Materials Required But Not Provided
- Specimen collection container
- Timer

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

1. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface. Hold the pipette vertically and transfer 3 full drops of urine (approx. 100 μL) to the specimen well of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.
3. 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.

Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.

PRINCIPLE
The One Step+ hCG Urine Cassette Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The assay is conducted by adding a urine specimen to the specimen well of the test cassette and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

REAGENTS
The test cassette contains anti-hCG particles and anti-hCG coated on the membrane.

PRECAUTIONS
- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test cassette should be discarded in a proper biohazard container after testing.

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 One Step+ hCG Urine Cassette Test is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the One Step+ hCG Urine Cassette Test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

MATERIALS
Materials Provided
- Test cassettes
- Disposable pipettes
- Instructional insert

SPECIMEN COLLECTION AND PREPARATION
A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage
Urine specimens may be stored at 2-8°C (36-46°F) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C (-4°F). Frozen specimens should be thawed and mixed before testing.

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 cassette. 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
Benzoylecgonine 10  Methamphetamine 10
Bilirubin 20  Methanol 10%
Caffeine 20  Oxalic Acid 40
Cannabidiol 10  Phenothiazine 20
Chlorophenyl 100  Phenylpropanolamine 20
Cocaine 10  Pregnenolone 2
Codeine 10  Salicylic Acid 20
Cholesterol 500  Tetracycline 20
Creatine 20  Triglycerides 1,200
Dextromethorphan 20  Theophylline 20
DMSO 5%  Urea 2,000
Diphenhydramine 20  Uric Acid 20
Ephedrine 20

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 Cassette 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 Cassette Test to another commercially available urine membrane hCG test. The study included 159 urine specimens: both assays identified 88 negative and 71 positive results. The results demonstrated a 100% overall agreement (for an accuracy of >99%) of the One Step+ hCG Urine Cassette Test when compared to the other urine membrane hCG test.

Sensitivity and Specificity
The One Step+ hCG Urine Cassette 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.

RE-ORDER
No. 9004073 (25 Tests) Distributed by: HENRY SCHEIN INC.
No. 9004074 (100 Tests) Melville, NY 11747 USA
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For Technical Assistance, call 1-800-637-3717

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