

UNIQUE STANDARDS FOR SPECIFIC APPROVED PROGRAMS

Clinical Assistant Standards

PREAMBLE

OBJECTIVE

The medical and health professions cooperate to establish, maintain and promote standards of quality for educational programs in the health professions and to provide recognition for such programs that meet or exceed the minimum Standards.

These Standards are used for the development and evaluation of clinical assistant programs. A list of approved programs is published for students, employers and the public.

DESCRIPTION OF THE CLINICAL ASSISTANT OCCUPATION

Clinical Assistant is the term NAACLS uses to designate a formally prepared multi-skilled healthcare provider. The Clinical Assistant Competencies define the required skills with a laboratory focus. The Clinical Assistant Standards are used to evaluate educational programs for the Clinical Assistant. For information regarding the level of laboratory testing appropriate for the Clinical Assistant, contact the Center for Disease Control or the United States Health Care Financing Administration.

In accordance with its mission, NAACLS provides leadership in fostering innovative educational approaches and actively supporting cooperative efforts with other agencies. NAACLS encourages employers to formalize training programs for the Clinical Assistant using this approval process. NAACLS also supports the addition of this approved Clinical Assistant program to the competencies of other accredited health service programs.

Clinical Assistants are able to:

- a) define the role of the clinical assistant in the healthcare delivery system.
- b) use common medical terminology.
- c) demonstrate knowledge of infection control and safety practices.
- d) follow standard operating procedures to collect specimens.
- e) prepare blood and body fluid specimens for analysis according to standard operating procedures.
- f) prepare/reconstitute reagents, standards and controls according to standard operating procedure.
- g) perform appropriate tests at the clinical assistant level, according to standard operating procedures.
- h) perform and record vital sign measurements.
- i) follow established quality control protocols.
- j) communicate (verbally and non-verbally) effectively and appropriately in the workplace.
- k) use information systems necessary to accomplish job functions.

- l) identify and report potential pre-analytical errors that may occur during specimen collection, labeling, transporting and processing.
-

20. Program Director

- A. The program must designate a qualified program director.
- B. Responsibilities
The program director must be responsible for the organization, administration, periodic review, planning, development, evaluation and general effectiveness of the program. The program director must have input into budget preparation and must be responsible for maintaining NAACLS approval of the program.
- C. Qualifications
The program director must be a clinical laboratory scientist/medical technologist who holds nationally recognized certification with a baccalaureate degree and three years of experience in clinical laboratory science education that includes teaching courses, conducting and managing learning experiences, evaluating student achievement, providing input into curriculum development, policy and procedure formulation, and evaluation of program effectiveness. The program director shall have knowledge of educational methods and current accreditation and certification procedures.

21. Faculty

The program must have qualified didactic and clinical faculty. (Didactic faculty are defined as instructors teaching the didactic components of the clinical assistant curriculum. Clinical faculty are defined as instructors teaching the applied components of the applied clinical assistant experiences.

- A. Didactic Faculty
 - 1. Responsibilities
The faculty must participate in teaching courses, supervising clinical laboratory learning experiences, evaluating student achievement, developing curriculum, formulating policy and procedure, and evaluating program effectiveness.
 - 2. Qualifications

Didactic faculty must hold an associate degree or higher, or 60 college credit hours from an accredited institution, or an equivalent combination of education and experience with a minimum of 30 college credit hours and three years of relevant teaching experience. They must also have current certification in clinical assistant or clinical laboratory science and document continuing education hours (2.0 CEUs or 20 hours) in clinical laboratory

science and/or education (including computer applications) within the previous two years.

3. Professional Development

The program must assure and document ongoing professional development of the program faculty to assure that the didactic faculty are able to fulfill their instructional responsibilities.

B. Clinical Faculty

1. Responsibilities

The clinical faculty must participate in instructing students during clinical experiences and evaluating student achievement.

2. Qualifications

Clinical instructors must hold current certification in clinical laboratory science or have one year of full time clinical assistant experience.

C. Consortium Education Coordinator (when required, one at each participating entity in a consortium or joint venture)

1. Responsibilities

The Consortium Education Coordinator, when required, is responsible for coordinating classroom teaching and applied education, evaluating program effectiveness, and must have appropriate communications with the Program Director.

2. Qualifications

The education coordinator, when required, must hold an appropriate nationally recognized certification required of a program director as stated in Standard 20, an academic degree appropriate to the program level, and at least one year of experience in clinical laboratory science education, including teaching courses, conducting and managing learning experiences, evaluation student achievement, and evaluating instructional effectiveness.

