Point-of-Care/CLIA Webinar Prep Series

Getting Your Pharmacy Started!

CLIA Waived Equipment
Presenters

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University of Pittsburgh School of Pharmacy
Objective

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

Additional Training

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.

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

<table>
<thead>
<tr>
<th>SCREENING</th>
<th>CLIA WAIVED ANALYTE</th>
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<tbody>
<tr>
<td>Diabetes</td>
<td>Glucose</td>
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<tr>
<td></td>
<td>Glycosylated hemoglobin (HGB A1C)</td>
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<tr>
<td>ASCVD 10-year risk</td>
<td>Cholesterol</td>
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<td></td>
<td>HDL, LDL</td>
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<td></td>
<td>Triglyceride</td>
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<tr>
<td>Infectious disease</td>
<td>Hepatitis C virus antibody</td>
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<td>HIV antibodies</td>
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<td></td>
<td>Influenza A/B</td>
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<td></td>
<td>Lyme Fluorescent Immunoassay</td>
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<td></td>
<td>Streptococcus, Group A</td>
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</table>
Electronic Preventative Services Selector (ePSS)

Search for Recommendations

Enter the following information to retrieve recommendations from the USPSTF Preventive Services Database. To view all specific recommendations of the USPSTF leave all search criteria blank and simply click "Show Recommendations". All fields are optional. When using this tool please read the specific recommendation to determine if the preventive service is appropriate for your patient. This tool is not meant to replace clinical judgment and individualized patient care.

- **Age:** [ ] Years
- **Sex:** [ ] Female [ ] Male
- **Pregnant:** [ ]
- **Tobacco User - ever:** [ ] Yes [ ] No
- **Sexually Active:** [ ] Yes [ ] No

[Reset] [Show Recommendations]

https://epss.ahrq.gov/ePSS/index.jsp
Monitor a patient’s treatment

<table>
<thead>
<tr>
<th>PHARMACOTHERAPY</th>
<th>CLIA WAIVED ANALYTE</th>
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</thead>
<tbody>
<tr>
<td>Antidiabetic medications</td>
<td>Glucose</td>
</tr>
<tr>
<td></td>
<td>Glycosylated hemoglobin (HGB A1C)</td>
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<tr>
<td>Cholesterol medications</td>
<td>Cholesterol</td>
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<td></td>
<td>HDL, LDL</td>
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<tr>
<td></td>
<td>Triglyceride</td>
</tr>
<tr>
<td>Lithium</td>
<td>Lithium serum concentration</td>
</tr>
<tr>
<td>Warfarin</td>
<td>Prothrombin time (PT)</td>
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</tbody>
</table>
Clinical Considerations

INSIGHTS
- Meaningful to patients
- Valuable to patient care

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 categorized 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**
- Prepare materials for testing

**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.

https://courses.cdc.train.org/ReadySetTest_LTT/Pretest_task_checklist_v4_07_07_2017.pdf
Manufacturer’s Instructions

CLIA requires that you follow** ALL** current instructions

<table>
<thead>
<tr>
<th>Intended Use</th>
<th>Sample Collections and Preparation</th>
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<tbody>
<tr>
<td>Summary</td>
<td>Quality Control</td>
</tr>
<tr>
<td>Test Principle</td>
<td>Test Procedure</td>
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<tr>
<td>Precautions</td>
<td>Interpretation of Results</td>
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<tr>
<td>Storage and Stability</td>
<td>Limitations of Procedure</td>
</tr>
<tr>
<td>Reagents and Materials Supplied</td>
<td>Expected Values</td>
</tr>
<tr>
<td>Materials Required But Not Provided</td>
<td>Performance Characteristics</td>
</tr>
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</table>
Modifications

Modification is using a test in ways other than those described by the manufacturer’s 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

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

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