NOTE: The ABO/Rh type of the patient's red blood cells must be determined by an appropriate test procedure. Tests on each sample must include forward and reverse grouping. Discrepancies between cell and serum groups must be resolved before ABO group is assigned.

Evidence of Compliance:

✓ Logs or computer records with forward and reverse grouping

HSC.29901 A1 Red Cell Subgrouping **Phase II**

There is evidence of the specificity of A1 subgroup testing in the ABO system to distinguish A1 from other red cell subgroups.

NOTE: If the organ donor has been transfused with red blood cells in the past three months, ABO subgroup typing must be performed on a pretransfusion sample. This is due to the possibility of misinterpretation of ABO subgroup typing.

HSC.29909 Antisera/Reagent Red Cell QC **Phase II**

There are records of acceptable reactivity and specificity of typing sera and reagent red cells on each day of use, including a check against known positive and negative cells or antisera, or manufacturer's instructions for daily quality control are followed.

NOTE: Unless manufacturer's instructions state otherwise, the following apply:

- *Typing reagents, including antisera (eg, anti-D, anti-K, anti-Fy(a)) and reagent red cells must be checked for reactivity and specificity on each day of use. Typing antisera must be checked with known positive and negative cells; reagent red cells must be checked with known positive and negative antisera.*
- *Each cell used for antibody screening must be checked each day of use for reactivity of at least one antigen using antisera of 1+ or greater avidity.*
- *Anti-IgG reactivity of antiglobulin reagents may be checked during antibody screening and crossmatching.*

This checklist requirement can be satisfied by testing one vial of each reagent lot each day of 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*. 1992(Feb 28):7171 [42CFR493.1256]

HSC.29925 Historical Record Check - Red Cell Typing **Phase II**

ABO, Rh, and antibody screen test results are compared with results of the same tests performed previously to detect discrepancies.

Evidence of Compliance:

✓ Records of historical result comparisons

HSC.29941 Results Reporting - ABO Antibody Titers **Phase I**

The laboratory defines how to perform and interpret ABO antibody titers.

HSC.29949 Anti-D Controls **Phase II**

Appropriate control(s) are used for anti-D testing.

NOTE: If an anti-D reagent contains a potentiating diluent, the appropriate control is the diluent alone. Controls used must be consistent with the manufacturer's instructions.

Evidence of Compliance:
- ✓ Records of anti-D control results

FLOW CYTOMETRY

INSTRUMENTATION AND PHENOTYPING

Inspector Instructions:

READ	• Sampling of flow cytometry policies and procedures • Sampling of QC policies and procedures (includes acceptable control type/frequency for each flow cytometric application) • Sampling of QC records • Sampling of optical alignment/laser output checks
ASK	• How does your laboratory monitor instrument reproducibility? • How does your laboratory ensure each fluorochrome is appropriately calibrated? • How does your laboratory determine appropriate color compensation settings? • How does your laboratory ensure nucleic acid dye specificity?

HSC.29957 QC - Quantitative Assays **Phase II**

The laboratory analyzes at least two levels of positive cellular controls for quantitative assays (eg, CD4+, CD34+ cell concentrations) each day of patient testing or after an instrument restart to verify the performance of reagents, preparation methods, staining procedures, and the instrument.

NOTE: One of the levels of these controls should be at (or near) clinical decision levels (eg, low CD34).Control testing is not necessary on days when testing is not performed.

Evidence of Compliance:
- ✓ Records of QC results

HSC.29965 Optical Alignment **Phase II**

The laboratory monitors optical alignment (where applicable) and instrument reproducibility on each day of use or after each time the flow cytometer is started.

NOTE: Instrument performance must be monitored under the same conditions used to run test samples.

Evidence of Compliance:
- ✓ Records for monitoring optical alignment (where applicable) and instrument reproducibility

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline—Second Edition*. CLSI document H43-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2007.

HSC.29973 Fluorochrome Standards **Phase II**

Appropriate standards for each fluorochrome (eg, fluorescent beads) are run each day that the instrument is used as part of the calibration.

NOTE: These steps are necessary to optimize the flow system and the optics of the instrument.