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Conclusions

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Despite a slight variation in the coverage of certain microorganisms, major issues remained unchanged when comparing the first and the second workshop. There are applications for a few key target organisms, e.g. CMV, HBV and HIV, when current methods either fail to give a timely and accurate diagnosis or do not allow for rapid and reliable typing for therapeutic monitoring or epidemiology. The same holds true for bacterial, fungal or protozoal pathogens. Here it appeared, however, that sample processing and nucleic acid extraction is of major concern and not yet optimal. In general, it seems to be far easier to solve technical problems than to approach standardization and quality control issues. There is a plethora of different primers for each organism, there are purification schemes galore, there is an ever increasing number of methods for detecting and quantifying amplified DNA fragments. But how do they perform in everyday routine use, how do they compare when rigorous quality standards are applied? Are there enough data on interlaboratory accuracy? What is the clinical significance of a result generated by PCR or any other nucleic acid in vitro amplification technique? There is an obvious lack of studies comparing currently available techniques in a large clinical setting using representative populations. How should these studies be evaluated, if definitive methods for establishing clinical diagnoses and laboratory 'gold standards' are lacking? It will be a difficult task to define the appropriate indications for using molecular diagnostics. A mere workup of the WHO hitlist of most prevalent organisms will not suffice. There are, however, applications where molecular genetic tools replace or complement current methodology, that is in molecular typing and identification or subtyping of culture isolates, e.g. molecular fingerprinting of *Staphylococcus aureus*.

There is also now doubt about the usefulness of in vitro amplification and comparative sequence analysis for identifying new bacteria and viruses, e.g. treponemes or hantaviruses, or for determining microbial diversity in environmental habitats. However, when it comes to clinical applications, when test results govern therapeutic decisions, extreme care is required to implement standardization, external quality control, and to plan and execute extended clincial evaluation programs.