WonderNews Pregnancy hCG Rapid Test

Catalog No.	Pack Size	Specimen Type
HCGLMR01	50 Test	Urine

INTENDED USE

The WonderNews Pregnancy hCG Rapid Test is a rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid for the early detection of pregnancy. The test is intended for in vitro diagnostic self-testing.

PRINCIPLE

The WonderNews adopts the principles of double antibody sandwich method and immunochromatography to test the human chorionic gonadotropin (hCG) in the urine. The membrane is pre-coated with anti-hCG antibodies in the test region (T) and anti-mouse antibodies in the control region (C). During testing, the urine sample reacts with the colored conjugate (mouse anti-hCG antibody colloidal gold conjugate) which has been pre-coated on the test strip. The mixture then migrates upward on the membrane to react with anti-hCG antibodies in the test region and generate a purplish pink line. Presence of the purplish pink line indicates a positive result, while its absence indicates a negative result. Regardless of the presence of hCG, as the mixture continues to migrate across the control region, a purplish pink line at the region will always appear. The presence of this purplish pink line serves as verification for sufficient sample volume and proper flow and as a control for the reagents.

PRECAUTIONS

1. For *In vitro* diagnostic use only.
2. Do not use after the expiration date.
3. The test strip should remain in the sealed pouch until use. Do not use if pouch is damaged or opened.
4. Read directions for use carefully before performing this test. Avoid skin, eyes, or clothing contact with test area.
5. As with all diagnostic tests, a confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
6. Do not reuse the test strip. Discard it in the dustbin after single use.
7. All urine specimens and used strip should be considered potentially infectious and avoided contact with skin.

STORAGE AND STABILITY

1. Store as packaged in the sealed pouched at room temperature (2-30℃). The kit is stable within the expiration date printed on the labeling.
2. Once open the pouch, the test strip should be used immediately. Prolonged exposure to ambient humidity will cause product deterioration.

MATERIAL PROVIDED

1. Test Device
2. Dropper
3. IFU
4. Silica

ADDITIONAL SPECIAL EQUIPMENT

1. Specimen collection container
2. Timer

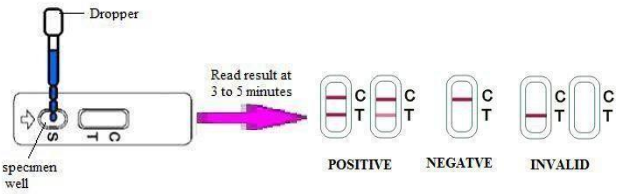
SPECIMEN COLLECTION

Fresh urine specimen must be collected in a clean, dry plastic or glass container. The first morning urine is preferred since it generally, contains the highest concentration of hCG. However, urine collected at any time of day may be used.

TEST PROCEDURE

Read the entire procedure carefully prior to performing any tests.

Allow test Cassette and urine samples to equilibrate to room temperature (20-30℃) prior to testing.



1. Remove the hCG pregnancy test cassette from foil pouch. Use cassette immediately removal from pouch.

2. Draw the urine specimen using the dropper provided and dispense **2-3 drops(approx. 50-75 µL**) onto the sample well of the cassette (see diagram).

3. Wait for purplish pink lines to appear. The test should be read in approximately 3-5minutes. Do not interpret results after 5 minutes.

INTERPRETATION OF RESULTS

[Refer above image]

Positive: Two distinct purplish pink lines will appear, one in the test region (T) and one in the control region (C). Positive test results are possible but not definitive for the diagnosis of pregnancy. It is strongly recommended that additional urine specimen be obtained after 48-72 hours and tested again, or consulting your physician.

Negative: Only a single purplish pink line appears in the control region (C). No purplish pink line appears in the test region (T). Negative test results mean that you may not be pregnant. However, you should re-test with the first morning specimen obtained 48-72 hours later.

Invalid: Control band fails to appear which means improper testing procedures or deterioration of reagents probably occurred.

Lord's Mark Industries Ltd., Plot No. A71, Royal Ind. Hub, Poman, Kaman-Bhiwandi Road, Taluka -Vasai, Palghar- 401208, Maharashtra (India). Customer Care No.: 8425982321. Email: ivdcare@lordsmark.com; Website:www.lordsmed.com

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Notes: The shade of purplish pink in the test region (T) willvary depending on the concentration of hCG present. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

PERFORMANCE CHARACTERISTICS

Sensitivity

The analytical sensitivity of the hCG Pregnancy Test Cassette is 25mIU/ml. The sensitivity was established byrepetitive testing of samples containing 25mIU/ml hCG during a period of several weeks.

Sensitivity & Specificity

	Positive sample	Negative sample	Rate
Positive sample	54	00	98.18% (Sensitivity)
Negative sample	01	20	100% (Specificity)
Total	55	20	98.67% (Total accuracy)

LIMITATION

1. As it is with any diagnostic procedure, a confirmed pregnancy diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
2. If a urine sample is too dilute (i.e., low specific gravity) it may not contain a representative level of hCG. If pregnancy is still suspected, another urine specimen should be collected 48 hours later and tested.
3. Low concentration of hCG in a very early pregnancy can give a negative result. In this case, another specimen should be obtained at least 48 hours later and tested.
4. Elevated levels of hCG can be caused by a few conditions other than pregnancy. Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results.
6. Sterility treatments, based on hCG, may cause false results. Please consult your physician for further diagnose.

LITERATURE REFERENCES

1. ISO 18113-4, In vitro diagnostic medical devices — Information supplied by the manufacturer (labeling） —Part 4: In vitro diagnostic reagents for self-testing.
2. EN 376:2002, Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing
3. Directive 98/79/EC of the European parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices, Official Journal of the European Union L331,7 December 1998.

REF	Catalog No		Attention Caution
LOT	Batch No.		Instruction foruse
	Manufacturing Date	IVD	*In-vitro* Diagnostics
	Expiry Date		Storage temperature
	Manufacturer	Σ	No. of Tests

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