

Cytology Collection - SurePath Collection Procedure with HPV Ordering Guidelines

I. **PRINCIPLE:** This Procedure provides basic instructions on how to collect GYN liquid based cytology specimens using SurePath collection devices and vials. It is intended for clinicians with formal training in specimen collection methods and techniques. These collection instructions are adapted from training materials provided by BD Diagnostics/SurePath. For more intensive training on this collection technique a physician representative from BD can be scheduled for an on-site visit to your location. Additionally, a training video is available for review. This procedure also includes basic guidelines for ordering an HPV test off of the same collection vial.

II. **RESPONSIBILITY:** All personnel responsible for collecting and ordering GYN cytology specimens should be familiar with this procedure.

III. **SPECIMEN COLLECTION (method of sample collection):** Direct sampling of uterine cervix with approved sampling device.

IV. MATERIALS:

- A. SurePath collection vial with preservative
- B. Collection device (e.g. cyto-broom)
- C. Access to electronic ordering and label printing (or equivalent).

V. PROCEDURE:

- A. GYN (Pap test) collection procedures.
 - 1. Conventional methods for sampling the cervix should be employed.
 - 2. Collect
 - A) SurePath sample collection with broom-type device with detachable head:
 - (1) Insert longer central bristles into cervical os.
 - (2) Begin rotating device in a **clockwise** direction
 - (3) Push towards the cervix while still rotating clockwise.
 - (4) The lateral bristles will fan out over the extocervix and the central bristles will penetrate the endocervical canal.
 - (5) Complete **5 full rotations**
 - (6) Remove and “pop-off” broom head into SurePath vial.
 - (7) **Contraindication: *The Cervix-Brush should not be used on patients after the first 10 weeks of pregnancy.***
 - (8) See Appendix A, option 1
 - b) SurePath sample collection with combination brush/plastic spatula device
 - (1) Insert the contoured end of the plastic spatula and rotate 360 degrees around the entire exocervix.

CYTOLOGY COLLECTION – SUREPATH COLLECTION PROCEDURE WITH HPV ORDERING GUIDELINES

Page 2 of 5

- (2) Insert cyto-brush into the endocervix until only the bottom-most bristles are exposed at the os. Slowly rotate $\frac{1}{4}$ to $\frac{1}{2}$ turn in one direction. To reduce unnecessary bleeding, do not over-rotate brush.
 - (3) **Warning: Do not use CytoBrush on pregnant patients or for endometrial sampling.**
 - (4) See Appendix A, Option 2
3. Drop
 - a) For the cyto-broom drop the detachable head of the device into the SurePath vial.
 - b) For the spatula and cyto-brush snap the device handle and drop the detachable head of the device(s) into the SurePath vial.
 - c) **Warning: FDA guidelines require the collection device to be submitted with the specimen.**
 - d) See Appendix A
 4. Send
 - a) Place the cap on the vial and tighten.
 - b) Order the pap test through Copia or other interfaced electronic ordering system.
 - c) Please note our “Zero Tolerance” specimen labeling policy requires two unique patient identifiers when labeling specimens.
 - d) **Patient Safety notes for labeling specimen vial:**
 - (1) Use standard operating procedures for Patient ID integrity – Ensure the correct patient (e.g., name and DOB), correct site (i.e., cervix), and correct procedure (i.e., Pap test).
 - (2) Avoid pre-labeling the collection vial.
 - (3) Ensure that the label has the correct patient information that matches the patient whose sample is being collected.
 - (4) Do not completely cover (obscure) any original patient labels with a new label. Leave as much of the original label exposed, showing the patient name, as possible.
 - (5) Use an appropriate ID double check with the patient (i.e., ask them what their name and date of birth is).
 - (6) Make sure all specimen labels agree with each other and the electronic order before sending
 - (7) Correct and reconcile any patient name or DOB discrepancies before sending
 - (8) These activities will help reduce errors, improve patient safety, and avoid specimen correction / rejection incidences
 - e) Send appropriately labeled SurePath vial to the lab for processing.
- B. HPV ordering guidelines:
1. The SurePath sample can be reflex tested for HPV high risk types using the Roche Cobas 4800. This molecular test is performed at Rice Laboratory.
 2. Recommendations, based on the ASCCP guidelines include:

