

**HACKETTSTOWN REGIONAL MEDICAL CENTER
LABORATORY POLICY MANUAL
URINE/SERUM PREGNANCY TEST**

Effective Date: July, 2009

Cross Referenced:

Reviewed Date: 6/2012

Revised Date:01/12

Policy No: UA140.00

Origin: Urinalysis

Authority: Laboratory Director

Page: 1 of 2

PRINCIPLE: Human chorionic gonadotropin (hCG) is a hormone normally produced by the placenta as is a 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 as early as 2 or 3 days before the expected menses.

SPECIMEN REQUIREMENTS:

Urine: collect urine specimens in a clean container. Urine collected anytime during the day can be used but 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 or up to 72 hours refrigerated. Do not FREEZE.

Serum: No special patient preparation is necessary. Serum specimens may be stored refrigerated for up to 48 hours or frozen once at -20°C or below. If frozen, mix after thawing.

REAGENTS AND SUPPLIES:

QuickVue Reaction Unit

Disposable Dropper

QUALITY CONTROL:

External positive and negative controls are run with each shipment of a new kit lot number. Quidel hCG Controls are used for this purpose.

Internal Controls - QuickVue+One-Step hCG Combo test contains built-in control features.

Internal Positive 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.

Internal Negative 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.

Document the internal control pass or fail on the log sheet with the patient results.

PROCEDURE:

1. Remove the Reaction Unit from the pouch.
2. Draw serum or urine into the disposable dropper and dispense **4 Drops** into the Add Sample well.
3. 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
4. Read result at 3 minutes for urine and 5 minutes for serum.

NOTE: Do not remove the Reaction Unit from the foil pouch until you are ready to begin testing. Use a new dropper for each sample

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INTERPRETATION OF RESULTS:

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.

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 Test: 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 the test interpretation. In the case of an invalid result, a new specimen should be tested using a new test kit.

REPORTING OF RESULTS:

Report results as positive or negative. Result by accession in Cerner and document on log.

REFERENCE:

QuickVue+One Step hCG Combo test package insert. Quidel Corporation, SanDiego, CA. rev. 0