Point-of-Care/CLIA Webinar Prep Series

Getting Your Pharmacy Started!

CLIA Waived Equipment

Pennsylvania Pharmacists Association

Presenters

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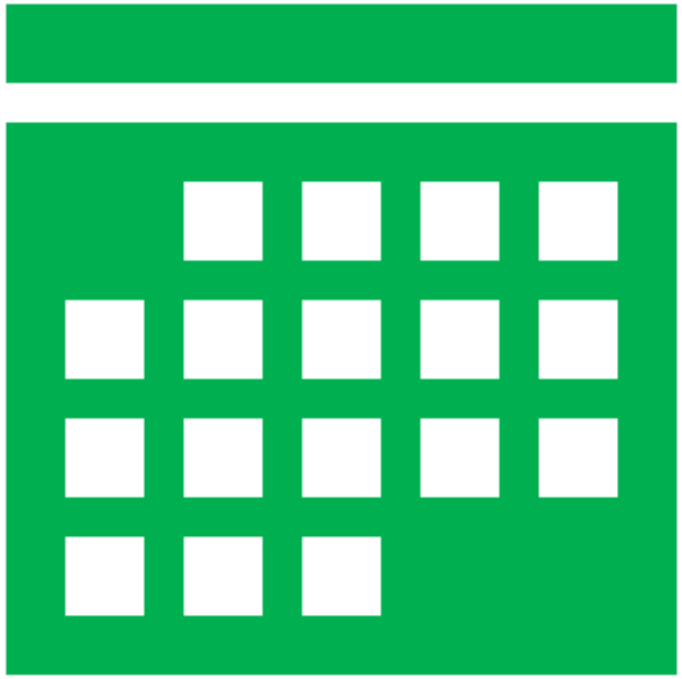
Objective

To help 20 pharmacists implement a point-of-care testing program in 2018-2019

Pennsylvania Pharmacists Association

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



Additional Training

Ready? Set? Test! Patient Testing is Important.
Get the Right Results.

On-demand eLearning, sponsored by the CDC

1 credit hour of ACPE-accredited continuing education

Learning Objectives

- Identify the CLIA requirements for performing waived testing.
- Follow the current manufacturer's instructions for the test.
- Describe good testing practices to be used while performing waived tests.

https://www.cdc.gov/labtraining/training-courses/ready-set-test.html

Additional Training

Ready? Set? Test! Patient Testing is Important.
Get the Right Results.

Booklet

Purpose

This booklet describes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a CLIA Certificate of Waiver.

https://wwwn.cdc.gov/CLIA/Resources/WaivedTests/pdf/15_255581-A_Stang_RST_Booklet_508Final.pdf

CLIA Categorizations

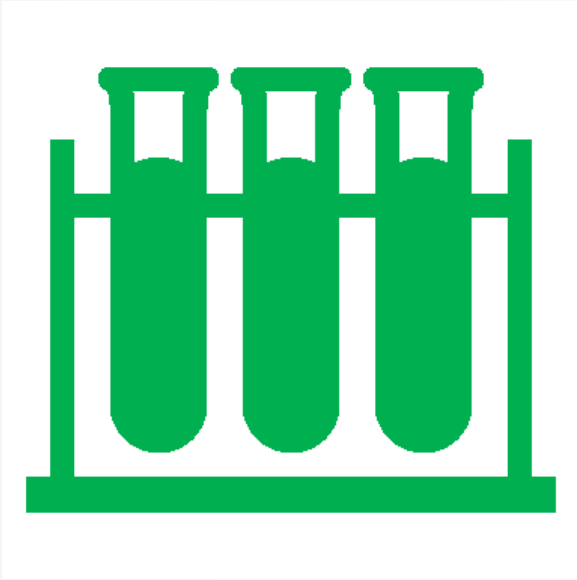
High
Moderate
Waived

https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm393229.htm

Waived Tests

Samples that are not subjected to any type of treatment prior to testing such as centrifugation of whole blood.

