

ANP.23027 Area of Analysis**Phase II**

A qualified pathologist selects or confirms the appropriate areas for analysis prior to reporting the results, as applicable.

NOTE: Specimens that do not represent "in situ" samples embedded in paraffin may not require pathologist review. Examples include cultured preparations and direct preparations of liquid specimens including blood, urine, pleural fluid, etc.

ANP.23028 Analysis Guidelines**Phase II**

There are written guidelines for identification of appropriate areas and cells for analysis.

NOTE: Evaluation of heterogeneous cell populations requires use of specific guidelines and procedures to ensure analysis of the appropriate areas and/or cells, particularly if there is background or nonspecific staining, or if there is cell debris, endogenous pigment, and/or artifacts of aging, sectioning or preparation.

Test results may be affected by fixation parameters, including time of fixation, type of fixative used, hemorrhage, necrosis, and autolysis of tissue.

REPORTS

Inspector Instructions:



- Sampling of patient reports for completeness

ANP.23036 Final Report Interpretation**Phase II**

The final report includes an interpretation by the responsible pathologist.

NOTE: Interpretation requires correlation with the light microscopic features such as routine histology, immunohistochemistry, cytologic material, cytogenetic and molecular studies, and/or clinical information.

ANP.23038 Final Report Elements - Digital Image Analysis**Phase II**

The final report includes the specimen source, name of the vendor and imaging system used, the antibody clone or probe, and the detection method, as well as any limitations of the test result, if applicable.