D5665

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§493.1274 Standard: Cytology

(g) Automated and semi-automated screening devices. When performing evaluations

using automated and semi-automated screening devices, the laboratory must follow manufacturer's instructions for preanalytic, analytic, and postanalytic phases of testing, as applicable, and meet the applicable requirements of this subpart K.

Interpretive **Guidelines §493.1274(g)**

Some automated devices, such as instruments where only a portion of the slide is reviewed, may have a higher workload limit than 100 slides. This must be stated in the manufacturer's product insert to be applicable. However, the maximum workload limit for those slides which require 100% manual review (as a result of automated or semi-automated analysis OR in the routine workload) remains 100 slides.

Probes §493.1274(g)

When technology (automated/semi-automated devices) is introduced into the laboratory, how does the laboratory ensure its operation is within the specifications of previous methods used by the laboratory?

Some automated devices remove a percentage of the slides from the workload. How does the laboratory ensure that the correct slides are archived?