
5. PROCESS CONTROL

5.0 Process Control

The laboratory shall have policies and validated processes and procedures that ensure the quality of the relationship test reports and relationship testing services. The laboratory shall ensure that these policies, processes, and procedures are carried out under controlled conditions.

5.1 General Elements



5.1.1 Change Control

The laboratory shall have a process to develop new processes and procedures or change existing ones. This process shall include identification of specifications and verification that specifications have been met. Before implementation, the new or changed processes and procedures shall be validated. Standard 5.3.14.1 applies.

5.1.1.1 The laboratory shall ensure that the implementation of new or changed processes is controlled. Laboratory employees shall be trained in the new or changed process(es) or procedure(s). Standard 2.1.2 applies.



5.1.2 Proficiency Testing Program

The laboratory shall participate in a proficiency testing program for each genetic system used for reporting test results. Standard 7.2 applies.



5.1.2.1 A laboratory seeking initial accreditation shall participate in either one of the following:

- 1) A proficiency testing program for 2 years with successful results.
- 2) An exchange of at least 12 blinded cases representative of the casework the laboratory proposes to perform with an accredited relationship testing laboratory and demonstrate concordant results.

5.1.2.2 The laboratory shall participate in graded proficiency testing for the assignment of phenotypes and the assessment of relationships.

5.1.2.3 When a formal graded external proficiency testing program is available for one or more of the genetic systems used to report test results, the laboratory shall participate three times a year for each genetic system analyzed in the laboratory.



5.1.2.4 When no formal graded external proficiency testing program is available for any of the genetic systems used to report test results, the laboratory shall use one of the following methods:

- 1) Test on a monthly basis known samples from when graded proficiency testing was available.
- 2) Test on a monthly basis a standard trio of samples developed from persons of an undisputed relationship.
- 3) Participate three times a year in a sample exchange program.

Standard 5.1.4.1 applies.



5.1.2.5 When formal graded proficiency testing programs are available for some but not all

genetic systems, the laboratory shall test the genetic systems not evaluated by a formal proficiency testing program using one of the following methods:

- 1) Test on a monthly basis known samples from when graded proficiency testing was available.
- 2) Test on a monthly basis a standard trio of samples developed from persons of an undisputed relationship.
- 3) Participate three times a year in a sample exchange program.



5.1.2.6 Proficiency testing, whether graded or not graded, shall be representative of the cases the laboratory performs, including standard trios, single parent, and family studies (reconstruction cases).



5.1.3 Quality Control

A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment, and methods function as expected. Results shall be reviewed and corrective and preventive action taken, where appropriate.

5.1.3.1 The validity of test results and methods and the acceptability of products or services provided shall be evaluated when quality control failures occur.

5.1.3.2 Quality control results shall be reviewed and evaluated against acceptance criteria. Quality control failures shall be investigated. Chapter 9, Process Improvement Through Corrective and Preventive Action, applies.