HC-G111
Human Chorionic Gonadotropin
Rapid Test Strip (Urine)

INTENDED USE
The HC-G111 Rapid Test Strip (Urine) is a rapid visual immunoassay for the qualitative, presumptive detection of human chorionic gonadotropin in human urine specimens. This kit is intended for use as an aid in the early detection of pregnancy.

INTRODUCTION
Human chorionic gonadotropin (hCG), a glycoprotein hormone secreted by viable placental tissue during pregnancy, is excreted in urine approximately 20 days after the last menstrual period. hCG levels rise rapidly, reaching peak levels after 60-80 days. The appearance of hCG in urine soon after conception and its rapid rise in concentration makes it an ideal marker for the early detection and confirmation of pregnancy. Levels of hCG are highest in the first trimester and approach normal levels in the second trimester. hCG levels are frequently associated with trophoblastic and non-trophoblastic neoplasms and hence these conditions should be considered before a diagnosis of pregnancy can be made.

PROCEDURE
Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch and use it as soon as possible. For best results, the assay should be performed within one hour.
2. Hold the strip by the end, where the product name is printed. To avoid contamination, do not touch the strip membrane.
3. Holding the strip vertically, dip the test strip in the urine specimen for at least 10-15 seconds. Do not immerse past the maximum (MAX) on the test strip.
4. Arise (T) will appear on the strip, color will appear in the control region (C) membrane.
5. After the test has finished running, flush the strip from the specimen and place it on a non-absorbent flat surface. Start the timer and wait for the colored bands to appear. The result should be read at 3 minutes. Do not interpret the result after 10 minutes.

NOTE: Low hCG concentrations may produce very weak test bands (T) after a prolonged period of time. Therefore, do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears in the control region (C). No colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:
1. The intensity of color of the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive; note that the appearance of a positive control does not determine the concentration of analytes in the specimen.
2. Inefficient specimen volume, incorrect operating procedure or performing expired tests are the most likely reasons for control band failure.

STORAGE AND STABILITY

• The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
• The test must remain in the sealed pouch until use.
• Do not freeze.
• Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIFICITY
The specificity of the HC-G111 Rapid Test (Urine) was determined in cross-reactivity studies with known amounts of Lubricating Hormone (LH), Follicle Stimulating Hormone (FSH) and Thyroid Stimulating Hormone (TSH). 300 mIU/mL LH, 1000 mIU/mL FSH and 1000 mIU/mL TSH all produced negative results.

INTERFERENCE TESTING
The following substances were added to MCG-free urine and urine samples spiked with 200mIU/mL MCG
None of the substances interfered with the assay at the listed concentrations.

LIMITATIONS
1. The HC-G111 Rapid Test Strip (Urine) has a sensitivity of 25 mIU/mL for urine and is capable of detecting pregnancy early as 1 day after the first missed menses. Test results which appear as very light bands in the test region are not definitive for the diagnosis of pregnancy. It is strongly recommended that an additional urine specimen be obtained after 48-72 hours and tested. Patients suspected to be pregnant after negative test results should be re-tested with first morning specimens obtained 48-72 hours later.

Table: Other MCG Rapid Test

<table>
<thead>
<tr>
<th>Relative Sensitivity</th>
<th>Relative Specificity</th>
<th>Overall Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;99.9% (97.8-99.9%)</td>
<td>&gt;99.9% (99.9-100.0%)</td>
<td>&gt;99.9% (97.9-99.9%)</td>
</tr>
<tr>
<td>% Confidence Interval</td>
<td>66 0 66</td>
<td></td>
</tr>
<tr>
<td>MCG</td>
<td>Test Device</td>
<td></td>
</tr>
<tr>
<td>66</td>
<td>142 142</td>
<td></td>
</tr>
<tr>
<td>66 208</td>
<td></td>
<td></td>
</tr>
<tr>
<td>142</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

REFERENCES

Glossary of symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>Control</td>
</tr>
<tr>
<td>T</td>
<td>Test</td>
</tr>
<tr>
<td>MB</td>
<td>MB isoenzyme</td>
</tr>
</tbody>
</table>

Number: 11100002781
REV: 2/Effective date: 2015-03-11

Page 1/1