INSTANT-VIEW® hCG Combo II Cassette Test CE

One Step Assay
Rapid Visual Results
For Qualitative In Vitro Diagnostic Use

INTENDED USE
The hCG Combo II Cassette Test is a qualitative immunoassay for the detection of human chorionic gonadotropin (hCG) in human urine or serum at a level of 10 mIU hCG/mL. This product is for health care professional investigational use only. Not for self testing. Not for the diagnosis of pregnancy. Not for sale in Canada.

SUMMARY AND EXPLANATION OF THE TEST
This pregnancy test is based on the detection of human chorionic gonadotropin (hCG) in urine and serum. hCG is a hormone produced by the placenta. In normal subjects, hCG in urine and serum provides an early indication of pregnancy. The hCG Combo II Cassette Test uses a mouse monoclonal antibody specific to hCG in a one-step lateral flow chromatographic immunoassay to detect hCG at levels equal to or greater than 10 mIU/mL (WHO 3rd IS 75/537).

PRINCIPLE OF THE PROCEDURE
This assay is a one-step lateral flow chromatographic immunoassay. The test strip in the device consists of a conjugate pad containing mouse monoclonal anti-hCG antibody conjugated to colloidal gold, and a nitrocellulose membrane strip containing a test line (T line) and a control line (C line).

When an adequate amount of specimen is applied to the sample pad of the device, hCG in the specimen binds to sites on the anti-hCG antibody-gold conjugate in the conjugate pad to form a complex and migrates along the membrane strip. If the specimen contains hCG at a level close to or greater than 10 mIU/mL, the complex will bind to the capture antibody coated on the T line to develop a colored band. If the specimen does not contain hCG or if the hCG level is below the detectable level, the T line will not develop.

The C line is coated with goat anti-mouse antibody, which should bind to the gold-antibody conjugate and forms a colored line regardless of the presence of hCG.

REAGENTS AND MATERIALS SUPPLIED
- 25 Test devices, each sealed in a foil pouch with a dropper pipette.
- 1 Package insert (Instructions for use).

MATERIAL REQUIRED BUT NOT PROVIDED
- Specimen collection container
- Timer

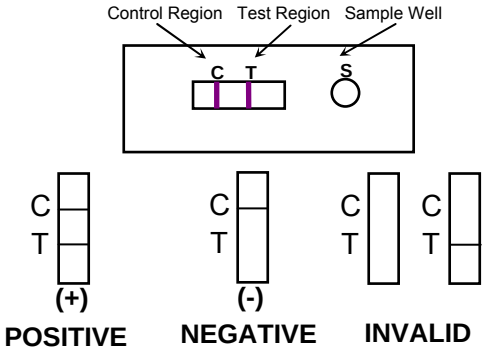
STORAGE AND STABILITY
Store the kit at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date if it remains sealed in its foil pouch. ***Do not freeze and/or expose the kit to temperatures over 30°C (86°F).***

SPECIMEN COLLECTION
- Urine specimens must be collected in clean, dry containers.
- Serum specimens must be collected following standard clinical procedures.
- Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for prolonged storage. Do not mix specimens.

PRECAUTIONS
- The instructions must be followed exactly to obtain accurate results.
- This test is for professional *in vitro* diagnostic use only.
- Do not open the sealed pouch until ready to conduct the assay.
- Do not use expired devices.
- Dispose of all specimens and used assay materials as potentially biohazardous.

ASSAY PROCEDURE
1. Refrigerated specimens and other test materials, including tests, **must be equilibrated to room temperature before testing**.
2. Remove the test from its pouch and place it on a flat surface.
3. Holding the dropper vertically, add four drops of the specimen to the sample well.
4. Strong positive results may take longer, up to 5 minutes.
   IMPORTANT: Do not interpret results after 7 minutes.

INTERPRETATION OF RESULTS



Positive:
If both the C line and T line appear, hCG is present in the specimen at a level equal to or greater than 10 mIU/mL.

Negative:
If only the C line appears, the hCG level in the specimen is not detectable. If pregnancy is suspected, repeat the test after 2 to 3 days with new devices and fresh samples.

Invalid:
If no C line develops within 5 minutes, the result is invalid. Repeat the assay with a new test. If the result is still invalid, stop using the test and contact the manufacturer.

