

## INSTRUCTIONS FOR USE

### Digital Pregnancy Rapid Test (Immunochromatography)

#### PACKING SPECIFICATION

Model	Packing specification	REF
DC811	1 test/box	0811S7X001
	2 tests/box	0811S7X002

#### INTENDED USE

This test device is used for in vitro qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine.

**This device is a self-testing IVD medical device for home use by lay person. It is suitable for the early diagnosis of pregnancy.**

#### TESTING PRINCIPLE

Human chorionic gonadotropin (HCG) is a glycoprotein produced by the placenta during pregnancy. It can be detected in the urine of pregnant women. This test midstream uses lateral flow immunoassay and light reflection for the detection of the HCG in urine specimens. When the specimen is applied to the test, the HCG will react with the anti-β-HCG antibody-colloidal gold conjugate and form a compound. As the liquid flows to the Test area of the test, the compound will be captured by the anti-α-HCG antibody immobilized on the Test area, then a colored line will be formed on the Test area. The test midstream 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 can perform early pregnancy diagnosis quickly and easily. The HCG levels can be detected in human urine 7 to 10 days after normal pregnancy.

#### COMPONENTS OF THE TEST KIT

Components \ REF	0811S7X001	0811S7X002
Test Midstream	1	2
Desiccant	1	2
Instructions for Use	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.
2. The shelf life is 30 months. Please use the test midstream within 1 hour after opening the foil pouch.
3. See the product package for manufacture date and expiration date.

#### SAMPLE REQUIREMENTS

The urine shall be collected with a Urine Collection Cup. Or directly urinate on the absorbent tip of the test midstream. Urine at any time is suitable for this product. However, the first morning urine is the best. 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.

#### TEST METHOD

The test should be performed at room temperature.

1. Remove the test midstream from the foil pouch and use as soon as possible within one hour.

**2. Either Test in Urine Stream:** put just the absorbent tip pointing downwards into your urine stream (Fig.2). **Caution:** Make sure that the rest of the test midstream does not get wet.

**Or Test in a Container:** after collecting the urine sample, dip more than half of the absorbent tip to the urine (Fig.3). **Caution:** Make sure that the rest of the test midstream does not get wet.

3. After adding sample, the hourglass symbol "⌚" will keep flashing on the display screen (Fig.4) to show the test is working.

4. When you hear two beeps, remove the test midstream. Replace the cap and lay it flat. **Caution:** Never hold the Test Midstream with absorbent tip pointing upwards (Fig.5).

5. Within **5 minutes** two beep sounds and your result will be shown on the display screen.



Fig.1 Subject to physical objects

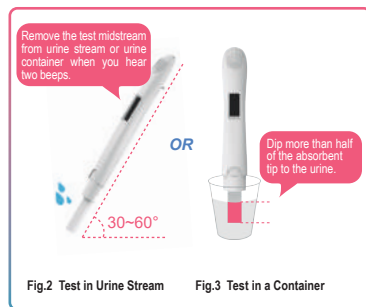


Fig.2 Test in Urine Stream

Fig.3 Test in a Container



Fig.4 Hourglass symbol



Fig.5 Never hold the test midstream with absorbent tip pointing upwards

#### INTERPRETATION OF TEST RESULTS

**Positive:** When the screen displays "+" (positive), it indicates you are possibly pregnant.

**Negative:** When the screen displays "-" (negative), it indicates you are not pregnant.

**Invalid:** When the screen displays "⌚" (invalid), it indicates that the test may be incorrect or invalid. Please check whether the operation is correct with the instruction for use and repeat with a new test.



