

**Test Ovulazione Autodiagnosi - midstream**  
**Ovulation Test for Self-testing - midstream**  
**Test de Ovulation usage individuel - applicateur**  
**Prueba de Ovulación para auto examen - midstream**  
**Teste para Ovulação para auto teste - midstream**  
**Τεστ Πρόβλεψης Ωορρηξίας Αυτοδιάγνωση - midstream**

**MANUALE D'USO**  
**OPERATOR'S MANUAL**  
**MANUEL D'UTILIZATION**  
**MANUAL DE USO**  
**MANUAL DE USO**  
**Εγχειρίδιο χρήσης**



**ATTENZIONE:** Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.

**ATTENTION:** The operators must carefully read and completely understand the present manual before using the product.

**AVIS:** Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.

**ATENCIÓN:** Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.





**ATENÇÃO:** Os operadores devem ler e entender completamente este manual antes de usar o produto.




**ΠΡΟΣΟΧΗ:** Οι χειριστές αυτού του προϊόντος πρέπει να διαβάσουν και να καταλάβουν πλήρως τις οδηγίες του εγχειριδίου πριν από την χρήση του.




0197

### Indice dei simboli

	Attenzione, consultare le istruzioni per l'uso
	Solo per uso diagnostico <i>in vitro</i>
	Conservare tra 2° e 30° C
	Conservare in luogo fresco ed asciutto

	N° pezzi per kit
	Usare entro
	Numero di lotto
	Conservare al riparo dalla luce solare

	Fabbricante
	Non riutilizzare
	Codice <b>29112</b>
	Leggere attentamente le istruzioni per l'uso

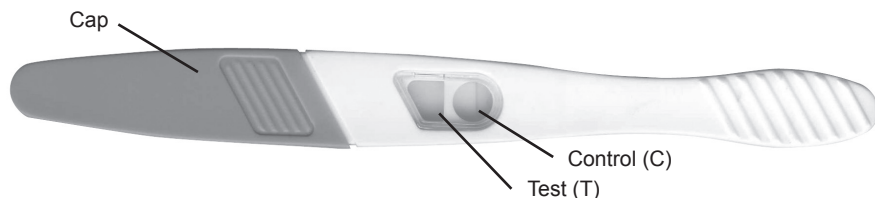


#### Fabbricante

GIMA Spa  
Via Marconi, 1 - 20060  
Gessate (MI) - Italia

### 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, the egg must be fertilized by sperm 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. It is important to note that an LH surge and ovulation may not occur in all cycles. The Ovulation Test midstream is a rapid, one-step lateral flow immunoassay for the qualitative detection of LH surges in urine, signaling that ovulation is likely to occur in the next 24-36 hours. The test utilizes a combination of antibodies including a monoclonal LH antibody to selectively detect elevated levels of LH. The assay is conducted by urinating on the Absorbent Tip or immersing the Absorbent Tip in urine, and obtaining the result from the colored lines.



### PRECAUTIONS

lease read all the information in this package insert before performing the test.

- Do not use after the expiration date printed on the foil pouch.
- Store in a dry place at 2-30°C or 36-86°F. Do not freeze.
- Do not use if pouch is torn or damaged.
- Keep out of the reach of children.
- For in vitro diagnostic use. Not to be taken internally.
- Do not open the test foil pouch until you are ready to start the test.
- The used test should be discarded according to local regulations.

**MATERIALS PROVIDED**

- Test Midstream

- Package insert

**INSTRUCTIONS**

This kit contains 5 tests, allowing you to test over several days to find your most fertile time. Calculate when to start testing using the chart below.

1) First, determine your Menstrual Cycle Length. Your Menstrual Cycle Length is the number of days from the first day of your period (menstrual bleeding) to the last day before the next period starts.

2) Next, determine the Days to Count Ahead after the period to start testing. Find the menstrual cycle length on the first row of the chart below, and read the corresponding number in the second row. This is the number of days after your period to begin testing.

