Accredited Laboratory

A2LA has accredited

MICROBAC LABORATORIES, INC.

Sterling, VA

for technical competence in the field of

Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *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 April 2017*).

Presented this 21st day of January 2025.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3376.01
Valid to January 31, 2027

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

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

MICROBAC LABORATORIES, INC.
105 Carpenter Drive
Sterling, VA 20164
Suneetha Veettil Phone: 703 925 0100

BIOLOGICAL

Valid To: January 31, 2027 Certificate Number: 3376.01

In recognition of the successful completion of the A2LA evaluation process, including an assessment of the laboratory's conformance with applicable U.S. EPA FIFRA Good Laboratory Practice Standard (GLP), the U.S. FDA GLP Regulations per 21 CFR Part 58[1] and Good Manufacturing Practice (cGMP) regulations per 21 CFR 210 and 211, accreditation is granted to this laboratory to perform the following tests on suspensions, and hard and soft surfaces:

Test	**Test Method(s)**
Adventitious Virus Testing	ICH Q5A Sept. 1999, FDA-PTC mAb for Human Use, EMEA-CHMP-BWP 398498 (July 2008); ISO 22442-3 (2007) LU Reference
Antiviral/Antimicrobial Testing for Treated Textiles and Masks	Per AATCC100 and JIS L1902
Basic Bactericidal Activity	EN 1040:2005
Basic Fungicidal Activity	EN 1275:2005
Condom Viral Barrier Testing	Per ISO 23409 Annex G, ISO 25841 Annex G, and FDA CDRH Guidance, June 29, 1995
Disinfectant Qualification	Chapter 1072 of the US Pharmacopeia and FDA (1993), "Guide to Inspections Validation of Cleaning Processes" <USP 1072>

5202 Presidents Court, Suite 220 | Frederick, MD 21703-8515 | Phone: 301 644 3248 | Fax: 240 454 9449 | www.A2LA.org

Test	**Test Method(s)**
Evaluation of Inactivators of Antimicrobial Agents	ASTM E1054
Fabric Sanitizer Test/Non-Food Contact Sanitizer Test	ASTM E1153
Healthcare Personnel Handwash	ASTM 1174
Measurement of Antiviral Activity on Plastics and other Non-Porous Surfaces	ISO 21702
Minimum Inhibitory Concentration Determinations	CLSI- M07 Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically
Preoperative Skin Preparation	ASTM E1173
Quantitative Non-Porous Surface Test for the Evaluation of Bactericidal and/or Fungicidal Activity of Chemical Disinfectants Used in Food, Industrial, Domestic and Institutional Areas	I.S. EN 13697:2015+A1(2019) E
Quantitative Non-Porous Surface Test Without Mechanical Action for the Evaluation of Viricidal Activity of Chemical Disinfectants used in the Medical Area	EN 16777
Quantitative Surface Suspension of Virucidal Activity for Veterinary Use	EN 14675
Quantitative Surface Test for the Evaluation of Residual Antimicrobial (Bactericidal or Yeasticidal) Efficacy of Liquid Chemical Disinfectants on Hard Non-Porous Surfaces	PAS 2424
Quantitative Suspension of Bactericidal Activity for Medical Area	BS EN 13727:2012+A2:2015
Quantitative Suspension of Fungicidal Activity for Medical Area	BS EN 13624:2013
Quantitative Suspension of Virucidal Activity Against Bacteriophages for Institutional Use	EN 13610
Surgical Scrub	ASTM E1115
Textiles-Determination of Antiviral Activity of Textile Products	ISO 18184
Viral Barrier Test for Medical Device Sheath	FDA CDRH “Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers (March 12, 2000)”

Test	**Test Method(s)**
Viral Clearance Studies	ICH Q5A Sept 1999, FDA-PTC mAb for Human Use, EMEA-CHMP-BWP 398498 (July 2008); ISO 22442-3 (2007) LU reference
Virucidal Efficacy Test on Hard Surface	ASTM E1053
Virucidal Quantitative Suspension Test for Human Medicine	EN 14476
Virucidal Suspension	ASTM E1052

[1]Assessment to the U.S. FDA GLP (Good Laboratory Practice) Regulations does not imply acceptance by the FDA.