Positive



Negative



Invalid

## LIMITATIONS OF TEST METHOD


1. This product is only for HCG test in human urine sample.
2. Unfresh or unclean test sample, or test sample with impurities, will produce incorrect results. Unclean urine collection containers, or improper operation will also produce incorrect results.
3. This test is used for qualitative detection in the early stage of pregnancy. The quantitative result should be further confirmed by other methods.
4. In some cases, the test results will be affected. **For example:** Injection or taking of hormone or steroid medications, those with history of previous injection of HCG, 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.
5. Test results of this product will not be affected by hematuria, bilirubin and turbid urine. Higher chyle level may affect the test result.
6. A false negative result may occur if the HCG level is too high, due to the limitation of the methodology.

## PERFORMANCE CHARACTERISTICS

**Sensitivity:** 25 mIU/ml.

**Specificity:** This product does not produce a cross-reaction with Luteinizing Hormone (LH) ( $\leq 500$  mIU/ml), Follicle-Stimulating Hormone (FSH) ( $\leq 1000$  mIU/ml), and Thyroid Stimulating Hormone (TSH) ( $\leq 1000$  mIU/L).

## PRECAUTIONS

1. This product is only for in vitro testing of human urine.
2. This product is for single-use. Please use within the validity period. Reuse is not allowed.
3. The test should be used indoor.
4. Please read the instruction for use carefully before use and operate strictly, otherwise the test results will be affected.
5. The desiccant in the foil pouch is for storage purposes only. Do not swallow.
6. Do not use the test if the pouch is punctured or not well sealed.
7. When using, take care not to get the urine touch the other parts of the test except absorbent tip, to avoid causing false negative results.
8. When "  " appears in the display screen, it indicates that the test is wrong or invalid. Please make sure that the operation is correct, and retest with a new test midstream.

9. In normal using, a hourglass symbol will appear in the display screen after adding samples. If it does not display on the screen one minute after sample adding, it indicates that the operation is abnormal. It is necessary to retest with a new test midstream.

10. The HCG test usually starts 2 days before your expected period, and can be performed 4 to 5 days before your expected period at the earliest. The urine collected at any time of the day can be used for the test. However, the first morning urine is the best. The highest level of HCG in the urine is more accurate for the test of early pregnancy.

11. General medications (such as cold medicines, antibiotics, painkillers, etc.) do not affect the accuracy of the test results, but injecting or taking fertility drugs will affect the results.

12. The positive test results may indicate pregnancy. Please go to a hospital for confirmation. The doctor will give you further suggestions and advices. That will ensure you and your fetus' health earlier and better.

13. Generally, a positive result indicates you are pregnant. However, a positive result may happen under the following cases: ① Women have abnormal pregnancy such as ectopic pregnancy, inevitable abortion, missed abortion or incomplete abortion; ② Uterine tumors, hydatidiform moles or higher levels of HCG in the urine for menopausal users. For pregnancy confirmation, further testing should be done by the doctor based on the user's medical history.

14. When the test result is negative, it indicates that you may not pregnant. Perform the test again if your expected period does not come within one week. Please see a doctor if the second test is still negative.

15. If the test result is negative, but the pregnancy is suspected, retest with morning urine after 48 - 72 hours.

16. The hook effect (2 - 3 months of pregnancy) may occur when the HCG level is too high, and the test result may be negative.

17. After use, open the cover of the test midstream at the end nearest the display and remove the battery (**Fig 1**). Dispose of it according to the appropriate recycling protocol. Do not take apart, recharge, or dispose of the battery in fire. Do not swallow. Keep away from children. Dispose of the rest of the midstream according to the appropriate recycling protocol for electrical equipment. Do not dispose of electrical equipment in fire.
















18. It is recommended to wear gloves during operation.

19. For any questions or suggestions during the use of this product, please contact the manufacturer.

## FAULT &amp; FAILURE ANALYSIS

Failures	Fault Analysis	Treatment
Display shows nothing.	No battery charge or the battery is in bad contact.	Please check the expiry date.
Show test invalid.	The sample volume is not enough or do not follow the instructions of use.	Test again with a new test following the instruction carefully.
The buzzer do not beep.	Connection wire disconnected.	Contact the distributor.

## KEY TO SYMBOLS USED

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

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