3) See the Example and Sample Calendar below to determine which day you should begin testing. First morning urine should NOT be used when testing for LH. For best results, you should test around the same time each day. You should reduce your liquid intake approximately 2 hours prior to testing.

**When to Start Testing Chart**

Menstrual Cycle Length	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38
Days to count Ahead	6	6	7	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21

**Example:** My usual cycle length is 28 days. My last period started on the 3rd. The "When to Start Testing Chart" shows that I will count ahead 11 days beginning with the 3rd. When I count 11 days ahead on the calendar, I find that I will collect and test my urine starting on the 13th.

First day of the last period

Begin testing with the Ovulation Test midstream

	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				

**DIRECTIONS FOR USE**

Determine the day you will begin testing using the "When to Start Testing Chart".

1. Bring the pouch to room temperature before opening it. Remove the midstream test from the sealed pouch and use it as soon as possible.

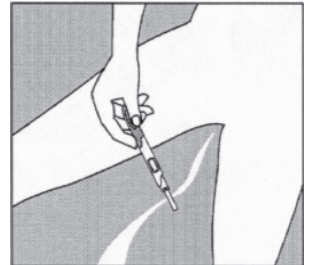
2. Remove the Cap. See illustration above.

3. Hold the midstream test by the Thumb Grip with the exposed Absorbent Tip pointing downward directly into your urine stream for at least 10-15 seconds until it is thoroughly wet. See illustration at right.

Note: Do not urinate on the Test and Control windows. If you prefer, you can urinate into a clean and dry container, then dip only the Absorbent Tip of the midstream test into the urine for 10-15 seconds.

4. After removing the midstream test from your urine, immediately replace the Cap over the Absorbent Tip, lay the midstream test on a flat surface with the Test and Control windows facing upwards, and then begin timing for 3 minutes.

5. As the test begins to work, you may notice a light colored flow moving across the Test and Control windows. Read the result at 3 minutes. If no result appears, wait one minute longer. Do not read the result after 10 minutes.

**READING THE RESULTS****POSITIVE**

Two colored lines are visible, and the line in the Test Window (T) is the same as or darker than the line in the Control Window (C). This indicates that you will probably ovulate in 24-36 hours.

**NEGATIVE**

Two colored lines are visible, but the line in the Test Window (T) is lighter than the line in the Control Window (C), or there is no line in the Test Window (T). This indicates that no LH surge has been detected and daily testing should be continued.

**INVALID**

Control line fails to appear. The result is invalid if no colored line appears in the Control Window (C), even if a line appears in the Test Window (T). You should repeat the procedure with a new test.

**LIMITATIONS**

There is the possibility that this test may produce false positive or false negative results. Invalid results are most likely caused by not following the instructions properly. Review the instructions and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**QUESTIONS & ANSWERS****1. Q: Can I use the Ovulation Test midstream to avoid pregnancy?**

A: No, the test should not be used as a form of birth control.

**2. Q: How accurate is the Ovulation Test midstream?**

A: A clinical evaluation was conducted comparing the results obtained using the Ovulation Test midstream to another commercially available urine membrane LH test. The in-house clinical trial included 1000 urine specimens. The results demonstrated >99.9% specificity and >98.9% sensitivity with an overall accuracy of >99.8%.

**3. Q: How sensitive is the Ovulation Test midstream?**

A: The Ovulation Test midstream detects luteinizing hormone (LH) in urine at concentrations of 40 mIU/mL or higher. The addition of FSH (1,000 mIU/mL), hCG (500 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL LH) and positive (40 mIU/mL LH) specimens showed no cross-reactivity.

**4. Q: Do alcohol or common medications affect the test?**

A: No, but you should consult your physician if you are taking any hormonal medication. Also, recent oral contraceptive use, breastfeeding, or pregnancy could affect the test results.

**5. Q: Why should I not use first morning urine? What time of the day should I perform the test?**

A: We do not recommend first morning urine because it is concentrated and may give a false positive result. Any other time of day is suitable. For best results, try to collect your urine at approximately the same time each day.

