One Step Pregnancy Test Device (Urine/Serum)

Pregnancy Test Device (Urine/Serum)

INTENDED USE

The ComfiTest™ hCG One Step Pregnancy Test Device (Urine/Serum) is a rapid chromatographic immunoassay for the presumptive detection of human chorionic gonadotropin in urine or serum to aid in the early detection of pregnancy.

SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception. hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period, and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both the urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

The ComfiTest™ hCG One Step Pregnancy Test Device (Urine/Serum) is a rapid test that qualitatively detects the presence of hCG in urine or serum specimens at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyvalent antibodies to detect elevated levels of hCG in urine or serum specimens, and both assays identified 88 negative and 71 positive results. The serum study demonstrated a >99% overall accuracy of The ComfiTest™ hCG One Step Pregnancy Test Device (Urine/Serum) compared to the other urine/serum membrane hCG test.

INTERPRETATION OF RESULTS

(See the illustration above)

POSITIVE: Two distinct coloured lines appear. One line should be in the control line region (C) and another line should be in the test line region (T). This result indicates the presence of hCG in the test sample. *NOTE: The intensity of the colour in the test line region (T) may vary depending on the concentration of hCG in the sample. Therefore, any shade of colour in the test line region (T) should be considered positive.

NEGATIVE: One coloured line appears in the control line region (C). No apparent coloured line appears in the test line region (T).

QUALITY CONTROL

A procedural control is included in the test. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural techniques. A clear background is an internal negative procedural control. If a background colour appears in the result window and interferes with the ability to read the test result, the result may be invalid. It is recommended that a positive hCG control (containing 25-250 mIU/mL hCG) and a negative hCG control (containing 0 mIU/mL hCG) be evaluated to verify proper test performance when a new shipment arrives.

LIMITATIONS

1. The ComfiTest™ hCG One Step Pregnancy Test Device (Urine/Serum) is a preliminary qualitative test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.

2. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. The test is not expected, a first morning urine specimen should be collected 48 hours later and tested.

3. Very low levels of hCG (less than 50 mIU/mL) are present in urine and serum specimens during the first week of pregnancy. Therefore, the number of first trimester pregnancies terminates for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning urine or serum specimen collected on the day of the day the test was performed. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle before a new specimen is tested.

4. This test may produce false positive results. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumours, prostate cancer, breast cancer, and lung cancer, can elevate levels of hCG.

5. This test may produce false negative results. False negative results may occur when the levels of hCG are low the sensitivity level of the test, or a premenopausal woman may be used. Urine specimens should be thawed and mixed before testing.

6. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received therapy for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.

This test provides presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals. The ComfiTest™ hCG One Step Pregnancy Test Device (Urine/Serum) has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

A multi-center clinical evaluation was performed comparing the results obtained using The ComfiTest™ hCG One Step Pregnancy Test Device (Urine/Serum) and another commercially available urine/serum membrane hCG test. The urine study included 159 specimens that were both urine and serum specimen tested. The results demonstrated a >99% overall accuracy of The ComfiTest™ hCG One Step Pregnancy Test Device (Urine/Serum) compared to the other urine/serum membrane hCG test.

Table: hCG Reference Method (Urine)

<table>
<thead>
<tr>
<th>Method</th>
<th>Other hCG Rapid Test</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>hCG Test Device</td>
<td>Results</td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>71</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>51</td>
</tr>
<tr>
<td>Total Results</td>
<td>71</td>
<td>88</td>
</tr>
</tbody>
</table>

Sensitivity: 100% (95%-100%) Specificity: 100% (95%-100%) Accuracy: 100% (95%-100%) * 95% Confidence Intervals

Table: hCG Reference Method (Urine/Serum)

<table>
<thead>
<tr>
<th>Method</th>
<th>Other hCG Rapid Test</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>hCG Test Device</td>
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<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
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<td>0</td>
</tr>
<tr>
<td>Negative</td>
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<td>21</td>
</tr>
<tr>
<td>Total Results</td>
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<td>21</td>
</tr>
</tbody>
</table>

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BIBLIOGRAPHY


For in vitro diagnostic use only

ComfiTest

Material Required But Not Provided

Materials Provided

Test devices

Materials Required But Not Provided

Dropers

Package insert

Urine or serum specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

• Test devices

• Materials Provided

• Dropers

• Package insert

• Specimen collection container

• Timer

BIBLIOGRAPHY


For in vitro diagnostic use only

Tests per kit

Manufacturer

Lot Number

Store between 2-30°C

REF

Catalog #

Number: 115983101

Effective date: 2010-xx-xx