

# One Step Rapid Test for Pregnancy

## MaxLINE One Step Pregnancy Test

### Human Urine Test Protocol

#### ORDERING INFORMATION

Ref. No.	Pack Size	Ref. No.	Pack Size	Ref. No.	Pack Size
AVPREC1-20	20 Tests	AVPREC2-20	20 Tests	AVPREST-25	25 Tests
AVPREC1-25	25 Tests	AVPREC2-25	25 Tests	AVPREST-50	50 Tests
AVPREC1-30	30 Tests	AVPREC2-30	30 Tests	AVPREST-100	100 Tests
AVPREC1-50	50 Tests	AVPREC2-50	50 Tests		

**NOTE : 20T, 25T, 30T Pack Sizes are not available for domestic trade.**

#### INTENDED USE:

MaxLINE hCG Test is an immunochromatographic assay designed for qualitative determination of human chorionic gonadotropin (hCG) in urine for the 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. Relative sensitivity : 100%.
5. Relative specificity : 100%.
6. 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 immunochromatographic device contains a unique set of dye-conjugated and immobilized monoclonal and polyclonal antibodies employed to produce a distinctive visual pattern indicating elevated concentration of hCG ( $\geq 25$  mIU/ml) in the test sample, in approximately five to ten minutes.

In the test procedure, the urine sample is allowed to migrate through the absorbent area. If hCG is present, labeled antibody-dye conjugate binds to it forming an antibody-antigen complex. As the reaction mixture continues to flow along the test membrane, the complex binds to the anti-hCG antibody in the test (T) zone of the membrane, and produces a pink-purple color band. Unbound conjugate binds to the reagents immobilized in the control (C) zone producing a pink-purple color band, demonstrating proper performance of the test.

#### 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.

#### KIT CONTAINS

Ref. No.	Pack Size	Test Device	Product Insert	
AVPREC1-20	20 Tests	20 Nos.	1 No.	} Mini
AVPREC1-25	25 Tests	25 Nos.	1 No.	
AVPREC1-30	30 Tests	30 Nos.	1 No.	
AVPREC1-50	50 Tests	50 Nos.	1 No.	
AVPREC2-20	20 Tests	20 Nos.	1 No.	} Maxi
AVPREC2-25	25 Tests	25 Nos.	1 No.	
AVPREC2-30	30 Tests	30 Nos.	1 No.	
AVPREC2-50	50 Tests	50 Nos.	1 No.	
AVPREST-25	25 Tests	25 Nos.	1 No.	} Strip
AVPREST-50	50 Tests	50 Nos.	1 No.	
AVPREST-100	100 Tests	100 Nos.	1 No.	

#### 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 (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

Urine is used as a specimen. Use first urine sample of the day, usually it contains the highest concentration of hCG and is therefore the best sample when performing the urine test. However, randomly collected urine specimens may be used. Collect a urine specimen in a clean glass, plastic, or wax coated container. Do not use preservatives. Specimen precipitates should be filtered, centrifuged or allowed to settle and clean aliquots thus obtained should be used for testing.

#### TEST PROCEDURE

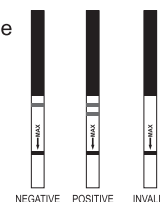
##### (A) MaxLINE ONE STEP PREGNANCY RAPID TEST (STRIP)

1. Remove the test strip from its foil pouch by tearing along the notch.
2. Dip the strip in to the urine up to the line below the arrow.
3. Dip till the urine starts migrating laterally and keep it on a flat surface.
4. Read the results between 5-10 minutes and discard the strip.
5. Do not read results after 10 minutes.



#### INTERPRETATION OF RESULTS

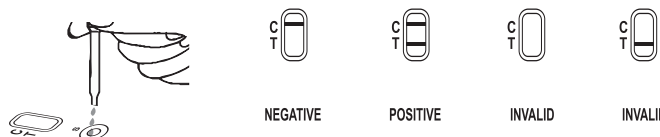
1. **Negative:** One pink-purple colored band appears in the control region (i.e Upper end of the strip).
2. **Positive:** Two pink-purple colored bands appear: one in the test region (i.e Lower end of the strip) and in the control region (i.e Upper end of the strip).
3. **Invalid :** Non appearance of any pink-purple colored bands indicates inconclusive result. In this case the test should be repeated with fresh Strip.



##### (B) MaxLINE ONE STEP PREGNANCY RAPID TEST (CASSETTE)

1. Remove the cassette from the foil pouch by tearing at the "notch" and place it on a flat surface.
2. Holding a sample dropper vertically, add exactly 2 drop in mini and 3 drops in maxi of urine to the sample port.

#### INTERPRETATION OF RESULTS



**Note : Always use 2 drops of urine for MaxLINE Mini & 3 drops of urine for MaxLINE Maxi**

1. **Negative :** One coloured band appears in the control region C.
2. **Positive :** Two coloured bands appear: one in the test region (T) and the other in the control region C.
3. **Invalid :** Non appearance of any coloured bands indicates inconclusive result. In this case the test should be repeated with fresh cassette.
4. Read results between 5-10 minutes and discard the cassette.
5. Do not read the results after 10 minutes.

#### QUALITY CONTROL:

MaxLINE pregnancy tests are provided with an built control to validate test results. A pink-purple colored 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. In case 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

1. The MaxLINE hCG Test is for *in vitro* diagnostic use only.
2. 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.
3. 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.

4. 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.
5. 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.
6. If a negative result is obtained with a urine specimen and pregnancy is still suspected, obtain a first urine specimen of the day 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:

1. Catt, K.J., Dufan, M.L., and Vaitukaitis, J.L., *J. Clin. Endocrinol. Metab.*, Vol. 40, 537, (1975).
2. Lenton, E.A., Neal, L.M., Sulaiman, R., *Fertility & Sterility*, Vol. 37, 773, (1982).
3. 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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