

## **Service Level Agreement between the Eurotransplant Reference Laboratory and the Tissue Typing Laboratory in Leiden**

**The Eurotransplant Reference Laboratory (ETRL)** is the leading organizer for transplantation related immunological proficiency testing in Europe. It is the link between Eurotransplant and the tissue typing laboratories affiliated to transplantation centres collaborating within the framework of Eurotransplant, or to countries exchanging organs with Eurotransplant.

The main activities of the ETRL are:

1. Organization of the External Proficiency Testing (EPT) including the release of the certificates of fulfilment and/or participation.
2. Organization and supervision of the Acceptable Mismatch (AM) program for highly sensitized patients.
3. Provision of immunological back-up for all transplant centres and the Eurotransplant allocation office.
4. Quality assurance and training of all tissue typing laboratories affiliated to Eurotransplant, as well as training and guiding of new laboratories and/or laboratories situated in possible future member states of Eurotransplant.
5. Performing histocompatibility related assays for laboratories not accredited by the European Federation for Immunogenetics (EFI), situated in future member states of Eurotransplant.

**The Tissue Typing Laboratory in Leiden (NLBTT)** is a renowned EFI accredited laboratory for histocompatibility testing, including HLA typing at low, medium, and high resolution level, screening for transplantation relevant antibodies, as well as crossmatching. For Eurotransplant related activities, NLBTT has the same responsibilities and competences as any other Eurotransplant-affiliated laboratory.

The ETRL and NLBTT agree that for the following activities ETRL can utilize the facilities, infrastructure and knowledge of the NLBTT. The responsibilities for these activities are as follows:

### 1. External Proficiency Testing:

ETRL:

- The EPT manager notifies the senior technician of the NLBTT screenings lab on the shipment dates of the upcoming EPT exercises in a timely manner. In case of potential planning issues, the senior technician of the NLBTT screenings lab will directly contact the EPT manager. Practical issues regarding the shipment will be discussed with the personnel from NLBTT that are directly involved with the shipment.
- Release the information on the shipment dates of upcoming EPT exercises.
- Inform NLBTT on the required number of samples for EPT exercises.
- Select blood samples for HLA typing and crossmatch EPT exercises.
- Select sera from the serum bank for screening and crossmatch EPT exercises.
- Active participation in the shipment of EPT samples by the EPT manager, and final inspection of the samples to be shipped by the managing director or the deputy EPT manager.
- Analysis of the data reported by the participants.

- Report the results to the participants.
- Release certificates at the end of every calendar year.

NLBTT:

- Provide support in logistics of EPT sample shipment following the appropriate SOP.
- Perform reference testing of EPT samples upon request.
- Prepare IgM control serum.

## 2. Acceptable Mismatch program:

ETRL:

- Evaluate eligibility of all patients submitted to the AM program.
- Is responsible for the administration and providing information to the NLBTT about the patient samples to be tested for the AM program.
- Evaluate all relevant histocompatibility data and accept or deny patients for inclusion into the AM program following the Eurotransplant manual Chapter 10.
- Inform the transplant centres on the decision regarding eligibility for the AM program, and request the signed acceptance form when appropriate.
- Enter the patients into the AM program and make changes in histocompatibility status when required.
- Perform data analyses with respect to all matters affecting the AM program.
- Release specifications and SOP for the AM program.

NLBTT:

- Is responsible for taking delivery, processing and storage of patient samples requested by ETRL following the appropriate SOP. In case of uncertainties the NLBTT will contact the ETRL for clarification.
- Perform additional antibody screening and HLA typing for (potential) AM patients if requested by the ETRL.
- Report of the raw data of the results to the ETRL of antibody screening and HLA typing of (potential) AM patients as requested by the ETRL.
- Provide back-up for administrative tasks related to the AM program. This back-up works according to the rules and regulations of the AM program as described in the Eurotransplant manual Chapter 10.

## 3. Immunological back-up

- The ETRL offers a 24/7 immunological back-up for all transplantation related immunological aspects both to the Eurotransplant allocation office and the transplantation centres. This duty is shared between immunologists of the ETRL and NLBTT with a back-up and final responsibility by the ETRL.

## 4. Quality assurance and training of tissue typing laboratories affiliated to Eurotransplant.