XII. Waived Urine Pregnancy Test			
A. Policy Statement/Clinical Usage B Test Principle C. Patient Preparation			
Effective: 09/10	Reviewed: 5/2015	Review Month: May	*Discontinue Date:*

A. Policy/Clinical Usage
The laboratory and designated nursing staff perform waived pregnancy testing. The urine pregnancy test is a rapid one-step, visual test for the qualitative detection of Human Chorionic Gonadotropin (HCG) in urine. The test provides a presumptive diagnosis for pregnancy in women of child bearing age before being started on therapeutic drugs.

1. Waived testing is a laboratory procedure, which has been cleared by the Federal Drugs Administration for home use; employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly.

2. The Urine Pregnancy Patient Control Log and the Policy and Procedure Manual will be maintained in the specimen processing workstation.

3. Human Chorionic Gonadotropin (HCG) is a hormone secreted during pregnancy and produced by the placenta after implantation.

4. Human Chorionic Gonadotropin becomes detectable as early as 7-10 days following conception. Since HCG is present in urine of pregnant women, it is an excellent marker for confirming pregnancy.

B. Test Principle:
The urine pregnancy test utilizes a unique combination of monoclonal and polyclonal antibody reagents to selectively detect elevated hCG in urine. The assay is conducted by the addition of urine specimen into the sample well and observing for the formation of colored lines in the result area. The urine specimen migrates by capillary action along the membrane and reacts with the antibody dye-conjugate. Positive hCG specimens react with the specific antibody-hCG colored conjugate and form a colored line in the Test Zone (T) portion of the membrane. Absence of this colored line suggests a negative result.

C. Patient Preparation:
None required. Morning specimens are preferred.

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D. Supplies E. Storage and Stability F. Specimen Collection			
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D. Supplies

1. hCG test device
2. Positive and Negative urine pregnancy controls
3. Plastic droppers
4. Timer
5. Sterile plastic container without a preservative tablet
6. Manufacturer's Test Kit Instructions
7. PPE: Gloves and Gown
8. Urine reagent strips for specific gravity

E. Storage and Stability

Store test kits and urine reagent strips at 8-30 degrees centigrade (room temperature). The test kit is stable until the date imprinted on the box label and/or foil pouch. Do not use past the expiration date. If the pouch is out of pocket for a day or longer, or becomes wet, do not use.

Urine controls are stored in the refrigerator between 2-8 degrees Centigrade.

F. Specimen Type and Collection

1. Prior to collecting the specimen, two patient identifiers must be used to accurately identify the patient. Label the specimen with the patient's data from the Lab orders.
2. For optimal detection of early pregnancy, a first morning urine specimen is preferred since it contains the highest concentration of HCG. However, randomly collected urine specimens may be used. Urine specimens collected any other time of day may be diluted by intake of liquids and thus have a lower concentration of the hormone rendering the test results questionable.
3. Wash hands, apply clean gloves.
4. Collect the urine specimen in a clean container without preservatives.
5. If testing is not immediate, the specimen should be stored refrigerated at 2-8 degrees centigrade for 24 hours. Bring the sample to room temperature prior to testing. If testing is delayed more than 24 hours, the specimen should be frozen.
6. Remove gloves, discard, and wash hands

A specific gravity check is performed on all urine specimens submitted for pregnancy testing. A disclaimer statement **"Recommend first voided early morning urine specimen for most reliable results"** will be reported on the specimens that meet the following criteria:

1. Specific gravity 1.015 or greater, test is negative; results will be reported as negative.

2. Specimens with a specific gravity of less than 1.015 may be diluted by fluid intake, test is negative; results will not be reported. The specimen must be recollected or serum pregnancy requested.

