

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

INTENDED USE

The **Actorfemme™ Home Ovulation Test** is fast and easy-to-use. It is a qualitative test for predicting when there is a luteinizing hormone (LH) surge, and in turn when you are likely to ovulate.

COMPONENTS

- 3 x Test Devices individually packed
- Desiccant
- Patient Information Leaflet

PRINCIPLE

Ovulation is the release of an egg from the ovary. The egg then passes into the fallopian tube where it is ready to be fertilized. In order for pregnancy to occur, sperm must fertilize the egg within 24 hours after its release. Immediately prior to ovulation, the body produces a large amount of luteinizing hormone (LH), which triggers the release of a ripened egg from the ovary. This is known as an "LH surge" and usually takes place in the middle of the menstrual cycle. It is during this fertile time that pregnancy is most likely to occur. The **Actorfemme™ Home Ovulation Test** detects the LH surge in the urine, signalling that ovulation is likely to occur in the next 24-36 hours. This period is considered to be the most fertile time. It is important to note that an LH surge and ovulation may not occur in all menstrual cycles.

PRECAUTIONS & WARNINGS

- Please read all the information in this leaflet before performing the test.
- 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 and may be harmful.
- Do not use after the expiration date printed on the foil pouch.
- Do not freeze.
- Keep out of reach of children.
- For *in vitro* diagnostic and self-testing use. Not to be taken internally.
- Do not open the test foil pouch until it has reached room temperature and you are ready to start the test.
- The pouch contains a silica gel pack (desiccant) to absorb humidity. Do not open the pack. Throw it away after using 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.

WHEN TO TEST

The **Actorfemme™ Home Ovulation Test** kit contains 3 tests, allowing you to test over several days to find your most fertile time. Calculate when to start testing using the chart below as follows:

1. First, calculate the length of your average menstrual cycle. Your menstrual cycle length is the number of days from the first day of your period (first day of bleeding) to the last day before your next period starts.
2. Based on your cycle length, the "When to start testing chart" indicates the day in your cycle that you should start testing for ovulation using the **Actorfemme™ Home Ovulation Test** kit.
Note: if your cycle is irregular, you may want to use your shortest cycle length when reading the chart.
3. Count the first day of your period as Day 1. Start testing on the day shown in the "When to start testing chart" that corresponds to your cycle length.
4. Repeat the test on a daily basis (at the same time) until a surge in LH is observed (test positive).
5. First morning urine should **not** be used when testing for LH. For best results, you should test around the same time each day for example, between 10:00 AM and 8:00 PM. You should reduce your liquid intake approximately 2 hours prior to testing.

"When to start testing chart"

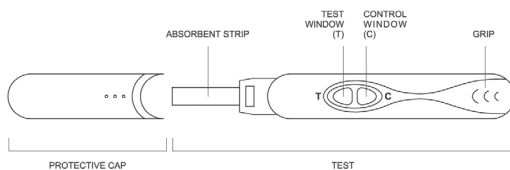
Cycle Length (Days)	Count the first day of your period as Day 1, Start testing on the day shown below that is adjacent to your cycle length.	Cycle Length (Days)	Count the first day of your period as Day 1, Start testing on the day shown below that is adjacent to your cycle length.	Cycle Length (Days)	Count the first day of your period as Day 1, Start testing on the day shown below that is adjacent to your cycle length.
21	Day 5	27	Day 9	33	Day 12
22	Day 5	28	Day 9	34	Day 13
23	Day 6	29	Day 9	35	Day 14
24	Day 7	30	Day 10	36	Day 15
25	Day 8	31	Day 10	37	Day 16
26	Day 9	32	Day 10	38	Day 17
				39	Day 18
				40	Day 19

6. **Example:** My usual cycle length is 28 days. My last period started on the 3rd of the month (**Day 1**). The "When to Start testing Chart" shows that I will start testing for ovulation on **Day 9**. Using the below Sample Calendar, if I begin with the 3rd of the month as **Day 1** and count ahead 9 days, I find that I will collect and test my urine for ovulation starting on the 11th of the month.

