

CLIA

Good Laboratory Practices

For CLIA waived sites/testing personnel, **MANDATORY READING AND COMPLIANCE**

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.
3. Are specimens stored at the proper temperature?
4. Are the appropriate collection containers used?
5. 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).
6. Be sure to label the patient's specimen for testing with an identifier unique to each patient.
7. Inform the patient of any test preparation such as fasting, clean catch urines, etc.
8. 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.
9. 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.
10. Do not mix components of different kits!
11. 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.
12. Perform any instrument maintenance as directed by the manufacturer