HSC.27438 Lymphocyte Source **Phase II**

The source of the lymphocytes is recorded.

NOTE: These may include blood, bone marrow, lymph nodes, spleen, or cultured cells.

SEROLOGICAL PROCEDURES

GENERAL

Inspector Instructions:

READ	• Sampling of complement reagent validation records
ASK	• How does your laboratory ensure cell death is appropriately measured?

HSC.27625 Scoring System **Phase II**

A scoring system is used for measuring cell death in cytotoxicity tests.

NOTE: There must be established limits for defining positive and negative results by approximate percentage of cell death.

HSC.27812 QC - Complement **Phase II**

Each lot, batch and/or shipment of complement is checked for effectiveness before or during use for each specific target cell and each test method.

NOTE: Each lot, batch and/or shipment of complement must be evaluated to determine that it can mediate cytotoxicity when a specific antibody is present, and is not cytotoxic in the absence of a specific antibody. For each specific target cell (T cell, B cell, monocyte, etc.), complement cytotoxicity studies must be performed to determine optimal dilution for each type of cell tested by cytotoxicity. Two HLA antibodies should have variable antibody strengths when utilized in complement testing against 2 different known antigen-containing cells that are reactive to the antibodies. Alternatively, one antibody may be utilized at variable dilutions for complement testing.

Evidence of Compliance:

- ✓ Records of validation of complement reagents

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7166 [42CFR493. 1256(e)]
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):[42CFR493.1278(a)(3)].