

## ASSAY PROCEDURE

### 1. DETERMINATION OF TEST DATE

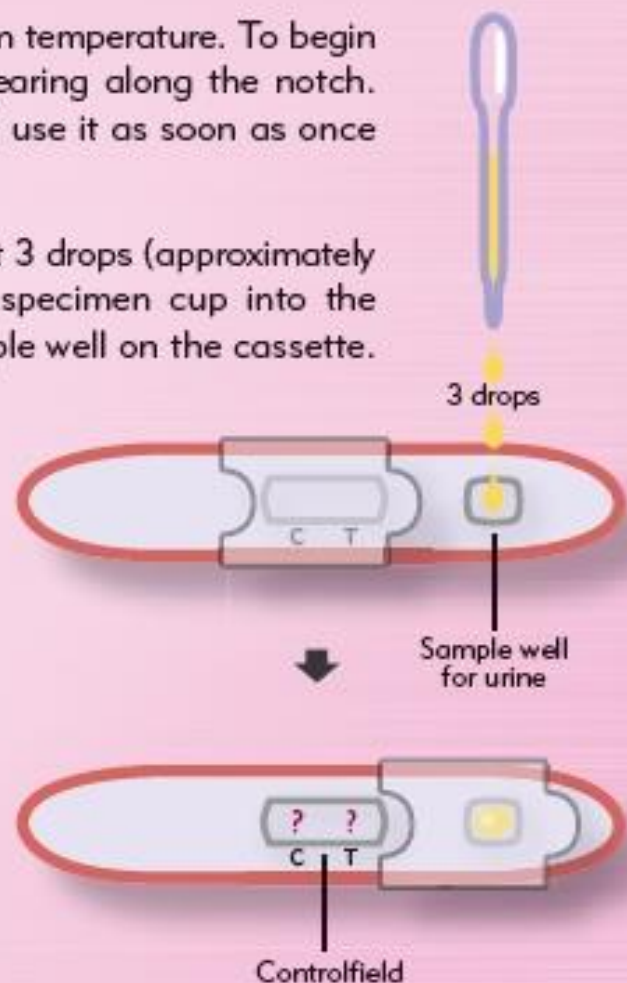
The test could be used from the first date of missed menstruation. In most cases the test is accurate at this date. However, because of variation in HCG concentration among women, or potential miscalculation of the last period, if there is a negative result, and pregnancy is still suspected, you should retest after a few days.

### 2. SPECIMEN COLLECTION AND HANDLING

First morning urine specimen is preferred due to its high concentration of HCG. However, urine specimens collected at any time of the day may be used. If specimens cannot be assayed immediately, they can be stored at 2-8°C for up to 72 hours prior to testing. Urine specimens exhibiting visible precipitates should be settled to obtain a clear specimen for testing.

### 3. TEST PROCEDURE

- Bring the test pouch and urine to room temperature. To begin testing, open the sealed pouch by tearing along the notch. Remove the test from the pouch and use it as soon as once opened.
  - Using the sample dropper, draw about 3 drops (approximately 120-150  $\mu$ l) urine sample from the specimen cup into the pipette, and dispense it into the sample well on the cassette. (See the picture).
  - Wait for colored bands to appear. Depending on the concentration of HCG in the test specimen, Positive results may be observed in as short as 40 seconds. However, to confirm Negative results, the complete reaction time (5 minutes) is required. So read the result within 5 minutes.
4. Do not read results after 30 minutes.



## 4. INTERPRETATION OF RESULT

### POSITIVE:



Two distinct color bands appear – one on the control and one on the test region. This indicates that pregnancy has been detected. The color intensity of the test bands may vary during pregnancy



### NEGATIVE:



Only one color band appears on the control line, and no band appears on the test region. This means there is no pregnancy detected.

### INVALID:



There are no visible bands at all, or if one red band appears only on the test region. If this happens, repeat a new test. If test still fails, please contact the distributor with the lot number.



## 5. QUALITY CONTROL

Testing of quality control material to verify the performance of the test is recommended for each new lot of test. In addition, users should follow their state and local regulations and guidelines regarding GLP requirements.

In addition, a built in procedural control is being used designated as control region (C) on the test device to indicate that sufficient sample volume was added.