

INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a cytopathology laboratory section or department.

Laboratories that do not file slides on-site (eg, "read-only" laboratories) must retain a sample of slides on-site for review by the inspector on all days when the laboratory is subject to its regular on-site inspection. The sample must, at minimum, include all slides accessioned over a continuous two-week period within the previous two years.

If telepathology is used by the pathologist or cytotechnologist to review slides or images for primary diagnosis of cytology or real time evaluation of FNA specimens for adequacy or triaging, refer to the Telepathology section of the Laboratory General Checklist for additional requirements. Telepathology occurs when a pathologist views digitized or analog video or still image(s), and renders an interpretation that is included in a formal diagnostic report or recorded in the patient record. This also includes the review of images by a cytotechnologist when a judgment of adequacy is recorded in the patient record.



Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.

Laboratories not subject to US regulations: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).

GENERAL CYTOPATHOLOGY

This Checklist is intended for laboratories that perform on-site preparation and/or interpretation of cytologic specimens. These include GYNECOLOGIC (cervicovaginal), and/or NON-GYNECOLOGIC (exfoliated specimens from other sites, fluids, and aspirates) cytopathology. If the laboratory does NOT perform any on-site examination of cytopathology specimens, but refers all submitted material to an outside laboratory, do NOT use this Checklist. Do NOT use this Checklist if the laboratory's involvement in cytopathology is limited to filing of reports and/or slides.

Cytopathology inspectors must be pathologists or cytotechnologists who have extensive experience in the practice of cytology, are knowledgeable about current CAP Checklist and CLIA requirements, and have completed appropriate inspector training prior to inspecting.

Regardless of the size of the laboratory, the Inspector should spend at least several hours inspecting the cytopathology laboratory. The on-site inspection will require review of case (slide) material, direct observation of technical procedures, and careful review of quality management monitors.

Laboratories that are doing histology processing of cell blocks and tissues must be inspected with the Anatomic Pathology Checklist.