

# **Unique Standards and Documentation Required for Accredited DMS Programs**

## UNIQUE STANDARDS AND THE REQUIRED DOCUMENTATION

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### Diagnostic Molecular Scientist Standards

#### PREAMBLE

##### Objectives

The purpose of these Standards and the Description of the Profession is to establish, maintain, and promote standards of quality for educational programs in the clinical laboratory sciences and to provide recognition for educational programs which meet or exceed the minimum standards outlined in these Standards.

The Standards are to be used for the development and evaluation of molecular diagnostic and molecular biotechnology programs. Paper reviewers and site visit teams assist in the evaluation of the program's compliance with the Standards. Lists of accredited programs are published for the information of students, employers, and the public.

##### DESCRIPTION OF THE PROFESSION

The diagnostic molecular scientist is a professional who is qualified by academic and applied education to provide service in the molecular diagnosis of acquired, inherited and infectious diseases. The diagnostic molecular scientist must also be responsible for his/her own actions, as defined by the profession.

The ability to relate to people, a capacity for calm and reasoned judgment and a demonstration of commitment to the client are qualities essential for diagnostic molecular scientists. They must demonstrate ethical and moral attitudes and principles which are essential for gaining and maintaining the trust of professional associates, the support of the community, and the confidence of the client and family. An attitude of respect for the client and confidentiality of the client's record and/or diagnoses must be maintained.

Diagnostic molecular scientists are competent in:

- A. Researching, evaluating, implementing and monitoring methods of collection, transport and handling of various specimen types for molecular analysis;
- B. Researching and developing principles, practices and applications of molecular based testing for laboratory utilization and clinical decisions for client outcomes;
- C. Performing appropriate techniques utilizing instrumentation and information management systems for molecular analysis and correlating results with acquired, inherited and infectious diseases;
- D. Researching, developing and implementing preventive and corrective maintenance programs for instruments and equipment, as well as troubleshooting and evaluating appropriate actions for problem resolution;
- E. Designing, conducting and disseminating results of studies on new technologies, procedures or diagnostic correlations in molecular science;
- F. Interpreting and evaluating data for making decisions related to laboratory practice, repeat analysis, correlation with disease states, organism identification and genetic testing;
- G. Applying principles of quality control which evaluate data for necessity of repeat analysis,

- correlation with disease states, organism identification and disease diagnosis;
- H. Applying principles of quality assurance and performing measurements to assure validity and accuracy of laboratory data generated;
  - I. Evaluating and selecting information systems for information exchange, data management and archival storage;
  - J. Interpreting, implementing and complying with laws, regulations and accrediting standards and guidelines of relevant governmental and non-governmental agencies;
  - K. Designing, implementing and evaluating resource management strategies to maintain optimal laboratory efficiency;
  - L. Interpreting and implementing established procedures for general laboratory safety, biohazard and radioactive containment and waste disposal;
  - M. Demonstrating leadership, professional and ethical conduct and interpersonal skills for clients, healthcare professionals and the public, and
  - N. Formulating a strategic plan for professional career development.

Upon graduation and initial employment in the field, the diagnostic molecular scientist will be able to demonstrate entry level competencies in the above areas of professional practice.

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## **20. Program Administration**

### **A. Program Director**

1. The program must have a qualified program director.
2. Responsibilities

The program director shall be responsible for the organization, administration, periodic review, planning, development, evaluation, and general effectiveness of the program. The program director shall have input into budget preparation and must be responsible for maintaining NAACLS accreditation of the program.

3. Qualifications:

The program director must be a clinical laboratory scientist/medical technologist, clinical laboratory specialist in cytogenetics or molecular biology laboratory specialist who holds nationally recognized certification and who has a master's or doctoral degree and three years of experience in clinical laboratory science or diagnostic molecular education that includes teaching courses, conducting and managing clinical laboratory learning experiences, evaluating student achievement, providing input into curriculum development, policy and procedure formulation, and evaluation of program effectiveness. The program director must have a knowledge of education methods and administration, as well as current accreditation and certification procedures.

4. Faculty Appointments

The program director must have a faculty appointment at the sponsoring institution or must have a faculty appointment in each affiliated academic institution. In the case of

a clinically based program, the program director's appointment at affiliated academic institutions may be a regular one, a non-salaried clinical or courtesy appointment, or an adjunct appointment, depending upon the regulations of the academic institution.

#### B. Advisory Committee

1. There must be an advisory committee composed of individual(s) from the community of interest, (i.e., pathologists, other physicians, scientific consultants, academic professionals, administrators. Practicing laboratory clinical laboratory scientist/medical technologists, practicing clinical laboratory technicians/medical laboratory technicians, and other health professionals) who have knowledge of molecular science education.

2. Responsibilities

The advisory committee of the program shall have input into any of the program/curriculum with regard to its current relevancy and effectiveness into the medical content of the program.

