The test has been standardized to the W.H.O. International Standard. The addition of FSH (1,000 mIU/mL), hCG (10,000 mIU/mL), and TSH (40mIU/mL hLH) specimens showed no cross-reactivity.

9. Do alcohol or common medications affect the test?

a. No, but you should consult your physician if you are taking any hormonal medication. Also, recent oral contraceptive use, breastfeeding, or pregnancy could affect the test results.

INTENDED USE

The GoldN™ Rapid Ovulation Test is a rapid chromatographic immunoassay for the qualitative detection of Luteinizing Hormone (LH) in urine to predict the time of ovulation. The test is intended for women who want to conceive.

SUMMARY AND EXPLANATION

Luteinizing hormone (LH) in elevated quantities causes ovulation (the release of the egg from the ovarian follicle). Throughout the menstrual cycle a small amount of LH is produced, but during the middle of the cycle LH briefly and dramatically increases. This increase is called the "LH surge" and precedes ovulation. Ovulation is most likely to occur within 24 to 48 hours following the LH surge. The GoldN™ Rapid Ovulation Test Kit is specifically designed to detect your LH surge - the time when you are likely to ovulate. If you receive a positive on an LH test, you are in your most fertile phase of your menstrual cycle.

PRINCIPLE OF THE TEST

The test reagent is exposed to urine, allowing urine to migrate through the absorbent test strip. The labelled antibody-dye conjugate binds to the LH in the specimen forming an antibody-antigen complex. This complex binds to the anti-LH antibody in the test region (T) and produces a colour line. In the absence of LH, there is no colour line in the test region (T). The reaction mixture continues flowing through the absorbent device past the test region (T) and control region (C). Unbound conjugate binds to the reagents in the control region (C), producing a colour line, demonstrating that the test strip is functioning correctly.

STORAGE AND STABILITY

1. Store as packaged in the sealed pouch at temperature 2 - 30°C and relative humidity between 40 - 60%. The kit is stable within the expiration date printed on the labelling.
2. The test strips must be used within 15 minutes after removal from the foil pouch.
3. The kit must not be used after the expiry date. The expiry date is stated on the label/packaging.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

1. For self-testing in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.

LIMITATIONS

1. For self-testing in-vitro diagnostic use.
2. The GoldN™ Rapid Ovulation Test cannot be used as a form of birth control.
3. Medication containing LH may affect the test and should not be taken while using any of these Rapid Tests. In addition, the test will not work properly for subjects who are pregnant, in menopause, or taking birth control pills.
4. The GoldN™ Rapid Ovulation Test Kit is a preliminary qualitative test, therefore, neither the quantitative value nor the rate of increase in LH can be determined by this test.
5. The test works only if the instructions are followed precisely. Although the GoldN™ Rapid Ovulation Test is highly accurate and sensitive in detecting ovulation, an extremely low incidence of false results (positive when no ovulation exists or negative when ovulation exists) can occur.
6. This test may produce false negative results. These may occur when the levels of LH are below the sensitivity level of the test.
7. This test provides a presumptive diagnosis. A confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

SYMBOLS USED			
	Reference number		Consult Instruction for Use
	Store at 20 - 30°C		Expiration Date
	Manufacturer		Keep Dry
	Lot Number		Do Not Reuse
	Keep Away From Sunlight		Tests per Kit
	In Vitro Diagnostic Medical Device		Do not use if the package is damaged
	Over the counter		

REF: GN013ST
Corresponds to Catalog #: GN013ST10 (10 Pack); GN013ST25 (25 Pack).
IFU: IFU-GN013ST-US-EN
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177 N US Highway 1
#309 Tequesta, FL 33469, USA
email: info@novo-dx.com
web: www.iamgoldn.com
Manufactured for NOVODX Corporation by Vitrosens Biyoteknoloji Anonim Sirketi
Add: Serifali Mh., Sehit Sk. No.17/1
Ümraniye/Istanbul/Türkiye