

**The HCG urine pregnancy test** is for the determination Human Chorionic Gonadotropin. There is an appearance of hCG in both urine and serum soon after conception, and a subsequent rapid rise in concentration during early gestational growth. This test is used to obtain a visual, qualitative result for the early detection of pregnancy.

## SPECIMEN COLLECTION & PREPARATION

**Urine Assay:** A urine specimen must be collected in a dry and clean container. The first morning urine specimen is preferred since it usually contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used.

## TEST PROCEDURE

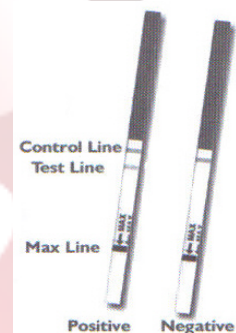
1. Immerse the strip into the urine sample with the arrow end pointing towards the urine. Do not immerse past the MAX line. Take the strip out after 10 seconds and lay the strip flat on a clean, dry, non-absorbent surface (such as the mouth of the urine container).
2. Wait for colored bands to appear. Depending on the concentration of hCG in the test specimen, positive results may be observed in as little as 40 seconds. However, to confirm negative results, the complete reaction time of 5 minutes is required. It is important that the background is clear before the result is read. Results read later than the specified time cannot be considered valid.

## INTERPRETATION OF RESULTS

**Negative:** Only one color band appears on the control region. This indicates that no pregnancy has been detected.

**Positive:** Distinct color bands appear on the control and test regions. Presence of both test line and control line indicates that you are probably pregnant. The color intensity of the test bands may vary since different stages of pregnancy have different concentrations of hCG hormone.

**Invalid:** No visible band at all or no band appears on the control region. Repeat with a new test kit.



## LIMITATIONS

1. Very diluted 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.

2. 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.
3. Very low levels of hCG (less than 50 mIU/ml) are present in urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
4. The 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.

## **STORAGE**

The test kit can be stored at temperatures between 4 to 30 C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.