



# Test Yourself @ Home™

## Home Pregnancy Test

TY@H™ One-Step Pregnancy Test

User Instruction (For Self-testing)

REF TY@H-HCG-M

English

### 【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 reach of children.
- 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.

### 【MATERIALS PROVIDED】

- Pregnancy Test
- Urine Cup
- User Instruction

### 【INSTRUCTIONS】

1. Remove the midstream from the foil pouch and test them immediately.
2. Remove the cap of the midstream, then urinate on it or place the head of sponge (≥2/3) into urine sample in a clean cup for at least 10 seconds.
3. Replace the cap on the testing midstream, then lay down the product on a clean and stable desk, start the timer immediately.
4. The result should be read within 3~10 minutes.

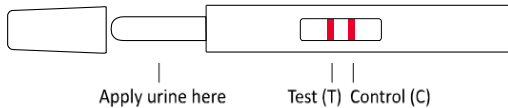


Figure 1

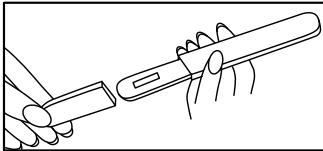


Figure 2

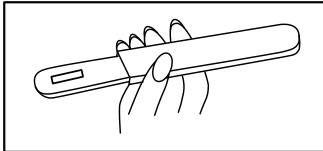
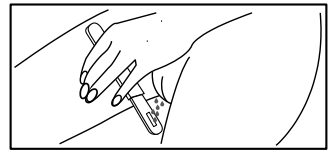


Figure 3



### 【READING THE RESULTS】

#### POSITIVE

Two colored lines, one in the control line region (C) and the other line in the test line region (T), is a positive result. This double line test result indicates that you are pregnant.

#### NEGATIVE

One colored line in the control line region (C), but no visible line in the result region is a negative result. This single line test result indicates that you are not pregnant.

#### INVALID

If there is no visible line in the control region, the test is not valid. This indicates an error in testing procedure or deterioration of reagents. If you obtain an invalid result, repeat the testing with a new kit.

#### Results

	C	C	C	
POSITIVE				
NEGATIVE				
INVALID				
	T	T	T	

## [LIMITATIONS]

There is the possibility that this test midstream may produce false results. Consult your physician before making any medical decisions.

1. Alcohol, oral contraceptives, painkillers, antibiotics or hormone therapies that do not contain hCG should not affect the test result. If you are under fertility drug treatment, please consult with your healthcare provider prior to using this product".
2. Very dilute urine specimen, 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. 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.
4. 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.

## [FAQ]

### Q. Is it important to follow the instructions exactly?

A. Yes. Accurate results depend upon correct performance of the test procedure.

### Q. How does the test midstream work?

A. The 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.

### Q. How soon after I suspect that I am pregnant can I take the test?

A. 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.

### Q. Do I have to test with first morning urine?

A. 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.

### Q. How accurate is the test?

A. A clinical evaluation was conducted comparing the results obtained using the HCG Pregnancy Rapid Test to another commercially available urine membrane hCG test. The results demonstrated >99% overall accuracy of the HCG Pregnancy Rapid Test when compared to the other urine membrane hCG test.

### Q. What should I do if the result shows that I am pregnant?

A. 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.













### Q. How do I know that the test was run properly?

A. 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.

### Q. What should I do if the result shows that I am not pregnant?

A. It means that no hCG has been detected in your urine and you are probably 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.

## Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Store between 35.6-86°F (2-30°C)
	In vitro diagnostic medical device		Batch code		Catalogue number
	Manufacturer		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Unique device identifier		Authorized representative in EU

**Hangzhou AllTest Biotech Co.,Ltd.**  
#550,Yinhai Street  
Hangzhou Economic & Technological Development Area  
Hangzhou, 310018 P.R. China  
Web: [www.alltests.com.cn](http://www.alltests.com.cn) Email: [info@alltests.com.cn](mailto:info@alltests.com.cn)

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

**Manufactured for:**  
CLIAwaived,Inc  
2721 Loker Ave W  
Carlsbad CA 92010  
[www.cliawaived.com](http://www.cliawaived.com)

**Toll-free number:**  
1-888-882-7739

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