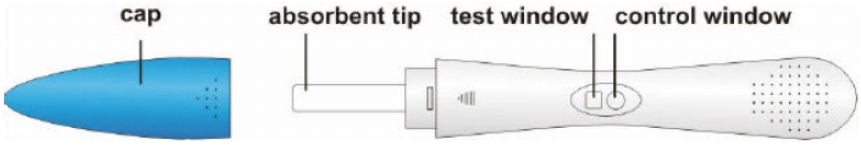
hCG MS5
Pregnancy Test
001A054

A RAPID, ONE STEP TEST FOR THE QUALITATIVE DETECTION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN URINE FOR PROFESSIONAL IN-VITRO DIAGNOSTIC USE ONLY

INTENDED USE

The *ultimed* hCG Midstream Pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the detection of pregnancy.



SUMMARY

Human chorionic gonadotropin is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, 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 both 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 *ultimed* hCG Midstream Pregnancy Test is a rapid test that qualitatively detects the presences 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 *ultimed* hCG Midstream Pregnancy Test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

The *ultimed* hCG Midstream Pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by immersing the test strip in a urine specimen 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 antibody-hCG-colored conjugate to 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 in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

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

PRECAUTIONS

Please read all the information in this leaflet before performing the test.

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test strip 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 strip should be discarded in a proper biohazard container after testing.
- Store in a dry place at 4-30°C or 39-86°F.
- Do not freeze.
- Keep out of the reach of children.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (4-30°C). The Midstream is stable through the expiration date printed on the sealed pouch. The Midstream must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

URINE ASSAY

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.

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SPECIMEN STORAGE
Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

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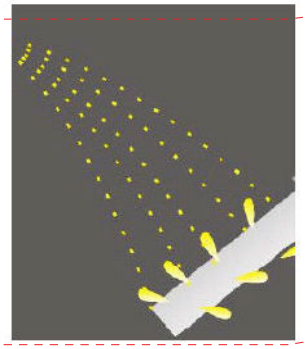
MATERIALS
Materials provided
Midstream
Package insert

Materials required but not provided
Timer

DIRECTION FOR USE
Allow the Midstream, urine specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1. Remove the Midstream test from the foil pouch and familiarize yourself with the product.
2. Remove the Cap.
3. Hold the Midstream test by the capped Thumb Grip with the exposed Absorbent Tip pointing downward directly into your urine stream for at least 10 seconds until it is thoroughly wet. See the illustration below.

Note: Do not urinate on the Test and Control windows. If you prefer, you can urinate into a clean and dry container, then dip only the Absorbent Tip of the Midstream test into the urine for at least 10 seconds.

4. After removing the Midstream test from your urine, immediately replace the Cap over the Absorbent Tip, lay the Midstream test on a flat surface with the Test and Control windows facing upwards, and then begin timing.
5. As the test begins to work, you may notice a light red flow moving across the Test and Control windows. Wait at least 3 minutes for the red line(s) to appear. If no red line appears, wait one minute longer. Some positive results may be observed in 1 minute or less depending on the concentration of hCG. Do not read the result after 10 minutes.



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INTERPRETATION OF RESULTS

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POSITIVE:* Two distinct red lines appear. One line should be in the control window (C) and another line should be in the test window (T).
***NOTE:** The intensity of the red color in the test line window (T) will vary depending on the concentration of hCG present in the specimen. Therefore, any shade of red in the test window (T) should be considered positive.

NEGATIVE: One red line appears in the control window (C). No apparent red or pink line appears in the test window (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.
Even if a line appears in the test window (T). You should repeat the test with a new Midstream test.

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QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control window (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
It is recommended that a positive hCG control (containing 25-250 mIU/mL hCG) and a negative hCG control (containing "0" mIU/mL hCG) be evaluated to verify proper test performance when a new shipment of test devices are received.

LIMITATIONS

1. The *ultimed* hCG Midstream Pregnancy Test is a qualitative test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
2. 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.
3. 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.
4. 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.
5. 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 should not be used to diagnose pregnancy unless these conditions have been ruled out.
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 and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals.
The *ultimed* hCG Midstream Pregnancy 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 *ultimed* hCG Midstream Pregnancy 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 accuracy of the *ultimed* hCG Midstream Pregnancy Test when compared to the other urine membrane hCG test.

hCG Reference Method

Method		Other hCG Rapid Test		Total Results
***ultimed* hCG Midstream Pregnancy Test**	**Results**	**Positive**	**Negative**	
	Positive	78	0	78
	Negative	0	72	72
Total Results		78	72	150

Relative Sensitivity: 100%
Relative Specificity: 100%
Accuracy: 100%

SENSITIVITY AND SPECIFICITY

The *ultimed* hCG Midstream Pregnancy 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 mIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

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INTERFERING SUBSTANCES

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

Acetaminophen	20mg/mL	Caffeine	20 g/mL
Acetylsalicylic Acid	20 mg/mL	Gentisic Acid	20 mg/mL
Ascorbic Acid	20 mg/mL	Glucose	2 g/dL
Atropine	20 mg/mL	Hemoglobin	1 mg/dL
Bilirubin	2 mg/dL		

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

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