

One Step Rapid Test for Pregnancy HCG Pregnancy Midstream Rapid Test

Human Urine Test Protocol

INTENDED USE:

MaxLINE Pregnancy Midstream Test is a rapid one step assay designed for qualitative detection of human Chorionic Gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

PRODUCT FEATURES :

1. Lateral Flow Immuno Chromatography Assay .
2. Double Antigen Sandwich Principle.
3. Detects Human chorionic gonadotropin hormone in human urine.
4. Uses Treponema specific recombinant Antigens .
5. Relative sensitivity : 100%
6. Relative specificity : 100%
7. Detection Limit : 25 mIU/ml.

INTRODUCTION

Human chorionic gonadotropin is a glycopeptide hormone produced by the placenta during pregnancy. The appearance and rapid rise in the concentration of hCG in the woman's urine makes it a good pregnancy marker. Usually, concentration of hCG in urine is at least 25 mIU/ml within seven to ten days after conception. The concentration increases steadily and reaches its maximum between the eighth and eleventh weeks of pregnancy. The MaxLINE hCG Test utilizes both conventional Polyclonal and Monoclonal antibodies to selectively identify hCG in urine

PRINCIPLE

The One Step HCG Pregnancy Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (HCG) in urine to aid in the early detection of pregnancy. The test utilizes antibodies including a monoclonal HCG- β antibody and goat anti-mouse IgG on the nitrocellulose membrane with colloidal gold marked anti-HCG- α monoclonal antibody as a mark tracer. The reagent is used to detect the HCG in urine according to the principle of double antibody sandwich method and gold immunochromatography assay.

There is a control line (C) controlling the reaction process shown on the coated film. Based on test line's (T) appearance to determine whether the tested sample contains HCG (Human Chorionic Gonadotrophin) or not.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (4-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

MATERIALS

1. Materials Provided

Each kit contains :

- a) Individually packed test device
- b) Sample Dropper
- c) Product insert

2. Materials Required But Not Provided

- Specimen collection container.
- Centrifuge capable of 1000 g (To remove the precipitates).
- Stop Watch

PRECAUTIONS

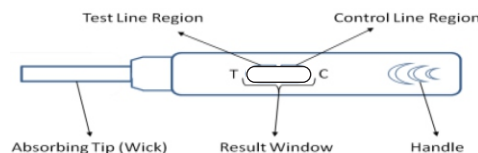
1. The device is sensitive to humidity as well as to heat. So it's very important to take off the device from the sealed pouch when it use.
2. Do not use the kit after the expiration date
3. For in vitro diagnostics use only.
4. Dispose all the samples and kits properly after test, in accordance with GLP.
5. Dispose of all used test components in a properly labeled container.
6. Read the package insert care fully before testing

SPECIMEN COLLECTION AND STORAGE

It is best to perform the test first thing in the morning because the first morning urine contains the highest amount of hCG. However, urine collected at any time of day may be used. Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For long-term storage, specimens may be frozen and stored below -20°C, the frozen specimens should be fully melted and restore to room

temperature and shake before testing .Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

TEST PROCEDURE



Step 1:

- Read instructions carefully before use.
- Allow the test and urine sample to equilibrate to room temperature (20-30°C) prior testing.
- Check that the test is completely sealed then open the pouch.

Step 2:

- Remove the cap from the device.

Step 3:

- Hold the device by the handle with the exposed absorbent tip pointing downwards.
- Place the wick into the urine stream for 3-4 seconds; making sure that the entire tip is wet.
- (Note: Do not urinate on the result window of the device. If you prefer, you can urinate into a clean and dry container, then dip only the absorbent tip of the midstream test into the urine for 3-5 seconds.)
- Remove the device from the urine stream (if you like, you may replace the cap - replacing the cap will not affect the results).

Step 4:

- Place the device on a flat surface with the window facing up. You will notice a red color moving across the result window indicating that the test reaction is taking place.
- Wait for colored lines in appear interpret the test results within 5 minutes.

Note: The result is invalid over 5 minutes.

INTERPRETATION OF RESULTS



Positive:

Two distinct red lines will appear. The presence of two red lines in the result window means you can assume that you are pregnant. A pink to red line (T), even if it is very thin, indicates a positive result. Check with your doctor to confirm pregnancy.



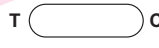
Negative:

Only one red line appears. The presence of one red line in the control area (C) means you are probably not pregnant.



Invalid:

The result is invalid if no red line appears in the control area (C), even if a line appears in the test area (T). You should repeat the test with a new test.



