



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>
Antimicrobial Effectiveness Test	USP <51> EP XVIC CTFA M3, M6	MB-029
Bacterial Endotoxin Test	USP <85>	MB-011 MB-016 MB-026
Biological Indicators	USP <55>	MB-027
Biological Reactivity Tests	USP <87>	CC-005
*Compressed Gas Sampling and Testing	USP <797> USP <1116> ISO 8573	EM-006 EM-010 EM-012 EM-014
Cytotoxicity in Cell Cultures	ISO 10993-5 USP <87>	CC-007
Detection of Mycoplasma and Virus by PCR	EU 2.6.7 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

<u>Test(s)</u>	<u>Reference Method(s)</u>	<u>SOP(s)</u>
*Environmental Monitoring Testing	USP <797> USP <1116> ISO 14644-1 ISO 14644-2	EM-002 EM-003 EM-005 EM-007 EM-009 EM-011 EM-013 EM-015 MB-023
Growth Promotion and Sterility Testing of Microbiological Media	USP <61> USP <62> USP <71> USP <2021>	MB-001
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
Microbiological Examination of Non-Sterile Products: Test for Specified Microorganisms for <i>Escherichia coli</i> , <i>Salmonella</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Clostridia</i> and <i>Candida Albicans</i>	USP <62>	MB-014 MB-015
Mycoplasma Detection by Direct and Indirect Methods	USP <63> USP <1211> EP 7 th 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
*Sampling of Water Systems	USP <1116>	EM-004
Sterility Test	USP <71> ANSI/AAMI ISO 11137-1, -2, -3	MB-018 MB-019 MB-034
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



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 7th 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
Revised September 19, 2017

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