QUALITY CONTROL
- **Built-in Control Features**
  This test contains a built-in control feature, the C line. The presence of the C line indicates that an adequate sample volume was used and that the reagents migrated properly. If a C line does not form, the result is invalid. Review the procedure and repeat with a new test.
- **External Quality Control**
  Good Laboratory Practice recommends using external controls, positive and negative, to ensure the proper performance of the assay.

LIMITATIONS
1. This kit is not intended for any use other than the early detection of pregnancy.
2. hCG may be detectable in some conditions other than normal pregnancy, which should be ruled out when diagnosing pregnancy.
   - Low titer elevations of hCG can occur in normal, non-pregnant subjects.
   - Ectopic pregnancy cannot be distinguished from normal pregnancy from hCG measurements alone.
   - Positive hCG levels may be detectable for several weeks following delivery or abortion.
3. Results must be evaluated with other data by a physician before diagnosing pregnancy.

EXPECTED VALUES

This test is capable of detecting hCG at levels as low as 10 mIU/mL (WHO 3rd IS 75/537) or the first day of a missed period and no sooner. In normal subjects, hCG in urine and serum provides an early indication of pregnancy. In a 28-day cycle with ovulation occurring at day 14, hCG can be detected in urine and serum in minute quantities around day 23, or 5 days before the expected menstruation. The hCG concentration doubles approximately every 2 days and peaks between 7-12 weeks after the first day of the last menstrual period with a mean concentration of 50,000 mIU/mL. Concentrations as high as 100,000 mIU/mL have been reported in normal pregnancies during the first trimester.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity**
   The hCG Combo II Cassette Test will produce positive results with specimens containing hCG at concentrations equal to or greater than 10 mIU/mL. This test is standardized to the WHO 3rd IS 75/537.

2. **Accuracy**
   - Samples studied
     Pooled urine specimens from forty healthy non-pregnant humans were spiked with hCG to concentrations of 0, 15, 20, 25, 30, 35, 50 and 100 mIU/mL in replicates of 5. All specimens were blind labeled.
   - Comparison studies
     Comparison studies on the hCG Combo II Cassette Test with a legally marketed device were performed in-house and in a clinical reference laboratory. Positive and negative results were compared and the correlation was 100%.
   - Physician's office laboratory (POL) studies
     The hCG Combo II Cassette Test was evaluated at three POL sites by persons with diverse educational backgrounds and work experiences. The results from all three POL studies showed 100% agreement.

3. **Specificity**
   The α subunits of hTSH, hLH and hFSH are similar to that of hCG, which may cause cross reactivity between those hormones. High physiological concentrations of hTSH (up to 1,000 µIU/mL), hLH (up to 300 mIU/mL) and hFSH (up to 1,000 mIU/mL) spiked in hCG positive (spiked to 10 mIU/mL) and negative specimens were tested separately with the hCG Combo II Cassette Test, and were shown not to affect the expected results in the study.

4. **Interfering Substances**
   The following analytes were spiked in urine pools containing 0 or 25 mIU/mL hCG (WHO 3rd IS) and were tested separately with the hCG Combo II Cassette Test, and were shown not to affect the expected results in the study.

REFERENCES

1. Braunstein GD, Grodin JM, Vaitukaitis J, Ross GT. Secretory rates of human chorionic gonadotropin by normal trophoblast. Am J Obstet Gynecol. 1973 Feb 15;115(4):447-50.
2. Brody S, Carlstrom G. Immuno-assay of human chorionic gonadotropin in normal and pathologic pregnancy. J Clin Endocrinol Metab. 1962 Jun;22:564-74.
3. Borkowski A, Muquardt C. Human chorionic gonadotropin in the plasma of normal, nonpregnant subjects. N Engl J Med. 1979 Aug 9;301(6):298-302.
4. Ross GT. Clinical relevance of research on the structure of human chorionic gonadotropin. Am J Obstet Gynecol. 1977 Dec 1;129(7):795-808.

15°C 30°C	Temperature limitation		Use by YYYY-MM
LOT	Batch/Lot code	IVD	*In vitro* diagnostic medical device
	Manufacturer	REF	Catalog number
Σ n	Contains sufficient for < n > tests		Consult instructions for use
2	Do not reuse	CE	CE Mark
	Caution, consult accompanying documents		

Alfa Scientific Designs Inc.
13200 Gregg St.
Poway, CA 92064 – USA
Made in USA

REF **2481**

EC REP
Obelis s.a
Boulevard Général Wahis 53
1030 Brussels, BELGIUM
Tel.: +32.2.732.59.54
Fax: +32.2.732.60.03
Email: mail@obelis.net