



CUSTOM SOLUTIONS



ATCC® | Credible leads to Incredible™

Custom Solutions

Since 1925, ATCC has set the standard for the manufacture, characterization, preservation, storage, and distribution of biological materials. With more than 3,800 primary, immortalized, and continuous cell lines as well as 85,000 microbial strains, ATCC has the knowledge, experience, and meticulous methodologies to support your custom biological needs. Whether you are looking for the large-scale manufacture of cell lines (master and working cell banks) or a different specification/format than offered in our catalog, ATCC laboratories are able to provide you with customized options grounded in decades of industry knowledge, making ATCC your preferred strategic partner. The ATCC team works with you through all stages of your custom project process, from the initial inquiry, design, and initiation of your project, to the production, characterization, packaging, storage, and distribution of your biological materials. Project managers work directly with ATCC subject matter experts to design, execute, and monitor your project. This allows you to focus on your core competencies while we focus on what we do best, producing, managing, and delivering the highest quality biological materials, globally.



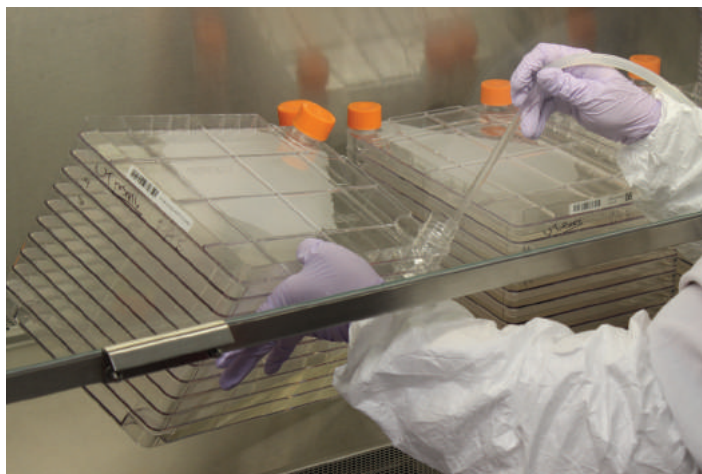
What We Offer

- Over 90 years of experience focused on biological material services and management
- We focus 100% of our resources on sourcing, producing, authenticating, standardizing, storing, and distributing biological materials
- The world's largest, most diverse collection of standardized biological materials
- We are the expert in growing and authenticating cell lines, microbial strains, and derivatives either by using standard production techniques or by developing specifically tailored protocols
- Scale-up of production from several vials up to thousands of vials
- We can produce, extract, and purify related biologicals such as quantitated nucleic acids
- We can provide alternative formats such as cell pellets; formalin-fixed, paraffin-embedded (FFPE) samples; and inactivated microbial strains, which can be used as process controls for molecular assays
- Utilization of a technology-agnostic approach, providing a broad range of expertise with a vast array of targeted analysis platforms
- Specialized laboratories, including BSL-3+ high-containment facilities
- Fill and finish for large-scale cell line production with fully automated vialing and labeling equipment
- With global reach to 150 countries and a network of distribution partners, we have the infrastructure needed to support global operations
- Preservation, (*e.g.*, lyophilization, cryopreservation, flash frozen) storage, and distribution of biological materials
- ATCC is an ISO 9001 certified, ISO 13485 certified, ISO 17025, and ISO 17034 accredited organization

Custom Primary Cell Derivation

ATCC's Cell Derivation Unit produces custom primary cells allowing the capability to study tissue specific characteristics on a cellular level in vitro and to develop more biologically relevant models. Healthy cells, as well as cells derived from diseased tissues such as asthma, COPD, pulmonary fibrosis, diabetes, and many other pathologies can be produced. For each cell type, careful consideration is given to maintain broad donor diversity, robust quality control, lot-to-lot consistency, and large-scale production capacity. Laboratories that may have started to isolate primary cell culture in-house face challenges with lots not being standardized therefore, may be unable to perform inter-laboratory studies and comparisons due to variability among the reagents and procedures used to derive primary cells.

ATCC's project management team can partner with you to develop custom protocols by working to understand your needs, from starting tissue requirements, production, scalability, automated vialing, to storage and distribution.



