



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/IEC 17025:2017

while demonstrating technical competence in the field of

TESTING

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

AT-1383

Certificate Number

ANAB Approval

Certificate Valid Through: 03/17/2021
Version No. 006 Issued: 03/05/2019



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

American Type Culture Collection (ATCC)

10801 University Blvd., Manassas, VA 20110

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TESTING

Valid to: March 17, 2021

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 Gel documentation system
Phenotypic ID <ul style="list-style-type: none"> bioMérieux api® assays bioMérieux VITEK® 2 assays bioMérieux VITEK® MS Remel RapID™ assays Biochemical assays Antibiotic susceptibility testing O antigen serotyping 	Internal and OEM Methods	Bacteria	bioMérieux VITEK® 2 Analyzer bioMérieux VITEK®MS Analyzer
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 Gel documentation system
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 Gel documentation system
Identification <ul style="list-style-type: none"> • PCR and sequencing • IFA 	Internal and OEM Methods	Viruses and Chlamydia	Thermocyclers and sequencers Gel documentation system 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 Gel documentation system
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 Gel documentation system




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 • Genetic marker testing • Sporulation efficiency testing 	Internal and OEM Methods	Fungi and Yeasts	bioMérieux VITEK® 2 Analyzer bioMérieux VITEK®MS Analyzer
<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 Gel documentation system

Note:

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



Vice President

