



Digital Pregnancy

Rapid Test

INSTRUCTIONS FOR USE

PLEASE READ ALL INFORMATION IN THE INSTRUCTIONS FOR USE BEFORE USING THE TEST!

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

Model: DC081A
REF: 01002-1

INTENDED USE

The Digital Pregnancy Rapid Test is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy. It is intended for use by people who would like to find out whether they are pregnant in a home environment.

**Only for use outside the body
For Over-the-Counter Use.**

MATERIALS

Materials Provided:

- 1 or more Midstream Test Device, (each containing a test and a bag of desiccant).
- Leaflet with Instructions for Use

Materials Required but not Provided:

- Urine collection cup.

STORAGE CONDITIONS AND SHELF LIFE

- Store in a dry place at 35.6 - 86°F (2-30°C) in the sealed pouch.
- **DO NOT FREEZE**
- The shelf life is 24 months, see the product labelling for expiration date.
- Use the test device within 1 hour of removing from the foil.
- Keep away from sunlight, moisture, and heat.

WARNING AND PRECAUTIONS

1. This test is only for *in vitro* testing of human urine.
2. Not for internal use
3. This product is for single use only. **DO NOT** reuse.
4. Reuse is not allowed.
5. **Keep out of the reach of children.**
6. The desiccant in the foil pouch is for storage purposes only **DO NOT** swallow.
7. **DO NOT** use the test if the pouch is damaged or not well sealed.
8. **DO NOT** use the product after the expiration date.
9. Please follow local regulations to discard used product.

SAMPLE REQUIREMENTS

The urine shall be collected in a urine collection cup. Or directly urinate on the absorbent tip of the test. A first morning urine specimen is preferred, however, urine specimens collected at any time of the day can be used.

Please perform the test immediately after urine collection.

TAKE THE TEST

The test should be performed at room temperature and avoid strong light.



1. Remove the test from foil, take off the cap and use immediately.

Test in Urine Stream: Holding the test with the absorbent tip pointing downwards into your urine stream.

Caution: Make sure that only the absorbent tip is wet during sampling and that other parts of the test remain dry.

Remove the test from the urine stream when you hear two beeps.



OR

Test in a urine collection cup: Collect your urine in a clean, dry container. Immediately after collection, dip more than half of the absorbent tip into the urine.

Caution: Make sure that only the absorbent tip is wet during sampling and that other parts of the test remain dry.

Dip more than half of the absorbent tip into the urine. Remove the test from the urine when you hear two beeps.



2. The hourglass symbol "⌚" will keep flashing on the display screen.



Caution: Never hold the test with the absorbent tip pointing upwards after sample addition.



3. After about ten seconds, you will hear two beeps. Then remove the test from the urine. Lay the test **flat** with the display screen facing upward. You may place the cap back onto the device.

4. Please wait for 5 minutes, 2 beeps with sound, then you can read the results.

READ YOUR RESULT



Positive

When the display screen displays "+" (positive), it indicates you are pregnant (See Q1).



Negative

When the display screen displays "-" (negative), it indicates you are not pregnant (See Q2).



Invalid

When the display screen displays "⌚" (invalid), it indicates that the test is invalid (See Q5).

TEST ERRORS

| Failures | Fault Analysis | Treatment |
|------------------------------|--|---|
| Display shows nothing. | No battery charge or the battery is not correctly connected. | Please check the expiration date of the test. |
| Display shows Invalid. | The sample volume is not enough or test was not conducted correctly. | Test again with a new test following the instruction carefully. |
| The test did not beep twice. | Circuit disconnected. | Contact the distributor. |

PERFORMANCE CHARACTERISTICS

Accuracy: The accuracy of the Digital Pregnancy Rapid Test is over 99%.

Sensitivity: The Digital Pregnancy Rapid Test detects hCG in urine at a concentration of 25 mIU/mL or greater.

QUESTIONS & ANSWERS

Q1: My result is Pregnant. What should I do?

A1: The positive test result may indicate pregnancy. See your doctor to confirm, who can advise you on your next steps.

Q2: My result is Not Pregnant. What does this mean?

A2: When the test result is negative, it indicates that you may not be pregnant. If pregnancy is still suspected, test again using a new Digital Pregnancy Rapid Test with morning urine 48 to 72 hours later. If you still get a negative result and your period is late, you should see your doctor.

Q3: How does Digital Pregnancy Rapid Test work?

A3: It detects the pregnancy hormone hCG (human Chorionic Gonadotropin) in urine.

Q4: Can any medication or conditions affect the results?

A4: Medications containing hCG can affect the result. A number of conditions other than pregnancy cause elevated levels of hCG and could cause misleading results. Unclean urine collection containers or improper operation will also produce incorrect results.

Q5: How do I know that the test was run properly?

A5: In normal operation, an hourglass symbol "⌚" will appear on the display screen after adding the urine sample. If it does not appear on the screen within one minute of adding the sample, it indicates that the operation is abnormal. It is necessary to retest with a new test. When an open book symbol "📖" appears on the display screen, it indicates that the test is invalid. Please ensure you have conducted the test correctly according to the instructions, and retest with a new test.

ASSISTANCE



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Questions or Comments?

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