University of California, San Francisco – Department of Laboratory Medicine
Zuckerberg San Francisco General Hospital and Trauma Center – Clinical Laboratory
1001 Potrero Avenue, San Francisco, CA 94110
Barbara Haller, MD, PhD, Director

48667.249 hCG Cassette Rapid Urine hCG Test

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Author
Clayton Hooper, MSN, RN and Jorge Mestayer Jr., CLS, Hematology Supervisor (Revised by Caroline Tolman-Salinas, CLS)

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Periodic review	Designated Reviewer	3/22/2021	2.1	Barbara Haller, MD, PhD Barbara Haller	
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Approval	Lab Director	1/10/2018	2.0	Barbara Haller, MD, PhD Barbara Haller	
Approval	Laboratory Manager	12/11/2017	2.0	Mary Eugenio-Allen Mary Allen	
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Signatures from prior revisions are not listed.

Prior History

Version History

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2.1	Approved and Current	Minor revision	10/31/2019	10/31/2019	Indefinite
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Linked Documents

- 48667.257 Urine Pregnancy QC & Patient Test Record

Author: Clayton Hooper, MSN, RN and Jorge Mestayer Jr., CLS, Hematology Supervisor (Revised by Caroline Tolman-Salinas, CLS)
Approved by Barbara Haller on 1/10/2018.
Reviewed by Barbara Haller on 3/22/2021.

hCG Cassette Rapid Urine hCG Test

PURPOSE

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

PRINCIPLE

The **hCG Cassette** Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gondadotropin (hCG) in urine to aid in the early detection of pregnancy. 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 cassette and observing the formation of colored lines, as the specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific antibody conjugates and form a 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 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. Outpatients may submit their first morning void for testing.

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^{o}C.

EQUIPMENT

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

REAGENTS

hCG Cassette Rapid Test cassettes contain mouse anti-hCG antibody conjugated to colloidal gold and goat anti-alpha hCG coated on the membrane.

Storage and Stability:
Store as packaged in the sealed pouch at 2-30º 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 expected result should show the following: the background in the result area should be white to light pink and not interfere with the ability to read the test results. **If the internal quality control result does not show the expected result, the patient test result is considered invalid and cannot be reported.**

External Quality Control Testing:
Positive and negative 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* **M**edical **R**ecord **N**umber 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* **M**edical **R**ecord **N**umber.

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 red line(s) 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 an extended period of time; therefore, **do not interpret the result after 4 minutes**.

I. Record date, patient's Medical Record Number, test result, and result for both positive and negative internal controls on log maintained in the nursing unit where test is performed. Chart test result on patient's medical record.

J. 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, or background is other than white to light pink. 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. **Do not report the test result if an invalid result is attained.** If the problem persists, discontinue using the test kit immediately and contact the Point of Care Service at 415.206.3037 or 415.206.4761.

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 hCG Cassette Rapid Test has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PROCEDURE NOTES:

Sensitivity and Specificity: The hCG Cassette Rapid Test detects hCG at a concentration of 25 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. 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. Gross hematuria may prevent an accurate reading of the test results by masking a positive line.

E. This test reliably detects intact hCG up to 500,000 mIU/mL. It does not reliably detect hCG degradation products, including free-beta hCG and beta core fragments. Quantitative assays used to detect hCG may detect hCG degradation products and therefore may disagree with the results of this rapid test.

F. 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.

G. 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 hCG Cassette 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. hCG Cassette Rapid Test package insert, Revised C 9/14
B. 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.