

# CERTIFICATE OF QUALITY

## Quality Control Microorganisms

This Certificate of Quality is a document which applies to microorganisms offered by Microbiologics.

**QSR.** All elements of the FDA Quality System Regulation (QSR) have been met for the microorganism(s).

**Purity.** Purity specifications have been met for the microorganism(s).

**Identification.** Microscopic examination, selected identification parameters, and when applicable, antibiotic sensitivity testing have been employed to confirm the identity of the microorganism(s) and verify special features. Identification specifications have been met for the microorganism(s).

**Alterations.** Selected tests are employed to confirm that phenotypic alterations have not occurred as a result of lyophilization processes. Phenotypic specifications have been met for the microorganism(s).

Selective and non-selective media, select identification protocols, and specific incubation conditions are employed in the assay methods. Information regarding morphology, phenotypic characteristics, and test results can be obtained by contacting the Microbiologics Technical Support Department at [techsupport@microbiologics.com](mailto:techsupport@microbiologics.com) or by visiting [www.microbiologics.com](http://www.microbiologics.com).

\*The Microbiologics Quality System Program is designed to meet standards set forth in 21 CFR Part 820: FDA Quality System Regulation (QSR). The QSR standards are only applicable to Microbiologics products marked as in-vitro diagnostic (IVD). The standards apply to methods used in, and the facilities and controls used for, the design; component purchasing; suppliers, contractors and consultant evaluation; manufacture; packaging; labeling; product specifications and performance; storage; and distribution of in-vitro, medical diagnostics products. These provisions are intended to ensure that finished product will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act. Products which are not under the jurisdiction of the Federal Food, Drug, and Cosmetic Act, are nevertheless, subjected to and meet the guidelines and standards set forth in 21 CFR Part 820: FDA QSR.



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