



CERTIFICATE OF ACCREDITATION

ANSI-ASQ 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/IEC 17025:2005

while demonstrating technical competence in the fields of

TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of calibrations and/or tests to which this accreditation applies.

AT-1383

Certificate Number

ANAB Approval

Certificate Valid: 03/03/2018-03/17/2019
Version No. 005 Issued: 03/17/2018



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. 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).

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

American Type Culture Collection (ATCC)

10801 University Blvd., Manassas, VA 20110

Michelle Sherman 703-365-2700

msherman@atcc.org www.atcc.org

TESTING

Valid to: **March 17, 2019**

Certificate Number: **AT-1383**

Biological / Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Viability and purity <ul style="list-style-type: none"> Gram staining and cell morphology Colony description Viability (culture, stain, and titer) Purity testing 	Internal and OEM Methods	Bacteria	Inverted, dissecting, and fluorescence microscopes
Genotypic ID <ul style="list-style-type: none"> PCR and sequencing of selected gene(s) 	Internal and OEM Methods	Bacteria	Thermocyclers and sequencers
Phenotypic ID <ul style="list-style-type: none"> bioMérieux api® assays bioMérieux VITEK® 2 assays bioMérieux VITEK® MS BiOLOG identification technology Remel RapID™ assays Biochemical assays Antibiotic susceptibility testing O antigen serotyping 	Internal and OEM Methods	Bacteria	bioMérieux VITEK® 2 Analyzer bioMérieux VITEK®MS Analyzer BiOLOG GEN III
Viability and identification <ul style="list-style-type: none"> Viability (cell count and growth) Growth properties Morphology 	Internal and OEM Methods	Cell Cultures	Inverted microscopes Automated cell counters

Biological / Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Sterility and Purity <ul style="list-style-type: none"> • Mycoplasma contamination testing • Bacterial and fungal contamination testing • Human virus testing • Membrane filtration test for bacterial and fungal contamination 	Internal and OEM Methods	Cell Cultures	Inverted and fluorescence microscopes bioMérieux BacT/ALERT® 3D Thermocyclers and sequencers
Genotypic ID <ul style="list-style-type: none"> • PCR and sequencing of selected gene(s) • COI assay (interspecies) • STR analysis (intraspecies) 	Internal and OEM Methods	Cell Cultures	Thermocyclers and sequencers
Identification <ul style="list-style-type: none"> • PCR and sequencing • IFA 	Internal and OEM Methods	Viruses and Chlamydia	Thermocyclers and sequencers Microscopes
Viability (infectivity) <ul style="list-style-type: none"> • CEID₅₀ by hemagglutination • TCID₅₀ by CPE or IFA 	Internal Methods	Viruses and Chlamydia	Inverted and fluorescence microscopes
Purity <ul style="list-style-type: none"> • Bacterial and fungal contamination testing • Mycoplasma contamination testing 	Internal and OEM Methods	Viruses and Chlamydia	bioMérieux BacT/ALERT® 3D Microscopes Thermocyclers and sequencers
Viability and purity <ul style="list-style-type: none"> • Viability (culture and titer) • Cell and/or colony morphology • Purity 	Internal Methods	Fungi and Yeasts	Inverted and dissecting microscopes
Genotypic ID <ul style="list-style-type: none"> • PCR and sequencing of selected genes 	Internal and OEM Methods	Fungi and Yeasts	Thermocyclers and sequencers

Biological / Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Phenotypic ID <ul style="list-style-type: none"> • bioMérieux VITEK® 2 assays • bioMérieux api® assays • bioMérieux VITEK® MS • BiOLOG identification technology • Genetic marker testing • Sporulation efficiency testing 	Internal and OEM Methods	Fungi and Yeasts	bioMérieux VITEK® 2 Analyzer bioMérieux VITEK®MS Analyzer BiOLOG GEN III
<ul style="list-style-type: none"> • 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 	Internal and OEM Methods	Nucleic Acids	Plate Readers Gel documentation system Spectrophotometers Thermocyclers and sequencers
<ul style="list-style-type: none"> • Viability (cell count) • Cell morphology • Purity • PCR and sequencing of selected genes 	Internal and OEM Methods	Protists	Inverted microscopes Thermocyclers and sequencers

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1383.



Vice President