RECORDS

Inspector Instructions:

READ	• Record retention policy (gated dot plots/histograms)

FLO.23706 Record Retention - Flow Cytometry **Phase II**

Flow cytometry data for evaluation of hematolymphoid neoplasias, PNH, and congenital immunodeficiency evaluations are retained for at least 10 years. Routine lymphocyte subset and CD34+ enumeration data are retained for at least two years.

NOTE: Stored data must include raw listmode data and final interpretation. Storage of gated data is encouraged but not required.

If the laboratory responsible for the interpretation component (interpretation only flow cytometry) does not retain the data locally, it must ensure that the data are being retained for the full retention period, such as with an agreement with the laboratory performing the flow cytometry technical component (see ANP.29670).

Evidence of Compliance:

✓ Data files with or without gated dot plots and histograms **OR**
✓ Written agreement with laboratory performing technical component for data storage

REFERENCES

1) CAP Policy PP, Retention of Laboratory Records and Materials

CONTROLS AND STANDARDS

Inspector Instructions:

READ	• Sampling of QC policies and procedures (includes acceptable control type/frequency for each flow cytometric application) • Sampling of QC records
ASK	• How do you determine when quality control is unacceptable and when corrective actions are needed? • How does your laboratory establish or verify acceptable QC ranges?
DISCOVER	• Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory procedure for corrective action