INTRODUCTION:

Ovulation is the release of an egg from the ovary. The egg then passes into the fallopian tube where it is ready to be fertilized. A baby is conceived when the male sperm successfully fertilizes the female egg. When a woman is about to ovulate, her body releases a large amount of a hormone called L.H. (Luteinising Hormone). L.H. is always present in your urine but the levels increase (surge) in the middle of your cycle, causing you to release an egg from the ovary.

INTENDED USE:

The One Step Ovulation Test is an immunochromatographic in-vitro assay for the qualitative and semi-quantitative determination of the human luteinizing hormone (LH) in urine to predict the time of ovulation in women. The test detects the sharp increase in LH concentration in urine, the so called “LH surge” which precedes ovulation. Conception is most likely to occur within 36 hours following the LH surge.

CONTENTS:

Each pouch contains one immunochromatographic test. Each test contains a membrane with anti-LH antibodies and conjugates, in a stabilizing matrix containing proteins and sodium azide.

STORAGE AND STABILITY:

Store below 30°C; do not freeze.

LIMITATIONS:

- The One Step Ovulation Test is for in vitro diagnostic use only.
- Elevated concentrations of Human Chorionic Gonadotropin (HCG) interfere with LH testing. Do not test samples from pregnant women and people with pathologic conditions causing higher HCG levels.
- The One Step Ovulation Test is not designed to prevent conception. As sperm can survive for 72 hours you might still become pregnant if you had intercourse before you detected your L.H. surge.

WHEN TO BEGIN TESTING:

First, you must determine the length of your menstrual cycle. This is the number of days from the first day of your menstrual bleeding to the day before your next bleeding begins again, count the first day of bleeding as day 1. Calculate what the usual length of your menstrual cycle has been over the last few months. Once you have worked out the length of your cycle refer to the chart to determine on which day of your menstrual cycle you should begin testing.

<table>
<thead>
<tr>
<th>Your Cycle Length</th>
<th>Start To Test On</th>
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<tbody>
<tr>
<td>21 days</td>
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<td>40 days</td>
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Example:

If your cycle is normally 28 days, the cycle chart above indicates you should begin testing on Day 11. The calendar below shows you how to work out when day 11 is.

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SAMPLE CALENDAR

3 = The first day of menstrual bleeding (day 1)
13 = The day to begin ovulation testing (day 11)

NOTE:

If your cycle is shorter than 21 days or longer than 40 days, consult your doctor. If you do not know your cycle length, you may begin the test 11 days after your first period since the average cycle length is 28 days. Perform 1 test each day until the LH surge has been detected.
**SPECIMEN COLLECTION:**

Once you have identified what day you should begin testing you should then begin to collect your urine on a daily basis.

1. Do not use first morning urine samples as LH is synthesized in your body early in the morning. It will not show up in your urine until later in the day.
2. The best time to collect your urine is between 10am - 8pm. Pick a regular time that suits you best.
3. Collect urine at about the same time each day. Reduce liquid intake about 2 hours before collecting your urine as a diluted urine sample can prevent the test from detecting LH surge.

**BEFORE YOU BEGIN:**

1. Read the instructions thoroughly before you begin.
2. Do not open the foil pouch until you are ready to begin the test.
3. Make sure you have a watch, clock or timer ready.
4. Allow urine samples and test kit to reach room temperature before testing (approx 20 mins).

**TEST PROCEDURE:**

1. Determine the day to begin testing.
2. Collect urine sample in a clean and dry container.
3. To begin testing, open the sealed pouch and remove the strip. Do not remove the strip until you are ready to begin testing.
4. With the arrows pointing downwards towards the urine, place the test strip vertically (straight) into the urine sample, for at least 10 seconds. **DO NOT** allow the urine to go above the MAX level line.
5. Remove the strip from the urine and place on a clean, dry surface.
6. Wait for coloured bands to appear. Positive results may be visible within 1 minute but to confirm a negative result wait up to 10 minutes and until the background is clear. Results obtained after 10 minutes may be considered invalid.

**INTERPRETATION OF RESULTS:**

After each test, you must decide if you are having a L.H. surge.

To determine your result you must compare the colour intensity of the test band to the control band. The control band is used to compare the test band against and also confirms that you have completed the test correctly.

