CE 0123

One Step HCG Urine Pregnancy Test (Midstream)

REF: HCG 114 | English

INTENDED USE:

One Step HCG Urine Pregnancy Test measures the presence of the hormone Human Chorionic Gonadotrophin (HCG) in human urine for the early detection of pregnancy.

SUMMARY AND EXPLANATION:

HCG is produced by the placenta during pregnancy, shortly after the embryo attaches to the uterine lining. Usually HCG can be detected by a home pregnancy test within 7-10 days after conception.
This test is capable of detecting pregnancy as early as the first day after you miss a period. The further into the pregnancy you are, the higher the levels of HCG in your urine. This pregnancy Midstream detects HCG in urine at a concentration of 25mIU/ml (Milli-International Units) or greater. The concentration of HCG in non-pregnant women is normally 5.0mIU/ml. At the time of the last missed menstrual period, urine HCG levels are about 100mlU/ml with peak levels of 100,000 to 200,000mlU/ml seen at the end of the first trimester.

CONTENTS:

Each pouch contains:
1. One Step HCG Urine Pregnancy Midstream Test.

Each box contains
1. One foil pouch.
2. Instruction for use.

STORAGE AND STABILITY:

The test kit can be stored at room temperature (2 °C to 30 °C) in the sealed pouch to the date of expiration. The test kits should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS:

1. FOR IN -VITRO DIAGNOSITC (IVD) USE ONLY, NOT for internal use.
2. Read directions for use carefully before performing this test.
3. Do not use beyond the expiration date.
4. Do not reuse the test Midstream. Discard it in the dustbin after single use.
5. Do not use the midstream if the foil pouch is damaged.
6. Once open the pouch, the test midstream should be used immediately. Prolonged exposure to ambient humidity will cause product deterioration.
7. Treat urine samples and used test devices as if they are potentially infectious. Avoid contact with skin.
8. Keep out of reach of children.

TEST PROCEDURE:

1. WHEN CAN I CARRY OUT THE TEST?
You can take this pregnancy test from the first day after a missed period and onwards.

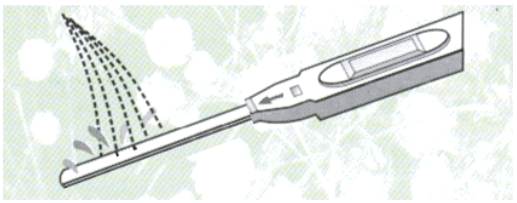
2. SPECIMEN COLLECTION AND HANDLING

A urine specimen must be collected in a clean and dry container. The first urine specimen in the morning is preferred since it generally contains the highest concentration of HCG; however, urine specimens collected at any time of the day may be used.

3. TO CARRY OUT TEST

1. Bring the sealed pouch and urine to room temperature. To begin testing, open the sealed pouch and remove the Midstream.
2. Hold the round end of cover with one hand. Use the other hand to pull out the test device and expose the absorbent.
3. Point the absorbent tip downward; place the absorbent tip in urine stream for at least 10 seconds to be thoroughly wet. Otherwise, you can collect your urine into a clean cup and dip half of the absorbent pad into the urine for at least 10 seconds.

⚠ Re-cap the device and wait for colour bands to appear. Depending on the concentration of HCG in the urine specimen, positive results may be observed in as short as 40 seconds. However, to confirm a negative result, the complete reaction time (5 minutes) is required. Do not read results after 10 minutes.
5. Discard the test after use. Put the used midstream into special container if possible and regard it as if it is infectious. Don't litter.

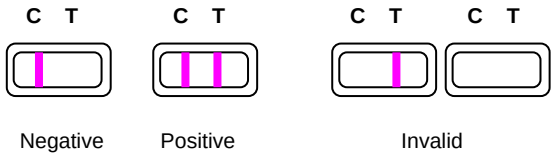


4. INTERPRETATION OF RESULTS

Negative: Only one visible colored band in control region, no colored band in test region, which indicate the result of the test is negative., no HCG has been detected in the urine. This means you are either not pregnant or you have tested too early. If you are not sure repeat the test in 48 hours.

Positive: Two visible colored bands in both test region and control region, which indicate the result of the test is positive, then this means there is a strong possibility that you are pregnant — HCG has been detected in your urine. One line may be lighter than the other, they do not have to match and this is still a positive result.

Invalid: No visible colored band(s) at all, or only one colored band in test region, which indicate the kit is invalid. Repeat the test with a new test kit!



