

§493.1273 Standard: Histopathology

(d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis.

Interpretive Guidelines §493.1273(d)

The laboratory must ensure that only those individuals qualified to evaluate histopathology specimens can release his or her electronic signature for reporting purposes.

The tests in histopathology include both gross examination (macroscopic) and microscopic examination of the slide(s) with evaluation and diagnostic interpretation, and diagnostic findings reported.

In the event of a computer-generated signature, the laboratory must ensure that the system is protected from use by unauthorized individuals.

If the technical supervisor who performed the examination and diagnosis is not available to sign the report, an individual, also qualified as a technical supervisor in Histopathology, must reexamine and diagnose in order to sign out the report.