Sample Calendar

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

- First day of your period
- Begin testing with the test



PROCEDURE

1. Read instructions carefully before use.
2. Determine the day you will begin testing. (See the above section: "When to test").
3. Check that the test is completely sealed.
4. Remove the midstream test from the foil pouch and familiarise yourself with the product. See the illustration above.
5. Remove the cap and hold the midstream test by the handle grip with the exposed absorbent strip pointing downward directly into your urine stream for at least 10 seconds until it is thoroughly wet.
Note: Do not urinate on the result window. 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.
6. After removing the midstream test from your urine, immediately replace the cap over the absorbent strip, lay the midstream test on a flat surface with the result window facing upward, and then begin timing.

As the test begins to work, you may notice a light red flow moving across the result window. Wait for the red line(s) to appear. Read results in 1 - 5 minutes. It is important that the background is clear before the result is read. Positive results may be observed in 1 to 5 minutes depending on the concentration of LH. Do not read the result after 10 minutes.

HOW TO READ THE RESULTS

<p>POSITIVE: Positive results = 2 lines with (T) line the same or darker than (C) line. Two lines are visible and the test line (T) is the same as or darker than the control line (C). This indicates that you will probably ovulate in 24-36 hours</p>	
<p>NEGATIVE: Negative results = 2 lines with (T) line lighter than (C) line or one line in the (C) area. Two lines are visible, but the test line (T) is lighter than the control line (C), OR test line (T) does not appear. This indicates that no LH surge has been detected and daily testing should be continued.</p>	
<p>INVALID: Invalid results = no lines or 1 line in the (T) area. The result is invalid if the control line (C) fails to develop, even if the test line (T) appears in the result window. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new midstream test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.</p>	

QUESTIONS AND ANSWERS

- Q. Can I use the Actorfemme™ Home Ovulation Test to avoid pregnancy?**
A. No, the test should not be used as a form of birth control.
- Q. How accurate is the Ovulation Test?**
A. In laboratory studies, the **Actorfemme™ Home Ovulation Test** has been proven to be > 99 % accurate.
- Q. Does alcohol or common medications affect the test?**
A. No, but you should consult your doctor if you are taking any hormonal medication. Also, recent oral contraceptive use, breastfeeding, or pregnancy could affect the test results.
- Q. Why should I not use the first morning urine sample? What time of the day should I perform the test?**
A. The first morning urine sample is concentrated and may give a false positive result. Any other time of the day is suitable. For best results, try to collect your urine at approximately the same time each day.
- Q. Will the amount of liquid I drink affect the result?**
A. Excessive intake of fluids prior to testing will dilute the LH hormone in your urine. It is recommended that you limit your fluid intake for about two hours before you perform the test.
- Q. How long will the line remain visible?**
A. The test should be read at 5 minutes for best results. A positive (surge) result will never disappear. The colour line(s) may become darker and a tinted background may appear after several hours. Some negative results may later display a faint second colour line because of evaporation from the test window. Therefore, you should not read the results after 10 minutes; discard the test once you have read the result.
- Q. Once I see a positive result, when is the best time to have intercourse?**
A. Ovulation is likely to occur within 24-36 hours. This is your most fertile time. Sexual intercourse within 24 - 36 hours from detecting the surge is advised.
- Q. I am now using the basal body temperature method (BBT). Does this test replace BBT?**
A. **Actorfemme™ Home Ovulation Test** does not replace the BBT method. The shift in basal body temperature primarily indicates that ovulation has already occurred. **Actorfemme™ Home Ovulation Test** indicates that ovulation is about to occur.
- Q. I received a positive result and had intercourse during these fertile days but I have not become pregnant. What should I do?**
A. There are many factors that can affect your ability to become pregnant. It can take normal, healthy couples many months to achieve a pregnancy and often you may need to use the test kit for 3-4 months before achieving pregnancy. If pregnancy is not achieved after 3-4 months, you and your partner should consult your doctor.
- Q. I have had a positive result and had intercourse during these fertile days. I think I may be pregnant. How soon can I find out?**
A. The **Actorfemme™ Home Pregnancy Test** can provide you with results as early as the first day of your missed period.

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 3 individually packaged ovulation tests.

NAME AND ADDRESS OF DISTRIBUTOR:

Actor Pharma (Pty) Ltd'
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 number		
	Store between 2 - 30 °C		Single use
	Catalogue number		Expiry date
	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