Nasopharyngeal swab
Oral fluid
Saliva
Throat swab
Whole blood (fingerstick)



Test Selection

Why do we use CLIA waived tests?

Diagnose diseases

Determine prognoses

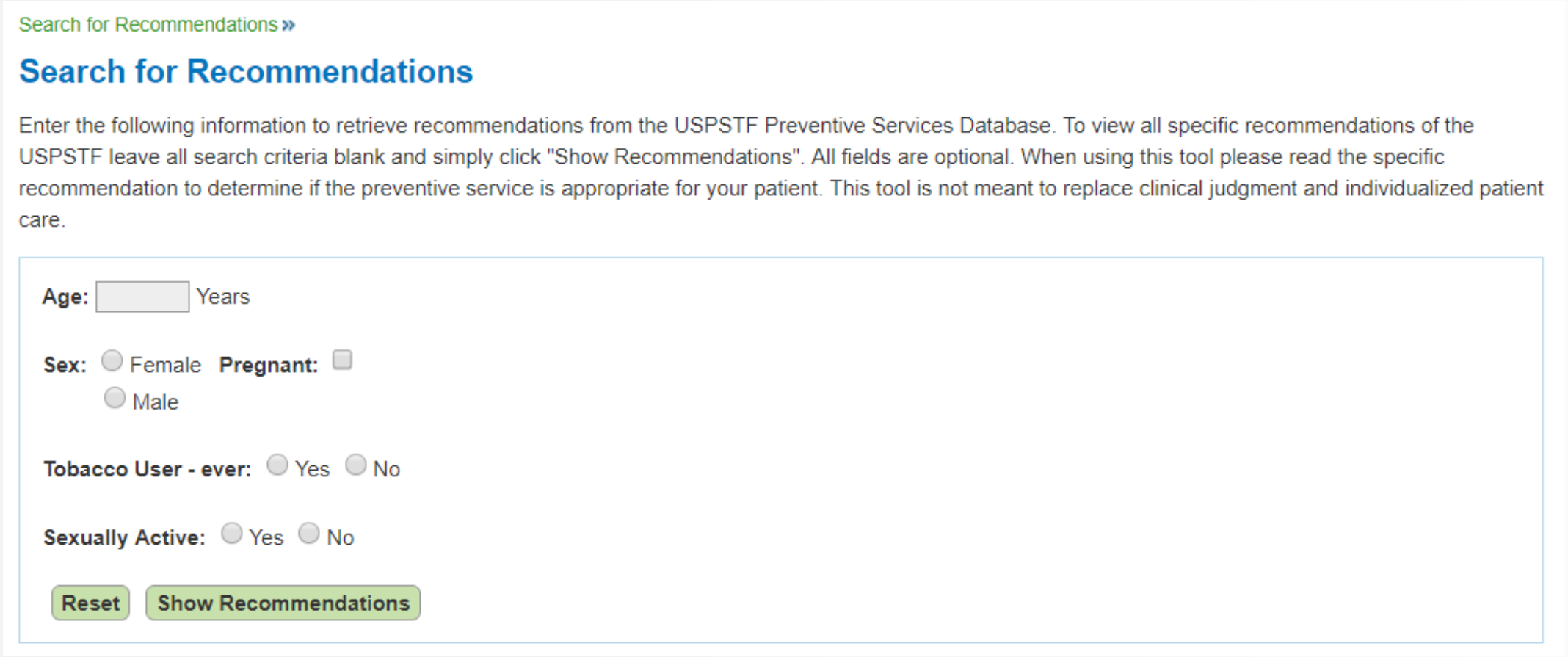
Monitor a patient's health status

Monitor a patient's treatment

Monitor a patient's health status

SCREENING	CLIA WAIVED ANALYTE
Diabetes	Glucose Glycosylated hemoglobin (HGB A1C)
ASCVD 10-year risk	Cholesterol HDL, LDL Triglyceride
Infectious disease	Hepatitis C virus antibody HIV antibodies Influenza A/B Lyme Fluorescent Immunoassay Streptococcus, Group A

