



Evidence of Compliance:

- ✓ Records of anti-D control results

FLOW CYTOMETRY

INSTRUMENTATION AND PHENOTYPING

Inspector Instructions:

	<ul style="list-style-type: none"> • 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
	<ul style="list-style-type: none"> • 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.