



Urine Pregnancy Screening

CHAPTER 9: URINE PREGNANCY SCREENING

Procedure: Quidel Quick-Vue Urine Pregnancy

PRINCIPLE

The Quidel QuickVue test is a sensitive immunoassay using a monoclonal antibody specific to the beta subunit of hCG in a single step for the qualitative detection of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy.

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-purple test (T) line will appear along with a blue procedural control (C) line in the result window. If hCG is present in lower levels, or not present in the specimen, only a blue procedural control (C) line will appear in the result window.

CLINICAL SIGNIFICANCE

Human chorionic gonadotropin (hCG) is a glycoprotein with two non-covalently bound subunits. The alpha subunit is similar to those of luteinizing hormone, follicle-stimulating hormone, and thyroid-stimulating hormone.

The beta subunit of hCG differs from the other pituitary glycoprotein hormones, which results in its unique biochemical and immunological properties. hCG is synthesized by the cells of the placenta and is involved in maintaining the corpus luteum during pregnancy.

In normal pregnancy, hCG can be detected as early as 6 days following conception with concentrations doubling every 32 to 48 hours. For some patients, a hCG level of 25 mIU/mL can be detected as early as two to three days before expected menses. By the first day of missed menses, concentrations often exceed 100 mIU/mL.

SPECIMEN REQUIREMENTS

No special patient preparation is needed.

Any voided urine collected in a clean container is suitable for testing. A preferred specimen is first morning urine, which contains the highest concentration of hCG.

Specimens should be tested immediately. If necessary, specimens may be kept at room temperature for 8 hours or stored at 2 to 8°C for up to 3 days. Do not freeze specimens.

REAGENTS

QuickVue One-Step Kit Catalog # 0269 75test/kit

Vendor: Quidel Corp. 10165 McKellar Court San Diego, CA 92121

Reagents are to be obtained by contacting UMG POCT program (see UMG CONTACT LIST)

EACH KIT CONTAINS

- 75 individually wrapped test cassettes, each containing murine monoclonal antibody and caprine polyclonal antibody to hCG.
- 75 disposable pipets

The cassettes require no preparation. Each cassette should be labeled with the patient's name before adding urine.

The cassettes are **stable** until the expiration date on the box **if stored at temperatures between 15-30°C**. Do not store in direct sunlight. Do not freeze.

QUALITY CONTROL

Quality Control Material

Quantamatrix Control Urine Set Catalog #: 1440-04

Vendor: Quantamatrix Corp. 10165 2005 Manhattan Beach Blvd., Redondo Beach, CA 90278

Each kit contains One Positive and One Negative Human Urine Control

The controls are liquid, ready to use, requiring no reconstitution or dilution.

The controls should be stored at room temperature (15 - 30°C) and are stable until the expiration date stated on the labels.

Quality control is performed at a minimum:

- Validation of new kits **lots** will be performed centrally prior to release through the UMG POCT program
- Quality control will be performed locally upon receipt of lot validated reagents and at least once per month afterwards

In addition, the QuickVue hCG urine test has a built in validation feature. A blue line develops next to the letter "C" on the cassette as a positive procedural control. If a blue line does not develop, the test result is invalid. Absence of interfering background is a negative control. If background color appears in the result window, which interferes with the ability to read the test, the result is invalid.

Quality Control Procedure

1. Remove two QuickVue test cassettes from the foil pouch and place on a clean, dry, level surface.
2. Write the control name on each cassette.
3. Don disposable gloves.
4. Add 3 drops of the control reagent to the round sample well of the appropriately labeled cassette. The test cassette should not be manipulated or jarred again until the assay is complete and ready for interpretation.
5. Wait three minutes and read.
6. Record cassette lot number and expiration date, control lot numbers and expiration date, results and operator initials in the Result Log. New sheets are started at the beginning of the month. A supervisor should be checking that the QC log is being filled out properly and signing off weekly. The completed QC sheets (or a copy) are to be sent to the UMG POCT Administrative office.
7. Any quality control failures requires investigation of controls, reagent or technical procedure. The problem must be corrected, documented on the QC log, and controls successfully run before reporting any patient results.

PROFICIENCY TESTING

The UMG Point of Care Testing program subscribes to the College of American Pathologists Clinical Microscopy Survey. Three challenges are sent per year, two samples per challenge.

PATIENT TESTING PROCEDURE

1. Identify the patient sample.
2. Remove the QuickVue test cassette from the foil pouch and place on a clean, dry, level surface.
3. Write the name of the patient on the cassette with pen.
4. Don disposable gloves.
5. **Using one of the disposable pipets supplied**, add 3 drops of urine to the round sample well of the labeled cassette. The test cassette should not be manipulated or jarred again until the assay is complete and ready for interpretation.
6. Wait three minutes and read.
7. Record the results on the result log and on the patient's chart.

Interpretation

Positive	The appearance of any pink-to-purple line next to the letter "T" in the result window, along with a blue procedural control line next to the letter "C".
Negative	The appearance of a blue procedural control line next to the letter "C" only. No pink-to-purple test line next to the letter "T".

