

REQUIREMENTS FOR APPROVAL

I. SPONSORSHIP

1. The sponsoring institution must provide post-secondary education. The sponsoring institution and affiliates, if any, must be accredited by a recognized national, regional or state agency.

In programs in which academic and clinical education are provided by two or more institutions, responsibilities of the sponsoring institution and each affiliate for program administration, instruction and supervision must be described in writing and signed by both parties. Each current agreement, with written documentation of continuing affiliation on an annual basis, must address the following items:

A. General

1. Reason for agreement
2. Clinical Assistant program responsibilities
3. Clinical affiliate responsibilities
4. Joint responsibilities

B. Specific

1. Supervisory responsibility for students
2. Professional liability coverage for students
3. Health and safety provision for students
4. Provision for annual renewal and review of the agreement
5. Termination clause providing for program completion of enrolled students

2. Approved programs must be in:

- A. Colleges and universities
- B. Hospitals and medical centers
- C. Laboratories
- D. Other post-secondary institutions or consortia that meet comparable standards

3. Approval is granted to the institution that assumes primary responsibility for curriculum planning, teaching and selection of course content; coordinating classroom teaching; supervising clinical education; appointing faculty to the program; receiving and processing applications for admission, and granting a certificate documenting completion of the program.

- A. The sponsoring institution or consortium shall be responsible for providing assurance that the activities assigned to students in the clinical setting are educational.
- B. There shall be documented ongoing communication between the sponsoring institution and its affiliates for exchange of information and coordination of the program. A meeting shall be held at least annually between representatives of the sponsoring institution or consortium and the affiliates.

II. RESOURCES

4. General Resources

Resources must support the number of students admitted into the program. The instructor/ student ratio shall be adequate to achieve the stated goals of the program.

5. Program Director

A. The program must designate a qualified program director.

B. The program director shall 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 supervising clinical laboratory 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.

C. Responsibilities

The program director shall be responsible for:

1. coordinating education experiences in the program
2. organizing the program
3. evaluating the program's outcomes, and
4. maintaining NAACLS approval of the program

6. Faculty

A. Responsibilities

The faculty shall participate in teaching courses, supervising clinical laboratory learning experiences, evaluating student achievement, developing curriculum, formulating policy and procedure, and evaluating program effectiveness.

B. Qualifications

Faculty designated by the program director must demonstrate the ability to teach effectively at the appropriate level.

7. Professional Development

The program shall assure and document ongoing professional development of the program director and faculty.

8. Financial Resources

Financial resources for continued operation of the program shall be ensured by an adequate, institutionally approved budget or by a statement of continued financial support from an executive officer of the sponsoring institution.

9. Physical Resources

A. Facilities

Classrooms, laboratories, administrative offices and other facilities shall be adequate, equipped for safety, and be in compliance with pertinent federal and state laws.

B. Equipment and Supplies

Modern equipment and supplies in sufficient quantities shall be provided.

C. Library

A library shall be readily accessible and contain current books, periodicals and other reference materials related to the curriculum.

D. Instructional Resources

Instructional resources such as clinical materials, reference materials and demonstration and other multimedia materials must be provided. Computer technology must be provided.

III. CURRICULUM

10. NAACLS Clinical Assistant Competencies must be used to design didactic and clinical experiences.

11. Instruction shall follow a plan that documents:

A. A structured curriculum including clearly written program goals and course syllabi that include individual course schedules and objectives.

B. Behavioral objectives for the didactic and clinical aspects of the program which address the cognitive, psychomotor and affective domains. Course objectives, cross-referenced to the NAACLS Clinical Assistant Competencies, must show progression to the level consistent with the entry into the occupation.

C. Learning experiences and curriculum sequencing to develop the competencies, including instructional materials, classroom presentations, discussions, demonstrations, laboratory sessions, supervised practices and experiences that support course objectives.

D. Program length that is appropriate for the competencies achieved.

E. Student evaluation that documents:

1. Criteria for passing, failing and progression in the program, and
2. Criterion-based evaluations for didactic and clinical areas that identify the objectives to be completed and state the criteria for evaluation. Evaluations must ensure that all objectives have been achieved. The criteria shall be given to each student at the time of entry to the program.

