

成品尺寸：93\*130mm展开尺寸：186\*130mm



## One Step Pregnancy Test

Please read the instruction for use carefully before performing the test or use after consulting your doctor.

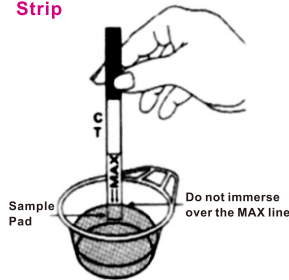
### INTENDED USE

One Step Pregnancy Test is used for the early diagnosis of pregnancy by rapid detection of fertility hormone of Human Chorionic Gonadotropin (HCG) in urine specimens. The test device is intended for self-testing.

### TEST PROCEDURE

Test device and specimen should be brought to room temperature (15~30°C) prior to testing. Do not open pouches until ready to perform the assay.

#### Strip

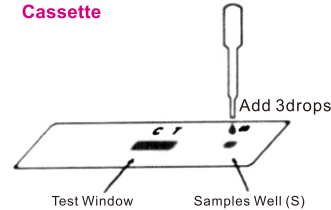


1. Remove the test strip from the foil pouch.
2. Dip the sample pad of the test strip downward into the urine specimen. Do not immerse over the MAX line. (Please refer to the illustration)
3. Take out the strip after a minimum of 10 seconds in the urine for sufficient absorption, and lay the strip flatly on a dry non-absorptive

clean surface.

4. Start to calculate the time, and read the result in 5 minutes. Do not read after 5 minutes.

#### Cassette

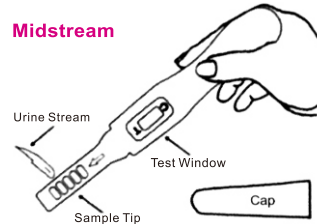


1. Remove the test cassette from the foil pouch and lay it a clean flat surface
2. Hold the dropper vertically and transfer 3-4 drops (about 80-100µl) of urine to the SAMPLE

WELL(S) of the test device.

3. Start the timer, and read the result in 5 minutes. Do not read after 5 minutes.

#### Midstream



1. Remove the test midstream from the foil pouch.
2. Remove the Cap of the midstream. Hold the midstream with the sample tip pointing downward

directly into your urine stream for a minimum 10 seconds.

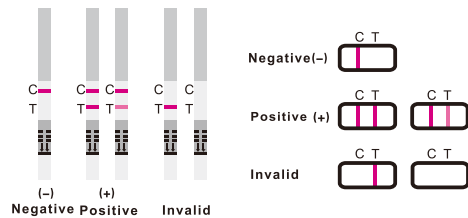
3. Take the midstream away from the urine and lay it on a flat surface with the Test Window facing upwards.

4. Start to calculate the time, and read the result in 5 minutes. Do not read results after 5 minutes.

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#### INTERPRETATION OF RESULTS

(Please refer to the illustration)



#### Negative

Only the red control line (C) appears. The result is negative.

#### Positive

Two red lines appear, namely the control line (C) and the test line (T). The result is positive. The intensity of the test line ("T") may be less than that of the control line ("C"); this still means positive result.

#### Invalid

If no red line appears in the position of control line (C), the test result is invalid regardless of color on the test line (T). Insufficient specimen volume or incorrect procedures are the most likely reasons for control line (C) failure. Review the procedure and repeat the test with a new test device.

#### QUALITY CONTROL

Built in Quality Control Features After addition of the sample these colored bands migrate along the membrane at the leading edge of the dye conjugate and are "removed" from the test strip completely.

When the test is complete, you will see a pink-purple colored band in the "C" area of the test strip on negative samples and a pink-purple colored band in the "T" and "C" area on positive samples. The appearance of the CONTROL band indicates that the test strip is performing properly and serves as a procedural control.

#### STORAGE AND STABILITY

- 1.The test kit should be stored at 4 °C–30°C. **DO NOT FREEZE.**
- 2.The shelf-life of the kit is as indicated on the sealed pouch.
- 3.Once open the pouch, the test device should be used immediately. Prolonged exposure to ambient humidity will cause product deterioration.

#### LIMITATION OF THE PROCEDURE

- 1.Alcohol may interfere the test result It is not recommended using the test after drinking.
- 2.Occasionally specimens containing less than 25mIU/ml for urine also yield positive results.
- 3.A very early pregnancy containing an extremely low concentration of HCG can give a negative result In this case, another specimen should be obtained at least 48 hours later and tested.
- 4.HCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section spontaneous abortion or therapeutic abortion.
- 5.In cases where very high levels of HCG are present (>500,000mIU/ml) a false negative result can occur due to a "Prozone" effect If pregnancy is still suspected, simply dilute specimen 1:1 with deionized water and retest
- 6.If a urine sample is too dilute (ie: low specific gravity) it may not contain a representative level of HCG. If pregnancy is still suspected, a first morning urine sample should be obtained from the user in 24-48 hours and retested.



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