


Velo™ hCG Pregnancy Rapid Test

(Cassette)

CARBONTECHNOLOGIES

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Intended Use

Velo™ Human Chorionic Gonadotropin (hCG) Pregnancy Rapid Test, one step test for the early detection of pregnancy. The test is intended for in vitro diagnostic self-testing.

Principle

Velo™ hCG Pregnancy Rapid Test takes a qualitative detection of a hormone called human chorionic gonadotropin (hCG) in your urine. Because the amount of hCG in your body increases rapidly during the first two weeks of pregnancy, the test can detect this hormone in your urine one week after a missed period.

The test reagent is exposed to urine, allowing urine to migrate through the absorbent test strip. The labeled antibody-dye conjugate binds to the hCG in the specimen forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the test region (T) and produces a red line when hCG concentration is equal to or greater than 25mIU/ml. In the absence of hCG, there is no line in the test region (T). The reaction mixture continues flowing through the absorbent device past the test region (T) and control region (C). Unbound conjugate binds to the reagents in the control region (C), producing a red line, demonstrating that the test strip is functioning correctly.

Kit Content

The test cassette consists of colloidal gold-monoclonal antibody against hCG coated on polyester membrane, and monoclonal antibody against hCG and goat-anti-mouse IgG coated on cellulose nitrate membrane.

Each pouch contains one test cassette, one urine cup, one dropper and one desiccant. Each box contains 20 pouches and one instruction for use.

Warnings & Precautions

- For in vitro diagnostic use only.
- Do not use the kit beyond the labeled expiry date.
- The test cassette should remain in the sealed pouch until use. Do not use if pouch is damaged or opened.
- Read instructions for use carefully before performing this test.
- Do not touch the test area.
- As with all diagnostic tests, a final 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 lab findings have been evaluated.
- Do not reuse the test cassette. Discard it in the dustbin after single use.
- All urine specimens and used cassette should be considered potentially infectious and avoided contact with skin.

Storage & Stability

- Store as packaged in the sealed pouch at room temperature (4°C-30°C). The kit is stable within the expiry date printed on the labeling.
- Once open the pouch, the test cassette should be used within one hour. Prolonged exposure to hot and humid

environment will cause product deterioration.

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Additional Materials Needed (but Not Included in the Kit)

- Specimen collection container
- Timer (Not provided)

Specimen

First morning urine usually contains the highest concentration of hCG and is therefore the best specimen when performing the urine test. However, urine collected at any time of day may be used. The urine specimen must be collected in the urine cup provided in the pack or a clean, dry container either plastic or glass.

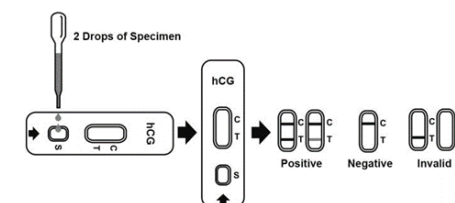
Test Procedure

- Read the entire procedure carefully prior to performing any tests.

Allow test Cassette and urine samples to equilibrate to room temperature (4-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch.
2. Draw the urine specimen using the dropper provided and dispense 3 drops (approx. 0.1 ml) onto the specimen well of the cassette (see diagram).
3. Wait for colored lines to appear. Interpret the test results in 3-5 minutes.

NOTE: Do not read results after 5 minutes.



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Interpretation of Results

- **Positive:** Two distinct red lines will appear, one in the test region (T) and another in the control region (C). You can assume that you are pregnant.
- **Negative:** Only one red line appears in the control region (C). No apparent line in the test region (T). You can assume that you are not pregnant.
- **Invalid:** The result is invalid if no red line appears in the control region (C), even if a line appears in the test region (T). In any event, repeat the test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

NOTE: If the test line is weak, it is recommended that the test be repeated with the first morning specimen obtained 48-72 hours later. No matter how the test results, it is recommended to consult your physician.

Quality Control

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal positive procedural control. A clear background in the result window is considered an internal negative procedural control.

Performance Characteristics

- **Sensitivity**
Velo™ hCG Pregnancy Rapid Test will detect hCG concentrations of 25mIU/ml or greater.
- **Specificity**
Negative results were obtained from all tests conducted

with 300mIU/ml hLH, 1000mIU/ml hFSH, 1000µIU/ml hTSH.

Limits

- False negative readings can occur when testing is done too early. In order to get the most accurate results, it is a good idea to wait for about a week after your period is due before testing. This allows more hCG to build up in your urine, which will allow for a more accurate test.
- False positive results can occur if you are taking a drug that contains hCG hormone. These drugs are commonly used in fertility treatments, so ask your health care provider about whether your medications could affect pregnancy test results.
- Drinking too much fluid before taking the test may cause a false-negative result. For the most accurate results, take the test first thing in the morning when your urine is the most concentrated.

Symbols



Do not reuse



For in vitro diagnostic use only



Temperature limit



Consult instruction for use



Caution



Lot Number



Keep away from sunlight



Catalogue Number



Use by



Contains sufficient for <n> tests



Do not use if package is damaged



Keep dry



CE Marking



Manufacturer



EU Representative



Date of manufacture

Contact Information



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Carrer de Tapioles 33, 2-1, 08004,
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After-sale Service Center: Carbon Technologies LLC



Release Date: Date of Manufacture: