

EXERCISE 10: URINE PREGNANCY TEST

Skill: 10 points

Objectives:

1. State the substance being detected in the urine pregnancy test.
2. State the principle of the urine pregnancy test.
3. State the samples of choice for a pregnancy test.
4. Describe the temperature and amount of time a urine sample may be stored for a pregnancy test.
5. Describe the quality control which must be performed on pregnancy test kits and the expected results.
6. Describe the course of action which must be taken if the controls do not give the expected results.
7. Define “false positive” as it relates to pregnancy testing and list two causes.
8. Define “false negative” as it relates to pregnancy testing and list two causes.
9. Describe the proper handling of specimens for urine pregnancy tests which cannot be tested right away.
10. Perform urine pregnancy testing on two samples and evaluate the results for validity based on the results of the quality control.

Discussion

Human chorionic gonadotropin (HCG) is a hormone produced by the placenta shortly after implantation of the embryo into the uterine wall. Since HCG is present in the urine of pregnant women, it is an excellent marker for confirming pregnancy.

Principle of the test

The test methodology used is called Enzyme Linked Immunoassay or ELISA. The test strip is briefly dipped in the urine sample or urine is applied to a specific location on the test cassette. The sample migrates by capillary action through a pad containing a monoclonal anti-HCG antibody; if the sample contains HCG, a complex is formed with the anti-HCG antibody. The complex will continue to migrate and be bound by a polyclonal anti-HCG antibody spotted on the test line. If HCG is present in the sample at a level of 25 mIU/mL or greater, a color change will occur. This may be a line, “plus” sign, etc. The visible reaction which occurs will be determined by the manufacturer. It is critical to read the product insert to interpret the results correctly. Most tests have a built in control which must react, whether or not the patient does. If HCG is not present in the sample, or present at very low levels, only the control will react.

Specimen Collection and Preparation

Collect at least one mL of urine in a clean, dry, plastic or glass container with no preservatives. Specimens may be collected at any time of the day; however the first morning sample generally has the highest concentration of HCG and is the specimen of choice. *Urine samples may be refrigerated and stored up to 72 hours prior to testing.* Samples may be frozen for long term storage.

If samples are refrigerated or frozen, they must be brought to room temperature before testing. **IMPORTANT:** Refer to the package insert for appropriate storage times. The recommendations given here are general. If the package insert states a different allowable storage time, you must follow those recommendations. Urine samples with visible precipitates should be filtered, centrifuged or allowed to settle so that clear aliquots can be used for testing.

Quality Control

Personnel performing laboratory testing must follow accepted guidelines to ensure accurate results. It is required that the kit be tested with commercially available positive and negative control samples and be tested upon each day of use and give acceptable results, i.e., the positive control must be positive and the negative control must be negative. Alternatively some laboratories will test a new lot number of a new kit with controls then rely on the build in controls in the test strip to validate the procedure. You must follow the procedure dictated in the laboratory Procedure Manual. If commercial positive and negative controls do not give the expected reactions OR if the internal controls do not give the expected reactions, repeat the test. If invalid results are still obtained, the manufacturer must be notified and documentation of these actions must be performed. The patient sample must then be tested using a different lot number or test methodology from a different manufacturer for which the controls work correctly.

Limitations of the Procedure

A “*false positive*” pregnancy test is one in which the pregnancy test is positive but *the patient is not pregnant*. HCG has been found in patients with both gestational and non-gestational trophoblastic disease. Since HCG of trophoblastic neoplasm is similar to that found in pregnancy, conditions such as choriocarcinoma and hydatidiform moles should be ruled out before a pregnancy is diagnosed. False positive tests are very uncommon, especially with the newer tests (using monoclonal antibodies to hCG).

A “*false negative*” pregnancy test is one in which the patient is pregnant but the result of the pregnancy test is negative. False negative results are more common and are especially undesirable because they delay onset of care for women who may then use potentially hazardous medications after being falsely reassured that they are not pregnant. The primary cause of false negative pregnancy tests is inaccuracies in timing of the test or the in the procedure itself. Following test instructions to the letter is very important but even then false negatives do occur. A second cause of a false negative test is that the sample was not a first morning and the patient is recently pregnant (HCG levels are too low). The test should be repeated weekly if the woman still does not have a period.

A normal pregnancy cannot be distinguished from an ectopic pregnancy based on HCG levels alone. Also, a spontaneous miscarriage may cause confusion in interpreting test results. If negative or questionable results are obtained and pregnancy is suspected, the test should be repeated on a fresh urine specimen at least 48 hours after initial testing. Most urine pregnancy tests can detect (become positive) as early as 2 or 3 days before the next expected menses.

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Name: _____ Date: _____ Points _____/10

Follow the instructions on the reagent package insert provided by the instructor to properly perform the test.

Interpretation of Results:

Based on the package insert correctly interpret the results of the pregnancy test on 2 patient samples.

Record results as "Positive" or "Negative"

SAMPLE TESTED	PATIENT ID NUMBER	RESULT
POSITIVE CONTROL	NOT ANY	
NEGATIVE CONTROL	NOT ANY	
1.		
2.		

EVALUATION OF RESULTS:

Based on the results obtained:

- 1. Can the results for patient #1 be reported out to the patient's physician: YES NO
- 2. Can the results for patient #2 be reported out to the patient's physician: YES NO

When you are finished testing both samples, turn in this sheet and your test cassettes to your instructor. Return your patient samples to the area designated by your instructor.

For Instructor Use Only

Award 1 point for each test result, patient name, identification number and evaluation of results. Count off 0.5 points for each instance if the student uses symbols instead of "positive" or "negative"

EXERCISE 10: URINE PREGNANCY TEST-STUDY QUESTIONS

Name: _____ Date: _____ Points: _____/8

1. State the principle of the urine pregnancy test, including the substance being detected which indicates a positive test. (2 points)
2. Define “false positive” as it relates to pregnancy testing and list two causes. (2 points)
3. Define “false negative” as it relates to pregnancy testing and list two causes. (2 points)
4. State when a urine sample should be collected for the most accurate result. (1 point)
5. Describe the procedure to follow if the urine pregnancy test cannot be performed right away. (1 point)