# INTRODUCTION

*This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a flow cytometry laboratory section or department.*

*Flow cytometry inspectors must be pathologists, clinical scientists or medical technologists who are actively involved with or have extensive recent experience in the practice of flow cytometry, are knowledgeable about current CAP Checklist and CLIA requirements, and have completed CAP Inspector Training. Inspectors should, to the greatest extent possible, be peers of the laboratory being inspected.*

***For laboratories performing only the interpretation component of flow immunophenotyping data** (the flow technical component is performed at an outside flow laboratory), the following Flow Cytometry Checklist requirements apply: FLO.18385, FLO.23706, FLO.30610, FLO.30640, FLO.30730, FLO.30790, and FLO.30820. Additionally, requirements located in the All Common Checklist addressing proficiency testing, quality management, procedure manual, specimen rejection, and results reporting are applicable.*

*Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.*

***Laboratories not subject to US regulations:** Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).*

# PROFICIENCY TESTING

## Inspector Instructions:

READ

- Sampling of peer education records

**FLO.18385 Peer Education Program** **Phase I**

**For laboratories that perform only interpretations of flow immunophenotyping data, the laboratory participates in a peer education program in interpretive flow cytometry.**

*NOTE: This checklist item applies to laboratories that do not perform staining and acquisition of flow cytometry data, but which receive list mode files and/or representative dot plots from an outside laboratory for interpretation.*

*Programs dealing with analysis of flow data from hematolymphoid neoplasias and related benign conditions provide valuable educational opportunities for peer-performance comparisons. While not completely emulating the clinical setting involved in flow immunophenotyping, the peer*

*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<br>• 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?<br>• How do you confirm the acceptability of new reagent lots?<br>• 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.*