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***

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Intended Use

The PregnanStick™ is a rapid visual immunoassay for the qualitative, presumptive detection of human chorionic gonadotropin in human urine or serum specimens. This kit is intended for use as an 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 serum and urine as early as 7 to 10 days after conception. hCG level continues to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period, and peaking in the 30,000 – 100,000 mIU/mL (in urine) range by 10-12 weeks into pregnancy. The appearance of hCG in both the 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. However, elevated hCG levels are frequently associated with trophoblastic and non-trophoblastic neoplasms and hence these conditions should be considered before a diagnosis of pregnancy can be made.

Principle

The PregnanStick™ detects human chorionic gonadotropin through visual interpretation of color development on the strip. Anti-hCG antibodies are immobilized on the test region of the membrane and anti mouse antibodies on the control region. During testing, the specimen reacts with anti-hCG antibodies conjugated to colored particles and pre-coated on the sample pad of the strip. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient hCG in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Materials

- Individually packed test strips

Materials Required but Not provided

- Specimen collection container
- Timer
- Centrifuge

Precautions

- For professional *in vitro diagnostic* use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

Storage and Stability

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

Specimen Collection and Preparation

- The PregnanStick™ is intended for use with human urine or serum specimens only.
- Though urine specimens from any time of day can be used, first morning urine specimens are preferred as they contain the highest concentration of hCG.
- Only clear specimens are recommended for use with this test. Serum should be separated with soonest possible opportunity to avoid hemolysis.

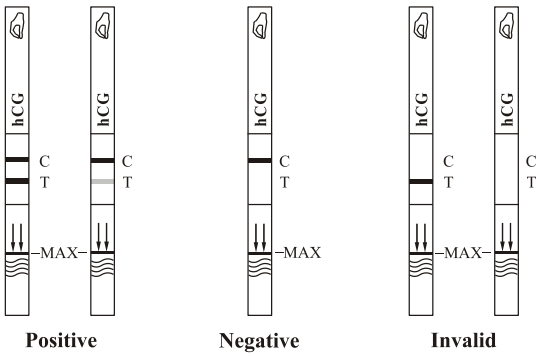
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Specimens must be collected in clean, dry containers. Ensure that the volume of specimen collected is sufficient to submerge the dip region of the strip.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. For long term storage, specimens should be kept below - 20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- Icteric, lipemic, hemolysed, heat treated and contaminated serum may cause erroneous results.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

Test Procedure

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch and use it as soon as possible. For best results, the assay should be performed within one hour.
2. Hold the strip by the end, where the product name is printed. To avoid contamination, do not touch the strip membrane.
3. Holding the strip vertically, dip the test strip in the specimen for at least 10-15 seconds. Do not immerse past the maximum line (MAX) on the test strip. As the test begins to work, color will migrate across the membrane.
4. After the test has finished running, remove the strip from the specimen and place it on a non-absorbent flat surface. Start the timer and wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

NOTE: Low hCG concentrations may produce very weak test bands (T) after a prolonged 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).

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. immediately contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure. Contact your local distributor.

Quality Control

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations

1. The PregnanStick™ is for professional in vitro diagnostic use, and should only be used for the qualitative detection of human chorionic gonadotropin.
2. Very dilute urine specimens, exhibiting low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine sample should be obtained 48-72 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine or serum shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be interpreted in conjunction with other clinical and laboratory data.
4. 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 (>10 mIU/mL). Therefore, the presence of hCG in urine as determined by using the PregnanStick™ (Urine/Serum) should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. When hCG levels are below the minimum detection level of the test, a false negative result might be obtained. If pregnancy is still suspected, a first morning urine 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. As with all diagnostic tests, a confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Expected Values

Urine hCG concentration in pregnant women rises very rapidly after implantation, reaching a peak concentration in excess of 200 IU/mL about 2-3 months after the last menstrual period. The PregnanStick™ has a sensitivity of 25 mIU/mL for urine or serum, and is capable of detecting pregnancy as early as 1 day after the first missed menses.
Reportedly, a level of 25 mIU/mL or more is present 7-10 days after conception or 4-5 days prior to the first missed menses. Test results which appear as very light bands in the test region are not definitive for the diagnosis of pregnancy. It is strongly recommended that an additional urine specimen be obtained after 48-72 hours and tested. Patients suspected to be pregnant but showing negative test results should be re-tested with first morning specimens obtained 48-72 hours later.

Performance Characteristics

Table: PregnanStick™ vs. Commercially Available hCG Rapid Test (Urine)

		PregnanStick™		
		Positive	**Negative**	**Total**
EIA	Positive	130	0	130
	Negative	0	178	178
		130	178	308

Relative Sensitivity: >99.9% (97.2%-100%)*
Relative Specificity: >99.9% (98%-100%)*
Overall Agreement: >99.9% (99.7%-99.9%)*
*** 95% Confidence Interval**

Table: PregnanStick™vs. Commercially Available hCG Rapid Test (Serum)

		PregnanStick™		
		Positive	**Negative**	**Total**
EIA	Positive	169	0	169
	Negative	0	250	250
		169	250	419

Relative Sensitivity: >99.9% (97.8%-100%)*
Relative Specificity: >99.9% (98.5%-100%)*
Overall Agreement: >99.9% (99.1%-100%)*
*** 95% Confidence Interval**

Specificity
The specificity of the PregnanStick™ was determined from cross reactivity studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH) and Thyroid Stimulating Hormone (hTSH). 300 mIU/mL hLH, 1000 mIU/mL hFSH and 1000 µIU/mL hTSH all produced negative results.

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Index of Symbols

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

CE

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