

THE ESSENTIALS OF
LIFE SCIENCE RESEARCH
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cGMP SAFE DEPOSIT SERVICE

Cell cultures, microorganisms, and other biological materials are valuable assets to organizations, and loss of these materials can be costly. Redundant storage is essential for the long-term security of biological materials. The experts at ATCC have been providing safe deposit services for corporations, government laboratories, and academic institutions for over 30 years, and we will store your proprietary materials efficiently, reliably, and confidentially, in full compliance with current good manufacturing practices (cGMP).

SECURITY

- Our facility is specially designed for large-capacity storage of cell lines, microorganisms, and other biological materials
- ATCC has a long history of safe, trouble-free operation
- All materials are stored in liquid nitrogen tanks equipped with monitoring systems and 24-hour surveillance to safeguard stored material

CONFIDENTIALITY

- All rights to cultures remain with the depositor
- All information concerning deposited material is retained in confidence
- Culture material is available only to the depositor or an individual designated in writing by the depositor

COMPLIANCE

- The liquid nitrogen tanks are dedicated and validated. Access is restricted to cGMP-trained staff with QA oversight
- Tracking labels are provided for your shipment to ensure segregation of cGMP materials immediately upon arrival at ATCC
- All freezer entry and retrieval activities are supervised and verified by QA personnel
- Specially trained employees perform all cGMP duties

cGMP SAFE DEPOSIT ENHANCED FEATURES

- Dedicated and validated liquid nitrogen tank with access restricted to cGMP-trained staff with QA oversight
- Tracking labels for your shipment to ensure segregation of cGMP materials immediately upon receipt at ATCC
- Separate storage boxes for each cell bank or multiple banks in one box (depositor's option). Only one customer per storage box
- Direct QA supervision of all freezer entry and retrieval activities



Quality Summary for cGMP Safe Deposit

STORAGE CONDITIONS

ATCC offers three storage temperature options: liquid nitrogen -145°C or lower; -80°C; and 2°C to 8°C cold room. Safe deposit materials are stored in vapor phase of liquid nitrogen tanks and validated by measuring the temperature in the inventory space under actual working conditions. Dedicated tanks are used exclusively for cGMP safe deposit material, and mammalian cell banks are segregated from microbial cell banks. These tanks are physically separated from other tanks in ATCC's repository. Depositors may choose separate storage boxes for each cell bank or place multiple banks in one box. Only one customer uses each storage box.

EQUIPMENT

Individual freezer, tank and cold room temperatures are monitored and a facility-wide alarm system indicates when temperatures are out of range. The alarm system is monitored by designated ATCC staff and the ATCC security guard 24 hours a day. The alarms are also monitored by an off-site central service, and redundancy includes several levels of staff equipped with pagers and cell phones that are on call for immediate response to any alarm conditions. Back-up units are available if equipment failure necessitates relocation of the inventory.

STAFF

All ATCC staff who handle deposits submitted for cGMP storage and who process the documentation associated with them are trained in cGMP regulations and in the specific SOPs for their activities, including how to make process changes and initiate corrective actions. All support staff who maintain the tanks and alarm systems and who perform equipment validations and proper handling of material stored at cryogenic temperatures are trained in cGMP compliance.

SECURITY

A security guard is on duty at the ATCC facility 24 hours a day, 7 days a week. Access to the liquid nitrogen repository is limited via a controlled and monitored electronic entrance system. The liquid nitrogen tanks containing the safe deposit culture material are locked and accessed only by authorized staff.

CONFIDENTIALITY

Information received by ATCC on cultures submitted for safe deposit will be maintained in confidence to the extent possible. Except as provided by law, information will not be released to any third party without prior written permission from the depositor. Under no circumstances will material be released to any party unless authorized by the depositor.

The identity of all depositors is held in confidence by ATCC. To ensure that this confidentiality is not breached, we take every precaution when requests for information or culture material are received. All requests should be made in writing on the depositor's stationery and signed by an individual who is familiar to ATCC.

PROPRIETY

All material submitted to ATCC for safekeeping remains the property of the depositor. ATCC will not release the material or use it in any way unless specifically requested in writing by the depositor.



10801 University Blvd.
Manassas, VA 20110

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PHONE

800.638.6597
703.365.2700

EMAIL

safedep@atcc.org

WEB

www.atcc.org