SPECIMEN ANALYSIS

Inspector Instructions:

- *Sampling of specimen analysis policies and procedures*

ANP.29570 Carryover Detection **Phase II**

The laboratory has a process to detect and evaluate potential carryover.

NOTE: The process must address criteria for the evaluation of potential carryover from a preceding elevated (high concentration) sample to the following sample in each analytical batch analysis and appropriate actions (eg, wash cycle) to be taken.

Evidence of Compliance:

✓ Records of reassessment of samples with potential carryover

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Preliminary Evaluation of Quantitative Medical Laboratory Measurement Procedures.* 4th ed. CLSI guideline EP10. Clinical and Laboratory Standards Institute, Wayne, PA; 2024.

ANP.29580 Analysis Guidelines **Phase II**

Written guidelines are available for differentiating circulating tumor cells from other nucleated circulating cells, such as leukocytes, as well as other artifacts.

NOTE: Evaluation of circulating tumor cells requires the use of specific guidelines and procedures to distinguish circulating tumor cells from white blood cells and artifacts.

REPORTS

Inspector Instructions:

- Sampling of patient reports for completeness

ANP.29590 Report Review **Phase II**

All reports are reviewed and signed by a pathologist or other qualified physician.

NOTE: The individual who signs the final report must be a pathologist or other physician who qualifies as high complexity laboratory director/technical supervisor and has at least one year of training and experience in the specific area of testing.

The inspector must review a sampling of reports issued since the previous on-site inspection, representing at least the most common types of specimens seen in the laboratory. When diagnostic reports are generated by computer or telecommunications equipment, the actual signature or initials of the pathologist or other qualified physician may not appear on the report. The laboratory must have a procedure that ensures and provides a record that the responsible

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-