



Standard Terminology Relating to Biotechnology¹

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1. Scope

1.1 This document is composed of terms, definitions of terms, descriptions of terms, and acronyms used in ASTM documents related to the field of biotechnology. Terms that are adequately defined in a general dictionary are not defined in this terminology standard.

1.2 This standard includes terminology used in biotechnology areas, such as, but not limited to: biological drug products, materials for biotechnology, characterization and identification of biological systems, aseptic sampling, preservation of biological samples, membrane filters, molecular biology, biomass conversion, fuel manufacturing facilities, and fuel analysis.

2. Referenced Documents

2.1 ASTM Standards:

- E 869 Test Method for Performance Evaluation of Fuel Ethanol Manufacturing Facilities²
- E 870 Test Method for Analysis of Wood Fuels²
- E 1117 Practice for Design of Fuel-Alcohol Manufacturing Facilities²
- E 1126 Terminology Relating to Biomass Fuels²
- E 1285 Guide for Identification of Bacteriophage Lambda (λ) or Its DNA²
- E 1286 Guide for Identification of Herpes Simplex Virus or its DNA²
- E 1287 Practice for Aseptic Sampling of Biological Materials²
- E 1298 Guide for Determination of Purity, Impurities, and Contaminants in Biological Drug Products²
- E 1342 Practice for Preservation by Freezing, Freeze-Drying, and Low Temperature Maintenance of Bacteria, Fungi, Protista, Viruses, Genetic Elements, and Animal and Plant Tissues²
- E 1344 Guide for Evaluation of Fuel Ethanol Manufacturing Facilities²
- E 1357 Test Method for Determining the Rate of Bleaching of Iron From Pyrite by Thiobacillus Ferrooxidans²
- E 1493 Guide for Identification of Bacteriophage M13 or Its DNA²
- E 1531 Practice for Direct Detection of Mycoplasma in Cell

Culture by Broth Enrichment and Agar Growth²

- E 1532 Practice for Indirect Detection of Mycoplasma in Cell Culture by DNA Binding with Bisbenzamide Fluorochrome Stain²
 - E 1533 Practice for Indirect Detection of Mycoplasma in Cell Culture by 4'-6-Diamidino-2-2 Phenylindole (DAPI) Staining²
 - E 1535 Test Method for Performance Evaluation of Anaerobic Digestion Systems²
 - E 1536 Practice for Large Volume Testing of Serum for Mycoplasma Contamination²
 - E 1564 Guide for Design and Maintenance of Low-Temperature Storage Facilities for Maintaining Cryopreserved Biological Materials²
 - E 1565 Guide for Inventory Control and Handling of Biological Material Maintained at Low Temperatures²
 - E 1566 Guide for Handling Hazardous Biological Materials in Liquid Nitrogen²
 - E 1567 Guide for Biopharmaceutical Facilities Architectural Design Considerations²
- #### 2.2 Federal Standards:
- Title 21, Code of Federal Regulations (CFR), Parts 210 and 211³

3. Terminology

3.1 Definitions:

- accessible**—permitting close approach or contact that could include requiring removal or opening of an access panel or door. **E 1117**
- aerobic**—able to live, grow, or take place only where free oxygen is present. **E 1126**
- aerobic fermentation**—fermentation processes that require the presence of air. **E 1126**
- alcohols**—series of liquid products composed of a hydrocarbon plus a hydroxyl group, such as ethanol (C₂H₅OH). **E 1344**
- alpha-amylase**—enzyme that acts specifically to accelerate the hydrolysis of starch to dextrins. **E 1344**
- alpha complementation**—the ability of a short amino-terminal fragment (alpha fragment) of β-galactosidase to form a functional complex with the carboxyl terminal fragment (omega fragment). **E 1493**

¹ This terminology is under the jurisdiction of ASTM Committee E-48 on Biotechnology and is the direct responsibility of Subcommittee E48.91 on Terminology.

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² Annual Book of ASTM Standards, Vol 11.05.

³ Available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.