SUNY Downstate Medical Center -University Hospital of Brooklyn Network
Department of Pathology Policy and Procedure

Subject: Point of Care Urine Pregnancy Quidel LAB 23B

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SUNY DOWNSTATE MEDICAL CENTER
UNIVERSITY HOSPITAL OF BROOKLYN
POLICY AND PROCEDURE MANUAL

	No. LAB-23 B
Subject: **POINT OF CARE – URINE PREGNANCY Quidel Quick Vue**	**Page 1 of 4**
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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 and Satellite Facilities to provide timely and accurate result for patient care.

PRINCIPLE: The Quick Vue One-Step hCG Urine Test is 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.

PERSONNEL: Registered Nurses, EKG Tech, Laboratory Personnel

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

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^{o}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
Urine Cup Container
Timer

Preparation: N/A

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

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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. When controls out document corrective action taken in control result log. If problem persist Point of Care staff should be notified for trouble shooting.

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.

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: Must be read in THREE minutes.

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

Negative for Non pregnant Females.

Positive for Positive Females.

REPORTING RESULTS:

Upon completion, each patient's urine hCG result will be entered into Cerner LIS.

Order entry in Point of Care Test in Cerner:

1) Click Point of Care Result entry
2) In Encounter Search Enter Patient's Name or Medical Record number or financial Account
3) Test Site: POC Urine
4) Orderable Field :
5) Specimen Type: Urine
6) Performed Date/Time:
7) Performed ID:
8) Type in Result: Negative or Positive
9) Click on Performed and submit.

PROFICIENCY TESTING:

Personnel who performs testing Urine Pregnancy will be presented with a challenge twice 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.

EMPLOYEE CERTIFICATION:

Personnel certification is completed upon in-servicing, and is required to be **renewed six months after first training and annually thereafter**. Documentation of certification is maintained in the employee's personnel folder.

Training and certification of personnel will be conducted by the Institute of Continuous Learning annually**.**

Participants must demonstrate competency in the use of the Quick Vue One-Step hCG Urine Test**.** This according to the established validation criteria:

a) Visual Observation of the operator performing the test and ensuring that written policy and procedures are consistently followed.
b) Evaluation of a problem solving skills.
c) Assessment of testing performance through an external proficiency testing (CAP).
d) Monitoring the recording and reporting of test results.
e) Review of intermediate test results (QC, PT results)

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 to 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.

REFERENCES:

Quidel QuickVue Test manufactures Pack Insert.

Davidson and Henry, Clinical Diagnosis and Management by Laboratory Methods. Seventeen Edition. W.B. Saunders Company, Philadelphia, PA. 1984