## 21. Faculty

The program must have qualified faculty (e.g., clinical laboratory scientist/medical technologists, administrators, managers and physicians).

#### A. Responsibilities

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

#### B. Qualifications

Faculty designated by the program must demonstrate adequate knowledge and proficiency in their content areas and demonstrate the ability to teach effectively at the appropriate level.

#### C. Professional Development

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

#### D. 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. Curriculum Requirements

### A. Curricular structure:

Instruction must follow a plan that documents a structured curriculum including applied education with clearly written program goals. Course syllabi must include individual course objectives and competencies to be achieved and evaluation criteria.

The curriculum must include pre-analytical, analytical, and post-analytical components of diagnostic molecular laboratory services covering diagnostic molecular tests used to detect or diagnose acquired (infectious and non-infectious) diseases and genetic predisposition or disorders. Behavioral objectives which address cognitive, psychomotor, and affective domains must be provided for didactic and applied (clinical practice) aspects of the program and must include clinical significance and correlation. Course objectives must show progression to the level consistent with entry into the profession.

### B. Instructional areas:

The following areas of study must be included in either the professional program or as pre-requisites:

1. organic and/or biochemistry, genetics, cell biology, microbiology, immunology, and diagnostic molecular biology.
2. principles, methodologies, and applications of molecular microbiology (infectious diseases), molecular pathology (hematology/oncology), and molecular genetics. Techniques of molecular science must include at least two techniques in each of separation and detection, amplification, and sequence analysis.
3. clinical significance of laboratory procedures in diagnosis and treatment;
4. principles and practices of quality management;
5. principles and practices of laboratory administration, supervision, safety, and problem solving;
6. principles and practices of professional conduct;
7. principles and practices of applied study design, implementation and dissemination of results.

### C. Learning Experiences

The learning experiences needed in the curriculum to develop entry level competencies must be properly sequenced and include instructional materials, classroom presentations, discussions, demonstrations, laboratory sessions, supervised practice and experience.

1. Student experiences must be educational and balanced so that all competencies can be achieved.
2. Student experiences at different applied 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 in order to avoid practices in which students are substituted for regular staff. After demonstrating proficiency, students, with qualified supervision, may be permitted to perform procedures. Service work by students in applied 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 shall be given to each student at the time of entry into the program. Evaluation systems shall be related to the objectives and competencies described in the curriculum for both didactic and applied components. They 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.

## Documentation Required for DMS Unique Standards

	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
Standard 20A1	<u><i>No Narrative Required</i></u>	<p>Submit a completed Faculty Fact Sheet for the program director.</p> <p><i>The Faculty Fact Sheet is located in the appendix of this Guide.</i></p>	
Standard 20A2	<u><i>No Narrative Required</i></u>	<p>Submit a position description which describes the responsibilities of the program director.</p>	<p>Verify that the program director is responsible for the required aspects of the program.</p>
Standard 20A3	<u><i>No Narrative Required</i></u>	<p>Submit the curriculum vita for the program director</p> <p>Indicate the date that NAACLS approved the program director.</p> <p>Indicate how knowledge of education, administration &amp; current accreditation/certification procedures was obtained.</p>	<p>Verify that the program director meets the qualifications listed in Standard 20 A1-3.</p>

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	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
Standard 20A4	<u>No Narrative Required</u>	Document the faculty appointment for the program director at each affiliated academic institution.	Verify documentation (e.g., notice of appointments, academic catalogs, faculty listings) of faculty appointments for the program director at each affiliated academic institution.
Standard 20B1	<u>No Narrative Required</u>	Submit the name(s) comprising the advisory committee.  Indicate the relationship of the advisory committee member(s) to the program.	
Standard 20B2	Describe the responsibilities of the advisory committee.	Submit a copy of the advisory committee meeting minutes.	Verify the responsibilities of the advisory committee.
Standard 21	<u>No Narrative Required</u>	List the <b>major</b> clinical/didactic faculty for each laboratory discipline.	
Standard 21A	Describe the responsibilities of the program faculty.	<u>No Documentation Required</u>	Verify that faculty are responsible for the required aspects of the program.

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	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
Standard 21B	Describe how faculty are evaluated relative to appropriate qualifications.	Submit completed Faculty Fact Sheets for the major didactic faculty for each laboratory discipline. List details of major clinical faculty on Clinical Faculty Fact Sheets.	<p>Verify that faculty have adequate knowledge and proficiency in their content areas.</p> <p>Verify that major clinical/didactic faculty have the ability to teach effectively at the appropriate level.</p> <p>Review faculty evaluations.</p>
Standard 21C	Describe how the program ensures ongoing professional development of its' clinical and didactic faculty.	Submit sample documentation of ongoing professional development of the clinical and didactic faculty to fulfill instructional abilities.	Verify that the program assures and documents the ongoing professional development of clinical and didactic faculty.

