



# GIMA

**Test Monofase di Gravidanza Diagnosi Precoce**  
***Early Detection One Step Pregnancy Test***  
**Test de Détection Précoce de la Grossesse en 1 Etape**  
***Detección Temprana de la Prueba de Embarazo de Un Solo Paso***  
**Teste para Detecção Precoce da Gravidez Em Un Só Passo**  
***Τεστ εγκυμοσύνης Ενός Σταδίου Πρώιμης Ανίχνευσης***

**USO PROFESSIONALE**  
**PROFESSIONAL USE**

**MANUALE D'USO E MANUTENZIONE**  
**USE AND MAINTENANCE BOOK**  
**INSTRUCTIONS DE FONCTIONNEMENT ET ENTRETIEN**  
**MANUAL DE USO Y MANTENIMIENTO**  
**MANUAL DE USO E MANUTENÇÃO**  
**ΕΓΧΕΙΡΙΔΙΟ ΧΡΗΣΗΣ ΚΑΙ ΣΥΝΤΗΡΗΣΗΣ**

**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.



**Fabbricante/Manufacturer:**

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

**ITALIA:** Tel. 199 400 401 (8 linee r.a.) - Fax 199 400 403




E-mail: [gima@gimaitaly.com](mailto:gima@gimaitaly.com) - [www.gimaitaly.com](http://www.gimaitaly.com)




**INTERNATIONAL:** Tel. ++39 02 953854209 - Fax ++39 02 95380056

E-mail: [export@gimaitaly.com](mailto:export@gimaitaly.com) - [www.gimaitaly.com](http://www.gimaitaly.com)





### Indice dei Simboli

	Attenzione, consultare le istruzioni per l'uso
	Solo per uso diagnostico <i>in vitro</i>
	Conservare a 2-30° C

	N° determinazioni per kit
	Usare entro
	Numero del lotto

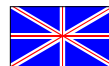
	Fabbricante
	Non riutilizzare
	Codice #

	Teme l'umidità
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	Conservare al riparo dalla luce solare diretta
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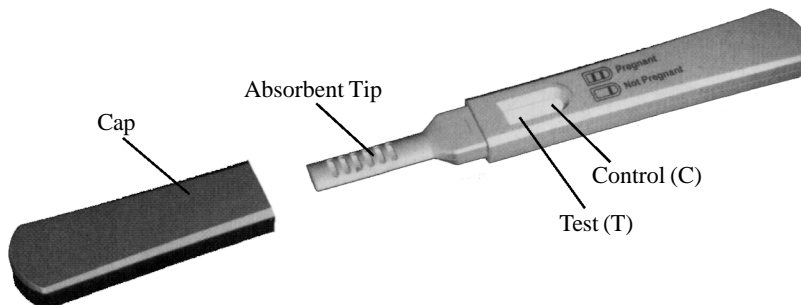
### Early Detection One Step Pregnancy Test Package Insert



#### PRINCIPLE

The Early Detection One Step Pregnancy Test is a rapid, one-step lateral flow immunoassay in midstream format for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated level of hCG. The assay is conducted by urinating on the Absorbent Tip in urine, and obtaining the result from the colored lines.

#### PRECAUTIONS



Please 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.

### KIT CONTENT

- Test midstream
- Package insert

### INSTRUCTION

1. Remove the midstream test from the foil pouch and familiarize yourself with the product.

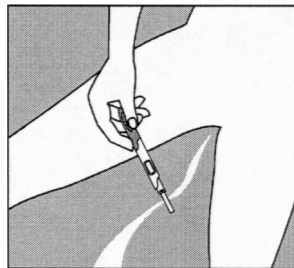
2. Remove the Cap and place it over the **Thumb Grip**. See illustration above.

3. Hold the midstream test by the capped **Thumb Grip** with the **exposed Absorbent Tip pointing downward directly into your urine stream for at least 10 seconds** until 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 at least 10 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 the timing.

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 colored line appears, wait one minute longer. Some positive results may be observed in 1 minute or less depending on the concentration of hCG. Do not read the result after 10 minutes.



### READING THE RESULTS



#### PREGNANT

Two distinct colored lines appear. One line should be in the Control Window (C) and another line should be in the Test Window (T). One line may be lighter than the other; they do not have to match.



#### NOT PREGNANT

One colored line appears into the Control Window (C). No line appears in the Test Window (T).



#### INVALID

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 test with a new midstream test.

### LIMITATIONS

There is the possibility that this test may produce false results.

1. Drugs which contain hCG (such as Pregnyl, Profasi, Pergonal, APL) can give a false positive result. Alcohol, oral contraceptives, painkillers, antibiotics or hormone therapies that do not contain hCG should not affect the test results.
2. A number of medical conditions other than pregnancy, including, ovarian cyst or ectopic pregnancy (pregnancy outside the uterus) can cause elevated levels of hCG, which can result in a false positive result.

### QUESTIONS & ANSWERS

#### 1. How does the test work?

The Early Detection One Step Pregnancy Test detects a hormone in your urine that your body produces during pregnancy (hCG - human chorionic gonadotropin). The amount of pregnancy hormone increases



as pregnancy progresses.

**2. How soon after I suspect that I am pregnant can I take the test?**

You can test your urine as early as the first day you miss your period. You can perform the test anytime of the day; however, if you are pregnant, first morning urine contains the most pregnancy hormone.

**3. Do I have to test with first morning urine?**

Although you can test at any time of the day, your first morning urine is usually the most concentrated of the day and would have the most hCG in it.












**4. How accurate is the test?**

A clinical evaluation was conducted comparing the results obtained using the Early Detection One Step Pregnancy Test to another commercially available urine membrane hCG test. The consumer clinical trial included 100 urine specimens: both assays identified 75 positive and 25 negative results. The results demonstrated > 99.0% overall accuracy of the Early Detection One Step Pregnancy Test when compared to the other urine membrane hCG test.

**5. How sensitive is the test?**

The Early Detection One Step Pregnancy Test detects hCG in urine at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

**Index of Symbols**

	Attention, see instructions for use		Tests per kit		Manufacturer
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Keep dry		Keep away from sunlight	