HEO TECHNOLOGY

HCG Pregnancy Rapid Test Kit
Midstream (Urine)

English	(25 mIU/mL)

A rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine.
For in vitro diagnostic use only.

INTENDED USE

The hCG Pregnancy Midstream Test (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin 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 fertilisation. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception.[1,2,3] 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 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 hCG Pregnancy Midstream Test (Urine) is a rapid test that qualitatively detects the presence of hCG in urine specimens at the sensitivity of 25 mIU/mL. The test utilises a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the hCG Pregnancy Midstream Test (Urine) shows no cross reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

The hCG Pregnancy Midstream Test (Urine) 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 uses two lines to indicate results. The test line utilises a combination of antibodies including monoclonal hCG antibody to selectively detect elevated levels of hCG. The control line is composed of goat polyclonal antibodies and colloidal gold particles. The assay is conducted by adding a urine specimen to the specimen well of the test device and observing the formation of coloured lines. The specimen migrates via capillary action along the membrane to react with the coloured conjugate.
Positive specimens react with the specific antibody hCG coloured conjugate to form a red line at the test line region of the membrane. Absence of this red line suggests a negative result. To serve as a procedural control, a red 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 midstream test contains anti-hCG particles and anti-hCG antibodies on the membrane.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test 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 used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch, refrigerated or at room temperature (2-30°C). The midstream test is stable until the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

MATERIALS

- Midstream Test
- Package insert

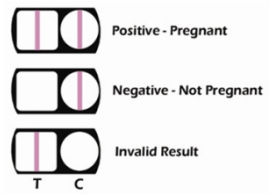
INSTRUCTIONS

1. Remove the midstream test from the foil pouch and familiarise yourself with the product.
2. Remove the Cap and place it over the Thumb Grip. See the illustration above.
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 opposite. Note: Do not urinate either on the Test or 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.

INTERPRETATION OF RESULTS

POSITIVE: Two distinct red lines appear*. One line should be in the control line region (C) and another line should be in the test line region (T).
***NOTE:** The intensity of the colour in the test line region (T) may vary depending on the concentration of hCG present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.
NEGATIVE: One red line appears in the control line region (C). No apparent coloured line appears in the test line 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. If the problem persists, discontinue using the test kit immediately and contact your local supplier.



QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If a background colour appears in the result window and interferes with the ability to read the test result, the result may be invalid.
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 tests is received.

LIMITATIONS

1. The hCG Pregnancy Midstream Test (Urine) is a preliminary 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. Very low levels of hCG (less than 50 mIU/mL) are present in urine specimens 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. This test may produce false positive results. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumours, prostate cancer, breast cancer and lung cancer can 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.
5. This test may produce false negative results. 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. In cases where pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
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 hCG Pregnancy Midstream Test (Urine) 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

A multi-center clinical evaluation was conducted comparing the results obtained using the HCG Pregnancy Rapid Test Midstream to another commercially available urine membrane hCG test. The study included 413 urine specimens, and both assays identified 296 negative and 117positive results. The results demonstrated >99% overall accuracy of the hCG Pregnancy Rapid Test Midstream when compared to the other hCG Rapid Test.

Method		Other hCG Rapid Test		Total Results
hCG Pregnancy Rapid Test Midstream	Results	Positive	Negative	
	Positive	117	0	117
	Negative	0	296	296
Total Results		117	296	413

Sensitivity: >99.9%(97.5%~100%) * Specificity: >99.9%(99.0%~100%)*
Accuracy: >99.9%(99.3%~100%)* *95% Confidence Intervals

The hCG Pregnancy Midstream Test (Urine) detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardised to the WHO 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.

Acetaminophen	20 mg/dL	Ethanol	1%
Acetoaceto Acid	2000mg/dL	Ephedrine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL	Gentisic Acid	20 mg/dL
Albumin	2000 mg/dL	Glucose	2000 mg/dL
Ascorbic Acid	20 mg/dL	Hemoglobin	1 mg/dL
Atropine	20 mg/dL	Methadone	10 mg/dL
Bilirubin	2 mg/dL	Methanol	10%
Caffeine	20 mg/dL	Phenothiazine	20 mg/dL
Codeine	10 mg/dL	Phenylpropanolamine	20 mg/dL
EDTA	20 mg/dL	Salicylic Acid	20 mg/dL

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

BIBLIOGRAPHY

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3. Braunstein GD, J Rasor, H. Danzer, D Adler, ME Wade *Serum human chorionic gonadotropin levels throughout normal pregnancy*, Am. J. Obstet. Gynecol. 1976; 126(6): 678-681
4. Steier JA, P Bergsjo, OL Myking *Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy*, Obstet. Gynecol. 1984; 64(3): 391-394
5. Dawood MY, BB Saxena, R Landesman *Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma*, Obstet. Gynecol. 1977; 50(2): 172-181
6. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross *Ectopic production of human chorionic gonadotropin by neoplasms*, Ann. Intern Med. 1973; 78(1): 39-45

Index of Symbols					
⚠	Attention, see instructions for use	Σ	Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by	②	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalogue #

Effective date: 2020-05-28