

§493.1278 Standard: Histocompatibility**(b)(5)(iv) The assignment of HLA antigens.*****Interpretive* Guidelines §493.1278(b)(5)(iv)**

Criteria for antigen and/or allele assignment must take into account basic principles of genetic inheritance.

Examples

1. No more than 2 antigens or alleles per HLA-A, B, and DR locus can be assigned to any patient; e.g., antigens HLA-A2, A24; B46, B61; DR8, 14; alleles HLA-A*02XX, 24XX; B*4002, 4601; DRB1*0803, 1401. Public specificities may be observed; i.e. for HLA-B, additional specificities of Bw4 and/or Bw6 are reported, for Class II antigens, additional gene products of DR51, DR52 and/or DR53 are reported.
2. When family studies are performed, typing interpretations should be in accordance with genetic relationships (i.e., haplotype assignments, determination of homozygosity at a particular locus).

Verify that the laboratory has established acceptability criteria for assignment of HLA antigens and/or alleles. Examples for alleles include signal intensity, band clarity and migration, specificity, and procedures to resolve ambiguous alternative combinations.

Determine if testing personnel follow the scoring and reporting system defined in the procedure manual. Two independent interpretations are recommended for each DNA analysis. Determine if the laboratory has validated computer software for the analysis of antigens and/or alleles.