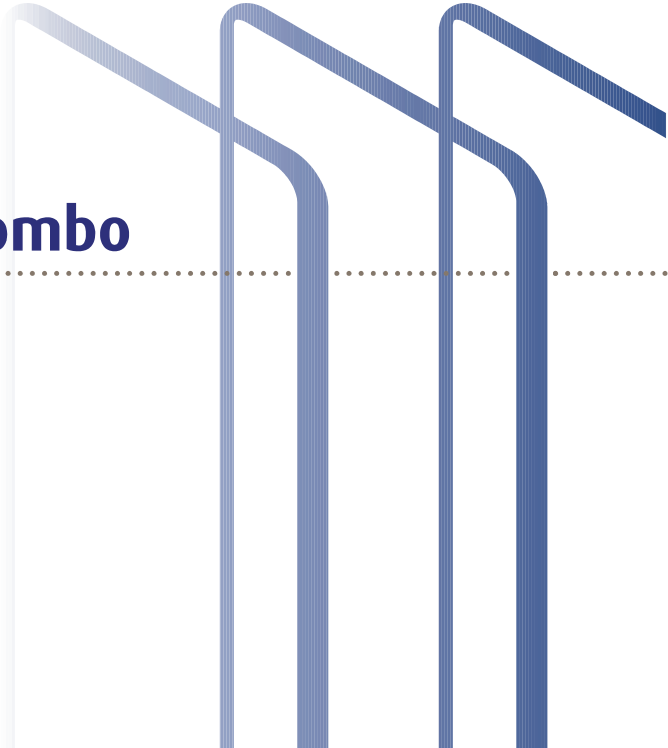
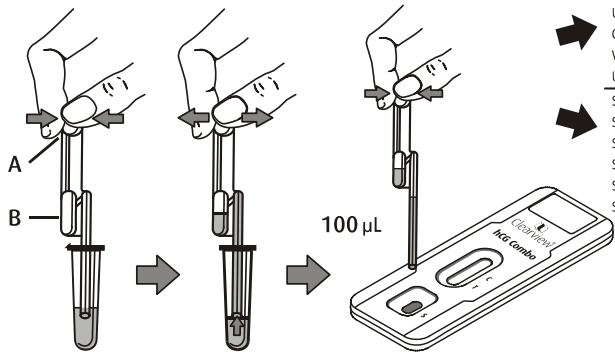


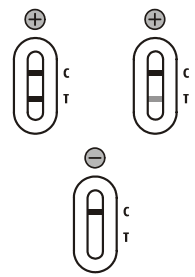
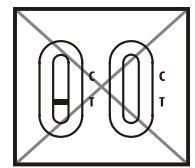


Clearview[®] **hCG Combo**





Urine	Ούρα
Urin	Urine
Urin	Urine
Orina	Urin
Virtsa	Urina
Urine	Urin
<hr/>	
Serum	Ορός
Serum	Siero
Serum	Serum
Suero	Blodserum
Seerumi	Soro
Sérum	Serum





Clearview[®] hCG Combo

INTENDED USE

Clearview hCG Combo is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy. For professional *in vitro* diagnostic use only.

INTRODUCTION

hCG is a glycoprotein hormone produced by the blastocyst.^{1,2} hCG normally begins to be detected in the urine from 7 days after conception. The sudden rapid rise in concentration of hCG in urine following conception makes it an excellent marker for pregnancy.^{3,4}

TEST PRINCIPLE

Clearview hCG Combo 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 line 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 adding a urine or serum sample to the sample well of the test device and observing the formation of colored lines. The sample migrates via capillary action along the membrane to react with the colored conjugate.

Positive samples 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 sample has been added and membrane wicking has occurred.

KIT CONTENTS AND STORAGE

Materials Provided

Each **Clearview hCG Combo** kit contains sufficient materials for 40 tests. Each device contains anti-hCG particles and anti-hCG coated on the membrane.

- 40 Pouched Devices: Each sealed foil pouch contains 1 **Clearview hCG Combo** device, 1 disposable pipette and 1 desiccant packet
- 1 Package insert

Store at 2-30°C. Do not use after the expiry date.

Safety data sheet available for professional user on request.

Materials Required But Not Provided

- Sample collection container
- Clock, timer or stopwatch

PRECAUTIONS

1. Do not open the foil pouch until ready to test.
2. Do not use devices that have become wet, or if the foil pouch has been damaged.
3. Properly dispose of all contaminated waste such as used tests and pipettes.
4. Do not use kit beyond expiration date printed on the outside of the kit carton.

SAMPLE COLLECTION AND PREPARATION

Urine Assay

A urine sample collected at any time of the day is suitable, but a first morning sample is recommended⁵. Urine samples must be collected in a clean and dry container. Urine samples exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear sample for testing.

Serum Assay

Blood should be collected aseptically into a clean tube without anticoagulants. Separate the serum from blood as soon as possible to avoid hemolysis. Use clear non-hemolyzed samples when possible.

