

Digital Fertility Testing System

Instruction for Use



In Vitro Diagnosis
For self-testing use only

PACKAGING SPECIFICATION

1T/box, 10T/box, 20T/box, 25T/box, 40T/box, 50T/box

PLEASE READ THE FOLLOWING ITEMS CAREFULLY BEFORE USING THIS PRODUCT

- 1.This product uses a CR2032 button battery.Please don't use other types avoid damage to the digital fertility tracker due to battery problems.
- 2.Never put an unused digital fertility tracker into any liquid or in one place where it might turn into a liquid.
- 3.The Digital fertility testing system is only used for women to measure human chorionic gonadotropin (HCG).Please do not use Systems used for other purposes.
- 4.The digital fertility tracker produced by our company is compatible with its test midstreams, so please do not mix with others company's products.
- 5.If you confirm that the system is not,do not continue using it works properly or has been damaged to avoid getting incorrect results.
- 6.Do not use this product near or near hot surfaces to avoid damage to digital fertility trackers.
- 7.Do not use in direct sunlight.
- 8.Do not put any object into the sample hole or observation window of the test midstream.
- 9.Do not use this product in the presence of organic solvent droplets.
- 10.This test midstream should not be used more than once.Because one test midstream can only complete one measurement.

INTENDED USE

The Digital Fertility Testing System is composed of the Digital Fertility Tracker and Test Midstreams.The Digital Fertility Testing System is intended to be used for the quantitative or semi-quantitative detection hormone in human urine.

TEST PRINCIPLE

The Digital Fertility Testing System is a lateral flow sandwich immunochromatographic assay.During the test procedures, hCG in the urine specimen reacts with the mouse antibody colloidal gold conjugate to form a complex.By capillary action,the complex migrates along the membrane to the monoclonal antibody line (T)and remains captured in the T line.The complex which is not captured by T-line will continue to migrate along the membrane to the polyclonal antibody line (C) and remains captured in the C line.A colored line will develop in the control zone is the basis for judging that the reagent chromatography process is normal.

The Digital Fertility tracker utilizes LED as a light source and light reflection to determine the presence or absence of the colored test and control lines.A procedure was implanted inside the device to judge negative and positive results and that the test results are displayed in symbolic form on the LED lamp of the device.

According to the display color and the type of test midstream,the hCG test midstream was negative (-)and positive (White" ✱ ").If it was positive,it also showed 1-2,2-3 and 3+gestational weeks.The darker the color is,the higher the concentration of the corresponding hormone is,the greater the intensity of the absorbed light is,and the lower the intensity of the reflected light collected by the instrument is.The error status is displayed in red " ✱ "

Product illustration

No.and name	Usage
1.Lid of the main body	Prevent other objects from entering the instrument
2.Maim body	The body of the instrument
3.PUSH button	Press the key to eject the Test midstream
4.LED dipla	For displaying measurement results and various information
5.Battery cover	Load the battery to power the instrument
6.Insulating sheet	Isolated battery conduction saves

	power
7.Sample area	Add the urine to be tested here
8.Inspection window	Color rendering area
9.Test midstream sticker	Test midstream types are distinguished by color
10.Test midstream name	Test midstream type mark
11.Holding aren	Insert the instrument

MATERIALS

Please confirm what's in the package you have purchased.The actual materials,especially the type of test midstream,will be up to which kind of kit you purchase.

Materials Provided

FM-101H:

1*DFT-101 Digital Fertility Tracker (battery included)	1*User manual
HCG-103B Test Midstream	1*Quick Guide

Materials Required(optional)

*Urine cups	For specimens collection
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Materials Required But Not Provided

