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Standard Guide for Identification of Herpes Simplex Virus or Its DNA[1]

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INTRODUCTION

This guide covers the identification of herpes simplex virus (HSV) or its DNA and was developed by Subcommittee E48.02 on Characterization and Identification of Biological Systems. The objective is to describe laboratory characterization procedures that would be sufficient to verify that a biological preparation believed to contain primarily HSV (or HSV DNA) for use in any step of a biotechnology process actually does contain this virus (or its DNA).

This guide assumes a basic knowledge of virology and molecular biology.

1. Scope

1.1 This guide covers laboratory characterization procedures sufficient to identify purified specimens of HSV types 1 and 2 (HSV-1 and HSV-2) or HSV-1 DNA and HSV-2 DNA used in biotechnology. For cases in which identification of HSV DNA specimens is required, the characterization criteria of 6.2 and 6.3 of this guide are sufficient.

1.2 This guide does not cover the identification of HSV in HSV-infected host cells. To apply this guide to such a case, it would first be necessary to isolate the virus from such samples using standard techniques of HSV purification. This guide does not cover characterization of segments of HSV DNA or of vectors containing HSV DNA segments.

1.3 This guide does not cover the specific methodology used in the identification characterization. It does not address the question of degree of purity required for herpesvirus preparations: this would vary depending on the particular biotechnology use of the virus.

1.4 **Warning—**Laboratory work involving herpes simplex viruses can be hazardous to personnel. **Precaution:** Biosafety 2 level facilities are recommended (**1**).[2] Safety guidelines shall be adhered to according to NCCLS M29–T2 and other recommendations (**1**).

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:* [3]

E 1873 Guide for Detection of Nucleic Sequences by the Polymerase Chain Reaction Technique

2.2 *NCCLS Standards:*

M29–T2 Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue—Second Edition; Tentative Guideline[4]

3. Terminology

3.1 Basic polymerase chain reaction (PCR) definitions apply according to the general PCR Guide E 1873 (Section 3).

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *capsomere*—a structural subunit of the outer protein shell (capsid) of a virus consisting of protein monomers.

3.2.2 *envelope*—a layer of cell membrane-derived lipoprotein that surrounds the protein coat (capsid) of some viruses.

3.2.3 *genome (of a virus)*—the genetic material consisting of nucleic acid (RNA or DNA).

3.2.4 *nucleocapsid*—the outer protein coat or shell (capsid) of a virus plus its inner core of nucleic acid and proteins.

3.2.5 *plaque*—a round, clear area in a layer of host cells caused by virus growth and resultant killing or lysis of the cells.

[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.

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[2] The boldface numbers in parentheses refer to a list of references at the end of this guide.

[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[4] Available from the National Committee for Clinical Laboratory Standards, 940 West Valley Road, Suite 1400, Wayne PA 19087.