

Cancer Cytology

ThinPrep Pap test

(919) 733-7146

Introduction

The Pap test is a non-sterile cellular specimen obtained for microscopic examination to screen for abnormal cellular changes suggestive of cancer and its precursor conditions. The State Laboratory of Public Health accepts only gynecological ThinPrep Pap specimens from local health departments and state-operated health facilities (public health patients).

The Pap test is a screening test for an asymptomatic population. Symptoms, which may be due to neoplasia, should be completely evaluated: the Pap test in this situation is not appropriate management.

False negative tests may occur due to sampling errors, screening difficulties inherent in Pap tests or due to the subjective nature of cytodiagnosis. Patients should have Pap test done on a routine basis.

Specimen Collection and Shipment

Detailed information on materials needed and illustrated instructions for collecting and shipping specimens can be found in the current issue of the DHHS document, Pap Screening: A Guide for Health Departments. Please notify the Cancer Cytology Branch at (919) 733-7146 or the Breast and Cervical Cancer Control Program (BCCCP) at (919) 715-0111.

Order of collection of gynecologic specimens: the Pap test can be collected anytime after the cervix has been cleaned. Collect gonorrhea, chlamydia and Pap specimens according to local protocol using review of patient symptoms and clinic requirements. **Please note:** Collecting any other test sample before collecting the Pap test may remove the diagnostic cells needed for the Pap test and render a false negative report.

Specimen Identification

Specimens must be properly labeled and forms must be completed. Mislabeled specimens are not processed.

- PRINT patient's first and last name on the Preservcyt vial. A computer-generated label is preferred.
- Place label toward top of vial with the name horizontal to the vial lid.
- **Collect patient's Social Security Number.** It becomes a part of the patient's unique identification number. Results cannot be reported without patient's identification number.
- **Include the patient's Medicaid number when applicable.** CLIA '88 mandates direct billing to Medicaid by the laboratory doing the testing. Without the Medicaid number, the State Laboratory cannot bill Medicaid.

Reporting Procedures and Interpretation

The Cancer Cytology Unit uses The Bethesda System (TBS) for reporting Pap results. Negative results are reported upon completion of quality control procedures. Abnormal results must be confirmed and signed by a pathologist (CLIA 88 regulation). The Cancer Cytology Unit contracts for pathology services thus requiring additional turn around

time for pathologist review and courier service.

A computer-generated report (not the DHHS form #1010 submitted with the Pap smear) is returned to the health department. A laboratory generated follow-up DHHS form #1011 for the collection of follow-up data is sent with all Pap smear results of HPV, dysplasia or more severe findings or second consecutive ASCUS (Atypical Squamous Cells of Undetermined Significance). Case follow-up/disposition is essential to determine program effectiveness, as a part of laboratory quality assurance and to meet CLIA '88 requirements.

Any slide can be read immediately upon request

Sometimes a backlog of slides results in delayed reporting of results. The Cytology Unit now maintains contracts for Pap screening services to prevent a backlog of slides.

Recommendations on interpretation of Pap test results, patient treatment and follow-up can be found in the DHHS document, PAP SCREENING: A Guide for Health Departments.

Records

DHHS #1010 forms are retained for two years. Results are recorded electronically and kept indefinitely. Slides are kept for five years. Physicians should be advised that the slides are available for review when patients are referred for follow-up.

Unsatisfactory Specimens

The two categories of unsatisfactory cytology specimens are specimen quality and form completion errors.

Unsatisfactory due to specimen quality:

- Insufficient number of cells. Usually as a result of excessive blood. Red blood cells clog the ThinPrep filter and prevent the epithelial cells from reaching the slide.
- Improper on unlabeled PreserCyt vial.
- Lack of endocervical cells.
- Failure to properly rinse collection devices into PreserCyt vial.
- Illegible writing on vial.
- Name on form and vial do not match.
- Expiration date is past.

Errors in completing the 1010 Form

- No patient ID number/ Social Security Number
- Failure to indicate patient name change
- Patient history is incomplete
- No return address of provider
- No name on form
- Writing is illegible

“Satisfactory for examination, but limited by...” followed by a statement explaining the limitation will be reported when specimen quality is less than optimal.

For detailed information on Pap specimen collection and preparation, see the DHHS document, PAP Screening: A Guide for Health Departments.

Cytology Quality Assurance Procedures in the State Laboratory of Public Health

To assure valid examinations and Pap reports, the Cytology Branch employs a number of Quality Assurance Procedures.

- Staff members are registered Cytotechnologists trained in examination of ThinPrep slides.
- Equipment, instruments, reagents, and stains are monitored daily.
- Senior Cytotechnologists randomly rescreen 10% of all negatives.
- The diagnostic trends of each individual Cytotechnologist are statistically monitored.
- The Chief Cytotechnologist works individually with a Cytotechnologist when Quality Control procedures indicate the need.
- All cellular changes suggestive of repair, atypia, HPV, dysplasia and more severe findings are referred for Pathologist confirmation and sign out.
- All previous smears reported as negative on a patient are rescreened when the current Pap has changes suggestive of HGSIL (High Grade Squamous Intraepithelial Lesion).
- Cytology reports are correlated with clinical and surgical follow-up reports (DHHS form #1011). When pathology and cytology reports differ, the smears are reviewed.
- Continuing Education seminars are conducted to keep staff informed of new developments in Cytology and to review difficult or unusual cases. Cytotechnologists participate in ASCP cytology teleconferences and keep up with new developments in the field on Internet cytology sites. Cytotechnologists are encouraged to attend local, state and (as resources permit) national Cytology meetings.
- Cytology staff participates in CAP Proficiency Testing.
- Quality Assurance Committee and Unit meetings are held monthly.