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G. Test Procedure			
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G. Test Procedure

Step	Action
1	Wash hands. Personal protective gown and gloves must be worn at all times.
2	Check the expiration date of all supplies. Do not use past the expiration date. Follow the manufacturer's instructions for testing.
3	Allow the specimen and controls to come to room temperature.
4	Check the specimen for proper identification, request and specimen identification must match.
5	Specific Gravity Check a. Remove only enough reagent strips from the container for immediate use. b. Completely immerse reagent areas of the strip in fresh, well- mixed urine. c. While removing, touch the side of the strip against the rim of the urine container to remove excess urine. d. Blot the lengthwise edge of the strip on an absorbent paper towel to further remove excess urine and avoid running over. e. Compare the specific gravity reagent area to its corresponding color block at 45 seconds. f. Record the specific gravity in the patient log.
6	Remove and label the required number of test devices with the patient's name and control identification.
7.	Using dropper(s) supplied, fill the dropper with specimen or control, and dispense sample drop-wise into the **SAMPLE(S)** well. Add **two (2)** full drops of urine in the **SAMPLE(S)** well.
8.	Set the timer for **3** minutes and read the results at **3** minutes after addition of the urine sample.
9.	Enter patient results in the Urine Pregnancy log.
10.	Remove gloves, discard, and wash hands.

XII. Waived Urine Pregnancy Test			
H. Interpretation of Results I. Quality Control Rationale			
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H. Interpretation of Results

1. Test results are interpreted based on the presence or absence of a line in the Test (T) and Control (C) regions of the test device. The interpretation should be performed at the end of the reaction time.

   a. Negative Result – One line appears in the CONTROL (C) area.

   b. Positive Result – A line appears in the CONTROL (C) area and a clearly distinguishable band also appears in the TEST (T) area.

   c. Invalid Result – A line should always appear in the CONTROL (C) area. If there is no distinct band visible in the CONTROL (C) area, the test is invalid. Do not report results.

2. If unable to confirm patient's results:
   a. Notify Provider of test not performed and request repeat testing.
   b. Call the nurse on the unit for recollection, preferably early morning urine sample.
   c. Rerun control and patient sample.

3. If results are invalid after repeat testing:
   a. Contact the Provider and request a serum pregnancy test.
   b. Contact the nurse on the unit for specimen collection.
   c. Send specimen to the reference lab.

I. Quality Control Rationale

Rusk State Hospital Lab adheres to the manufacturer's quality control guidelines for pregnancy testing.

External Controls: Positive and negative HCG controls are performed each day tests are run, as suggested by the manufacturer to ensure adequate performance of the test. Refrigerate controls between 2-8 degrees Celsius. No dilution is necessary. All controls should be at room temperature prior to use.

If controls do not perform as described in the procedure:

1. Check the expiration date on the controls and test device.
2. Verify controls are room temperature prior to testing.
3. Rerun positive and negative controls.
4. If there is no distinct band visible in the control area, the test is invalid.
5. Repeat using a new test device.

The laboratory evaluates the performance of the urine HCG test device whenever a new lot number, new shipment, or when test kits are received. Correlation studies are performed before testing begins. At least 5 urine specimens will be run in-house and sent to the reference lab for confirmation of results.

XII. Waived Urine Pregnancy Test			
J. Limitations & Confirmatory Testing			
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Internal Controls: A (1) positive procedural control is built into the hCG test device. This control line will always appear if the test is performed correctly, and if the device is working properly. An absence of this control line indicates incorrect procedure or deterioration of reagents. The absence of interfering background is a (2) negative procedural control.

J. Limitations, Confirmatory Testing

1. The 20 hCG Test Device is a qualitative test for the detection of hCG in urine. As with all pregnancy tests, the final diagnosis should be based on a correlation of test results with typical signs and symptoms.
2. If a urine sample is too diluted (i.e., low specific gravity), it may not contain representative levels of HCG. If pregnancy is still suspected, a first morning urine sample should be obtained and retested.
3. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms cause elevated levels of hCG. These diagnoses should be considered if appropriate to clinical evidence.
4. High urine hCG is often decreased in extra uterine pregnancy, toxemia of pregnancy or threatened abortion. Such circumstances can yield false negative results.
5. An ectopic pregnancy and spontaneous miscarriage can cause confusion in interpreting test results.
6. A very early pregnancy containing an extremely low concentration of HCG can give a negative result.

Expected Values: Healthy men and non-pregnant women do not have hCG levels detectable by the True 20 hCG Test. In normal pregnancy, levels of 20 mIU/ml hCG can be reached 2 to 3 days before the first missed menstrual period.

Citation(s):
Stanbio True® 20 Plus One-Step Pregnancy Test. Manufacturer's Package Insert. *A Qualitative Immunoassay for the Detection of Human Chorionic Gonadotropin (hCG) in Serum or Urine. Procedure No. 1440; 2010*