NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

COMMENTS and RESPONSES to PROPOSED HISTCOMPATIBILITY STANDARDS

The Proposed Standards in the area of Histocompatibility were circulated for comment on October 11, 2024. The announcement was sent to NYS-permitted facilities that held or were in application for a permit. This distribution was by e-mail to the Director's e-mail address, and the laboratory contact person's e-mail address. The documents were posted to the CLEP website.

The comment period ended November 10, 2024. Two (2) comments were received.

The standards are considered to be accepted and will be adopted and effective as of February 12, 2026.

Proposed Standard	*Proposed Guidance*
Histocompatibility Standard of Practice 3 (HC S3): Human Leukocyte Antigen Antibody Screening and Identification The laboratory must, as applicable, make a reasonable attempt to have available monthly serum specimens for all potential transplant beneficiaries for periodic antibody screening and crossmatching.	

Comment 1:
Banking of monthly sera specimens is standard practice in laboratories supporting various solid organ transplantation (SOT) programs because periodic antibody screening and ensuring availability of a sample for crossmatch is aligned with the process for participation in organ allocation networks. However, current Bone Marrow/Stem Cell Transplantation (BMT) clinical guidelines and recommendations do not include banking of monthly serum, periodic antibody screening, and crossmatching.
This proposed standard does not make a distinction between management for BMT vs SOT candidates. This proposed standard should be clarified to indicate applicability to SOT potential beneficiaries.

Response 1:
According to the Centers for Medicare and Medicaid Services (CMS), this applies to each type of cell, tissue, or organ to be infused or transplanted. Laboratories performing histocompatibility testing for infusion and/or transplantation purposes must comply.

Comment 2 : Please clarify if standards HC S3, HC S4 and HC S5 are only applicable to solid organ cells or if they are applicable to stem cells, as well.

Response 2:
According to the Centers for Medicare and Medicaid Services (CMS), these apply to each type of cell, tissue, or organ to be infused or transplanted. Laboratories performing histocompatibility testing for infusion and/or transplantation purposes must comply.
**Histocompatibility Standard of Practice 4 (HC S4) and Histocompatibility Standard of Practice 5 (HC S5) below for reference.

Histocompatibility Standard of Practice 4 (HC S4): Transplantation

If a laboratory provides histocompatibility testing for infusion and transplantation, the laboratory must:

a. have and follow policies and protocols specifying the histocompatibility testing (i.e., HLA typing, antibody screening and identification, crossmatching) to be performed for each type of cell, tissue or organs to be infused or transplanted, as applicable:
   i. testing protocols for deceased donor, living, paired, and combined organ transplants;
   ii. testing protocols for patients at high risk for allograft rejection vs. unsensitized; and

   type and frequency of testing required to support clinical transplant protocols;

b. have a process to obtain a recipient specimen, if possible, for crossmatch that is collected on the day of the transplant. If the laboratory is unable to obtain a recipient specimen on the day of the transplant, the laboratory must have a process to document its efforts to obtain the specimen.

Histocompatibility Standard of Practice 5 (HC S5): Crossmatching The laboratory must, as applicable: a) Establish and follow written policies and procedures for performing a crossmatch. b) Have available and follow written criteria for the following: i. Defining donor and recipient HLA antigens, alleles, and antibodies to be tested; ii. Defining the criteria necessary to assess a recipient's alloantibody status; iii. Assessing recipient antibody presence or absence on an ongoing basis; iv. Typing the donor, to include those HLA antigens to which antibodies have been identified in the potential recipient, as applicable; v. Describing the circumstances in which pre- and post- transplant confirmation testing of donor and recipient specimens is required; vi. Making available all applicable donor and recipient test results to the transplant team; vii. Ensuring immunologic assessments are based on test results obtained from a test report from a CLIA- certified laboratory; and viii. Defining time limits between recipient testing and the performance of a crossmatch. c) The test report must specify the type of crossmatch performed.	