DISCOVER

- Review a sampling of QC data over the previous two-year period. Select several occurrences in which QC is out of range and follow documentation to determine if the steps taken follow the laboratory procedure for corrective action

HSC.21850 Daily Controls **Phase II**

The laboratory performs positive and negative controls daily, using positive controls for specific cell types (T cells, B cells, etc.), where available.

NOTE: Positive and negative controls must be run with each test procedure where appropriate. This must include daily positive controls for specific cell type (T cells, B cells, etc.), as well as appropriate antibody isotypes as needed for each assay. This must also include one positive control serum that is historically reactive to all Class I and/or Class II positive cells at the same dilutional titer as appropriate for the methodology utilized.

Evidence of Compliance:

✓ Records of control results

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):7168 [42CFR493. 1256(d)(3)(iii)]

HSC.21950 Viability Checks **Phase II**

Viability checks on lymphocyte preparations are performed by recording negative control results or by performing and recording a separate test each time they are used.

NOTE: For cytotoxicity procedures, cell viability after initial incubation should be greater than 80% in the negative control well.

Evidence of Compliance:

✓ Records of viability checks on lymphocyte preparations

HSC.22070 Compatibility Testing Controls **Phase II**

The laboratory includes control material for each phase of compatibility testing.

NOTE: Results of patient testing must not be reported until control values are reviewed and found acceptable.

HSC.22140 QC Handling **Phase II**

The laboratory tests control specimens in the same manner and by the same personnel as patient/client samples.

NOTE: Personnel who routinely perform patient testing must analyze QC specimens; however, this does not imply that each operator must perform QC daily. Personnel must participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled.

Evidence of Compliance:

✓ Records reflecting that QC is run by the same personnel performing patient testing

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(d)(8)]