External Proficiency Testing evaluation

Table I − *Tools for EPT evaluation*

Tools for EPT evaluation

EFI Standards Version 8.0, approved 28-8-2019

Standards for Providers of External Proficiency Testing (EPT) schemes in H&I Version 7.3, approved April 2021

Manual for inter-laboratory exchanges Version 1-4, approved 9-5-2018

Application file Accreditation EFI and specific addenda

Onsite inspection: check-list, Inspector report, Commissioner report

Accreditation Committee

EPT Committee

Standards Committee

Table II – Cross-talk between EFI Standards, EPT Provider Standards and the Manual for inter-laboratory exchanges

Topic	EFI Standards Version 8.0, approved 28-8-2019		Standards for Providers of External Proficiency Testing (EPT) schemes in H&I Version 7.3, approved April 2021		Manual for inter-laboratory exchanges Version 1-4, approved 9-5-2018	
	Yes/No	SECTION	Yes/No	SECTION	Yes/No	SECTION
Minimum number of EPT samples	Yes	D1.5	NO (refer to EFI Standards)	4.1	No*	N.A.
Successful performance in EPT	No	D3.2	Yes	25	No*	N.A.
Tests for which no EPT is available	No	D1.1.2	No	N.A.	Yes	Whole document

^{*} The manual for interlaboratory changes gives recomendations for number of samples (section 7) and successful performance (section 8)

Table III – Minimum number of samples and acceptable performance in EPT

Test	Minimum number of EPT samples as defined by EFI Standards 8.0, section D1.5	Successful performance in EPT as defined by Standards for Providers of External Proficiency Testing (EPT) schemes in H&I, section 25**	
Serological typing	10	90% correct complete types. A complete type is defined as all loci/genes the laboratory reports for a sample	
Each low resolution DNA-based typing technique	10	90%	
Each high resolution DNA-based typing technique	10	90%	
Each allelic resolution DNA-based typing technique	10	90%	
HPA/HNA/KIR/MICA typing	10	90%	
HLA class I antibody detection	10	80% correct results of each accredited category	
HLA class II antibody detection	10	80%	
HLA antibody identification by CDC	10	75% of the total number of specificities reaching consensus for each accredited category	
HLA antibody identification by solid phase assays (see D1.5.1.8)	10	75%	
HPA/MICA antibody detection and identification	5	80% detection, 75% identification	
Crossmatching (see D1.5.1.10)	20	85% of the total number of results reaching consensus for each accredited category	
Haematopoietic chimaerism and engraftment monitoring (see D1.5.1.11)	10	90% of the different donor/recipient mixtures correct as defined in 24.1	
Supplemental techniques	N. of EPT samples tested must be in accordance to the policies described in D1.2 and D1.3	N.A.	

^{**} please note that these percentages may deviate depending on national rules