A. Purpose:
The QuickVue One-Step hCG Test is a sensitive immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine for the early detection of pregnancy.

Human chorionic gonadotropin is a hormone produced by the placenta shortly after implantation. 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 Test uses a monoclonal antibody specific to the beta subunit of hCG in a single-step technology to accurately detect hCG.

B. Principle:
Urine is added to the sample well of the test cassette. The sample migrates by capillary action through a pad containing a monoclonal anti-hCG detection reagent. If the sample contains hCG, a complex is formed with the anti-hCG detection reagent. The hCG complex will continue to migrate to the result window and be bound by polyclonal anti-hCG spotted on the test line.

If hCG is present in the sample at a level of 25 mIU/mL or greater, a pink or purple Test (T) line along with a blue procedural Control (C) Line will appear in the result window. If the hCG is present at low levels, or not present in the sample, only a blue procedural Control Line will appear.

C. Policy:
1. A physician’s or PA’s order is required.
2. A Northwest trainer will be identified and trained by the POCC.
3. List of trainers will be kept in the POCC’s office.
4. Initial certification of trainers will require completing a test and running a sample in front of a trainer.
5. Re-certification of operators will be performed yearly.
6. Training information will be recorded and stored in the Rals system.
7. The POCC will supply the Nursing directors or designees with a monthly report identifying problems concerning POC testing.
8. Documentation of follow-up investigation and corrective actions taken will be returned to Pathology to be maintained by the POCC.
9. Results will be recorded:
   a. For ER and Surgery locations:
      Will be entered into the glucose meter and then downloaded to PowerChart. For any problems in entering patient identification or entry of incorrect results, operators will fill out Documentation of Error form and fax to POCC. Certified operators will be entered in the MAS system, so they only have access to entering pregnancy results.

Procedure for Entering Pregnancy results into Accu-chek Meter:

- Turn the meter on.
- Scan /Enter Operator identification. This should be 7 Digits.
- Select: Patient Test
- Select: Other Patient Test
- Select: Pregnancy
- Scan barcode on patient’s wrist band(account number). This is strongly encouraged in the ER.

If this is not possible due to testing being done away from the bedside, scan the chart label attached to urine cup. **Do not scan lab label.**

- See if the lot number and expiration date is correct. If not, select no and then enter the correct lot number and expiration date. ER staff use the lot number on the individual cassette and the Surgical will use the lot number on the box. Both are recorded and are in the Rals system.
- Enter the test results

**Select a Pregnancy control bar result:**
- **Acceptable:** If control line on test cartridge has a blue line.
- **Not acceptable:** If control line on the test cartridge did not turn blue.
- **Back:** If you want to change information you already entered.

**Enter Pregnancy result:**
- **Positive:** Test Line: Turn Pink in color
- **Negative:** Test line: No line present
- **Back:** If you need to change information already entered.

**Note about meter entry of results:** The time you entered the results will be documented test time, so please have meter on hand when starting the test.

b. For Out-Patient locations:
Results will be entered in the Patient’s Medical Record or in Cerner using if they have that availability. Out patient locations will need to make their own corrections.

D. Specimen:
   1. Specimen type: Urine
   2. Patient Preparation: N/A
   3. Handling Conditions: Collect specimen 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 sample is suitable for testing.
   4. Storage Requirements: Urine specimens are tested immediately.
   5. Rejection Criteria: If patient has heavy vaginal bleeding, blood should be drawn and sent to the lab. If urine is too dilute for testing, the physician may need to order a quantitative hCG test.

E. Equipment and Materials:
   1. Equipment: QuickVue One Step Urine hCG Test
   2. Materials/Supplies:
      a. Individually wrapped Test Cassettes. Each device contains murine monoclonal antibody and caprine polyclonal antibody to hCG.
      b. Disposable pipettes (come with kit)
      c. Timer
      d. Sample collection containers
      e. Patient label
   3. Preparation: N/A
   4. Performance Parameters: The QuickVue One-Step hCG Test will detect urine hCG concentrations as low as 25 mIU/mL.
   5. Storage Requirements: Store kit at room temperature (59-86°F) out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box carton or on the individual cassette. Do not freeze.

F. Calibration:
   1. Standard Preparation: N/A
   2. Calibration Procedure: N/A

G. Quality control:
   1. Materials used: QuickVue One-Step hCG Test and Reagents and Quantimetrix level 1 and level 2 controls
   2. Preparation and Handling: N/A
3. **Frequency Run:** Liquid quality controls using a positive and negative control are performed once per shipment received at the hospital and then weekly thereafter by units performing the testing. Internal QC is noted with patient result for each patient test run.

4. **Tolerance Limits:** The QuickVue One-Step hCG 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 result is invalid. The absence of interfering background is a negative procedural control. If background color appears in the Result window which interferes with your ability to read the test result, your result may be invalid.

5. **Correction Action:** Contact Quidel Technical Assistance (800-874-1517) or POCC (x55816)

H. **Procedure:**
   1. Apply gloves.
   2. Collect urine sample from patient in unused plastic, labeled container with patient’s name and unit number.
   3. Remove the QuickVue One Step hCG test from the foil pouch and place on a clean, dry, level surface.
   4. Using one of the disposable pipettes supplied, add 3 drops of urine to the round sample well on the test cassette. Do not pick up the cassette.
   5. Wait exactly 3 MINUTES to read results. Use a timer: **timing is critical.**
   6. Record results as stated in Policy related to the location where test was performed.
   7. Discard all contaminated materials in appropriate biohazard containers.
   8. Notify doctor if necessary.

