



# CERTIFICATE OF ACCREDITATION

## ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

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 17034:2016

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 Through: 03/17/2021  
Version No. 005 Issued: 03/05/2019



**SCOPE OF ACCREDITATION TO ISO 17034:2016**

**American Type Culture Collection (ATCC)**

10801 University Blvd., Manassas, VA 20110

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**REFERENCE MATERIAL PRODUCER**

Valid to: **March 17, 2021**

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"> <li>• Gram staining and cell morphology</li> <li>• Colony description</li> <li>• Viability (culture, stain, and titer)</li> <li>• Purity testing</li> <li>• PCR and sequencing of selected gene(s)</li> <li>• bioMérieux api® assays</li> <li>• bioMérieux VITEK® 2 assays</li> <li>• bioMérieux VITEK® MS</li> <li>• Remel RapID™ assays</li> <li>• Biochemical assays</li> <li>• Antibiotic susceptibility testing</li> <li>• O antigen serotyping</li> </ul>
Bacteriology and Mycology	B8.1	Fungal and Yeast Cultures	<ul style="list-style-type: none"> <li>• Viability (culture and titer)</li> <li>• Cell and/or colony morphology</li> <li>• Purity</li> <li>• PCR and sequencing of selected gene(s)</li> </ul>

**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"> <li>• bioMérieux VITEK® 2 assays</li> <li>• bioMérieux VITEK® MS</li> <li>• bioMérieux api® assays</li> <li>• Genetic marker testing</li> <li>• Sporulation efficiency testing</li> </ul>
Virology	B9	Viruses and Chlamydia	<ul style="list-style-type: none"> <li>• PCR and sequencing</li> <li>• IFA</li> <li>• CEID<sub>50</sub> by hemagglutination</li> <li>• TCID<sub>50</sub> by CPE or IFA</li> <li>• Bacterial and fungal contaminant testing</li> <li>• Mycoplasma contamination testing</li> </ul>
Other biological and clinical reference materials	B10	Cell Cultures	<ul style="list-style-type: none"> <li>• Viability (cell count and growth)</li> <li>• Growth properties</li> <li>• Morphology</li> <li>• Mycoplasma contamination testing</li> <li>• Bacterial and fungal contamination testing</li> <li>• PCR and sequencing of selected gene(s)</li> <li>• Human virus testing</li> <li>• COI assay (interspecies)</li> <li>• STR analysis (Intraspecies)</li> </ul>
Other biological and clinical reference materials	B10	Nucleic Acids	<ul style="list-style-type: none"> <li>• PicoGreen® or RiboGreen® analysis</li> <li>• Agarose gel electrophoresis</li> <li>• OD<sub>260</sub>/OD<sub>280</sub> ratio</li> </ul>

**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"> <li>• PCR and sequencing of selected gene(s)</li> <li>• Inactivation of source organism (BSL 2 or higher)</li> <li>• Digital PCR for quantitative testing</li> <li>• qPCR for quantitative testing</li> </ul>
Other biological and clinical reference materials	B10	Protist Cultures	<ul style="list-style-type: none"> <li>• Viability (cell count)</li> <li>• Cell morphology</li> <li>• Purity</li> <li>• PCR and sequencing of selected gene(s)</li> </ul>

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.



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Vice President

