Methodist Health Service Corporation &
UnityPoint Health Methodist
Department of Pathology
Peoria, IL 61636

Effective: October 3, 2016
New Procedure

Urine hCG

Qualitative Chromatograpic Immunoassay
hCG Cassette Rapid

I. PRINCIPLE

The hCG Cassette Rapid test is a sensitive chromatographic immunoassay for the rapid qualitative detection of human chorionic gonadotropin (hCG) in urine. HCG is a hormone produced by the placenta shortly after implantation. Since hCG is present in urine of pregnant women, it is an excellent marker for confirming pregnancy. This test uses a monoclonal and polyclonal antibody to detect hCG. Urine is added to the sample well on the test cassette. If hCG is present in the specimen at a level of 25 mIU/ml with urine samples, a red test (T) line will appear along with a red procedural control line (C) in the result window. If hCG is present at very low levels, or not present in the specimen, only a red procedural control line will appear in the result window. Urine testing for qualitative hCG has a waived CLIA classification.

II. CLINICAL SIGNIFICANCE

Human Chorionic Gonadotropic (hCG) is a hormone secreted by the developing placenta shortly after fertilization. It becomes detectable as early as 7-10 days after fertilization. The appearance and rapid rise in the concentration of hCG in the mother's urine makes it an excellent marker for pregnancy. The test detects the presence of hCG in the urine at the sensitivity of 25 mIU/mL

III. SPECIMEN

Urine – if possible the first voided in the morning should be collected as this specimen will normally contain the highest concentration of the pregnancy hormone and is the preferred specimen, when early diagnosis of pregnancy is desired. However, specimens collected at any time of the day may be used but hCG levels may be diluted.Urine specimens may be stored at room temperature for up to 8 hours; in the refrigerator 0-8℃ for up to 48 hours; and if frozen the urine must be well mixed after thawing. If the urine has been refrigerated, it must equilibrate to room temperature before testing. It is normally not necessary to centrifuge urine specimens for this test; however, **very turbid or cloudy urine containing high concentrations of particulate matter should be centrifuged prior to testing**.

IV. REAGENTS

Cassettes are stored at room temperature out of direct light. Stocked in the Lab and are stable through the expiration date on the pouch.
Urine Control Level I store at 2-8 degrees
Urine Control Level II store at 2-8 degrees

V. INSTRUMENTATION/EQUIPMENT

Timer
Specimen container
Disposable pipettes

VI. CALIBRATION

None

VII. QUALITY CONTROL

Performed by the Point of Care personnel upon receipt of new lot number/shipment. Internal controls are evaluated each day of use by the Urinalysis section personnel.

VIII. PROCEDURE:

A. Remove the hCG test cassette from the foil pouch and place it on a clean, dry, level surface. Open foil pouch just before use.
B. Label the cassette with a patient label or sharpie marker.
C. Using one of the disposable pipets supplied, add 3 drops urine to the round sample well on the test cassette (precision pipetting of 120µl may also be used). The test cassette should not be moved again until the assay is complete and ready for interpretation.
D. Read results at 3 minutes.

INTERPRETATION OF THE RESULTS

POSITIVE; The appearance of ay red Test line next to the letter “T” in the result window, along with a red procedural control line next to the letter “C”.

NEGATIVE; The appearance of the red procedural control line next to the letter "C" only. No red color development at the test line next to the letter "T" at three minutes

NO RESULT/INVALID RESULT; no red procedural control line appears or background in not white to light pink.

a. Check the expiration date and repeat testing with the same lot number.
b. If the test does not work again, obtain a new lot number from POC area in the storeroom, if we have one.
c. Consult with the Lab POC Coordinator, if still not performing as expected.

IX. REPORTING RESULTS

A. Using the Urinalysis manual result entry screen. Modify→hit the << button→find patient and using the > key bring that patient to the right side. Hit the result key at the bottom
B. Enter the patient result as POS or NEG
C. On the line below please type in the lot #, expiration date, and that QC is OK.
D. Save and accept.

X. PROCEDURAL NOTES/PROBLEM-SOLVING TIPS

A. If a negative result is obtained but pregnancy is suspected, another specimen should be collected after 48-72 hours and tested.
B. The contents of this kit are for use in the qualitative detection of hCG in urine.
C. The test results should always be evaluated with other data available to the physician.
D. While pregnancy is the most likely reason for the presence of hCG in serum and urine, elevated hCG concentrations unrelated to pregnancy have been reported and may be caused by hydatidiform moles, choriocarcinoma, ovarian cancer and non-endocrine tumors of the lung, kidney, GI tract, pancreas, liver and breast.
E. hCG may remain detectable for a few days to several weeks after delivery, abortion or hCG injections.
F. Very low levels of hCG are present in serum and urine shortly after implantation. Positive test results from very early pregnancy may later prove negative due to natural termination of pregnancy. If a very low, faint positive serum result is obtained, another sample should be obtained in 48 hours and retested. If waiting 48 hours is not medically advisable, the test result should be confirmed with a quantitative hCG test.
G. Nonspecific color development may appear on the test line after extended

incubation times. Test results should be interpreted at 3 minutes specifically**.**

H. An invalid test result displayed by no color development at the control line is sample specific. This may be caused by the removal of the control color by some compound in the patient's sample. Serum can be drawn and a Quantitative hCG can be performed
I. Personnel performing urine UCG testing will be initially educated and skills validated on an annual basis.
J. UCG testing will be used as a diagnostic test.

XI. REFERENCES

A. hCG Cassette Rapid Test test kit package insert, September 2014.
B. Todd and Sanford 15th edition (per Dr Campbell 8/13

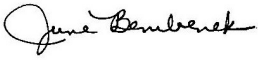
MMCI Laboratory is a CAP accredited facility, as of 7/1/11 the responsibility of new and/or substantially revised policies and procedures will be restricted the Laboratory Director whose name appears on the CLIA certificate, whose signature appears below. The biennial review will be completed by the Administrative Director.

Policy Created by: Kim Paige Date: October 3, 2016
Medical Director Approval: Elizabeth A. Bauerlein MD **Date: January 20, 2017**

CHANGE OF/TO SECTION MEDICAL DIRECTOR		
DATE	NAME	SIGNATURE
1/20/2017	Katherine Kasper, M.D.	Katherine A. Kasper MD

REVISION HISTORY			
Rev	**Description of Change**	**Author**	**Effective Date**
1	Initial Release	K. Paige	10/3/16

Reviewed by

LEAD	DATE	COORDINATOR/ MANAGER	DATE	MEDICAL DIRECTOR	DATE
K. Paige	1/19/17		1/20/17		1/20/17