Note: Clear background in the Result Window can be seen as a basis for effective testing if the test line is weak; it is recommended that the test be repeated with the first morning specimen obtained 48-72 hours later.

QUALITY CONTROL:

MaxLINE pregnancy tests are provided with an built control to validate test results. A pink-rose coloured band appearing nearer to the upper end of the strip/cassette i.e control area indicates proper performance of the test. However the intensity of control and test bands depends on the concentration of hCG present in the specimen. Incase of appearance of a very faint test band at 3 minutes, the hCG concentration in urine may be below 25 mIU/ml

EXPECTED VALUES

The hCG Rapid Test has been compared with a leading commercial hCG test, demonstrating an overall accuracy greater than or equal to 99.7%.

PERFORMANCE CHARACTERISTICS

Method	Other hCG Rapid Test			
	Results	Positive	Negative	Total
MaxLINE hCG Card	Positive	71	0	71
	Negative	0	88	88
Pregnancy Test	Total	71	88	159

Relative Sensitivity: 100%
Relative Specificity: 100%
Accuracy: 100%

Sensitivity

MaxLINE hCG Test will detect hCG in urine at concentrations 25 mIU/ml or greater. This sensitivity level has been confirmed with hCG concentrations (25, 50, 100, 1000, 450,000, and 900,000 mIU/ml) spiked in urine. Occasionally, specimens containing less than 25 mIU/ml hCG can also give positive results.

Specificity

Related hormones potentially cross-reactive with anti-hCG were added to hCG-free urine samples in the following concentrations: LH: 50, 100, 300, and 500 mIU/ml; FSH: 50, 100, 500, and 1000 mIU/ml; TSH: 100, 500, and 1000 mIU/ml and tested for cross reactivity with MaxLINE pregnancy rapid tests and the results were found to be Negative. In addition, these concentrations of LH, FSH and TSH were spiked to urine samples containing hCG at 25 and 450,000 mIU/ml and tested for cross reactivity. In all the cases the results of hCG testing were not affected by added glycoprotein hormones (No cross reactivity of MaxLINE rapid tests was detected).

ACCURACY

A multi-center clinical evaluation was conducted comparing the results obtained using the hCG Card Pregnancy Test to another commercially available urine membrane hCG test. The study included 159 urine specimens: both assays identified 88 negative and 71 positive results. The results demonstrated a 100% overall accuracy of the hCG Card Pregnancy Test when compared to the other urine membrane hCG test.

INTERFERING SUBSTANCES

The following potentially interfering substances were added to hCG negative and positive specimens.

Acetaminophen:	20 mg/dL	Caffeine:	20 mg/dL
Acetylsalicylic Acid:	20 mg/dL	Gentisic Acid:	20 mg/dL
Ascorbic Acid:	2g/dL	Albumin:	2 g/dL
Creatin:	200 mg/dL	Hemoglobin	1.1 mg/dL
Bilirubin:	1g/dL	Oxalic Acid:	600mg/dL

None of the substances at the concentration tested interfered in the assay.

LIMITATIONS OF THE TEST

- The MaxLINE hCG Test is for *in vitro* diagnostic use only.
- Besides pregnancy, elevated concentrations of hCG may be found in patients with both gestational and non-gestational trophoblastic diseases. These conditions should be ruled out in the interpretation of hCG levels to establish a diagnosis of pregnancy.
- A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone. Also, a spontaneous miscarriage may cause confusion in interpreting the test results.
- As with all diagnostic tests, a definitive diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
- A negative result from a urine specimen collected from a woman in very early pregnancy may be due to an unusually low concentration of hCG. In such cases, the test should be repeated on a fresh specimen obtained approximately two days later.
- If a negative result is obtained with a urine specimen and pregnancy is still suspected, obtain a first morning urine specimen and re-test.

DISCLAIMER:

The manufacturer has taken every precaution to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by user error and/or environmental factors. A person who is the subject of the diagnosis should consult a clinician for further confirmation of the result.















WARNING:

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

REFERENCES:

- Catt, K.J., Dufan, M.L., and Vaitukaitis, J.L., J. *Clin. Endocrinol. Metab.*, Vol. 40, 537, (1975).
- Lenton, E.A., Neal, L.M., Sulaiman, R., *Fertility & Sterility*, Vol. 37, 773, (1982).
- Batzer, F.R., *Fertility & Sterility*, Vol. 34, 1, (1980).

Symbols Used on Pack

	Catalogue Number		Warning/Caution
	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Do Not Reuse		Contains sufficient no. of test



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