

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