



<b>Subject</b>	Pregnancy Test Procedure - Urine	<b>Attachments</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Key words</b> hCG		<b>Number</b> GHI-PC-CLINIC LAB- Procedures- Pregnancy v. 7-2009
<b>Category</b> Provision of Care		<b>Effective Date</b> June 1994
<b>Manual</b> Clinic Laboratory Procedure Manual W@W Laboratory Procedure Manual Quick Clinic Laboratory Procedure Manual		<b>Last Review Date</b> April 2015
<b>Issued By</b> Clinic Laboratory – Laboratory Technical Consultants		<b>Next Review Date</b> February 2016
<b>Applicable</b> Clinic Laboratory Staff		<b>Origination Date</b> June 1994
		<b>Retired Date</b>
<b>Level of Complexity</b> Waived		<b>Contact</b> Laboratory Technical Consultants
<b>Review Responsibility</b> Laboratory Technical Consultants		<b>Approved Date</b> June 1994
<b>APPROVAL(S)</b> Laboratory Medical Director		

**Pregnancy Test – Urine**

Clinic Lab Procedure (Pages 1-4)  
Troubleshooting (Page 3)  
Computer Test (Page 5)

**I. PURPOSE/PRINCIPLE**

Human Chorionic Gonadotropin (hCG) is a hormone secreted by the placenta during pregnancy. Conditions other than normal pregnancy that may be associated with detectable hCG include ectopic pregnancy, molar pregnancy, trophoblastic disease and non-trophoblastic neoplasms. In ectopic pregnancy, hCG concentrations may remain below 50 mIU/mL. HCG may remain detectable for a few days to several weeks after delivery or abortion.

The QuickVue One-Step hCG Combo test is a sensitive immunoassay for the qualitative detection of hCG in urine for the early detection of pregnancy. The QuickVue One-Step hCG Combo test uses a monoclonal antibody specific to the beta subunit of hCG in a single step technology to accurately 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 or greater, a pink to red Test (T) line will appear along with a blue procedural Control (C) line in the Result Window. If hCG is present at very low levels, or not present in the specimen, only a blue procedural Control line will appear in the Result Window.

**II. POLICY**

Laboratory Staff will follow the approved techniques outlined in this procedure.

**Specimen:**

1. **Urine:** Patients are instructed to collect first morning specimens, but any urine specimen is acceptable. Collect specimens in clean container. Urine specimens may be kept at room temperature for 8 hours or refrigerated for up to 72 hours. Samples may be frozen once. If frozen, mix after thawing. Do not refreeze.

**Reagents/Materials:**

1. Individually wrapped Test Cassettes
2. Disposable pipettes
3. Timer
4. External hCG controls

**Storage Options:**

1. Store kit at room temperature, out of direct sunlight. Do not freeze.
2. Expiration date is that which is printed on the outer box carton.
3. The Test Cassette must remain sealed in the pouch just prior to use.

**Quality Control:**

*External*

HPMG Clinics and Well @ Work Clinics

- QC should be performed **monthly AND with changes** to lot numbers or as a guide in interpretation of a questionable result. Document the positive and negative commercial controls on the pregnancy worksheet when they are run.

Quick Clinics

- QC should be performed **every day** testing is performed or as a guide in interpretation of a questionable result. Document the positive and negative commercial controls on the pregnancy worksheet when they are run.

**Negative External Control:**

Process the negative commercial control as you would a patient sample.

**Positive External Control:**

Process the positive commercial control as you would a patient sample.

*Internal*

The QuickVue test contains built-in control features. Document this procedural internal quality control on the pregnancy worksheet for each sample that is run.

**Negative Internal Control:**

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 to 5 minutes and not interfere with the reading of the test result.

**Positive Internal Control:**

The appearance of a blue procedural Control 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.

If any of the controls do not perform as expected, do not use the test results. Refer to the Quality Control/Troubleshooting section of this procedure or contact a Technical Consultant or Technical Assistance at 1-800- 874-1517.

### III. PROCEDURES

1. Remove the Test Cassette from the foil pouch just before use and place it on a clean, dry, level surface.
2. Draw urine into the disposable pipette and dispense **3 drops** to the round sample well on the test cassette. The test cassette should not be handled or moved until the test is complete and ready for reading.
3. Read result at 3 minutes for urine. **Note:** Some positive results may appear sooner.
  - a. **Positive Result:** Any pink to red Test line (T) along with a blue Control line (C) is a positive result for the detection of hCG.
  - b. **Negative Result:** A blue Control line (C) and no pink Test line (T) is a negative result.
  - c. **Invalid Result:** The test result is invalid if a blue Control line (C) is not visible at 3 to 5 minutes. If this happens, retest using a new sample and a new Test Cassette or contact Quidel Technical Assistance Line at 1-800- 874-1517 or a Technical Consultant.
  - d. **Inconclusive Result:** If you are unable to determine whether a result is positive or negative and the procedural controls are valid you can result the test as INCN (Inconclusive, Suggest Repeat information will be appended). See the Lab Computer Procedure for further instructions.

