

MLAB 2362: Clinical III

Reading Package Inserts

Objectives:

1. Discuss the purpose of package inserts and list the types of information found on package inserts.
2. Identify the hazards associated with a specific assay
3. Identify the proper reagent preparation and storage of a specific assay.
4. Recall the sample type and volume for a specific assay.
5. Identify the calibration frequency.
6. Define the principle for a specific assay.
7. Discuss potential interferences for a specific assay.
8. Compare the expected range of an assay with the analytical measurement range for a specific assay.
9. Cite the sensitivity of a specific assay.

Materials:

1. Pen
2. Reagent Package insert

Purpose:

Package inserts are informational documents that are included with various laboratory products. Package inserts are found in items such as quality control products and reagents. Package inserts follow a standard outline of information. Depending on the type of product, and the manufacturer, the information may slightly differ.

Procedure:

1. Obtain a package insert from the instructor.
2. Reviewing the package insert, answer the questions on the report form.

Student Name: _____
Date: _____

Reading Package Inserts
Report Form
Points= 16

Instructions: Unless otherwise noted, each question is worth one (1) point.

1. Manufacturer: _____
2. Analyzer/System: _____
3. Assay: _____

4. Methodology:

5. Principle of Procedure:

6. Specimen Type:

7. Sample Size/Volume:

8. Specimen Storage and Stability:

9. Reagent Preparation:

10. Reagent Expiration:

11. Frequency of Calibration:

12. Analytical Measurement range (AMR):

13. What material is used for dilutions?

14. Interferences:

15. Expected Values (serum):

- Male
- Female

16. Sensitivity: