

My After Plan®
One Step HCG Urine Pregnancy Test Kit
(Midstream)
For in-vitro diagnostic and OTC Use Only

INTENDED USE

The One Step HCG Urine Pregnancy Test Kit (midstream) 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 home users.

SUMMARY AND EXPLANATION

The 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. During pregnancy, the placenta produces HCG after the embryo attaches to the uterine lining. This test is capable of detecting pregnancy the first day after a missed period. As pregnancy progresses, urine contains higher levels of HCG at concentrations 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 100mIU/ml with peak levels of 100,000 to 200,000mIU/ml.

PRINCIPLE

The HCG assay is a rapid one-step test based on immunochromatographic technology. A membrane with an absorbent pad over a strip of fiber 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 colored 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. In less than 5 minutes, levels of HCG as low as 25mIU/ml can be detected.

CONTENTS, STORAGE AND STABILITY

Each box contains: 1 foil pouch and Instruction for use.

Each pouch contains: 1 step HCG Urine Pregnancy Test stick and one desiccant.

The test kit can be stored at room temperature (39°F-86°F; 4°C-30°C) in the sealed pouch to the date of expiration. The test kits should be kept away from direct sunlight, moisture and heat.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer

PRECAUTIONS

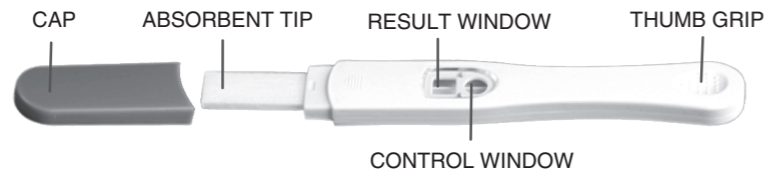
- FOR IN-VITRO DIAGNOSTIC AND OTC USE ONLY, NOT for internal use.
- Read directions for use carefully before performing this test. Perform each step exactly as described.
- Do not use beyond the expiration date marked on the foil pouch.
- Each Midstream Test can only be used once; do not re-use the Midstream Test.
- Do not use the Midstream Test if the foil pouch is damaged.
- Once the foil pouch has been opened, the Midstream Test should be used immediately.
- Discard each Midstream Test after use. Treat urine samples and used test devices as if they were potentially infectious. Avoid contact with skin.
- KEEP OUT OF REACH OF CHILDREN.

TEST PROCEDURE

1. SAMPLE COLLECTION AND HANDLING

To perform this test, hold the Midstream Test's absorbant tip directly into the urine stream. The first urine sample in the morning is ideal because it generally contains higher concentration of HCG. However, urine samples may be tested at any time of the day.

2. TO CARRY OUT THE TEST

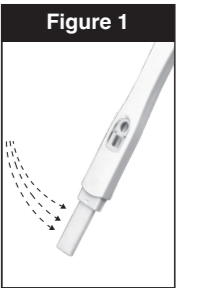


DIRECTIONS FOR USE

- Bring the sealed pouch to room temperature.
- Carefully remove the Midstream Test from the sealed pouch.
- Hold the Midstream Test and remove the cap to expose the absorbent tip.
- Point the absorbent tip downward; place the absorbent tip into the urine stream for 10-15 seconds to ensure it is thoroughly wet.
- Re-cap the device and wait for the color bands to appear.
- Read results in 5 minutes.

Depending on the concentration of HCG in the urine sample positive results may be seen within 40 seconds. Wait the full five minutes to confirm the result. Do not read the Midstream Test after 5 minutes as this may also give an incorrect test result.

- This is a single use test. Please safely dispose of the Midstream Test; regard this as infectious material and dispose of the test appropriately after use.



3. HOW TO READ THE RESULT

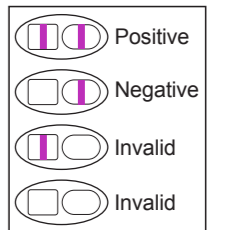
Positive: If two pink/purple colored lines appear on the one step HCG Pregnancy Test, one in the control area and one in the test area, then this means HCG has been detected in the urine and there is a strong possibility of pregnancy.

The lines seen may be faint and one line may be lighter than the other; however this is still a positive result. The lines do not have to match in strength or color.

Negative: If one colored pink/purple line appears in the control area on the Midstream Test and there is no line in the test area, then this indicates a negative result. This means no HCG has been detected in the urine.

This indicates you are either not pregnant or you have tested too early. If you are not sure repeat the test in 48 hours.

Invalid: If no lines appear anywhere in the control zone, the test is invalid and repeat the test using another Pregnancy Test.



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 minutes reaction time is required.

For further information, see LIMITATIONS OF THE PROCEDURE

4. QUALITY CONTROL

Built in Quality Control Features:

The appearance of a line in the control area indicates that the Midstream Test is performing properly and serves as a procedural control.

LIMITATION OF THE PROCEDURE

Performing the test too early can yield a false negative result due to low HCG levels. 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.

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. Retest a first morning urine sample with another Midstream Test. 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.

ASSISTANCE

If you have any question regarding to the use of this product, please call our Technical Support Number 1-800-406-7984 (9:00 a.m. to 5 p.m. EDT)

MY AFTER PLAN is a registered trademark of Sun Pharmaceutical Industries Limited.

Distributed by:
Ohm Laboratories Inc.
 New Brunswick, NJ 08901

5252857