

These general rules for External Proficiency Testing (EPT) represent the minimum criteria which must be followed in order to conform with the accreditation procedures of the European Federation for Immunogenetics (EFI).

General Rules for EPT Organisers and Laboratories participating in External Proficiency Testing (EPT) Exercises – Version 3 (effective date 1/1/07)

1. The Standards of EFI in their latest version must be followed.
2. The EPT organiser must provide the minimum number of samples for each EPT, as agreed by the EFI Executive Committee, after the proposal of the EFI EPT Committee and published in the EFI Newsletter.

Minimum number of samples for EPT (both organisers and laboratories) per calendar year:

Serological HLA-A, B, (DR) typing :
10 samples

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

Screening for HLA antibodies :
10 samples

Crossmatching: 20 tests

EPT organisers may use the same samples for more than one of the above. Use of additional samples is optional.

3. A 75% consensus for all serological based EPT must be used by EPT organisers if the Exercise includes more than 15 participants.

The 75% consensus rule only applies for serological based EPT. These are serological typing, screening for HLA specific antibodies and crossmatching.

In cases where less than 15 laboratories participate in an EPT scheme, the results of the majority are regarded as correct.

When there are 15 or more participants the 75% consensus rule must be applied. If a consensus cannot be reached then no discrepancies can be reported.

4. For all DNA based EPT (2-or 4-digits) the HLA typing accepted by the EPT organiser is defined as the correct result.
5. There must be a documented procedure for instances of formal disagreement (including discrepancies) between the EPT organiser and a participant laboratory. Any confirmatory third party testing performed on behalf of the organiser must be done by an EFI accredited laboratory.

6. The EPT organiser must issue an annual EPT certificate to participating laboratories summarising the laboratory's performance in each of the schemes assessed. This document must include the full name of the participating laboratory, the period covered by the EPT, the type of EPT schemes assessed, the total number of samples tested and the number of results in agreement with the organiser. This certificate must be provided on the EPT scheme's headed/official/stamped paper and be sent to the participating laboratory by the 31st January of the following year. Several EPTs can be reported on the same document.

7. The EPT organiser must provide a timetable of sample distribution dates to participating laboratories at the beginning of each calendar year. Any deviations from these dates must also be notified to the participating laboratories.

8. The EPT organiser must make available a prospectus or equivalent document (paper/website) to participating laboratories.

9. HLA Typing :

(i) Serological or DNA typing (2 digits):

The following must be reported by participants: HLA-A, HLA-B, HLA-DR or HLA-A*, B*, DR, or HLA-A*, B*, DRB1*, or HLA-A, B, DRB1*. The report of HLA-Cw or Cw* and DQ or DQB1* is optional. For laboratories only routinely performing class I typing (2/4 digits) reporting of class II is optional.

Examples of possible discrepancies:

1. A participant reports an additional specificity, e.g. the participant reports HLA-A2, A3; B7, B8; and the consensus is HLA-A2, -, B7, B8. This is counted as a discrepancy.
2. A participant does not report a specificity, e.g. the participant reports HLA-A2, A-; B7, B8; and the consensus is HLA-A2, A3; B7, B8. This is counted as a discrepancy.
3. A participant reports another specificity, e.g. the participant reports HLA-A2, A23; B7, B8 and the consensus is HLA-A2, A24; B7, B8. This is counted as a discrepancy.

(ii) 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. Reporting of HLA-Cw*, HLA-DRB3/4/5*, HLA-DQB1*, HLA-DQA1*, and HLA-DPB1* is optional. HLA alleles must be assigned on the basis of differences in exons 2 and 3 for class I and exon 2 for class II, as a minimum requirement.

Examples of possible discrepancies:

1. A participant reports an additional allele, e.g. the participant reports for HLA-A: HLA-A*0202, A*0301 and the correct typing is HLA-A*0201, -. This is counted as a discrepancy.
2. A participant does not report an allele, e.g. the participant reports for HLA-A: HLA-A*0201, – and the correct typing is HLA-A*0201, A*0301. This is counted as a discrepancy.
3. A participant reports another allele, e.g. the participant reports for HLA-A: HLA-A*0201, A*0301 and the correct typing is HLA-A*0201, A*2402. This is counted as a discrepancy.
4. A participant reports a different allele, e.g. the participant reports HLA-A*0102 while the correct typing is HLA-A*0101. This is counted as a discrepancy.

10. 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.

11. Identification of HLA specific antibodies

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

Examples of possible discrepancies:

1. The participant reports an HLA antibody specificity corresponding to an HLA antigen expressed by the serum donor.
2. The participant reports a specificity for a consensus HLA antibody negative serum.
3. The participant fails to report a specificity defined to be the consensus.

12. Crossmatching :

The participant must report the method(s) used.

Examples of possible discrepancies:

1. The participant reports a positive crossmatch where the consensus is negative.
2. The participant reports a negative crossmatch where the consensus is positive.

13. Maximum number of discrepancies allowed for participants in calendar year :

Serological typing:

1 single HLA phenotype discrepancy per 10 samples tested or 10% of the total number of samples tested.

DNA typing 2 digits:

1 single HLA phenotype discrepancy per 10 samples tested or 10% of the total number of samples tested.

DNA typing 4 digits:

1 single HLA phenotype discrepancy per 10 samples tested or 10% of the total number of samples tested.

HLA Antibody Detection:

2 discrepant results per 10 samples tested or 20% of the total number of samples tested.

Crossmatching:

3 discrepant results per 20 tests or 15% of the total number of tests.