

Accreditation under the International Standard ISO 15189: Experience of a Genetics Laboratory in DNA Sequencing

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Introduction: Health care is to some extent influenced by the results of laboratory tests. In order to provide the best care for the patient, laboratories must seek to achieve high levels of quality and competence. International Standard ISO 15189 specifies these requirements and may be used by laboratories to perform accredited genetic tests of materials derived from the human body. Here we describe the procedures to establish Accreditation of DNA sequencing in our laboratory and the first Accreditation of its kind in Portugal.

Methods: Our laboratory started to prepare to comply with ISO 15189 Accreditation requirements for DNA sequencing in 2010. Documents describing administrative and technical procedures of the sequencing workflow including sample registries, laboratory protocols, operation and maintenance of equipments, as well as preparation and use of reagents were produced. Regular examination of laboratory equipments by an external entity was implemented to confirm compliance with working requirements. Requisites for personnel training and demonstration of competence were also implemented. The laboratory participated regularly in the DNA sequencing scheme organized by the European Molecular Genetics Quality Network (EMQN).

Results: The laboratory obtained formal recognition by Instituto Português de Acreditação (IPAC) in May 2014. A maximum genotyping score for DNA sequencing has been obtained in the external quality assessment scheme since 2010. Sequencing quality measured in terms of the quality read overlap metrics is currently of approximately 96% according to the EMQN scheme. The laboratory processes and analyzes an average of 28.750 samples per year.

Discussion: Accreditation of a genetic test under ISO 15189 is a highly demanding and laborious task for a genetic laboratory. However, it is an important step in order to guarantee the highest quality and reproducibility of genetic test results.