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SurePath Collection Procedure with HPV Ordering Guidelines - Cytology Collection

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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.

RESPONSIBILITY

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

SPECIMEN COLLECTION (method of sample collection)

Direct sampling of uterine cervix with approved sampling device.

MATERIALS

A. SurePath collection vial with preservative

B. Collection device (e.g. cyto-broom)

C. Access to electronic ordering and label printing (or equivalent).

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:
        i. Insert longer central bristles into cervical os.
        ii. Begin rotating device in a **clockwise** direction
        iii. Push towards the cervix while still rotating clockwise.
        iv. The lateral bristles will fan out over the extocervix and the central bristles will penetrate the endocervical canal.
        v. Complete **5 full rotations**
        vi. Remove and "pop-off" broom head into SurePath vial.
        vii. **Contraindication:** ***The Cervix-Brush should not be used on patients after the first 10 weeks of pregnancy.***
        viii. See Appendix A, option 1
    b. SurePath sample collection with combination brush/plastic spatula device
        i. Insert the contoured end of the plastic spatula and rotate 360 degrees around the entire exocervix.
        ii. Insert cyto-brush into the endocervix until only the bottom-most bristles are exposed at the os. Slowly rotate ¼ to ½ turn in one direction. To reduce unnecessary bleeding, do not over-rotate brush.
        iii. **Warning:** ***Do not use CytoBrush on pregnant patients or for endometrial sampling.***
        iv. 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 interfaced electronic ordering system. For non-interfaced clients, fill out approved cytology requis

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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:**

i. 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).

ii. Avoid pre-labeling the collection vial.

iii. Ensure that the label has the correct patient information that matches the patient whose sample is being collected.

iv. 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.

v. Use an appropriate ID double check with the patient (i.e., ask them what their name and date of birth is).

vi. Make sure all specimen labels agree with each other and the electronic order before sending

vii. Correct and reconcile any patient name or DOB discrepancies before sending

viii. 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 5800. This molecular test is performed at Rice Hospital Laboratory.
2. For current HPV testing recommendations, refer to the United States Preventative Services Task Force (USPSTF) guidelines (www.uspreventiveservicestaskforce.org), which are currently endorsed by the American Society for Colposcopy and Cervical Pathology (ASCCP).
3. HPV Reflex Options when ordering paps in the LIS or as part of a manual paper requisition order:
    a. None: No HPV testing will be reflexed or performed.
    b. Pap test with HPV Co-Testing: A HPV test will be reflexed regardless of any pap smear diagnosis including an unsatisfactory diagnosis.
    c. Reflex ASCUS only: A HPV test will be reflexed for any diagnosis of "Atypical Squamous Cells of Undetermined Significance" (ASCUS). Paps that have a diagnosis of "Atypical Squamous Cells cannot rule out HSIL" (ASC-H) will also be reflexed for HPV under this reflex option.
    d. Reflex if ASCUS or LSIL (SAGE Program): This option was created for patients enrolled in the SAGE Screening program.
4. hrHPV specimen stability using the cobas 5800 is 14 days from time of collection. If an HPV test wasn't originally ordered on the sample and you would like to order an HPV test after the cytology report is complete and it is in the 14 day collection window:

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a. Order the test in electronically using test code "LAB0203414 HUMAN PAPILLOMAVIRUS DNA DETECTION W/GENOTYPING, HIGH-RISK TYPES, PCR". If you are non-interfaced client, call RMH RMH Laboratory Laboratory Client Services.

b. Contact RMH Laboratory Laboratory Client Services to let them know that you are adding this test to the original pap sample. 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.

REGULATORY CITATIONS

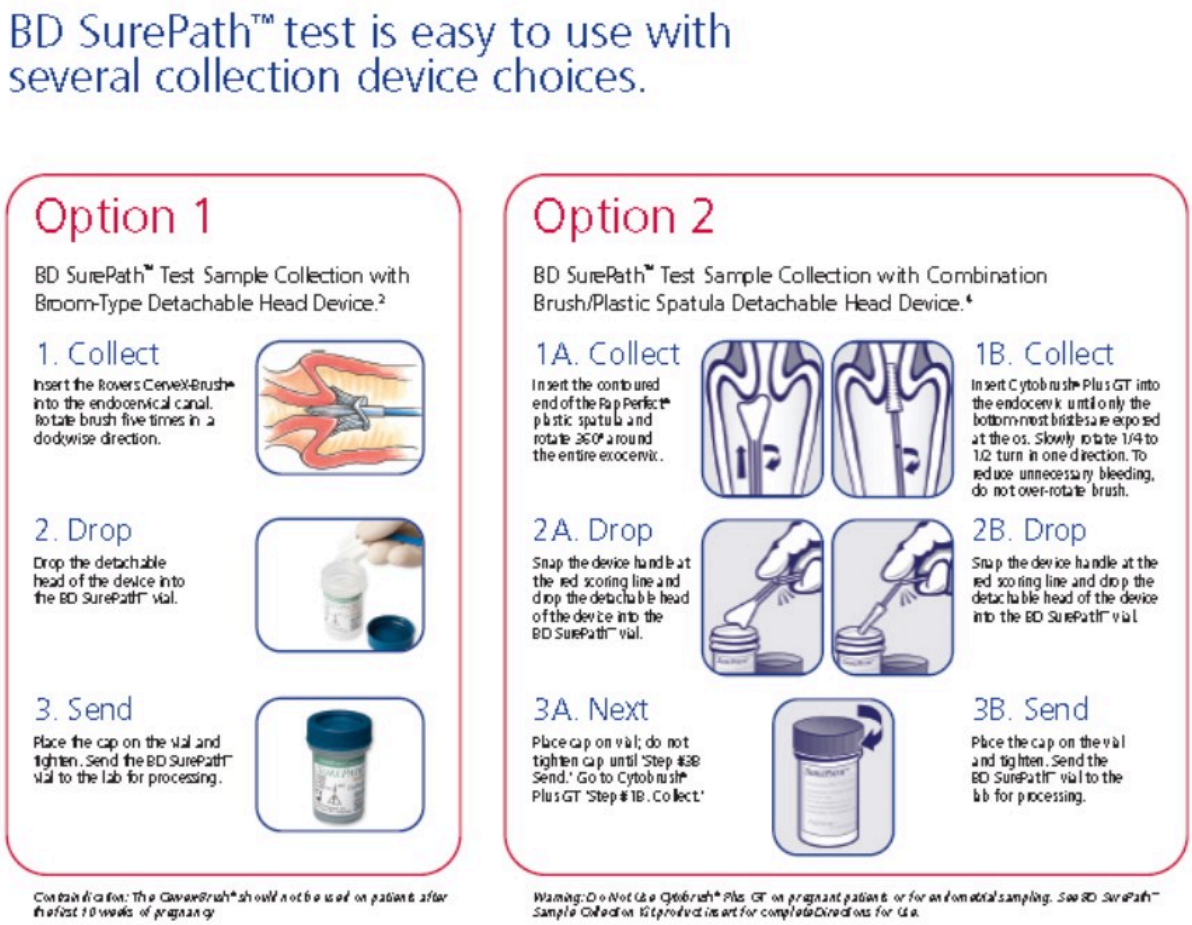
Facility specific, none stated

REFERENCE CITATIONS

http://www.bd.com/tripath/physicians/surepath.asp

http://www.asccp.org

APPENDIX A







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

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Applicability

CentraCare - Laboratories