

ANP.29670 Record Retention - Flow Cytometry Phase II

Flow cytometry data for evaluation of hematolymphoid neoplasia, 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 FLO.23706).

Evidence of Compliance:

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

****NEW** 12/26/2024**

ANP.29680 Cellular Viability Phase II

The laboratory ensures that the percentage of viable cells in each test specimen is provided by the laboratory performing the flow technical component, when applicable.

NOTE: Selective loss of cell subpopulations and/or the presence of dead cells may lead to spurious results. This does not mean that all specimens with low viability must be rejected. Finding an abnormal population in a specimen with poor viability may be valuable but the failure to find an abnormality should be interpreted with caution. If specimen viability is below the established laboratory minimum, test results may not be reliable and this should be noted in the test report. Routine viability testing may not be necessary. However, viability testing of specimens with a high risk of loss of viability, such as disaggregated lymph node specimens, is required.

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.

ANP.29690 Appropriate Antibodies Phase II

The panel of antibodies used is sufficiently comprehensive to address the clinical problem under consideration.

NOTE: Knowledge of the clinical situation and/or the morphologic appearance of the abnormal cells may help to guide antibody selection. Because antibodies vary in their degree of lineage specificity, and because many leukemias lack one or more antigens expected to be present on normal cells of a particular lineage, it is recommended that a certain degree of redundancy be built into a panel used for leukemia phenotyping.

Laboratories interpreting immunophenotyping data from an outside facility (ie, technical flow laboratory) must ensure that antibody panels used for interpretation are appropriate. There must be a process by which individuals interpreting the results can provide feedback on the appropriateness of the antibody panels used. Records of such feedback and corrective action taken when problems are identified may be incorporated into the laboratory's quality management system.

Evidence of Compliance:

- ✓ Gated data plots, histograms, and patient reports

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.

- 2) Rimsza LM, et al. The presence of CD34+ cell clusters predicts impending relapse in children with acute lymphoblastic leukemia receiving maintenance chemotherapy. *Am J Clin Pathol.* 1998;110:313-320
- 3) Siebert JD, et al. Flow cytometry utility in subtyping components of composite and sequential lymphomas. *Am J Clin Pathol.* 1998;110:536
- 4) Kampalath B, et al. CD19 on T cells in follicular lymphocytic leukemia/small lymphocytic lymphoma, and T-cell-rich B-cell lymphoma: an enigma. *Am J Clin Pathol.* 1998;110:536
- 5) Krasinskas AM, et al. The usefulness of CD64, other monocyte-associated antigens, and CD45 gating in the subclassification of acute myeloid leukemias with monocytic differentiation. *Am J Clin Pathol.* 1998;110:797-805
- 6) Wood BL, et al. 2006 Bethesda International Consensus Recommendations on the Immunophenotypic Analysis of Hematolymphoid Neoplasia by Flow Cytometry: Optimal Reagents and Reporting for the Flow Cytometric Diagnosis of Hematopoietic Neoplasia. *Cytometry Part B (Clinical Cytometry)* 2007;72B:S12-S22

ANP.29710 Gating Technique**Phase II**

The laboratory interpreting flow cytometry immunophenotyping data ensures that appropriate gating techniques are used.

NOTE: There must be a process by which individuals interpreting the results can provide feedback on the appropriateness of the gating techniques used. Records of such feedback and corrective action taken when problems are identified may be incorporated into the laboratory's quality management system.

****NEW** 12/26/2024**

ANP.29720 Rare Event Flow Cytometric Assays**Phase I**

For rare event flow cytometric assays, the lower limit of enumeration is included in the diagnostic report.

NOTE: When performing rare event flow cytometric assays (such as minimal residual disease (MRD) and/or high sensitivity PNH testing) on low cellularity samples, the number of events needed to achieve the laboratory's validated lower limit of enumeration/sensitivity may not be able to be collected. In these cases, laboratories must clearly state in the flow cytometric assay report that the sample was paucicellular and may thus have reduced analytical sensitivity.

ANP.29730 Final Report**Phase II**

The final report includes information about the immunophenotype of the abnormal cells, if identified, and comments necessary to facilitate the interpretation.

NOTE: Clinical information and available pathologic material should be reviewed to select appropriate antibodies. In cases of suspected hematolymphoid neoplasia direct morphologic correlation of all applicable sample types should be performed when possible and clinically appropriate. In cases involving leukemia and lymphoma phenotyping, correlation should be made between the immunologic and pathologic results. The flow histograms, rather than just the percentage of positive cells, should be reviewed by the interpreting pathologist in difficult cases. The peak channel and shapes of the curves may be helpful in identifying clonal populations.

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).

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.
- 2) Nguyen AND, et al. A relational database for diagnosis of hematopoietic neoplasms using immunophenotyping by flow cytometry. *Am J Clin Pathol.* 2000;113:95-106
- 3) Wood BL, et al. 2006 Bethesda International Consensus Recommendations on the Immunophenotypic Analysis of Hematolymphoid Neoplasia by Flow Cytometry: Optimal Reagents and Reporting for the Flow Cytometric Diagnosis of Hematopoietic Neoplasia. *Cytometry Part B (Clinical Cytometry)* 2007;72B:S12-S22