Supplementary

Contents

Guidance for the Establishment, Implementation and Performance for Proficiency Testing Programs

Scope

Thrombosis and hemostasis testing is one of the most difficult areas of pathology testing for obtaining accurate results. Coagulation testing is difficult because of a number of factors. There is variability in the pre-analytical, analytical and post-analytical processes, variability of reagents, differences in reference intervals, and arbitrary expression of units. With these shortcomings, attempting to compare patient results is sometimes close to impossible. Because of this, it is extremely important that a good External Quality Assurance Scheme (EQAS) be in-place to evaluate the assays and analytes of the coagulation laboratory.

The objective of this document is to outline the major requirements of an EQAS for thrombosis and hemostasis testing. In this document, the establishment of EQAS, the major components necessary for the program, the basic methods to evaluate data and the reporting of results will be discussed. Since thrombosis and hemostasis testing is unique, the differences associated with thrombosis and hemostasis testing will be highlighted.

Objectives:

* To provide guidance to ensure adequate planning for the EQAS program
* Outline the process for providing an EQAS service
* Assess the quality of the EQAS system
* Provide the components for running an EQAS service
* Provide information necessary for the report to participants

Terminology

Quality Assurance: the maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of delivery or production.

Quality Control (QC): The process through which a laboratory seeks to ensure that test result quality is maintained or improved with reduced or zero errors. QC requires the laboratory to create an environment in which all aspects of the laboratory strives for perfection.

Quality Assessment: An evaluation of the extent to which the laboratory's design and management are able to prevent systematic errors and biases.

Regulatory Agency: Government body formed or mandated under the terms of a legislative act (statute) to ensure compliance with the provisions of the act, and in carrying out its purpose.

EQAS Organization: An organization either mandated by the regulatory agency or part of the regulatory agency to provide an external quality assessment program for clinical laboratories.