



2

The Molecular Laboratory

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Chapter summary

- The need for diagnostic molecular testing is increasing in line with the understanding of cellular pathway perturbations in disease, together with the emergence of therapies that target specific elements of these.
 - Options available for the physical construction of a molecular laboratory are outlined. Special emphasis is placed on the need to avoid cross-contamination of samples requiring nucleic acid analysis.
 - Best practice for the operation and organization of an accredited laboratory is considered from practical viewpoints.
 - The necessity for diagnostic laboratories to have formal external accreditation is noted. To obtain this the need for a dynamic QMS to be in place that is, in turn, driven by a Quality Management Cycle is emphasized.
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- Validation and verification are defined in the context of ensuring that tests meet acceptable levels of specificity, sensitivity, and reproducibility.
 - EQA is defined. The necessity for participation in EQA schemes and their benefit to the laboratory in improving its service is discussed.