



# GIMA

PROFESSIONAL MEDICAL PRODUCTS

## ULTRA

### PREGNANCY TEST

### TEST DI GRAVIDANZA

### TEST DE GROSSESSE

### TEST DE EMBARAZO

### TESTE DE GRAVIDEZ

### SCHWANGERSCHAFTSTEST

### ΤΕΣΤ ΕΓΚΥΜΟΣΥΝΗΣ

### TEST CIAŻOWY

### TEST DE SARCINĂ

### GRAVIDITETSTES

### TEST TRUDNOĆE

الاختبار الفائق للحمل

**GIMA 29103**



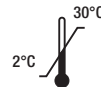
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Technological Development Area, Hangzhou,  
310018 P.R. China - Made in China



**FHC-U103H**



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**INTENDED USE**

The hCG Pregnancy Enhanced Sensitivity Rapid Test Midstream is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

**PRINCIPLE**

HCG Pregnancy Enhanced Sensitivity Rapid Test Midstream 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 early detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by adding urine to the hydrophilic stick and obtaining the result from the colored lines.

**REAGENTS**

The test contains anti-hCG particles and anti-hCG coated on the membrane.

**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 35.6-86°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 midstream foil pouch until you are ready to start the test.
- The used test midstream should be discarded according to local regulations.

**STORAGE AND STABILITY**

The kit can be stored at room temperature or refrigerated (2-30 °C). Do not open the pouch until ready for use. **DO NOT FREEZE.** Do not use beyond the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

The urine specimen should be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

If the urine specimen cannot be detected immediately, it should be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS PROVIDED	
• Test Midstream	• Package Insert
MATERIALS REQUIRED BUT NOT PROVIDED	
• Timer	• Specimen Collection Container

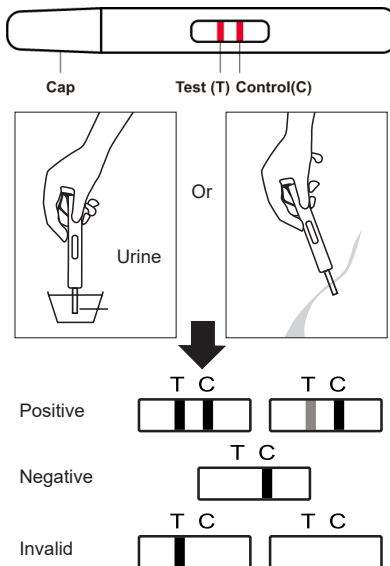
**INSTRUCTIONS**

**Allow the test, urine specimen to reach room temperature (15-30°C) prior to testing.**

1. Remove the midstream from the foil pouch and test it immediately in one hour.
2. Take down the cap of the midstream, hold the midstream so as to place the absorbent tip in the urine stream or place the absorbent tip (≥2/3) in urine in a clean cup for **at least 15 seconds**.

**NOTE:** Do not urinate on the Result Window.

3. Cover the cap on the testing midstream, then lay down the midstream on a clean and stable desk, start the timer immediately.
4. **Read the result at 3 minutes;** don't interpret the result after 10 minutes.



**READING THE RESULTS**

**POSITIVE:** Two colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T). One line may be lighter than the other; they do not have to match. This means that you are probably pregnant.

**NEGATIVE:** One colored line appears in the control line region (C). No line appears in the test line region (T). This means that you are probably not pregnant.

**INVALID:** The result is invalid if no colored line appears in the control line region (C), even if a line appears in the test line region (T). You should repeat the test with a new test midstream.

**QUALITY CONTROL**

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

**LIMITATIONS**

This test might give wrong results. Talk to your doctor before making medical decisions.

1. Some drugs with hCG (such as Pregnyl, Profasi, Pergonal, APL) can cause false positives. But alcohol, birth control pills, painkillers, antibiotics, and non-hCG hormone therapies shouldn't affect it.
2. If your urine is very dilute, it might not have enough hCG. If you still think you're pregnant, test again with first morning urine after 48 hours.
3. Low hCG levels (less than 50mIU/mL) can happen right after implantation. If the test is weakly positive, retest with first morning urine after 48 hours.

4. False positives can happen due to conditions like trophoblastic disease or cancers (testicular, prostate, breast, lung), cause elevated levels of hCG.<sup>1,2</sup> Don't use hCG to diagnose pregnancy unless other causes are ruled out.
5. False negatives can happen if hCG levels are too low. If you still suspect pregnancy, test again with first morning urine after 48 hours. If it's still negative, see a doctor.
6. This test only suggests pregnancy. A doctor must confirm it after checking all findings.

