

OECD GUIDELINES FOR QUALITY ASSURANCE IN MOLECULAR GENETIC TESTING

C. Proficiency testing: monitoring the quality of laboratory performance

Principles

- C.1 The performance of laboratories offering clinical molecular genetic tests should be measured.
- C.2 Governments, regulatory and professional bodies should support the availability of and access to proficiency testing.
- C.3 Providers of proficiency testing schemes should be competent to provide such schemes, as established by accreditation or equivalent recognition.
- C.4 Accreditation or equivalent recognition should be the basis for the international recognition of proficiency testing scheme providers.
- C.5 Governments, regulatory and professional bodies should take steps to encourage laboratories to participate in accredited proficiency testing schemes or, when not available, to use alternative methods to assess the quality of the tests they perform.
- C.6 Systems to monitor laboratory performance, and address persistent poor performance, should be in place.

Best Practices

- C.i Proficiency testing providers and professional bodies should collaborate to establish acceptable performance levels for laboratories offering molecular genetic tests.
- C.ii Regulatory and professional bodies responsible for monitoring laboratory performance against agreed standards should identify persistent poor performance and ensure that timely corrective actions are taken and documented.
- C.iii Proficiency testing schemes should be structured to assess all phases of the laboratory process, including result reporting.
- C.iv Providers of proficiency testing should develop and modify proficiency testing schemes to take into account the evolution of analytical methods.
- C.v Laboratories should participate in a proficiency testing scheme for every disease for which they test, where such schemes are available. When not available, they should participate in alternative methods relevant to the tests they perform.
- C.vi Laboratories should make the fact that they participate in proficiency testing publicly known.
- C.vii Individual laboratory performance in proficiency testing schemes may be disclosed on a voluntary basis by the laboratory concerned but should not be made public by proficiency testing scheme providers unless so required by law.

D. Quality of result reporting

Principles

D.1 All laboratories should issue molecular genetic testing results in the form of a written and/or electronic report to the referring clinician or health professional.

D.2 Within jurisdictions where reports may be issued directly to patients, governments, regulatory and professional bodies should encourage all laboratories performing clinical molecular genetic tests to recommend that patients consult an appropriate clinician or health care professional to help them understand the implications of the test result.

D.3 Governments and regulators should require that in issuing and archiving reports, all laboratories comply with applicable law and regulations, including those concerning the confidentiality of information.

D.4 The interpretation of molecular genetic test results should be appropriate to the individual patient and clinical situation and should be based on objective evidence.

Best Practices

D.i Reports should communicate information effectively taking into account that the recipient may not be a specialist health care professional.

D.ii Reports should be timely, accurate, concise, comprehensive, and communicate all essential information to enable effective decision-making by patients and health care professionals.

D.iii Reports should use applicable internationally accepted terminology and nomenclature including identification of reference sequences.

D.iv Laboratories should inform service users of the patient and family information the laboratory requires to ensure the appropriateness of the test request and to interpret the results.

D.v In jurisdictions that allow laboratories to enter reports into a conventional or electronic patient record, all essential and relevant elements should be included.

D.vi Reports should include at a minimum the following information:

1. Identification that unequivocally links the report to the patient.
2. The name of the referring health care professional and contact information.
3. The indication for testing and specific medical information where it is relevant to test interpretation.
4. The test performed and the methodology used (including the scope of the analysis, the limitations of the test and its analytical sensitivity and specificity).
5. The primary sample type where necessary for the interpretation.
6. The date of receipt of the sample.
7. The name and location of laboratory(ies), including any referral laboratory(ies), which performed the actual testing on the sample.
8. The test result.
9. An interpretation of the result in the context of the indication for testing and all other information provided to the laboratory.
10. The identity of the individual approving the report.
11. Laboratory contact information.
12. The date of issue of the report.

D.vii Where appropriate, the test report should also include the following information:

1. A recommendation for genetic counselling by a qualified health care professional.
2. Implications for other family members.
3. Recommendations for follow up testing.

D.viii All the essential and relevant elements of test results and interpretation reported by a referral laboratory should be included in the report to the health care professional who ordered the test.