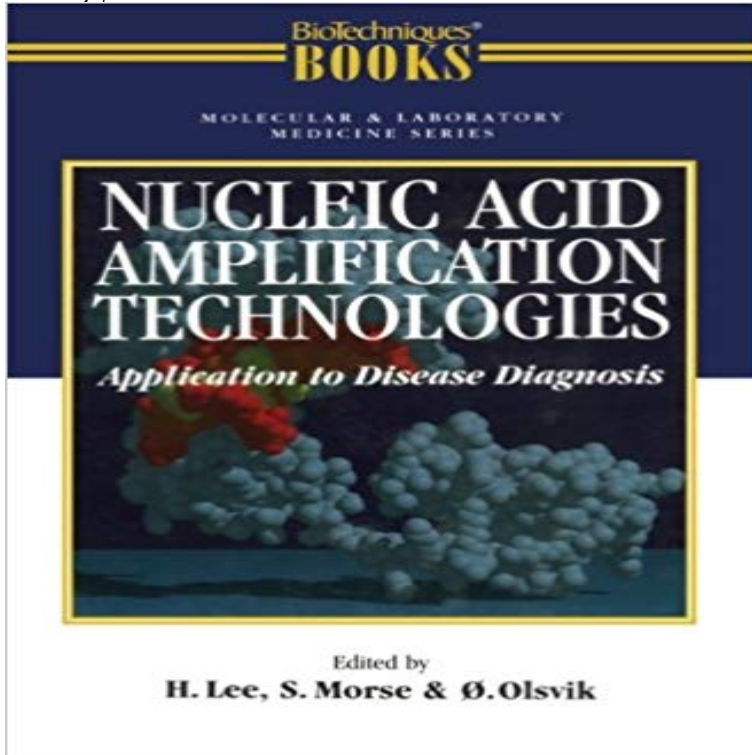


Nucleic Acid Amplification Technologies: Application to Disease Diagnosis



The polymerase chain reaction (PCR) has proved to be a powerful and versatile tool and has opened new avenues in molecular biology. Alternative nucleic acid amplification techniques, such as the ligase chain reaction (LCR), nucleic acid sequence-based amplification (NASBA), and transcription-mediated amplification (TMA), a variation of NASBA, are also now available. These techniques are all designed to amplify specific nucleic acid sequences in an exponential manner, thus providing a basis for extremely sensitive diagnostic assays. However, despite the widespread and successful application of genomic amplification techniques in biological research, they have not yet reached the point of routine use in clinical laboratories. Thus, although the R&D investment in nucleic acid diagnostics is in excess of \$250 million annually, clinical applications remain relatively modest. One of the principal reasons for this delay in clinical application has been the problem of accidental contamination of negative clinical specimens with minute amounts of amplified products from a previous positive reaction. Carry-over contamination of amplicons can now be prevented by chemical means or the use of a closed reaction system. However, the current instrumentation is essentially modular in nature, comprising machines that perform the three essential steps of nucleic acid amplification technology: sample preparation, the amplification reaction, and detection of products. Consequently, the test procedures are more complicated with somewhat lower sample throughput than the enzyme immunoassays currently performed in clinical laboratories.

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