SP™ Brand Rapid Urine hCG Test

PURPOSE

To aid in the early detection of pregnancy at the point of care.

PRINCIPLE

The SP™ Brand Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding a urine specimen to the specimen well of the test device and observing the formation of colored lines, as the specimen migrates via capillary action along the membrane to the test area.

Specimens containing increased hCG concentrations react with the specific antibody conjugates and form a line at the test line region of the membrane (positive result). Absence of this line indicates a negative result. To serve as a procedural control, a line will always appear at the control line region if the test has been performed properly.
TESTING PERSONNEL

- Qualified Licensed Registered Nurses (RNs) and approved Health Care Providers

SPECIMEN

A. First morning urine specimen is preferred – this sample contains the highest concentration of hCG hormone.

B. The urine collection container should be clean and dry, and must not contain any preservatives.

**NOTE:** Test should **not** be performed on urine specimens exhibiting visible precipitates.

C. Stability: up to 48 hours refrigerated at 2-8°C.

EQUIPMENT

A. Disposable specimen droppers (included in test pouch)
B. Package insert
C. Specimen collection container
D. Timer

REAGENTS

SP™ Brand Rapid Test cassettes contain anti-hCG gold conjugate and anti-hCG coated on the membrane.

Storage and Stability:
Store as packaged in the sealed pouch at 2-30°C. The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

QUALITY CONTROL

**Internal Quality Controls:**
Internal quality controls are included in the test. A line appearing in the control region (C) is the positive internal quality control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white and not interfere.
External Quality Control Testing:
Controls are run on all new lot numbers or shipments of test cassettes and as needed by the Clinical Laboratory prior to distribution.

PROCEDURE:

Allow the test cassette and urine to equilibrate to room temperature prior to testing.

A. Using two patient identifiers, verify the patient’s identity, and explain the procedure to patient and/or family.

B. Observe universal precautions; wear gloves and other personal protective equipment as appropriate.

C. Label a urine cup with the patient’s name and Medical Record Number and hand it to the patient for urine collection.

**NOTE:** Pre-collected urine specimens (i.e., from home) must meet acceptable Specimen Criteria (see SPECIMEN heading prior page) and be labeled with two patient identifiers.

D. The test device should be at room temperature before it is removed from its protective pouch. This avoids condensation of moisture on the test membrane.

E. Remove the test cassette from the sealed pouch and use it as soon as possible.

F. **Label the test cassette** with the patient’s name and Medical Record Number.

G. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100µl) to the specimen well of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well.

H. Wait for the line to appear. The result should be read at 3 minutes. It is important that the background is clear before the result is read.

**NOTE:** A low hCG concentration might result in a weak line appearing in the test region (T) after and extended period of time; therefore, do not interpret the result after 5 minutes.

I. Record date, patient’s Medical Record Number, test result, and QC result on log maintained in the nursing unit where test is performed. Chart test result on patient’s medical record.

I. Discard the test cassette in a proper biohazard container after testing.
INTERPRETATION OF TEST RESULTS:

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

**NOTE:** The intensity of the line in the test region (T) will vary depending on the concentration of hCG present in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

**NEGATIVE:** One line appears in the control region (C). No apparent line appears in the test 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 device. If the problem persists, discontinue using the test kit immediately and contact the Point of Care Service at 415.206.8588.

REPORTING RESULTS:

Negative results are expected in healthy non-pregnant women. 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 SP™ Brand Rapid Test has a sensitivity of 20 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PROCEDURE NOTES:

Sensitivity and Specificity: The SP™ Brand Rapid Test detects hCG at a concentration of 20 mIU/mL or greater. The test has been standardized to the W.H.O. Fourth International Standard.

LIMITATIONS:

This test cassette is for professional *in vitro* diagnostic use only. Do not use after the expiration date. The test cassette should remain in the sealed pouch until use.

A. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG and give a negative result. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.

B. 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 specimen
should be collected 48 hours later and tested.

C. Very low levels of hCG (less than 50 mIU/mL) are present in urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive may be confirmed by retesting with a first morning urine specimen collected 48 hours later.

D. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including some breast cancer tumors and lung cancer tumors may cause elevated levels of hCG. Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.

E. Gross hematuria may prevent an accurate reading of the test result by masking a positive line.

F. The 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.

CONFIRMATORY TESTING

If the clinical impression does not agree with the SP™ Brand Rapid Test result, and repeat testing on a fresh first morning urine sample collected 48 hours after the initial sample is not an appropriate option, a blood sample may be submitted to the Clinical Laboratory for quantitative serum hCG hormone measurement.

REFERENCES:

A. SP™ Brand Rapid Test package insert, Revised 10-07

DISTRIBUTION:

A. Point of Care Master Procedure Book (2M14).
B. Approved Point of Care Testing Locations.

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