#### **EXTRA INFORMATION**

**How it works:** It detects hCG, a hormone produced during pregnancy, in your urine.

**When to test:** The test can detect hCG 6 days before your missed period (5 days before day of the expected period). Use first morning urine for the best results, as it has the highest hCG concentration.

**Accuracy:** Over 99% accurate compared to another urine hCG test in a clinical evaluation.

**Sensitivity:** Detects hCG at 10 mIU/mL or higher.

**If pregnant:** See your doctor to confirm and discuss next steps.

**If not pregnant:** If your period doesn't start within a week, retest. If still negative and no period, see a doctor.

**Disposal:** Dispose of the used test according to local regulations.

#### **BIBLIOGRAPHY**






1. Dawood MY, BB Saxena, R Landesman Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma, *Obstet. Gynecol.* 1977; 50(2): 172-181
2. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross "Ectopic production of human chorionic gonadotropin by neoplasms", *Ann. Intern. Med.* 1973; 78(1): 39-45







#### **GIMA WARRANTY TERMS**






The Gima 12-month standard B2B warranty applies

Indice dei simboli - Symbol index - Index des symboles - Índice de símbolos- índice de símbolo - Symbolindex - Ευρετήριο συμβόλων - Indeks symboli - Symbol index - Index de simbol - Indeks simbola

تيالوبوموس تارشؤم

	<p><b>IT</b> - Fabbricante <b>GB</b> - Manufacturer <b>FR</b> - Fabricant  <b>ES</b> - Fabricante <b>PT</b> - Fabricante <b>DE</b> - Hersteller  <b>GR</b> - Παραγωγός <b>PL</b> - Producent <b>SE</b> - Tillverkare  <b>RO</b> - Producător <b>HR</b> - Proizvođač  <b>SA</b> - الشركة المصنعة</p>
	<p><b>IT</b> - Conservare al riparo dalla luce solare <b>GB</b> - Keep away from sunlight <b>FR</b> - À conserver à l'abri de la lumière du soleil <b>ES</b> - Conservar al amparo de la luz solar <b>PT</b> - Guardar ao abrigo da luz solar  <b>DE</b> - Vor Sonneneinstrahlung geschützt lagern <b>GR</b> - Κρατήστε το μακριά από ηλιακή ακτινοβολία <b>PL</b> - Przechowywać z dala od światła słonecznego <b>SE</b> - Skyddas från solljus <b>RO</b> - A se păstra ferit de razele soarelui <b>HR</b> - Čuvati zaštićeno od sunčeve svjetlosti  <b>SA</b> - يحفظ بعيداً عن ضوء الشمس</p>
	<p><b>IT</b> - Non utilizzare se l'imballaggio è danneggiato <b>GB</b> - Don't use if package is damaged <b>FR</b> - Ne pas utiliser si le colis est endommagé <b>ES</b> - No usar si el paquete está dañado <b>PT</b> - Não use se o pacote estiver danificado <b>DE</b> - Nicht verwenden, wenn das Paket beschädigt ist <b>GR</b> - Μην το χρησιμοποιείτε αν η συσκευασία είναι κατεστραμμένη <b>PL</b> - Nie używać, jeśli opakowanie jest uszkodzone <b>SE</b> - Använd inte en förpackning som är skadad <b>RO</b> - A nu se utiliza dacă ambalajul este deteriorat <b>HR</b> - Ne koristiti ako je pakiranje oštećeno  <b>SA</b> - لا تستخدم في حالة تلف الحزمة</p>
	<p><b>IT</b> - Importato da <b>GB</b> - Imported by <b>FR</b> - Importé par <b>ES</b> - Importado por <b>PT</b> - Importado por <b>DE</b> - Eingeführt von <b>GR</b> - Εισαγωγή από <b>PL</b> - Importowane przez <b>SE</b> - Importerad av <b>RO</b> - Importat de <b>HR</b> - Uvezeno od strane  <b>SA</b> - مستورد عن طريق</p>
	<p><b>IT</b> - Conservare in luogo fresco ed asciutto <b>GB</b> - Keep in a cool, dry place <b>FR</b> - À conserver dans un endroit frais et sec <b>ES</b> - Conservar en un lugar fresco y seco <b>PT</b> - Armazenar em local fresco e seco <b>DE</b> - An einem kühlen und trockenen Ort lagern <b>GR</b> - Διατηρείται σε όψοερό και στεγνό περιβάλλον <b>PL</b> - Przechowywać w suchym miejscu <b>SE</b> - Förvara på svalt och torr ställe <b>RO</b> - A se păstra într-un loc răcoros și uscat <b>HR</b> - Čuvati na hladnom i suhom mjestu  <b>SA</b> - يحفظ بعيداً عن ضوء الشمس</p>

