GIMA
PROFESSIONAL MEDICAL PRODUCTS

TEST RAPIDO DI GRAVIDANZA MIDSTREAM HCG (URINA) PER AUTODIAGNOSI

HCG PREGNANCY RAPID TEST MIDSTREAM (URINE) FOR SELF TEST

TEST DE GROSSESSE RAPIDE HCG (URINE) POUR AUTODIAGNOSTIC

HCG SCHWANGERSCHAFTS-SCHNELLTEST MIDSTREAM (URIN) PACKUNGSBEILAGE FÜR SELBSTTEST

TEST DE EMBARAZO RÁPIDO EN FORMATO MIDSTREAM (ORINA) HORMONA GCH

TESTE RÁPIDO DE GRAVIDEZ MIDSTREAM HCG (URINA) PARA AUTODIAGNÓSTICO

SZYBKI TEST CIĄŻOWY HCG TYPU MIDSTREAM (STRUMIENIOWY) ULOTKA INFORMACYJNA DO TESTÓW SAMODZIELNEGO UŻYTKU

ΓΡΗΓΟΡΟ ΤΕΣΤ ΕΓΚΥΜΟΣΥΝΗΣ MIDSTREAM HCG (ΟΥΡΩΝ) ΓΙΑ ΑΥΤΟΔΙΑΓΝΩΣΗ

	REF
GIMA 29097	**FHC-F103H**
GIMA 29098	**FHC-F103H**

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IVD

2°C 30°C

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INTENDED USE
The hCG Pregnancy 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 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 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 hydrophil 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.

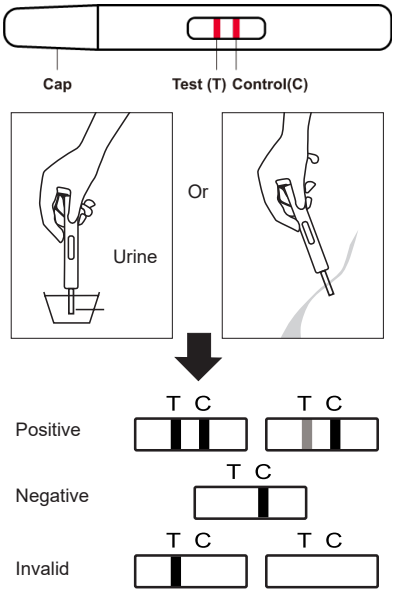
SPECIMEN COLLECTION AND PREPARATION
The urine specimen should be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting 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 product 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
There is the possibility that this test midstream may produce false results. Consult your physician before making any medical decisions.
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 result.
2. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.

3. Very low levels of hCG (less than 50mIU/ml) are present in urine specimens shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons,1 a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
4. This test may produce false positive results. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG.2,3 Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. This test may produce false negative results. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested. In case pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
6. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXTRA INFORMATIONS

1. **How does the test midstream work?**
   HCG Pregnancy Rapid Test Midstream 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 hCG Pregnancy Rapid Test Midstream to another commercially available urine hCG test. The consumer clinical trial included 608 urine specimens: both assays identified 231 positive and 377 negative results. The results demonstrated >99% overall accuracy of the hCG Pregnancy Rapid Test Midstream when compared to the other urine hCG test.
5. **How sensitive is the test?**
   HCG Pregnancy Rapid Test Midstream detects hCG in urine at a concentration of 20 mIU/mL or greater. The test has been standardized to the W.H.O. 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 (20 mIU/mL hCG) specimens showed no cross-reactivity.
6. **What should I do if the result shows that I am pregnant?**
   It means that your urine contains hCG and you are probably pregnant. See your doctor to confirm that you are pregnant and to discuss the steps you should take.
7. **How do I know that the test was run properly?**
   The appearance of a colored line in the control line region (C) tells you that you followed the test procedure properly and the proper amount of urine was absorbed.
8. **What should I do if the result shows that I am not pregnant?**
   It means that no hCG has been detected in your urine and probably you are not pregnant. If you do not start your period within a week of its due date, repeat the test with a new test midstream. If you receive the same result after repeating the test and you still do not get your period, you should see your doctor.

BIBLIOGRAPHY

1. Steier JA, P Bergsjo, OL Myking Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy, Obstet Gynecol. 1984; 64(3): 391-394
2. Dawood MY, BB Saxena, R Landesman Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma, Obstet. Gynecol. 1977; 50(2): 172-181
3. 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