What We Offer

- Custom primary cells can be produced in large lots, making them ideal for scale-up as ready-to-use cells or ready-to-store for longer term studies
- By removing time dependencies with tissue procurement and isolations, we offer our customers flexibility
- All tissues utilized for human primary cell derivation are ethically obtained with documented, legal permission for research use; upon request, detailed donor information can be provided both for normal and diseased cells
- Characterization with full quality control testing that can include phenotyping by immunocytochemistry (ICC) or flow cytometry
- Offering reagents matched and optimized to work with each primary cell type

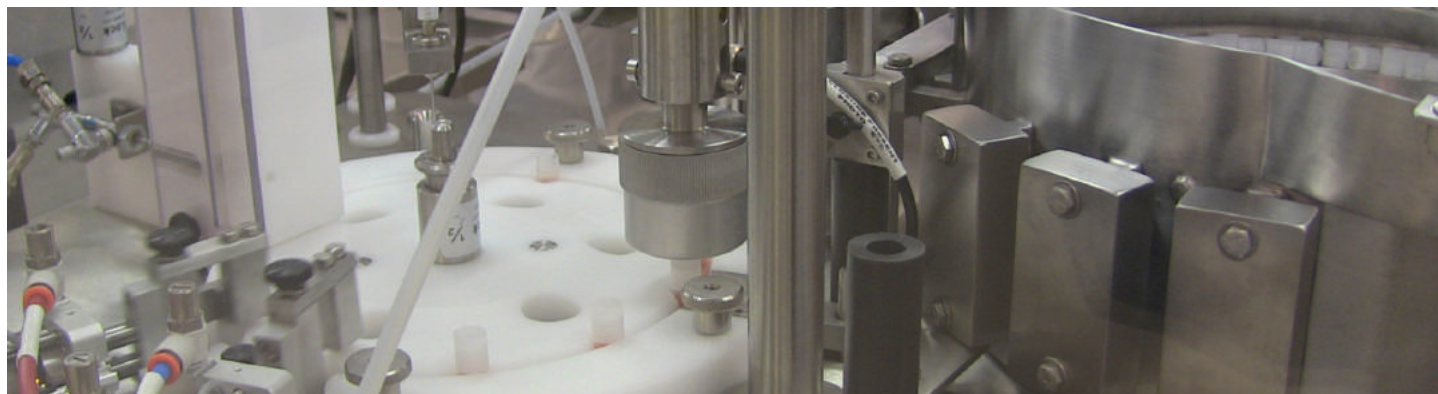
Custom Cell Immortalization Solutions

Immortalized cell lines offer extended proliferative capacity in vitro, while closely mimicking the physiology of cells in vivo. Unlike primary cells, immortalized cells are not susceptible to replicative senescence, reducing the need to repurchase and re-initiate growth, saving time and expense.

ATCC offers cell immortalization services using various technologies such as human telomerase reverse transcriptase (hTERT), which provides stable genotypes of diverse cell types and tissue sources. Immortalized cell lines have an extended lifespan and typically are karyotypically, morphologically and phenotypically similar to the primary parent cells.

What We Offer

- Custom immortalization services produce cell lines that have an extended lifespan and typically are similar to the primary parent cells
- The ability to overcome the limited lifespan of primary cells by combining our custom cell derivation service with our custom cell immortalization service
- In addition to standard ATCC cell authentication testing, immortalized cell lines can be tested for extended proliferative capacity and selected phenotypic markers from the tissue of interest (*e.g.*, the continuous expression of hTERT)
- Experienced project managers and subject matter experts will work with you to produce an immortalized cell line tailored to your requirements

