

AU – AUSTRALIA

LADY MARY FAIRFAX CELLBANK AUSTRALIA (CBA)

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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

CBA will accept for deposit, human and animal cell lines and hybridomas that can be preserved in liquid nitrogen vapour without significant damage to or loss of their properties or viability.

CBA will not at this time accept for deposit, genetically modified organisms requiring physical containment level 3 or 4 (PC3 or PC4). Deposits should be accompanied by a favourable Biohazard Risk Assessment statement.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Human and animal cell lines and hybridoma must be submitted to CBA for deposit in the form of frozen cultures. CBA may refuse deposits that have not been packed in sufficient dry ice to keep them frozen during transit.

The minimum number of replicates that must be provided by the depositor when making the deposit is 12. All hybridoma, human and animal cell cultures must contain at least 4×10^6 cells/ampoule.

Any requests to deposit human embryo stem cell lines will be subject to current Australian Government regulations and guidelines.

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by CBA is given below, but depositors should realize that, in some cases, viability testing might take longer. Customers will be advised of this prior to deposit being accepted.

Animal cell cultures	10 days (or up to 15 days)
Human cell cultures	10 days (or up to 15 days)
Hybridoma cultures	10 days (or up to 15 days)

(iii) Depositor Checks and Renewal of Stocks

CBA generally does not prepare its own batches of the deposited organisms, and when the furnishing of samples depletes stocks, the depositor will be asked to make a new deposit. The depositor is asked to check the authenticity of samples prepared by CBA.

(c) Administrative Requirements and Procedures

(i) General

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

Contract. The CBA application form, which the depositor is required to complete, binds the depositor:

- to provide material only in the required form and quantity;
- to provide a biohazard statement;
- to pay all necessary fees including all charges for the transportation of deposits to CBA;
- to observe the terms and conditions of the Budapest Treaty;
- to accept the terms and conditions of deposit of samples in CBA.

Import and/or Quarantine Regulations. Deposits must be covered by the appropriate regulatory documentation before being accepted. The customer will be advised to obtain the regulatory documentation once CBA has received a biohazard statement from the customer.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. As well as the CBA application form referred to in (i), above, the depositor must complete a CBA deposit form and biohazard statement (available on the CBA website).

At least 48 hours before the microorganism is dispatched, CBA must be informed of the number of ampoules being sent, the method of transportation and the estimated time of arrival. If dispatch is by air, CBA must be told the flight number and destination, waybill number and handling agent for delivery.

CBA does not require a special form to be completed in the event of a later indication or amendment of the scientific description and/or proposed taxonomic designation, or for a request for attestation that CBA has received such information.

Official Notifications to the Depositor. The receipt and viability statement are issued on mandatory “international forms” BP/4 and BP/9, respectively, but standard forms are not used for other official notifications.

Unofficial Notifications to the Depositor. If requested, CBA will telephone, fax or email the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The result of the viability test will be communicated before the issue of a viability statement only where the viability of the deposit is unacceptably low.

Supply of Information to a Patent Agent. CBA does not routinely ask the depositor for the name and address of his or her patent attorney. However, if requested, it will send copies of the receipt and viability statement to both the depositor and the patent attorney.

(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 are subject, on conversion, to the storage fee normally levied for Budapest Treaty deposits.

The administrative requirements for conversion are the same as those to be met in respect of an original deposit, except that requirements relating to shipping procedures do not apply.

(iv) Making a New Deposit

The depositor is required to complete the CBA deposit form and biohazard statement when making a new deposit, to send copies of the relevant documents and declaration (Rule 6.2) and to conform to the procedures mentioned previously in respect of shipping requirements.

2. Furnishing of Samples

(a) Requests for Samples

CBA does not advise requesting parties of the correct procedures to follow in order to make a valid request and does not supply copies of request forms in the case of requests requiring proof of entitlement. Such forms must be obtained from the relevant intellectual property office.

Notwithstanding any entitlement of third parties to receive samples under patent regulations or by written authorization of the depositor, CBA will withhold samples of potentially hazardous microorganisms until the requesting party has confirmed that it has the appropriate containment facilities to handle such organisms.

When responding to requests from overseas, CBA assumes that the requesting party has met the import requirements of their own country, and the customer is responsible for provision of the relevant documentation to do so.

Samples furnished by CBA are usually from preparations supplied by the depositor.

(b) Notification of the Depositor

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

CBA does not list Budapest Treaty deposits in its published catalogue.

3. Schedule of Fees

1. <u>Cell lines</u>	Australian dollars
For the storage of the microorganism in accordance with the Treaty, including certification and viability statement	2,600
Issuance of a new or updated viability statement	170
2. <u>General</u>	
Furnishing of a sample (excluding shipping costs)	210
Issuance of (new or amended) certification	110
Administration fee for amendments	110

Fees plus GST, where applicable, are payable to CellBank Australia.

4. Guidance for Depositors

Guidance for depositors is provided on the CBA application form and CBA website (www.cellbankaustralia.com)