I. **Expected Values:**
   Specimens containing as low as 25 mIU/mL hCG will yield positive results when tested with the QuickVue One-Step hCG Test. In normal pregnancy, hCG can be detected as early as 6 days following conception with concentrations doubling every 32 to 48 hours. Levels of 25 mIU/mL are reportedly present in urine as early as two to three days before expected menses.

J. **Interpretation of Results:**
   1. **Positive**
      The appearance of any pink to purple line next to the letter “T” in the Result test window, along with a blue procedural Control line next to the letter “C”.
   2. **Negative**
      The appearance of the blue procedural Control Line next to the letter “C” only and not pink to purple line next to the letter “T” at 3 minutes.
3. **No result**
   If no blue procedural Control Line appears, the test is invalid, and the specimen must be retested.

**K. Limitations:**
The contents of this kit are for use in **qualitative** detection of hCG in urine only. While pregnancy is the most likely reason for the presence of hCG in serum and urine, elevated hCG concentrations unrelated to pregnancy have been reported in some patients. HCG may remain detectable for a few days to several weeks after delivery, abortion, or hCG injections. Natural termination occurs in 31% of pregnancies overall and 22% of clinically unrecognized pregnancies. Abnormal pregnancies cannot be diagnosed by qualitative hCG results. The above conditions should be ruled out when diagnosing pregnancy.

Very dilute urine specimens, as indicated by low specific gravity, may not contain representative urinary hCG concentrations. The presence of hCG in urine as determined by using the QuickVue One-Step hCG test must always be evaluated in conjunction with other clinical and laboratory data available to the clinician.

**M. Reporting Results:** In Powerform or on the Point of care result sheets

**N. Procedure Notes:**
1. **Reference Range:** Negative
2. **Critical Value:** N/A
3. **Reporting format:** Positive or Negative
4. **Hazardous materials:** Urine samples and quality control
5. **Protective Equipment Requirements:** gloves

**O. Limitation of Procedure:**
1. **Linearity:** N/A
2. **Interfering Substances:** The following chemical and biological compounds were evaluated using the QuickVue One-Step hCG test. All compounds were tested in urine pools containing 1, 25, or 100 mIU/mL of hCG. None of the compounds, at the concentrations tested, interfered with the assay.
   a. **Chemical Interference:**

<table>
<thead>
<tr>
<th>Analytes</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>20 mg/dL</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>20 mg/dL</td>
</tr>
<tr>
<td>β-Hydroxybutyrate</td>
<td>2000mg/dL</td>
</tr>
<tr>
<td>Caffeine</td>
<td>20 mg/dL</td>
</tr>
<tr>
<td>Ephedrine</td>
<td>20 mg/dL</td>
</tr>
<tr>
<td>Gentisic Acid</td>
<td>20 mg/dL</td>
</tr>
<tr>
<td>Phenylpropanolamine</td>
<td>20 mg/dL</td>
</tr>
<tr>
<td>Salicylic Acid</td>
<td>20 mg/dL</td>
</tr>
<tr>
<td>Phenothiazine</td>
<td>20 mg/dL</td>
</tr>
</tbody>
</table>
EDTA 80 mg/dL
Acetylsalicylic Acid 20 mg/dL
Benzoylcegonine 10 mg/dL
(cocaine metabolite)
Cannabinol 10mg/dL
Methadone 10mg/dL
Ethanol 1.0%
Methanol 10.0%
DMSO 5.0%
Uric Acid 20 mg/dL

b. Urine Analytes

<table>
<thead>
<tr>
<th>Analytes</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin(Serum)</td>
<td>2000 mg/dL</td>
</tr>
<tr>
<td>Glucose</td>
<td>2000 mg/dL</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>1000 ug/dL</td>
</tr>
<tr>
<td>Estriol 17-β</td>
<td>1400 ug/dL</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>1000 ug/dL</td>
</tr>
<tr>
<td>Pregnanediol</td>
<td>1500 ug/dL</td>
</tr>
<tr>
<td>Urine pH</td>
<td>5-9</td>
</tr>
</tbody>
</table>

c. Hormones

<table>
<thead>
<tr>
<th>Hormones</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>hLH</td>
<td>1000 mIU/mL</td>
</tr>
<tr>
<td>hFSH</td>
<td>1000 mIU/mL</td>
</tr>
<tr>
<td>hTSH</td>
<td>1000 uIU/mL</td>
</tr>
<tr>
<td>Estriol 17-beta</td>
<td>1400 ug/mL</td>
</tr>
<tr>
<td>Pregnanediol</td>
<td>1500 ug/mL</td>
</tr>
</tbody>
</table>

d. Bacteria

<table>
<thead>
<tr>
<th>Bacteria</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>E. Coli</td>
<td>$10^8$ CFU/mL</td>
</tr>
<tr>
<td>Group B Streptococcus</td>
<td>$2.2 \times 10^8$ CFU/mL</td>
</tr>
<tr>
<td>Chamydia trachomatis</td>
<td>$10^4$ IFU/mL</td>
</tr>
</tbody>
</table>

P. REFERENCES:

Q. ATTACHMENTS: N/A