

**HACKETTSTOWN REGIONAL MEDICAL CENTER  
LABORATORY – POINT OF CARE POLICY MANUAL**

**Point of Care Urine Pregnancy Test**

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**Effective Date:** August 7, 2006

**Policy No:** POC 0006

**Cross Referenced:**

**Origin:** Point of Care Tests

**Reviewed Date:** 7/10; 11/11; 6/12;6/13; 6/15

**Authority:** Dr. Jun Li MD, PhD

Laboratory Director

**Revised Date:** July 14, 2010

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**SCOPE:** All certified clinicians in Emergency Room, Same Day Surgery and Minor Procedure departments and Vascular Lab.

**PURPOSE:** To confirm that the patient is not pregnant before undergoing a procedure that may pose harm to the embryo/fetus.

**POLICY:**

1. Standard precautions must be observed and disposable gloves must be worn.
2. New employees must be checked for Color Blind Test in Employee Health and complete an in service regarding the test.
3. All employees will be recertified through the annual competency test by direct observation of unknown samples and a quiz with a passing grade.
4. All urine containers must be properly labeled with patient information before doing the test.
5. Use only the pipette that is included in the kit.
6. No test kits will be dispensed without the evidence of performing an external liquid control. External liquid QC will be performed per kit lot or every 30 days.
7. Results can only be entered in ER POC Result Form during downtime and/or if the patient is unregistered at the time of test. Symbols like (+) for positive or (-) negative are not allowed to be entered on the form as patient result, however POS or NEG abbreviations are acceptable.

**PRINCIPLE:**

Human chorionic gonadotropin is a hormone normally produced by the placenta. Since hCG is present in the serum and urine of pregnant women, it is an excellent marker for confirming pregnancy. The QuickVue One Step hCG Urine test uses a monoclonal antibody specific to the beta subunit of hCG. The kit is for a qualitative detection of hCG in urine only

**DEFINITIONS:**

hCG – Human Chorionic Gonadotropin

QC – quality control

**REAGENTS AND EQUIPMENT:**

QuickVue One Step hCG Urine kit

Transfer pipette (included in kit)

Timer that measures minutes and seconds

**STORAGE:**

QuickVue One Step hCG Urine kit are stored inside the pyxis and in the laboratory at room temperature (59-86° F)

Quality control materials are stored in the laboratory at room temperature (59 – 86° F).

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**PROCEDURES:**

1. Collect urine specimen in a clean container. Urine collected anytime during the day can be used however, for optimal results it is best to test the first urine voided in the morning because it contains the greatest concentration of hCG.
2. Remove the Reaction Unit from the foil pouch and place on a flat surface.
3. Add **3 drops** of urine into the round sample well on the test cassette using **ONLY** the kit pipette.
4. Set the timer for 3 minutes. Use of clock or personal watches to time the test is prohibited.
5. Read result at **3 minutes**. Some positive results may appear sooner. Result shouldn't be finalized before 3 minutes.
6. Enter results in Cerner making sure the answer for the QC of either Pass or Fail is filled in.

**REPORTING RESULTS:**

**Positive Results:**

Any pink to red line next to the letter "T" (Test) along with a blue Control line (C) is a positive result for the detection of hCG.

**Negative Results:**

A blue Control line (C) and NO pink Test line (T) is a negative result.

**Invalid Results:**

The test result is invalid if a blue Control line (C) is not visible at 3 minutes. If this happens, retest using a new sample cassette. If pregnancy is suspected, the test should be confirmed with a quantitative hCG test.

**QUALITY CONTROL:**

The laboratory will use an external liquid control for each new lot of the QuickVue One Step hCG Urine test kit. Each reaction unit kit has a built-in internal control. A blue Control (C) line is an internal positive control. This indicates that sufficient sample fluid was added for capillary flow to occur and the correct procedural technique was used. If this line does not develop, the test result is considered invalid. A clear background in the test result window is an internal background negative control. If the test has been performed correctly, the background should be white to light pink within 3 minutes.

1. Gently mix the hCG Controls by shaking the vials prior to use.
2. Add three drops of either the Positive or Negative Liquid Control to the QuickVue One Step hCG Urine test cassette sample well.
3. Read test results at 3 minutes.
4. Enter results in the POCT log book under Urine Pregnancy QC Log book including the kit lot #, expiration date, date received and date of test.

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**LIMITATIONS:**

- ◆ The contents of this kit are for use in the qualitative detection of hCG in urine.
- ◆ Test results must always be evaluated with other data available to the physician.
- ◆ A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone .
- ◆ Very low levels of hCG are present in serum and in urine shortly after implantation. Positive test results from very early pregnancy may later prove negative due to natural termination of pregnancy. This is estimated to occur on up to 50% of all conceptions.
- ◆ If a urine is too dilute, it may not contain a representative urinary hCG concentration. If a negative result is obtained and pregnancy is still suspected, a first morning sample should be obtained and tested or a serum hCG quantitative test should be ordered.

**REFERENCED**

QuickVue One Step hCG Urine Test package insert, Quidel Corporation, San Diego, California.  
Quidel hCG Control Set package insert, San Diego, California.