

*LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists.*

**Evidence of Compliance:**

- ✓ Records of qualifications including diploma, transcript(s), primary source verification report, equivalency evaluation, or current license (if required)
- ✓ Work history in related field

**REFERENCES**

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28):[42CFR493.1489].

## FLOW CYTOMETRY DATA INTERPRETATION

*This section applies to laboratories that perform the interpretation component of flow cytometry data where the flow cytometry technical component is performed at another laboratory (different CAP or CLIA number).*

### Inspector Instructions:

	<ul style="list-style-type: none"> <li>• Sampling of flow cytometry immunophenotyping interpretation policies and procedures</li> <li>• Sampling of peer education records</li> <li>• Sampling of patient reports and histograms (to include abnormal cell immunophenotypes, interpretive comments, disclaimer when Class I ASRs are used, lower level of enumeration for rare event flow cytometric assays, etc.)</li> <li>• Record retention policy (gated dot plots/histograms)</li> </ul>
	<ul style="list-style-type: none"> <li>• Under what circumstances does your laboratory evaluate the percentage of viable cells?</li> <li>• How does your laboratory ensure that the testing is sufficiently comprehensive to facilitate accurate diagnosis, with appropriate gating and retention of records?</li> <li>• How does your laboratory distinguish neoplastic from non-neoplastic cells?</li> </ul>

### ANP.29650 Peer Education Program

### Phase II

**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.