One Step® Pregnancy Test Strip CE 0123

Operating Instructions

INTENDED USE

One Step hCG Urine Pregnancy Test Kit (Strip) is a rapid chromatographic immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine samples to aid in the early detection of pregnancy by both professional and home users.

SUMMARY AND EXPLANATION

During pregnancy, the placenta produces hCG after the embryo attaches to the uterine lining. As pregnancy progresses, the levels of hCG in your urine increase. 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 100mIU/mL with peak levels of 100,000 to 200,000mIU/mL seen at the end of the first trimester.

CONTENTS

Each pack contains:

1. One Step hCG Urine Pregnancy Strip Test.
2. Desiccant (Discard - Do not eat).
3. Package insert.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer

STORAGE AND STABILITY

The test kit can be stored at room temperature (4 °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. Do not freeze

PRECAUTIONS

1. For in-vitro diagnostic use only (IVD); not for internal use.
2. Read this instruction set carefully before performing the test. Perform each step exactly as described.
3. Do not use beyond the expiration date marked on the foil pouch.
4. Each One Step hCG pregnancy Test can only be used once; do not re-use the One Step hCG pregnancy Test
5. Do not use the Test if the foil pouch is damaged.
6. Once the foil pouch has been opened, the Test should be used immediately.
7. Discard each One Step hCG pregnancy Test after use. Treat urine samples and used test devices as if they were potentially infectious. Avoid contact with skin.
8. Keep out of reach of children.

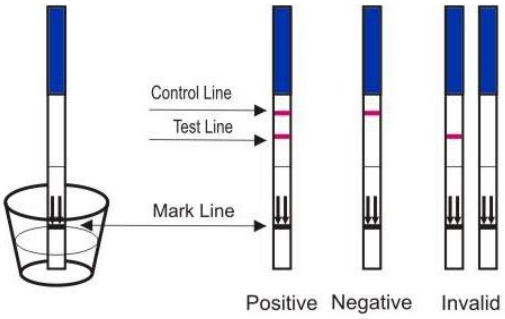
TEST PROCEDURE

SPECIMEN COLLECTION AND HANDLING

You can take this pregnancy test from the first day you suspect you might be pregnant, but for the most accurate results it is recommended to wait until the first day after your missed period.
A urine specimen must be collected in a clean and dry container. The first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used.

TO CARRY OUT THE TEST

1. Bring the sealed test pouch to room temperature.
2. Open the sealed pouch and remove the strip.
3. Immerse the test strip vertically (straight) into the urine sample for at least 15 seconds, making sure the arrows are pointing downwards. **Do not allow the urine level to go above the MAX (maximum) level line (marked by arrows) on the test strip.**
4. Remove the strip from the urine and place the strip on a non-absorptive, clean and dry surface.
5. Wait for the coloured bands to appear. Positive results may be visible within 40 seconds depending on the concentration of hCG present but to confirm a negative result wait up to 5 minutes and until the background is clear. Results obtained after 5 minutes may be considered invalid.
6. Discard the test after use.



INTERPRETATION OF RESULTS

Negative: If one coloured line appears in the control region on the test strip and there is no line in the test region, then this indicates a negative result and 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: If two coloured lines appear on the test strip, one in the test region and one in the control region, then this means hCG has been detected in your urine and there is a strong possibility that you are pregnant. One line may be lighter than the other, but this is still a positive result.

Invalid: If a red line appears in the test region but there is no visible line at all in the control region of the strip then the test is invalid. If no lines appear anywhere on the test strip then the test is also invalid and should be repeated using another test strip.

Invalid Test Results can be caused by:

- The absorbent tip not being wetted thoroughly.
- Reading the test result too early or too late. A 5-minute reaction time is required.

For further information, see LIMITATIONS OF THE PROCEDURE.

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QUALITY CONTROL

Built in Quality Control Features:
The appearance of a line in the control area indicates that the One Step hCG pregnancy Test is performing properly and serves as a procedural control. It is recommended that a positive hCG control (containing 10-250mIU/mL hCG) and a negative hCG control (containing 0mIU/mL hCG) are evaluated to verify proper test performance when a new shipment of tests is received.

PERFORMANCE CHARACTERISTICS

1. **SENSITIVITY**
   One Step hCG Urine Pregnancy Test Kit will display positive results with specimens containing HCG at levels of 10mIU/mL or greater.
2. **ACCURACY**
   Comparison studies on the One Step hCG Urine Pregnancy Test Kit 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 10 mIU/mL.
   hLH……500mIU /mL
   hFSH……1000mIU/mL
   hTSH…… 1000μIU/mL

Acetaminophen	20mg/dL	Codeine	6ug/dL
Acetoacetic Acid	2000mg/dL	Ethanol	1.0%
Asorbic Acid	20mg/dL	Methanol	10%
B-hydroxybutyrate	2000mg/dL	Albumin	2000mg/dL
Caffeine	20mg/dL	Glucose	2000mg/dL
Ephedrine	20mg/dL	Bilirubin	2mg/dL
Gentisic Acid	20mg/dL	Atropine	20mg/dL
Phenylpropanolamine	20mg/dL	Estriol-17-beta	1400ug/dL
Salicylic Acid	20mg/dL	Hemoglobin	500mg/dL
Phenothiazine	20mg/dL	Pregnanediol	1500ug/dL
EDTA	80mg/dL	Thiophene	20mg/dL
Acetylsalicylic Acid	20mg/dL	Ampicillin	20mg/dL
Benzoylecgonine	10mg/dL	Tetracycline	20mg/dL
Cannabinol	10mg/dL	Ketone	20mg/dL

PRINCIPLE:

The hCG assay is a rapid one-step test based on immunochromatographic technology. A membrane with an absorbent pad over a strip of fibre glass paper is impregnated with a colloidal conjugate of gold particles and monoclonal antibodies to hCG. Other absorbent pads at the end of the assay absorb excess sample fluid. The urine sample is introduced into 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 antibodies affixed on the test zone (“T”) will bind the HCG-gold conjugate complex, forming a pink line (“T”). Any sample will cause a pink coloured line to appear in the control zone (“C”).

This line is formed by the binding of 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.

LIMITATIONS OF THE PROCEDURE

1. Performing the test too early can yield a false negative due to low HCG levels. In this case, another urine specimen should be obtained at least 48 hours later and tested.
2. HCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, or spontaneous abortion.
3. If urine sample is too dilute (ie: low specific gravity) it may not contain a representative level of hCG. If pregnancy is still suspected, wait 48 hours, collect a urine sample first thing in the morning and retest it with another strip test.
4. As is true with any diagnostic procedure, the user should evaluate data obtained by the use of this kit with consideration to other clinical information and consult their doctor for the final diagnosis of pregnancy before making any decision of medical relevance.

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INTERPRETATION OF THE SYMBOLS

	Storage temperature	LOT	Lot number
IVD	For in vitro diagnostic use only		Expiry date
	See instruction for use		Manufacturer
EC REP	Authorized representative		Do not reuse
	Keep Dry		Keep away from sunlight
Σ	Number of Tests in Pouch		

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