Fecuntest
strips

Immunochromatographic test for pregnancy detection in serum, plasma or urine

SUMMARY

Human Chorionic Gonadotropin (hCG) is a glycoprotein produced by placental trophoblast cells. Secretion starts during the earliest phase of the gestational stage and increases steadily up to a peak, about 9 weeks after the onset of the last normal menstrual period. Since hCG production indicates placental growth, it is possible to establish a direct relationship between the appearance of hCG and pregnancy.

PRINCIPLE

Fecuntest strips test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum.

The nitrocellulose membrane is conjugated with anti-hCG antibodies in the test zone (T) and anti-mouse goat antibodies in the control zone (C). The assay is conducted by immersing the test strip in a urine, serum or plasma specimen and observing the formation of colored lines.

Samples react with colloidal gold particles conjugated with mouse monoclonal anti-hCG antibodies. The mixture migrates via capillary action along the membrane. If the result is positive, a colored line will be formed with the complex particle in the test zone. Absence of this colored line in the test zone suggests a negative result. 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, regardless of hCG presence in the sample.

PROVIDED REAGENTS

Test strips: nitrocellulose strips conjugated with anti-hCG antibodies and colloidal gold particles conjugated with mouse anti-hCG monoclonal antibody.

WARNINGS

- Reagents are for “in vitro” diagnostic use. Do not use after the expiration date.
- Test strips should remain in the can until use.
- Test strips should be disposed in a proper biohazard container after use.
- All specimens should be handled as capable of transmitting infectious agents.
- The results obtained with the tests are strictly qualitative and do not show any correlation with the increase or decrease of hCG concentration.
- Test results should be used with the information of the patient’s clinical evaluation available and further diagnostic procedures.
- Use the reagents according to the working procedures for clinical laboratories.
- All reagents and samples should be discarded according to current regulations.

STABILITY AND STORAGE INSTRUCTIONS

If stored in a sealed can, Provided Reagents are stable at room temperature (2-30°C) until the expiration date stated on the box.

Once the can is opened, remove the required test strips and immediately close the container to avoid moistening of the remaining strips.

SAMPLE

Serum, heparinized plasma or urine

a) Collection: obtain the sample in the usual way. First morning urine usually contains the highest concentration of hCG and is therefore the best sample when performing urine test.

b) Additives: not required. Collect with heparin if plasma is used.

c) Known interfering substances: strong hemolysis may lead to erroneous results.

Urine samples with sedimentation or turbidity should be filtered or centrifuged before testing. Interference is not produced in urine, serum or plasma by: acetaminophen (20 mg/dl), acetylsalicylic acid (20 mg/dl), ascorbic acid (20 mg/dl), ethinyl estradiol (1400 mg/dl), progesterone (1500 mg/dl), caffeine (20 mg/dl), bilirubin (20 mg/dl), glucose (2 mg/dl) and triglycerides (1200 mg/dl).

See Young, D.S. in References for effect of drugs and diseases on the present method.

d) Stability and storage instructions: samples can be stored for up to 48 hours at 2-10°C. If kept for longer periods of time, the specimens should be frozen at -20°C or less. Avoid repeated freezing and thawing. Bring the sample to room temperature before testing.

REQUIRED MATERIAL (non-provided)

- Container for sample collection
- Stopwatch

ASSAY CONDITIONS

- Reaction time: 3 minutes for urine and 5 minutes for serum or plasma
- Reaction temperature: room temperature (< 30°C)

PROCEDURE

1- The test strip and the sample should be kept at room temperature (< 30°C) before use.

2- Remove the test strip from the can, and label with the corresponding patient identification.

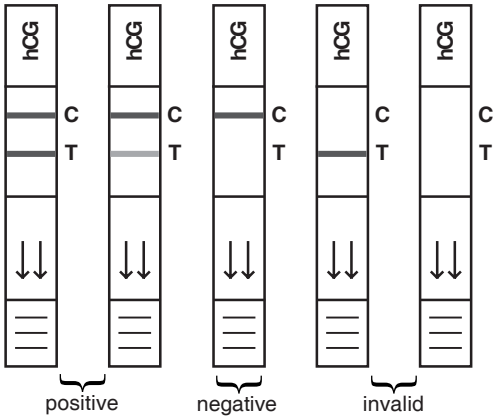
3- Dip the test strip in the sample to be tested, holding it in a vertical position for at least 15 seconds, being careful to not go beyond the specified maximum band allowed (MAX).

