

Instruction Manual

Digital Pregnancy Test (HDP-700)



CE 0197

Intended Use

The Digital Pregnancy Test is an in vitro diagnostic (IVD) test device for use by the lay user for the rapid qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. This test is designed for self-testing use only.

Introduction

Human chorionic gonadotropin (hCG) is produced by trophoblastic tissue and appears around the 8-9th day after ovulation when fertilization has occurred. Its function includes facilitation of implantation as well as maintenance and development of the corpus luteum. The hormone concentration doubles approximately every 2 days and peaks between 7-12 weeks after the first day of the last menstrual period with a mean concentration of 50,000 mIU/ml. The Digital Pregnancy Test can detect hCG as early as 4 days before expected period, but even then a significant percentage of women who are indeed pregnant will still show a negative result. You can take the test at any time of day or night, and you do not have to use first-morning urine, in general, your first-morning urine contains the highest level of pregnancy hormone.

The Digital Pregnancy Test is a rapid test that qualitatively detects the presence of hCG in urine at the sensitivity of 25 mIU/ml. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the Pregnancy Test Device shows no cross-reactivity interference from the structurally related glycoprotein hormones FSH, LH and TSH at high physiological levels.

Storage and Stability

- Store as packaged in the sealed pouch at 4-30°C.
- The test kits should be kept away from direct sunlight, moisture and heat.
- The test device is stable through the expiration date printed on the sealed wrapper. The test device must remain in the sealed wrapper until use.
- Do not freeze.
- Do not use after the expiration date; the expiration period is 18 months.

Instructions



STEP 1 Take the test

When you are ready to test

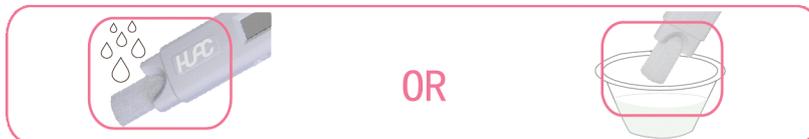
- Remove the Test Stick from the foil wrapper.
- Remove the overcap, place the overcap back to the stick tail part, and slide the switch to turn on the device, various symbols will flash on the Display Screen for several seconds followed by a steady Hour Glass symbol. The device is ready for use. (Do not use the test unless the steady Hour Glass symbol is on the Display Screen.)

NOTE: Place the overcap back to the stick tail part, which can extend the length of the device to hold the stick more comfortable and avoid urine splashed onto the hand.



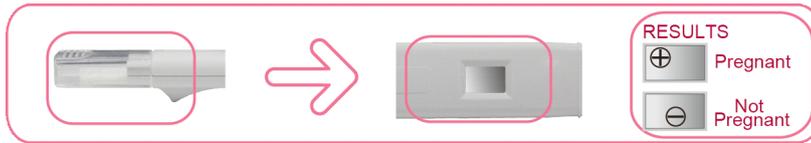
STEP 2 Test your urine

- Hold plastic holder of the Test Stick so that the Absorbent Tip is pointing downward.
 - Place the Absorbent Tip in your urine stream for 5seconds. Be careful not to get the urine on the plastic holder.
- OR
- Collect your urine in a clean, dry container and immerse the entire Absorbent Tip in the urine sample for 10 seconds.



STEP 3 Read your result, the result appear automatically after 5 minutes

- Replace the overcap and lay the stick on a flat surface with the Display Screen facing up.
- The Hour Glass symbol will blink after urine is applied to indicate the test is working.
- In approximately 5 minutes, an unmistakable result "+" or "-" will appear on the Display Screen.

**NOTE:**

This device is a single-use test. Do not reuse.

Keep the stick on a flat surface with the LCD facing up until the result appear.

Limitations

- Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
- False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
- Very low levels of hCG (less than 50 mIU/ml) are present in urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first-morning urine or serum specimen collected 48 hours later.
- A number of other conditions than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG in urine or serum specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
- As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.
- This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Performance Characteristics**Accuracy**

A multi-center clinical evaluation was conducted comparing the Digital Pregnancy Test and another commercially available urine membrane hCG test. The urine study included 100 specimens and both assays identified 60 negative and 40 positive results. The results demonstrated a 100% overall agreement (for an accuracy of > 99%) of the Digital Pregnancy Test when compared to the other urine membrane hCG test.

