INTRODUCCIÓN

Human chorionic gonadotropin (hCG) is a hormone produced by the placenta of pregnant women and detectable both in the urine and in the serum 7 to 10 days after conception and is therefore an ideal pregnancy detector.

PROPOSED USE

A quick pregnancy test based on the detection of Human Chorionic Gonadotropin (hCG) in urine.

The test is used only for obtaining preliminary results. In all cases, results should be interpreted by a professional especially in case of positive results. In order to confirm analytical results, a more specific alternate method is required.

FUNDAMENT OF THE METHOD

Human chorionic gonadotropin (hCG) Strips is a lateral flow chromatography immunoassay. The method is based on a unique combination of monoclonal antibody-colorant conjugate and solid phase polyclonal antibodies for selectively identifying the presence of hCG in the sample with high degree of sensitivity. In less than 5 minutes, it is possible to detect hCG levels as low as 25 UI/L.

When a certain amount of the sample is added to the adsorbent portion, it migrates across the strip through capillarity. The monoclonal antibody-colorant conjugate binds with hCG forming an antibody–antigen complex. This complex binds with the anti-hCG antibody in the positive portion of the strip resulting in a pink band when the hCG concentration in the reaction zone is over 25 UI/L. Bands will not form in the positive reaction zone of the strip there is no hCG in the sample. The reaction continues throughout the strip until it reaches the control area. Conjugates that are still free will bind with the reagents in the control zone, forming a pink band, thus indicating that the pregnancy test is working correctly.

REAGENTS

hCG Strips: 50 strips

STABILITY AND PRESERVATION

The product will remain stable until the date of expiry indicated on the label when stored in a moisture-free environment at 15-30 ºC.

IMPORTANT: Do not leave the container with the strips open. Make sure the container is closed after every use.

TAKING THE SAMPLE

1- For an optimum detection of early pregnancy, urine from the first micturition should be collected in the morning, as it contains maximum hCG concentration. However, samples can be collected randomly.

2- Collect urine in a clean container.

3- Samples should be refrigerated (2-8 ºC) or kept in a cool environment if they will not be used immediately (below 25 ºC) up to 24 hours. Allow the sample to stand at room temperature before conducting the test.

4- Freeze the sample if the test cannot be carried out before 24 hours. However, before conducting the test, the sample must be thawed, homogenized and allowed to stand at room temperature. Avoid repeated freezing and thawing.

PROCEDURE

1- Allow the sample and other materials to reach room temperature before conducting the test.

2- Identify each of the strips with data pertaining to the sample.

3- Transfer 0.5 ml of the sample to a small tube or flask.
4- Introduce the hCG strip vertically in the urine sample for 5 seconds. Avoid introducing the strips beyond the red mark. If the level of the sample in the tube is less than 1.5 cm, leave the strip in the tube until the reaction has concluded.

5- Place the strip on a clean, flat dry surface.

6- Read the results after 3–5 minutes.

DO NOT INTERPRET RESULTS AFTER 10 MINUTES.

LIMITATIONS OF THE METHOD

1- The test is for professional “in vitro” use only.

2- Qualitative results obtained with this test are preliminary and should not be considered conclusive. Positive results should be confirmed with a more specific test.

3- The presence of hCG has been detected in patients with gestational and non-gestational trophoblastic disease. As hCG levels in trophoblastic cancer are similar to that detected during pregnancy, these conditions, including choriocarcinoma and hydatiform mola should be discarded before conducting a pregnancy test.

4- A normal pregnancy cannot be distinguished from an ectopic pregnancy based solely on hCG levels. Furthermore, spontaneous miscarriage may create confusion when interpreting results.

5- hCG levels can be detected in normal secretions, secretions due to caesarean section, spontaneous miscarriages or therapeutic abortions for several weeks.

6- The presence of dihidroxiethyl-cellulose in the lubricant applied to catheters can lead to false positives in concentrations equal to or over 0.1%.

QUALITY CONTROL

Internal quality control
The test has an internal quality control procedure: called the control band. Its presence indicates that the right volume of the sample has been used and that the reagents have migrated correctly. If the control band does not appear, the test is not valid.

External quality control
Users must follow quality control standards of each locality, region or country.

INTERPRETATION

Negative: Only a perpendicular RED line is visible in the upper white zone of the strip (control band).

Positive: Besides a RED perpendicular band (control), a second RED perpendicular band is visible in the central white zone of the strip.

Not valid: If there are no colored bands visible. This is an indication that the test should be repeated using a new strip.

FUNCTIONAL CHARACTERISTICS

1- Accuracy
A study was conducted on a total of 150 positive and negative urine samples. The samples were tested, in keeping with the relevant procedures, on hCG strips and Tandem II test.

<table>
<thead>
<tr>
<th></th>
<th>hCG strips</th>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Hybritech</td>
<td>90</td>
<td>0</td>
<td>90</td>
</tr>
<tr>
<td>Tandem II</td>
<td>0</td>
<td>60</td>
<td>60</td>
</tr>
<tr>
<td>Total</td>
<td>90</td>
<td>60</td>
<td>150</td>
</tr>
</tbody>
</table>

Results show good a correlation between both diagnostic tests.

An accuracy test was conducted for the purpose of determining the qualitative recovery of known quantities of chorionic gonadotropin added to pools of negative urine.

<table>
<thead>
<tr>
<th>hCG Concentration in the urine pool (UI/L)</th>
<th>Expected</th>
<th>Observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>25</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>50</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>100</td>
<td>Positive</td>
<td>Positive</td>
</tr>
</tbody>
</table>
2- Reproducibility

During the assay
Accuracy was determined using 5 replicas of 5 samples containing 0, 10, 25, 5000 and 500 000 IU/l. Positive and negative values were correctly identified in 100 % of the cases.

Between assays
The same 5 samples were used with three different production batches. Positive and negative values were identified in 100 % of the cases.

3- Specificity

Crossed reactions:
The following concentrations of hCG homologous hormones did not interfere with the hCG strip diagnostic kit.

<table>
<thead>
<tr>
<th>Hormone</th>
<th>Concentration</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSH</td>
<td>1000 mUI/L</td>
<td>WHO 68/38</td>
</tr>
<tr>
<td>hLH</td>
<td>500 UI/L</td>
<td>WHO 2nd IS 80/552</td>
</tr>
<tr>
<td>hFSH</td>
<td>1000 UI/L</td>
<td>WHO 1st IS 83/575</td>
</tr>
</tbody>
</table>

4- Sensitivity

1- hCG strips can detect 25 IU/l levels of hCG.

2- Urine samples with hCG levels (1 000 000 IU/l) are systematically positive.

3- The urine of healthy men and of non-pregnant women exhibit non-detectable levels of hCG.

hCG strips can confirm pregnancy since the first day of delay of a woman’s menstrual period.

PRECAUTIONS

1- Do not open the container until the moment of performing the test.

2- Handle all the samples and materials as potentially infectious.

REFERENECES


PRESENTATION

Code: 1501130 50 strips