A rapid, one step test for the qualitative detection of human chorionic gonadotropin (HCG) in human serum or plasma.

For in vitro diagnostic use only.

PRODUCT NAME
One Step HCG Pregnancy Rapid Test Kit (Serum/Plasma)

INTENDED USE
The reagent is used to detect the HCG in serum/plasma qualitatively according to the principle of double antibody sandwich method.

Human chorionic gonadotropin (HCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization, including protein subunits of α and β. Its function is to stimulate the corpus luteum to continue producing progesterone, to maintain the endometrium suitable for embryo attachment and embryo implantation. In normal pregnancy, HCG can be produced as early as 4 to 5 days after conception, HCG levels continue to rise very rapidly until delivery, peaking in about 8-10 weeks into pregnancy, and fall to normal level 2 weeks after the delivery.

PRINCIPLE
The One Step HCG Pregnancy Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (HCG) in serum/plasma to aid in the early detection of pregnancy. The test utilizes antibodies including a monoclonal HCG-α antibody and goat anti-mouse IgG on the nitrocellulose membrane with colloidal gold marked anti-HCG-α monoclonal antibody as a mark tracer. The reagent is used to detect the HCG in serum/plasma according to the principle of double antibody sandwich method and gold immunochromatography assay.

There is a control line (C) controlling the reaction process shown on the coated film. Based on test line’s (T) appearance to determine whether the tested sample contains HCG (Human Chorionic Gonadotrophin) or not.

MAIN COMPONENTS
Basic components: Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board. Colloidal gold marked pad coated with HCG-α monoclonal antibody, nitrocellulose membrane coated with HCG-β monoclonal antibody, control line coated with goat anti-mouse IgG.

STORAGE AND EXPIRY
Store as packaged in the sealed pouch at 4°C to 30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

SAMPLE REQUIREMENTS
1. Serum: Use disposable syringe (vacuum blood collection tube) to extract a certain amount of venous blood, and place at room temperature for blood coagulation, take the supernatant after centrifugation of blood for detection.
2. Plasma: Use vacuum blood collection tube with anticoagulation to extract a certain amount of venous blood, and rock repeatedly, take plasma separation for detection.

TEST METHODS
1. Instruction for Use must be read carefully before taking the test. Allow the required test device to come to room temperature for 30 minutes (20°C~30°C) before use. Do not open the inner packaging (pouch) until ready, it must be used in one hour once opened (Humidity:20%~90%, Temp:10°C~50°C).
2. Test Procedure
Strip:
Remove the test strip from the sealed pouch, put the end of the test strip which printed with arrows into the samples, the interface of serum/plasma should not exceed the max line, take it out after 10 seconds and place the test cassette on a clean and level surface and then start the timer.
Observe the test results immediately within 5-7 minutes, the result is invalid over 7 minutes.

Cassette:
Collect the samples, remove the test cassette from the sealed pouch and place on a clean and level surface. Using the dropper, vertically transfer 2 full drops of serum/plasma (approx. 80~100μl) to the specimen well (S) of the test cassette avoiding the formation of bubbles and then start the timer.

Observe the test results immediately within 5-7 minutes, the result is invalid over 7 minutes.

INTERPRETATION OF RESULTS
POSITIVE: Two distinct red lines appear. A red line in the control region (C), and another red line in the test region (T). A pink to red line (T), even if it is very thin, indicates a positive result.
NEGATIVE: A red line appears in the control region (C). No line appears in the test region (T). (NOT PREGNANT)
INVALID: No red lines appear or control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the kit and contact your local distributor.

REFERENCE VALUE
The One Step HCG Pregnancy Rapid Test Kit (Serum/Plasma) has a sensitivity of 25mIU/mL.

LIMITATIONS
1. The reagent only can be used for screening tests, just like all qualitative detection reagents.
2. Concentration of HCG cannot be determined by this qualitative test.
3. This reagent is designed for the qualitative screening test. A confirmed pregnancy diagnosis should be made only by a physician after all clinical and laboratory findings have been evaluated.
4. False negative results may occur when the HCG levels of the ectopic pregnancy are below the sensitivity level of the test. When pregnancy is still suspected, a b-mode ultrasonograph diagnosis is suggested.
PERFORMANCE CHARACTERISTICS

1. Limit of detection: The limit of detection concentration of HCG test is not higher than 25mIU/ml.

2. Specificity

2.1 Negative specificity:

<table>
<thead>
<tr>
<th>Samples</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>500mIU/mL hLH, 0mIU/mL HCG</td>
<td>Negative</td>
</tr>
<tr>
<td>1000mIU/mL hFSH, 0mIU/mL HCG</td>
<td>Negative</td>
</tr>
<tr>
<td>1000mIU/mL hTSH, 0mIU/mL HCG</td>
<td>Negative</td>
</tr>
</tbody>
</table>

2.2 Positive specificity:

<table>
<thead>
<tr>
<th>Samples</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>500mIU/mL hLH, 25mIU/mL HCG</td>
<td>Positive</td>
</tr>
<tr>
<td>1000mIU/mL hFSH, 25mIU/mL HCG</td>
<td>Positive</td>
</tr>
<tr>
<td>1000mIU/mL hTSH, 25mIU/mL HCG</td>
<td>Positive</td>
</tr>
</tbody>
</table>

3. Diagnostic specificity and sensitivity

A clinical evaluation was conducted on 230 specimens (including 80 positive specimens and 150 negative specimens) comparing the results obtained using HCG test kits of HIGHTOP and other commercially available HCG tests. The results are as follows:

<table>
<thead>
<tr>
<th>Positive specimens</th>
<th>80</th>
<th>HCG test kits of MR</th>
<th>HCG test kits of control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>80/80(100%)</td>
<td>80/80(100%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Negative specimens</th>
<th>150</th>
<th>HCG test kits of MR</th>
<th>HCG test kits of control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>150/150(100%)</td>
<td>150/150(100%)</td>
</tr>
</tbody>
</table>

4. Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the 25mIU/mL of HCG standards by 10 kits of the same batch.

5. Lot tolerance: Detecting with three different batches HCG test kits, the results should all meet the requirements of repeatability.

6. Analytical sensitivity: Chyluria proteinuria, hematuria, bilirubinuria and proteinuria has no effect on the detection results, however injection or oral administration of human chorionic gonadotropin may affect the detection results.

7. Hook effect: When the concentration of HCG exceeds 50000mIU/ml, the detection result may be negative due to the hook effect and should be diluted and test again.

ATTENTIONS

1. The test line is significant when the concentration of HCG is high, and the control line maybe weak. It is a normal phenomenon.

2. A number of conditions other than pregnancy, including uterine cancer, hydatidiform mole or menopause, cause elevated levels of HCG and positive result.

3. If ectopic or abnormal pregnancy is still suspected, a confirmed pregnancy diagnosis should be made by other methods.

4. Reagents should be used as soon as possible after opened. This reagent cannot be reused for disposable.

5. The test device should remain in the sealed pouches until use. If sealing problem happens, do not test. Don’t use after the expiration date.

6. A small bag of desiccant is in the aluminum foil bag, do not eat.

7. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.

BIBLIOGRAPHY


INSTRUCTIONS OF SYMBOL

Consult instruction for use
Keep dry
Store between
LOT
Batch number