

PRINCIPLE

Read the entire package insert carefully before using the test.

The PHRONESIA ovulation test is a quick, easy-to-use, single-use self-test. It is intended for the qualitative detection of luteinising hormone (LH) in urine to help predict the time of ovulation, and thus determine the most fertile and favourable days for conceiving a child.

Ovulation is the release of an egg from the ovary. Immediately before ovulation, the body produces a large amount of luteinising hormone (LH) which triggers the release of an egg from the ovary. This luteinising hormone (LH) peak usually occurs in the middle of the menstrual cycle¹. Once released, the egg travels down the Fallopian tube, where it may be fertilised.

The PHRONESIA ovulation test is a complete kit to help predict the time of ovulation, the period during which fertilisation is most likely to occur. It is therefore possible to determine that ovulation is likely to occur within 24 to 36 hours by detecting the LH surge in the urine. The LH surge and ovulation may not occur during each menstrual cycle.

The PHRONESIA Ovulation Test is a lateral flow immunochromatographic test using a combination of antibodies including an LH monoclonal antibody for the selective detection of elevated LH levels.

PRECAUTIONS FOR USE

Read all the information in this leaflet before performing the test.

- Do not use after the expiry date printed on the foil pouch.
- Store in a dry place at a temperature between 2 and 30 °C.
- Do not freeze.
- Do not use if foil pouch is torn or damaged.
- Single use, do not reuse.
- Keep out of reach of children.
- For in vitro diagnostic use only.
- Do not open the foil pouch until you are ready to perform the test, and use the test as soon as possible after opening.
- External use only, not suitable for internal use.
- The tests used must be discarded and/or recycled in compliance with environmental standards.

MATERIAL

Material supplied

tests

instructions for use

Material not supplied

Watch or timer

Container to collect urine sample (optional)

WHEN TO CARRY OUT THE TEST?

This kit contains several tests to allow you to test yourself at different times over several days in order to help you predict when you will ovulate, and thus determine the most favourable days for conceiving a child.

To find out when in your menstrual cycle to start a first test, please refer to the table (A) below.

TABLE A:

Duration of the menstrual cycle (days)	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38
Number of days to count	6	6	7	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21

1. Determine the average length of your menstrual cycle. The length of your menstrual cycle is the number of days from the first day of your period (start of bleeding) to the last day before your next period begins.

2. Circle the number corresponding to the average length of your menstrual cycles in Table A.

Note: In case your menstrual cycles are irregular, it is possible to use the shortest duration of your cycles.

3. Use the sample calendar (B) below to determine the day you need to start the test.

CALENDAR B:

Sample calendar						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
	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			

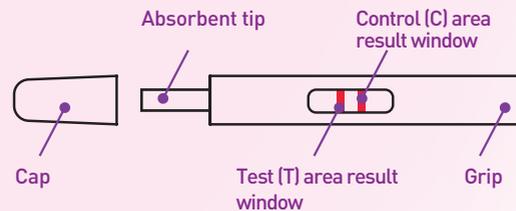
First day of your last period

Date to start testing

Example: My cycle is on average 28 days. My period started on day 3. Table A tells me to count 11 days from day 3. Calendar B shows that I have to start the test on day 13.

4. Once the day of the test has been determined, the first morning urine should not be used. For best results, it is also recommended to perform the test at the same time every day. Drinking should be avoided in the two hours preceding the test.

HOW TO USE



Important:

Before starting the test, determine the date on which you must start the test (see section "When to carry out the test?")

Step 1:

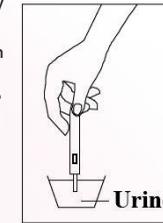
- Determine the optimal time to perform the test. For best results, it is advisable to perform the test every day at the same time on urine collected at the same time. Do not do the test upon waking with the first urine of the day. Reduce fluid intake about 2 hours before collecting urine.
- Record the date, day and time the urine is collected on the sample calendar (B)

Step 2:



- Leave the foil pouch at room temperature before opening it, if it has been refrigerated.
- Remove the test from its foil pouch and use it within an hour.
- Point the absorbent tip down directly under your stream of urine for at least 15 seconds until it is completely soaked (see illustration C)
- Be careful not to urinate on the result window.

OR



- It is also possible to urinate in a clean and dry container. Collected urine can be stored at room temperature for a maximum of 8 hours or at 2 to 8°C for 24 hours. For best results, perform the test immediately after collecting the urine. In the event that sediment forms at the bottom of the container, use only the urine from the upper part to soak the absorbent tip.

- Once the urine has been collected in the container, immerse the absorbent tip for at least 15 seconds.

Step 3:

- After removing the test from your urine stream or container, replace the cap and lay the test on a flat surface with the result window facing up.

- When the test is developing, a light-coloured stream may move across the result window.

- Read the result after 3 minutes.

- If no results appear after 3 minutes, wait 1 more minute.

- Do not read the result more than 10 minutes after removing the test from your urine stream or container.

READING THE RESULTS



POSITIVE

If both lines are visible and the line on the T (Test) side is of equal or greater intensity than the line on the C (Control) side, this indicates that you are likely to ovulate within the 24-36 next hours.



