

Instant-View[®] Pregnancy Urine Dip-Strip Test C€

One Step Assay

Rapid Visual Results

For Qualitative In Vitro Diagnostic Use

INTENDED USE

The Pregnancy Urine Dip-Strip Test is a qualitative immunoassay for the detection of human chorionic gonadotropin (hCG) in human urine for the early detection of pregnancy. This test is for health care professional use only. Not for self testing.

SUMMARY AND EXPLANATION OF THE TEST

This pregnancy test is based on the detection of human chorionic gonadotropin (hCG) in urine. hCG is a hormone produced by the placenta. In normal subjects, urine hCG provides an early indication of pregnancy. The Pregnancy Urine Dip-Strip Test uses a monoclonal antibody specific to hCG to accurately detect hCG at levels 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 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 test, 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 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 a goat anti-mouse antibody, which binds to the gold-antibody conjugate and forms a colored line regardless of the presence of hCG.

REAGENTS AND MATERIALS SUPPLIED

- 50 Test strips, each sealed in a pouch with desiccant.
- 1 Package insert (Instructions for Use).

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

STORAGE AND STABILITY

Store the kit at room temperature 15-30°C (59-86°F). Each test 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.
- 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 tests.
- Dispose of all specimens and used assay materials as potentially biohazardous.

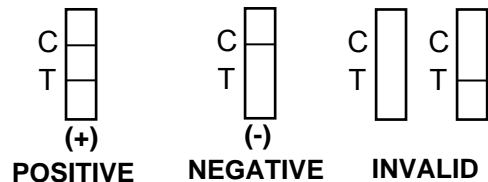
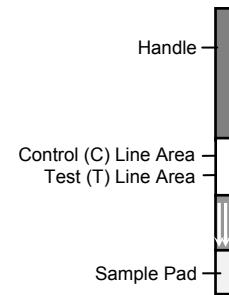
ASSAY PROCEDURE

1. Refrigerated specimens and other test materials, including tests, **must be equilibrated to room temperature before testing.**
2. Remove a dip-strip from its pouch. Label the test and sample container (not provided) accordingly.
3. Hold the dip strip vertically from the handle end. Dip the sample pad in the specimen for about 10 seconds. Keep the specimen surface at the level indicated by the arrows on the test.
4. Remove the test from the specimen and place it on a flat, dry surface.
5. Strong positive results may be observed in 2-3 minutes. Weak positive results may take longer, up to 5 minutes, to develop.

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 the T line appear, hCG is present in the specimen at a level equal to or greater than 25 mIU/mL.

Samples producing positive results should be confirmed by a more specific method before a positive determination is made.^{2,4}

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 tests 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

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.

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LIMITATIONS

- This kit is not intended for any use other than the early detection of pregnancy.
- 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 by hCG measurements alone.
 - Positive hCG levels may be detectable for several weeks following delivery or abortion.
- 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 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 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

This test will produce positive results with specimens containing hCG at concentrations equal to or greater than 25 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 Pregnancy Urine Dip-Strip 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**
This 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 μ IU/mL), hLH (up to 300 mIU/mL) and hFSH (up to 1,000 mIU/mL) spiked in hCG positive (spiked to 25 mIU/mL) and negative specimens were tested separately with the Pregnancy Urine Dip-Strip Test, and were shown not to affect the expected results in the study.

4. Interfering Substances

The following analytes spiked in urine pools containing 0 or 25 mIU/mL hCG (WHO 3rd IS) were tested separately with the Pregnancy Urine Dip-Strip Test and did not affect the expected results.

Chemical Analytes

Compound	Concentration	Compound	Concentration
Acetoacetic acid	2,000 mg/dL	Ethanol	1%
Acetaminophen	20 mg/dL	Gentisic acid	20 mg/dL
Acetylsalicylic acid	20 mg/dL	Methadone	10 mg/dL
Ascorbic Acid	20 mg/dL	Methanol	10%
Benzoyllecgonine	10 mg/dL	Phenothiazine	20 mg/dL
Caffeine	20 mg/dL	Phenylpropanolamine	20 mg/dL
Cannabinol	10 mg/dL	Salicylic acid	20 mg/dL
DMSO	5%	β -Hydroxybutyrate	2,000 mg/dL
EDTA	80 mg/dL	Uric acid	20 mg/dL
Ephedrine	20 mg/dL		

Biological Analytes

Compound	Concentration
Albumin (serum)	2,000 mg/dL
Bilirubin	1,000 μ g/dL
Hemoglobin	1,000 μ g/dL
Glucose	2,000 mg/dL












Positive and negative urine pools were tested at various pH levels. pH ranges from pH 5 to pH 9 did not affect the expected results in the study.


Bacteria

Bacteria	Concentration
<i>E. coli</i>	10 ⁸ CFU/mL
Group B Streptococcus	2.5x 10 ⁸ CFU/mL
<i>Chlamydia trachomatis</i>	10 ⁴ IFU/mL

REFERENCES

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- 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
	Batch/Lot code		In vitro diagnostic medical device
	Manufacturer		Catalog number
	Contains sufficient for < n > tests		Consult instructions for use
	Do not reuse		CE Mark
	Caution, consult accompanying documents		

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