MD hCG Pregnancy Strip Test

Rapid test for the detection of elevated hCG levels in urine

MEDICAL DIAGNOSTECH

Product Code: MDHCGS001
Version 221125

BACKGROUND

When a fertilized ovum is implanted into the chorionic tissue, the human chorionic gonadotrophin (hCG) hormone is released. This produces a luteotrophic effect, maintaining the corpus luteum, and thus enabling it to continue secreting progesterone, needed to maintain pregnancy. Consequently, hCG is a specific marker for pregnancy. Similarly to the other glycoprotein hormones, luteinizing hormone (LH), follicle stimulating hormone (FSH) and thyroid stimulating hormone (TSH); hCG is composed of two sub-units. The alpha sub-unit is nearly identical in all four but the beta sub-unit is characteristic of the specific hormone. Antibodies to the alpha and beta sub-units have been developed which provide high specificity and sensitivity for the detection of hCG.

PRINCIPLE OF THE TEST

The test strip consists of two immobilized lines printed onto nitrocellulose. The test uses an antibody sandwich test system. The first line is the capture or test line, consisting of monoclonal anti -alpha antibody. The control lineis composed of goat anti-mouse IgG. The conjugate pad consists of the complementary antibody in the respective sandwiches, namely, an anti-beta hCG. This antibody is conjugated to a homogenous gold colloid. During the test, capillary action draws the sample through the conjugate pad where it binds to the immobilized capture antibody. The development of a pink line indicates presence of hCG and thus is suggestive of pregnancy, while only a control line demonstrates that the test procedure was completed successfully, and validates the test reagents.

REAGENTS AND MATERIAL PROVIDED IN THE KIT

Units	Components
1	hCG strip test in single foiled pouches with desiccant
1	Instruction for use insert

Urine cup and Timer required but not provided.

STORAGE CONDITIONS AND SHELF LIFE

The following indications must be adhered to, in order to ensure accurate test performance:

1. Store kits at room temperature between 4 and 40°C.
2. Store in a dry place, humidity can affect test performance.
3. The test strips must remain pouched until usage.
4. The kits will have a shelf-life of 24 months after manufacturing.
5. Verify the expiration date printed on the kits and pouches.
6. Kits should not be frozen.

PRECAUTIONS AND WARNINGS

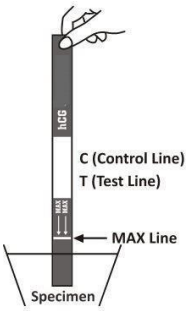
1. For in vitro diagnostic use only.
2. All tests are for single use; do not re-use.
3. Follow the test procedure exactly as shown in this insert in order to get the most accurate results.
4. Do not open the sealed pouch, unless ready to conduct the test.
5. Verify the expiration date, do not use expired tests.
6. Do not use the test if pouch is damaged or seal is broken.
7. Do not eat, drink or smoke while handling specimens and test devices.
8. Wear protective gloves and eye protection while handling specimens.
9. Respect standard procedures to dispose specimens and potentially contaminated material, in biohazard containers.
10. The MD hCG Pregnancy Strip test does not present any risk to the user if used as recommended.

SPECIMEN COLLECTION AND STORAGE

Use a clean, dry container to collect urine. Although early morning urine is often considered best because of relatively greater concentration of hCG in the urine, samples from any other time in the 24-hour cycle may be used. Urine specimens may be stored at 2-8°C for 72 hours prior to use.

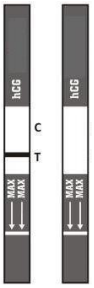
TEST PROCEDURE

1. Remove the test from the foil pouch.
2. Collect urine in a dry container (not provided) and dip only the area below the MAX line into the urine for 10 seconds.
3. Lay the test on a flat surface.
4. Read the results in 5-15 minutes. Do not read after 15 minutes.

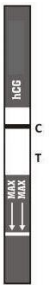


INTERPRETATION OF RESULTS

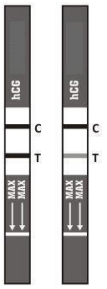
Invalid:
Either no lines are observable or either test line (T) without a control line (C) is present. Improper test procedure was carried out or reagents have deteriorated. Re-test.



Negative (-):
The control line (C) is present but no test line (T), demonstrating the test was performed correctly but no hCG was detected.



Positive (+):
The top (control) line and bottom (test) lines, are visible.



Manufactured by:
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LIMITATIONS OF THE TEST

1. It is possible that the concentration of the hCG in the sample is too low to be detected. If pregnancy continues to be suspected, the test should be repeated 48 hours later.
2. hCG levels may be detectable several weeks after spontaneous abortion.
3. Neoplasms and tumors may in certain circumstances secrete hCG. Such possibilities should be excluded before pregnancy is diagnosed.
4. Information obtained from this test should always be used in conjunction with other clinical and laboratory procedures before a definitive diagnosis can be made.
5. Testing woman who are more than 3 months pregnant may present a faint line at the test line region instead of an expected dark red line due to the extremely high concentration of hCG causing a hook effect.

INTERNAL QUALITY CONTROL

The strip contains an internal procedural control line that confirms that the test was carried out correctly and/or that the test has not deteriorated. During routine quality control, the MD hCG Pregnancy strip test is standardized using the WHO 4th International hCG reference standard.

EXPECTED hCG LEVELS AFTER CONCEPTION

Implantation normally occurs 6-8 days post conception, after which very low levels of hCG can be detected. The level of hCG reaches about 30 mIU/ml at about 10 days following fertilization. During the first missed period, the level is generally between 50-250 mIU/ml and peaks between 20-200 IU/ml with a mean of 46 IU/ml at about 10 weeks of pregnancy. From about 18 weeks after parturition, the level remains at about 5 IU/ml.

TEST PERFORMANCE

Sensitivity

The MD hCG Pregnancy Strip test has a sensitivity of less than 25 mIU/ml as defined by theWHO reference standard.

Specificity

In a standard assay of 300 random characterized samples (negative 109 and positive 191), the hCG Pregnancy Test achieved complete agreement with a commercially available ELISA automated analyzer, and all results were validated by clinical follow-up. The following substances added to samples will not interfere with the result:

hLH	-	200mIU/ml
hFSH	-	1000mIU/ml
hTSH	-	1000mIU/ml
Protein	-	2000mg/ml

REFERENCES

1 Batzer F.A. Fertility and Sterility 34 1-13 (1980)
2 Chard T. Human Reproduction 7, 701-710 (1990)
3 Norman R.J. et al, Obstet.Gynaecol 69, 590-593 (1987)

SYMBOLS

IVD	For in-vitro diagnostic use only	2	For single use only
	Content		Expiry date
LOT	Lot number		Storage temperature

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