



Standard Guide for Detection of Nucleic Acid Sequences of the Human Immunodeficiency Virus HIV-1 by the Polymerase Chain Reaction Technique¹

This standard is issued under the fixed designation E 2146; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

This guide covers the amplification and detection of nucleic acids [ribonucleic acid (RNA) and deoxyribonucleic acid (DNA)] of the human immunodeficiency virus type 1 (HIV-1) by the polymerase chain reaction (PCR) technique. PCR is used in clinical laboratories to aid in the diagnoses of genetic and infectious diseases; it is also used as a general tool in molecular biology and biotechnology laboratories. PCR involves the replication, or amplification, of a fragment of DNA by as many as several million times in only several hours. The amplified DNA fragments, which are identical or nearly identical, can then be detected, identified and quantified by classical procedures of molecular biology and biochemistry. An advantage of PCR is that as few as several molecules of target RNA or DNA in a biological test specimen can be rapidly and accurately amplified and subsequently identified. The value of using PCR to detect HIV is the rapidity of the procedure (~1 day for amplification and detection). Rapid clinical intervention can delay disease progression and prevent opportunistic infections.

Acquired immune deficiency syndrome (AIDS) is the end-stage outcome of infection with HIV. It is one of the leading causes of human death in the world. As of 1998, about 12 million people have died from AIDS. In the United States, until 1996, AIDS was the leading cause of death among persons 25 to 44 years of age (1)². In 1996 the total number of HIV-infected adults and children worldwide was over 20 million (1).

At present two serotypes of HIV are recognized: HIV-1 and HIV-2. HIV-1 is the primary serotype found in the United States; two principal genetic groups have been identified: M (main) and O (outlying). Subtype M is further classified into 10 envelope subtypes, A through J. HIV-2 is primarily restricted to West Africa. At present, no generally accepted primers exist for the detection of HIV-2 nucleic acids.

This guide was developed by Subcommittee E48.02 on Characterization and Identification of Biological Systems in collaboration with DIN (German Institute for Standardization) Committee E9 on Serodiagnosis of Infectious Diseases and Diseases of the Immune System of DIN's Department for Medical Standards (Normenausschuss Medizin). It is recommended that this HIV-specific PCR guide be used in conjunction with ASTM's general PCR guide E 1873 (Standard Guide for Detection of Nucleic Acid Sequences by the Polymerase Chain Reaction Technique). The combination of the two guides provides guidelines, recommendations, basic considerations, criteria, and principles that should be employed when developing, utilizing or assessing PCR protocols for the detection of the RNA or DNA form of HIV nucleic acid.

This guide assumes a basic knowledge of virology and molecular biology. It assumes the availability of, and the ability to search the literature for, HIV target-specific PCR protocols.

1. Scope

1.1 This guide covers considerations, criteria, principles and

recommendations that should be helpful when developing,

¹ This guide is under the jurisdiction of ASTM Committee E48 on Biotechnology and is the direct responsibility of Subcommittee E48.02 on Characterization and Identification of Biological Systems.

Current edition approved May 10, 2001. Published June 2001.