

Technical Report No. 50
Alternative Methods for
Mycoplasma Testing



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1.0 Introduction

1.1 Purpose and Scope

The scope of this Technical Report is the application of non-culture testing methodology, including Nucleic Acid Amplification Technique (NAT) assays and others (e.g., enzyme activity based), for detection of mycoplasmas, members of the class Mollicutes, in cell cultures and biologics. The purpose of the Technical Report is to describe assay procedures, assay validation, demonstration of comparability to reference methods, and potential applications for alternative mycoplasma testing methods.

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