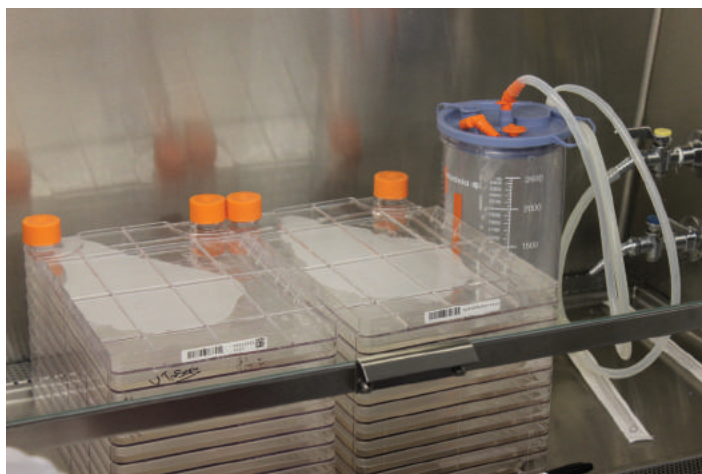


Custom Cell Banking/ Cell Line Manufacturing

ATCC was entrusted with its first cell line in 1962 and has consistently maintained the highest standards, using the most reliable and standardized procedures to manufacture continuous lines. We offer expert capabilities for the preparation and characterization of master and working cell banks, either from ATCC cell lines or your proprietary cell lines. Whether it is the preliminary testing of seed stocks, cell line production, cell bank characterization, or testing and storage services, our experienced team is ready to meet your cell banking needs.

What We Offer

- Flexible manufacture of your cell lines or ATCC cell lines by working with you to define cell culture conditions, preliminary testing of your seed stocks, production, scalability, automated vialing, storage, and distribution
- Comprehensive quality control analysis of your cell line by ATCC experts
- Scalable production from several vials up to thousands of vials
- Fill and finish of both small- and large-scale cell line production with our fully automated vialing and labeling equipment
- ISO/IEC 17025 accredited process for quality control tests
- Storage and global distribution



Cell Authentication Solutions

ATCC is the leader in delivering standardized methods for cell line authentication used to test for contamination and identity. Authentication of a cell line is the sum of the processes by which a cell line's identity is verified and shown to be free of contamination from other cell lines and microbes. Using standardized techniques for authentication, we can ensure valid and reproducible results. ATCC is at the nexus of the recognized problem of cell line misidentification and offers standardized methods to ensure cell line identity and quality.

What We Offer

ATCC offers numerous tests to authenticate your cell lines. These can be ordered separately or as quality control testing with the production of cell banks.

- Viability (*e.g.*, Trypan blue dye exclusion)
- Sterility (testing for the absence of bacteria and fungi)
- Mycoplasma (PCR as well as direct and indirect culture assays)
- STR (short-tandem repeat) profiling of human cell lines and mouse cell lines to confirm identity
- Animal species identification (Cytochrome Oxidase C1 barcoding; multiplex PCR CO1 testing)
- Viral testing (HIV, Hepatitis B, HPV, EBV, and CMV)
- Phenotyping by ICC or flow cytometry and molecular assays (*e.g.*, NGS and target sequencing)
- Comprehensive analysis of your cell line by ATCC experts in cell authentication
- ISO/IEC 17025 certified process for quality control tests



Custom Production of Biological Controls and Derivatives from Cell Cultures and Microbial Strains

ATCC designs and produces external controls and derivatives in a variety of formats to verify, validate, and/or routinely monitor the performance of workflows and assays. We custom extract, produce, and purify related biologicals such as both qualitative and quantitated nucleic acids, and we provide alternative formats such as cell pellets; formalin-fixed, paraffin-embedded samples; and inactivated microbial strains, which can be used as whole process controls for molecular assays.

Nucleic Acids

If you can't find the nucleic acid that you need from ATCC catalog products currently available, ATCC can produce it for you, either small or large scale. Larger-scale custom native or synthetic nucleic acids can be quantified by genome copy number using Droplet Digital PCR and produced under ISO 9001 certified as well as ISO/IEC 17025 accredited processes, ensuring consistent results with each assay.

Native

Small-scale quantities of nucleic acids from ATCC Genuine Cultures are ideal for the quality control of molecular-based assays. If you require larger quantities of nucleic acids, we can grow, extract, and purify nucleic acids from most ATCC cell and microbial cultures or your own internal cultures, either qualitative or quantitative. Custom nucleic acids at any scale are prepared from minimally passaged ATCC cell lines and microorganisms that have been phenotypically and genotypically authenticated to confirm species identity and functional activity. These whole-genome preparations save you the cost and time associated with culturing and extracting nucleic acids yourself.

Synthetic

ATCC now offers the custom production of synthetic microbial nucleic acids. Nucleic acids that represent clinically relevant organisms that cannot be reliably cultured in vitro, such as Hepatitis C, *Treponema pallidum*, and Norovirus can be developed and provided in either a qualitative or quantitative format.

