ELISURE

Pregnancy (hCG) Rapid Test (Serum/Plasma/Urine) For professional use

IVD REF SIC-RDT-SHCG-202024

A rapid test for the qualitative detection of human chorionic gonadotropin (hCG) in plasma or serum or urine.
For professional in vitro diagnostic use only.

INTENDED USE

The Pregnancy (hCG) Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum or plasma 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 both urine and serum or plasma 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 both the urine and serum or plasma 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 Pregnancy (hCG) Rapid Test is a rapid test that qualitatively detects the presence of hCG in urine or serum or plasma 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 or serum or plasma. At the level of claimed sensitivity, the Pregnancy (hCG) Rapid Test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLES

The Pregnancy (hCG) Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum or plasma to aid in the early detection of pregnancy. The test uses two lines to indicate results. The test utilizes a combination of antibodies including a 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 immersing the test dipstick in a urine or serum or plasma 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.

MATERIALS

Materials provided

- Test dipsticks
- Package insert

Materials required but not provided

- Timer
- Specimen collection containers

WARNINGS AND PRECAUTIONS

Please read all the information in this package insert before performing the test.

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date
2. The test should remain in the sealed pouch or closed canister until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE.** Do not uses 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.

Serum or Plasma Assay

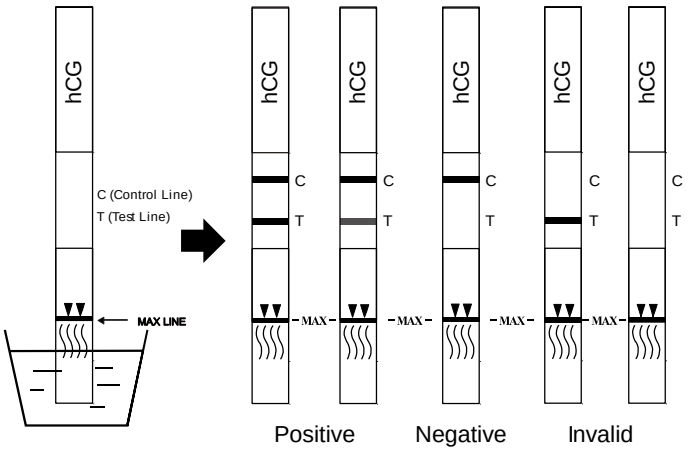
Blood should be collected aseptically into a clean tube without anticoagulants (Serum) or with anticoagulants (Plasma). Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Use clear non-hemolyzed specimens when possible.

Specimen Storage

Urine or serum or plasma 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.

DIRECTIONS FOR USE

1. Bring the pouch or canister to room temperature before opening it. Remove the test dipstick from the sealed pouch or closed canister and use it within one hour.
   NOTE: For canister packaging, immediately close the canister tightly after removing the required number of the test dipstick(s). Record the initial opening date on the canister. Once the canister has been opened, the remaining test dipstick(s) are stable for 90 days only.
2. With arrows pointing toward the urine or serum or plasma specimen, immerse the test dipstick vertically in the urine or serum or plasma specimen for at least 15 seconds. **Do not pass the maximum line (MAX) on the test dipstick** when immersing the dipstick. See illustration below.
3. Place the test dipstick on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. **Read the result at 3 minutes when testing a urine specimen, or at 5 minutes when testing a serum or plasma specimen.**
   NOTE: A low hCG concentration might result in a weak line appearing in the test line region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration)

POSITIVE: Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T). One line may be lighter than the other; they do not have to match. This means that you are probably pregnant.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This means that you are probably not pregnant.

INVALID: The result is invalid if no colored line appears in the control line region (C), even if a line appears in the test line region (T). You should repeat the test with a new test dipstick.

QUALITY CONTROL

A procedural control is included in the test. A colored 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 color 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 Pregnancy (hCG) Rapid Test 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 and serum or plasma specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, 5a test result that is weakly positive should be confirmed by retesting with a first morning urine or serum or plasma 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 tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG.[6,7] Therefore, the presence of hCG in urine or serum or plasma specimens 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 case pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
6. 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.
7. 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.

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the Pregnancy (hCG) Rapid Test to another commercially available urine and serum or plasma hCG Rapid test. The urine study included 608 specimens, and both assays identified 377 negative and 231 positive results. The serum or plasma study included 308 specimens, and both assays identified 240 negative and 68 positive results. The results demonstrated a >99% overall accuracy of the Pregnancy (hCG) Rapid Test when compared to the other urine and serum or plasma hCG Rapid test.

hCG Reference Method (Urine)

Method		Other hCG Rapid Test		Total Results
Pregnancy (hCG) Rapid Test	Results	Positive	Negative	
	Positive	231	0	231
	Negative	0	377	377
Total Results		231	377	608

Sensitivity: >99.9% (98.7%~100%)*

Specificity: >99.9% (99.2%~100%)*
Accuracy: >99.9 %(99.5%~100%) * * 95% Confidence Intervals

hCG Reference Method (Serum or Plasma)

Method		Other hCG Rapid Test		Total Results
Pregnancy (hCG) Rapid Test	Results	Positive	Negative	
	Positive	68	0	68
	Negative	0	240	240
Total Results		68	240	308

Sensitivity: >99.9% (95.7%~100%)*
Specificity: >99.9% (98.8%~100%)*
Accuracy: >99.9% (99.0%~100%) * * 95% Confidence Intervals

Tests were performed with serum and found to be positive or negative as reported. Plasma specimens from the same individuals were tested with the Pregnancy (hCG) Rapid Test to validate the efficacy with plasma specimens

Sensitivity and Cross-Reactivity

The Pregnancy (hCG) Rapid Test detects hCG at a concentration of 25 mIU/mL or greater.

The test has been standardized to the W.H.O. 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.

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens containing 25 mIU/mL, 100 mIU/mL, 250 mIU/mL and 0 mIU/mL of HCG. The negative and positive values were correctly identified 100% of the time.

Inter-Assay

Between-run precision has been determined by using the same three specimens of 25 mIU/mL, 100 mIU/mL, 250 mIU/mL and 0 mIU/mL of HCG in 10 independent assays. Three different lots of the Pregnancy (hCG) Rapid Test have been tested. The specimens were correctly identified 100% of the time.

Interfering Substance

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

Acetaminophen	20 mg/dL	Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL	Gentisic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL	Glucose	2 g/dL
Atropine	20 mg/dL	Hemoglobin	1 mg/dL
Bilirubin	2 mg/dL	Bilirubin (serumor plasma)	40 mg/dL
Triglycerides (serum or plasma)	1,200 mg/dL		

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

BIBLIOGRAPHY

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INDEX OF SYMBOLS

	Consult instructions for use		Contains sufficient for <n> tests
IVD	*In vitro* diagnostic medical device		Use-by date
	Temperature limit	LOT	Batch code
	Do not use if package is damaged		Manufacturer
REF	Catalogue number		Do not re-use

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