
Point-of-Care/CLIA Webinar Prep Series

Getting Your Pharmacy Started!

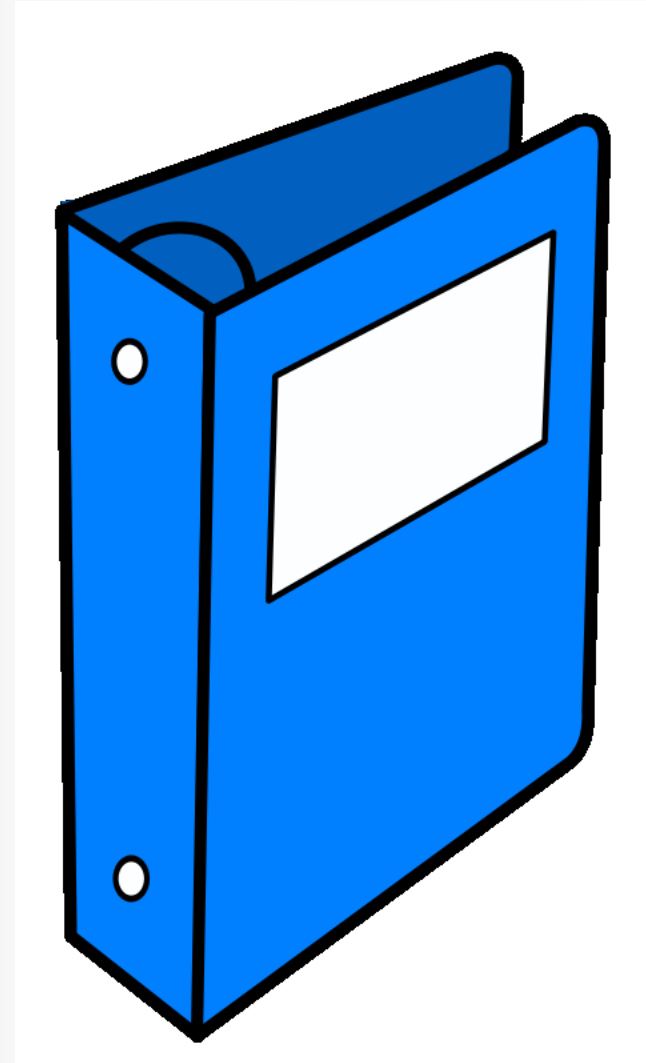


Webinar Prep Series

1. Overview
2. CLIA Application
3. CLIA Waived Equipment
4. Laboratory Director & Staff
5. OSHA-Compliance
6. **Policies and Procedures/Wrap Up**

Components of a Laboratory Binder

- General Information
- Permits
- Consent forms
- Compliance and Training
- **Policies and procedures**
- Safety inspections
- Quality improvement/assurance
- Job descriptions



Requirements

- All testing personnel should be required to read the entire procedure manual
- Include a page at the front of the manual where personnel can “sign-off” when they have read the manual
- An annual review by the lab director should be performed as part of the annual quality assurance program

Policy and Procedure Manual

- A foundation for the lab's quality assurance program
- Purpose is to ensure consistency while striving for quality
- Used to
 - **Document** how tests are performed
 - **Train** new personnel
 - **Remind** personnel of how to perform infrequently ordered tests
 - **Troubleshoot** testing problems
 - **Measure** acceptable test performance when evaluating staff

An Overview

- Each lab test must have a written procedure in the lab
- The manual must be readily available and followed by laboratory personnel
- Information includes
 1. Specimen collection, processing, and rejection criteria requirements
 2. Step by step procedures
 3. Preparation of controls and reagents
 4. Reference and normal ranges
 5. Critical values and reporting
 6. Specimen storage
 7. Criteria for referral

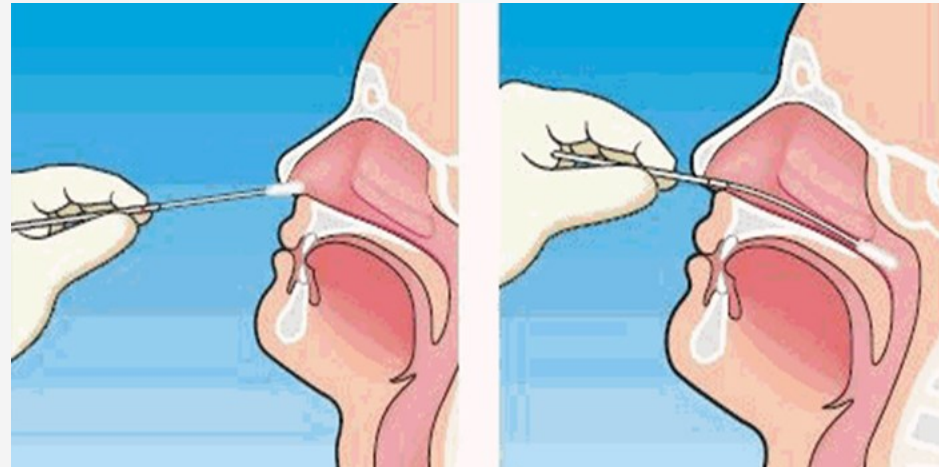
1. Specimen Collection

- Physical collecting of specimen
- Specimen labeling
- Form completion
 - Consent to test and release of information
- Guidelines for releasing results



