



# Digital Ovulation

## Rapid Test

### INSTRUCTIONS FOR USE

#### PLEASE READ ALL INFORMATION IN THE INSTRUCTIONS FOR USE BEFORE TESTING!

For *in vitro* diagnostic use only.  
For Over-the-Counter use.

Model: DC0891

REF: 01007-1

#### INTENDED USE

This Suresign™ Digital Ovulation Rapid Test is used for the qualitative detection of Luteinizing Hormone (LH) level in human urine. It is suitable for the prediction of ovulation.

A self-testing *in vitro* diagnostic (IVD) medical device for home use by lay person.

#### PRINCIPLE

The LH in female urine is a hormone and its concentration periodically changes with the female menstrual cycle. The LH secretion amount increases sharply in the female mid-menstrual cycle, existing in abundance in female urine. The LH can stimulate ovulation within 24 - 48 hours once the LH peak is found. Therefore, 1 - 3 days pre-and post-LH peak is the best times for fertilization. The test device uses lateral flow immunoassay and light reflection for the detection of LH in urine specimens. When the specimen is applied to the Test Stick, the LH will react with anti-β-LH antibody-colloidal gold conjugate and form a compound. As the liquid flows to the Test area (T) of the Test Stick, the compound will be captured by the anti-α-LH antibody immobilized in the Test area (T), then a colored line will be formed in the Test area (T). To serve as a procedure control, a colored line will appear in the Control area (C) if the test has been performed properly. The Test Holder uses an LED light source to analyze the Test Stick, via light intensity, to determine the test result. The test result is then displayed on the Test Holder screen where the user reads the test result. The Digital Ovulation Rapid test is an accurate, rapid, and convenient method for the detection of ovulation.

#### MATERIALS

##### Materials Provided:

- 1 or more Test Stick (each in a foil pouch with a desiccant)
- 1 Test Holder
- Instructions for Use

##### Materials Required but not Provided:

- Urine collection cup

#### STORAGE CONDITIONS AND SHELF LIFE

1. Store in dry places at 35.6°F - 86°F (2°C - 30°C). Do not freeze.
2. Please use the Test Stick within 1 hour after opening the foil pouch.
3. See the product package expiration date. The shelf life of the product is 30 months.

#### SAMPLE REQUIREMENTS

1. Collect your urine in a clean urine collection cup OR directly urinate on the absorbent tip of the Test Stick.
2. Perform the test immediately after urine collection. If an immediate test cannot be carried out, the urine should be stored at 35.6°F - 46.4°F (2°C - 8°C) for not more than two days. Restore the urine to room temperature before the test.
3. Avoid drinking plenty of water or other liquids 2 hours before urine collection in order not to affect the detection of LH peak.
4. The recommended time for collecting the urine sample should be from 10:00 A.M. to 8:00 P.M. daily. **DO NOT collect the first morning urine.**

#### TEST METHODS

1. Determine the days of your period cycle. A period cycle refers to the duration calculating from the first day of the last period onset (the day of bleeding as the first day) until the day before the period onset of this month.
2. Determine the start date for starting the test. Refer to Table 1 below for determining the number of days after the period onset for starting the test. Consecutively test for 5 - 10 days.  
**For example:** If the number of days of your previous period cycle is 25 days, then find that number of days in the Menstrual Cycle (days) row in table 1 below, e.g. (25) and record the number in the row below (Test start date (Date) in the same column, e.g. [8]. **Important: Consult with a specialist physician if your cycle is irregular, less than 21 days or more than 40 days, before starting to test.**

The day of the period onset is taken as the first day, and the testing should be performed in this example on the [8] day of the period onset of this month, and so on. The testing should be performed at a relatively fixed time daily from the test start date. It is suggested to test twice daily (noon and night respectively).

