

D5753

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1278 Standard: Histocompatibility

(c) Disease-associated studies. The laboratory must check each typing for disease-associated HLA antigens using control materials to monitor the test components and each phase of the test system to ensure acceptable performance.

Interpretive Guidelines §493.1278(c)

Disease association studies are single or limited antigen typings usually performed by serologic typing methods and more rarely performed by flow cytometric methods.

Positive and negative controls must be run with each test.

Control cells must be tested with each lot and shipment of reagents. Use D5753.

For serologic typings, the control cells should include at least two cells known to express the specified antigen and two cells known to express cross-reacting antigens that might be confused with the specific antigen. Control cells should also include at least two cells lacking the specific and cross-reacting antigen.

For typing sera acceptability, use D5745.