The ATCC team of experts in microbial genomics will work with you to design and develop key consensus target regions that will align with your primers. Multiple sequence alignment allows for the development of a consensus sequence that is used to synthetically build the finished product. Each custom preparation is supported by stringent quality control analyses to ensure product identity, stability, and functionality with molecular applications.

What we offer

- Nucleic acids (Genomic DNA and RNA from mammalian cell lines, genomic DNA from microbial strains, DNA/RNA from viruses)
- Both small- and large-scale extraction of nucleic acids
- Qualitative or Quantitative formats available from large-scale preps
- Quantitative format allows for generation of a standard curve and monitoring assay-to-assay and lot-to-lot variation
- Native nucleic acids extracted from ATCC cell lines or microbial strains
- Custom production of synthetic microbial nucleic acids

Other Custom Mammalian Cell Derivatives:

- Custom production of cell pellets from ATCC cell lines or your own cell lines
- Formalin-fixed, paraffin-embedded blocks from ATCC cell lines
- Custom production of exosomes from ATCC cells or your own cells

Other Custom Microbial Strain Derivatives:

Inactivated microbial cultures

What We Offer

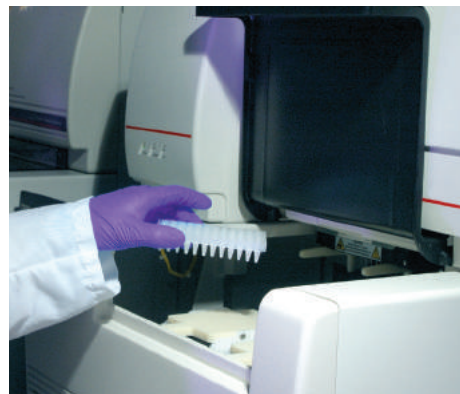
- Custom inactivation of bacterial, fungal, viral, and parasitic strains available
- Fully intact, whole genome, non-viable
- Inactivation is tested and verified and a Certificate of Analysis (COA) is provided
- Mimics a clinical specimen, can be used in protocols identical to clinical samples
- Can be used as independent external controls to routinely monitor the performance of your workflows and assays
- We can provide a qualitative or quantitative format
- Both pre- and post-inactivation quantitation available by Droplet Digital PCR
- Quantitative format allows for generation of a standard curve and monitoring assay-to-assay and lot-to-lot variation

Custom Microbial Manufacturing

ATCC was established in 1925 with the first bacterial strain and has consistently attained the highest standards, using the most reliable, consistent protocols to manufacture and characterize microbial strains. We offer expert capabilities for the preparation, quality control, and preservation of microbial cultures, either from ATCC catalog cultures or your own microbial cultures. Whether it is the culture expansion, quality control testing, preservation, packaging formats, or storage and distribution services, our experienced team is ready to meet your microbial production needs.

What We Offer

- Flexible manufacture of your microbial strains or ATCC strains, working with you to define and standardize culture conditions, scalability, quality control testing, preservation methods, packaging, and storage and distribution
- Comprehensive quality control analysis of your microbial strain by ATCC experts
- Scalable production from several vials up to thousands of vials
- Fill and finish of both small- and large-scale production with our automated vialing and labeling equipment
- ISO/IEC 17025 accredited processes available for quality control tests, including both phenotypic and genotypic tests
- Storage and global distribution



Custom Microbial Quantitation Solutions

ATCC offers several custom solutions to quantitate microbial strains including titering, qPCR, and Droplet Digital PCR. These tests can be ordered separately or as part of the quality control testing with the production of microbial banks.

Viral quantification is also available to determine infectious virus particles in a sample. As appropriate, tissue culture infective dose (TCID₅₀), chicken embryo infectious dose (CEID₅₀) and the plaque assays are utilized for measuring the number of plaque forming units (PFU) are methods used for viral titering at ATCC. Bacterial and fungal cultures are titered via determining the number of colony forming units per milliliter (CFU/mL) and protist cell counts are measured per volume, typically cells/mL, qPCR, and Droplet Digital PCR are measurements methods that measure target nucleic acid copies per input sample. If you are developing molecular based assays and need quantification such as CFU/mL or TCID₅₀ for analytical sensitivity, reactivity and specificity studies, please engage our experts to grow and quantify microbial strains for you. Whether you need one or many strains grown and quantitated, we offer the complete solution.