F. Evaluation that is 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.

IV. STUDENTS

12. Program Description

Students shall be provided with a clear description of the program and its content, including program goals, course objectives, required competencies and supervised clinical education assignments.

13. Publications

A. Current publications that include a description of the program and curriculum must be available.

B. These publication(s) may be brochures, catalogs or student handbooks that must contain the following items:

1. Academic and non-academic admission criteria;
2. Application procedures;
3. A list of course descriptions;
4. Tuition and fees with refund policies;
5. All program policies and procedures, including appeal procedures and policy for retention and dismissal;
6. A description of clinical facilities;
7. Length of the program and
8. Essential functions.

14. Appeals

Appeal procedures shall be distributed to students at the start of the program. They shall include provisions for academic and nonacademic types of grievances and a mechanism for neutral evaluation that insures due process. Rules and regulations governing acceptable conduct must be clearly defined and published.

15. Service Work

Policies and processes by which students may perform service work must be compatible with the program. Students must meet the NAACLS Clinical Assistant Competencies by demonstrating proficiency before they are allowed to work independently.

16. Admission of students, including advanced placement, shall be made in accordance with the clearly defined and published practices of the institution. Specific academic standards and essential functions required for admission to the program shall be clearly defined, published and provided to prospective students and made available to the public.

17. Student Capacity

The number of students admitted must be based on the capacity of the clinical facilities to accommodate students.

18. Student Records

The program must have written policies and procedures by which permanent student records are maintained for enrolled students and graduates. The program shall maintain the student records for a reasonable period of time and conform to any federal or state regulations.

19. Health and Safety

There shall be a procedure for determining that the applicants' or students' health will permit them to meet the written essential functions of the program. Students shall be informed of and have access to the usual student health care services of the institution.

The program must insure that the safety of all those involved (student, faculty, staff) in the program's sponsoring and affiliated institutions is adequately protected. Emergency medical care shall be available for students while in attendance.

Programs must meet all established, federally mandated safety standards and provide documentation of appropriate training.

20. Guidance

Guidance shall be available to assist students in understanding and observing program policies and practices, for advising on professional and career issues, and for providing counseling or referral for personal problems that may interfere with progress in the program. Confidentiality and impartiality shall be maintained in dealing with student problems.

V. OPERATIONAL POLICIES

21. Fair Practices

- A. Announcements and advertising must accurately reflect the program offered.
- B. Student recruitment and admission shall be non-discriminatory in accordance with local state and federal regulations.
- C. Faculty recruitment and employment practices shall be non-discriminatory in accordance with local state and federal regulations.
- D. Academic credits and costs to the student shall be accurately stated, published, and made known to all applicants.
- E. Policies and procedures for student withdrawal and refunds of tuition and fees shall be published and made known to all applicants.
- F. If more than one level of clinical laboratory science education program is offered at an institution, the sponsoring institution must demonstrate that each program is being conducted to ensure appropriate instruction for the students at the different educational levels.
- G. The program must culminate in a certificate or other award recognizing completion of the program. The granting of the certificate or award must not be contingent upon the student's passing any type of external certification or licensure examination. Academic standards for the program must be acceptable to the institution that grants the certificate or award.

VI. PROGRAM EVALUATION

22. The program must have a continuing system for periodically and systematically reviewing the effectiveness of the program.
23. The results of program evaluation shall be reflected in the curriculum and other elements of the program.

VII. MAINTAINING APPROVAL

24. Program/Sponsoring Institution Responsibilities

Programs are required to comply with administrative requirements for maintaining approval, including:

- A. Submitting the Self-Study Report, an Application for Initial or Continuing Approval, or a required Progress Report as determined by NAACLS;
- B. Paying approval fees as determined by NAACLS; and,
- C. Completing an Annual Report provided by NAACLS and returning it by the established deadline.

NAACLS 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. Note: The instructional content appropriate to the achievement of these Competencies should be consistent with the entry level job responsibilities.