5. QUALITY CONTROL

Built in Quality Control Features:
After addition of the urine sample, coloured bands migrate along the membrane at the leading edge of the dye conjugate and are "removed" from the test strip completely.
When the test is complete, you will see a pink-purple coloured band in the "C" area of the test strip for negative samples and a pink-purple coloured band in the "T" and "C" area for positive samples. The appearance of the CONTROL band indicates that the test Midstream is performing properly and serves as a procedural control.

PERFORMANCE CHARACTERISTICS:

1. SENSITIVITY

One Step HCG Urine Pregnancy Test will display positive results with specimens containing HCG at the level close to or greater than 25mIU/ml.

2. ACCURACY

Comparison studies on the **One Step HCG Urine Pregnancy Test** with a legally marketed device were performed in-house and in a clinical reference laboratory. Positive and negative results were compared and the correlation was >99 %.

3. SPECIFICITY

The following compounds exhibited no interference when dissolved in urine, which had HCG levels of 0 and 25 mlU/ml.

3.1 Non-cross reacting homologous hormones

hFSH……..1000 mIU/ml (WHO 1st IS)
hLH……500mIU/ml (WHO 1st IRP)
hTSH…….1000μIU/ml (WHO 2nd IRP)

3.1Cross Reactivity

The cross reactivity of hCG test kits was evaluated with hCG homologous hormones. Homologous hormones FSH, LH and TSH were added to urine samples containing hCG at concentration of 0, 25 or 100 mIU/mL. No cross reactivity was observed in the study (shown in Table 1).

Table 1 - Cross-reactivity study of One-Step hCG test kit

hCG conc. in sample (mIU/mL)	Unspiked serum or urine samples	Urine samples spiked with homologous hormones		
		FSH	LH	TSH
		1000 mIU/ml	500 mIU/ml	1000 μ IU/ml
0	-	-	-	-
	-	-	-	-
	-	-	-	-
25	+	+	+	+
	+	+	+	+
	+	+	+	+
100	+	+	+	+
	+	+	+	+
	+	+	+	+

3.2 None cross reacting

The cross reacting of HCG test kits was evaluate with the following SubstanceNo cross reacting was observed (showing in the table 2)

Table 2-**Non-cross reacting compounds:**

Acetaminophen	20mg/dl
Acetosal	20mg/dl
Salicylic Acid	20mg/dl
Ascorbic Acid	20mg/dl
Caffeine	20mg/dl
Gentisic	20mg/dl
Thiophene	20mg/dl
Ampicillin	20mg/dl
Tetracycline	20mg/dl
Hemoglobin	20mg/dl
Albumin	1000mg/dl
Glucose	20mg/dl
Ketone	20mg/dl
Bilirubin	20mg/dl
Theelol	20mg/dl
Pregnanedione	20mg/dl

Non-specific interference

One-Step hCG test was checked for possible interference from visibly hemolyzed, lipemic and icteric samples. Human hemoglobin, bilirubin or albumin was spiked into samples with different concentration of hCG and tested using un-spiked samples as controls. No significant interference was observed in 20 samples with results that were either positive or negative for hCG. The results are shown in Table 3.

Table 3- Non-specificity study of One-Step hCG test kits

Sample No	Unspiked samples	Urine samples spiked with (mg/mL)		
		Hemoglobin	Bilirubin	Albumin
		10	1	0.06	100
---	---	---	---	---	---
1	-	-	-	-	-
2	-	-	-	-	-
3	-	-	-	-	-
4	-	-	-	-	-
5	-	-	-	-	-
6	-	-	-	-	-
7	-	-	-	-	-
8	-	-	-	-	-
9	-	-	-	-	-
10	-	-	-	-	-
11	+	+	+	+	+
12	+	+	+	+	+
13	+	+	+	+	+
14	+	+	+	+	+
15	+	+	+	+	+
16	+	+	+	+	+
17	+	+	+	+	+
18	+	+	+	+	+
19	+	+	+	+	+
20	+	+	+	+	+

Empirical Evidence:

According to ISO14971:2012 method for Implementation of risk analysis can refer to the list of judgment of risk analysis report in following:

Urine samples: 168 randomly selected urine samples from specimen bank which is maintained in Dept. of Obstetrics and Gynecology at the Hospital.

