
1. ORGANIZATION

1.0 Organization

The laboratory performing molecular testing (herein after referred to as the laboratory) shall have a structure that clearly defines and documents the parties responsible for the provision of reports containing molecular test results and services, and the relationship of individuals responsible for key quality functions.

1.1 Executive Management

The laboratory shall have a defined executive management team. Executive management shall have:

- 1) Responsibility and authority for the laboratory's operations.
- 2) Authority to establish or make changes to the laboratory's quality system.
- 3) Responsibility for compliance with these *MT Standards* and applicable laws and regulations.
- 4) Involvement in review of the quality system.
- 5) A process to identify the laboratory's customers and their needs and expectations for tests and services.

1.1.1 Laboratory Director Responsibilities

The laboratory shall have a director who has a doctoral degree in medical, biological, clinical laboratory sciences, or genetics and has at least 2 years of relevant training or experience in molecular testing. The laboratory director shall have responsibility and authority for all policies, processes, and procedures. The laboratory director may delegate these responsibilities to another qualified individual; however, the laboratory director shall retain ultimate responsibility for laboratory director duties.

1.1.2 Laboratory Supervisor Responsibilities

The laboratory shall have a supervisor who is qualified by training or experience. The supervisor shall have responsibility for technical aspects of molecular testing.

1.1.2.1 The supervisor shall have at least 2 years of relevant experience in molecular testing and one of the following qualifications:

- 1) Medical license and certification in blood banking/transfusion medicine or Molecular Genetic Pathology by the American Board of Pathology or non-US equivalent organization or agency.
- 2) Certification as a Specialist in Blood Banking (SBB) from the American Society for Clinical Pathology (ASCP), as a Certified Histocompatibility Specialist (CHS) from the American Board of Histocompatibility and Immunogenetics (ABHI), certified in Molecular Biology (MB) by ASCP, or certification from an organization or agency issuing an equivalent credential.
- 3) Advanced science degree in a related field.

1.1.2.1.1 When the individual does not meet the requirements stated in Standard 1.1.2.1, exceptions shall be considered on a case-by-case basis by the Molecular Testing Accreditation Committee.

1.2 **Quality System**

A quality system shall be defined, documented, implemented, and maintained. All personnel shall be trained in its application.

1.2.1 **Quality Representative**

The quality system shall be under the supervision of a designated person who reports to executive management.



1.2.2 **Management Reviews**

Management shall assess the effectiveness of the quality system through scheduled management reviews.

1.3 **Policies, Processes, and Procedures**

Quality and operational policies, processes, and procedures shall be developed and implemented to ensure that the requirements of these *MT Standards* are satisfied. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.



1.3.1 Any exceptions to policies, processes, and procedures warranted by clinical situations shall require justification and preapproval by the laboratory director. Chapter 7, Deviations and Nonconformances, applies.

1.4 **Operational Continuity**

Executive management shall ensure that the facility has policies, processes, and procedures that address continuity of operations for potential events that put operations at risk.