Specimen Collection Example

- Influenza specimen collection
 - Insert swab into one nostril straight back (not upwards) and horizontally to the nasopharynx up to the measured distance on the swab handle. Rotate the swab up to 5 times and hold in place for 5-10 seconds to collect sample material. Remove swab and insert into a vial containing 1-3ml of viral transport media



Nasopharyngeal swab picture. Accessed December 17, 2018 with permission.

https://www.google.com/search?client=safari&rls=en&biw=1199&bih=837&tbm=isch&sa=1&ei=xfcYXLTdIM6G5wK9r7rwBQ&q=nasopharyngeal+swab+collection&oq=nasophar&gs_l=img.1.1.0j0i67l2j0l6j0i67.56994.58080..60585...0.0..0.76.533.8.....1.....1..gws-wiz-img.....35i39.BZKL3Tdp8mE#imgsrc=H_wKtX4CVJk-0M:

2. Procedures

- Manufacturer's package inserts or operator manuals may be used to meet this requirement
 - Any information not included by the manufacturer must be included by the laboratory
- All procedures must be approved, signed, and dated by the laboratory director
 - Procedures must be re-approved, signed and dated if the director of the laboratory changes
- The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance, retaining records for two years after the procedure has been discontinued

Example: One Touch[®] Glucose Testing

- Check the **expiration date on the vial** of test strips. Do not use the test strips after the expiration date.
- On the vial label, write down the date you first open the vial. This date is used as a reference for the **discard date**—you must throw out any unused test strips 6 months after you first open the vial.
- Get test results
- **Insert a new test strip**
- Wash and dry your hands thoroughly with warm water. Take a test strip from the vial. With the gold side and silver prongs of the test strip facing you, insert the silver prongs into the test strip port as far into the meter as it can go. Your meter will turn on automatically. When **Apply Blood** shows on your meter display, it is ready to read your blood sample. Note: This meter doesn't require any coding.

Example: One Touch® Glucose Testing

- Put a new sterile lancet into your lancing device. Hold the lancing device firmly against the side of your finger. Press the release button and take the device away from your finger. Squeeze your fingertip until you get a drop of blood.
- You can put the blood drop on either side of the channel of the test strip. After the channel fills completely and turns red, the meter will count down from 5 to 1. If the meter does not count down, throw the strip away and start over at step 1.
- **Read the result on the meter**
- Discard the used lancet and test strip

3. Preparation of Controls and Reagents

- Use the most recent package insert of manufacturer's instructions
- Kit instructions may change slightly from lot to lot
 - Date the insert with the date the shipment was received as documentation
- Perform quality control and/or calibration as specified by the kit manufacturer
- Use the test kits/reagents in the form they are received
 - **Do not alter in any way**
- Store and handle all test kits according the manufacturer's instructions
- Never use outdated reagents

4. Reference and Normal Ranges

- Value sets and ranges to interpret analytes where 95% of a given population falls within
- You may begin patient testing using the manufacturer's suggested reference range(s) or may use other published reference ranges from a textbook or a journal publication
- Reference ranges can vary based on the type of patient
 - Pediatric
 - Gender
 - Disease state

Performance Specifications

- Refer to State Operations Manual
- Appendix C-Interpretive Guidelines
 - §493.1253
- CMS website at: www.cms.hhs.gov/clia



5. Critical Laboratory Values (Panic Values)

- Laboratory test results that exceed established limit(s) as defined by the laboratory for certain analytes as listed in the Critical (Panic) Limit plan
 - Can be defined as high or low
- Considered life-threatening and require immediate notification of the oversight physician and/or other clinical personnel responsible for patient's care
- Abnormal results are **not** considered critical values
 - Results that are outside the laboratory's established reference intervals may be considered abnormal
 - These should not be used interchangeably

6. Specimen Storage

- Testing should be performed in an area with adequate space to safely conduct testing while maintaining patient privacy
- Testing and storage areas should be monitored to be sure they meet specific environmental requirements described in the manufacturer's instructions
- Check and record temperatures of the testing and reagent storage areas
 - Twice daily on temperature logs
- Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired
- Inspect reagents for damage, discoloration, or contamination, and discard if found
- Allow time for refrigerated reagents/samples to come to room temperature prior to testing

7. Criteria for Referral

- A policy should be made for each of the following:
 - When patients should and should not be tested
 - Based on screening parameters, population limits, and disease states
 - When patients are tested and referred to other health care providers
 - Normal verses abnormal laboratory values
 - When patients are referred to emergency care services
 - Critical/panic values
 - All reporting of laboratory finding to oversight physician

Next Steps

Friday, January 25, 2019

8:30-12:30pm (registration with Continental Breakfast 8 a.m.)

Community Pharmacy-based Point-of-Care Testing Certificate Program

- Register in advance
- 16 hours of self study prior to live seminar