Analysis of the Results

The sensitivity and specificity will be calculated as follows:

$$\text{Sensitivity (\%)} = 100X \frac{\text{No. of urine samples with positive results}}{\text{No. of positive urine samples confirmed as pregnancy}}$$

$$\text{Specificity (\%)} = 100X \frac{\text{No. of urine samples with negative results}}{\text{No. of negative urine samples confirmed as non-pregnancy}}$$

From 168 urine samples taken, both Sensitivity and Specificity figures are more than 99 %. Hence, the risk of false positives and false negatives is less than 1 %.

PRINCIPLE:

The HCG assay is a rapid one-step test, based on an immunochromato graphic technology. A membrane with an absorbent pad overlapping a strip of fiber glass paper that is impregnated with a lyophilized colloidal conjugate of gold particles and monoclonal solid phase antibodies to HCG. Other absorbent pads at the end of the assay absorb excess sample fluid. The urine sample is introduced into the device, and moves along the absorbent pad, then laterally onto a chromatographic membrane. As it contacts the membrane, the sample dissolves the lyophilized conjugate. In a reactive sample, the HCG antigen will attach to the antibodies in the colloidal solution. As the conjugate moves forward on the membrane, anti-HCG monoclonal antibody affixed on the test zone ("T") will bind the HCG-gold conjugate complex, forming a pink line ("T"). Any sample will cause a pink

colored line to appear in the control zone (“C”).

This line is formed by the binding of the polyclonal antibodies (Anti-mouse IgG) affixed onto the control zone to the sample-colloidal gold conjugate. Presence of this line indicates that the test has been carried out correctly. In less than 5 minutes, levels of HCG as low as 25mlU/ml can be detected.

REAGENTS:

One Step HCG Urine Pregnancy Test midstream per foil pouch.

Ingredients: Test device comprised colloidal gold coated with anti β-HCG antibody； NC membrane coated with mouse anti α-HCG antibody and rabbit anti mouse IgG.

LIMITATION OF THE PROCEDURE:

Alcohol may interfere with the test result. It is not recommended to use the test after drinking alcohol.

Occasionally urine specimens containing less than 25mlU/ml also yield positive results.

If you test too early, HCG level may still be low and so can give a negative result. In this case, another urine specimen should be obtained at least 48 hours later and tested.

HCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion or therapeutic abortion.

In cases where very high levels of HCG are present (>500,000mlU/ml) a false negative result can occur due to a “Prozone” effect. If pregnancy is still suspected, simply dilute specimen 1:1 with deionized water and retest.

If a urine sample is too dilute (ie: low specific gravity) it may not contain a representative level of HCG. If pregnancy is still suspected, a first morning urine sample should be obtained and retested 48 hours later.

As is true with any diagnostic procedure, the user should evaluate data obtained by the use of this kit in light of other clinical information and consult their doctor for the final diagnosis of pregnancy before making any decision of medical relevance.

BIBLIOGRAPHY

1. Batzer FR. Hormonal evaluation of early pregancy,Feril.Steril.1980:34(1):1-13

2. Catt KJ,ML Dufau, JL Vaitukatitis Appearance of HCG in pregnacy plasma following the initiation of implantation of the blastocyte, J ,Clin. Endocrino;. Metab.1975:40(3):537-540

3. Braunstein GD,J Rasor, H.Danzer, D Adler, ME Wade Serum human chorionic gonadotropin levels throughout normal pregnancy .Am. J.Obstet. Gynecol.1976:126(6):678-681

4. Lenton EA ,LM Neal, R Sulaiman Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy, Fertil, Steril. 1982:37(6):773-778

5. Steier JA ,P B ergsjo, OL Myking Human chorionic gonadotropin in maternal plasma after spontaneous abortion and induced abortion, removed ectopic, Obstet Gynecol.1984:64(3) 391-394

6. Dawood MY, BB Saxena, R Landesman Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma, Obstet. Gynecol. 1977:50(2):172-181

7. Braunstein GD ,JL Vaitukaitis, PP Carbone, GT Ross Ectopic production.

Index of Symbols

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse
	Attention, see instructions for use		Do Not use if package is
	Tests per kit		Authorized Representative

Manufactured by:
Atlas Link (Beijing) Technology Co., Ltd
Room 811 Zeyang Plaza, No.166 Fushi Road Shijingshan Dist.
Beijing 100043, China
Tel: 86-10-88909113
Website: https://www.invitro-test.com

EC REP

MT Promedt Consulting.
Altenhofstr. 80
66386 St. Ingbert Germany
E-mail: ear@mt-procons.com