One Step®

CE 0197

Pregnancy Test (Midstream)

For self-testing and In Vitro diagnostic use only

INTENDED USE

The One+Step Pregnancy test is an immunnoassay designed for the qualitative determination of human chorionic gonadotropin(HCG) in urine for early detection of pregnancy.

SUMMARY AND EXPLANATION

Human Chorionic gonadotropin (HCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. During normal pregnancy, HCG can be detected in urine as early as 7 days following conception, doubling every 1.3 to 2 days. 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. The presence of HCG soon after conception and its subsequent increase in concentration during early gestational growth make it an ideal marker for the early detection of pregnancy.

PRINCIPLE

The One+ Step Pregnancy test is a rapid qualitative one step assay for the detection of HCG in urine. The method employs a combination of monoclonal dye conjugate and polyclonal-solid phase antibodies to selectively identify the HCG in the test samples. In less than 5 minutes, levels of HCG as low as 10 mIU/mL can be detected.

As the test sample flows through the absorbent device, the labeled antibody-dye conjugate binds to the HCG forming an antibody-antigen complex. This complex binds to the anti-HCG antibody in the positive reaction zone ("T"area) and produces a pink-purple coloured band when the HCG concentration is greater than 10 mIU/mL. In the absence of HCG, there is no line in the positive reaction zone. Unbound conjugate binds to the reagents in the control zone ("C" area), producing a pink-purple band, demonstrating that the reagents are functioning properly.

REAGENTS

The One+Step Pregnancy midstream per foil pouch.

Ingredients: colloidal gold coated with goat anti mouse, mouse anti-a hCG antibody and mouse anti-B hCG antibody.

MATERIALS

Materials provided

1. One+Step Pregnancy test midstream
2. Desiccant
3. Package insert

Materials required but not provided

1. Timer
2. Specimen collection container

STORAGE AND STABILITY

Store test midstream at 2~30℃ . The test is stable until the date imprinted on the pouch label

Do the test within 1 hour of opening the pouch.

DO NOT FREEZE.

Store the urine sample at 2-8℃ for 48 hours or at -20℃ for Long-term preservation, if you can't test in time. Avoid repeated freezing and thawing.

WARNINGS AND PRECAUTIONS

For IN VITRO DIAGNOSTIC USE ONLY

1.Read directions for use carefully before performing this test. Pay attention to the position of the C and T line.

2.Do not use beyond the labeled expiration date.

3.Do not reuse the test devices. Discard it in the dustbin after single use.

4.Do not use if pouch is damaged or opened.

5.Do not touch the membrane located within the windows.

6.After opening the pouch, the test device should be used immediately. Prolonged exposure to ambient humidity will cause product deterioration.

7.Treat urine samples and used devices as if they are potentially infectious. Avoid contact with skin.

ASSAY PROCEDURE

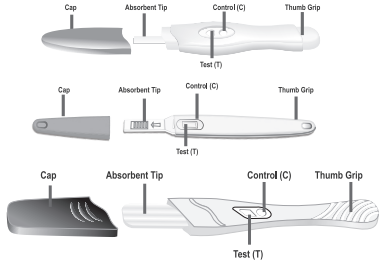
1. Determination of test date

The test can be used from the first day of missed period

2. Specimen collection

The One+Step Pregnancy test is formulated for use with fresh urine specimens.If you are immersing the test into a urine sample, the test should be used right after specimen collection. A urine cup should be used to collect specimens, and the urine does not require any special pretreatment. For the most accurate results, it is recommended to test first morning urine.

3. Test Procedure



1) Remove the test from the foil pouch and remove the cap to expose the absorbent tip.

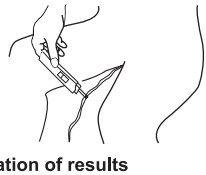
2) Hold the midstream test by the thumb grip with the exposed Tip pointing downward, directly into your urine stream until you see the dye start to fill the test window (this should take no more than 5 seconds). Alternatively, you can urinate into a clean and dry container, then dip only the tip of the midstream test into the urine for at least 5 seconds.

MAKE SURE YOU DO NOT HOLD THE TEST IN YOUR URINE STREAM FOR LONGER THAN ADVISED AND THAT YOU DO NOT URINATE DIRECTLY INTO THE TEST WINDOW AS YOU MAY FLOOD THE TEST. ALSO MAKE SURE YOU DO NOT INVERT THE TEST (I.E. DO NOT HOLD IT WITH THE TIP POINTING UPWARDS) AS THIS WILL CAUSE THE URINE TO SURGE UP THE TEST WINDOW AND AGAIN MAY FLOOD THE WINDOW.

3) After removing the midstream test from your urine, immediately replace the Cap over the Tip, lay the midstream test on a flat surface with the Test and Control window facing upwards, and then begin timing.

4) Wait for the coloured bands to appear. Positive results may be visible within 1 minute 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.

5) Discard the test device after single use in a dustbin.



4. Interpretation of results

Negative
If only one pink line appears in the control area, you can assume that you are not pregnant.

Positive
If two pink lines appear in the control area and test area, you can assume that you are pregnant.