Timer



PRECAUTIONS AND WARNINGS

- 1.You can choose to use the urine of any of the three periods-morning,afternoon,or evening.
- 2.The test midstream in the bag should be used immediately after unpacking to avoid failure caused by dampness.
- 3.Stop drinking water 2 hours before collecting the urine sample to prevent it from being diluted.
- 4.There is a desiccant in the aluminum foil bag.Do not eat it.
- 5.Product expired may not be used.
- 6.Test midstream are disposable and cannot be reused.
- 7.Please discard the test midstream in a non-recyclable bin after use.
- 8.This product is for in vitro diagnostic use only.
- 9.This product is an auxiliary diagnostic device only.It cannot determine the actual amount of hormone in a urine sample.The test results cannot serve as a basis for diagnosis.
- 10.The test results will be displayed by LED lights.Once the test is complete,the icon will appear for 30 seconds,then blink for 5 minutes before finally turn off automatically.If you want to check the result again, simply pull out the test midstream,or try to put the lid of back on and pull it out again.The result from your latest test will be shown.
- 11.Used test midstream, meter and the battery disposal must comply with the regulations of the national government and environmental protection agencies.
- 12.When there are stains,it is recommended to wipe with alcohol cotton or damp cloth.
- 13.Do not attempt to disassemble or repair the meter.Doing so may result in inaccurate readings.
- 14.If this product is used in a manner not specified by the manufacturer,the protection provided by the product may be impaired.
- 15.Please check the delivery information of products, including unpacking,completeness,and any damages during transport,and contact the customer services if any damages.
- 16.This instrument can only be used with the matching batch test midstream. Different batches of instruments and test midstreams can not be mixed.
- 17.Disposing of your Digital Test Midstream:Once your result has been displayed, dispose of the Test Midstream with your normal household waste.To do this, press the eject button on the DFT-101.The Test Midstream will automatically be released.When you eject the Test Midstream you may notice one or two red lines on the Test Midstream.These must be ignored;only refer to the display on the DFT-101 to determine your results.The Test Midstream is not reusable.



18. Throughout testing never hold the test stick with the absorbent tip pointing upwards.



19. Any measurement done by this product is for personal reference only. It is very dangerous for a patient to conduct self-diagnosis and self-treatment based on measurements only. Please be sure to follow your doctor's instructions.

20. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Digital Fertility Tracker, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

21. Keep away hospitals except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

22. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

23. Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

24. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging electrostatic discharges that may cause erroneous results.

25. Keep the instrument screen facing up and lie flat on the table during the test. Do not place the instrument in an incorrect state, such as reverse placement or no horizontal placement.

DIRECTIONS FOR USE

Step 1: Remove the insulation sheet, the instrument "beep" and the screen full 1s, it indicates that the battery has been successfully inserted.

Step 2: Collect urine in user prepared containers. You can choose the urine from any of the three different times of the day—morning, afternoon and evening.

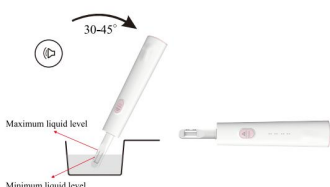


Step 3: Remove the cover, if the first use, the instrument "beep" and all lights are on (The indicator lights go out after 1s); If the test has been performed, the last test result is displayed 15 seconds. Lights off waiting for test. Insert the test Midstream until you hear a "click" sound, all lights will display for 1s, and then the indicator lights (2-lights) will cycle flash alternately to wait for sample adding measurement.



Step 4: Dip the test midstream into the urine (note: the best tilt Angle is 30-45°) for 3-5 seconds, take it out, and put it flat on the table, hearing the "beep" sound and the 2-lights cycle flashes alternately switches to a 4-lights cycle flashes alternately, indicating entry into the test mode.

Note 1: Do not drink excessive amounts of water two hours before testing.



Note 2: The operation method shown in the following figure cannot appear during the process of taking it out from urine and laying flat after adding the sample.



Step 5: Wait for about 6-10 minutes till you hear three beeps which indicate that the test is completed. The last test result will be shown again when pulling out the test midstream or the main body lid (pulling out the battery and the last test result will be cleared).

TEST RESULT

The measurement result will be displayed for 30 seconds and then blink for 5 minutes before finally turn off automatically.

HCG	Symbol "—"	For HCG, "—" means no pregnant.
	Symbol White "✱" 1-2 ✱	Assume that you are pregnant once White "✱" is displayed. Then you can check the gestational weeks "1-2, 2-3, 3 +".

REFERENCES

- [1] Yang X M, Xing G J, Kuan X U, et al. Quantitative detection of human chorionic gonadotrophin using colloidal gold immunochromatographic assay[J]. Journal of Shanghai Normal University(Natural Sciences), 2012.
- [2] Chan K W, Lo C, Chu C S, et al. Development of a Colloidal Gold-based Immunochromatographic Test Strip for Detection of Cetacean Myoglobin[J]. J Vis Exp, 2016(113).
- [3] Ju Y, Hao H J, Xiong G H, et al. Development of colloidal gold-based immunochromatographic assay for rapid detection of Streptococcus suis serotype 2[J]. Veterinary Immunology & Immunopathology, 2010, 133(2-4): 207-211.
- [4] Gnath C. and Johnson S. Strips of Hope: Accuracy of Home Pregnancy Tests and New Developments. Geburtshilfe Frauenheilkunde 2014; 74(7): 661-669.

Code: GKPD047-1 Effective date: May 28, 2024

Index of CE Symbols

	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
	Temperature scope within which the product is reserved		Batch number
	Catalog #		Tests per kit
	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

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