4- Place the test strip on a clean, flat and dry surface, start the stopwatch and wait until the colored bands appeared. Use a new test strip for each sample.

Holding the sample dropper vertically, place 3 drops (approximately 100 ul) of sample in the sample well (S) as indicated in the diagram. Use a new test device and dropper for each sample.

5- Observe the appearance of colored bands. Read the result after 3 minutes when urine is tested or after 5 minutes when serum is tested. Results should not be interpreted 10 minutes after the recommended time for each sample type.

INTERPRETATION OF RESULTS



Positive: two red bands are observed on the test strip, one corresponds to the control and the other to hCG presence.
Negative: a red band appears in the control zone (C).
Invalid: lack of appearance of red band in the control zone, which may be caused by:
- insufficient sample volume
- incorrect technical procedure
- reagent deterioration

If the result is not valid, retest using other strip. If the result is uncertain retest using a sample obtained 48-72 hours later. Uncertain samples with a negative result may be attributed to decreased hCG levels after spontaneous or induced abortions. The color intensity in the test zone band (T) will change according to the hCG concentration present in the sample.

QUALITY CONTROL METHOD

The test includes a control procedure. Commercial controls may be additionally tested.

PROCEDURE LIMITATIONS

False positive results may be observed in certain pathologies such as trophoblastic disease and non-trophoblastic neoplasms (testicular cancer), prostate, breast and lung cancer with increased hCG levels.

False negative results may be observed in very recent pregnancy, where hCG concentration is below any distinctive value, and also in extremely diluted urines. Therefore, it is recommended to do the test again after 48-72 hours.

As any other test using murine antibodies, positive or negative interference is possible due to the presence of human anti-murine antibodies (HAMA), which are present in patient samples (veterinarians, individuals treated with antibody therapy, etc.). The test is used to obtain a visual and qualitative result.

REFERENCE VALUES

Healthy non-pregnant men and women do not have hCG detectable by the **Fecuntest strips** kit.

Typically in healthy pregnant women hCG concentration is doubled every 2 days during the first days of pregnancy and after 10 days reaching values between 10-30 mIU/ml; after a month values close to 100 mIU/ml and at the end of the first quarter a peak of activity with values between 100,000-200,000 mIU/ml. Then, hCG concentration gradually decreases to a normal value after childbirth. Therefore, **Fecuntest strips** has the sensitivity required (25 mIU/ml) to detect Chorionic Gonadotropin hormone (hCG) in the serum, plasma and urine of healthy pregnant women.

PERFORMANCE

a) Sensitivity: Fecuntest strips detects hCG concentrations in urine equal or higher than 25 mU/ml (calibrated according to WHO Fourth International Standard NIBSC code: 75/589).

b) Specificity: negative results were obtained performing cross-reaction studies with 300 mU/ml LH, 1000 mU/ml FSH and 1000 uU/ml TSH.

c) Prozone effect: it is not observed up to a concentration of 625,000 mIU/ml.

d) Population studies: a correlation study of the product under evaluation was performed (Fecuntest strips) using Wiener lab. **Fecuntest un paso v.2**. Results were obtained following NCCLS protocol EP12-A. One hundred urine samples were tested, 102 serum samples and 87 heparinized plasma samples. The results show 100% sensitivity and specificity when compared to other immunochromatographic hCG test of similar features.

WIENER LAB. PROVIDES

Kit for 25 tests (Cat. Nr. 1999705)

REFERENCES

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SYMBOLS

The following symbols are used in packaging for Wiener lab. diagnostic reagents kits.

CE	This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices
EC REP	Authorized representative in the European Community
IVD	"In vitro" diagnostic medical device
Σ	Conteins sufficient for <n> tests
	Use by
	Temperature limitation (store at)
	Do not freeze
	Biological risks
→	Volume after reconstitution
Cont.	Contents
LOT	Batch code
	Manufactured by:
Xn	Harmful
	Corrosive / Caustic
Xi	Irritant
	Consult instructions for use
Calibr.	Calibrator
CONTROL	Control
CONTROL +	Positive Control
CONTROL −	Negative Control
REF	Catalog number

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