

Pap Smears

Surepath Liquid Pap Test

Surepath Pap test with Reflex to Human Papillomavirus (HPV) DNA Probe, High Risk

Test indication: The <u>SurePath™</u> liquid-based Pap test produces a monolayer slide that is an alternative to the conventional gynecologic pap methods. The Pap smear is used in the screening and detection of cervical cancer, precancerous lesions, atypical cells and all other cytologic categories as defined by the Bethesda System for Reporting Cervical Cytology.

Specimen required: Cervicovaginal/ endocervical sampling. Methodology: PrepStain[™] Slide Processor, routine cytopathologic evaluation, Hybrid Capture® II DNA Test (Nucleic acid, hybridization assay with signal amplification)

Supplies: This test requires a SurePath[™] special collection kit, which includes a SurePath[™] preservative fluid collection vial and the sampling device(s). Kits may be ordered separately through Samaritan Health Services Laboratory Cytology Department fax as 541768-5047 or by using Samaritan's Laboratory Supply Request form or by calling 541-768-4339. Also required is a Samaritan Health Services Laboratory Pap

Collection procedure:





(Surepath Sample Collection Kit)

or

(541) 768-5059 (541) 812-4150 (541) 451-7135



Record the patient's first and last name, date of birth, specimen source and date collected on the vial. Record the patient's information and medical history on the Samaritan Health Pap Requisition or into the electronic medical record.

1. Obtain cervical specimen prior to bimanual examination. Use an un-lubricated speculum (saline or warm water may be used). Vaginal discharge or secretion, when present in large amounts, should be removed before obtaining the cervical sample so as not to disturb the epithelium (e.g. cellulose swab). Small amounts of blood will not interfere with the cytologic evaluation; however, large amounts of blood as present during menses may interfere with cytologic evaluation because cells may be obscured by blood. Use of liquid-based specimen collection minimizes the interference from these factors. If testing for sexually transmitted disease is indicated, the cervical cytology sample should be ROVER'S CERVEX-BRUSH[™] or the Pap Perfect® plastic spatula/Cytobrush® Plus GT (Surpath Sample Collection Kit).

2. To use the broom, insert the long central bristles into the cervical os until the lateral bristles bend against the ectocervix and rotate 360° in a clockwise direction five (5) times in the same direction while maintaining gentle pressure.

- The device should be twisted slowly. While maintaining gentle pressure hold the stem between the thumb and the forefinger and rotate the brush five times in a clockwise direction. The direction must be consistent. Do not alter or vary the direction of the broom during sampling.
- Transfer the entire sample by placing your thumb against the back of the brush pad, and simply disconnect the entire brush from the stem into the SurePath[™] preservative vial.
- Recap the vial and tighten
- Place the vial and test request form in a biohazard specimen bag for transport to the laboratory. Samaritan Health Services Laboratories will not accept samples in expired SurePath[™] preservative.





3. To use the Surepath Sample Collection Kit scrape the ectocervix using the Pap Perfect® plastic spatula. Disconnect the spatula head into the SurePath[™] Preservative vial. 3

- Insert the Cytobrush[®] Plus GT into the cervix until only the bottom most fibers are exposed. Slowly rotate or turn one half turn in one direction. DO NOT OVER-ROTATE. Disconnect the brush head and place in the SurePath[™] preservative vial.
- Recap the vial and tighten.
- Place the vial and test request form in a biohazard specimen bag for transport to the laboratory. Samaritan Health Services Laboratories will not accept samples in expired SurePath[™] preservative.

NOTE:

The pap test is a screening test for cervical cancer with inherent false negative results.

Failure to follow recommended procedures for SurePath[™] collection may compromise performance.

Remarks: This test includes a Cytology, SurePath[™] Liquid-Based Pap Test (AutoCyte Prep[™], Routine cytopathologic evaluation and a Human Papillomavirus (HPV) DNA Probe, recommended High Risk ONLY if the SurePath[™] Liquid-Based Pap Test is interpreted as atypical squamous cells of undetermined significance (ASC-US).



Unacceptable conditions: Frozen, older than 28 days, samples not collected in a SurePath[™] special collection kit provided by lab, Expired SurePath[™] vials will not be processed.

Stability: Ambient: 1 month; Refrigerated: 1 month; Frozen: Unacceptable.

SurePath test reference interval: By Report.

Note: Store SurePath[™] preservative fluid without cytologic samples at 15-30°C in this vials provided. Do not use SurePath[™] solution beyond expiration date marked on the vial. Please rotate the stock of SurePathTM and use vials with closest expiration date first. No specimen will be accepted in expired solution.

Warning: SurePath[™] preservative contains denatured ethanol which may be fatal if swallowed. Vapor is harmful if inhaled. May cause blindness. SurePath[™] is flammable. Keep away from fire, heat, sparks, and flames. Other solutions must not be substituted for SurePath[™] preservative