AMERICAN SOCIETY OF Cytopathology

GUIDELINES FOR REVIEW OF GYN CYTOLOGY SAMPLES
IN THE CONTEXT OF LITIGATION OR POTENTIAL LITIGATION

The Pap test is the most effective cancer-screening test in medical history and remains the most effective screening method for the identification of pre-malignant cervicovaginal conditions. The Pap test has been associated with a 70% or greater decrease in the United States death rate from cervical cancer.

If the Pap test is to continue as an effective cancer-screening procedure, it must remain widely accessible and reasonably priced for all women, including those economically disadvantaged and at high risk for cervical cancer. There must also be an understanding of the inherent limitations of this screening test and an objective and scientific method for review of questioned cases that is fair to both the patient and the laboratory.

The Pap test is a screening test that involves subjective interpretation by a cytotechnologist or pathologist of the thousands of cells that are present on a typical GYN cytology sample. Experience indicates an irreducible false-negative rate of around 5%. Although rescreening can reduce the false-negative rate, zero-error performance cannot currently be attained. Many factors, including the subjectivity involved in interpreting difficult cases and sampling problems with specimen collection, prevent zero-error performance.

The following guidelines should be used for review of GYN cytology samples for litigation or potential litigation.

1. The finding of a false-negative sample is not necessarily evidence of practice below the standard of care. The decision as to whether a false-negative GYN cytology sample is the result of negligence should be made not only on the basis of evaluation of a single sample but should also include an evaluation of the patient's past clinical history and previous GYN cytology results. The test results should also be viewed in the context of the accredited laboratory's overall performance on GYN cytology samples.

2. *Atypical cells of undetermined significance* represent an equivocal interpretive category with poor inter- and intra-observer reproducibility. Therefore, most cases of ASCUS (atypical squamous cells of undetermined significance) and AGUS (atypical glandular cells of undetermined significance) do not represent consistently identifiable abnormalities and a reasonable basis for allegations of practice below a reasonable prudent practitioner standard of care.

3. Pap test slides being assessed for an objective unbiased basis on which to assert a violation of a reasonable prudent practitioner standard of practice should first be reviewed without knowledge of clinical outcome and in an environment that simulates the normal screening practice. A violation of a reasonable prudent practitioner standard of practice based on how specific Pap tests were screened and interpreted can only be established through an unbiased blinded rescreening review process that includes the contested case as one of a number of normal and abnormal GYN cytology samples representing a variety of disease states. Focused review or review with knowledge of subsequent development of carcinoma inevitably biases the objectivity of the review against the laboratory and does not reflect standard practice.

4. The standard of care should be that of the reasonable and prudent practitioner. Courts and experts should recognize that a false-negative result by itself is not sufficient proof of negligence. Rather, the courts should evaluate whether the overall Pap-test practices of the laboratory meet the standard of care and whether

unbiased blinded rescreening consistently detects significant abnormalities not initially identified by the laboratory.

5. Professional expert witnesses who do not have significant practical experience in Cytopathology are not qualified to express an expert opinion on the standard of care. Instead, a court should rely upon the testimony of expert physician-witnesses who have, at a minimum, the following qualifications:

    - Maintains a current and unrestricted license to practice medicine in the state where he/she is practicing.
    - Certified by the appropriate A.B.M.S. specialty or subspecialty board, and is fully trained in the practice of Cytopathology; and
    - Knowledgeable in the practice of Cytopathology as indicated by years of practice experience, current up-to-date continuing medical education, and active engagement in the practice of Cytopathology.

    Alternatively, to adjudicate the performance of cytotechnologists, the court may rely upon the testimony of expert cytotechnologist witnesses who have, at a minimum, the following qualifications:

    - Maintains a current and unrestricted license to practice cytotechnology in his/her state if this is a state requirement.
    - Certified as a cytotechnologist by the ASCP Board of Certification, and fully trained in the practice of cytopathology; and
    - Knowledgeable in the practice of cytotechnology as indicated by years of experience, current up-to-date continuing education, and active engagement in the practice of cytotechnology.

6. Compensation of the expert witness should reasonably reflect the time and effort expended by the witness in preparation, depositions, and trial. Compensation of an expert witness contingent on the outcome of the case introduces the possibility of bias and should not be permitted.

7. The parties should also strongly consider mediation or non-binding arbitration by a panel of individuals trained and having experience in Cytopathology before proceeding with civil litigation relating to a Pap test. Such panels could be developed through national societies with interest and experience in GYN cytology.

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