QuickStripe™ hCG

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

Instruction Manual

Test kit for 25 tests individually pouched
(Catalog No. 41110)

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

Savyon® **Diagnostics Ltd.**
3 Habosem St. Ashdod 7761003
ISRAEL
Tel.: +972.8.8562920
Fax: +972.8.8523176
E-mail: support@savyondiagnostics.com

Intended Use

The *QuickStripe*™ hCG 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 early detection of pregnancy.
For professional in vitro diagnostic use only.

Summary

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by viable placental tissue during pregnancy, is excreted in urine approximately 20 days after the last menstrual period. [1-4] hCG levels rise rapidly, reaching peak levels after 60-80 days. The appearance of hCG in urine soon after conception and its rapid rise in concentration makes it an ideal marker for the early detection and confirmation 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 *QuickStripe*™ hCG is a rapid chromatographic immunoassay for the detection of human chorionic gonadotropin through visual interpretation of color development in the internal strip. Anti-hCG antibodies are immobilized on the test region of the membrane, and anti-mouse antibodies immobilized on the control region. During testing, the specimen reacts with anti-hCG antibodies conjugated to colored particles and pre-coated onto 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

Materials Provided

- Test devices
- Droppers

Materials Required but not Provided

- Specimen collection container
- Timer
- Centrifuge (for serum samples)

Precautions

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device 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 device should be discarded in a proper biohazard container after testing.

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 *QuickStripe*™ hCG *is intended for use with* human urine or serum specimens only.

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.

Turbid specimens should be centrifuged, filtered or allowed to settle and only the clear supernatant should be used for testing.

Specimen Storage

Do not leave specimens at room temperature for prolonged period. 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.

Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

Procedure

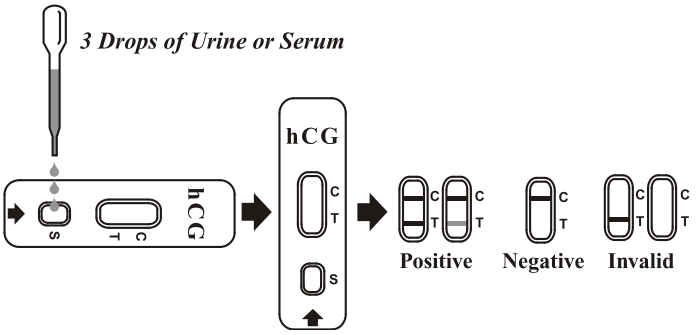
Allow the test device, urine or serum specimen and/or controls to equilibrate to room temperature (15-30ºC) prior to testing.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed within one hour.
2. Add 3 drops of specimen (approximately 120 µL) directly into the specimen well (S) and start the timer.

   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.

   As the test begins to work, color will migrate across the result area in the center of the device.
3. 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: A low hCG concentration might result in a weak line appearing in the test 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 colored bands appear on the membrane. One band appears in the control line region (C) and another line should be in the test line region (T).

NEGATIVE: Only one colored band appears in the control line region (C). No apparent colored appears in the test line region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and 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.

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 *QuickStripe*™ hCG is a test (Urine/Serum) 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 suspected after a negative result, 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/serum as determined by using the The *QuickStripe*™ hCG 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 may be obtained. If pregnancy is suspected after a negative result, a first morning urine specimen should be collected 48-72 hours later and tested. If 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 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

hCG concentration in pregnant women rises very rapidly after implantation, reaching a peak concentration in excess of 200IU/mL about 2-3 months after the last menstrual period. The *QuickStripe*™ hCG has a sensitivity of 25 mIU/mL for urine/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/serum specimen be obtained after 48-72 hours and tested again. 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

A clinical evaluation was conducted comparing the results obtained using the *QuickStripe*™ hCG to ELISA test in 2 different POC sites. All samples were masked prior to analysis. Testing was performed according to labeling.

QuickStripe hCG vs EIA (Urine)

Method		EIA		Total Results
QuickStripe hCG	Results	Positive	Negative	
	Positive	130	0	130
	Negative	0	178	178
Total Results		130	178	308

Relative Sensitivity: >99.9% (97.2%-100%)*
Relative Specificity: >99.9% (98%-100%)*
Overall Agreement: 99.9% (98.8%-100%)*
*** 95% Confidence Interval**

hCG Reference Method (Serum)

Method		EIA		Total Results
QuickStripe hCG	Results	Positive	Negative	
	Positive	169	0	169
	Negative	0	250	250
Total Results		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**

Cross Reactivity

The specificity of the *QuickStripe*™ hCG was determined in 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

gave negative results.

Interfering Substances

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

• Acetoaminophen	20 mg/dL	• Glucose	2000 mg/dL
• Acetoacetic Acid	20 mg/dL	• Bilirubin	2 mg/dL
• Ascorbic Acid	20 mg/dL	• Hemoglobin	1 mg/dL
• Caffeine	20 mg/dL	• Urea	2000 mg/dL
• Gentisic Acid	20 mg/dL	• Creatinine	20 mg/dL
• EDTA	20 mg/dL	• Atropine	20 mg/dL
• Acetylsalicylic Acid	20 mg/dL	• Oxalic Acid	40 mg/dL
• Ethanol	1.0%	• Uric Acid	20 mg/dL
• Methanol	10%	• THC	10mg/dL

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

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Index or Symbols

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

CE

European Authorized Representative: Obelis s.a.
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