Electronic Preventative Services Selector (ePSS)

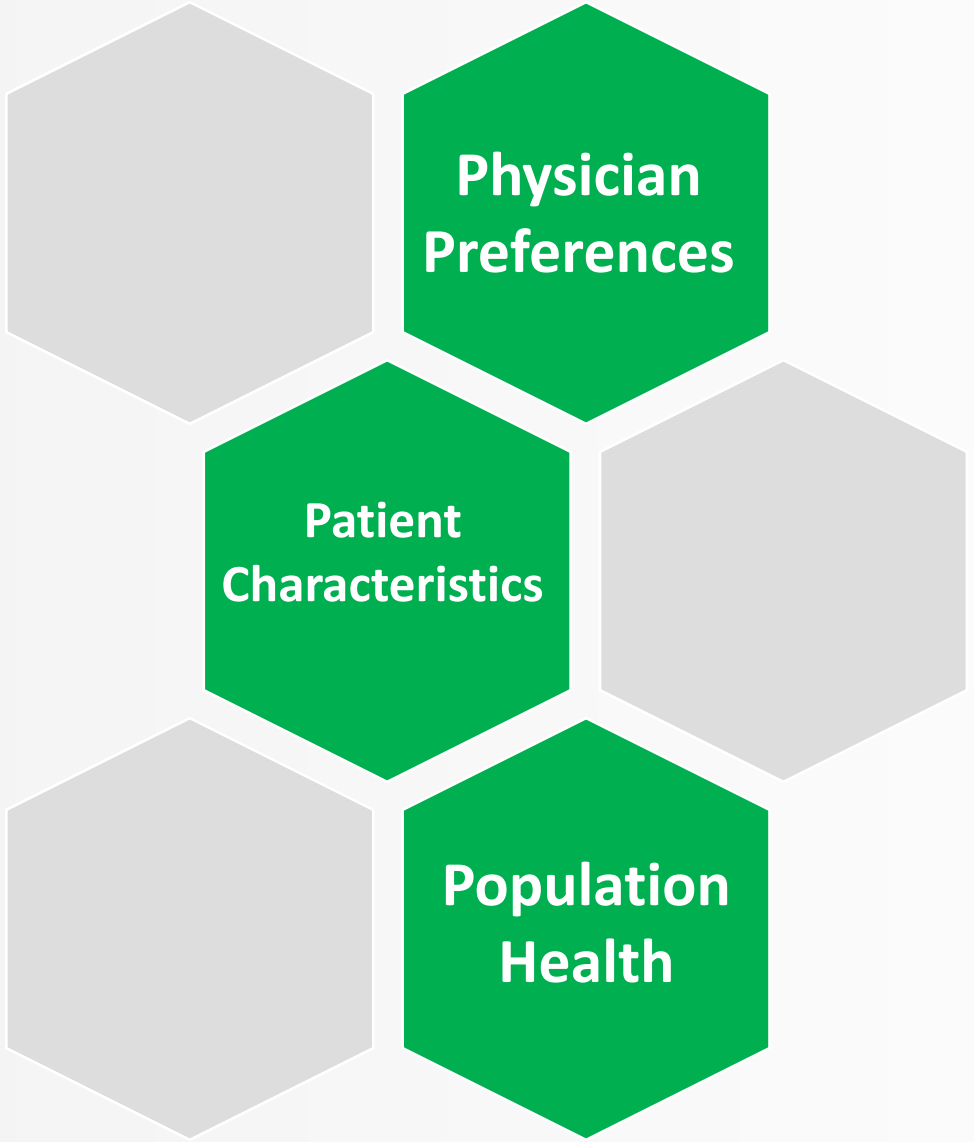


https://epss.ahrq.gov/ePSS/index.jsp

Monitor a patient's treatment

PHARMACOTHERAPY	CLIA WAIVED ANALYTE
Antidiabetic medications	Glucose Glycosylated hemoglobin (HGB A1C)
Cholesterol medications	Cholesterol HDL, LDL Triglyceride
Lithium	Lithium serum concentration
Warfarin	Prothrombin time (PT)