Invalid
Control Line fails to appear.

NOTE: Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, please contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A coloured line appearing on the control region (C) is considered an internal positive procedural control, indicating proper performance and reactive reagents. A clear background in the membrane is considered an internal negative procedural control. If the test has been performed correctly and reagents are working properly, the background will clear to give a discernible result.

PERFORMANCE CHARACTERISTICS

1. ANALYTICAL SENSITIVITY & ANALYTIC SPECIFICITY

Analytic Sensitivity: HCG Standard substance was added to diluent to obtain different concentrations (0mIU/mL, 10mIU/mL, 25mIU/mL). 10 samples were tested at each concentration for every batch. All samples were positive at 10mIU/mL. It indicates that the One+Step Pregnancy Test's analytical sensitivity is no more than 10mIU/mL.

Analytic Specificity: The test results show negative for the 500mIU/mL hLH, 1000mIU/mL hFSH and 1mIU/mL hTSH samples, which have 0mIU/mL HCG. The test results show positive for the 500mIU/mL hLH, 1000mIU/mL hFSH and 1mIU/mL hTSH samples, which have 10mIU/mL HCG.

2. ACCURACY

80 clinical samples were collected and HCG Standard was added to obtain different concentrations (0mIU/mL, 5mIU/mL, 10mIU/mL, 25mIU/mL). 80 clinical samples were tested with the One+Step Pregnancy Test and the Predicate Device. The results show that the accuracy of the One+Step Pregnancy test is more than 99.9%.

3. REPEATABILITY (Intra-lot)

HCG standard was added to diluent to obtain different concentrations at 0 mIU/mL and 10 mIU/mL. Each specimen, at each concentration of analyte, was tested ten times, and results were read within 5 minutes. The result shows that the repeatability of the One+Step Pregnancy test is 100%.

HCG Concentration (mIU/mL)	Test Number	Result		Repeatability
		Positive	Negative	
0	40	0	40	100%
10	40	40	0	100%
25	40	40	0	100%
37.5	40	40	0	100%
50	40	40	0	100%

4. REPRODUCIBILITY (Inter-lot)

HCG standard was added to diluent to achieve concentrations at 0 mIU/mL and 10 mIU/mL.Test samples from three lots were obtained and each specimen, at each concentration of analyte, was tested ten times, and results were read within 5 minutes. No variable result was observed.

HCG Concentration (mIU/mL)	LOT1		LOT2		LOT3		Reproducibility
	Positive	Negative	Positive	Negative	Positive	Negative	
0	0	8	0	8	0	8	100%
10	8	0	8	0	8	0	100%
25	8	0	8	0	8	0	100%
37.5	8	0	8	0	8	0	100%
50	8	0	8	0	8	0	100%
Total	32	8	32	8	32	8	100%

5. INTERFERENCE TESTING

Urine pH studies were conducted by comparing HCG positive samples with HCG negative urine samples at different pH levels. It showed that pH does not interfere with the results.

PH LEVELS	NEGATIVE URINE RESULTS	POSITIVE URINE RESULTS
6.13	NEGATIVE	POSITIVE
5.11	NEGATIVE	POSITIVE
4.25	NEGATIVE	POSITIVE
3.16	NEGATIVE	POSITIVE

Potentially interfering substances were added to normal male urine, which had HCG levels of 0 and 10 mIU/mL. In each case, no interference with the One+Step Pregnancy test occurred.

Substance	Concentration (ug/mL)
Acetaminophen	100
Aspirin	100
Vitamine C	100
Atropine	100
Caffeine	100
Brilirubin	100
Glucose	100
Hemoglobin	100
Ampicillin	100

LIMITATION OF THE TEST

1. Alcohol may interfere with the test result. It is not recommended to use the test after drinking.
2. Occasionally specimens containing less than 10 mIU/mL for urine also yield positive results.
3. A very early pregnancy containing an extremely low concentration of HCG can give negative result. In this case, another specimen should be obtained at least 48 hours later and tested.
4. HCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion or therapeutic abortion.
5. In cases where very high levels of hCG are present (>500,000mIU/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.
6. 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 from the user in 24-48 hours and retested.
7.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 a physician for final diagnosis of pregnancy before making any medical decisions.

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INDEX OF SYMBOLS

	Do not reuse	IVD	For in vitro diagnostic use only
	Stored between 2-30°C		Attention, see instruction for use
	Manufacturer	EC REP	Authorized Representative
LOT	Lot number		Use by
Σ	Contains sufficient for <n> tests	REF	Catalogue number

W.H.P.M Bioresearch & Technology Co., Ltd
No.2 Zhongxin Street, LouZiZhuang, Jinzhanxiang,
Chaoyang District, Beijing, 100018 P.R. China
Tel: 0086-10-84391888, 84319330
Fax: 0086-10-84391888-117
Email: customerservice@ whpm.com.cn
Website: www.whpm.com.cn

EC REP
Medical Device Safety Service Gmbh
Schiffgraben 41,30175 Hannover Germany
Tel: +49-511-62628630
Fax: +49-511-62628633
Email: info@mdss.com
Website: www.mdss.com

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