	<p><b>IT</b> - Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso <b>GB</b> - Caution: read instructions (warnings) carefully <b>FR</b> - Attention: lisez attentivement les instructions (avertissements) <b>ES</b> - Precaución: lea las instrucciones (advertencias) cuidadosamente <b>PT</b> - Cuidado: leia as instruções (avisos) cuidadosamente <b>DE</b> - Achtung: Anweisungen (Warnungen) sorgfältig lesen <b>GR</b> - Προσοχή: διαβάστε προσεκτικά τις οδηγίες (εισαγγελίες) <b>PL</b> - Ostrzeżenie - Zobacz instrukcję obsługi <b>SE</b> - Varsamhet: läs anvisningarna (varningar) noga <b>RO</b> - Atenție: Citiți și respectați cu atenție instrucțiunile (avertismentele) de utilizare <b>HR</b> - Pozor: Pročitajte i pažljivo slijedite upute (upozorenja) za upotrebu</p> <p>- ليس معقم - <b>SA</b></p>
	<p><b>IT</b> - Leggere le istruzioni per l'uso <b>GB</b> - Consult instructions for use <b>FR</b> - Consulter les instructions d'utilisation <b>ES</b> - Consultar las instrucciones de uso <b>PT</b> - Consulte as instruções de uso <b>DE</b> - Gebrauchsanweisung beachten <b>GR</b> - Διαβάστε προσεκτικά τις οδηγίες χρήσης <b>PL</b> - Przeczytaj instrukcje użytkowania <b>SE</b> - Läs bruksanvisningen <b>RO</b> - Citiți instrucțiunile de utilizare <b>HR</b> - Pročitajte upute za uporabu</p> <p><b>AA</b> - اقرأ بدة وحرص تعليمات الاستخدام</p>
	<p><b>IT</b> - Dispositivo monouso, non riutilizzare <b>GB</b> - Disposable device, do not re-use <b>FR</b> - Dispositif pour usage unique, ne pas réutiliser <b>ES</b> - Dispositivo monouso, no reutilizable <b>PT</b> - Dispositivo descartável, não reutilizar <b>DE</b> - Für einmaligen Gebrauch, nicht wiederverwenden <b>GR</b> - Προϊόν μιας χρήσεως. Μην το χρησιμοποιείτε εκ νέου <b>PL</b> - Jedno użyczenie, nie używaj ponownie <b>SE</b> - Engångsanordning, får ej återanvändas <b>RO</b> - Dispozitiv de unică folosință, a nu se refolosi <b>HR</b> - Uređaj za jednokratnu upotrebu, nemojte ponovo koristiti</p> <p><b>SA</b> - اداة أحادية الاستخدام، لا تستخدم من جديد</p>
	<p><b>IT</b> - Limite di temperatura <b>GB</b> - Temperature limit <b>FR</b> - Limite de température <b>ES</b> - Limite de temperatur <b>PT</b> - Limite de temperatura <b>DE</b> - Temperaturgrenzwert <b>GR</b> - Διατηρείται μεταξύ -10 και 49°C <b>PL</b> - Przechowyj pomiędzy i °C <b>SE</b> - Lagras mellan och °C <b>RO</b> - A se păstra la temperaturi cuprinse între și °C <b>HR</b> - Čuvati između i °C</p> <p><b>SA</b> - يحفظ بين و درجة مئوية</p>
	<p><b>IT</b> - Rappresentante autorizzata nella Comunità europea <b>GB</b> - Authorized representative in the European community <b>FR</b> - Représentant autorisé dans la Communauté européenne <b>ES</b> - Representante autorizado en la Comunidad Europea <b>PT</b> - Representante autorizado na União Europeia <b>DE</b> - Autorisierter Vertreter in der EG <b>GR</b> - Εξουσιοδοτημένος αντιπροσωπος στην Ευρωπαϊκή Ένωση <b>PL</b> - Upoważniony przedstawiciel we Wspólnocie Europejskiej <b>SE</b> - Auktoriserad representant i Europeiska gemenskapen <b>RO</b> - Reprezentant autorizat pe teritoriul Comunității Europene <b>HR</b> - Ovlašteni predstavnik u Europskoj zajednici</p> <p><b>SA</b> - ممثل معتمد في الإتحاد الأوروبي</p>
	<p><b>IT</b> - Data di scadenza <b>GB</b> - Expiration date <b>FR</b> - Date d'échéance <b>ES</b> - Fecha de caducidad <b>PT</b> - Data de validade <b>DE</b> - Ablaufdatum <b>GR</b> - Ημερομηνία λήξεως <b>PL</b> - Data ważności <b>SE</b> - Utgångsdatum <b>RO</b> - Valabil până la data de <b>HR</b> - Datum isteka</p> <p><b>SA</b> - تاريخ انتهاء الصلاحية</p>