What We Offer

- TCID₅₀ quantifies the amount of virus required to produce a cytopathic effect in 50% of inoculated tissue culture cells.
- CEID₅₀ for viruses normally propagated in chicken eggs (such as Influenza virus) viral titer is calculated as the chicken embryo infectious dose.
- The viral plaque assay measures the ability of a single infectious virus to form a plaque on a cell culture monolayer. The number of plaque forming units (PFU) is determined per volume of inoculum.
- Bacterial and fungal cultures can be titered via determining the number of colony forming units per milliliter (CFU/mL).
- Quantitation of *Chlamydia trachomatis* strains at ATCC utilizes the IFU (inclusion forming unit) assay method to determine the titer. The IFU Assay determines the number of infectious units (elementary bodies) per preparation, by counting the number of inclusion bodies produced by elementary bodies in a dilution set.
- Hemocytometers are commonly used to determine protist cell density, which is reported as the number of cell counts per volume, typically cells/mL.
- qPCR and Droplet Digital PCR are quantitation methods used at ATCC for the quantitation of viral, bacterial, fungal, and protist strains as well as nucleic acids.
- qPCR allows for the determination of the copy number of template DNA with accuracy and high sensitivity.
- Quantification by genome copy number using Droplet Digital PCR provides an absolute count of target DNA copies per input sample without the need for running standard curves, making this technique ideal for measurements of target DNA, viral load analysis and microbial quantification.
- Offering flexible solutions, we can produce and titer from one to several vials in ready to use frozen formats or a format of your choice.
- Pre- and/or post-freeze titers available.

Storage

With over 90 years' experience focused on biomaterial services and management, ATCC has the expertise to store and distribute biological materials worldwide. ATCC offers secure and reliable biological material management with temperature-controlled supply chain, 24/7 equipment monitoring, and on-call after-hours personnel. All of our materials are stored in units that are equipped with monitoring systems and 24-hour surveillance.

What We Offer

- Extensive support to customers needing Master Cell Banks (MCB) and Working Cell Banks (WCB) produced, stored, and distributed to global locations
- Sample processing and analysis
- Offering long-term storage of biomaterials in a secure, controlled, and monitored environment
- Our new specially designed biorepository allows for the large capacity storage of cell lines, microorganisms, and other biological materials
- Flexible storage level choices, sample, box, or freezer
- Short- and long-term storage of small- and large-scale samples; we have managed over 23 million samples
- Inventory management system to assure biomaterial traceability
- ATCC is your trusted source for storage needs as we have a long history of safe operations in storing biological materials
- Both the cGMP compliant and the non-cGMP biorepository services offer secure and confidential storage of valuable materials
- All information concerning stored materials is retained in confidence and all rights to materials remain with the customer
- Biological material is available only to you or a third party that is designated in writing
- We can ship worldwide, either directly to you or to your specified third party



Enhanced features for cGMP-compliant storage

- Dedicated and validated units, with access restricted to cGMP-trained staff with QC and QA oversight
- Tracking labels are supplied to ensure the proper segregation immediately upon receipt at ATCC
- Separate storage boxes for each cell bank or multiple banks in one box (customer's option); only one customer per storage box
- Direct QA supervision of all tank entry and retrieval activities

Global Distribution

ATCC has unparalleled experience in the packing and shipping of biological materials, with a dedicated staff of customer care representatives who handle phone and web contacts and technical support staff that handle requests for technical assistance from our customers. ATCC can reliably ship your material worldwide. Our ability to provide material to the international community is supported by a global network of distributors and by direct shipment.

- ATCC has knowledge of the regulations for all countries we ship to, including compliance with U.S. export and import requirements permits and licenses
- We pack and ship biological material to over 150 countries each year and move biomaterials efficiently and safely from our facility directly to our customers and distributors



Engage Us Today!


For more information on our Custom Solutions, visit www.atcc.org/services or contact us at atccbioservices@atcc.org.

For information on our Biorepository Service, visit www.atcc.org/biorepository or contact us at biorepository@atcc.org.



CREDIBLE TECHNIQUE INCREDIBLE TRIUMPH

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