22. Curricular Requirements

A. Curricular Structure

Instruction shall follow a plan that documents a structured curriculum including clearly written program goals and course syllabi that include individual course schedules and objectives.

Behavioral objectives for the didactic and clinical aspects of the program which address the cognitive, psychomotor and affective domains must be provided for didactic and applied aspects of the program. Course objectives must show progression to the level consistent with the entry

into the profession and be cross-referenced to the NAACLS Clinical Assistant Competencies.

B. Instructional Areas

The curriculum must include instruction/experiences in the following:

1. 100 hours of applied experiences;
2. Core module competencies must be completed.
3. Instruction in a variety of skills including: blood collection, preparation/reconstitution of reagents, standards and controls, perform tests at the Clinical Assistant level and follow established quality control protocols
4. Curriculum in any module(s) beyond the core module must meet the minimum required standards as stated for the core module. These modules include but are not limited to: chemistry, donor room, hematology, immunology, microbiology and/or urinalysis.

C. Learning Experiences

Learning experiences needed in the curriculum to develop and support entry level competencies must be properly sequenced and include instructional materials, classroom presentations, discussions, demonstrations, laboratory sessions, supervised practice and experience. NAACLS Clinical Assistant Competencies must be used to design didactic and applied experiences.

1. Student experiences must be educational and balanced so that all competencies can be achieved. Program length must be appropriate for the competencies achieved.
2. Student experiences at different clinical sites must be comparable to enable students to achieve entry level competencies.
3. Policies and processes by which students may perform service work must be published and made known to all concerned to avoid practices in which students are substituted for regular staff. Students must meet the NAACLS Clinical Assistant Competencies by demonstrating proficiency before they are allowed to work independently. Service work by students in clinical settings outside of regular academic hours must be noncompulsory.

D. Evaluations

Written criteria for passing, failing and progression in the program must be provided. These must be given to each student at the time of entry into the program. Evaluation systems must be correlated to the objectives and competencies described in the curriculum for both didactic and applied components, and in all three domains. Evaluations must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress and to serve as a reliable indicator of the effectiveness of instruction and course design.

NAACLS Entry Level Clinical Assistant Competencies

Core Module

These competencies describe duties at a level below that of the established Clinical Laboratory Technician/ Medical Laboratory Technician. As a member of the health care delivery team, the clinical assistant works under the supervision of an appropriate qualified person.

- 1.0 Define the role of the clinical assistant in the healthcare delivery system as it relates to the point-of-care or clinical laboratory environment.
- 2.0 Use common medical terminology.
- 3.0 Demonstrate knowledge of infection control and safety practices.
 - 3.1 Demonstrate accepted practices for infection control, isolation techniques, aseptic techniques and methods for disease prevention.
 - 3.2 Comply with federal, state and locally mandated regulations regarding safety practices.
 - 3.2.1 Observe the OSHA Bloodborne Pathogens Standard and Needle Safety Precaution Act.
 - 3.2.2 Use prescribed procedures to handle electrical, radiation, biological and fire hazards.
 - 3.2.3 Use appropriate practices, as outlined in the OSHA Hazard Communication Standard, including the correct use of the Material Safety Data Sheet as directed.
- 4.0 Follow standard operating procedures to collect specimens.
 - 4.1 Demonstrate basic knowledge of the circulatory, urinary, and other body systems necessary to perform assigned specimen collection tasks.
 - 4.2 Describe the difference between whole blood, serum and plasma.
 - 4.3 Identify and use blood collection equipment.
 - 4.31 Identify the additive by the evacuated tube color.
 - 4.32 Identify and properly use equipment needed to collect blood by venipuncture and capillary (dermal) puncture.

