EXERCISE 5: Urine Pregnancy Enzyme Immunoassay Test

Skills: 15 points

Objectives:

- 1. Define human chorionic gonadotropin and state its function.
- 2. State the principle of the enzyme immunoassay procedure for the detection of HCG.
- 3. State when the urine sample for pregnancy testing should be collected and how it must be stored if not tested immediately.
- 4. Follow instructions of the reagent package inserts to select, and evaluate appropriate specimens for urine pregnancy testing.
- 5. Perform urine pregnancy testing to obtain control and patient results that match instructor values with 100% accuracy.
- 6. Evaluate reagent package inserts to determine the significance of abnormal results, limitations of the procedure, and troubleshooting procedures to follow if/when control results are unacceptable.
- 7. Appropriately record and report results as instructed.
- 8. Utilize lecture notes, textbook and laboratory (including product insert) information to answer study questions.

Introduction:

All serology pregnancy tests are designed to detect human chorionic gonadotropin (hCG) which is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. In normal pregnancy, the hCG hormone can be found in detectable amounts in serum and urine of pregnant women 7-10 days following fertilization. The concentration of hCG rises rapidly, frequently exceeding 100 mlU/ml by the first missed menstrual period and peaks in the range of 30,000- 200,000 mlU/ml by 8-10 weeks into pregnancy. The appearance of hCG in urine soon after conception and its subsequent rise in concentration during early gestational growth make it an excellent marker for the early detection of pregnancy.

The hormone level doubles every 36 - 48 hours during the early weeks until a peak level is achieved sometime during the tenth to twelfth week (end of first trimester). During the second and third trimesters, the hCG levels fall considerably to plateau at about 1/6 of the peak level. Following delivery, the hCG hormone is rapidly cleared from the blood and pregnancy tests become negative in three to four days.

Principle:

Modern pregnancy tests utilize the use of monoclonal antibodies selective for the *beta* area of the hCG molecule for the qualitative detection of human chorionic gonadotropin in urine. Most of these urine test systems incorporate monoclonal anti-hCG antibody which after binding with the hCG (if present in the sample being tested), migrate along a membrane to an area where the molecules become bound to a "fixed" anti-hCG. The fixed anti-hCG is complex with an enzyme or other color producing molecule. The result will be the production of a visible marker. Controls must be routinely tested on the kits to verify the validity of patient results.

Sample Requirements

Random urine specimen is appropriate for hCG testing, but the first morning urine is optimal because it generally contains the highest concentration of hCG.

Urine specimens should be collected in any clean, dry, plastic container. **NOTE:** Urine specimen should be stored in the smallest possible plastic container. Large containers (especially glass) are to be avoided because hCG sticks to the surface of containers.

Specimens may be stored at room temperature for up to 8 hrs prior to testing, or may be refrigerated (2 to 8C) and run within 72 hours after collection.

Standard Precautions must be followed when handling body fluids.

Clinical Indications:

While confirmation to diagnose pregnancy is the most common reason a pregnancy test is ordered there are many other conditions which may warrant this test:

- Suspected choriocarcinoma
- Suspected hydatidiform mole
- Testicular tumors
- Prostatic cancer
- Breast cancer
- Lung cancer
- Pre-surgical procedures
- Pre-X-ray and Radioisotopic procedures

Review the principle of the specific kit being used in this laboratory.

EXERCISE 5: Urine Pregnancy Test

Name _____

Test Kit Name	
Manufacturer	
Lot Number	
Expiration Date	

Patient Name and Identification Number	Result
1.	
2.	
Positive Control Zone	
Negative Control Zone	

- 1. Based on the results obtained state whether the results can be reported out on the patient samples:
- 2. Briefly state the principle of the procedure of this test kit.

- 3. What enzyme is used as an indicator:
- 4. How long can *urine* specimens be utilized if refrigerated:
- 5. How should a *serum* sample be stored if it cannot be tested immediately:
- 6. State the recommended room temperature for procedure performance: