One Step Cassette Style HCG Urine Pregnancy Test

10/2003

Cat. No. 100-4 to 100-11

INTRODUCTION

One Step Cassette Style HCG Urine Pregnancy Test is a test kit for the determination of hCG (Human Chorionic Gonadotropin) in urine specimens. There is an appearance of hCG in both urine and serum soon after conception, and its 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

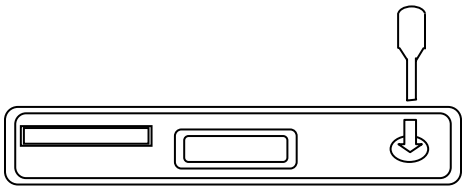
A urine specimen must be collected in a dry and clean container. The first morning urine specimen is preferred since it usually contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and stirred before testing.

TEST PROCEDURE

1. To begin testing, open the sealed pouch by tearing along the notch. Remove the test kit from the pouch and use it as soon as possible.
2. Draw the urine or sample using the pipette provided, and dispense 3-4 drops (approx. 0.2 mL) onto the sample well of the cassette (see diagram).
3. Wait for the colored bands to appear. Depending on the concentration of hCG in the test specimen, positive results may be observed in as soon 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. Do not read results after more than 30 minutes.



PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.

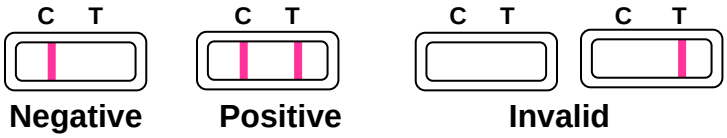
SENSITIVITY-: 20mIU/ml of HCG in urine sample.

INTERPRETATION OF RESULTS

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

➢ **Positive**: Distinct color bands appear on both the control and test regions. Presence of both test line and control line indicate 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 colored band appears on the control (C) region. Repeat with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Negative **Positive** **Invalid**

LIMITATIONS

1. Very dilute 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 (5), a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
4. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG (6-7). Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. This 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 AND STABILITY

The test kit can be stored at temperatures between 2 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.

IND DIAGNOSTIC INC.
1629 Fosters Way Delta BC V3M 6S7 Canada
www.ind.ca

Tel: 604-522-1619
Fax: 604-522-6331
Email: sales@ind.ca