- 4.4 Collect blood specimens by venipuncture
- 4.5 Collect blood specimens by capillary (dermal) puncture
- 4.6 Identify special precautions necessary during blood collections by venipuncture and capillary (dermal) puncture.
- 4.7 List and apply the criteria that would lead to rejection or recollection of a patient sample.
- 4.8 Instruct patients in the proper collection and preservation for non-blood samples.
- 5.0 Prepare blood and body fluid specimens for analysis according to standard operating procedures.
- 5.1 Follow standard operating procedures for labeling, transport and processing of specimens, including transport to reference laboratories.
- 5.2 Describe and follow the criteria for specimens and test results that will be used as legal evidence.
- 6.0 Prepare/reconstitute reagents, standards and controls according to standard operating procedure.
- 6.1 Follow laboratory protocol for storage and suitability of reagents standards and controls.
- 6.2 Recognize and report contamination and/or deterioration in reagents, standards and controls.
- 6.3 Maintain inventory control.
- 7.0 Perform appropriate tests at the clinical assistant level, according to standard operating procedures.
- 7.1 Identify and report potential pre-analytical errors that may occur during specimen collection, labeling, transporting and processing.
- 7.2 Compare test results to reference intervals.
- 7.3 Record results by manual method or computer according to laboratory protocol.
- 7.4 Report STAT results of completed tests according to laboratory protocol.

- 7.5 Recognize critical values and follow established protocol regarding reporting.
- 7.6 Use and handle measurement equipment appropriately.
- 8.0 Perform and record vital sign measurements.
 - 8.1 Perform and record blood pressure measurement.
 - 8.2 Perform and record pulse rate.
 - 8.3 Perform and record body temperature.
- 8.4 Recognize and report abnormal values for vital sign measurement using predetermined criteria.
- 9.0 Follow established quality control protocols to include maintenance and calibration of equipment.
 - 9.1 Perform quality control procedures.
 - 9.2 Record quality control results.
- 9.3 Identify and report control results that do not meet pre-determined criteria.
- 10.00 Communicate (verbally and nonverbally) effectively and appropriately in the workplace.
- 10.1 Maintain confidentiality of privileged information on individuals, according to federal regulations (e.g. HIPAA).
- 10.2 Demonstrate respect for diversity in the workplace.
- 10.3 Interact appropriately and professionally.
- 10.4 Demonstrate an understanding of the major points of the American Hospital Associations' Patient's Bill of Rights and the Patient's Bill of Rights from the workplace.
- 10.5 Comply with the American Hospital Associations' Patient's Bill of Rights and the Patient's Bill of Rights from the workplace.
- 10.6 Model professional appearance and appropriate behavior.
- 10.7 Follow written and verbal instructions.

- 10.8 Define and use medicolegal terms and discuss policies and protocol designed to avoid medicolegal problems.
- 10.9 List the causes of stress in the work environment and discuss the coping skills used to deal with stress in the work environment.
- 10.10 Demonstrate ability to use computer information systems necessary to accomplish job functions.

NAACLS Entry Level Clinical Assistant Competencies
Chemistry Module

- 1.0 Use common clinical chemistry terminology as it relates to the point-of-care or clinical laboratory environment.
- 2.0 Prepare, store and dispose of specimens for chemistry analysis according to standard operating procedures.
- 3.0 Determine suitability of specimens for chemistry procedures according to:
 - the test requested.
 - appropriate patient preparation/method of collection.
 - time of collection/processing.
 - storage.
 - Specimen rejection criteria.
- 4.0 Assemble/prepare reagents, standards and controls for chemistry tests.
- 5.0 Perform appropriate tests at the clinical assistant level.
- 6.0 Recognize technical testing errors for each test performed.
- 7.0 Report results of procedures using pre-determined criteria.
- 8.0 Follow established quality control procedures specific to chemistry tests, including maintenance and instrument calibration.

NAACLS Entry Level Clinical Assistant Competencies
**Donor Room Collection /Screening and
Component Processing Module**

Performance may be done in a clinical setting or in a simulated lab.

- 1.0 Use common donor room, collection processing and component preparation terminology as it relates to the point-of-care or clinical laboratory environment.
- 2.0 According to standard operating procedures, demonstrate the ability to perform donor screening.
 - 2.1 Complete donor medical/social history.
 - 2.2 Complete measurement of donor temperature.
 - 2.3 Complete donor hemoglobin measurement.
 - 2.4 Complete blood pressure measurement.
 - 2.5 Perform donor pulse rate.
- 3.0 Demonstrate the ability to perform unit collection procedures as defined by established regulations.
 - 3.1 Follow the procedure for donor identification.
 - 3.2 Follow the proper skin preparation procedure and describe its importance.
 - 3.3 Demonstrate the ability to perform donor collection, donor assessment during and after collection and troubleshooting actions for inadequate blood flow and donor reaction.
 - 3.4 Strip unit tubing, mix and package for transport.
- 4.0 Describe the procedures for the component preparation system.
 - 4.1 Describe the procedure to prepare components according to established regulations.
 - 4.2 Follow the procedure for packing and shipping of collected blood bags and testing tubes.
 - 4.3 Receive and distribute collected blood components.

