

US – UNITED STATES OF AMERICA

AMERICAN TYPE CULTURE COLLECTION (ATCC)

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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

Algae, animal viruses, animal cell cultures, bacteria (pathogenic and nonpathogenic), bacteriophages, embryos¹, DNA, fungi (pathogenic and nonpathogenic), human cell cultures, hybridomas, oncogenes, plant cell cultures, plant viruses, plasmids (in host and not in host), protozoa (nonparasitic, parasitic and pathogenic), RNA, seeds and yeasts (pathogenic and nonpathogenic).

The highest acceptable containment level for deposits is biosafety level (BSL) 3 as described in the current edition of the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories*.

When materials to be deposited cannot be tested for viability *in vitro*, ATCC should be contacted for guidance on whether or not the material can be accepted. In addition, some material may require special permits for transport to ATCC, and ATCC should be contacted in advance for assistance.

CDC = U.S. Centers for Disease Control and Prevention
NIH = U.S. National Institutes of Health

¹ ATCC must be notified before sending.

(b) Technical Requirements and Procedures

(i) Form and Quantity

ATCC does not accept test tubes or other actively growing cultures. The number of replicates that must be provided by the depositor when making the deposit is as follows:

Microorganisms (either containing a plasmid or not containing a plasmid), including bacteriophages, fungi, algae, yeast and protozoa	25 cryopreserved or freeze-dried vials from same harvest (0.5 ml per vial)
Cell lines and hybridomas	25 cryopreserved vials from same harvest (2 – 6 million cells per vial)
Plasmids ¹ and vectors not in host (e.g., purified DNA, libraries associated rDNA material)	25 vials (100 ng per vial)
Animal and plant viruses	25 cryopreserved or freeze-dried samples (1 ml per vial)
Plant tissue cultures	25 cryopreserved vials. Must be callus tissue. Seed preferred
Seeds	25 packets (25 seeds per packet)

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by the ATCC will differ dependent on the type of material and the testing procedures provided by the depositor.

(iii) Depositor Checks and Renewal of Stocks

The ATCC generally does not prepare its own batches of material. In such cases, the depositor is responsible for replenishing the stock to ensure that there is sufficient stock to make the deposit available to the general public for the required period of deposit. However, ATCC may prepare additional samples whenever necessary for the renewal of distribution stocks.

¹ For plasmids, “viability” testing consists of inserting the plasmid into a host. If the host is transformed, the “viability test” is regarded as positive.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the ATCC is English. Communications in any other language are not accepted.

Contract. The ATCC does not enter into any written contract with the depositor defining the liabilities of either party, except in the case of certain dangerous organisms, where the depositor must agree to accept and handle them at his own risk. Also, by completing the ATCC BP/1 deposit form, the depositor surrenders any right to withdraw his deposit during the required storage period and accepts that the microorganism will be distributed according to the relevant patent requirements.

Import and/or Quarantine Regulations. The ATCC may need to obtain an import or domestic transfer permit from an US regulatory agency for the import of material into the United States or transfer across state lines

The ATCC will advise prospective depositors about import and quarantine regulations and the procedures that must be followed. Information may also be obtained from the Veterinary Services and/or the Plant Protection and Quarantine Biological Assessment Support Staff both at the US Department of Agriculture, Animal and Plant Health Inspection Service, and from the Department of Health and Human Services, Public Health Service, Office of Biosafety at the Centers for Disease Control.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. Depositors are required to complete ATCC form BP/1 “Budapest Treaty Deposits” in all cases. In the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, and a request for attestation that the ATCC has received such information, the depositor must complete ATCC form BP/7-8.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and 9, which are combined in form BP/4-9. Attestation of receipt of a later indication or amendment of the scientific description and/or proposed taxonomic designation is issued on form BP/7-8. Notification of release of a sample to a third party is issued on form BP/14. Standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor.

Supply of Information to a Patent Agent. The ATCC asks that the depositor supply the name, address, phone, fax number and email of the patent attorney or agent. The ATCC sends copies of the certificates and notifications to the depositor’s attorney or agent as indicated on the form BP/1.

(iii) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits, whether or not they were originally deposited

for patent purposes. However, any deposits previously made free of charge are subject on conversion to the storage fees normally levied for Budapest Treaty deposits. The administrative requirements for conversion are the same as those required for an original deposit made under the Treaty, except that requirements relating to import and/or quarantine procedures do not apply.

(iv) Making a New Deposit

New Deposit

In the event that the ATCC determines that a biological material is no longer viable, although originally found viable upon initial deposit, the depositor may replace the nonviable deposit with a new deposit. The deposit will retain its initial deposit number and date as long as (1) the replacement deposit is viable, (2) the ATCC receives the replacement deposit within three months of receipt by the depositor of the notification of nonviability, and (3) the ATCC receives a statement signed by the depositor alleging that the newly deposited biological is the same as that originally deposited. The only charges are for viability testing.

Supplemental Deposits

In the event that the ATCC determines that the deposit, although still viable, no longer retains the characteristics as originally thought, the depositor will be asked to provide a Supplemental Deposit. This deposit will obtain a new date and a new accession number. All the normal forms for deposit must be filled out and the regular fees for an original deposit apply.

2. Furnishing of Samples

(a) Requests for Samples

Generally, availability of the biological material is required only after the issuance of a pertinent patent. Prior to that time, the deposit need only be made available to a requesting party if (1) the Commissioner of the United States Patent and Trademark Office, in accordance with 35 U.S.C. paragraph 122, issues a decision to release such deposit; (2) the patent office of another country signatory to the Budapest Treaty issues such a decision to release the deposit to a particular requesting party; or (3) the original depositor requests in writing that the deposit be released to a particular requesting party. The ATCC will provide requesting parties with form BP/12 or request forms used by an individual industrial property office.

Notwithstanding any entitlement of third parties to receive samples under patent regulations, the ATCC will withhold samples of organisms that are subject to health and safety regulations until it has confirmed that the requesting party can comply with such regulations. For organisms considered potentially very dangerous, the requesting party must sign an assurance of acceptance of responsibility. Also, in some cases a permit is required to work with certain material in the United States of America, and a requesting party in the United States of America must obtain such a permit before he can receive a sample. If a valid request is received from overseas for a sample of a microorganism that would require a permit to be worked with in the United States of America, the ATCC advises the requesting party to check the import requirements of his own country. If the ATCC knows that a country requires an import permit for a microorganism (even if the United States of America does not), it will so advise a requesting party in that country.

(b) Notification of the Depositor

The ATCC offers a notification service in which a depositor is notified on form BP/14 of the deposit furnished to a third party. For the fee relating to this service, see below under 3 (Schedule of Fees).

3. Schedule of Fees

	<u>USD</u>
(a) Storage and issuance of a viability statement:	2,500
- 30 years of storage and notification of request	
- Issuance of a viability statement	
(b) Furnishing of a sample	
- All ATCC Cultures	per item
- US Non-Profit Institutions	86 ¹ to 281 ¹
- Foreign Non-Profit Institutions	86 ¹ to 281 ¹
- Other US and Foreign Institutions	107 ¹ to 330 ¹
Biosafety Level 1	21 to 107
Biosafety Level 2	90 to 310
Biosafety Level 3	90 to 310

Because of the diversity of ATCC holdings, and the requirements for complicated and varied culture media and growth conditions, the fees for furnishing ATCC cultures vary. Therefore, the current fees have been listed as a range representing all currently available ATCC cultures.

4. Guidance for Depositors

The ATCC publishes a brochure giving details of its requirements and practices for the deposit of cultures for patent purposes.

¹ Additional handling and processing – dependent on destination and hazard level.