- 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.**
 - 3.21 Use the OSHA Universal Precaution Standards.**
 - 3.22 Use prescribed procedures to handle electrical, radiation, biological and fire hazards.**
 - 3.23 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 (skin) puncture.**
 - 4.4 Collect blood specimens by venipuncture**
 - 4.5 Collect blood specimens by capillary (skin) puncture**
 - 4.6 Identify special precautions necessary during blood collections by venipuncture and capillary (skin) 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 various samples, including:**
 - blood.**
 - sputum.**
 - stools.**
- 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.**
- 7.0 Perform appropriate tests at the clinical assistant level, according to standard operating procedures.**
 - 7.1 Compare test results to reference intervals.**
 - 7.2 Record results by manual method or computer according to laboratory protocol.**
 - 7.3 Report STAT results of completed tests according to laboratory protocol.**
 - 7.4 Recognize critical values and follow established protocol regarding reporting.**
 - 7.5 Clean glass and plastic labware.**
 - 7.6 Use pipetting equipment.**
 - 7.7 Use measurement equipment such as beakers and flasks.**
- 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.**
- 10.0 Communicate (verbally and non-verbally) effectively and appropriately in the workplace.**
 - 10.1 Maintain confidentiality of privileged information on individuals.**
 - 10.2 Value diversity in the workplace.**
 - 10.3 Interact appropriately and professionally with other individuals.**
 - 10.4 Discuss the major points of the American Hospital Association's Patient's Bill of Rights or the Patient's Bill of Rights from the institution.**
 - 10.5 Model professional appearance and appropriate behavior.**
 - 10.6 Follow written and verbal instructions in carrying out testing procedures.**
- 11.0 Use information systems necessary to accomplish job functions.**
- 12.0 Identify and report potential pre-analytical errors that may occur during specimen collection, labeling, transporting and processing.**

NAACLS Clinical Assistant Competencies
Chemistry 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. Note: The instructional content appropriate to the achievement of these Competencies should be consistent with the entry level job responsibilities. In developing this module, please refer to the competencies in the Core 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.**
 - **hemolysis/lipemia and interfering substances.**
- 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.**
- 9.0 Maintain inventory control and supplies for chemistry tests.**

NAACLS Clinical Assistant Competencies
**Donor Room Collection /Screening and
Component Processing 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. Note: The instructional content appropriate to the achievement of these Competencies should be consistent with the entry level job responsibilities.

- 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, 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 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 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 Follow procedures for the component preparation system.**
 - 4.1 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.**
- 7.0 Maintain inventory control and supplies for donor screening, collection processing and component preparation.**

NAACLS Clinical Assistant Competencies

Hematology 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. Note: The instructional content appropriate to the achievement of these Competencies should be consistent with the entry level job responsibilities. In developing this module, please refer to the competencies in the Core 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
 - interfering substances
- 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 Recognize technical testing errors for each test performed.**
- 8.0 Follow established quality control procedures specific to hematology tests, including maintenance and instrument calibration.**
- 9.0 Maintain inventory control and supplies for hematology tests.**

NAACLS Clinical Assistant Competencies

Immunology 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. Note: The instructional content appropriate to the achievement of these Competencies should be consistent with the entry level job responsibilities. In developing this module, please refer to the competencies in the Core 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**
 - **interfering substances**
- 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.**
- 9.0 Maintain inventory control and supplies for immunology tests.**

NAACLS Clinical Assistant Competencies

Microbiology 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. Note: The instructional content appropriate to the achievement of these Competencies should be consistent with the entry level job responsibilities. In developing this module, please refer to the competencies in the Core 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**
 - interfering substances**
- 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.**
- 11.0 Maintain inventory control and supplies for microbiology procedures.**

NAACLS Clinical Assistant Competencies

Urinalysis 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. Note: The instructional content appropriate to the achievement of these Competencies should be consistent with the entry level job responsibilities. In developing this module, please refer to the competencies in the Core 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**
 - **interfering substances**
- 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.**
- 11.0 Maintain inventory control and supplies for urinalysis testing.**