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	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
<b><i>IN CASES OF CONSORTIA OR JOINT VENTURES, SUBMIT INFORMATION FOR STANDARDS 21D1 AND 21D2.</i></b>			
Standard 21D	<u><i>No Narrative Required</i></u>	Submit a completed Faculty Fact Sheet for the consortium education coordinator.	
Standard 21D1	<u><i>No Narrative Required</i></u>	Submit a position description which describes the responsibilities of the consortium education coordinator.	Verify that the consortium education coordinator is responsible for the required aspects of the program
Standard 21D2	<u><i>No Narrative Required</i></u>	Submit a curriculum vita for the consortium education coordinator.  Indicate how knowledge of educational methods and current accreditation/certification procedures was obtained.	Verify that the consortium education coordinator meets the qualifications listed in Standard 20AA2.

## Documentation Required for DMS Unique Standards

	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
<p style="text-align: center;">Standard 22A</p> <p><i>See appendix for Guidelines to Standard 22.</i></p>	<p><u><i>No Narrative Required</i></u></p>	<p>Submit a structured curriculum plan (or sequence of courses).</p> <p>Submit the program goals and competencies.</p> <p>Submit course syllabi with course goals and behavioral objectives for <b>ONE SAMPLE UNIT OF INSTRUCTION</b>. The sample unit should have both lecture and laboratory/clinical components.</p> <p>Submit objectives in the cognitive, psychomotor and affective domains for <b>ONE SAMPLE UNIT OF INSTRUCTION</b>.</p>	<p>Verify that student's progress through the program as indicated in the Self-Study Report.</p> <p>Verify that the program has clearly written goals and competencies.</p> <p>Review course objectives for each subject area.</p> <p>Verify that the program has appropriate objectives in the cognitive, psychomotor and affective domains.</p> <p>Verify that the course objectives show progression to the level consistent with entry into the profession.</p>

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	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
Standard 22B	<p>Describe the coursework required for completion of the program and indicate whether the course work is addressed as part of the professional program or prior to admission to the program.</p> <p>Identify where the items described in Standard 22B1-7 are included in the curriculum.</p>	<p>Submit brief summaries or course descriptions for each unit of instruction or course in the program.</p> <p>A matrix is provided in the appendix to assist you in identifying where units of instruction are located in the program's curriculum.</p> <p><i>*Use of the matrix is optional.</i></p>	<p>Verify that the curriculum includes the required areas described in Standard 22B1-7.</p> <p>Verify that course work includes all instructional areas.</p>

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	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
Standard 22C	<p>Briefly describe how the required material and activities listed in Standard 22B are used in the program to develop entry-level competencies.</p> <p>If applicable, describe how student experiences at different clinical sites are ensured as comparable.</p> <p>Justify learning experiences during hours other than the normally scheduled clinical experience.</p> <p>Describe how policies and procedures regarding service work are distributed to students and clinical facilities.</p>	<p>Submit a brief summary of the types of laboratory tests performed in each clinical area.</p> <p>Submit objectives and evaluation instruments for any learning experiences during hours other than the normally scheduled clinical experience.</p> <p>Submit policies and procedures explaining when students may perform service work</p>	<p>Verify that instruction provides sequenced learning experiences.</p> <p>Verify that the required materials and activities found in Standard 22B are used in the program to develop entry-level competencies.</p> <p>Review the laboratory tests performed in each clinical area.</p> <p>If applicable, verify that student experiences at different clinical sites are ensured as comparable.</p> <p>Review the justification, objectives and evaluation instruments for any learning experiences during hours other than the normally scheduled clinical experience.</p>

**Documentation Required for DMS Unique Standards**

	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
Standard 22C (continued)			<p>Verify that clinical training is sufficiently balanced to assure that all objectives and competencies are achieved.</p> <p>Verify that policies and procedures explaining when students may perform service work are published, distributed to students and distributed to clinical affiliates.</p> <p>Verify that service work by students in the clinical settings outside of regular academic hours is non-compulsory.</p>

## Documentation Required for DMS Unique Standards

	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
Standard 22D	<u>No Narrative Required</u>	<p>Submit the criteria for passing, failing and progression in the program.</p> <p>Indicate when the criteria for passing, failing and progression in the program are given to students.</p> <p>Submit evaluation systems for <b>ONE SAMPLE UNIT OF INSTRUCTION. Evaluation systems must correlate with objectives and competencies submitted for Standard 22A.</b></p> <p>Indicate the frequency of student evaluation in lectures and student and/or clinical laboratories.</p>	<p>Verify that the criteria for passing, failing and progression in the program are established and given to students at the time of entry into the program.</p> <p>Review the evaluation systems for each subject.</p> <p>Review the evaluation systems in the affective domain.</p> <p>Verify that the evaluation systems are employed frequently enough to provide faculty and students with timely indications of a student's academic standing and progress, and to serve as a reliable indicator of the effectiveness of instruction and course design.</p>



