

Attachment II-B

UNOS Test Data Criteria for New HLA Laboratories and for the Addition of New Techniques

Purpose

Among the most critical aspects of laboratory evaluation is the assessment of test performance and outcome. This evaluation process includes a review of results of not only proficiency test surveys but also of tests performed during the various situations found in the laboratory and of internal quality assurance procedures. These situations include tests performed using various types of material (blood, lymph nodes, spleen, etc.). The purpose of these guidelines is to describe the minimum data from different tests that must be submitted by new laboratories or laboratories that are adding new testing techniques. For purposes of these guidelines, a new laboratory is defined as one that has not yet been approved as a UNOS laboratory. A new technique is defined as a major change or addition in testing methodology including but not limited to the addition of molecular typing for class I, the addition of molecular typing for class II, a major addition or change in methodology for molecular typing (e.g., SSP vs. SSOP vs. sequencing), the addition of flow cytometry phenotyping and/or crossmatching, and a major addition or change in method for antibody identification and/or crossmatching (e.g., ELISA or Flow methods).

Data Submission

New Laboratories are required to submit procedures and test validation data for all categories and methods of testing unless such work is performed, without exception, by another approved laboratory. Laboratories adding or changing a major category or test methodology are required to submit procedures and test validation data only for those new tests/methods. In addition, the laboratory must submit the curriculum vitae for the Laboratory Director documenting experience in performing the testing for which approval is requested with such objective criteria as publications or years of experience as the Director of another Laboratory approved for those techniques. In the absence of such documented experience, Director review for each of the 5 cases requested (see below) for each type of test sample would need to be submitted including a summary of the testing and the interpretations.

These materials are required to be submitted to an Agency with deemed status for the Accreditation of UNOS Laboratories, with a copy to the UNOS Histocompatibility committee.

VALIDATION DATA REQUIRED FOR EACH MAJOR TYPE OF TEST

1. A Summary of the internal validation data and the Director's Summary of that data;
2. The step-by-step procedure including worksheets, lists of reagents (typing sera, primers and/or probes, etc.);
3. The clinical protocol for use of the procedure;
4. The program for personnel training;
5. Documentation of the competency of personnel who will be performing the test and reviewing the test results;
6. Performance specifications to include accuracy, precision, sensitivity, specificity, reportable range of test results, normal values, and any other relevant characteristics;
7. Quality control procedures;

8. Calibration data for necessary equipment;
9. Quality assurance data;
10. Evidence that the Laboratory is currently enrolled in a Proficiency Testing (PT) Program, if available;
11. Tests results including worksheets and sample reports with interpretative comments for 10 samples including at least one of each of the test materials that will be used by the laboratory (e.g., peripheral blood, pre-mortem blood, lymph nodes, spleen, serum, etc.). Laboratories without access to a particular type of sample may request that it be supplied by another UNOS accredited laboratory. Multiple samples from the same individual may not be used.;
12. External blinded*, parallel validation tests:
 - a) Specimens from a UNOS accredited laboratory, or well-characterized reference materials (ASHI repository, commercial panels, etc.) equivalent in number to those provided by the selected PT Program; or
 - b) A complete set (one year) of PT; or
 - c) A combination of a and b (if b is partial).

*NOTE: results from the reference laboratory and the validating laboratory must be reported independently.