Quidel QuickVue + One-Step hCG Pregnancy Test

PURPOSE
The QuickVue+ One-Step hCG Combo test is a one-step immunoassay intended for the qualitative detection of hCG in urine for the early detection of pregnancy.

SCOPE
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 Combo test is a lateral-flow test using a monoclonal antibody specific to the beta subunit of hCG to accurately detect hCG. The test may be used in ambulatory, and inpatient settings.

PERSONNEL
Intended for use by clinical personnel who have received training and demonstrated competency in this procedure. In the hospital setting, this includes Clinical Laboratory Scientists, Registered Nurses, Nurse Practitioners, Physician Assistants, Physicians, Respiratory Tech. In the ambulatory setting, this includes the aforementioned personnel as well as Medical Assistants, Licensed Vocational Nurses and other licensed Technologists. Staff members who have difficulties with color discrimination must demonstrate ability to read the test.

PRINCIPLE
To perform the test, a urine sample is collected and added to the Reaction Unit. If the sample contains hCG, a pink vertical line forms in the Read Result Window. This pink vertical line, together with the pre-printed blue horizontal line, form a plus sign (+) to indicate a positive result. If hCG is not present in the sample, the Read Result Window shows only the pre-printed blue horizontal line, forming a minus sign (−) to indicate a negative result.
As the sample continues to move through the test, a bar in the Control Window becomes blue. Blue color in the Control Window indicates that the test is functionally active and is also evidence that the test has been performed correctly.

The sensitivity of QuickVue+ One-Step hCG Combo test is 20 mIU/mL for urine (WHO 3rd IS 75/537). In normal pregnancy, hCG levels in urine can reach 25 mIU/mL as early as 7 to 10 days post conception, and continue to increase exponentially to reach a maximum concentration in excess of 200,000 mIU/mL at the end of the first trimester.

REAGENTS, EQUIPMENT, AND MATERIALS

- Patient Urine
- Box of Reaction Units (Test Devices) (Cat. No. 00178)
  Each unit is sealed in an individual foil pouch. Store units at room temperature (15-30°C), away from direct sunlight or heat sources. Do not freeze. Do not use test units beyond expiration date.
- Disposable droppers supplied with each box
- hCG Control Set (Positive and Negative) from Quidel (Cat. No. 00272)
  Store at room temperature (15 - 30°C). Do not freeze.
  Note: The controls must be used at room temperature. Performance of the QC at other temperatures may yield invalid results.
  Do not use reagents beyond labeled expiration date, marked on the outer kit label.
  Do not interchange the caps of the control vials.
- Gloves
- Timer

SPECIMEN REQUIREMENTS

Collect urine specimens in a clean container. Urine collected anytime during the day can be used. For optimal results, it is best to test the first urine voided in the morning because it contains the greatest concentration of hCG. Samples can be stored for 8 hours at room temperature (59–86°F; 15–30°C) or up to 72 hours refrigerated (36–46°F; 2–8°C). DO NOT freeze the urine sample.

If testing is not done by the person obtaining the sample and/or if testing is delayed, then the specimen container (not the lid) must be labeled with two forms of patient identification, in the presence of the patient.

As part of our Bloodborne Pathogen Exposure Control Plan, standard precautions must be followed when handling specimens. Gloves should be worn while testing the specimen.

CONTROLS

External Quality Control
Positive and negative controls must be run each time a new box of QuickVue+ One-Step hCG Combo test is opened. The hCG Control Set (Catalog No. 00272) is used for this purpose. The use of any other hCG controls is incompatible with the test.
1. **External Positive Control:**
Process the control as you would a patient sample. A positive result is indicated by a pink and blue plus sign (+) in the Read Result Window along with a blue procedural Control Line in the Control Window.

2. **External Negative Control:**
Process the control as you would a patient specimen. A negative result is indicated by a blue minus sign (–) in the Read Result Window along with a blue procedural Control Line in the Control Window.

**Internal Control Features**
The QuickVue+ One-Step hCG Combo test contains built-in control features. The appearance of the internal control line must be documented with each patient result.

1. **Internal Positive Procedural Control:**
A blue line in the Control Window is considered an internal positive procedural control. If the test has been performed correctly and the Reaction Unit is working properly, this indicator will appear.

2. **Internal Negative Procedural Control:**
A clear background in the Read Result Window is considered an internal negative procedural control. If the test has been performed correctly and the Reaction Unit is working properly, the background will clear to give a discernable result.

If the controls do not perform as expected, do not use the test results. Repeat the test. If performance failure persists, contact Technical Support (800-874-1517) and the POCT Supervisor 353-1976.

