introduced during sample processing or during data acquisition. The definition of a paucicellular sample may vary with sample type and composition, and the procedure must include such a definition per the discretion of the laboratory director (for example, a total cell count of 200 or less for a CSF sample).

The assay procedure must define limits for carryover during assessment and include methods for reducing possible carryover, if detected. Appropriate corrective action must be taken when defined carryover limits are exceeded. Methods for reducing this possibility include (but are not limited to):

- *Cleaning the instrument prior to running an assay*
- *Washing or flushing the sample probe between sample tubes*
- *Use of a blank tube (eg, tube containing cell-free liquid (PBS, dH20, diluent) or an unstained control tube prior to running a specimen).*

Evidence of Compliance:

✓ Records of carryover studies performed at validation and following major maintenance/repair

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Validation of Assays Performed by Flow Cytometry - Approved Guideline-First Edition.* CLSI Document H62. Clinical and Laboratory Standards Institute, Wayne, PA, 2021.
2) Oldaker TA, Wallace PK, Barnett D. Flow cytometry quality requirements for monitoring of minimal disease in plasma cell myeloma. *Cytometry B Clin Cytom*. 2016;90(1):40-46.

PROCEDURES AND TEST SYSTEMS

NOTE: Reticulocyte quantification by flow cytometry is separately covered in the Hematology and Coagulation Checklist.

IMMUNOPHENOTYPING

Inspector Instructions:

	• Select a representative assay and follow the entire process from specimen receipt to final result reporting • If problems are identified during the review of immunophenotyping procedures, further evaluate the laboratory's responses, corrective actions and resolutions.

BLOOD LYMPHOCYTE SUBSET ENUMERATION

Inspector Instructions:

	• Sampling of lymphocyte subset analysis policies and procedures (includes procedure describing method to set markers (cursors) to distinguish between negative and positive fluorescence cell populations)
	• How does your laboratory ensure specimen integrity? • How are specimens stored after initial processing? • How does your laboratory validate lymphocyte gates? • How are results of lymphocyte subset analysis corrected for gate purity?