MissLan™

INSTRUCTIONS FOR USE

Digital Ovulation Rapid Test

(Immunochromatography)

PACKING SPECIFICATION

Model	Packing specification	REF
DC0891	5 tests/box	0891D9G005
	7 tests/box	0891D9G007
	10 tests/box	0891D9G010

Model	Packing specification	REF
DC0891	15 tests/box	0891D9G015
	25 tests/box	0891D9G025
	40 tests/box	0891D9G040

INTENDED USE

This test device is used for in vitro qualitative detection of Luteinizing Hormone (LH) level in human urine. It is suitable for the prediction of ovulation.
It is a self-testing IVD medical device for home use by lay person.

TESTING PRINCIPLE

The LH in female urine is a hormone and its concentration periodically change with the female menstrual cycle. The LH secretion amount is increased sharply in the female mid-menstrual cycle, existing in abundance in female urine. The LH can stimulate the ovulation within 24 - 48 hours once 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 the LH in urine specimens. When the specimen is applied to the test stick, the LH will react with the anti-β-LH antibody-colloidal gold conjugate and form a compound. As the liquid flows to the Test area of the test stick, the compound will be captured by the anti-α-LH antibody immobilized on the Test area, then a colored line will be formed on the Test area. To serve as a procedure control, a colored line will appear at the Control area (C), if the test has been performed properly. The test holder would detect the light intensity by using the LED as the light source. After that, the result can be displayed on the display screen. It is an accurate, rapid, and convenient method for the detection of ovulation.

COMPONENTS OF THE TEST KIT

Components \ REF	0891D9G005	0891D9G007	0891D9G010	0891D9G015	0891D9G025	0891D9G040
Test Holder	1	1	1	1	1	1
Test Stick	5	7	10	15	25	40
Desiccant	5	7	10	15	25	40
Instructions for Use	1	1	1	1	1	1

Materials required but not provided: A Urine Collection Cup to collect the urine.

STORAGE CONDITIONS AND SHELF LIFE

1. Store in dry places at 2°C ~ 30°C. Do not freeze. The shelf life is 30 months.
2. Please use the test stick within 1 hour after opening the foil pouch.
3. See the product package for manufacture date and expiration date.

SAMPLE REQUIREMENTS

1. The urine shall be collected with a Urine Collection Cup. Or directly urinate on the absorbent tip of the test stick. Please perform the test immediately after urine collection. If an immediate test cannot be made, the urine should be stored at 2°C ~ 8°C for not more than two days, Restore the urine to room temperature before the test.
2. Avoid drinking plenty of water or other liquid 2 hours before urine collection in order not to affect the detection of LH Peak.
3. 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) till the day before the period onset of this month.

2. Determine the test start date. Refer to Table 1 for determining days after the period onset for starting the test. Consecutively test for 5 - 10 days. **For example**: If days of the previous period cycle for subjects are 25 days (please consult with a specialist physician if the cycle is irregular, less than 21 days or more than 40 days), then find the days of period cycle 25 in the upper column in the Table and the relative figure 8 in the next column. The day of the period onset is taken as the first day, and the testing should be performed on the 8th 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 (10°C ~ 30 °C) and avoid strong light.

4. When you are ready for a test, take out the test from the foil.

5. Insert the test stick into the test holder: The test stick should be kept in parallel with test holder, and make sure the arrows line up. The test stick should be fully fixed with the test holder ***(Fig. 3)***. Then you will hear two beeps and the symbols of the test holder will be displayed one by one. After that, the hourglass symbol " ⌛ " will begin to flash on the screen and you can start testing. If not sampling after 3 minutes of insertion, the test holder will prompt error " 📖 " with three beeps. Please eject the test stick and wait 30 seconds before inserting it again. ***NOTE: test stick that has already been loaded urine sample cannot be reinserted.***

6. ***Either Test in a Container:*** Collect your urine in a 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). Take care not to get the test holder wet.***

Or Test in Urine Stream: Remove the test stick cap gently ***(Fig.4)***, and directly urinate on the absorbent tip of the test stick for 5-10 seconds ***(Fig.6). Take care not to get the test holder wet.***

7. Remove the test device from the urine stream or urine in container. Put back the cap 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 hear two beeps, and your result will be displayed on the 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: 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.

Graphical representation (pictures subject to physical objects)

Fig.1: Test stick

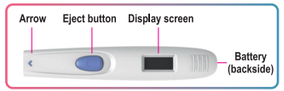

Fig.2: Test holder

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. It is required to take a new test stick to repeat the test.

LIMITATIONS OF TEST METHOD

1. The product is only suitable for detection of the LH in urine, but 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 rest results will be affected, **for example:** Injection or taking of hormone or steroid medications, ectopic pregnancy, germ cell tumor of ovary (GCTO) and others. It is suggested to repeat the test or further confirm from the specialized laboratory and make a comprehensive judgement in combination with clinical symptoms and signs, provided that the test results are suspected.
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.
5. Test results of this product will not be affected by hematuresis, bilirubin and turbid urine. Higher chyle level may affect the test result.

PERFORMANCE CHARACTERISTICS

Sensitivity: 25 mIU/mL.

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 μIU/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 validity 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 the physician in comprehensive consideration of all test indicators as well as clinical symptoms and signs.
6. Please read the Instruction for Use carefully before use and operate strictly. Otherwise the test results will be affected.
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 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 appropriate recycling protocol. 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 appropriate recycling protocol for electrical equipment. Do not dispose of electrical equipment in fire.
10. It is recommended wearing gloves during operation.
11. Please wipe the 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 during the use of this product, please contact the manufacturer.

FAULT & FAILURE ANALYSIS

Failures	Fault Analysis	Treatment
Display shows nothing.	No battery charge or the battery is in bad contact.	Please check the expiry date. Contact distributor.
Show test invalid.	The sample volume was not enough or do not follow the instructions of use.	Test again with a new stick and follow the instruction carefully.
The reagent strip does not pop up after the test is completed.	Aging of ejected parts.	Please check the expiry date. Contact distributor.
The buzzer do not beep.	Connection wire disconnected.	Contact the distributor.

KEY TO SYMBOLS USED

	Consult instructions for use		Date of manufacture
2°C 30°C	Store at 2°C~30°C		Keep dry
	Use-by date		Keep away from sunlight
	Manufacturer	Σ	Contains sufficient for <n> tests
LOT	Batch code	REF	Catalogue number
IVD	*In vitro* diagnostic medical device		Do not reuse
	Do not use if package is damaged		WEEE (Waste Electrical and Electronic Equipment)
EC REP	Authorized representative in the European Community		

[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 Qiuheng, 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.

Guangzhou Decheng Biotechnology Co., Ltd.
Room 405, Room 212, Room 218, Room 107, Building 2, No. 68, 1st Nanxiang Road, Science City, Huangpu District, 510000 Guangzhou, Guangdong, P.R. China
Tel: +86-020-82557192 Email: service@dochekbio.com
www.dochekbio.com

EC REP **Qarad EC-REP BV**
Pas 257, 2440 Geel, Belgium

Doc No.: DC-IN-0891C01 Ver 1.5 GB
Rel.: 2023/02/28

CE 0123