

# Quality assurance principles for analytical laboratories

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Therefore during the clinical evaluation of the assay it is important to consider the testing purpose such as whether it is for diagnosis, screening, or therapeutic monitoring purposes; the environment the testing is likely to take place in such as the central clinical laboratory, out-reach clinic, or point of care setting; the specimen type e. For example, most common serological tests are performed on either serum or plasma and are best tested within 48—72 h after collection in order to prevent degradation of the analytes, unless they are stored and shipped to the laboratory at between 2—8°C.

## 9. Quality assurance and accreditation

These concepts and general principles formed the QA and QM foundation commonly used within the clinical virology laboratory which continue to evolve in order to meet present regulatory demands and assure the safety and effectiveness of the virology testing service.

### Handbook of Quality Assurance for the Analytical Chemistry Laboratory

Where there is limited reference material available or a lack of suitably characterized patient material, the laboratory can use residual material from proficiency testing PT or external quality assessment EQA schemes. The scientific and technical staff will be responsible for specimen processing, carry out the various testing procedures and other laboratory activities such equipment maintenance and calibration. Quality Management System QMS In the context of the clinical virology laboratory, the QMS covers all the policies, documented processes, procedures, and records used in order to deliver the diagnostic testing service to the patient under its defined scope of accreditation.

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For example, 20 patient specimens over 2—5 testing events. In some cases, the manufacturer may only have performed an analytical assessment of AMR on contrived or synthesized control materials such as target viral nucleic acid in a plasmid construct and not true clinical samples at

relevant titers. For example, for employees within the first year of their laboratory duties, competency must be assessed at least twice a year when engaged in moderate to high complexity testing i.

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This enables the laboratory to take immediate action as well as helps with the identification of trends over time.

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