- 4.4 Prepare packed red blood cells, plasma, platelets and cryoprecipitates.
- 4.5 Follow storage requirements for blood and blood components.
- 5.0 Follow established quality control procedures specific to donor room collection/component screening, including maintenance and instrument calibration.
 - 5.1 Comply with current Good Manufacturing Practices (GMP).
 - 5.2 Determine suitability of specimens according to pre-determined criteria.
- 6.0 Follow pre-determined criteria for unit suitability and lot release.

NAACLS Entry Level Clinical Assistant Competencies
Hematology Module

- 1.0 Use common hematology terminology as it relates to the point-of-care or clinical laboratory environment.
- 2.0 Prepare, store and dispose of specimens for hematology analysis according to standard operating procedures.
- 3.0 Determine suitability of specimens for hematology procedures related to:
 - the test requested
 - appropriate patient preparation/method of collection
 - time of collection/processing
 - storage
 - Specimen rejection criteria
- 4.0 Assemble/prepare reagents, standards and controls for hematology tests.
- 5.0 Prepare and stain slides for further analysis.
- 6.0 Perform hematology procedures at the clinical assistant level.
- 7.0 Report results of tests using pre-determined criteria.
- 8.0 Recognize technical testing errors for each test performed.
- 9.0 Follow established quality control procedures specific to hematology tests, including maintenance and instrument calibration.

NAACLS Entry Level Clinical Assistant Competencies
Immunology Module

- 1.0 Use common immunology terminology as it relates to the point-of-care or clinical laboratory environment.
- 2.0 Prepare, store and dispose of specimens for immunology testing according to standard operating procedures.
- 3.0 Determine suitability of specimens for immunology procedures related to:
 - the test requested
 - appropriate patient preparation/method of collection
 - time of collection/processing
 - storage
 - Specimen rejection criteria
- 4.0 Assemble/prepare reagents, standards and controls for immunology tests.
- 5.0 Perform immunology tests at the clinical assistant level.
- 6.0 Recognize technical testing errors for each test performed.
- 7.0 Report results of tests using pre-determined criteria.
- 8.0 Follow established quality control procedures specific to immunology tests, including maintenance and instrument calibration.

NAACLS Entry Level Clinical Assistant Competencies
Microbiology Module

- 1.0 Use common microbiology terminology as it relates to the point-of-care or clinical laboratory environment.
- 2.0 Follow special safety procedures and aseptic technique required for processing microbiology specimens.
- 3.0 Prepare, store, dispose of and properly transport specimens for microbiology testing according to standard operating procedure.
- 4.0 Determine suitability of specimens for microbiology procedures related to:
 - the test requested
 - appropriate patient preparation/method of collection
 - time of collection/processing
 - storage
 - Specimen rejection criteria
- 5.0 Assemble/prepare reagents, standards and controls for microbiology procedures.
- 6.0 Prepare and stain slides for further analysis.
- 7.0 Perform microbiology testing at the clinical assistant level.
- 8.0 Recognize technical errors for each test performed.
- 9.0 Report results of procedures using pre-determined criteria.
- 10.0 Perform pre-determined quality control procedures specific to microbiology testing, including maintenance and instrument calibration.

NAACLS Entry Level Clinical Assistant Competencies
Urinalysis Module

- 1.0 Use common urinalysis terminology as it relates to the point-of-care or clinical laboratory environment.
- 2.0 Prepare, store, dispose of and properly transport specimens for urinalysis testing according to standard operating procedure.
- 3.0 Instruct patients in the proper collection and preservation for various urine samples, including:
 - mid-stream.
 - random.
 - clean catch.
 - timed collections.
 - collections for drug screening.
 - urine pregnancy tests.
- 4.0 Determine suitability of specimens for urinalysis procedures related to:
 - the test requested
 - appropriate patient preparation/method of collection
 - time of collection/processing
 - storage
 - Specimen rejection criteria
- 5.0 Assemble/prepare reagents, standards and controls for urinalysis testing.
- 6.0 Prepare slides for microscopic examination.
- 7.0 Perform urinalysis tests at the clinical assistant level.
- 8.0 Recognize technical errors for each test performed.
- 9.0 Report results of tests using pre-determined criteria.
- 10.0 Perform pre-determined quality control procedures for urinalysis tests, including maintenance and instrument calibration.