Clinical Considerations

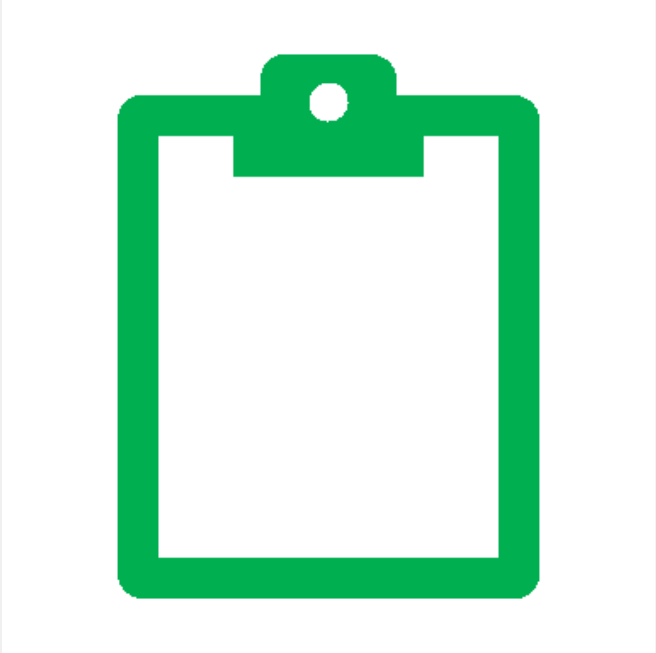


INSIGHTS

Meaningful to patients

Valuable to patient care

Steltenpohl EA, Barry BK, Coley KC, McGivney MS, Olenak JL, Berenbrok LA. Point of care testing in community pharmacies: Keys to success from Pennsylvania pharmacists. J Pharm Pract. 2017.



Available Tests

Public Databases

CLIA Database

Updated monthly, all commercially marketed laboratory tests categorized under CLIA

