

EXERCISE 3: Urine Pregnancy Enzyme Immunoassay Test

Skills: 40 points

Objectives:

1. Define human chorionic gonadotropin (hCG) and state its function.
2. State the principle of the enzyme immunoassay procedure for the detection of hCG.
3. Differentiate between a qualitative and quantitative assay.
4. State when the urine sample for pregnancy testing should be collected and how it must be stored if not tested immediately.
5. Follow instructions of the reagent package insert to select and evaluate appropriate specimens for urine pregnancy testing.
6. Perform urine pregnancy testing to obtain control and patient results that match instructor values with 100% accuracy.
7. Evaluate reagent package inserts to determine the significance of abnormal results, limitations of the procedure, and troubleshooting procedures to follow when control results are unacceptable.
8. Appropriately record and report results as instructed.
9. State whether the results can be reported out to the physician.
10. List 8 conditions, other than pregnancy, for which hCG levels may be ordered.

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 mIU/ml by the first missed menstrual period and peaks in the range of 30,000- 200,000 mIU/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 complexed 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

Some kits use serum, others urine and some can use both types of samples. Read the instructions carefully to determine acceptable sample types.

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.

Refer to the package insert for specific storage requirements. Pay close attention to the: storage temperature, length of time a sample may be stored and other storage requirements required by the manufacturer. All samples must reach room temperature prior to testing.

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:

1. Suspected choriocarcinoma
2. Suspected hydatidiform mole
3. Testicular tumors
4. Prostatic cancer
5. Breast cancer
6. Lung cancer
7. Pre-surgical procedures
8. Pre-X-ray and Radioisotopic procedures

Review the principle of the specific kit being used in this laboratory. PRINCIPLE: What is reacting with what to give what type of reaction to indicate its presence.

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Name _____

Date _____

Kit 1

Test Kit Name _____

Manufacturer _____

Lot Number _____

Expiration Date _____

Refer to the package insert as to the terminology used to report out the results and to answer the following questions.

Patient Name	ID Number	Patient Result	Positive Control Zone Result
1.			
2.			

- Can these results be reported out? (**Circle ONE**) YES NO
If “No” state why the results cannot be reported out.
- List the types of samples which may be used with this kit.
- State the storage temperature(s) for patient samples **AND** length of time they can be used.
- List and describe the limitations of the procedure. (**Use the back of paper if necessary**)
- Review the Sensitivity, Specificity and interfering substances section of the procedure. Do any of the potentially interfering substances listed interfere with the test results?
- State the appropriate storage temperature of the kit.
- Describe the type of quality control (QC) which must be performed, the expected results and what must be done if the QC does not give the expected results.
- State the **PRINCIPLE** (what is reacting with what) of the procedure, provide description of positive result - refer to PACKAGE INSERT - **Use back of this paper or attach another sheet.**

Name _____

Date _____

Kit 2 - IF AVAILABLE

Test Kit Name _____

Manufacturer _____

Lot Number _____

Expiration Date _____

Refer to the package insert as to the terminology used to report out the results and to answer the following questions.

Patient Name	ID Number	Patient Result	Positive Control Zone Result
1.			
2.			

1. Can these results be reported out? **(Circle ONE) YES NO**
If “No” state why the results cannot be reported out.
2. List the types of samples which may be used with this kit.
3. State the storage temperature(s) for patient samples AND length of time they can be used.
4. List and describe the limitations of the procedure. **(Use the back of paper if necessary)**
5. Review the Sensitivity, Specificity and interfering substances section of the procedure. Do any of the potentially interfering substances listed interfere with the test results?
6. State the appropriate storage temperature of the kit.
7. Describe the type of quality control (QC) which must be performed, the expected results and what must be done if the QC does not give the expected results.
8. State the **PRINCIPLE** (what is reacting with what) of the procedure, provide description of positive result - refer to PACKAGE INSERT - **Use back of this paper or attach another sheet.**

**EXERCISE 3:Urine Pregnancy Test
Additional Questions**

Name _____

Date _____

1. What substance is being detected in most pregnancy test kits on the market? (1 point)

2. State the principle of pregnancy tests which use monoclonal antibodies. (2 points)

3. If a refrigerated sample is used, what must be done first prior to performing the test? (1 point)

4. List 4 causes of false positive results. Note: false positive means the patient is **NOT** pregnant but has a positive test for pregnancy. (2 points)