

## **Rapid Pregnancy Test Card**

## What is this product?

Rapid **Pregnancy Test Card** - individually wrapped test devices. Each device contains an anti-alpha hCG capture antibody coated membrane and colloidal gold particles coated with mouse anti-beta hCG monoclonal antibody.

# What should I know about Storage and Stability?

The test kit is to be stored refrigerated (2-8°C) or at room temperature (up to  $30^{\circ}$ C) in the sealed pouch for the duration of the shelf-life.

# What should I know about Test Procedure?

Test devise, patient's samples, and controls should be brought to room temperature (20-30°C) prior to testing. Do not open pouches until ready to perform the assay.

Remove the test device from its protective pouch (bring the device to room temperature before opening the pouch to avoid condensation of moisture on the membrane). Label the device with patient or control identification.

Draw sample to the line marked on the pipette (approximately 0.2 ml). Dispense entire contents into the sample well. For each sample or control, use a separate pipette and device.

Wait for pink-colored bands to appear. Depending on the concentration of hCG, positive results may be observed as soon as 40 seconds. However, to confirm negative results, the complete reaction time of 4 minutes is required. Do not interpret results after 10 minutes.

#### INTERPRETATION

POSITIVE: Two distinct pink-colored bands appear, one in the patient test region and one in the control region.

NEGATIVE: Only one pink-colored band appears in the control region. No apparent pink band appears in the patient test region.

INVALID: A total absence of pink-colored bands in both regions is an indication of procedural error or that test reagent deterioration has occurred.

#### Notes on the interpretation of results

Negative test results in patients suspected to be pregnant should be retested with a sample obtained 48 to 72 hours later, or by performing a quantitative assay. When testing with an urine specimen, the first-morning specimen would contain the biobest concentration of bCG.