

GOOD LABORATORY PRACTICES

The Package Insert--IMPORTANT INFORMATION FOR EVERYONE

Tiny print, multiple pages...who has the time to read that?!?

It's good lab practice to read the package insert. If you are evaluating tests to run in your lab, you'll want to read the entire insert. If you have established tests, you should read at least the following sections each time you open a new box. Check to make sure you have the most current version of the package insert so that you will be following the most current version of the instructions. To check the version, look on the last page of the insert and check the date. Make sure you have the most current date.

Intended Use

This section describes what the test will detect. It informs the tester what sample is needed for the test, e.g. urine, throat swab, whole blood, etc.

Specimen Collection and Preparation

Instructions on obtaining a proper sample, and how that sample should be preserved and transported for that particular test. Useful and accurate results come only from correct specimens.

Storage Requirements or Stability

The temperature range for proper storage of the reagents is found in this section. Expiration information will also be listed here.

Procedure

Explicit step by step instructions are presented here. Exactly following the procedures developed by the manufacturer is the only way to get accurate and meaningful test results. You will find important warnings, acceptable procedures and disposal information in this section.

Quality Control

This is a very important section. It contains instructions regarding the use of quality control (QC) material and the frequency of QC testing. You must follow the procedures exactly to ensure the testing process is working.

Interpretation of Results

This section has explicit detail on how to read and interpret the test results.

Limitation of Procedures

The test only works within certain prescribed situations. There are limits to accurate test results. Make sure your results and testing procedures are within manufacturer's specifications. Certain factors, called interfering substances, will prevent the test from performing correctly. Be aware of the circumstances that will give false results that may lead to incorrect treatment of the patient.

Don't forget the manufacturer's telephone number!

Often a toll-free number, keep it handy for technical assistance if the need arises.

- 1) Keep the manufacturer's product insert for the laboratory test in use and be sure it is available to the testing personnel. Use the manufacturer's product insert for the kit currently in use; do not use old product inserts.
- 2) Follow the manufacturer's instructions for specimen collection and handling.
 - a) Are specimens stored at the proper temperature?
 - b) Are the appropriate collection containers used?
- 3) Be sure to properly identify the patient.
 - a) Does the name on the test requisition (or prescription) match the patient's name?
 - b) Does the name on the patient's chart match the name on the patient's identification?
 - c) If more than one patient is present with the same first and last name, how do you determine which one is the test patient? (Look for possible gender differences, social security number, patient identification number, birthdates, different middle name, and relevance of the test to the patient's history).
- 4) Be sure to label the patient's specimen for testing with an identifier unique to each patient.
- 5) Inform the patient of any test preparation such as fasting, clean catch urines, etc.
- 6) Read the product insert **prior** to performing a test.
 - a) Become familiar with the test procedure.
 - b) **Study** each step and perform them in the proper order.
 - c) Know the time required for performing the test and achieving the optimal result.
 - d) Be sure to have all of the required reagents and equipment ready **before** actually performing the test.
 - e) Be able to recognize when the test is finished – e.g. will there be a blue plus or minus sign against a white background?
 - f) Follow the manufacturer's instructions and when a new kit is opened, perform the quality control to be sure that the kit works prior to testing patient samples.
- 7) Follow the storage requirements for the test kit. If the kit can be stored at room temperature but this changes the expiration date, write the new expiration date on the kit.
- 8) Do not mix components of different kits!
- 9) Record the patients' test results in the proper place, such as the patient's chart or the laboratory test log, but not on unidentified post-it notes or pieces of scrap paper that can be misplaced.
 - a) Record the results according to the instructions in the manufacturer's product insert.
 - b) If it's a qualitative test, spell out **positive/negative or pos/neg** because symbolic representations can be altered (the – can be altered to a +).
 - c) Include the name of the test, the date the test was performed, and the initials of the testing personnel in the test record. Include the calendar year in the date.
 - d) If the same test is performed on a patient multiple times in one day, include the time of each test.
- 10) Perform any instrument maintenance as directed by the manufacturer.

10/18/2010