

Actorfemme™ Home Pregnancy Midstream Test (Urine)
For *in vitro* diagnostic and self testing use

INTENDED USE

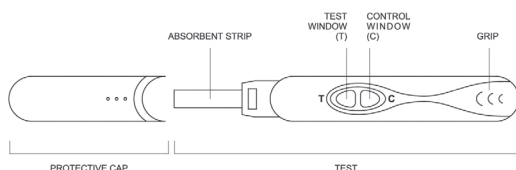
The Actorfemme™ Home Pregnancy Midstream Test is a rapid test to detect human Chorionic Gonadotropin (hCG) in urine to aid in the early detection of pregnancy. hCG is produced during pregnancy and released by the placenta right after implantation and rapidly increases in the early stages of pregnancy.

COMPONENTS

- Test Device
- Desiccant
- Patient Information Leaflet

PRECAUTIONS & WARNINGS

- Do not use the test after the expiration date.
- If the package is not completely sealed do not use the test.
- The test should be performed in a well-lit area.
- Use the test device immediately after opening it.
- Do not touch the test window. This could affect results.
- The pouch contains a silica gel pack to absorb humidity. Do not open the pack. Throw it away with the remainder of the test.
- At the end of the test, wrap everything you have used in a plastic bag and throw away in the waste bin. Do not forget to wash your hands properly.



PROCEDURE

Step 1:

- Read instructions carefully before use.
- It is best to perform the test first thing in the morning because the first morning urine contains the highest amount of hCG.
- Check that the test is completely sealed and then open the pouch.

Step 2:

Remove the protective cap from the device.

Step 3:

- Hold the device by the grip with the exposed absorbent strip pointing downwards.
- Place the absorbent strip into the urine stream for at least 10 seconds; making sure that the entire absorbent strip is wet.
- NOTE: Do not urinate on the result window of the device. If you prefer, you can urinate into a clean and dry container, then dip only the absorbent strip of the midstream test into the urine for at least 10 seconds.
- Remove the device from the urine stream (you may replace the cap – replacing the cap will not affect the results).

Step 4:

- Place the device on a flat surface with the window facing up. You will notice a pink colour moving across the result window indicating that the test reaction is taking place.

Step 5:

- Read results after 1 – 5 minutes. Look for coloured bands (lines) which should appear in the results window.
- Test results should not be read after 10 minutes.

HOW TO READ THE RESULTS

<p>PREGNANT: Positive results = 2 bands</p> <p>The presence of two red lines in the result window means you are probably pregnant. One line may be lighter than the other; they do not have to match. Check with your doctor to confirm pregnancy.</p>	
<p>NOT PREGNANT: Negative results = one band in the (C) area</p> <p>The presence of one red line in the control area (C) means you are probably not pregnant.</p>	
<p>INVALID RESULT: Invalid results = no bands or 1 band in the (T) area</p> <p>The result is invalid if no red line appears in the control area (C), even if a line appears in the test area (T). You should repeat the test with a new test.</p>	

WHAT THE RESULTS MEAN?

A positive result indicates that your urine contains hCG (the pregnancy hormone) at a concentration more than or equal to 25 mIU/ml (which is our device sensitivity) and you can assume you are pregnant. You should consult your doctor who is best able to further advise you on proper prenatal care. If you are taking any medication, inform your doctor immediately and make sure it is safe for your baby.

A negative result means that no hCG has been detected and you can assume you are not pregnant. If a week passes and your menstrual period is still delayed, you should do another test after two days. If the result is still negative in the second test, there is little chance that you are pregnant and there could be other health-related reasons why you are

not menstruating; in this case you should see your doctor without delay. If your menstrual cycle is irregular, it can be difficult to know the day you have missed your period. If your test indicated you are not pregnant and your menstrual cycle does not begin within a few days, you may have miscalculated your cycle and should use a second test after two days.

LIMITATION OF THE TEST

The test is not reusable and works only if the instructions are followed precisely. Although the test is highly accurate in detecting pregnancy, a low incidence of false results can occur. Check with your doctor if you get unexpected or inconsistent test results. Certain health conditions can also cause a false or irregular test result.

False negative results may occur for some women who are more than 5 weeks pregnant.

This is due to excess hCG variants in the urine that have been noticed in some uncommon cases of 10 weeks of pregnancy. If such cases are suspected, a dilution of 1:10 of the samples needs to be retested to confirm the negative results.

QUESTIONS & ANSWERS

Q. How does the test work?

A. When a woman is pregnant; her body produces a special pregnancy hormone known as hCG (human Chorionic Gonadotropin). This hormone appears in the urine as early as the first day of a missed menstrual cycle. A positive result indicates that your urine contains hCG and you can assume you are pregnant. A negative result means that no hCG has been detected and you can assume you are not pregnant.

Q. What if the two pink lines appear, but one is much lighter than the other; am I pregnant?

A. Yes. You should assume you are pregnant.

Q. What if I am uncertain about the pink line in the “T” area?

A. It is recommended that you retest three days later using another test.

Q. Can the result change after a certain length of time?

A. A positive test result may not change after the test is completed or for several hours thereafter. However, a negative test result should not be read after 10 minutes.

Q. What should I do if the test result is negative and I still suspect that I am pregnant?

A. You may have miscalculated when your period was due. If your period does not start within a week, repeat the test. If you still get a negative result and your period has not started, you should see your doctor.

STORAGE

Store in original packaging, in a dry place below 25 °C. Do not use after the expiry date stated on the packaging. The expiry date refers to the last day of the month.

KEEP OUT OF THE REACH OF CHILDREN.

Do not dispose of unused or used tests in drains or sewerage systems (e.g. toilets).

PRESENTATION

Each carton contains a single pregnancy test or two pregnancy tests.

NAME AND ADDRESS OF DISTRIBUTOR

Actor Pharma (Pty) Ltd¹
Unit 7, Royal Palm Business Estate
646 Washington Street, Halfway House,
Midrand, 1685

NAME AND ADDRESS OF MANUFACTURER

Atlas Medical
William James House,
Cowley Road, Cambridge,
CB4 0WX, UK

LOT	Lot number		Manufactured by
	Store between 2 - 30 °C		Single use
REF	Catalogue Number		Expiry Date
IVD	For <i>in vitro</i> Diagnostic use		Read instructions before use
	Do not use if pouch is damaged		

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¹ Company Registration nr: 2008/008787/07