

## Component III: Clinical

### Module E: Laboratory Procedures

#### Topic 1: Introduction to the Physician's Office Laboratory Equipment and Safety

##### Statement of Purpose

To prepare the learner with basic knowledge and skills necessary to describe the purpose of the Physician office laboratory, to employ the necessary procedures and to identify the equipment used to perform testing.

##### Student Learning Outcomes

Upon completion of this topic, the learner will be able to:

1. Spell and define key terms.
2. List the reasons for clinical laboratory testing and purpose of Physician Office Laboratory (POL).
3. List the Medical Assistant's duties in a Physician's Office Laboratory.
4. Identify the regulatory controls under Clinical Laboratory Improvement Amendment (CLIA), which govern procedures completed in the Physician's office.
5. Describe quality control and quality assurance programs and identify documentation.
6. List common reference materials used for the performance standards of a test.
7. Identify and give the purpose of equipment found in a Physician's Office Laboratory.
8. List safety rules employed within the Physician's office laboratory to prevent accidents and properly dispose of hazardous waste.

##### Terminology

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|---|--|
| 1. Aliquots   | 12. Microhematocrit                                      |
| 2. Biohazardous waste   | 13. Objective  |
| 3. Centrifuge   | 14. Ocular   |
| 4. Certificate of waiver  | 15. Occupational Health and Safety Administration (OSHA) |
| 5. Clinical Laboratory Improvement Amendment (CLIA)             | 16. Personal Protective Equipment (PPE)                  |
| 6. Glucometer   | 17. Physician's Office Laboratory (POL)                  |
| 7. Hazardous Waste Operations and Emergency Response Final Rule | 18. Point-of-Care Tests (POCT)                           |
| 8. Healthcare Financing Administration (HFCA)                   | 19. Proficiency testing                                  |
| 9. Hemoglobinometer   | 20. Qualitative  |
| 10. Material Safety Data Sheet (MSDS)                           | 21. Quantitative   |
| 11. Medical biohazardous waste                                  | 22. Quality assurance (QA)                               |
|   | 23. Quality control (QC)                                 |
|   | 24. Standard precautions                                 |

##### References

1. Kronenberger, J., Southard D. L., & Woodson, D. (2012). *Comprehensive Medical Assisting* (4<sup>th</sup> Ed.). Philadelphia, PA: Lippincott, Williams & Wilkins.
2. Booth, K.A., Whicker, L.G., Wyman, T.D., & Moaney-Wright, S. (2011). *Medical Assisting: Administrative & Clinical Competencies with Anatomy and Physiology*. (4<sup>th</sup> Ed.). New York, NY: McGraw-Hill Company, Inc.

Content Outline/Theory Objectives	Suggested Learning Activities
<p><b>Objective 1</b>  <b>Spell and define key terms.</b></p> <ul style="list-style-type: none"> <li>A. Review the terms listed in the terminology section.</li> <li>B. Spell the listed terms accurately.</li> <li>C. Pronounce the terms correctly.</li> <li>D. Use the terms in their proper context.</li> </ul>	<ul style="list-style-type: none"> <li>A. Games: word searches, crossword puzzles, Family Feud, Jeopardy, bingo, spelling bee, hangman and concentration.</li> <li>B. Administer vocabulary pre-test and post-test.</li> <li>C. Discuss learning gaps and plan for applying vocabulary.</li> </ul>
<p><b>Objective 2</b>  <b>List the reasons for clinical laboratory testing and purpose of Physician Office Laboratory (POL).</b></p> <ul style="list-style-type: none"> <li>A. Reasons to perform clinical tests               <ul style="list-style-type: none"> <li>1. Diagnose or rule out disease.</li> <li>2. Monitor a patient's medication and treatment.</li> <li>3. Identify the cause of an infection.</li> <li>4. Preventing disease.</li> </ul> </li> <li>B. Purpose of Physician Office Laboratory(POL)               <ul style="list-style-type: none"> <li>1. Diagnostic testing on site                   <ul style="list-style-type: none"> <li>a. Screening test for diabetes.</li> <li>b. Establish dietary or insulin related treatment plans.</li> <li>c. Monitor effectiveness of treatment plan using Point-of-Care Test (POCT) for glucose.</li> </ul> </li> <li>2. Convenience for patient.</li> <li>3. Cost-effective (managed care).</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>A. Lecture/Discussion</li> <li>B. Assigned Readings</li> </ul>
<p><b>Objective 3</b>  <b>List the Medical Assistant's duties in a Physician's office laboratory.</b></p> <ul style="list-style-type: none"> <li>A. Medical Assistant duties in POL               <ul style="list-style-type: none"> <li>1. Specimen collection.</li> <li>2. Specimen handling.</li> <li>3. Specimen processing.</li> <li>4. Performing CLIA waived tests.</li> <li>5. Instrument maintenance.</li> <li>6. Quality control (QC)                   <ul style="list-style-type: none"> <li>a. Control Logs.</li> <li>b. Record keeping.</li> <li>c. Proficiency testing.</li> </ul> </li> <li>7. Quality assurance (QA).</li> <li>8. Reporting results (per office protocol).</li> <li>9. Documentation.</li> <li>10. Laboratory safety                   <ul style="list-style-type: none"> <li>a. Chemicals.</li> <li>b. Physical.</li> <li>c. Personnel.</li> </ul> </li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>A. Lecture/Discussion</li> <li>B. Assigned Readings</li> </ul>

