

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, Winkelman, 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:



- 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-