### REPORTING RESULTS

Clinic Labs: see the Computer Entry section of this procedure

Quick Clinics:

1. enter results on test log sheet
2. send test log sheet to Clinic Lab for result entry into the Laboratory Computer System

Well@Work Clinics:

1. enter results on test log sheet
2. fax test log sheet to Central Lab for result entry into the Laboratory Computer System

### PROCEDURE NOTES

1. Since hCG levels at 25 mIU/mL have been observed as early as 7 to 10 days post conception, hCG MAY be detected before a missed menses.
2. If a negative result is obtained, but pregnancy is suspected, another sample should be collected after 48-72 hours and tested.
3. While pregnancy is the most likely reason for the presence of hCG in urine, elevated hCG concentrations unrelated to pregnancy have been reported in some patients. Conditions other than normal pregnancy may be associated with detectable hCG, including for example, ectopic pregnancy or molar pregnancy. Patients with trophoblastic and nontrophoblastic disease may have elevated hCG levels, therefore, the possibility of hCG secreting neoplasms should be eliminated prior to the diagnosis of pregnancy.
4. HCG may remain detectable for a few days to several weeks after delivery, abortion, natural termination or hCG injections.
5. The concentration of hCG in urine is approximately equal to the concentration in serum due to fact that serum hCG is rapidly cleared into the urine.

### TROUBLESHOOTING

1. Verify two levels of Internal Procedural Quality Control.
  - A blue line appearing in the control region (C) is considered an internal positive procedural control.
  - A clear background in the result area is considered an internal negative procedural control.
2. Check expiration date of kit and controls.
3. Repeat the controls.
4. If the controls are still not performing as expected, open and run a new set of controls.
5. If control results are still unacceptable, try a kit with a different lot number.
6. Notify a lab technical consultant. The manufacturer may also be called.

- Reminder: According to the Internal Quality Control Policy, if expected QC values are not attained, patient results will not be reported until troubleshooting is complete.

## **REFERENCES**

QuickVue hCG Serum/Urine kit package insert.

## **AUTHOR/REVIEWER(S)**

Denise Bergo, Gail Brors, Barb Johnson

Sherry Cooper

Anne Howard

Nancy Butala

JAGayken

## **IV. DEFINITIONS**

## **V. COMPLIANCE**

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

## **VI. ATTACHMENTS**

## **VII. OTHER RESOURCES**

## **VIII. ENDORSEMENT**

Laboratory Administration

## Computer Order and Result Entry

### PREGNANCY TEST Order Codes: HCGU (HCG, Urine)

**RESULTING:**

**WORKSHEET:**

Function MEM          Worksheet CP\_\_ (Chem Preg)

**RESPONSE:**

**NOTE:** If results are invalid (control line not visible), re-test per procedure instructions.

<b>HCGU</b>	(A battery which includes the HCGUR test for the result and QA tests to document your kit quality tests.)	
<b>Code</b>	<b>Name</b>	<b>Response</b>
<b>HUCON</b>	HCGU Pos Con Bar	Y or N  Y (= YES, the control bar is present) N (= NO, the control bar is NOT present)
<b>HUBAC</b>	HCGU Neg Clear Background	Y or N  Y (= YES, the background is clear) N (= NO, the background is NOT clear)
<b>HUKIT</b>	HCGU Kit Lot Number	Enter the lot number (12345) from the kit box.  If there is a letter in the kit lot number, put a ; in front of the lot number (;A1234)
<b>HCGUR</b>	HCG, Urine	POS, NEG, INCN <ul style="list-style-type: none"> <li>• If NEG, computer will append result with NPREG and RPREG. (Negative=&lt;25 mIU/ml. If pregnancy is suspected, suggest repeat in 48-72 hours or confirm results with a quantitative hCG test).</li> <li>• If POS, computer will append result with PPREG (Positive=&gt;25 mIU/ml).</li> <li>• If inconclusive, and controls are valid, result with INCN (Inconclusive). Computer will append results with RPREG (If pregnancy is suspected, suggest repeat in 48-72 hours or confirm results with a quantitative hCG test).</li> </ul>

**NOTE:** If results are invalid (control line not visible), re-test per procedure instructions.

**AUTHOR/REVIEWER(S)**

SMHoehn  
LEJohnson  
GEFelland  
SMDent  
AKHoward