hCG Rapid Pregnancy Test

Cassette 25mIU/mL

PRINCIPLE

The Suresign Pregnancy Test Cassette is a rapid, one-step lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the detection of pregnancy. The test utilises a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by dispensing 3 drops of urine (120 µl) into the circular sample well of the cassette, and obtaining the result from the formation of coloured lines in the test cassette window.

Human chorionic gonadotropin (hCG) is a hormone produced by the developing placenta shortly after fertilisation. In normal pregnancy, hCG can be detected in urine as early as 7 days following conception. Levels of hCG rise rapidly, frequently exceeding 100mIU/mL by the first missed menstrual period, and peaking at 100,000-200,000mIU/mL about 10-12 weeks into pregnancy.

PRECAUTIONS

- Please read all the information in this package insert before performing the test. Pay particular attention to the position of the C and T lines.
- Do not use after the expiration date printed on the foil pouch.
- Store in the sealed pouch in a dry place at 4-30°C. Do not freeze.
- Do not use if pouch is torn or damaged.
- Do not open the foil pouch until you are ready to start the test.
- Do not reuse the test device. Dispose of hygienically in clinical waste.
- Do not touch the membrane.
- Treat urine samples and used devices as potentially infectious. Avoid contact with skin.
- Keep out of the reach of children.
- For in vitro diagnostic use. Not to be taken internally. Do not eat the desiccant in the package.

KIT CONTENTS

- 1 Pregnancy Test Cassette (in foil pouch)
- Package insert
- Pipette (in foil pouch)

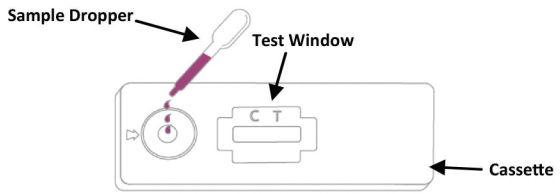
MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Sample container
- Disposable gloves (optional)

SPECIMEN

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG. However, urine specimens collected at any time of the day may be used.

TEST DEVICE

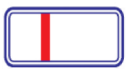


INSTRUCTIONS

1. Allow the Pregnancy Test device and urine sample to reach room temperature 15-30°C (59-86°F) before opening the foil pouch.
2. Remove the Pregnancy Test device from the pouch and use it immediately.
3. Lay the test device down on a flat, non-absorbent, clean surface.
4. Using the sample dropper, collect urine from the sample container (not supplied) and slowly dispense 3 drops (120 µl) of urine into the cassette well.
5. Start the timer and wait for the red line(s) to appear.
6. Read the result at 5 minutes. Do **not** read the result after 15 minutes.

READING THE RESULTS

POSITIVE
Two red-purple coloured lines appear. One line should be in the Control region (C) and another line should be in the Test region (T).



NEGATIVE
One red-purple coloured line in the Control region (C). No apparent red or purple line appears in the Test region (T).

INVALID
The result is invalid if the Control Line (C) fails to appear. Insufficient volume of urine or incorrect procedure are the most likely reasons for an invalid result. Review the procedure and repeat with a new test. If the problem persists, discontinue use of the test and contact the Manufacturer.

QUALITY CONTROL

A red-purple line appearing in the control region (C) confirms that the test is performing properly. It indicates that sufficient urine has been applied to the device and that the correct procedure has been carried out.

LIMITATIONS

1. Alcohol may interfere with the test result. It is not recommended to test the patient if they have been drinking alcohol.
2. If a woman has recently been pregnant, (even if not carried to full term), a false "Pregnant" result may be obtained. Occasionally, urine specimens containing less than 25mIU/mL hCG can also give a positive result.
3. Ectopic pregnancy, ovarian cysts, menopause and some very rare medical conditions can give misleading results.
4. In cases where very high levels of hCG are present (>500,000mIU/mL), a false negative result can occur due to a "prozone" effect
5. Excessive fluid intake should be avoided before testing. A "Not Pregnant" result may be obtained if the urine sample is too dilute.
6. Fertility drugs containing hCG can give misleading results. These fertility drugs are usually given by injection and testing too soon after administration may give a false "Pregnant" result.
7. Other fertility therapies (e.g. clomiphene citrate), painkillers and hormonal contraceptives (e.g. contraceptive pill) should not affect the results.
8. A number of conditions other than pregnancy including trophoblastic disease and certain non-trophoblastic neoplasms, including testicular tumours, prostate cancer, breast cancer and lung cancer, cause elevated levels of hCG. Therefore the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
9. The Pregnancy Test Cassette is not reusable.

EXPECTED VALUES

Negative results are expected in healthy, non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with the gestational age and between individuals.

SENSITIVITY AND SPECIFICITY

The Suresign hCG Rapid Pregnancy Test (25mIU/mL) detects hCG at a concentration of 25mIU/mL or greater. The test has been standardised to the WHO 3RD International standard. The addition of LH (300 mIU/ml), FSH (1000 mIU/ml) and TSH (1000 µIU/ml) to negative (0 m IU/ml hCG) and positive (25mIU/mL) specimens showed no cross reactivity.

PERFORMANCE CHARACTERISTICS

A clinical evaluation was conducted comparing the results obtained using the Suresign hCG Rapid Pregnancy Test Cassette (25mIU/mL) to another commercially available hCG test. The study included 320 urine specimens; both assays identified 200 negative and 120 positive results. The results demonstrated 100% overall agreement, for an accuracy > 99%, of the Suresign hCG Rapid Pregnancy Test Cassette when compared to the other urine membrane hCG test.

	Comparison reagent (Commercially available Pregnancy Test)		Examination reagent (Suresign hCG Rapid Pregnancy Test)		Total
Results	+	-	+	-	
Positive	120	0	120	0	120
Negative	0	200	0	200	200
Total	120	200	120	200	320

INTERFERING SUBSTANCES

The following potentially interfering substances were added to hCG negative and positive specimens. None of the substances at the concentration tested interfered with the assay.

Acetoacetic Acid	2000mg/ dL	Gentistic Acid	20mg/ dL
Acetaminophen	20mg/ dL	Methadon	10mg/ dL
Acetylsalicylic Acid	20mg/dL	Methanol	10%
Atropine	20mg/ dL	Phenothiazine	20mg/ dL
Benzoylecgonine	10mg/ dL	Phenylpropanalamine	20mg/ dL
Caffeine	20mg/ dL	Salicylic Acid	20mg/ dL
Cannabinol	10mg/ dL	β-Hydroxybutyrate	2000mg/ dL
DMSO	5%	Uric Acid	20mg/ dL
EDTA	80mg/ dL	Ascorbic Acid	20mg/ dL
Ephedrine	20mg/ dL	ampicilline	20mg/ dL
Ethanol	1%		

REFERENCES

Dawood MY, BB Saxena , R Landesman
" Human Chorionic Gonadotropin and its subunits in hydatidiform mole and choriocarcinoma" Obset Gynecol. 1977;50 (2):172-181

Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross
"Ectopic production of human chorionic gonadotropin by neoplasms" Ann. Intern Med. 1973:

!	Attention, see instructions for use	Σ	Tests per kit		Manufacturer
IVD	For *in vitro* use only		Use by		Do not re-use
4°C 30°C	Store between 4-30°C	LOT	Lot Number	REF	Catalogue #

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