

§493.1278 Standard: Histocompatibility

(a)(5) Participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

Interpretive Guidelines §493.1278(a)(5)

Programs offered by proficiency testing companies and cell exchanges for histocompatibility laboratories are readily available. An example of a regional exchange program is the Southeastern Organ Procurement Foundation (SEOPF). UCLA provides an international monthly exchange program with sera, cells and DNA. The College of American Pathologists (CAP) and the American Society for Histocompatibility and Immunogenetics (ASHI) each offer programs that assess the primary areas of testing in histocompatibility laboratories by test techniques (i.e., antibody screening and identification, HLA typing for Class I (HLA-A, B, C) and Class II (HLA-DR, DQ), lymphocyte crossmatching (T cell and B cell)).

Laboratories participating in a local exchange should record information concerning the frequency of exchange and the grading system.

Cite a deficiency if the laboratory is not enrolled in a cell exchange program or is enrolled in a program, but fails to return the results. A laboratory's performance in a regional or national exchange program should be evaluated against a peer group performing the same technique.