



News from the EFI Committee for External Proficiency Testing

The present EPT Standards for Laboratories (Version 7.0) claiming ten samples as the minimum number of EPT samples for every HLA typing method led to inconsistent interpretation: Some laboratories used ten samples for every technique (SSP, SSO, etc.), but others used only ten samples for every category (e.g. low resolution typing) and therefore split the samples (e.g. five for SSP low. res. and five for SSO low. res. if both assays were established in the lab). In addition, the minimum numbers of EPT samples for supplemental typing techniques, for example only applied for resolving ambiguities after SBT, were not clearly defined in the present EPT Standards.

The EFI community is kindly asked to note the following changes:

The EFI Committee for External Proficiency Testing (EPTC) announces new EPT Standards in chapter D of the next EFI Standards (Version 8.0, effective from January 1st 2020).

For the implementation of external proficiency procedures (EPT) laboratories must now prospectively define core and supplemental techniques according to their Accreditation Application. They are defined as follows: core techniques are used individually or in combination to produce a final result whereas supplemental techniques are used only occasionally for rare cases in combination with core techniques to refine the final result.

Example 1: SSP and SSO are used in a laboratory to produce final results for low resolution typing (e.g. SSO in daily routine and SSP as additional technique also for 24/7 organ donation duty service). Both techniques are thought to be defined as core techniques.

Example 2: SBT is used as a core technique in a laboratory, but SSP is also used to resolve ambiguities. Depending on the frequency of use of SSP by the laboratory, it may be defined as a core technique (frequent, routine use) or a supplemental technique (occasional use for rare situations).

Laboratories are expected to justify the basis for defining techniques as supplemental and regularly review this to ensure it remains accurate.

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D1.2	The laboratory must prospectively define core and supplemental techniques according to the Accreditation Application.
D1.2.1	Core techniques are used individually or in combination to produce a final result
D1.2.2	Supplemental techniques are used occasionally for rare cases in combination with core techniques to refine final results
D1.3	The laboratory must
D1.3.1	Prospectively document the relevant EPT schemes or workshops on an annual basis
D1.3.2	Have a predetermined policy for testing EPT samples and must document this prior to the annual commencement of the EPT cycle
D1.3.3	Have a predetermined policy if they select individual shipments or samples for EPT
D1.3.4	Have a predetermined policy for the selection of samples or shipments for supplemental techniques

It is essential that each laboratory prospectively documents all relevant EPT schemes or workshops on an annual basis. Moreover, there must be a predetermined policy defined for testing EPT samples, which must be documented prior to the annual commencement of the EPT cycle. The policy must also include information relating to the selection of individual shipments and how samples are selected for supplemental techniques (if relevant).

Impact of change on minimum EPT sample requirements:

The minimum numbers of samples for EPT per year (as defined in D1.5) now only applies to all core techniques used to produce a final result. For supplemental techniques the number of EPT samples tested must be in accordance with the laboratory's predetermined policies.

D1.5	Minimum number of samples for EPT per year
D1.5.1	The minimum number of samples applies to all core techniques used to produce a final result:
D1.5.1.1	Serological typing: 10 samples
D1.5.1.2	Each low resolution DNA-based typing technique: 10 samples
D1.5.1.3	Each high resolution DNA-based typing technique: 10 samples
D1.5.1.4	Each allelic resolution DNA-based typing technique: 10 samples
D1.5.2	For supplemental techniques the number of EPT samples tested must be in accordance to the predetermined policies described in D1.2 and D1.3.

How can the EPT for supplemental techniques be implemented in routine practice?

According to ISO and good laboratory practice each laboratory must establish a documented procedure for interlaboratory comparisons (i.e. EPT) that includes defined responsibilities, instructions for participation, and any performance criteria that differ from the criteria used in the interlaboratory comparison programmes. However, minimal sample numbers for specific diagnostic assays are generally not defined for interlaboratory comparisons.



The EFI EPTC has tried to obtain relevant information about national regulations within the various EFI regions regarding samples numbers for interlaboratory comparison in medical diagnostic laboratories. A small survey revealed that there are no specific numbers defined in most European countries that were checked (F, I, UK, DK, ES, P, NL), instead it is referred to by monitoring authorities (e.g. EFI) in specific regulations. Only a few countries have national regulations specifying numbers of samples and when defined, the numbers varied for each country (CH: four/year, D: two/year, BG: variable from one/year to five/year).

How many EPT samples must be tested for supplemental techniques?

Due to the national and international regulations mentioned above it is the responsibility of the laboratory to determine how many EPT samples should be processed for supplemental techniques. However, to enable useful result evaluation, the EFI EPT Committee recommends analysing at least two samples per year for every supplemental technique.

It is expected that supplemental techniques are used in addition to the core technique(s) for the selected EPT samples. According to the EFI EPT Standards the same samples can be used for more than one technique or category, but the results must be analysed independently and must be available for inspection.

Example: *SBT is used as a core technique. In some cases it is necessary to resolve ambiguities which is done with SSP as a supplemental technique. For SBT a minimum of ten samples must be tested in EPT, and it is recommended that for at least two of these samples, SSP testing is also performed.*

In case of any questions please contact the EFI EPTC chairpersons or your regional representative within the EPTC.

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