CLIA – Currently Waived Analytes

Updated monthly, all tests that are categorizes as waived

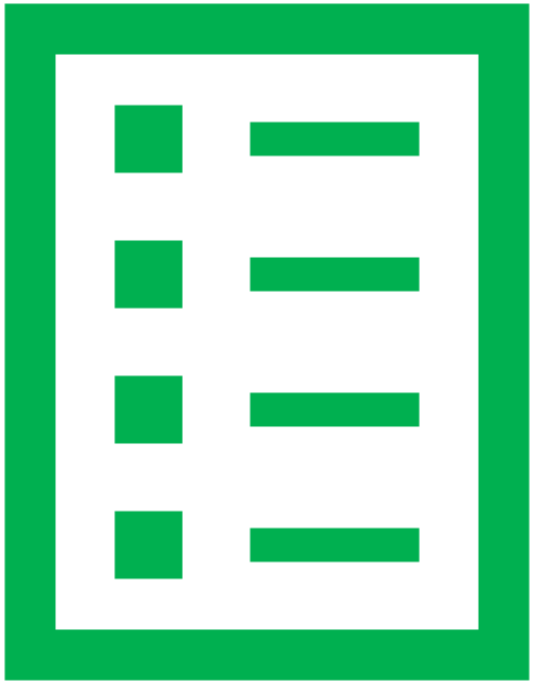
Over-the-Counter Database

Updated monthly, all tests cleared or approved for over-the-counter use

https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm393285.htm

Currently Waived Analytes

CLIA - Clinical Laboratory Improvement Amendments **Currently Waived Analytes**

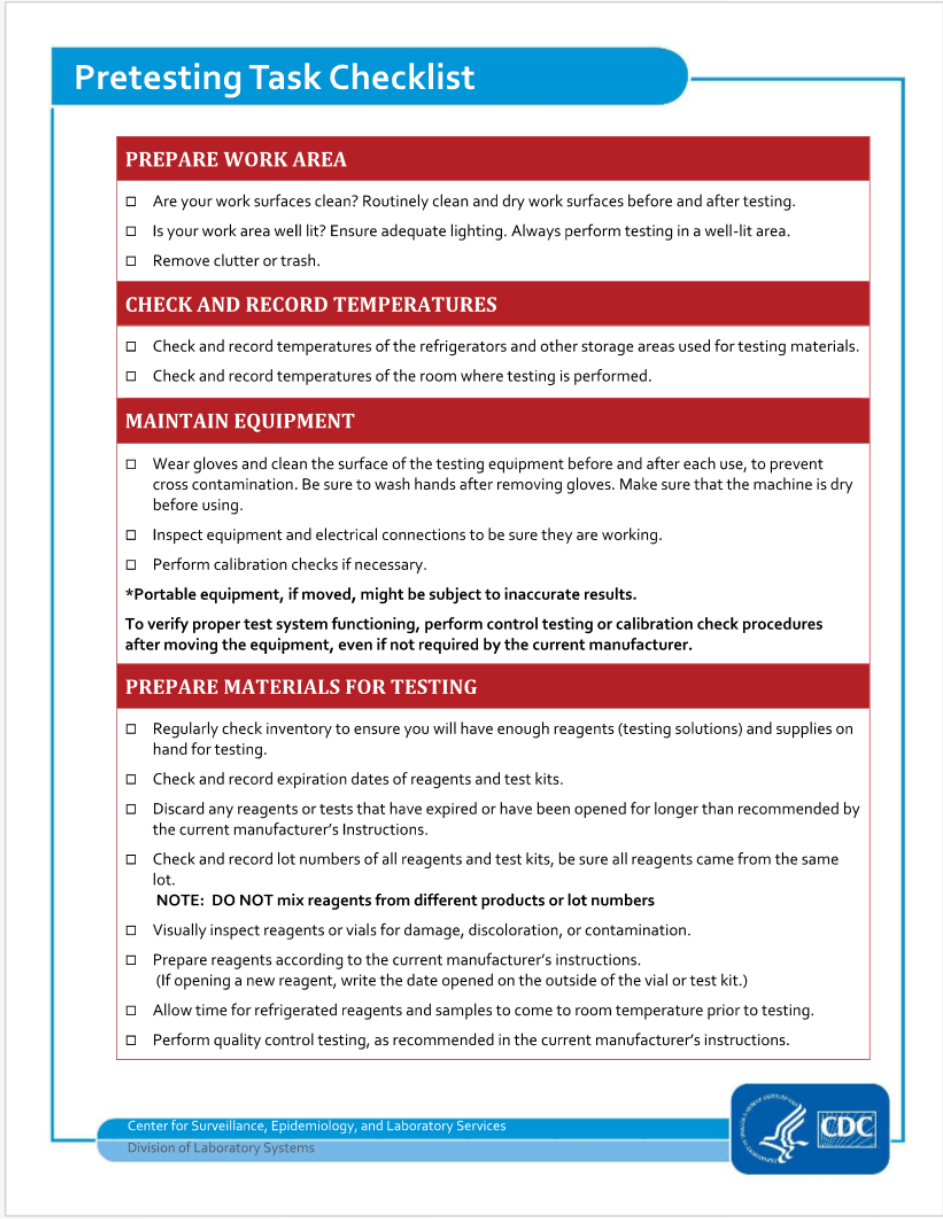


https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

Getting Ready to Test

Pretesting Task Checklist

Prepare work area
Check and record temperatures
Maintain equipment
Prepare materials for testing



Pretesting Task Checklist

PREPARE WORK AREA

- ☐ Are your work surfaces clean? Routinely clean and dry work surfaces before and after testing.
- ☐ Is your work area well lit? Ensure adequate lighting. Always perform testing in a well-lit area.
- ☐ Remove clutter or trash.

