# OSCAR

## One Step hCG Pregnancy Test Strip

### INTENDED USE

The **Oscar One Step hCG Pregnancy strip test** is a rapid chromatographic immuno-assay for the qualitative detection of hCG (human chorionic gonadotropin) in urine to aid in the early diagnosis of pregnancy.

### SUMMARY

Human chorionic gonadotropin (hCG) is glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conceptions. hCG levels continue to rise very rapidly frequently exceeding100 mIU/ml by the first missed menstrual period and peaking in the100,000-200,000 mIU/ml range about 10-12 weeks into pregnancy. The appearance of hCG in both the urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early diagnosis of pregnancy.

The **Oscar One Step hCG Pregnancy strip test** is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 25 mIU/ml. The test utilizes a combination of antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the **Oscar One Step hCG Pregnancy strip test** Shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

### TEST PRINCIPLE

The **Oscar One Step hCG Pregnancy strip test** is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in early detection of pregnancy. The test uses two lines (C&T) to indicate results. The test line (T) is coated with anti hCG antibodies ( monoclonal antibodies).The monoclonal antibody is purified agglutinating sera so making the test more reliable and accurate. The control line (C) is coated with Goat anti mouse IgG antibodies and colloidal gold particles is coated with anti hCG antibodies ( monoclonal antibodies).

The assay is conducted by adding urine specimen to the specimen well of the test strip and observing the formation of pink/purple line (s). The specimen migrates via capillary action along the membrane to react with the antibodies at C & T lines.

Positive specimens containing hCG (Antigen) when passes through the membrane, at test line reacts with the anti hCG antibody (Antigen - Antibody reaction). Positive reaction is made visible by colloidal gold conjugate. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line should always appear in the control line region(C). It indicates that proper volume of specimen has been added and membrane wicking has occurred.

### REAGENTS & MATERIALS PROVIDED

1. **Test strips :** Packed in poly laminated pouch along with desiccant pouch. Each strip has test strip containing monoclonal anti-hCG, Goat anti mouse IgG and dried pad of colloidal gold particles coated with anti hCG antibodies.
2. Product insert

### MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen Collection Container & Timer

### PRECAUTIONS

- For *in-vitro* diagnostic use only.
- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature / refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

**Urine Assay**

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

### SPECIMEN STORAGE

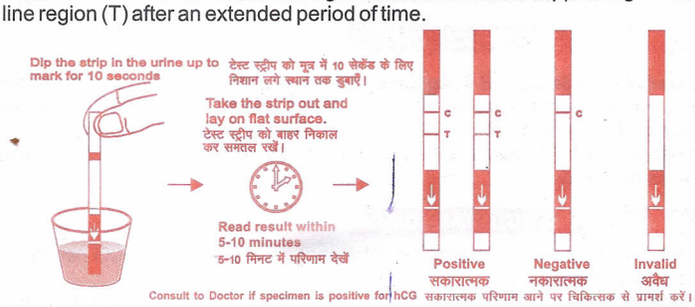
Specimen may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

### DIRECTIONS FOR USE

**Allow the test strip, specimen and/or controls to reach room temperature (15-30°C) prior to testing.**

1. Remove the test strip from the sealed pouch by tearing from the notch provided and use it as soon as possible.
2. Hold the strip from holding end, dip in the urine specimen up to arrow mark at least for 10 seconds.
3. Remove the test strip from urine specimen and place on flat surface away from high flow air / fan.
4. Wait for the pink / purple line(s) to appear in result area of the membrane. The result should be read at 5-10 minutes. **Do not interpret the result after 10 minutes.**

**NOTE:** A low hCG concentration might result in a weak line appearing in the test line region (T) after an extended period of time.




### INTERPRETATION OF RESULTS

**POSITIVE: Appearance of two distinct pink/purple colored lines,** one in the control region "C" and another line in the test line region "T", indicates that specimen is positive for hCG.

***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of hCG present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

**NEGATIVE: Appearance of only one pink/purple colored line** in the control line region "C", indicates that specimen is negative for hCG.

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If a background color appears in the result window and interferes with the ability to read the test result, the result may be invalid.

It is recommended that a positive hCG control (containing 25-250 mIU/ml hCG) and a negative hCG control (containing "0" mIU/ml hCG) be evaluated to verify proper test performance when a new shipment of tests are received.

### LIMITATIONS

1. The **Oscar One Step hCG Pregnancy strip test** is a preliminary qualitative test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
2. 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.
3. Very low levels of hCG (less than 50 mIU/ml) are present in urine specimens 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. This test may produce false positive results. 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. Therefore, the presence of hCG should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. This test may produce false negative results. False negative results may occur when the level 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. In case pregnancy is suspected and the test Continues to produce negative results, see a physician for further diagnosis.
6. 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.