SUNY DOWNSTATE MEDICAL CENTER
UNIVERSITY HOSPITAL OF BROOKLYN
POLICY AND PROCEDURE

No. LAB-23B

Subject: **POINT OF CARE – URINE PREGNANCY – Quidel Quick Vue One Step Urine Hcg**

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I. PURPOSE:

The Quick Vue One-Step hCG Urine Test is used to detect early stages of pregnancy by screening for the presence of human chorionic gonadotropin in low levels. The test requires a fresh void urine and will be performed in the Emergency Department to provide timely and accurate result for patient care.

II. PRINCIPLE:

A sensitive immunoassay 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 Control (C) line in the result Window. If hCG is present at lower levels, or not present in the specimen, only a blue Control Line will appear in the result window.

SPECIMEN:

Urine collected in a clean container. First morning specimens generally contain the highest concentrations of hCG and are recommended for early detection of pregnancy. However, any urine specimen is suitable for testing.

Patient Preparation: No patient preparation is necessary.

Handling Conditions: A freshly voided and appropriately labeled urine specimen may be kept at room temperature for 8 hours or stored at 2-8°C for up to three days. Do not freeze specimens.

EQUIPMENT AND MATERIALS:

Equipment: N/A

Materials: Kit contains 75 individually wrapped test Cassettes.
Each cassette contains murine monoclonal antibody and caprine polyclonal, antibody to hCG.

75 disposable pipettes

Preparation: N/A

Storage Requirements: Store kit at room temperature 59 - 86°F (15 - 30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box carton.

LEVEL OF FUNCTION: Unit staff in collaboration with Laboratory staff.

LEVEL OF PERSONNEL: Physicians. Physicians Assistants, Registered Nurses, Laboratory Personnel

Each staff member must be trained to perform testing and there after be recertified annually. Records will be kept in the P.O.C. testing coordination office and in Human Resources department.

CALIBRATION: N/A

QUALITY CONTROL: The Quick Vue test contains built-in control features. The development of the blue procedural Control Line next to the letter "C" is a Positive procedural control. If this line does not develop, the test is invalid.

EXTERNAL CONTROL: Hycor Liquitrol Normal and Abnormal (Positive and Negative) controls will be tested and documented once per day or on day of testing and must be initialed by the Nurse performing QC. Control documentation record will be submitted to the Point of Care Coordinator at the end of each month for review.

PROFICIENCY TESTING:
Staff who performs testing will be presented with a challenge at least once per year and they will process this testing as a patient. The result of this proficiency will be sent to the nursing supervisor where regular testing is performed.

PROCEDURE - STEPWISE:
- Remove the QuickVue Test Cassette from the foil pouch and place it on a clean, dry surface.
- Using one of the disposable pipettes supplied, add 3 DROPS of urine to the Round Sample Well on the Test Cassette.
- Wait three minutes and read.

Note: <u>Must be read</u> at THREE minutes.

III. RESULTS:

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 the blue procedural Control Line next to the letter "C" only and no pink-to-purple Test Line next to the letter "T".

NO RESULT: If no blue procedural Control Line appears, the test result is invalid and the specimen must be retested using a new test cassette

REPORTING RESULTS:

All patient results must be documented in a Patient Logbook containing the following information:

DATE, TIME, PATIENT'S NAME, PATIENT'S MR#, ORDERING PHYSICIAN, TEST RESULT, NURSE.

Upon completion, each patient's urine hCG result will be entered into Cerner LIS via one of the following methods:

a) Fill out patient result sheet containing Name of Patient, MR# and Test Result. Result forms are kept in the Patient Log Binder. Give completed Result Form to Clerk who will order and result in Cerner.

b) Order Point of Care Test in Cerner:
   1) Click on Department Order Entry
   2) Enter Patient's Name in Person Name Field
   3) Type "POC" in Orderable Field
   4) Type in result (Pos. or Neg.)
   5) Choose "Central Receiving" in Specimen Received Location Field.
   6) Click on Submit Order

LIMITATIONS OF THE PROCEDURE:
The contents of this kit are for use in the qualitative detection of hCG in urine only.

Sensitivity = 25mIU/ml.
If a negative result is obtained but pregnancy is suspected, hCG levels may be too low or urine may be too diluted for detection. Another specimen should be collected after 48-72 hours and tested. If waiting 48 hrs is not medically advisable, then test result should be confirmed with a quantitative hCG test.

IV. REFERENCES: Quidel QuickVue Test manufactures Pack Insert.

Date Reviewed	Revision Required		Responsible Staff Name and Title
	Yes	No	
	Yes	No	