when compared to the other urine membrane hCG test.

Sensitivity and specificity: The McKesson Consult® Diagnostics hCG Urine Cassette detects hCG at concentrations of 20 mIU/mL or greater in urine. The test has been standardized to the W.H.O. Fourth International Standard (75/589). 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 (20 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.

Acetaminophen	20	Acetone	1,000
Acetylsalicylic Acid	20	Acetoacetic Acid	2,000
Ampicillin	20	Ascorbic Acid	20
Atropine	20	Albumin	2,000
ß-Hydroxybutyrate salt	2,000	Benzoylecgonine	10
Bilirubin	20	Brompheniramine	20
Caffeine	20	Cannabinol	10
Clomiphene	100	Cocaine	10
Codeine	10	Cholesterol	500
Creatine	20	Dextromethorphan	20
DMSO	5%	EDTA	80
Ephedrine	20	Ethanol	1%
Estriol	2	Estrone 3-Sulfate	10
Gentisic Acid	20	Glucose	2,000
Hemoglobin	1,000	Heroin	1
Ibuprofen	20	Methadone	10
Methamphetamine	10	Methanol	10%
Morphine	0.6	Oxalic Acid	40
Phenothiazine	20	Phenylpropanolamine	20
Pregnanediol	2	Salicylic Acid	20
Tetracycline	20	Triglycerides	1,200
Theophylline	20	Urea	2,000
Uric Acid	20		

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

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CONSULT® diagnostics

MCKESSON

hCG URINE TESTS **CASSETTE**

A rapid test for the qualitative detection of human chorionic gonadotropin (hCG) in urine. For professional use only. For *in vitro* diagnostic use only. Rx only. For use with MFR # 5001.

CLIA Category: Waived

INTENDED USE

The McKesson Consult® Diagnostics hCG Urine Cassette is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine 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 urine as early as 7 to 10 days after conception.[1,2,3,4] hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period,[2,3,4] and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in urine 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 McKesson Consult® Diagnostics hCG Urine Cassette is a rapid test that qualitatively detects the presence of hCG at the sensitivity of 20 mIU/mL in urine. 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 McKesson Consult® Diagnostics hCG Urine Cassette shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

The McKesson Consult® Diagnostics hCG Urine Cassette 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 test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding 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 gold conjugate 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.
- The test cassette should not be reused.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 36-86°F/2-30°C. The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

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

MATERIALS

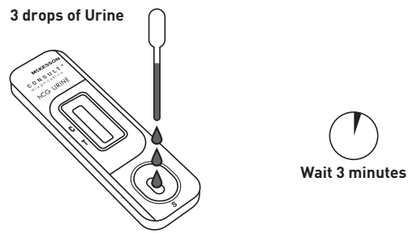
Materials provided: 25 Test cassettes, 25 disposable specimen pipettes and 1 Package insert.

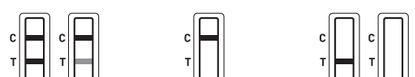
Materials required but not provided: Specimen collection container, timer

DIRECTIONS FOR USE

Allow the test cassette, urine, and/or controls to equilibrate to room temperature (59-86°F/15-30°C) 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 (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration.
3. Wait for the red line(s) to appear. Read the result at 3 minutes. It is important that the background is clear before the result is read.





POSITIVE

NEGATIVE

INVALID

INTERPRETATION OF RESULTS

(Please refer to the illustration)

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).

NOTE: A sample hCG concentration below the cut-off level of this test might result in a weak line appearing in the test region (T) after an extended period of time. Because of the high sensitivity of this test, results should be read between 3 and 5 minutes only. A result seen after these times could be indicative of a low hCG level in the sample. If such results are seen, it is recommended that the test be repeated with a new sample in 48-72 hours or that an alternate confirmation method is used.

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 Technical Support at (866) 216-0094.

***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 ≥ 20 mIU/mL hCG) 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, each new untrained operator and as otherwise required by your lab internal quality system procedures.

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,[5] 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.[6,7] Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. 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 preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.
6. 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 specimens. The amount of hCG will vary greatly with gestational age and between individuals.

The McKesson Consult® Diagnostics hCG Urine Cassette has a sensitivity of 20 mIU/mL in urine 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 McKesson Consult® Diagnostics hCG Urine Cassette and another commercially available urine membrane hCG test. The study included 100 urine specimens and both assays identified 50 negative and 50 positive results. The results demonstrated 100% overall agreement (for an accuracy of > 99%) of the McKesson Consult® Diagnostics hCG Urine Cassette