***REVISED** 12/26/2024*

CYP.04150 Cross-Contamination **Phase II**

The laboratory prevents cross-contamination of cytologic specimens during processing and staining.

NOTE: Procedures must prevent cross-contamination between the following:

- *Gynecologic and non-gynecologic specimens.*
- *Non-gynecologic cases that have high potential for cross-contamination from other non-gynecologic specimens.*

Laboratories must define what is considered a specimen that has a high potential for cross-contamination. Methods to prevent cross-contamination between specimens may include cytocentrifuge, filter, air dried preparations, and monolayer preparations. Direct smears made from the sediment of highly cellular cases should be stained after the other cases, and the staining fluids must be changed or filtered between each of the highly cellular cases. One procedure to detect highly cellular specimens is to use a toluidine blue, or other rapid stain, on a wet preparation.

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): [42CFR493.1274(b)(2-3)].

CYP.04300 Cytologic Preparation Technical Quality **Phase II**

The pathologist or supervisory-level cytotechnologist performs daily review of the technical quality of cytologic preparations.

NOTE: The technical quality of cytologic preparations must be checked daily (on days processing occurs). This includes checking all stains for predicted staining characteristics each day of use. This check must include all of the types of preparations seen that day such as cytospins, cell blocks, and liquid-based preparations.

If preparation and staining is performed by a different laboratory, there must be a procedure for the laboratory performing the preparation and staining to verify the acceptability of the quality of preparations and the acceptability of controls (if needed) before transfer. Records of this verification must be readily available to the laboratory performing interpretations. There should also be a mechanism for feedback from the interpreting laboratory to the laboratory that prepared the slides of any issues with the preparations.

Evidence of Compliance:

✓ Records of daily review of cytologic preparations

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1256(e)(2)]

IMMUNOCYTOCHEMISTRY (ICC)

This section is intended for cytology only laboratories performing immunocytochemistry (ICC) within the cytology laboratory. This section does not apply to cytology laboratories for which all ICC is performed in a general anatomic pathology immunohistochemistry laboratory that is inspected using the Anatomic Pathology Checklist. ***Cytology laboratories that are doing histology processing of cell blocks and tissues must be inspected with the Anatomic Pathology Checklist.***

Please refer to the Definition of Terms section in the All Common (COM) Checklist for definitions of analytical validation and analytical verification.