

CLARITY

hCG Combo Cassette

(Urine/Serum)

User Instruction

REF DTG-COMBO English Rx Only

A rapid test for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine.

For professional *in vitro* diagnostic use only.

【INTENDED USE】

The CLARITY hCG Combo Cassette is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum to aid in the early detection of pregnancy.

The test is for health care professionals use including professionals at point of care (POC).

【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 hCG Combo Cassette is a rapid test that qualitatively detects the presence of hCG in urine at the sensitivity of 20 mIU/mL or serum at the sensitivity of 10 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 hCG Combo Cassette shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

【PRINCIPLE】

The hCG Combo Cassette is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum 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 cassette in a urine or serum 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 contains anti-hCG particles and anti-hCG coated on the membrane.

【PRECAUTIONS】

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

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until ready to 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 at room temperature or refrigerated (35.6-86 °F) (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test 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.

Serum Assay

Blood should be collected aseptically into a clean tube without anticoagulants (Serum). Separate the serum from blood as soon as possible to avoid hemolysis. Use clear

non-hemolyzed specimens when possible.

Specimen Storage

Urine or serum specimens may be stored at 35.6-46.4°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】

•Test Cassettes (with desiccant) •Droppers •User Instruction

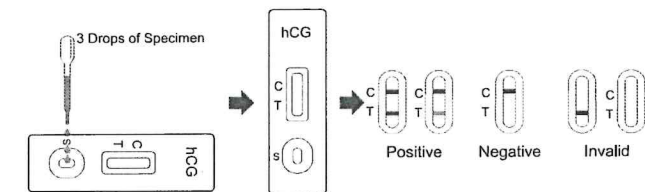
Materials required but not provided

•Specimen collection containers •Timer

【DIRECTIONS FOR USE】

- Bring the pouch to room temperature (59-86 °F) (15-30 °C) before opening it. Remove the cassette from the sealed pouch and use it within one hour.
- Place the cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine or serum to the specimen well of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
- 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 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 above)

POSITIVE Two colored lines appear. One line should be in the control line region (C) and another 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 cassette.

【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 10-100 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】

- The hCG Combo Cassette is a preliminary qualitative test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
- 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.
- Very low levels of hCG (less than 50 mIU/mL) are present in urine and serum 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 or serum specimen collected 48 hours later.
- This test may produce false positive results. A number of conditions other than pregnancy can cause elevated levels of hCG. Therefore, the presence of hCG in urine

or serum specimens should not be used to diagnose pregnancy unless these conditions have been ruled out.

- 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.
- 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.
- Patient samples containing human anti-mouse antibodies (HAMA) may give falsely results.

【EXPECT VALUE】

Negative results are expected in healthy non-pregnant women. 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 Combo Cassette (Urine/serum) has a sensitivity of 20 mIU/mL for urine and 10 mIU/mL for serum, 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 hCG Combo Cassette to another commercially available urine and serum hCG Rapid test. The urine study included 105 specimens, and both assays identified 52 negative and 53 positive results. The serum study included 107 specimens, and both assays identified 49 negative and 58 positive results. The results demonstrated a >99% overall accuracy of the hCG Combo Cassette when compared to the other urine and serum hCG Rapid test.

hCG Reference Method (Urine)

hCG Combo Cassette	Predicated Device	
	Positive	Negative
Positive	53	0
Negative	0	52

hCG Reference Method (Serum)

hCG Combo Cassette	Predicated Device	
	Positive	Negative
Positive	58	0
Negative	0	49

The study results show 100% agreement for all samples.

Sensitivity and Cross-Reactivity

The hCG Combo Cassette detects hCG at a concentration of 20 mIU/mL or greater for urine and 10 mIU/mL or greater for serum.

The test has been standardized to the W.H.O. International Standard. The addition of LH (500 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 µIU/mL) to negative and positive specimens showed no cross-reactivity.

Precision

This study is performed in 3 sites. Three lots of product were tested with 0, 5, 10, 15, 17.5, 20, 30, 50, 100 mIU/mL hCG urine specimen and 0, 3, 5, 8, 10, 12, 15, 20, 50 mIU/mL hCG serum specimen. The results as following:

Serum:

hCG Concentration (mIU/mL)	Site 1		Site 2		Site 3		Total Result	
	-	+	-	+	-	+	-	+
0	30	0	30	0	30	0	90	0
3	30	0	30	0	30	0	90	0
5	30	0	30	0	30	0	90	0
8	7	23	7	23	8	22	22	68
10	0	30	0	30	0	30	0	90
12	0	30	0	30	0	30	0	90
15	0	30	0	30	0	30	0	90
20	0	30	0	30	0	30	0	90
50	0	30	0	30	0	30	0	90

Urine:

hCG Concentration (mIU/mL)	Site 1		Site 2		Site 3		Total Result	
	-	+	-	+	-	+	-	+
0	30	0	30	0	30	0	90	0
5	30	0	30	0	30	0	90	0
10	30	0	30	0	30	0	90	0
15	15	15	16	14	15	15	46	44
17.5	6	24	6	24	6	24	18	72
20	0	30	0	30	0	30	0	90
30	0	30	0	30	0	30	0	90
50	0	30	0	30	0	30	0	90
100	0	30	0	30	0	30	0	90

Interfering Substance

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












Acetaminophen	20 mg/dL	Methadone	10 mg/dL
Acetoacetic Acid	2000 mg/dL	Phenylpropanolamine	20 mg/dL
Ascorbic Acid	20 mg/dL	Phenothiazine	20 mg/dL
Atropine	20 mg/dL	Pregnanediol	1.5 mg/dL
Acetosalicic Acid	20 mg/dL	Salicylic Acid	20 mg/dL
Albumin	2000 mg/dL	B-hydroxybutyrate	2000 mg/dL
Bilirubin(urine)	2 mg/dL	Benzoylecgonine	10 mg/dL
Caffeine	20 mg/dL	Cannabinol	10 mg/dL
Codeine	10 mg/dL	Methanol	10%
Ephedrine	20 mg/dL	Estriol-17-beta	1.4 mg/dL
EDTA	80 mg/dL	Thiophene	20 mg/dL
Ethanol	1%	Ampicillin	20 mg/dL
Genitic Acid	20 mg/dL	Tetracycline	20 mg/dL
Glucose	2000 mg/dL	Ketone	20 mg/dL
Hemoglobin	2000 mg/dL	Triglycerides (serum)	1200 mg/dL
Total cholesterol (serum)	250 mg/dL	High-density lipoprotein (serum)	70 mg/dL
Bilirubin (serum)	40 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 Serum or plasma human chorionicgonadotropin levels throughout normal pregnancy, Am. J. Obstet. Gynecol. 1976; 126(6):678-681
4. Lenton EA, LM Neal, R Sulaiman Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy, Fertil. Steril. 1982; 37(6): 773-778
5. Steier JA, P Bergsjo, OL Myking Human chorionic gonadotropin in maternal plasma afterinduced abortion, spontaneous abortion and removed ectopic pregnancy,Obstet.Gynecol.1984; 64(3): 391-394

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Store between 35.6-86°F (2-30°C)
	In vitro diagnostic medical device		Batch code		Catalogue number
	Caution		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		

Manufactured for:

Clarity Diagnostics, LLC.

1701 Green Rd., Ste A

Deerfield Beach, FL 33064, USA

Toll Free No.: 1-877-722-6339

Hours of operation: Monday – Friday 9 AM to 5:30 PM (EST)

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