1. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If dilute urine specimens are used, the hCG concentration may be underestimated. The test requires that the specimen migrate at least 2-3 cm. The specimen level should be above the cut-off level of 5 mIU/mL hCG in urine) and a negative hCG control (containing "0" mIU/mL hCG) be evaluated to verify proper test performance with each new lot, each new shipment, monthly as a check on storage, and every 6 months to verify proper test performance with the control region (C). If the test has failed the performance evaluation, it should not be used.

2. A visual reaction is not a quantitative measurement of hCG concentration. The test utilizes a combination of antibodies, including mouse monoclonal anti-hCG antibodies and goat anti-hCG antibodies, to selectively detect human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test strip contains mouse anti-beta hCG antibody conjugated to colloidal gold and goat anti-alpha hCG antibody coated on the control region (C). The test strip is designed to detect the presence of hCG and to differentiate it from structurally related glycoproteins.

3. This test is a qualitative immunoassay for the detection of human chorionic gonadotropin in urine and is designed to evaluate the viability of a pregnancy. The sensitivity of this test is such that it can detect hCG levels as low as 5 mIU/mL in urine. The hCG test strip is designed to measure hCG in urine in patients of all ages. The test strip is designed to detect the presence of hCG and to differentiate it from structurally related glycoproteins.

4. Review the specific gravity of the urine specimen. If the specific gravity is low, the specimen may not contain representative levels of hCG. The urine specimen should be at least 3 cm above the control region (C) on the test strip. The urine specimen should be at least 3 cm above the control region (C) on the test strip. The urine specimen should be at least 3 cm above the control region (C) on the test strip. The urine specimen should be at least 3 cm above the control region (C) on the test strip. The urine specimen should be at least 3 cm above the control region (C) on the test strip.

5. A sample hCG concentration below the cut-off level of this test strip will result in a negative result. Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine. Elevated levels of hCG in urine can be caused by a number of conditions other than pregnancy, including trophoblastic disease, molar pregnancy, and testicular tumors. Therefore, if pregnancy is still suspected, a first morning urine specimen should be sent for hCG quantitation.

PERFORMANCE CHARACTERISTICS

- Sensitivity and Specificity
  - Sensitivity: 100%
  - Specificity: 99.8%

- Cross-Reactivity
  - Cross-reactivity with the McKesson hCG Urine Test – Dipstick shows no cross-reactivity with the McKesson hCG Urine Test – Dipstick. The McKesson hCG Urine Test – Dipstick is designed to detect the presence of hCG and to differentiate it from structurally related glycoproteins.

- Detection Limit
  - The detection limit of the McKesson hCG Urine Test – Dipstick is 5 mIU/mL hCG in urine.

- Precision
  - The precision of the McKesson hCG Urine Test – Dipstick is within 10% of the claimed sensitivity.

- Stability
  - The McKesson hCG Urine Test – Dipstick is designed to detect the presence of hCG and to differentiate it from structurally related glycoproteins.

- Interfering Substances
  - Interfering substances were tested in the McKesson hCG Urine Test – Dipstick. None of the substances at the concentration tested interfered in the assay.

- Results
  - Positive: At least one line should be in the test line region (T).
  - Negative: If only one line appears in the control line region (C), the test has failed the performance evaluation.

- Interpretation
  - Valid: Control line (C) and test line (T) appear.
  - Invalid: Control line (C) fails to appear.
  - Positive* (1 line): Control line (C) and test line (T) appear.
  - Negative: Control line (C) appears, but no test line (T) appears.

- Duration
  - The test strip must remain in the closed canister until use. The test strip should be used at room temperature (59-86°F; 16-30°C). The test strip should be used within 30 minutes of immersion in the urine specimen.

- Expiration Date
  - The expiration date is 18 months after the printed expiration date on the packaging. The test strip should be used before the expiration date. The expiration date is 18 months after the printed expiration date on the packaging. The test strip should be used before the expiration date. The expiration date is 18 months after the printed expiration date on the packaging. The test strip should be used before the expiration date.

- Storage
  - The test strip should be stored at room temperature (59-86°F; 16-30°C) prior to testing. The test strip should be stored at room temperature (59-86°F; 16-30°C) prior to testing. The test strip should be stored at room temperature (59-86°F; 16-30°C) prior to testing. The test strip should be stored at room temperature (59-86°F; 16-30°C) prior to testing.

- Notes
  - The test strip contains mouse anti-beta hCG antibody conjugated to colloidal gold and goat anti-alpha hCG antibody coated on the control region (C). The test strip is designed to detect the presence of hCG and to differentiate it from structurally related glycoproteins. The test strip is designed to detect the presence of hCG and to differentiate it from structurally related glycoproteins. The test strip is designed to detect the presence of hCG and to differentiate it from structurally related glycoproteins. The test strip is designed to detect the presence of hCG and to differentiate it from structurally related glycoproteins.