

Rules for LABORATORIES participating in External Proficiency Testing (EPT) Exercises – Version 4. These Rules represent the minimum criteria which must be followed in order to conform to the accreditation procedures of EFI. The implementation date for version 4 being 1st January 2008.

1. EFI Standards

The Standards of EFI in their latest version must be followed.

2. Minimum number of samples for EPT per calendar year:

2.1 HLA Serological typing: 10 samples

2.2 HLA DNA Typing (2 / 4 digits): 10 samples

2.3 HLA antibody analysis (detection and /or identification): 10 samples

2.4 Crossmatching: 20 tests

The same samples may be tested for 2/4 digit DNA typing and for HLA antibody detection/identification.

3. Registration:

3.1 The laboratory must participate in EPT scheme(s) to cover all the EFI accredited laboratory applications.

3.2 For HLA typing schemes participants may register for HLA class I typing only or HLA class I and II typing depending on their clinical testing practice.

3.3 Laboratories undertaking DNA based typing may register for: HLA –A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1 and/or DPB1 at low (2 digit) or high (4 digit) resolution level. However, the loci and resolution reported must follow the EFI Standards for the clinical applications performed.

3.4 Laboratories may register for HLA antibody analysis (detection and/or identification) EPT schemes as appropriate for their clinical testing.

3.5 Laboratories may register for crossmatching as appropriate for their clinical testing.

4. Nomenclature :

4.1 Participant laboratories must report their findings using the correct nomenclature relevant to the methodology used.

4.2 The most recently published full WHO Nomenclature Report should be taken as the ‘reference’ baseline nomenclature, i.e. participants will be expected to report their findings in accord with this report as a minimum.

HLA Nomenclature Reports and the HLA Dictionary can be found at www.anthonynolan.org.uk/HIG/index.html . Laboratories can access and download the HLA Nomenclature Reports, HLA Dictionary and HLA Nomenclature Updates from this site.

The following convention for reporting groups of alleles is recommended:

- i Use the published up-to-date HLA nomenclature, see above.
- ii Report alleles fully, e.g. DRB4*0102-0103 and not as DRB4*0102-03 which may be interpreted as DRB4*0102-0103 or as DRB4*0102-0301.
- iii Groups of alleles should be reported as allele x / allele y, where “/” means “or”, e.g. DRB1*0101/0102/0104 means DRB1*0101 or DRB1*0102 or DRB1*0104.
- iv Groups of alleles that include sequential allele numbers may be reported as allele x – allele y, where “-” means “to”, e.g. DRB1*1501-1504 means that the allele in question could be any of the alleles between DRB1*1501 to DRB1*1504 inclusive, i.e. DRB1*1501 or DRB1*1502 or DRB1*1503 or DRB1*1504.
- v For DNA typing schemes report DRB5*, DRB3* and DRB4* and not their serological equivalents, i.e. DR51, DR52 and DR53.

5. HLA Typing:

5.1 Serological or DNA typing (2 digits):

The following must be reported by participants: HLA-A, HLA-B, HLA-DR or HLA-A*, B*, DRB1*. HLA-Cw or Cw* and DQ or DQB1* must be reported if required by the transplant protocol.

For laboratories only routinely performing HLA class I typing (2/4 digits) reporting of class II is optional.

5.2 DNA typing (4 digits):

For class I typing the following must be reported by participants: HLA-A* and HLA-B*. For class II typing HLA-DRB1* must be reported. HLA- Cw*, HLA-DRB3/4/5*, HLA-DQB1*, HLA-DQA1*, HLA-DPA1* and HLA-DPB1* must be reported if required by the transplant protocol. Laboratories performing high resolution DNA typing must report 4 digit allele (s) for those alleles that have a unique sequence within exons 2 and 3 for class I loci and exon 2 for class II loci.

6. **Detection of HLA class I and/or class II antibodies**

The participant must report the presence or absence (i.e. Positive or Negative) of HLA class I and/or class II antibodies and must report the method(s) used.

7. **Identification of HLA class I and/or class II antibodies**

The participant must report the HLA specificities recognized by the serum and the method(s) used.

8. **Crossmatching:**

The participant must report the test results and method(s) used.

9. **EPT documentation**

Participating laboratories must ensure that all EPT related documents including submitted worksheets, EPT summary/scheme reports, participation and performance certificates, outcomes of investigations of any unsatisfactory results, corrective or preventative actions are maintained and are made available to EFI inspectors for assessment.

10. **Laboratory Conduct**

10.1 Laboratories performing proficiency testing must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the reporting deadline has passed. This includes situations in which one Director oversees multiple laboratories.

10.2 Laboratories must not send their own EPT samples or results for analysis to another laboratory until after the reporting deadline has passed.

10.3 EPT samples must be incorporated into the laboratory's regular patient workload and rotated among all testing personnel. The individual testing the samples and the laboratory Director must attest that the EPT samples were tested in the same manner as the patient samples.