



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

MICROBIOLOGY & QUALITY ASSOCIATES, INC.  
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BIOLOGICAL

Valid To: December 31, 2018

Certificate Number: 3383.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following biological tests:

<u>Test(s)</u>	<u>Reference Method(s)</u>	<u>SOP(s)</u>
Biological Reactivity Tests	USP <87>	CC-005
Cytotoxicity in Cell Cultures	In-house	CC-007
*Environmental Monitoring and Compressed Gas Testing	USP <797> USP <1116> ISO 14644-1 ISO 14644-2 ISO 8573	EM-002 EM-003 EM-005 EM-006 EM-007 EM-009 EM-010 EM-011 EM-012 EM-013 EM-014 EM-015 MB-023
*Sampling of Water and Gas Systems	USP <1116>	EM-004 EM-008
Growth Promotion and Sterility Testing of Microbiological Media	USP <61> USP <62> USP <71> USP <2021>	MB-001
Sterility Test	USP <71> ANSI/AAMI ISO 11137-1,-2,-3	MB-018 MB-019 MB-034

<u>Test(s)</u>	<u>Reference Method(s)</u>	<u>SOP(s)</u>
Water Microbial Testing Total Heterotrophic Plate Count, Coliform Test	USP <1231> Standard Methods for the Examination of Water and Wastewater 9222 EPA Method 1604	MB-003 MB-017
Microbial Identification	USP <1113>	MB-004 MB-006 MB-007 MB-024
Microbiological Examination of Non-Sterile Products: Pour Plate, Spread Plate, Membrane Filtration Methods and Microbial Enumeration Method Suitability	USP <61> USP <2021>	MB-008 MB-009 MB-030
Bacterial Endotoxin Test	USP <85>	MB-011 MB-016 MB-026
Microbiological Examination of Non-Sterile Products: Test for Specified Microorganisms for <i>Escherichia coli</i> , <i>Salmonella</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus</i> <i>aureus</i> , <i>Clostridia</i> and <i>Candida Albicans</i>	USP <62>	MB-014 MB-015
Biological Indicators	USP <55>	MB-027
Antimicrobial Effectiveness Test	USP <51> EP XVIC CTFA M3, M6	MB-029
Mycoplasma Detection by Direct and Indirect Methods	USP <63> USP <1211> EP 7 <sup>th</sup> ED 2.6.7 FDA Points to Consider in Characterization of Cell Lines Used to Produce Biologicals (1993)	MY-001 MY-003 MY-004 MY-005 MY-006 MY-007 MY-008
Detection of Mycoplasma and Virus by PCR	In-House	PC-007 PC-008 PC-010 PC-014 PC-015 PC-023
Detection of Virus in Test Articles	9 CFR 113.46; 9 CFR 113.47; 9 CFR 113.53; 21CFR 210, 211 FDA Points to Consider in Characterization of Cell Lines Used to Produce Biologicals (1993) USP <1050> USP <1237>	VI-002 VI-003 VI-004



CHEMICAL

<u>Test(s)</u>	<u>Reference Method(s)</u>	<u>SOP(s)</u>
Total Organic Carbon	USP <643>	CH-001
Conductivity Test	USP <645>	CH-004
Appearance Test	USP <851>	CH-008

\* This laboratory meets A2LA R104 – *General Requirements: Accreditation of Field Testing and Field Calibration Laboratories* for these tests.





## *Accredited Laboratory*

A2LA has accredited

**MICROBIOLOGY & QUALITY ASSOCIATES, INC.**

*Concord, CA*

for technical competence in the field of

**Biological Testing**

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated 8 January 2009).



Presented this 7<sup>th</sup> day of March 2017.

A handwritten signature in black ink, written over a horizontal line.

President and CEO  
For the Accreditation Council  
Certificate Number 3383.01  
Valid to December 31, 2018

*For the tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.*