DIRECTIONS FOR USE
Allow the test strip, urine specimen and/or controls to equilibrate to room temperature (15-30°C/59-86°F) prior to testing.

1. Remove the test strip from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 5 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The result should be read at 3 minutes. It is important that the background is clear before the result is read.

INTERPRETATION OF RESULTS
(Please refer to the illustration above)

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). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

*NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.
QUALITY CONTROL
Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

It is recommended that a positive hCG control (containing ≥25 mIU/mL hCG) and a negative hCG control (containing 0 mIU/mL hCG) be evaluated to verify proper test performance. It is recommended that federal, state, and local guidelines be followed.

LIMITATIONS
1. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
2. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, 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 specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
4. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. This test provides a 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 One Step+ hCG Urine Strip Test 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

Accuracy
A multi-center clinical evaluation was conducted comparing the results obtained using the One Step+ hCG Urine Strip Test to another commercially available urine membrane hCG test. The study included 150 urine specimens; both assays identified 72 negative and 78 positive results. The results demonstrated 100% overall agreement (for an accuracy of >99%) of the One Step+ hCG Urine Strip Test when compared to the other urine membrane hCG test.

Sensitivity and Specificity
The One Step+ hCG Urine Strip Test detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

Interfering Substances
The following potentially interfering substances were added to hCG negative and positive specimens.

All substances listed in mg/dL unless otherwise noted.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>20</td>
</tr>
<tr>
<td>Acetone</td>
<td>1,000</td>
</tr>
<tr>
<td>Acetylsalicylic Acid</td>
<td>20</td>
</tr>
<tr>
<td>Acetooacetic Acid</td>
<td>2,000</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>20</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>20</td>
</tr>
<tr>
<td>Albumin</td>
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<tr>
<td>β-Hydroxybutyrate salt</td>
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</tr>
<tr>
<td>Benzoylcegonine</td>
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</tr>
<tr>
<td>Bilirubin</td>
<td>20</td>
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<tr>
<td>Brompheniramine</td>
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<tr>
<td>Caffeine</td>
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<tr>
<td>Cannabinol</td>
<td>10</td>
</tr>
<tr>
<td>Chlomiphene</td>
<td>100</td>
</tr>
</tbody>
</table>

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

BIBLIOGRAPHY

RE-ORDER
No. 9004072 (25 Tests)
One Step+ is a registered trademark of Henry Schein Inc.
Distributed by:
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Melville, NY 11747 USA

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