<ul style="list-style-type: none"> <li>d. Patient.</li> <li>11. Hazardous waste disposal.</li> <li>12. Patient education and instruction.</li> </ul>	
<p><b>Objective 4</b>  <b>Identify the regulatory controls under Clinical Laboratory Improvement Amendment (CLIA), which govern procedures completed in the Physician's office.</b></p> <ul style="list-style-type: none"> <li>A. Laboratory regulations for Physician office lab <ul style="list-style-type: none"> <li>1. CLIA <ul style="list-style-type: none"> <li>a. Categories of testing <ul style="list-style-type: none"> <li>1) Waived tests.</li> <li>2) Moderate complexity tests.</li> <li>3) High complexity tests.</li> </ul> </li> <li>b. Testing personnel.</li> <li>c. Documentation.</li> <li>d. Proficiency testing.</li> <li>e. Fees.</li> </ul> </li> </ul> </li> <li>B. State <ul style="list-style-type: none"> <li>1. Laws and regulations.</li> <li>2. Inspections.</li> <li>3. Fees.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>A. Lecture/Discussion</li> <li>B. Assigned Readings</li> </ul>
<p><b>Objective 5</b>  <b>Describe quality control and quality assurance programs and identify documentation.</b></p> <ul style="list-style-type: none"> <li>A. Quality control (QC) <ul style="list-style-type: none"> <li>1. To detect problems that can happen due to <ul style="list-style-type: none"> <li>a. Operator error.</li> <li>b. Reagent or test kit deterioration (expiration dates).</li> <li>c. Instrument malfunction (calibration and general maintenance).</li> <li>d. Improper environmental conditions.</li> </ul> </li> <li>2. Quality of work.</li> <li>3. Accuracy of testing <ul style="list-style-type: none"> <li>a. Qualitative, positive or negative.</li> <li>b. Quantitative, numeric value.</li> </ul> </li> <li>4. Documentation/logs.</li> </ul> </li> <li>B. Quality assurance programs <ul style="list-style-type: none"> <li>1. Ensures thorough patient care.</li> <li>2. Prevent problems before they occur.</li> <li>3. Corrective action must begin and be documented.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>A. Lecture/Discussion</li> <li>B. Assigned Readings</li> </ul>

