physician has reviewed and approved the completed report before its release. In the occasional situation when the diagnosing physician is not available for timely review and approval of the completed report, the laboratory may have a policy and procedure for review and approval of that report by another qualified individual. In that circumstance, the names and responsibilities of both the individual who made the diagnosis and the individual who performs final verification must appear on the report.

ANP.29600 Final Report Elements **Phase II**

The final report includes the criteria for favorable and unfavorable results.

NOTE: The range determining favorable and unfavorable results may be determined by the laboratory's validation of the test system, or through evaluation of manufacturer's or other published information.

REFERENCES
1) Henry, Cannon, Winkleman, Eds., Clinical Chemistry-Principles and Technique, 2nd Ed., 1974:343-371
2) Clinical and Laboratory Standards Institute (CLSI). *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory - Approved Guideline-Third Edition.* CLSI Document EP28-A3c. Clinical and Laboratory Standards Institute, Wayne, PA; 2010.

ANP.29610 Final Report Elements **Phase II**

The final report includes the specimen source, name of the vendor and analyzer used, as well as any limitations of the test result, if applicable.

PERSONNEL

Inspector Instructions:

READ

- Records of personnel education and experience

ANP.29620 Morphologic Observation Assessment **Phase II**

The laboratory at least annually assesses morphologic observations among non-pathologist personnel performing CTC analysis, to ensure consistency.

NOTE: Suggested methods to accomplish this include:
1. *Circulation of images with specific qualitative abnormalities for the different cell populations evaluated*
2. *Use of digital images*

Evidence of Compliance:
✓ Employee records documenting morphologic assessment

*****REVISED** 12/26/2024***
ANP.29630 Testing Personnel Qualifications **Phase II**

Personnel who operate the analyzer are qualified as high-complexity testing personnel.

NOTE: Refer to the Laboratory General Checklist for high complexity testing personnel (GEN.54750) and general supervisor (GEN.53600) qualifications. Detailed information on personnel qualifications can be found in the CAP Personnel Guidance Document located in e-

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:

READ	• Sampling of flow cytometry immunophenotyping interpretation policies and procedures • Sampling of peer education records • 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.) • Record retention policy (gated dot plots/histograms)
ASK	• Under what circumstances does your laboratory evaluate the percentage of viable cells? • How does your laboratory ensure that the testing is sufficiently comprehensive to facilitate accurate diagnosis, with appropriate gating and retention of records? • How does your laboratory distinguish neoplastic from non-neoplastic cells?

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.