



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

American Type Culture Collection (ATCC)
10801 University Blvd.
Manassas, VA 20110

Fulfills the requirements of

ISO 17034:2016

In the field of

REFERENCE MATERIAL PRODUCER

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

A handwritten signature in black ink, appearing to read 'R. Douglas Leonard Jr.', is positioned above a horizontal line.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 17 March 2023

Certificate Number: AR-1384



This reference material producer is accredited in accordance with the recognized International Standard ISO 17034:2016.
This accreditation demonstrates technical competence for a defined scope and the operation of a reference material producer quality management system.

SCOPE OF ACCREDITATION TO ISO 17034:2016

American Type Culture Collection (ATCC)

10801 University Blvd., Manassas, VA 20110

Michelle Sherman 703-365-2700

msherman@atcc.org www.atcc.org

REFERENCE MATERIAL PRODUCER

Valid to: **March 17, 2023**

Certificate Number: **AR-1384**

Biological

Sub-Category of Reference Material	ILAC RM Category	Class or Type of Reference Materials Produced (Include Range Where Applicable)	Methods or Techniques Used in the RMP Laboratory (if Appropriate)
Bacteriology and Mycology	B8.1	Bacterial Cultures	<ul style="list-style-type: none"> • Gram staining and cell morphology • Colony description • Viability (culture, stain, and titer) • Purity testing • PCR and sequencing of selected gene(s) • bioMérieux api® assays • bioMérieux VITEK® 2 assays • bioMérieux VITEK® MS • Remel Rapid™ assays • Biochemical assays • Antibiotic susceptibility testing • O antigen serotyping
Bacteriology and Mycology	B8.1	Fungal and Yeast Cultures	<ul style="list-style-type: none"> • Viability (culture and titer) • Cell and/or colony morphology • Purity • PCR and sequencing of selected gene(s)

Biological

Sub-Category of Reference Material	ILAC RM Category	Class or Type of Reference Materials Produced (Include Range Where Applicable)	Methods or Techniques Used in the RMP Laboratory (if Appropriate)
			<ul style="list-style-type: none"> • bioMérieux VITEK® 2 assays • bioMérieux VITEK® MS • bioMérieux api® assays • Genetic marker testing • Sporulation efficiency testing
Virology	B9	Viruses and Chlamydia	<ul style="list-style-type: none"> • PCR and sequencing • IFA • CEID₅₀ by hemagglutination • TCID₅₀ by CPE or IFA • Bacterial and fungal contaminant testing • Mycoplasma contamination testing
Other biological and clinical reference materials	B10	Cell Cultures	<ul style="list-style-type: none"> • Viability (cell count and growth) • Growth properties • Morphology • Mycoplasma contamination testing • Bacterial and fungal contaminant testing • PCR and sequencing of selected gene(s) • Human virus testing • COI assay (interspecies) • STR analysis (Intraspecies)
Other biological and clinical reference materials	B10	Nucleic Acids	<ul style="list-style-type: none"> • PicoGreen® or RiboGreen® analysis • Agarose gel electrophoresis • OD₂₆₀/OD₂₈₀ ratio • PCR and sequencing of selected gene(s)

Biological

Sub-Category of Reference Material	ILAC RM Category	Class or Type of Reference Materials Produced (Include Range Where Applicable)	Methods or Techniques Used in the RMP Laboratory (if Appropriate)
			<ul style="list-style-type: none"> • Inactivation of source organism (BSL 2 or higher) • Digital PCR for quantitative testing • qPCR for quantitative testing
Other biological and clinical reference materials	B10	Protist Cultures	<ul style="list-style-type: none"> • Viability (cell count) • Cell morphology • Purity • PCR and sequencing of selected gene(s)

Notes:

1. Please contact the RMP organization for more information on CRM uncertainty values, Ucrm values, and other specific lot values. Some of this information may also be available on the RMP's website.
2. This scope is formatted as part of a single document including Certificate of Accreditation No. AR-1384.