<p><b>Objective 6</b>  <b>List common reference materials used for the performance standards of a test.</b></p> <ul style="list-style-type: none"> <li>A. Performance standards <ul style="list-style-type: none"> <li>1. Accuracy.</li> <li>2. Precision.</li> <li>3. Calibration.</li> <li>4. Control samples.</li> <li>5. Relevance .</li> </ul> </li> <li>B. Reference materials <ul style="list-style-type: none"> <li>1. Package inserts.</li> <li>2. Manufacturer's user guide.</li> <li>3. Clinical laboratory technical procedure manuals.</li> <li>4. OSHA standards.</li> <li>5. CLIA '88 requirements.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>A. Lecture/Discussion</li> <li>B. Assigned Readings</li> </ul>
<p><b>Objective 7</b>  <b>Identify and give the purpose of equipment found in a Physician's office laboratory.</b></p> <ul style="list-style-type: none"> <li>A. Basic equipment <ul style="list-style-type: none"> <li>1. Microscope.</li> <li>2. Centrifuge.</li> <li>3. Electronic <ul style="list-style-type: none"> <li>a. Photometers.</li> <li>b. Mechanical pipettes.</li> <li>c. Computerized cell counters.</li> </ul> </li> <li>4. Equipment used for measurement <ul style="list-style-type: none"> <li>a. Glucometers.</li> <li>b. Hemoglobinometers.</li> <li>c. Microhematocrit readers.</li> </ul> </li> <li>5. Autoclave.</li> <li>6. Incubator.</li> <li>7. Refrigerator/freezer.</li> </ul> </li> <li>B. Basic components of a standard light microscope <ul style="list-style-type: none"> <li>1. Oculars (eye pieces).</li> <li>2. Objectives.</li> <li>3. Arm and focus controls.</li> <li>4. Stage and substage.</li> <li>5. Light source.</li> <li>6. Diaphragm.</li> <li>7. Iris.</li> <li>8. Condenser.</li> <li>9. Slides and cover slips.</li> </ul> </li> <li>C. Using a microscope <ul style="list-style-type: none"> <li>1. Plug the microscope cord into an electrical outlet .</li> <li>2. Place the slide onto the shelf and lift the slide arms over the slide to hold it in place.</li> <li>3. Turn on the microscope light.</li> <li>4. Place eyes over the eyepieces of the microscope. Image will be bright but blurry.</li> <li>5. Using low power objective, turn the coarse</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>A. Lecture/Discussion</li> <li>B. Assigned Readings</li> <li>C. Show pictures or actual equipment if available.</li> </ul>

<p>tuning knob (the larger knob on the side of the microscope.)</p> <ol style="list-style-type: none"> <li>Look through the eyepiece of the microscope as the knob is turned. The object will begin to become clearer as you turn the knob.</li> <li>Once the object is clear and in focus, stop turning the knob.</li> <li>Using high power objective, turn the fine tuning knob, which is the smaller knob on the side of the microscope. Look through the eyepiece of the microscope as the knob is turned. The object on the microscope slide will begin to become very clear and you will be able to see the minute detailing on it. Once the object is clear, stop turning the knob.</li> </ol>	
<ol style="list-style-type: none"> <li>Personal Protective Equipment (PPE).</li> <li>OSHA Bloodborne Pathogen Standard.</li> <li>Hazard Communications Standard               <ol style="list-style-type: none"> <li>Material Safety Data Sheets (MSDS).</li> <li>Biohazard symbol.</li> <li>Hazard labels.</li> <li>Record keeping.</li> </ol> </li> <li>Accident Prevention Guidelines               <ol style="list-style-type: none"> <li>Physical safety.</li> <li>Fire and electrical safety.</li> <li>Biologic safety.</li> <li>Sharps safety.</li> <li>Accident reporting.</li> <li>Housekeeping.</li> </ol> </li> <li>Hazardous Waste Operations and Emergency Response Final Rule               <ol style="list-style-type: none"> <li>The rule regulates the safety and health of employees involved in clean-up operations at                   <ol style="list-style-type: none"> <li>Uncontrolled hazardous waste sites cleaned up under government mandate.</li> <li>Voluntary clean-up operations at sites recognized by Federal, State, local or other governmental bodies as uncontrolled hazardous waste sites.</li> <li>In certain hazardous waste treatment, storage, and disposal (TSD) operations conducted under the Resource Conservation and Recovery Act of 1976 as amended (RCRA) [42 U.S.C. 6901 et seq.]</li> <li>In any emergency response to incidents involving hazardous substances as defined by OSHA in 29 CFR 1910.120.</li> </ol> </li> </ol> </li> <li>Hazardous Waste Disposal (OSHA regulations)               <ol style="list-style-type: none"> <li>Definition                   <ol style="list-style-type: none"> <li>Hazardous waste is waste that is</li> </ol> </li> </ol> </li> </ol>	<ol style="list-style-type: none"> <li>Lecture/Discussion</li> <li>Assigned Readings</li> </ol>

<p>dangerous or potentially harmful to our health or the environment.</p> <ol style="list-style-type: none"><li>2. Proper disposal<ol style="list-style-type: none"><li>a. Chemicals.</li><li>b. Biohazardous.</li><li>c. Medical Sharps.</li></ol></li><li>3. Proper storage prior to pick up.</li><li>4. Disposal companies.</li><li>5. Record keeping.</li></ol>	
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