

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.

GLOSSARY

- 1) **CLIA** means the Clinical Laboratory Improvement Amendments of 1988.
- 2) **Certificate of waiver (COW)** allows a facility to do only waived tests.
- 3) **PPMP Certificate** allows qualified providers to do waived testing and certain microscopic examinations during the patients' visit.
- 4) **Certificate of registration or registration certificate** means a certificate issued to a laboratory that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined to be in compliance through a survey by the Centers for Medicare and Medicaid Services (CMS) or its agent; or in accordance with Sec. 493.57 to an entity that is accredited by an approved accreditation organization.
- 5) **HHS** means the Department of Health and Human Services, or its designee.
- 6) **Kit** means all components of a test that are packaged together.
- 7) **Laboratory** means a facility for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.
- 8) **MedWatch:** FDA service for health care facilities to voluntarily report a serious adverse event or product problem that the user suspects is associated with a drug or medical device used, prescribed, or dispensed.
Online: www.fda.gov/medwatch/report/hcp.htm
Phone: 1-800-FDA-1088
- 9) A **pipet/pipette** is a narrow, usually calibrated glass or plastic tube into which small amounts of liquid are suctioned for transfer or measurement.
- 10) **Plasma** is the usually clear, yellowish fluid portion of blood, lymph, or intramuscular fluid in which cells are suspended. It is the fluid produced when a blood specimen is collected in a vacuum tube with anticoagulant.
- 11) **Serum** is the usually clear yellowish fluid obtained upon separating whole blood into its solid and liquid components after it has been allowed to clot. Also called blood serum.
- 12) A **reagent** is a substance or material or ingredient used in a lab test to detect, measure, examine, or produce other substances.
- 13) **Controls** are materials with known values of the substance measured that help the laboratory achieve accurate and reliable testing by checking if the test system is working. **Controls**, also known as **quality control material**, are external or internal. **External controls** are usually a liquid and are processed or tested in the same manner as a patient specimen. **Internal** or **procedural controls** are indicators that the test procedure was performed in the proper order.

14) Quality Control (QC) procedures help to ensure the excellence of the patient testing. If the QC results are not within the prescribed range or the expected pattern, then the laboratory cannot be sure that the patients test results are accurate and reliable. **See Controls above.**

15) Quality Assessment (QA) is the laboratory's self-examination of the specimen collection, testing, and test reporting processes. What does the laboratory do to **assure accurate results**? Ten recommended QA questions to ask are:

- **Are the patients and specimens properly identified?**
- **Are the patients' charts up-to-date with the proper patient test information?**
- **Is the quality control performed and documented?**
- **Did the laboratory get the right answers for the quality control?**
- **Do the waived test results correlate with the patients' history or symptoms?**
- **Are there any complaints about the laboratory testing?**
- **Are the testing personnel trained prior to performing laboratory testing?**
- **Are there periodic discussions about laboratory concerns?**

16) Screening tests – initial tests to determine if a disease or medical condition exists.

17) Diagnostic tests – tests to identify a disease or medical condition that exists in a patient.

18) Monitoring tests – once a patient is diagnosed with a disease or medical condition, these tests help the clinician keep track of the patient's specific medical condition or response to treatment on a periodic basis.

19) Routine order of draw (when the laboratory collects more than one tube of blood at a time on a patient):

- Blood culture tube
- Non-additive serum tube
- Citrate tube
- SST (serum separator tube), plastic serum tube
- Heparin tube
- EDTA tube
- Glycolytic inhibitor tube

Please consult with the reference laboratory for specific specimen collection requirements.

20) Package Insert – Instructions included by the manufacturer in the kit or test package. Read these carefully each time a new kit is opened to check for changes in procedures or quality control. Retain the current package insert for reference. The language used to convey the instructions is important. Words like 'always', 'shall', 'must', '*test*', '*perform*', '*do*' and 'required' mean the instruction is regulatory and must be performed. 'Should' or 'recommend' mean the action is not regulatory, but it is good laboratory practice to perform those actions.

NOTE: THIS DOCUMENT IS INTENDED AS A PRELIMINARY EDUCATION TOOL FOR LABORATORIES THAT HAVE A CLIA CERTIFICATE OF WAIVER. THE STATEMENTS ARE RECOMMENDATIONS THAT MAY HELP TO IMPROVE THE QUALITY OF LABORATORY TESTING. ADHERENCE TO THIS DOCUMENT IS VOLUNTARY AND IS NOT CONSIDERED TO BE ALL INCLUSIVE. FOR A MORE COMPREHENSIVE MODEL OF GOOD LABORATORY PRACTICES, READ THE ARTICLE “GOOD LABORATORY PRACTICES FOR WAIVED TESTING SITES” IN THE MORBIDITY AND MORTALITY WEEKLY REPORT (MMWR) WHICH IS AVAILABLE ON THE INTERNET AT www.cdc.gov/mmwr/PDF/rr/rr5413.pdf

CLIA INFORMATION IS AVAILABLE ON THE INTERNET AT <http://www.cms.hhs.gov/clia/>

11-02-2009