PregnanStick™

A rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum.

Instruction Manual

Test kit for 50/100 tests individually pouched
(Catalog No. 41210)

For *In Vitro* Diagnostic Use
For professional use only
Store at 2-30°C. ***Do Not Freeze***

Savyon® **Diagnostics Ltd.**
3 Habosem St. Ashdod 77610
ISRAEL
Tel.: +972.8.8562920
Fax: +972.8.8523176
E-mail: support@savyondiagnostics.com

Intended Use
The PregnanStick™ is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum to aid in the early detection of pregnancy.
For *in vitro diagnostic* use only.

Summary

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception.[1,2,3,4] hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period,[2,3,4] and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.
The PregnanStick™ is a rapid test that qualitatively detects the presence of hCG in urine or serum specimens at a sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine or serum. At the level of claimed sensitivity, the PregnanStick™ shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

Principle

The PregnanStick™ is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum to aid in the early detection of pregnancy. The test uses two lines to indicate results. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The control line is composed of goat polyclonal antibodies and colloidal gold particles. The assay is conducted by immersing the test strip in a urine or serum specimen and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.
Positive specimens react with the specific antibody-hCG-colored conjugate to form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve 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.

Reagents

The test strip contains anti-hCG particles and anti-hCG coated on the membrane.

Precautions

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test strip should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test strip should be discarded in a proper biohazard container after testing.

Storage and Stability

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

Specimen Collection and Preparation

Urine Assay
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. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.
Serum Assay
Blood should be collected aseptically into a clean tube without anticoagulants. Separate the serum from blood as soon as possible to avoid hemolysis. Use clear non-hemolyzed specimens when possible.
Specimen Storage
Urine or serum specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

Materials

Materials Provided
- Test strips
- Package insert

Materials Required but not Provided
- Specimen collection container
- Timer

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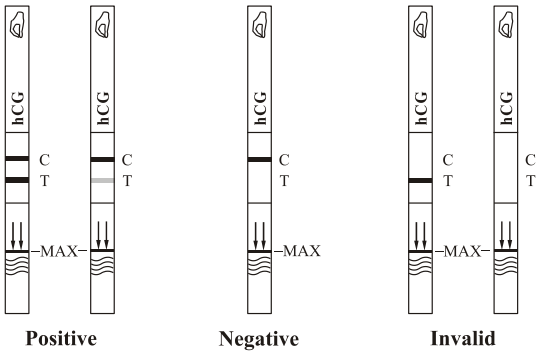
Directions for Use

Allow the test strip, urine or serum specimen and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the urine or serum specimen, **immerse the test strip vertically in the urine or serum specimen for at least 10-15 seconds**. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. **Read the result at 3 minutes when testing a urine specimen**, **or at 5 minutes when testing a serum specimen**.

NOTE: A low hCG concentration might result in a weak line appearing in the test line region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.



Interpretation of Results

(Please refer to the illustration above)

POSITIVE:* Two distinct red lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).

***NOTE:** The intensity of the red color in the test line region (T) may vary depending on the concentration of hCG present in the specimen. Therefore, any shade of red in the test line region (T) should be considered positive.

NEGATIVE: One red line appears in the control line region (C). No apparent red or pink line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Quality Control

A procedural control is included in the test. A red line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If a background color appears in the result window and interferes with the ability to read the test result, the result may be invalid.

It is recommended that a positive hCG control (containing 25-250 mIU/mL hCG) and a negative hCG control (containing "0" mIU/mL hCG) be evaluated to verify proper test performance when a new shipment of test strips is received.

Limitations

1. The PregnanStick™ is a preliminary qualitative test. Therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
2. Diluted urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine and serum specimens shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons,[5] a test result that is weakly positive should be confirmed by retesting with a first morning urine or serum specimen collected 48 hours later.
4. This test may produce false positive results. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG.[6,7] Therefore, the presence of hCG in urine or serum specimens should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. This test may produce false negative results. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine or serum specimen should be collected 48 hours later and tested. In case pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
6. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.
7. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

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 gestational age and between individuals.

The PregnanStick™ has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

Performance Characteristics

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the PregnanStick™ to another commercially available urine and serum membrane hCG test. The urine study included 155 specimens, and both assays identified 76 negative and 79 positive results. The serum study included 57 specimens, and both assays identified 38 negative and 19 positive results. The results demonstrated a > 99.0% overall accuracy of the PregnanStick™ when compared to the other urine and serum membrane hCG test.

hCG Reference Method (Urine)

Method		Other hCG Rapid Test		Total Results
PregnanStick	Results	Positive	Negative	
	Positive	79	0	79
	Negative	0	76	76
Total Results		79	76	155

Sensitivity: 100% (95%-100%)*
Specificity 100% (95%-100%)*
Accuracy 100% (98%-100%)*
* 95% Confidence Intervals

hCG Reference Method (Serum)

Method		Other hCG Rapid Test		Total Results
PregnanStick	Results	Positive	Negative	
	Positive	19	0	19
	Negative	0	38	38
Total Results		19	38	57

Sensitivity: 100% (82%-100%)*
Specificity 100% (91%-100%)*
Accuracy 100% (94%-100%)*
* 95% Confidence Intervals

Sensitivity and Specificity
The PregnanStick™ detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

Interfering Substances
The following potentially interfering substances were added to hCG negative and positive specimens.

Acetaminophen	20 mg/dL	Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL	Gentisic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL	Glucose	2 g/dL
Atropine	20 mg/dL	Hemoglobin	1 mg/dL
Bilirubin (serum)	40 mg/dL	Bilirubin (urine)	2 mg/dL
Triglycerides (serum)	1200 mg/dL		

None of the substances at the concentration tested interfered in the assay.

Bibliography

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6. Dawood MY, BB Saxena, R Landesman *Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma*, Obstet. Gynecol. 1977; 50(2): 172-181
7. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross *Ectopic production of human chorionic gonadotropin by neoplasms*, Ann. Intern Med. 1973; 78(1): 39-45

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30℃	LOT	Lot Number	REF	Catalog #

CE

European Authorized Representative: Obelis s.a.
Boulevard Général Wahis 53, B-1030 Brussels
Tel: +32.2.732.59.54 Fax: +32.2.732.60.03
E-mail:mail@obelis.net