**6. Q: Will the amount of liquid I drink affect the result?**

A: Heavy intake of fluids prior to testing will dilute the hormone in your urine. We suggest that you limit your fluid intake for about two hours before you perform the test.

**7. Q: How long will the lines remain visible?**

A: The test should be read at 3 minutes for best results. A positive (Surge) result will never disappear. The colored line(s) may become darker and a tinted background may appear after several hours. Some negative results may later display a faint second color line because of evaporation from the test line. Therefore, you should not read the results after 10 minutes, discard the test once you have read the result.

**8. 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 this time frame is advised.

**9. Q: I am now using the basal body temperature method (BBT). Does this test replace BBT?**

A: The Ovulation Test midstream does not replace the BBT method. The shift in basal body temperature primarily indicates that ovulation has already occurred. The Ovulation Test midstream indicates that ovulation is about to occur.

**10. Q: I received a positive result and had intercourse during these fertile days but I have not become pregnant. What shall 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 physician.



**11. 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: Our Pregnancy Test can provide you with results as early as the first day of your missed period.

### Index of Symbols

	Attention, see instructions for use
	For <i>in vitro</i> diagnostic use only
	Store between 2-30°C
	Keep in a cool, dry place

	Tests per kit
	Use by
	Lot Number
	Keep away from sunlight

	Manufacturer
	Do not reuse
	Catalog <b>29112</b>
	Please read instructions carefully



**Manufacturer**  
GIMA Spa  
Via Marconi, 1 - 20060  
Gessate (MI) - Italia

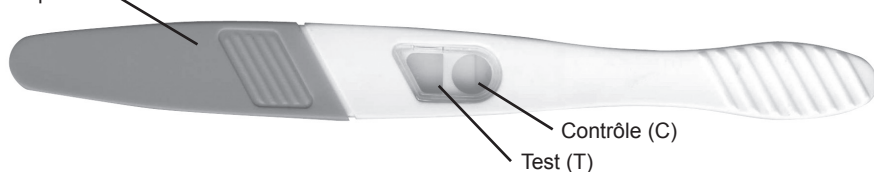


### PRINCIPE

L'ovulation est l'expulsion d'un ovule de l'ovaire. L'ovule passe ensuite dans la trompe de Fallope où il est prêt à être fécondé. Pour que la grossesse ait lieu, l'ovule doit être fécondé par le spermatozoïde dans les 24 heures qui suivent son expulsion. Juste avant l'ovulation, le corps produit une quantité importante d'hormones lutéinisantes (LH) qui provoque l'expulsion de l'ovule mûr. Cette "augmentation des LH" a souvent lieu au milieu du cycle menstruel. C'est pendant cette période de fécondité que la grossesse peut avoir lieu. Il est important de noter qu'une augmentation des LH et l'ovulation peuvent ne pas avoir lieu dans tous les cycles.

Le Test de Ovulation est un test immunologique de chromatographie rapide à 1 étape qui permet la détection qualitative de l'augmentation des hormones lutéinisantes (LH), signalant que l'ovulation aura probablement lieu dans les 24-36 heures. Le test utilise une combinaison d'anticorps incluant un anticorps monoclonal LH pour détecter sélectivement des niveaux élevés de LH. Le test est effectué en urinant sur la Mèche Absorbante ou en immergeant la Mèche Absorbante dans l'urine, et obtenant un résultat à partir des lignes colorées.

Capuchon



### PRECAUTIONS

Lire toutes les informations sur ce mode d'emploi avant d'effectuer le test.

- Ne pas utiliser après la date de péremption indiquée sur le sachet aluminium.
- Conservée dans un endroit sec à 2-30°C ou 36-86°F. Ne pas congeler.
- Ne pas utiliser le test si le sachet est déchiré ou endommagé.
- Ne pas laisser à la portée des enfants.