

ACCUR PREGNANCY CARD

INTENDED USE:

For the rapid detection of Human Chorionic Gonadotropin (hCG) in urine specimens. This test is used to obtain a visual, qualitative result and is intended by professional and laboratory use only.

SUMMARY AND EXPLANATION OF PROCEDURE:

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after implantation. HCG can be detected in the urine and serum of pregnant women as early as 6 to 15 days after conception. The concentration of hCG increases to 50 mIU/ml one week post implantation and reaches to about 100 mIU/ml at the time of the first missed menstrual period and the peak at 100,000-200,000 mIU/ml at the first trimester.

The ACUR hCG test card is a rapid test to detect the presence of hCG in urine specimens in a qualitative format sensitive to 10 mIU hCG/ml. The test utilizes a combination of monoclonal and polyclonal antibodies reagents to selectively detect elevated level of hCG in urine. The immunological specificity of the test card virtually eliminates cross reactivity interferences from the structurally related glycoprotein hormones FSH, LH, TSH at physiological levels.

STORAGE AND STABILITY:

The test card can be stored at room temperature max. 30° up to the expiry date. The test card should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS:

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiration date.

CONTENTS OF THE KIT:

1. Test devices (Cards).
2. Droppers.
3. Silica gel.

SPECIMEN COLLECTION:

The urine specimen must be collected in a clean & dry container, either plastic or glass. It is preferable to use first morning urine as specimen it generally contains the highest concentration of hormone. Urine specimen may be refrigerated (2-8⁰C) and stored upto 72 hours prior to assay. If sample is refrigerated, they must be equilibrated to room temperature (25⁰ -30⁰ C) before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle and clear specimen should be obtained for testing.

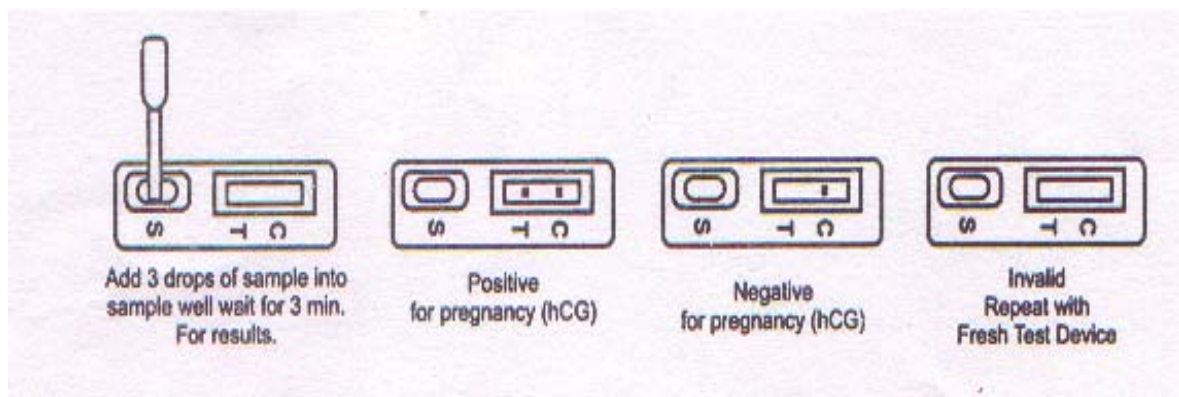
TEST PROCEDURE:

Review “Specimen Collection Instructions”. Test device patient’s sample and controls should be brought to room temperature (25⁰ – 30⁰ 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.

Dispense 3 drops into the sample well allowing each drop to be absorbed fully before adding further drops. 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 3 minutes are required. Do not interpret the test result after 10 minutes.



INTERPRETATION OF RESULTS:

Positive: Two distinct pink-coloured bands appear, one in the Test Region (T) and other in the Control region (C).

Negative: Only one pink-coloured band appears in the Control region (C).

Invalid: A total absence of pink-coloured bands in both regions is an indication of procedural error and the sample may be repeated with a Fresh Test Device.

LIMITATIONS:

- 1) The number of conditions other than pregnancy, including disease and certain non-trophoblastic disease and certain non-trophoblastic neoplasms, cause levels of hCG. These diagnoses should be considered if appropriate to the clinical evidence.
- 2) If a urine specimen, is too dilute (i.e. low specific gravity) it may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine should be obtained from the patient 48-72 hours later and tested.
- 3) As with all diagnostic tests, a definite clinical diagnosis should not be based on the results of a single test, but should only be made by a physician after all clinical and laboratory findings have been evaluated.
- 5) Immunologically interfering substance such as those used in antibody therapy treatments may invalidate the test result.

PERFORMANCE CHARACTERISTICS:

SENSITIVITY AND SPECIFICITY:

The ACUR hCG card detects urine hCG concentrations greater than 10 mlu/ml as indicated by the appearance of a colour band at the test region.

Specificity of the ACUR card has been determined from cross reaction studies with known amounts of Luteinizing hormone (LH), Follicle stimulating hormone (FSH) and Thyroid stimulating hormone (TSH) 300 mlu LH/ml and 1000mlu TSH/ml all give negative results.

INTEREFERENCE TESTING:

The following substances were added in hCG free and 50 mlu/ml. hCG spiked urine samples. At the concentrations tested, none of the substances interfered assay.

Acetaminophen 20mg/ml

Acetyl salicylic Acid 20mg/ml

Absorbic Acid 20mg/ml

Caffeine 20mg/ml

Gentesic Acid 20mg/ml

Glucose 20g/dl

Haemoglobin 1mg/ml

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