**QUALITY CONTROL PROCEDURE**

- Check expiration dates on Reaction Unit pouches and control reagents.
- If new bottles of control are opened, record open date, and initial the bottles.
- Remove 2 reaction units from their sealed pouches.
- Thoroughly mix contents of each control bottle by gently swirling.
- Add 4 drops of hCG Control Set Positive Control into the sample well of one device.
- Wait 3 minutes for the colored bands to appear.
- A Positive reading (appearance of pink line, with preprinted blue line, forming a plus sign (+)) should appear on Read Results Window of the Positive Control unit. In addition to the + sign, a distinct blue band also appears in the Control Window.
- Dispense 4 drops of hCG Control Set Negative Control into the sample well of the second unit.
- Wait 3 minutes to confirm a negative outcome.
- A Negative reading (minus sign) in the Read Results Window is confirmed when only the preprinted blue minus sign (–) is visible in the Results Window. A distinct blue band should appear in the Control Window.
- Record result in QC log.
- Write the date and “QC performed” on the box.
As part of our Bloodborne Pathogen Exposure Control Plan, standard precautions must be followed when handling controls. Gloves should be worn while performing QC.

URINE TESTING PROCEDURE

- Verify patient identification using two patient identifiers and explain procedure to patient and/or family.
- If sample is not obtained from the patient by the person who will perform the test, and the test is not performed immediately, then the specimen container (not the lid) must be labeled with two forms of patient identification, in the presence of the patient.
- Check expiration date of pouch. Remove Reaction Unit from sealed pouch.
- Holding a clean pipette in a straight up and down position, not at an angle, draw the urine sample up the pipette. Dispense 4 drops of urine into the sample well of the device.
- Shortly after the sample is added, a pink-to-purple color will be seen moving across the Reaction Unit’s windows. The Read Result Window contains a pre-printed horizontal blue line on the membrane.
- Read results at 3 minutes.

INTERPRETING RESULTS

Note: As an aid, you may refer to the color procedure card included in the kit.

Positive Result:
The sample contains a detectable amount of hCG when you see:
A pink and blue plus sign (+) in the large square Read Result Window, along with a blue line in the small square Control Window.

NOTE: any shade of a pink vertical line in the Read Result Window should be interpreted as a positive result.

Negative Result:
The sample does not contain detectable amounts of hCG when you see:
A blue minus sign (–) in the large square Read Result Window, along with a blue line in the small square Control Window.

Invalid Result:
The result is invalid if: No blue line appears in the small square Control Window; or background color in the large square Read Result Window interferes with test interpretation. In the case of an invalid result, a new patient specimen should be tested using a new QuickVue+ One-Step hCG Combo test.
RESULTS REPORTING

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<tr>
<th>Control Window</th>
<th>Result Window</th>
<th>Interpretation</th>
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<tr>
<td>Blue Band</td>
<td>Pink and Blue plus sign(+)</td>
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<tr>
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<td>Blue minus sign(−)</td>
<td>Negative</td>
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<tr>
<td>No color</td>
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<td>Do not report; Repeat with new device and pipette</td>
</tr>
<tr>
<td>No color</td>
<td>Blue minus sign(−)</td>
<td>Do not report; Repeat with new device and pipette</td>
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Document test result and appearance of internal control in patient’s medical record. Report result to provider.

Whenever a user identifies that an incorrect result has been reported, they are responsible for correcting/commenting the incorrect result (if possible), contacting the ordering provider, notifying them of the error, and documenting this notification, including the time and date, in the patient record.

PROCEDURAL NOTES
- DO NOT remove the Reaction Unit from the foil pouch until you are ready to perform the test.
- Use a new disposable dropper for each sample to avoid cross-contamination.
- If a negative result is obtained, but pregnancy is suspected, another sample should be collected after 48–72 hours and tested. Blood specimens may also be sent to the Clinical Laboratory for confirmatory quantitative testing.

LIMITATIONS
- The QuickVue+ One-Step hCG Combo test is for use in the qualitative detection of hCG in urine.
- Test results must always be evaluated with other data available to the healthcare provider.
- A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone.
- Very low levels of hCG are present 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 in up to 50% of all conceptions. If a very low, faint positive serum result is obtained, another sample should be obtained in 48 hours and retested. Blood specimens may also be sent to the Clinical Laboratories for confirmatory quantitative testing.
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.

If a urine sample 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.

DOCUMENTATION

Lot number (on the outer box) and expiration dates of all controls and reaction units are recorded on QC logs.

For each patient test, the Internal control (appearance of blue band in Control Window) must be documented along with patient test results.

RECORD MAINTENANCE

Retired records containing laboratory worksheets and logs are kept in an accessible area for three years as required by law.

REFERENCES

1. Quidel Corporation QuickVue+ One-Step hCG Combo TEST package insert (01/06)
2. Quidel Corporation hCG Control Set (Positive and Negative package insert (06/10)
Revised QuickVue+ One-Step hCG

SR Sup Review

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Med Dir Apprvl

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