**Positive for L.H. surge**

If two colour bands are visible and the test band is of almost equal or greater colour intensity (darker) than the control band, this is a positive result and a good indication that the L.H. surge is occurring. You should ovulate within the next 24-36 hours. Sexual intercourse is advised at anytime after the first positive test.

**Negative for L.H. surge**

If two bands are visible but the test band is of a less intense colour (paler) than the control band or cannot be seen, this means the L.H. level is at or near its normal level and that the surge is not in progress. You should continue with daily testing.

**Invalid result**

If no control band appears within 5 minutes, the result is invalid and should be ignored. A visible control line is needed in all cases to confirm a proper test result. Repeat test with a new test kit.

**Interpretation of the symbols:**

- Storage temperature
- In vitro diagnostic device
- Read instructions before use
- Catalogue Number
- Number of tests in pouch
- Lot number
- Expiry date
- Manufacturer
- Do not reuse
- Manufacturer
- Catalogue Number
- Number of tests in pouch
- Lot number
- Expiry date
- Manufacturer
- Do not reuse

Nantong Egens Biotechnology Co., Ltd, Block A No.1b building No.1692, Xinghu Avenue Nantong Economy & Technology Development Zone Jiangsu Province P.R.China

Shanghai International Holding Corp. GmbH (Europe), Eiffestrasse 80, D-20537 Hamburg, Germany

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Version 1.0 23/07/15
One Step® Pregnancy Test

One Step HCG Urine Pregnancy Test (Strip)

INTENDED USE:
One Step HCG Urine Pregnancy Test measures the presence of the hormone Human Chorionic Gonadotrophin (HCG) in your 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. The further in to the pregnancy you are the higher the levels of HCG in your urine. 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 50mIU/ml with peak levels of 100,000 to 200,000mIU/ml seen at the end of the first trimester.

CONTENTS:
Each pouch contains:
1. One Step HCG Urine Pregnancy Strip Test.
2. Desiccant (Discard - Do not eat).
3. Package insert.

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:
FOR IN -VITRO DIAGNOSTIC USE ONLY
1. Read directions for use carefully before performing this test.
2. Do not use the test beyond the expiration date on the foil pouch.
3. Each test strip can only be used once; do not re-use the test strips. Discard each test after use.
4. Do not use if the foil pouch is damaged or has been opened.
5. Hold the test strip by the handle only.
6. Once the foil pouch has been opened, the test should be used immediately.
7. Treat urine samples and used tests as if they are potentially infectious. Avoid contact with skin.

TEST PROCEDURE:
1. WHEN CAN I CARRY OUT THE TEST?
You can take this pregnancy test from the first day you suspect you might be pregnant.

2. SPECIMEN COLLECTION AND HANDLING
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 test pouch and urine to room temperature. To begin testing, open the sealed pouch and remove the strip.
2. Place the test strip vertically (straight) into the urine sample for at least 10 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.
3. Remove the strip from the urine and place the strip on a clean, dry surface.
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. If the background is clear. Results obtained after 5 minutes may be considered invalid.
5. 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, 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 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: 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.
**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 on negative samples and a pink-purple coloured band in the "T" and "C" area on positive samples. The appearance of the CONTROL band indicates that the test strip is performing properly and serves as a procedural control.

**PERFORMANCE CHARACTERISTICS:**

**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 >99.5%.

**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 fibre 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 proceeds through 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"). All samples 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. All Fastest One Step HCG Urine Pregnancy Tests will display positive results with specimens containing HCG at the level close to or greater than 10mlU/ml or close to or greater than 25mlU/ml depending on which test you have purchased.

**REAGENTS:**
One Step HCG Urine Pregnancy Test strip 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:**
1. Alcohol may interfere with the test result. It is not recommended to use the test after drinking alcohol.
2. If you test too early HCG levels 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.
3. HCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion or therapeutic abortion.
4. 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.
5. 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.
6. 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.

**INTERPRETATION OF THE SYMBOLS:**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Storage temperature</td>
<td>Lot number</td>
</tr>
<tr>
<td>IVD</td>
<td>In vitro diagnostic device</td>
<td>Expiry date</td>
</tr>
<tr>
<td>I</td>
<td>Read instructions before use</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>REF</td>
<td>Catalogue Number</td>
<td>Do not reuse</td>
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<tr>
<td>σ</td>
<td>Number of Tests in Pouch</td>
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</tbody>
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