The McKesson hCG Urine Test – Cassette has a sensitivity of 25 mIU/mL. The test utilizes a combination of anti-β hCG antibodies to selectively detect elevated levels of hCG. This assay is intended to be used for the qualitative detection of hCG in urine specimen at concentrations ≥ 25 mIU/mL hCG in urine.) and a negative hCG control (containing “0” background in the result area should be white to light pink and not

**Performance Characteristic**

<table>
<thead>
<tr>
<th>Sensitivity and Specificity</th>
</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>

**Materials Provided**

- Specimen collection container
- Test cassette
- Test solution
- Control solution
- Pipette
- timer

**Interpretation of Results**

**POSITIVE**: Two distinct red lines appear . One line should be in the control region (C) and another line should be in the test region (T). 

**NEGATIVE**: One red line appears in the control region (C). 

**INDETERMINATE**: Neither a red line appears in the control region (C) nor a line appears in the test region (T).*NOTE:* A sample hCG concentration below the cut-off level of this test should also be included in the assay (e.g., a patient with a serum hCG concentration of 5 ng/mL) to ensure the test results are valid.

**BIBLIOGRAPHY**


**Functionality**

1. Very dilute urine specimens, as indicated by a low specific gravity. Specimens exhibiting a specific gravity of 1.000 or less are recommended not be used.
2. Very low levels of hCG (less than 50 mIU/mL) are present in urine specimens exhibiting a specific gravity of 1.000 or less.
3. Urine specimens exhibiting a visible precipitate should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

**US**: Distributed By McKesson Medical-Surgical Inc.

**Quality Control**

- Special procedural controls are included in the test kit. A visually negative result in the control line of the test cassette should not be interpreted as indicating a negative test result. 
- It is recommended that a positive hCG control (containing 25 mIU/mL hCG) be included in each test run. 

**Interfering Substances**

- The following potentially interfering substances were added to the hormone hCG specimens and did not affect the results obtained using the McKesson hCG Urine Test – Cassette.

**LIMITATIONS**

- It is recommended that a positive hCG control (containing 25 mIU/mL hCG) be included in each test run. 
- The test cassette should be disposed of in a proper container after testing.

**Sensitivity and Specificity**

- Sensitivity and Specificity: The McKesson hCG Urine Test – Cassette results obtained using the McKesson hCG Urine Test – Cassette show a sensitivity and specificity of >99% when compared to an in vitro immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine specimen.

**BIBLIOGRAPHY**

- None of the substances at the concentration tested interfered in the assay.

**Expected Values**

- Human chorionic gonadotropin (hCG) specimens showed no cross-reactivity with hFSH, hLH and hTSH at high physiological levels.

**BIBLIOGRAPHY**

- The McKesson hCG Urine Test – Cassette was developed with the qualitative detection of hCG in urine specimen at concentrations ≥ 25 mIU/mL hCG in urine.) and a negative hCG control (containing “0” background in the result area should be white to light pink and not

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