Table 1 Menstrual Cycle Test Table

Menstrual cycle (days)	21	22	23	24	(25)	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
Test start date (Date)	6	6	7	7	[8]	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23

3. The test should be performed at room temperature 50°F - 86°F (10°C - 30°C) and avoid strong light.
4. When you are ready to start a test, take out the Test Stick from the foil (See Fig.1 and Fig.2).
5. Insert the Test Stick into the Test Holder: The Test Stick should be kept parallel with the Test Holder, ensure that the arrows on the Test Holder and Test Stick line up. The Test Stick should be fully fitted with the Test Holder (Fig. 3).  
You will hear two beeps, the symbols on the Test Holder will be displayed one by one. After that, the hourglass symbol "⌚" will begin to flash on the Test Holder and you can start testing. If sampling has not started within 3 minutes of insertion of the Test Stick, the Test Holder will prompt error "📄" with three beeps. In this case eject the Test Stick and wait 30 seconds before inserting it again. **NOTE: A Test Stick that has already been loaded with a urine sample cannot be reinserted.**
6. **Either Test in a Container:** Collect your urine in a clean urine collection cup. Remove the Test Stick cap gently (Fig.4). Insert the entire absorbent tip of the Test Stick into the urine for 10-15 seconds (Fig. 5).  
**Note:** Take care not to get the Test Holder wet.  
**OR Test in Urine Stream:** Remove the Test Stick cap gently, (Fig.4). Directly urinate on the absorbent tip of the Test Stick for 5-10 seconds (Fig.6).  
**Note:** Take care not to get the Test Holder wet.
7. Remove the Test device from the urine stream or the urine in the container. Put the cap back on the Test Stick and lay the Test device flat. The Test Holder will prompt error "📄" with three beeps if the sample is not loaded normally for over 3 minutes.
8. The hourglass symbol "⌚" will keep flashing while waiting for your result (Fig. 7), for about 5 minutes, you will then hear two beeps, and your result will be displayed on the Test Holder screen.

9. After reading your result, push the button on the Test Holder to eject the Test Stick and throw it away in your normal household waste.

**NOTE: Your results will be only maintained on the screen for about 10 minutes. Do not eject the Test Stick before you read the result. Eject the Test Stick as soon as possible after completing testing to reduce battery consumption.**

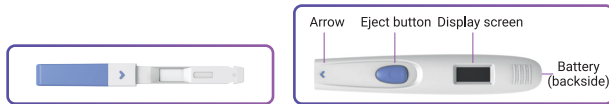


Fig. 1: Test Stick

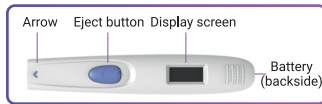


Fig. 2: Test Holder



Fig. 3: Insertion of Test Stick into the Test Holder



Fig. 4: Removal of Test Stick cap

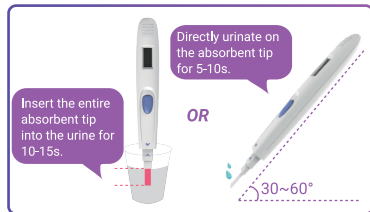


Fig. 5: Test in a Container

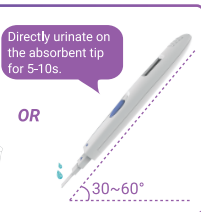


Fig. 6: Test in Urine Stream



Fig. 7: Hourglass symbol



Fig. 8: Never hold the test device with absorbent tip pointing upwards

## INTERPRETATION OF TEST RESULTS

1. "-" (**Low value**) on the display screen indicates low LH concentration level, and continuous monitoring is required.
2. "+" (**High value**) on the display screen indicates the LH concentration level reaches a high value. Having sexual intercourse within the coming 48 hours can improve your natural fertilization probability.
3. "++" (**Peak value**) on the display screen indicates the LH concentration level reaches the peak value. Having sexual intercourse within the coming 24 - 48 hours of ovulation can improve your natural fertilization probability.
4. "📖" (**Invalid**) on the display screen indicates a test error or invalid test. Please make sure that the test instructions are followed, and retest with a new Test Stick. If the problem persists then please contact the distributor.

