

Microbiology

Competency Assessment Orientation

Overview

- CLIA/CAP requirements
 - Competency is the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly. Competency assessment is used to ensure that the laboratory personnel are fulfilling their duties as required by federal regulation.
- Lab General Procedure – Annual Competency Assessment

Elements of Competency Assessment

for Moderate & High Complexity Testing*

1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
2. Monitoring the recording and reporting of test results;
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
4. Direct observations of performance of instrument maintenance and function checks;
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Assessment of problem solving skills.

*Only 2 competency elements are required for waived tests.

Definition of a Test System

- CLIA defines a test system as "the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results."

Microbiology Test System Categories

- Bacteriology
- DFA Stain
- Parasitology
- Misc. Tests
- Immunology/Rapid Antigen
- Molecular
- Mycology
- Mycobacteriology

Example: Bacteriology Test Systems

- Gram stain
- Aerobic culture
- Anaerobic culture
- Bordetella culture
- Legionella culture
- Myco/Ureaplasma culture
- Streptococcal grouping
- Serologic typing
- ID – automated
- ID – manual
- ID – abbreviated
- AST – automated
- AST – manual

Frequency of Assessment

- Semiannually during first year of employment
- Annually thereafter
- Competency assessment will be done throughout the entire year
 - *Note: If test methodology or instrumentation changes, an individual's competency must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.*

Notebooks

- Quarterly due dates
- Check to be sure that you have been assigned all of the correct test systems. You may only be responsible for the specimen processing portion of some test systems.
- Access forms on the intranet (Microbiology/Competency)
- Add all documentation to your notebook
- Notebooks will be reviewed at the end of each quarter by one of the assessors (Jason, Michael, or Jennifer)
- Ask the assessors or any Micro Council member if you have questions.

Complete a Competency Form for Each Test System

Bacteriology Competency Assessment

Microbiology Test System Competency Form

Employee Name:

Date:

Semi-Annual Annual

Test System: Select from drop-down menu

Instructions: Provide documentation for each of the following competency elements. Documentation may be provided by printing test results, worksheets or records. For elements requiring direct observation, a Direct Observation Form must be completed by a designated observer.

Employee Documentation

Assessor Approval

1. Direct observations of routine patient test performance, including, as applicable, specimen collection, handling, processing and testing.

Documentation: Completed Direct Observation Form

Satisfactory Unsatisfactory

2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results.

Documentation: Printed example of test results

Satisfactory Unsatisfactory

3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

Documentation: Printed example of results

Satisfactory Unsatisfactory

4. Direct observation of performance of instrument maintenance and function checks.

Documentation: Completed Direct Observation Form if applicable

Satisfactory Unsatisfactory

5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency samples.

Documentation: Printed or written results

Satisfactory Unsatisfactory

6. Evaluation of problem-solving skills.

Documentation: Quiz results or an example

Satisfactory Unsatisfactory

The employee is deemed to be competent on this test system. _____ (Assessor Signature)

The information documented is complete and accurate. _____ (Employee Signature)

Use a Direct Observation Form when Required (competency elements 1 & 4)

Bacteriology Competency Assessment

Microbiology Direct Observation Form	
Employee Name:	Date: <input type="checkbox"/> Semi-Annual <input type="checkbox"/> Annual
Test System: Select from drop-down menu ▼	

Observation of Instrument Maintenance

Observation of Testing

Observer requirements: Direct observers must have worked in the department for a minimum of 1 year, and must be trained to perform the testing or instrument maintenance that they are observing.

Instructions: Directly observe the employee perform the indicated procedure and verify that testing or maintenance is performed as listed in the Standard Operating Procedure (SOP) or maintenance manual. Observe that the employee is following proper safety precautions, recognizing specimen requirements, recognizing proper storage of materials and reagents used for testing, adhering to procedural steps, and performing quality control testing when appropriate. After observing the employee, check the appropriate statement below:

- The procedure was performed correctly according to the steps in the SOP manual or maintenance manual.**
- The procedure was NOT performed correctly (please provide specific details below).**

Comments:

Observed by: _____

Title: _____

Observer Signature: _____

Date: _____

Employee Signature: _____

Date: _____