NEGATIVE

If both lines are visible but the line on the T side (Test) is lower in intensity than the line on the C side (Control), this indicates that the ovulation peak was not detected and that the test must be repeated daily in the days to come.



INVALID

The result is invalid if no line appears on the C (Control) side, even if a line appears on the T (Test) side. The main reasons for an invalid test are insufficient urine volume or incorrect test performance. In this case, reread the entire leaflet and start again with a new test.

LIMITS AND RESTRICTIONS OF THE TEST

- This test is intended for *in vitro* diagnostic use.
- This test cannot be used to avoid getting pregnant.
- Test results are not expected to be affected by the use of painkillers, antibiotics, or other common medications.
- Since treatments containing hCG and LH may affect results, the test should not be performed during a treatment period.
- The test does not work well for women who are already pregnant, post-menopausal or still on birth control pills.

ADDITIONAL INFORMATION

1. Can I use the PHRONESIA ovulation self-test to avoid pregnancy?

No, the test should not be used as a contraceptive method.

2. How reliable is the PHRONESIA ovulation self-test?

A clinical evaluation was carried out by comparing the results obtained using the PHRONESIA ovulation self-test with another commercially available test. The test involved 300 urine samples. The results showed a specificity > 99.9%, a sensitivity > 99.9% with an overall precision > 99.9%.

3. What is the sensitivity of the PHRONESIA ovulation self-test?

The PHRONESIA ovulation self-test detects the presence of luteinising hormone (LH) in urine at concentrations greater than or equal to 30 mIU/ml. Addition of FSH (1000 mIU/ml), hCG (10000 mIU/ml) and TSH (1000 µIU/ml) to negative (0 mIU/ml LH) and positive (30 mIU/ml LH) samples did not show cross-reactivity.

4. Does the intake of alcohol or common drugs affect the test?

No, but you should consult your doctor if you are taking hormonal treatments. In addition, recent oral contraceptive use, breastfeeding, or pregnancy may affect the test result.

5. Why is it not recommended to use the first morning urine? What time of day should I take the test?

First morning urine is not recommended for testing as it is concentrated and may give a false positive result. Any other time of day is fine. For best results, and in case of repeated tests, it is best to collect urine at the same time each day.

6. Does the amount of liquid I drink affect the result?

Ingesting a large amount of drink before performing the test is likely to dilute the hormone in your urine. We suggest that you limit your liquid intake for about two hours before performing the test.

7. How long do the lines remain visible?

The test result should be read at the end of 3 minutes for best results. A positive result will not disappear. The colour line may become darker and a tinted background may appear after several hours. Some initially negative results may later show a second faint line of color due to the evaporation of the control (C) line. Therefore, you should not read the results once 10 minutes have elapsed and should discard the test once you have read the result.

8. If the result is positive, when is the best time to have sex?

Ovulation is likely to occur within 24-36 hours. This is your most fertile time. Intercourse within this time frame is advised.

9. I use the temperature curve method. Does this test replace it?

The PHRONESIA ovulation self-test does not replace the temperature curve method. The change in basal body temperature indicates that ovulation has already occurred. The PHRONESIA ovulation self-test predicts when ovulation is likely to occur.

10. I tested positive, had sex during my fertile window and think I might be pregnant. When can I find out the earliest?

Our PHRONESIA digital pregnancy self-test can provide you with a result from the first day your period is late.

11. I tested positive, had sex during my fertile window but did not get pregnant. What should I do?

Many factors can affect your ability to get pregnant. Healthy couples can wait several months before pregnancy occurs. You may need to use this test kit for 3-4 months before pregnancy occurs. If you have not become pregnant after 3 to 4 months, it is best to consult a health professional with your partner.

REFERENCES

1. *Elkind-Hirsch, K;Goldzieher, JW;Gibbons, WE and Besch, PK. Obstetrics and Gynecology, 67(3): 450-453, 1986.*

INDEX OF SYMBOLS

	Consult the leaflet		Number of tests per kit		Authorised representative
	For in vitro diagnostic use only		Expiry date		Do not reuse
	Store between 2 °C and 30 °C		Batch number		Catalogue No.
	Do not use if packaging is damaged		Manufacturer		Supplier



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CE
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EC REP

MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster, Germany

REF FLH-U103H

Number: 146801700
Effective date: 10/06/2022



US OUS DOMESTIC OTHER

<i>Description</i>	INNOVA CE0123 FLH-U103H 彩色双面法语说明书(For A1932)	<i>Part Number</i>	146801700	<i>Size</i>	307x220mm
<i>Designer</i>	Fang	<i>Design Date/Version</i>	10 Jun 2022/C	<i>Mold Num.</i>	
<i>Artwork Checked By</i>		<i>Material Checked By</i>	80g双铜,双面		
<i>Approved By Customer/Date</i>		<i>Approved By R&D/Date</i>			
<i>Approved By QA/RA/Date</i>		<i>Approved By P.M.T./Date</i>			
<i>Approved By QA/Date</i>		<i>Effective Date</i>			