

Pregnancy Rapid Test Midstream

INSTRUCTIONS FOR USE

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

Catalogue No. See Box label

INTENDED USE

Amazewell™ Pregnancy Rapid Test Midstream is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human 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 (OTC) use.

KIT CONTENT

Materials provided

1. One pouch containing a test and a bag of desiccant.
2. Leaflet with instructions for use.

Materials needed but not provided

1. A urine collection cup to collect the urine.
2. Timer or clock.

STORAGE CONDITIONS AND SHELF LIFE

1. Store in dry places at 35 - 86°F (2 - 30°C), **DO NOT** freeze.
2. The product is stable until the expiration date printed on the outer packaging.
3. Use the test within 1 hour of removing from the foil.

WARNING AND PRECAUTIONS

1. This product is only for in vitro testing of human urine. **NOT** for internal use.
2. **DO NOT** make any decision of medical relevance without first consulting your doctor.
3. This product is for single-use. Reuse is **NOT** allowed.
4. Keep out of the reach of children.
5. The desiccant in the foil pouch is for storage purposes only. **DO NOT** swallow.
6. **DO NOT** use the test device if damaged or not well sealed.
7. **DO NOT** use the product after the expiration date.
8. Please follow local regulations to discard used product.

SAMPLE REQUIREMENTS

Use the urine collection cup or directly urinate on the absorbent tip of the test to collect the sample. It is preferable to collect the urine sample first thing in the morning, however, urine samples collected at any time of the day can be used for the test. Please perform the test immediately after urine collection.

TAKE THE TEST

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

Test in Urine Stream: Holding the test with the absorbent tip pointing downwards into your urine stream (Fig.2). Keep the absorbent tip in the urine stream for **5 - 10 seconds**.

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

Or Test in a urine collection cup: Collect your urine in a clean, dry container. Immediately after collection, dip the entire absorbent tip to the urine for **5 - 10 seconds** (Fig.3). **Caution:** Make sure that only the absorbent tip is wet during sampling and that other parts of the test remain dry.

2. After removing the test from your urine, immediately replace the cap, lay it flat with the result window facing upwards, and then begin timing. **Caution:** Never hold the test with the absorbent tip pointing upwards during testing (Fig.4).
3. Positive results may sometimes appear as early as 3 minutes, but you should wait the full 5 minutes to confirm a result.
4. **DO NOT** read the result after 10 minutes.

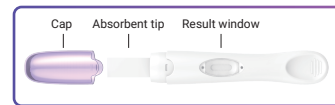


Fig.1 Test

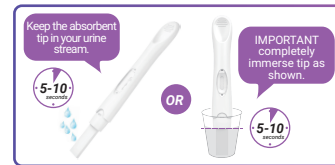


Fig.2 Test in urine stream

Fig.3 Test in a urine container cup

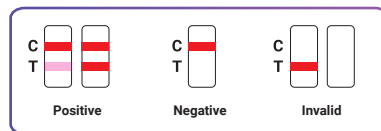


Fig.4 Never hold the test with the absorbent tip pointing upwards during testing.



Fig.5 WAIT 5 mins before checking results. NOT after 10 mins.

READ YOUR RESULT



Positive (pregnant): TWO distinct colored lines appear. A colored line is visible in both the Control Zone (C) and the Test Zone (T), the test result is positive and valid. It indicates you are pregnant (See Q1).

Negative (not pregnant): Only ONE colored line appears in the Control Zone (C), and no apparent line in the Test Zone (T), the result is negative and valid. It indicates you are not pregnant (See Q2).

Invalid: No colored line appears in the Control Zone (C), even if a colored line appears in the Test Zone (T), it indicates that the test is invalid (See Q5).

QUESTIONS & ANSWERS

1. My result is Pregnant. What should I do?

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

2. My result is Not Pregnant. What does this mean?

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

3. How does Amazewell™ Pregnancy Rapid Test Midstream work?

It uses a sandwich immunoassay to detect the hCG (human Chorionic Gonadotrophin) in urine.

4. Can any medication or conditions affect the results?

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.

5. How do I know that the test was run properly?

The appearance of a colored line in the Control Zone (C) indicates that the test was performed properly. If no colored line appears in the Control Zone (C), even if a colored line appears in the Test Zone (T), it indicates that the test is wrong or invalid. Please make sure that the operation is correct, and retest with a new test midstream.

6. What if the colored lines in the Test Zone (T) is very light, am I pregnant?

The test has worked if a colored line appears in the Control Zone (C), and even if the colored line in the Test Zone (T) is very light, you should assume that you are pregnant. Please see your doctor to confirm.

7. The colored lines in the Control Zone (C) differs between the two tests. Is this a concern?

No. Differences in the color of the colored lines in the Control Zone (C) do not affect the test result.

8. Can test results be interpreted after more than 10 minutes?

Test results must be read in 10 minutes. A negative result may change to a false positive within minutes after the end of the 10-minute testing period, which would not be an accurate reading. It is always best to read the result at the 5 minutes and then discard the test to avoid confusion.

ASSISTANCE

Call toll-free (888) 695-5248 (Monday – Friday 9:00 am – 5:00 pm, EST) or email to support@dochekusa.com.

Any serious incident related to the device shall be reported to the manufacturer and the competent authority in your country.

MEANING OF SYMBOLS ON PACKAGE



Consult instructions for use



Keep dry



Store at 35°F - 86°F
(2°C - 30°C)



Keep away from sunlight



Use-by date



Catalogue number



Batch code



Do not reuse



In vitro diagnostic medical device



Do not use if package is damaged

Distributed By:

Dochek USA INC

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Made in China

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