CHECK AND RECORD TEMPERATURES

- ☐ Check and record temperatures of the refrigerators and other storage areas used for testing materials.
- ☐ Check and record temperatures of the room where testing is performed.

MAINTAIN EQUIPMENT

- ☐ Wear gloves and clean the surface of the testing equipment before and after each use, to prevent cross contamination. Be sure to wash hands after removing gloves. Make sure that the machine is dry before using.
- ☐ Inspect equipment and electrical connections to be sure they are working.
- ☐ Perform calibration checks if necessary.

***Portable equipment, if moved, might be subject to inaccurate results.**

To verify proper test system functioning, perform control testing or calibration check procedures after moving the equipment, even if not required by the current manufacturer.

PREPARE MATERIALS FOR TESTING

- ☐ Regularly check inventory to ensure you will have enough reagents (testing solutions) and supplies on hand for testing.
- ☐ Check and record expiration dates of reagents and test kits.
- ☐ Discard any reagents or tests that have expired or have been opened for longer than recommended by the current manufacturer's Instructions.
- ☐ Check and record lot numbers of all reagents and test kits, be sure all reagents came from the same lot.
  NOTE: DO NOT mix reagents from different products or lot numbers
- ☐ Visually inspect reagents or vials for damage, discoloration, or contamination.
- ☐ Prepare reagents according to the current manufacturer's instructions.
  (If opening a new reagent, write the date opened on the outside of the vial or test kit.)
- ☐ Allow time for refrigerated reagents and samples to come to room temperature prior to testing.
- ☐ Perform quality control testing, as recommended in the current manufacturer's instructions.

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https://courses.cdc.train.org/ReadySetTest_LTT/Pretest_task_checklist_v4_07_07_2017.pdf

Manufacturer's Instructions

CLIA requires that you follow <u>ALL</u> current instructions

Intended Use
Summary
Test Principle
Precautions
Storage and Stability
Reagents and Materials Supplied
Materials Required But Not Provided
Sample Collections and Preparation
Quality Control
Test Procedure
Interpretation of Results
Limitations of Procedure
Expected Values
Performance Characteristics

Modifications

Modification is using a test in ways other than those described by the manufacturer' instructions

