Pregnancy Test Operating Instructions

This product is composed of the glass fiber strips of monoclonal antibody against human chorionic gonadotropin (hCG), anti-mouse IgG solid cellulose nitrate membrane and the bonders of absorptive colloidal gold - monoclonal antibody against hCG. It adopts the principles of double antibody sandwich method and immunochromatography to test the hCG in the urine.

Intended Use: used for early diagnosis of pregnancy
Model: Cassette User: for lay person

Kit list: each pouch contains one test cassette one dropper and one desiccant Each box contains One pouch, one urine cup and one instruction sheet.

Test Procedure:

Before the use please prepare a timer.

- 1. The Pregnancy test is formulated for use with fresh urine specimens. Wear glove and use urine cup to collect urine
- **2.** Remove the test cassette from its foil pouch.
- 3. Draw urine sample into dropper, and dispense it into <u>Sample well Test line</u> <u>Control line</u> the sample well on the cassette (2 drops, approximately 100uL). Be careful not to overfill the absorbent pad.

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- **4.** Read results within five minutes.
- **5.** Discard the test device after single use in the dustbin.

Interpretation of results

Negative: If only one pink line appears in the control area, you can assume that you are not pregnant.

Positive: If two pink lines appear both in the control area and test area, you can assume that you are pregnant.

Inconclusive: If there is no distinct pink-purple colored band visible both in the TEST area and CONTROL area the test is inconclusive. It is recommended that in this case the test should be repeated. If the problem persists, contact your local distributor.

Warnings & Precautions

For in vitro diagnostic use only

- 1. As with all diagnostic tests, a definitive diagnostic should not be based on the results of a single test, but should only be made by the physician after all clinical and lab findings have been evaluated.
- 2.Read directions for use carefully before performing this test. Pay attention to the position of the C and T line .
 - 3. Do not use beyond the labeled expiration date.
 - 4. Do not reuse the test devices. Discard it in the dustbin after single use.
 - 5. Do not use if pouch is damaged or opened.
 - 6. Do not touch the membrane located within the windows.
- 7. Once open the pouch, the test device should be used immediately. Prolonged exposure to ambient humidity will cause product deterioration.
 - 8. Treat urine samples and used devices as if they are potentially infectious. Avoid contact with skin.
 - 9. Examine if the urine dropper and urine cup exists before usage.