Sensitivity and Specificity

The Digital Pregnancy Test detects hCG at concentrations of 25 mIU/ml or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (500 mIU/ml), FSH (1000 mIU/ml), and TSH (1000 μ IU/ml) showed

no cross-reactivity to negative (0 mIU/ml hCG) and positive (25 mIU/ml hCG) specimens.

Interfering Substances

The following potentially interfering substances were added to hCG negative and positive specimens.

Acetaminophen	20mg/mL	Ampicilline	20mg/mL
Acetylsalicylic Acid	20mg/mL	Gentisic Acid	20mg/mL
Ascorbic Acid	20mg/mL	Glucose	2g/dL
Atropine	20mg/mL	Caffeine	20mg/mL
Cortisol	200ng/mL	Albumin	2000mg/mL
DHEAS	500ng/mL	Estradiol(E-2)	25ng/mL
Estradiol(E-3)	25ng/mL	Tetracycline	20mg/dL
Uric Acid	10mg/dL		

None of the substances at the concentration test interfered in the assay.

Display Message

Display	What it means	Action
	A "+" test result shows that the pregnancy hormone (hCG) was detected, which normally indicates pregnancy.	You should visit your doctor who can advise you on what steps you should take next.
	You may not be pregnant, or it may be too early to tell.	If you suspect that you may be pregnant, you may have miscalculated the day your period was due, or your urine may not have had enough pregnancy hormone to be detected in the test, you should retest with another Test Stick after 48 hours. If the second test gives you another "-" result and your period is overdue, you should visit your doctor.
	Hour Glass symbol	A steady Hour Glass symbol means the device is ready for use. The Hour Glass symbol will flash to show the test is working.
	An error has occurred during testing.	You should retest with another Digital Pregnancy Test. Please carefully follow all the instructions.

Notes

- Read the instructions carefully before use.
- For in vitro diagnostic use only.
- Not for internal use.
- Home pregnancy test. Single-use device. Do not reuse. Once the switch is opened, you can not close it, please turn the switch on when you are ready to test.
- Store in a cool and dry place, do not freeze.
- Keep out of the reach of children.
- You can use the Digital Pregnancy Test at any time of day or night, but first-morning urine is the best.
- Avoid direct sunlight when using the test device.
- Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.
- Do not use if the foil wrapper containing the Test Stick is damaged.
- Do not use if the Test Stick is past its expiration date.
- Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
- Do not remove the Test Stick from the foil wrapper until you are ready to use it.
- Do not get the urine unless the steady Hour Glass symbol is on the Display Screen.
- Being tested, avoid the Test from collision.
- This product incorporates the battery (The components include Ag_2O , MnO_2 , Zn , KOH , etc.). Remove the battery and dispose of it in accordance with local regulations.
- Residual urine and electronic components in the used device may impact the environment, so please dispose according to the local appropriate regulations.

Specifications

- Simple and clear indication
 - LCD display
 - Reliable result displays within 5 minutes
 - Operating Temperature Range: 10°C - 40°C (50° - 104°F)
 - Storage Temperature Range: 4°C - 30°C (39° - 86°F)
 - Power: 3VDC, 3mA
 - Battery: L736*2, or other kinds with the same specifications
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No.	Symbol	Instruction
1		"DO NOT REUSE"
2		"USE BY"
3		"BATCH CODE"
4		"DATE OF MANUFACTURE"
5		"CAUTION"
6		"MANUFACTURER"
7		"AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"
8		"IN VITRO DIAGNOSTIC MEDICAL DEVICE"
9		"CONSULT INSTRUCTIONS FOR USE"
10		"KEEP DRY"
11		"DO NOT USE IF PACKAGE IS DAMAGED"
12		"BIOLOGICAL RISKS"
13		"TEMPERATURE LIMITATION"
14		"SYMBOL FOR BATTERIES, ACCUMULATORS AND BATTERY PACKS FOR SEPARATE COLLECTION"
15		"MARKING OF THE WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT DIRECTIVE"
16		"RECYCLING"