Good Testing Practices

Keep a copy of current instructions

Check new lots and shipments for updated instructions

Keep outdated instructions for record keeping

Verify specimen type, reagents, order, and procedures

Communicate changes with ALL members of the pharmacy team

Update protocol with new instructions

Quality Control Testing

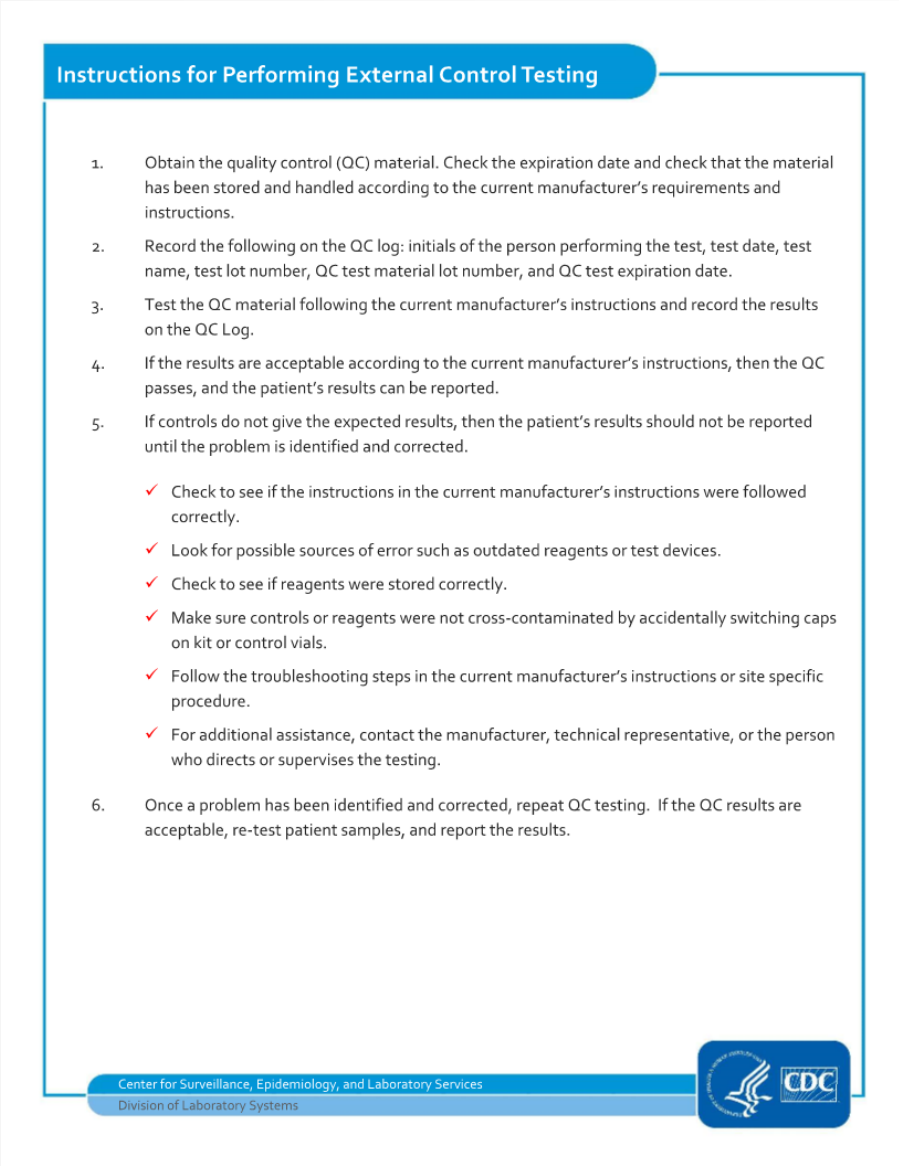
CLIA requires **Quality Control testing** when indicated in the current manufacturer's instructions.

QC testing should be performed by the same personnel who routinely perform patient testing

Quality Control Log

CLIA requires **Quality Control testing** when indicated in the current manufacturer's instructions.

QC testing should be performed by the same personnel who routinely perform patient testing



Instructions for Performing External Control Testing

1. Obtain the quality control (QC) material. Check the expiration date and check that the material has been stored and handled according to the current manufacturer's requirements and instructions.
2. Record the following on the QC log: initials of the person performing the test, test date, test name, test lot number, QC test material lot number, and QC test expiration date.
3. Test the QC material following the current manufacturer's instructions and record the results on the QC Log.
4. If the results are acceptable according to the current manufacturer's instructions, then the QC passes, and the patient's results can be reported.
5. If controls do not give the expected results, then the patient's results should not be reported until the problem is identified and corrected.
   - ✓ Check to see if the instructions in the current manufacturer's instructions were followed correctly.
   - ✓ Look for possible sources of error such as outdated reagents or test devices.
   - ✓ Check to see if reagents were stored correctly.
   - ✓ Make sure controls or reagents were not cross-contaminated by accidentally switching caps on kit or control vials.
   - ✓ Follow the troubleshooting steps in the current manufacturer's instructions or site specific procedure.
   - ✓ For additional assistance, contact the manufacturer, technical representative, or the person who directs or supervises the testing.
6. Once a problem has been identified and corrected, repeat QC testing. If the QC results are acceptable, re-test patient samples, and report the results.

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https://courses.cdc.train.org/ReadySetTest_LTT/Instructions_for_performing_external_CT_v4_07_07_2107.pdf

Additional Resources

Pharmacists' Patient Care Toolkits

Point of Care Management Toolkit

Tools for Pharmacists

https://www.papharmacists.com/page/POCToolkit

Next Session

Thursday, November 15, 8:30-9:30a

Topic: Laboratory Director & Staff

Presenter: Suzanne Higginbotham

Register Now!

https://bit.ly/2MLUr5F