data developed by these programs can provide a useful benchmark against which laboratory performance can be evaluated.

Evidence of Compliance:

✓ Records of enrollment/participation in an educational peer-comparison program for interpretive flow cytometry **OR** records for participation in a laboratory-developed program circulating cases with other laboratories or within the laboratory's own practice with records of peer review

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.

QUALITY MANAGEMENT

REAGENTS

Inspector Instructions:

	• Sampling of new antibody validation records • Sampling of new lot/shipment antibody and detection system reagent confirmation records
	• What procedure does your laboratory follow to ensure manufacturer's recommendations are followed regarding the use of kit reagents/controls? • How do you confirm the acceptability of new reagent lots? • How do you evaluate the performance of newly prepared antibody cocktails?

Additional requirements are in the REAGENTS section of the All Common Checklist. Reporting requirements for use of analyte-specific reagents and other reagents used in laboratory-developed tests are included in the All Common Checklist (COM.40850).

FLO.23250 Reagent Usage **Phase II**

The laboratory follows manufacturer's instructions for the proper use of reagents and controls or provides validation records if alternative procedures are used.

Evidence of Compliance:

✓ Records of method validation if alternative procedures are used

REFERENCES

1) Caldwell CW. Analyte-specific reagents in the flow cytometry laboratory. *Arch Pathol Lab Med.* 1998;122:861-864

FLO.23275 Antibody Validation **Phase II**

The laboratory has records of initial validation of new antibodies prior to use in patient diagnosis.

NOTE: Antibodies used are validated on the cell sub-population of interest in the context of the antibody combination used in an assay.