



The laboratory has the capability to detect HLA antibodies with sufficient sensitivity and to distinguish HLA antibodies from IgM autoantibodies or non-HLA antibodies.

NOTE: Methods to detect HLA antibodies must be more sensitive than the basic/NIH technique. There must be written procedures to differentiate HLA antibodies from autoantibodies.

REFERENCES

- 1) Foundation for the Accreditation of Cellular Therapy (FACT) and Joint Accreditation Committee ISCT and EBMT (JACIE). FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration. 8th Edition, December 14, 2021.
- 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28): [42CFR1278(d)(1)].
- 3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28): [42CFR1278(e)(1)].

HSC.32861 Antigenic Diversity and Targets

Phase II

There is sufficient antigenic diversity (individual antigens and/or crossreactive groups) for HLA Class I and II, and sufficient numbers of antigenic targets for optimal HLA antibody detection and specificity determination.

NOTE: There must be sufficient diversity for Class I and II HLA antigens and cross reactive groups, as well as sufficient numbers of well-characterized panel cells or HLA-purified protein targets for antibody detection and specificity determinations, and strength/avidity of the antibody when applicable.

Evidence of Compliance:

- ✓ Listing of antigenic targets for each panel cell

HSC.33048 Antibody Detection and Specificity QC

Phase II



For HLA antibody detection and specificity determinations, positive and negative controls are used, and sera tested undiluted and diluted when appropriate.

Evidence of Compliance:

- ✓ Records of QC for antibody detection and identification

HSC.33235 Target Source for Class I/II Antibody Determination

Phase II



There are records that the appropriate target sources are used for separate HLA Class I and II antibody determination including appropriate methods to distinguish antibody mixtures.

NOTE: There must be records that the appropriate target sources are used for HLA Class I and II antibody determination. The targets for HLA Class I antibody determination should be blood, spleen, lymph nodes, and cell lines. In addition, well-characterized purified HLA protein targets may also be used. Class II antibodies are best detected utilizing B-lymphocytes, B-lymphoblastoid cell lines, CLL cells or specific Class II purified HLA protein. Mixtures must be defined by methods shown to distinguish Class I from Class II reactivity.

Evidence of Compliance:

- ✓ Records of target sources used for HLA Class I/II antibody determination and to differentiate antibody mixtures

HSC.33422 Recipient Sera Screening

Phase II



All recipient sera are screened for HLA antibodies including, at minimum, an initial sample at the time of HLA typing, after sensitizing events and upon request.