CYTOLOGY COLLECTION – SUREPATH COLLECTION PROCEDURE WITH HPV ORDERING GUIDELINES

Page 3 of 5

- a) Most patients should have reflex HPV testing for ASCUS, unless the HPV status is already known within two years. See Appendix B for management of women with ASC-US
- b) HPV testing is contraindicated in women under 21.
- c) HPV “regardless” is typically ordered in patients following colposcopic evaluation and/or treatment.
- d) HPV can also be reflex test ordered *if ASCUS or higher*
- e) A Pap diagnosis of ASC-H should not have an HPV test but rather the patient should be referred straight to colposcopy.
- f) All SurePath specimens are saved for 14 days at Rice Laboratory, during which time the specimen is still considered viable for HPV testing. If you would like to order an HPV test after the cytology report is complete, then order it in Copia (or EMR) and call Rice Laboratory Client Services to let them know. Note: If it is approaching the 14 day expiration period then call the lab to verify that the sample is still available to test and won't be discarded.
- g) A special request for HPV testing, by the ordering provider (or designee), may be honored even if the testing parameters fall outside of recommended guidelines.
- h) For more information see <http://www.asccp.org/ConsensusGuidelines/AbnormalCervicalScreeningTests/tabid/5958/Default.aspx>

VI. REFERENCES:

- A. <http://www.bd.com/tripath/physicians/surepath.asp>
- B. <http://www.asccp.org/ConsensusGuidelines/AbnormalCervicalScreeningTests/tabid/5958/Default.aspx>

CYTOLOGY COLLECTION – SUREPATH COLLECTION PROCEDURE WITH HPV ORDERING GUIDELINES

Page 4 of 5

Appendix A:

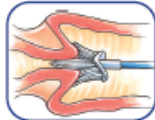
BD SurePath™ test is easy to use with several collection device choices.

Option 1

BD SurePath™ Test Sample Collection with Broom-Type Detachable Head Device.²

1. Collect

Insert the Rovers Cervix-Brush™ into the endocervical canal. Rotate brush five times in a clockwise direction.



2. Drop

Drop the detachable head of the device into the BD SurePath™ vial.



3. Send

Place the cap on the vial and tighten. Send the BD SurePath™ vial to the lab for processing.



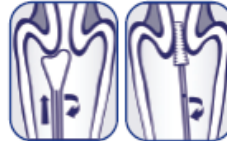
Contraindication: The Cervix-Brush™ should not be used on patients after the first 10 weeks of pregnancy.

Option 2

BD SurePath™ Test Sample Collection with Combination Brush/Plastic Spatula Detachable Head Device.⁴

1A. Collect

Insert the combined end of the Pap Perfect™ plastic spatula and rotate 360° around the entire exocervix.



1B. Collect

Insert Cytobrush Plus GT into the endocervix until only the bottom-most bristles are exposed at the os. Slowly rotate 1/4 to 1/2 turn in one direction. To reduce unnecessary bleeding, do not over-rotate brush.

2A. Drop

Snap the device handle at the red scoring line and drop the detachable head of the device into the BD SurePath™ vial.



2B. Drop

Snap the device handle at the red scoring line and drop the detachable head of the device into the BD SurePath™ vial.

3A. Next

Place cap on vial; do not tighten cap until Step #3B. Send. Go to Cytobrush Plus GT Step #1B. Collect.



3B. Send

Place the cap on the vial and tighten. Send the BD SurePath™ vial to the lab for processing.

Warning: Do Not Use Cytobrush Plus GT on pregnant patients or for endometrial sampling. See BD SurePath™ Sample Collection Reproductive for complete Directions for Use.

Alternative Methods to Detach Heads of Collection Devices: Two-Hand 'SNAP'⁴



Do not touch the head of the device while detaching.

Alternative Methods to Detach Heads of Collection Devices: Cap-Assisted 'SNAP'⁴



Care must be taken to avoid splashing and/or contamination of the head(s) of the device(s).

² See Rovers® Cervix-Brush product insert for complete Directions for Use.

⁴ See BD SurePath™ Sample Collection Kit product insert for complete Directions for Use. Cervix-Brush is a product and registered trademark of Rovers B.V., Oss, The Netherlands. BD SurePath™ Sample Collection Kits manufactured by Hologic, a CooperSurgical Company, Franklin, CT.

Cervix-Brush is a trademark of Rovers Medical Devices, B.V.

Cytobrush and Pap Perfect are trademarks of CooperSurgical, Inc.

BD, BD Logo and all other trademarks are property of Becton, Dickinson and Company. © 2008 BD. 080-05666-00 REVE 05/08



Helping all people
live healthy lives

CYTOLOGY COLLECTION – SUREPATH COLLECTION PROCEDURE WITH HPV ORDERING GUIDELINES
 Page 5 of 5

Appendix B

