

PAP SMEAR QUALITY ASSURANCE PROGRAM

The Pap smear was originally intended as a screening test to be applied to the general population to identify those women with cancerous and precancerous changes of the cervix. It is not meant to be a diagnostic test. Any abnormal result should be followed by additional tests as indicated clinically or as recommended in the "PSIP Table of Comparable Diagnoses and Recommended Follow-up." In addition, it should be noted that the Pap smear is not 100% sensitive. The reported sensitivity of Pap smears varies widely in literature. However, it is safe to estimate that it is no better than 80 to 90% . False negatives probably occur most frequently due to the absence of diagnostic cells on smears. Therefore, every effort should be made to obtain a representative, well-preserved Pap smear.

To assure an adequate Pap smear, it should be taken at the optimal time and under optimal conditions. It is suggested that it be done in the mid portion of the menstrual cycle in the absence of discharge of excessive inflammation. It is also recommended that smears not be taken following recent sexual activity, use of vaginal douches, medications, foams, jellies or lubricants.

A thorough scraping of the ectocervix and endocervix must be performed to ensure that the entire area at risk has been adequately sampled on the smear. Cytobrushes are available to assist in endocervical sampling. Instructions for taking optimal smears are included on the inside cover of each Pap Pak kit as well as in the PSIP service manual. The importance of immediate fixation of the smear is stressed, as air-drying occurs in a matter of seconds and may cause artifactual distortion of cells.

If a slide is received broken, inadequately stained or poorly coverslipped, abnormal cells may be missed, overlooked or misinterpreted. If the slide is misidentified or the data is improperly entered into the computer, the patient may receive an erroneous report. The laboratory is responsible for assuring proper processing. PSIP will inform you if the slide is broken beyond repair and request a repeat smear. The personnel processing the smears are appropriately trained. Stains are monitored daily and adjustments are made as needed to provide optimal color differentiation and clarity. Slides are identified by name and accession number and matched with the corresponding requisition. We require that you write the patient's name in pencil on the frosted end of the slide to ensure positive identification.

PSIP is inspected and accredited by the College of American Pathologists and the State of Washington, and meets or exceeds all standards outlined in the 1988 Federal Clinical Laboratory Improvement Act. Optimal screening is assured by hiring only registered cytotechnologists who have undergone specialized college level training, by providing a quiet work environment with state-of-the-art microscopes, and by monitoring volume to ensure that there is ample time for thorough examination of each smear. In an average workday, 70 to 75 slides are reviewed by each Cytotechnologist, which is far fewer than the limit set by the federal and state guidelines.

Ten percent of all normal smears are randomly screened by a second cytotechnologist. An additional 10-15% of normal smears are rescreened based on high risk criteria defined by CLIA '88.

All abnormal smears are reviewed by a pathologist, who determines the final diagnosis. Significant cytotechnologist/pathologist discrepancies are reviewed by the cytology supervisor and discussed with the cytotechnologist to ensure uniformity of diagnosis within the lab. Every effort will be made to correlate smears with follow-up biopsies. A search and review of previous smears are done on any patient found to have a high grade squamous epithelial lesion.

PSIP puts strong emphasis on continuing education. Two hours of continuing medical education is provided for each of the cytotechnologists on a monthly basis. Attendance at local, regional and national cytology meetings is also encouraged and subsidized.

Monthly statistical summaries of each cytotechnologist's and pathologist's work are reviewed. Reports of cytology/histology correlation are also reviewed on a regular basis. These reports identify any significant deviations from the laboratory mean of performance and allow for early intervention. We also request biopsy follow-up by questionnaire for all significant abnormal smears for which we do not receive tissue.

Monthly patient summaries are sent to all clients. Recall lists are also sent to clients monthly.