## INDEX OF SYMBOLS

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


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Effective Date: 11/12/2020

PN: Y031117970 1

# One Step®

## Pregnancy Test ( strip )

*For self-testing and In Vitro diagnostic use only*

CE 0197

ENGLISH

## INTENDED USE

The One Step Pregnancy test is an immunoassay 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 10mIU/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 10mIU/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 test per foil pouch. Ingredients: colloidal gold coated with goat anti mouse, mouse anti-α hCG antibody and mouse anti- β hCG antibody.

## MATERIALS

**Materials provided**

1. One Step Pregnancy test strip
2. Desiccant
3. Package insert

**Materials required but not provided**

1. Timer
2. Specimen collection container

## STORAGE AND STABILITY

Store test cassette at 2~ 30°C. The test is stable until the date imprinted on the pouch label.
Do the test immediately when you open the pouch. DO NOT FREEZE.

## 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. 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 strip from the foil wrapper .

2) Immerse the strip vertically (as pictured below) into the urine sample for at least 15 seconds, making sure the arrows are pointing downwards. Do NOT allow the urine to go above the MAX level line. Remove the strip from the urine and place the strip on a clean and dry surface.

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

4) Discard the test device after single use in an appropriate place.

## 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 both 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 cassette. 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 normal male urine to obtain different concentrations (0mIU/mL, 5 mIU/mL, 10 mIU/mL, 25mIU/mL ) . Test 10 samples at each concentration for every batch . All samples were positive at 10 mIU/mL. It indicates that the One•Step Pregnancy Test's analytical sensitivity is no more than 10 mIU/mL.

**Analytic Specificity:** The test results show negative for the 500mIU/mL hLH, 1000mIU/mL hFSH and 1mIU/mL hTSH samples.

### 2. ACCURACY

4057 clinical samples were tested at Beijing Tiantan hospital, Tianjin Medical Examination Center, 301 Hospital, Renmin Hospital and National Family Planning Institute, The results shows that the accuracy of the One•Step Pregnancy Test is more than 99.9%.

### 3. REPEATABILITY

HCG standard solution was calibrated against WHO 4th international standard added to normal male urine to achieve concentrations at 0 mIU/mL, 10 mIU/mL, 25mIU/mL, 37.5mIU/mL and 50 mIU/mL. Each specimen, at each concentration of analyte, was tested four times daily, in duplicate, for five consecutive days. A total of 40 samples at each concentration were tested. 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% |
| 5 | 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

HCG standard solution calibrated against WHO 4th international standard was added to normal male urine to achieve concentrations at 0 mIU/mL, 10 mIU/mL, 25mIU/mL, 37.5mIU/mL and 50 mIU/mL. Test sample from three lots were obtained and each specimen, at each concentration of analyte, was tested four times daily, in duplicate. A total of 120 samples were tested. 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% |
| 5 | 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 | 16 | 32 | 16 | 32 | 16 | 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 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(mg/dL) |
|---|---|
| Acetaminophen | 100 |
| Acetylsalicylic Acid | 100 |
| Ascorbic Acid | 100 |
| Atropine | 100 |
| Caffeine | 100 |
| Gentesic Acid | 100 |
| Glucose | 100 |
| Hemoglobin | 100 |
| Ampicillin | 100 |
| Tetracycline | 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 a 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

## REFERENCES


1. L.A. Cole. Hyperglycosylated hCG Original Research Article Placenta, Volume 28, Issue 10, October 2007, Pages 977-986.
2. Batzer, F.R. Fertility & Sterility, Vol 34, 1 1980.
3. Catt, K.J. Dufan, M.L. and vaitukaitis, J.L. J. Clin. Endocrinol Metab., Vol. 40,537, 1975.
4. Braunstein, G.D., Rasor, J., Alder, D., Danzer H., Wade, M.E. Am. J. Obster. Gynecol., Vo. 126,678,1976
5. Lenton, E.A., Neal L.M., Sulaiman, R. Fertility and Sterility, Vol. 37,773, 1982.
6. Dawood, M.Y., Sexeba, B.B., and Lanesman, R. Ob. Gyn. Vol. 126, 678, 1976.
7. Braustein, G.D., et Al. AM. Inter. Med. Vol. 78, pp. 419-439, 1980.
8. Uotila, M., Ruoslahti, E. And Engvall, H.J. Immunol. Methods, Vol. 42, 11, 1981
C. Galfre, S.C. Howe, C. Milstein, G.N. Butcher, and J. C. Howard, Nature 266, 550, 1977.
9. M.N. Iscove and F. Melchers, J. Exp Med. 147, 923, 1978.
10. P.L., Ey, et. AL, Immunochemistry 15, 429, 1978