Sample Storage

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

ASSAY PROCEDURE

Allow the device, urine or serum sample and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

1. Remove the device from the sealed pouch and place on a clean and level surface.
2. Using the plastic pipette supplied, insert the tip into the sample and press the top bulb fully (A). DO NOT press the bottom bulb (B) when using the pipette. Release the top bulb to draw up the liquid. An exact quantity of sample (100µL) will be drawn into the lower part of the pipette. Excess sample will be drawn into the bottom bulb.
3. Remove the pipette from the sample. Press the top bulb fully to dispense the sample **carefully** onto the sample well. Use a new pipette for each test performed, even if using the same urine sample.

4. Wait for the colored line(s) to appear. **Read the result at 3 minutes when testing a urine sample. Do not interpret the result after 3 minutes. Read the result at 5 minutes when testing a serum sample. Do not interpret the result after 5 minutes.**

INTERPRETATION OF RESULTS

(Please refer to the illustration)

POSITIVE: **Two distinct colored 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 color in the test line region (T) may vary depending on the concentration of hCG present in the sample. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C).** No apparent colored line appears in the test line region (T).

INVALID: **Control line fails to appear.** Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new device. If the problem persists, discontinue using the kit immediately and contact your local distributor.

LIMITATIONS

1. Positive results from very early pregnancy may later prove negative due to natural termination of the pregnancy.⁶ It is therefore recommended that weak positive results are retested 48-72 hours later with a first morning urine sample.
2. A negative result may be obtained if a urine sample is too dilute. If pregnancy is still suspected, it is recommended the patient should be retested 48-72 hours later with a first morning sample.
3. Concentrations of hCG are generally lower in ectopic

pregnancy than expected normal values for a given gestational age. Abnormal pregnancy cannot be distinguished from normal pregnancy by hCG levels alone.^{2,7}

4. hCG remains elevated for a time after pregnancy. Pregnancy tests carried out less than 3 weeks after giving birth or 9 weeks after natural loss or termination may need further evaluation.⁸
5. A number of conditions other than pregnancy can cause elevated levels of urinary hCG e.g. menopause,⁴ trophoblastic disease and certain non-trophoblastic neoplasms.⁹
6. Occasionally, samples containing <25mIU/mL hCG may test positive. **Clearview hCG Combo** has been shown to be over 99% accurate.
7. Drugs containing hCG may interfere with **Clearview hCG Combo**, and produce misleading results.
8. False positive and false negative pregnancy tests may be observed in patients with abnormal bladder or kidney function e.g. enterocystoplasties and renal failure.
9. If the test result with **Clearview hCG Combo** is not consistent with clinical evidence, further evaluation may be required.
10. Samples from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such samples may cause false positive or false negative results.
11. Inconsistent results may be obtained if the urine sample contains excessive amounts of bacteria.

EXPECTED VALUES

Urine and serum samples from healthy males and post-menopausal females generally contain <10mIU/mL hCG.¹⁰ Levels are generally <5mIU/mL in pre-menopausal females. On the

first day of the first missed period, the levels of maternal urinary hCG are normally 50-250mIU/mL. During the first trimester hCG levels peak at up to 200,000mIU/mL in a typical pregnancy.^{3,11}

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using **Clearview hCG Combo** and another commercially available urine/serum membrane hCG test. The urine study included 159 samples, and both assays identified 88 negative and 71 positive results. The serum study included 73 samples and both assays identified 51 negative, 21 positive and 1 invalid results. The results demonstrated a >99% overall accuracy of **Clearview hCG Combo** when compared to the other urine/serum membrane hCG test.

hCG Reference Method (Urine)

Method		Other hCG Rapid Test		Total Results
Clearview hCG Combo	Results	Positive	Negative	
	Positive	71	0	71
	Negative	0	88	88
Total Results		71	88	159

Sensitivity: 100% (95%-100%)*

Specificity: 100% (96%-100%)*

Accuracy: 100% (98%-100%)*

* 95% Confidence Intervals

hCG Reference Method (Serum)

Method		Other hCG Rapid Test		Total Results
	Results	Positive	Negative	
Clearview hCG Combo	Positive	21	0	21
	Negative	0	51	51
Total Results		21	51	72

Sensitivity: 100% (84%-100%)*

Specificity: 100% (93%-100%)*

Accuracy: 100% (95%-100%)*

* 95% Confidence Intervals

Sensitivity and Specificity

Clearview hCG Combo 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 μ IU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) samples showed no cross-reactivity.

Prozone Effect

Clearview hCG Combo has been shown to produce positive results with samples containing up to and including 500,000mIU/mL hCG, which is higher than the maximum level expected during a typical pregnancy.

Interfering Substances

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

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 (serum)	40 mg/dL	Bilirubin (urine)	2 mg/dL
Triglycerides (serum)	1,200 mg/dL		

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

Advice line

Further information can be obtained from your distributor, or call Inverness Medical Technical Support on:

+44 (0)1234 835959.

www.clearview.com

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