## LIMITATIONS OF TEST METHOD

1. The product is only suitable for detection of the LH in urine, and not for the diagnosis and screening of ovulation as well as the test of LH related with hormone secretion disorder.
2. Unfresh or unclean test sample, or test sample with impurities, will all interfere with the test and produce incorrect results. Unclean urine collection containers or improper operation will also produce incorrect results.
3. In some cases, the test results will be affected, for example by: Injection or taking of hormone or steroid medications, ectopic pregnancy, germ cell tumor of ovary (GCTO) and others. If the test result is suspect, it is recommended to repeat the test or contact your physician to discuss your results.
4. The accurate LH level of the sample cannot be confirmed with this product. Other methods should be used for the precise quantification, if required please consult your physician.
5. Test results of this product will not be affected by hematuria, bilirubin and turbid urine. Higher chyle level may affect the test result.

## PERFORMANCE CHARACTERISTICS

**Sensitivity:** The Digital Ovulation Rapid Test Midstream detects LH in urine at a concentration of 25 mIU/mL or greater.

**Specificity:** For the cross reaction with Follicle Stimulating Hormone (FSH) at 200 mIU/mL, the result should be negative. For the cross reaction with Thyroid Stimulating Hormone (TSH) at 250  $\mu$ IU/mL, the result should be negative.

## PRECAUTIONS

1. This product is only for *in vitro* testing of human urine.
2. The Test Stick is for single use. Please use within the expiry period. Reuse is not allowed.
3. The desiccant in the foil pouch is for storage purposes only. Do not swallow.
4. Do not use the test if the pouch is punctured or not well sealed.
5. The test result is for reference only. The final diagnosis should be confirmed by your physician. If you have questions or concerns with your test results contact your physician to discuss your results.
6. Please read the Instruction for Use carefully before use and follow exactly. Failure to follow the test instructions will affect the test results.
7. This test device is not suitable for use as contraceptives.
8. The Test Holder and Test Stick cannot be used in combination with products from other manufacturers. The Test Holder should be used with the same batch of Test Sticks.
9. Before discarding the Test Holder, separate the upper and lower halves starting at the end nearest the display (Fig 2). Then remove the battery and dispose of it according to the local recycling regulations. Do not take apart, recharge, or dispose of the batteries in fire. Do not swallow. Keep away from children. Dispose of the rest of the holder according to the local recycling regulations for electrical equipment. Do not dispose of electrical equipment in fire.
10. It is recommended to wear gloves during testing and operation of the device.
11. Please wipe the Test Holder (Fig. 2) surface with a clean cloth or alcohol cotton balls if the product in use is splashed by urine or other liquids.
12. For any questions or suggestions on the use of this product, please contact the distributor.

## FAULT & FAILURE ANALYSIS

Failures	Fault Analysis	Treatment
Display shows nothing.	No battery charge or the battery is in bad contact.	Check the expiry date, if the expiry date is still valid then contact the distributor.
Display shows invalid test 📖	The sample volume was not sufficient or the Instructions For Use were not exactly followed.	Test again with a new stick and follow the Instructions For Use exactly.
The reagent strip does not pop up after the test is completed.	Aging of ejected parts.	Check the expiry date, if the expiry date is still valid then contact the distributor.
The buzzer does not beep.	Connection wire disconnected.	Contact the distributor.

## REFERENCES

- [1] Chen Yanru, Lin Junmin, Hou Quanling, Chen Siyao, Liu Lianlian, Lu Yingli. Application of Luteinizing hormone in ovulation[J]. Maternal and Child Health Care of China, 2018,33 (04): 951-954.
- [2] Zheng Qiheng, Hu Lizhen. Clinic application of predicting the ovulation by determination of LH peak value. Fujian Medical Journal, 1991, 13 (5): 9-10.
- [3] GB/T 18990-2008 luteinizing hormone (LH) test paper (colloidal gold immunochromatography)[S]. CFDA, 2009.
- [4] Esposito MA, et al Role of periovulatory luteinizing hormone concentrations during assisted reproductive technology cycles stimulated exclusively with recombinant follicle-stimulating hormone. Fertil Steril. 2001 Mar;75(3):519-24.
- [5] Themmen APN. An update of the pathophysiology of human gonadotrophin subunit and receptor gene mutations and polymorphisms[J]. Reproduction, 2005, 130: 263 ~ 274.

## ASSISTANCE



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