

CERTIFICATE OF ACCREDITATION

ANSI-ASO National Accreditation Board

500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

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

has been assessed by ANAB and meets the requirements of international standard

ISO Guide 34:2009

while demonstrating technical competence in the field of

Reference Material Producer

Refer to the accompanying Scope of Accreditation for information regarding the types of materials to which this accreditation applies.

AR-1384
Certificate Number

ANAB Approval

Certificate Valid 03/03/2018-03/17/2019 Version No. 004 Issued: 03/03/2018





SCOPE OF ACCREDITATION TO ISO GUIDE 34:2009

American Type Culture Collection (ATCC)

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REFERENCE MATERIAL PRODUCER

Valid to: March 17, 2019 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	 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 BiOLOG identification technology Remel RapID™ assays Biochemical assays Antibiotic susceptibility testing O antigen serotyping





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	Fungal and Yeast Cultures	 Viability (culture and titer) Cell and/or colony morphology Purity PCR and sequencing of selected gene(s) bioMérieux VITEK® assays bioMérieux VITEK® MS BiOLOG identification technology bioMérieux api® assays Genetic marker testing Sporulation efficiency testing
Virology	В9	Viruses and Chlamydia	 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	 Viability (cell count and growth) Growth properties Morphology Mycoplasma contamination testing



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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)
Other biological and clinical reference materials	B10	Nucleic Acids	 Bacterial and fungal contamination testing PCR and sequencing of selected gene(s) Human virus testing COI assay (interspecies) STR analysis (Intraspecies) PicoGreen® or RiboGreen® analysis Agarose gel electrophoresis OD₂₆₀/OD₂₈₀ ratio PCR and sequencing of selected gene(s) 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	 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.



