

IT – ITALY

OSPEDALE POLICLINICO SAN MARTINO IRCCS

Interlab Cell Line Collection (ICLC)
UOS Centro Risorse Biologiche
IRCCS Ospedale Policlinico San Martino
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1. Requirements for deposit

(a) Kinds of Microorganisms that may be Deposited

Human and animal cell lines and hybridomas, provided that they can be stored in liquid nitrogen vapors, without any significant loss of viability. The genetically modified cell lines are also accepted if they belong to category 1 of genetically modified microorganisms, and if they have been registered by the depositor. No deposits are accepted of cell lines and hybridomas beyond category of containment 2.

The ICLC reserves the right to refuse any material whose manipulation represents an unacceptable risk or technical difficulty. The ICLC requests that a form on the cell line/hybridoma characteristics be filled in on deposit.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Cell lines and hybridomas. At least 12 frozen ampoules must be provided for each cell line deposited, containing not less than 2×10^6 cells per ampoule. The ampoules must be sent with a quantity of dry ice sufficient to remain frozen during the transport. If the package is found inadequate, the culture will not be accepted.

(ii) Time Required for Viability Testing

The average delay needed for the control of viability of the cell lines and hybridomas is of 10-14 days (the depositors should be aware that in some cases the control may take longer).

(iii) Depositor Checks and Renewal of Stocks

In general, the Ospedale Policlinico San Martino IRCCS does not prepare its stocks of cell lines/hybridomas, and when the stocks are exhausted because of the delivery of samples, it requests the depositor to make a new deposit. In some special cases, by an agreement with the depositor, the Ospedale Policlinico San Martino IRCCS can prepare its stocks of the material, asking the depositor to verify the authenticity and quality of the material.

(c) Administrative Requirements and Procedures

(i) General

Language. The official language of the Ospedale Policlinico San Martino IRCCS is Italian. Deposits are also accepted in English and French.

Contract. The depositor must fill in a form in which he declares his agreement on the following:

- to deposit the material only in the required form and quantity;
- to indicate the characteristics of the cell line/hybridoma relating to danger and pathogenicity;
- to pay all required fees, including the postal expenses for the shipment(s) of the cell line/hybridoma to the Ospedale Policlinico San Martino IRCCS;
- to comply with the requirements of the Budapest Treaty;
- to comply with the requirements of the Ospedale Policlinico San Martino IRCCS concerning the deposit of microorganisms.

Import and/or Quarantine Regulations. The kind of material accepted for deposit by Ospedale Policlinico San Martino IRCCS is not required to follow any particular rule.

(ii) Making the Original Deposit

Requirements to be Met by the Depositor. The depositor is required to fill in a deposit form which includes a declaration on the pathogenicity of the cell line/hybridoma.

Forty eight hours before shipping the material, the depositor must inform the Ospedale Policlinico San Martino IRCCS about the number of samples sent for deposit, the means of transport chosen and the expected time of arrival. If the material is sent by air, the Ospedale Policlinico San Martino IRCCS must be informed of the flight number, destination, number of bill and carrier.

Official Notifications to the Depositor. The receipt and the viability statement are issued on mandatory “international forms” BP/4 and BP/9.

Unofficial Notifications to the Depositor. If requested, the Ospedale Policlinico San Martino IRCCS will communicate by telephone the date of deposit and the accession number of the cell line/hybridoma, before the official receipt is issued.

Supply of Information to a Patent Agent. If requested, the Ospedale Policlinico San Martino IRCCS will send a copy of the viability statement to the patent agent.

(iii) Converting a Previous Deposit

Deposits made outside the Budapest Treaty can be converted by the original depositor to deposits under the Budapest Treaty. In this case, the fees normally payable under the Budapest Treaty are due. The other requirements are the same as for an original deposit.

(iv) Making a New Deposit

When making a new deposit, the depositor must fill in a deposit form which includes a declaration on the pathogenicity of the cell line/hybridoma, and the depositor must send a copy of the documents and of the declaration indicated in Rule 6.2. As to the shipment, the depositor must follow the technical requirements and procedures described in point 1(b) above.

2. Furnishing of Samples

(a) Requests for Samples

The Ospedale Policlinico San Martino IRCCS does not inform the requesting parties about the procedure to be followed for the request, and does not provide the forms of request which can be obtained from the relevant Patent Offices.

The Ospedale Policlinico San Martino IRCCS assumes that the requesting parties have satisfied all the national requirements concerning importation.

(b) Notification to the Depositor

When Ospedale Policlinico San Martino IRCCS delivers samples of the deposited microorganisms to third parties, it notifies the depositor by letter.

(c) Cataloguing of Budapest Treaty Deposits

The Ospedale Policlinico San Martino IRCCS does not include the deposits made under the Budapest Treaty in its catalogs.

3. Schedule of Fees

	<u>EUR</u>
Cell lines and hybridomas	
(a) Storage	1,350
(b) Issuance of a viability statement	100
(c) Furnishing of a sample	150
(d) Communication and request of authorizations to the competent authorities	130

4. Guidance for Depositors

The forms of the Ospedale Policlinico San Martino IRCCS for the deposit contain the recommendations for the depositors.