	<p><b>IT</b> - Codice prodotto <b>GB</b> - Product code <b>FR</b> - Code produit <b>ES</b> - Código producto <b>PT</b> - Código produto <b>DE</b> - Erzeugniscode <b>GR</b> - Κωδικός προϊόντος <b>PL</b> - Numer katalogowy <b>SE</b> - Produktkod <b>RO</b> - Cod produs <b>HR</b> - Šifra proizvoda</p> <p><b>SA</b> - كود المنتج</p>
	<p><b>IT</b> - Numero di lotto <b>GB</b> - Lot number <b>FR</b> - Numéro de lot <b>ES</b> - Número de lote <b>PT</b> - Número de lote <b>DE</b> - Chargennummer <b>GR</b> - Αριθμός παρτίδας <b>PL</b> - Kod partii <b>SE</b> - Satsnummer <b>RO</b> - Număr de lot <b>HR</b> - Broj serije</p> <p><b>SA</b> - رقم الدفعة</p>
	<p><b>IT</b> - Dispositivo medico-diagnostico in vitro conforme alla direttiva 98/79/CE <b>GB</b> - In vitro diagnostic medical device compliant with Directive 98/79 / EC <b>FR</b> - Dispositif médical de diagnostic in vitro conforme à la directive 98/79/CE <b>ES</b> - Producto sanitario para diagnóstico in vitro conforme con la Directiva 98/79/CE <b>PT</b> - Dispositivo médico de diagnóstico in vitro em conformidade com a Diretiva 98/79 / CE <b>DE</b> - In-vitro-Diagnostikum im Sinne der Richtlinie 98/79/CE <b>GR</b> - Διαγνωστικό ιατροτεχνολογικό προϊόν in vitro που συμμορφώνεται με την οδηγία 98/79 /CE <b>PL</b> - Wyrób medyczny do diagnostyki in vitro zgodny z dyrektywą 98/79 /CE <b>SE</b> - Den medicintekniska produkten för in vitro-diagnostik överensstämmer med Direktiv 98/79/EG <b>RO</b> - Dispozitiv medical pentru diagnostic in vitro, realizat în conformitate cu prevederile Directivei 98/79/CE <b>HR</b> - In vitro dijagnostički medicinski uređaj u skladu s direktivom 98/79/EZ</p> <p>- <b>SA</b> في الجهاز الطبي التشخيصي في المختبر في 98/79/CE الامتثال للتوجيه</p>
	<p><b>IT</b> - Dispositivo medico-diagnostico in vitro <b>GB</b> - In vitro diagnostic medical device <b>FR</b> - Uniquement pour usage diagnostique in vitro <b>ES</b> - Producto sanitario para diagnóstico in vitro <b>PT</b> - Dispositivo médico de diagnóstico in vitro <b>DE</b> - Nur zum Gebrauch für In-vitro-Diagnostika <b>GR</b> - Μόνο για διαγνωστική χρήση σε δοκιμαστικό σωλήν <b>PL</b> - Wyłączniedo diagnostyki in vitro <b>SE</b> - Medicinteknisk produkt för in vitro-diagnostik <b>RO</b> - Dispozitiv medical pentru diagnostic in vitro <b>HR</b> - In vitro dijagnostički medicinski proizvod</p> <p><b>SA</b> - فقط للاستخدام التشخيصي المجهرى</p>
	<p><b>IT</b> - Contiene &lt;n&gt; di test <b>GB</b> - Contains sufficient for "n" tests <b>FR</b> - Contiens sufficient for "n" tests <b>ES</b> - Contiene &lt;n&gt; de test <b>PT</b> - Contém &lt;n&gt; de teste <b>DE</b> - Enthält &lt;n&gt; Tests <b>GR</b> - Περιέχει &lt;n&gt; τέστ <b>PL</b> - Liczba testów w zestawie <b>SE</b> - Innehåller tillräckligt för &lt;n&gt; tester <b>RO</b> - Conține suficient pentru &lt;n&gt; teste <b>HR</b> - Sadržaji dovoljno za &lt;n&gt; testiranja</p> <p><b>SA</b> - راجعى تعليمات الاستخدام أو راجعى التعليمات الإلكترونية للاستخدام</p>