

ATCC Quality System Letter

The American Type Culture Collection (ATCC®) is a private, non-profit global biological materials and information resources and standards organization and the leading developer and supplier of authenticated cell lines and microorganisms whose mission focuses on the acquisition, authentication, production, preservation, development, and distribution of standard reference microorganisms, cell lines, and other materials for research in the life sciences. ATCC houses more than 3,400 human, animal, and plant cell lines, 18,000 strains of bacteria, 2,000 different types of animal viruses, and 1,000 plant viruses as well as collections of protozoans, yeasts, and fungi with over 49,000 yeast and fungi strains and 2,000 strains of protists. ATCC is a nonprofit 501(c)(3) organization. The culture fees paid by purchasers support the functions of our mission. A wide range of services are offered by ATCC including:

- Custom Solutions: cell and microbial authentication and banking, custom nucleic acids
- Testing Services: cell authentication and Mycoplasma testing
- Biorepository Management Services: biorepository storage
- Deposit Services: general collection, type strain, patent deposit

ATCC is committed to providing quality products and services to the life science community. An experienced quality assurance team ensures that the company mission is served under a documented quality management system.

GENERAL COMPANY INFORMATION

Company Name	American Type Culture Collection (ATCC)
Parent Company	None
Global Headquarters	10801 University Boulevard Manassas, VA 20110 USA
Telephone Number	+1-703-365-2700
Fax Number	+1-703-365-2701
Mailing Address	P.O. Box 1549 Manassas, VA 20108 USA
Website	https://www.atcc.org/
Email	sales@atcc.org
Manufacturing Location	10801 University Boulevard Manassas, Virginia 20110 USA

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Facility Size	126,000 ft ² Biorepository: 18,000 ft ² Laboratory: 35,000 ft ²		
Secondary Location	217 Perry Parkway Gaithersburg, Maryland 20877 USA		
Number of Employees	Approximately 639	QA	Approx.36
		QC	Approx.34
		Manufacturing	Approx.75
Annual Revenue	Not disclosed		
Year Established	1925		
Year of Incorporation	1947		
Age of Facility	1998 (Manassas, Virginia) 1997 with 2016 renovations (Gaithersburg, Maryland)		
Business Description	Manufacturer and service provider		
Type of Business Entity	501(c)(3) Nonprofit Corporation		
Federal ID Number	53-0196548		
D&B Number	05-795-4067		
Standard Industry Codes	SIC 8730, NAICS 541712		
Business Classification	ATCC is a private, non-profit corporation. Not Small Disadvantaged Business Concern. Not Women-Owned Business Concern. Not HUBZone Small Business Concern. Not Veteran-Owned Business Concern. Not Service-Disabled Veteran-Owned Small Business Concern. Not Indian-Owned Economic Enterprise. Not Historically Black College or Minority Institution.		
Principal Customers	ATCC serves customers throughout the global scientific community including researchers and scientists in academia, government, and industries such as pharmaceutical, biotechnology, and diagnostics.		
Bank Reference	Bank of America 1101 Wootton Parkway, 4 th Floor Rockville, MD 20852 +1-703-761-8435 Attention: Gloria Holt		

GENERAL CONTACT INFORMATION

General Information	Sales@atcc.org
Sales Inquiries	Sales@atcc.org
Technical Inquiries	Tech@atcc.org
Quality Systems	QAAssistance@atcc.org
Licensing	Licensing@atcc.org
Biorepository Services SM	Biorepository@atcc.org
Custom Solutions	ATCCBioservices@atcc.org

QUALITY CERTIFICATIONS

ISO 9001:2015 BSI Registered Certificate No. FM 516121	ISO/IEC 17025:2017 ANAB Registered Certificate No. AT-1383
ISO 13485:2016 BSI Registered Certificate No. FM 610678	ISO 17034:2016 ANAB Registered Certificate No. AR-1384

Refer to current certifications on our website for certificate expiration information.

https://www.atcc.org/en/About/About_ATCC/Quality_Accreditations.aspx

QUALITY SYSTEMS

Section I – Quality Management System	
AREA/PROCESS	
Does the ATCC allow onsite audits for catalog item customers?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
Does ATCC allow onsite audits for cGMP-compliant Biorepository Services SM and Custom Solutions customers?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the organization have a Quality Manual?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

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Are annual quality objectives established for the organization?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the organization maintain operating policies and procedures?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the organization have a document management system?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Are procedures reviewed and updated at planned intervals?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is a system in place to track customer complaints?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is an internal audit program maintained?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the organization implement actions to address risks and opportunities?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the organizational structure define quality responsibility and authority?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is the status of the quality management system periodically reviewed by management?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Are quality data and trends reported to management?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the organization have a documented employee training program?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the organization have a calibration program?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is equipment calibrated to traceable measurement standards prior to being put into use?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is nonconforming product tracked and trended?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the organization have a corrective/preventive action program?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the organization have a documented safety program in place?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Section II – Design Information	
AREA/PROCESS	
Are processes validated?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the organization have a master validation plan?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Are records maintained to reflect changes in design and production?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Are changes to design and production verified by quality?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the organization have a formal deviation procedure?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Section III – Procurement Control	
AREA/PROCESS	
Are procurement sources evaluated, approved, and monitored?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
For critical raw materials, are back-up suppliers identified and approved?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Are quality requirements and inspection procedures specified?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the organization maintain a system for the evaluation of purchased materials?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

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Are incoming materials identified and segregated until acceptance?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Section IV – Material Control	
AREA/PROCESS	
Does the organization have a business continuity plan in place?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the organization have provisions for backup power?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Do procedures exist for storage, release, and movement of material?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Are materials identified and controlled?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Do storage areas provide control to protect material degradation?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the organization have backup storage in the event of catastrophic event?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is nonconforming product identified, segregated, and controlled?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Are catalog customers notified of changes to product specifications or raw materials?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
Are custom contract and cGMP-compliant Biorepository Services SM customers notified of changes to product specifications or raw materials?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is a recall notification system in place?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Are certificates of analysis provided for purchased products?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Are any manufacturing processes outsourced?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
Can animal origin documentation be provided?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

The information presented above is typically sufficient for supplier evaluation purposes. Please contact Quality Assurance at QAAssistance@atcc.org for further assistance.