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

	**IT -** Fabbricante **GB -** Manufacturer **FR -** Fabricant **ES -** Fabricante **PT -** Fabricante **DE -** Hersteller **GR -** Παραγωγός **PL -** Producent
	**IT -** Non utilizzare se l'imballaggio è danneggiato **GB -** Don't use if package is damaged **FR -** Ne pas utiliser si le colis est endommagé **ES -** No usar si el paquete está dañado **PT -** Não use se o pacote estiver danificado **DE -** Nicht verwenden, wenn das Paket beschädigt ist **GR -** Μην το χρησιμοποιείτε αν η συσκευασία είναι κατεστραμμένη **PL -** Nie używać, jeśli opakowanie jest uszkodzone
	**IT -** Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso **GB -** Caution: read instructions (warnings) carefully **FR -** Attention: lisez attentivement les instructions (avertissements) **ES -** Precaución: lea las instrucciones (advertencias) cuidadosamente **PT -** Cuidado: leia as instruções (avisos) cuidadosamente **DE -** Achtung: Anweisungen (Warnungen) sorgfältig lesen **GR -** Προσοχή: διαβάστε προσεκτικά τις οδηγίες (ενστάσεις) **PL -** Ostrzeżenie - Zobacz instrukcję obsługi
	**IT -** Leggere le istruzioni per l'uso **GB -** Consult instructions for use **FR -** Consulter les instructions d'utilisation **ES -** Consultar las instrucciones de uso **PT -** Consulte as instruções de uso **DE -** Gebrauchsanweisung beachten **GR -** Διαβάστε προσεχτικά τις οδηγίες χρήσης **PL -** Przeczytaj instrukcje użytkowania
	**IT -** Dispositivo monouso, non riutilizzare **GB -** Disposable device, do not re-use **FR -** Dispositif pour usage unique, ne pas réutiliser **ES -** Dispositivo monouso, no reutilizable **PT -** Dispositivo descartável, não reutilizar **DE -** Für einmaligen Gebrauch, nicht wiederverwenden **GR -** Προϊόν μιας χρήσεως. Μην το χρησιμοποιείται εκ νέου **PL -** Jedno urządzenie, nie używaj ponownie
	**IT -** Limite di temperatura **GB -** Temperature limit **FR -**Limite de température **ES -** Límite de temperatur **PT -** Limite de temperatura **DE -** Temperaturgrenzwert **GR -** Διατηρείται μεταξύ -10 και 49°C **PL -** Przechowuj pomiędzy i ° C
	**IT -** Rappresentante autorizzato nella Comunità europea **GB -** Authorized representative in the European community **FR -** Représentant autorisé dans la Communauté européenne **ES -** Representante autorizado en la Comunidad Europea **PT -** Representante autorizado na União Europeia **DE -** Autorisierter Vertreter in der EG **GR -** Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Ένωση **PL -** Upoważniony przedstawiciel we Wspólnocie Europejskiej
	**IT -** Data di scadenza **GB -** Expiration date **FR -** Date d'échéance **ES -** Fecha de caducidad **PT -** Data de validade **DE -** Ablaufdatum **GR -** Ημερομηνία λήξεως **PL -** Data ważności
	**IT -** Codice prodotto **GB -** Product code **FR -** Code produit **ES -** Código producto **PT -** Código produto **DE -** Erzeugniscode **GR -** Κωδικός προϊόντος **PL -** Numer katalogowy
	**IT -** Numero di lotto **GB -** Lot number **FR -** Numéro de lot **ES -** Número de lote **PT -** Número de lote **DE -** Chargennummer **GR -** Αριθμός παρτίδας **PL -** Kod partii **SE -** Satsnummer **RO -** Număr de lot **HR -** Broj serije
	**IT -** Dispositivo medico-diagnostico in vitro conforme alla direttiva 98/79/CE **GB -** In vitro diagnostic medical device compliant with Directive 98/79 / EC **FR -** Dispositif médical de diagnostic in vitro conforme à la directive 98/79/CE **ES -** Producto sanitario para diagnóstico in vitro conforme con la Directiva 98/79/CE **PT -** Dispositivo médico de diagnóstico in vitro em conformidade com a Diretiva 98/79 / CE **DE -** In-vitro-Diagnostikum im Sinne der Richtlinie 98/79/CE **GR -** Διαγνωστικό ιατροτεχνολογικό προϊόν in vitro που συμμορφώνεται με την οδηγία 98/79 /CE **PL -** Wyrób medyczny do diagnostyki in vitro zgodny z dyrektywą 98/79 /CE
	**IT -** Dispositivo medico-diagnostico in vitro **GB -** In vitro diagnostic medical device **FR -** Uniquement pour usage diagnostique in vitro **ES -** Producto sanitario para diagnóstico in vitro **PT -** Dispositivo médico de diagnóstico in vitro **DE -** Nur zum Gebrauch für In-vitro-Diagnostika **GR -** Μόνο για διαγνωστική χρήση σε δοκιμαστικό σωλήν **PL -** Wyłącznie do diagnostyki in vitrod
	**IT -** Contiene <n> di test **GB -** Contains sufficient for "n" tests **FR -** Contains sufficient for "n" tests **ES -** Contiene <n> de test **PT -** Contém <n> de teste **DE -** Enthält <n> Tests **GR -** Περιέχει <n> τέστ **PL -** Liczba testów w zestawie