Instant-View® Pregnancy Combo Test *(Cassette)* CE

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

INTENDED USE
The Pregnancy Combo Test is a qualitative immunoassay for the detection of human chorionic gonadotropin (hCG) in human urine or serum for the early detection of pregnancy. It is for health care professional use only and not for self testing.

SUMMARY AND EXPLANATION OF THE TEST
This pregnancy test is based on the detection of the 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 Pregnancy Combo Test uses a mouse monoclonal antibody specific to hCG in a one-step lateral flow chromatographic immunoassay to detect hCG at the level close to or greater than 25 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 25 mIU/ml, the complex will bind to the capture antibody coated on the T line to develop a burgundy-colored band. If the specimen does not contain hCG or 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 burgundy 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 and a desiccant.
- 1 package insert (Instructions for Use).

MATERIAL REQUIRED BUT NOT PROVIDED
- Specimen collection containers
- 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 printed on the label if it remains sealed in its foil pouch.

Do not freeze and/or expose the kit to temperatures over 30°C (86°F).



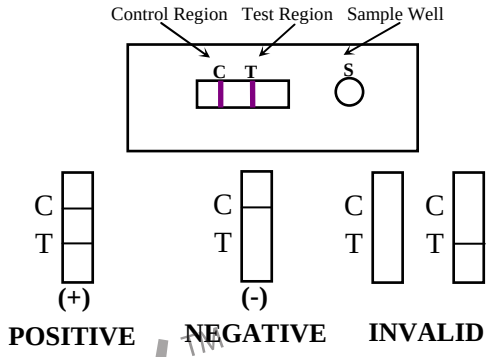
SPECIMEN COLLECTION
1. Each urine specimen must be collected in a clean container.
2. Each serum specimen must be collected following standard clinical procedure.
3. Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for prolonged storage. Do not mix specimens.

PRECAUTION
1. The instructions must be followed exactly to obtain accurate results.
2. This test is for professional in vitro diagnostic use only.
3. Do not open the sealed pouch, unless ready to conduct the assay.
4. Do not use expired devices.
5. Dispose of all specimens and used assay materials as potentially biohazardous.

ASSAY PROCEDURE
1. Refrigerated specimens and other test materials including devices, **must be equilibrated to room temperature before testing**.
2. Remove the test device 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 be observed in 2-3 minutes. Weak positive results may take longer time, up to 5 minutes.

INTERPRETATION OF RESULTS

***IMPORTANT*: Do not interpret the results after 7 minutes. The T Line should always be interpreted independently of the C Line.**



Positive:
If both the C line and T line appear in the viewing area, the test indicates that hCG is present in the specimen at the level close to or higher than 25 mIU/ml.

Negative:
If only the C line appears, the test indicates that the hCG level in the specimen is not detectable and the result is negative. **If pregnancy is suspected, repeat the test after 2 to 3 days with a new device and fresh sample.**

Invalid:
If no line is visible in the control region within 5 minutes, repeat the assay with a new test device.

QUALITY CONTROL
- **Built-in Control Features**
  The Pregnancy Combo Test contains a built-in control feature, the C line. The appearance of the burgundy C line indicates that the test has been performed correctly, including that an adequate volume of specimen has been absorbed and capillary flow has occurred. The C line should always appear regardless of the presence of hCG. If the C line does not develop within 5 minutes, the result is invalid. In his case, review the whole procedure and repeat test with a new device.

- **External Quality Control**
  Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay.

LIMITATIONS
1. This kit is not intended for any use other than 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. The results must be evaluated with other data by a physician before diagnosing pregnancy.

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EXPECTED VALUES

This test is capable of detecting hCG at the level as low as 25 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 hormone 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. [1]

PERFORMANCE CHARACTERISTICS

1. Sensitivity

The Pregnancy Combo Test will display positive results with specimens containing hCG at the level close to or greater than 25 mIU/ml. The test is standardized to the WHO 3rd IS 75/537.

2. Accuracy

- Samples studied

  Forty serum and urine pools from healthy non-pregnant humans were spiked with hCG to the concentrations of 0, 15, 20, 25, 30, 35, 50, 100 mIU/ml in an evenly distributed number, 5 of each. All specimens were blind labeled.

- Comparison studies

  Comparison studies on the Pregnancy Combo 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 is 100%.

- Physician's Office Laboratory (POL) Studies

  The Pregnancy Combo Test was evaluated at three POL sites by persons with diverse educational backgrounds and work experiences. The results from all three POL sites agreed 100%.

3. Specificity

The α subunit of hTSH, hLH, and hFSH is 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 25mIU/ml) and negative specimens were tested, separately, in the Pregnancy Combo Test, and did not effect the expected results.

4. Interfering Substances

The following analytes spiked in serum and urine pools containing 0, or 25mIU/ml hCG (WHO 3rd IS) were tested separately in the *Instant-View*® Pregnancy Combo Test, and did not affect the expected results.

Chemical Analytes

Description	Concentration
Acetoacetic Acid	2,000 mg/dL
Acetaminophen	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL
Benzoylecgonine	10 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
DMSO	5%
EDTA	80 mg/dL
Ephedrine	20 mg/dL
Ethanol	1%
Gentisic Acid	20 mg/dL
Methadone	10 mg/dL
Methanol	10%
Phenothiazine	20 mg/dL
Phenylpropanalamine	20 mg/dL
Salicylic Acid	20 mg/dL
ß-Hydroxybutyrate	2,000 mg/dL
Uric Acid	20 mg/dL

Biological Analytes

Description	Concentration
Albumin(serum)	2,000 mg/dL
Bilirubin	1,000 μg/dL
Hemoglobin	1,000 μg/dL
Glucose	2,000 mg/dL
pH	5-9

Bacteria

Description	Concentration
E. Coli	10^8 CFU/mL
Group B streptococcus	$2.5x\ 10^8$ CFU/mL
Chlamydia trachomatis	10^4 IFU/mL

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- Ross GT. Clinical relevance of research on the structure of human chorionic gonadotropin. American Journal of Obstetrics and Gynecology 1977; 129:795

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
	For IVD performance evaluation only	2	Do not reuse
	Caution, consult accompanying documents	CE	CE Mark

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