HUMAN PAPILLOMAVIRUS (HPV)-DNA COLLECTION IN SUREPATH-Cervical/Endocervical

NOTE:
HPV TESTING IS NOT FUNDED BY MOHLTC
Patient payment is required

HPV testing can be used to refine the management of women over the age of 30 years with atypical squamous cells of undetermined significance (ASCUS). (www.cancercareontario.ca)

Specimen Anatomic Source

Cervical/Endocervical collected as a SurePath Pap
***NOTE**: ThinPrep Pap are accepted but kit is not supplied by LifeLabs*

Reflex HPV testing if ASCUS

This is a follow-up option for women with ASCUS ≥30 years of age (www.cancercareontario.ca)
HPV testing on Paps reported as ASCUS can be requested after receipt of the Pap report provided the request is received within 30 days of the specimen collection date.
The clinician should phone Cytology Customer Service (416-675-4530 ext. 46802) to order the HPV test

For anal/rectal HPV Collection instructions, refer to:

www.lifelabs.com/healthcare-providers/requisition & collection instructions

Specimen Labeling

All specimens should be clearly labeled **BEFORE** being sent to the laboratory for testing, to ensure correct identification of the patient and sample.

All specimens/containers must be labeled with:

- The patient's full name (printed in the same format as patient's health card)
- A second identifier such as date of birth or health card number

Specimen/container labeling options:

- Computer printed label affixed to the side of the sample vial.
- Clearly printed handwritten information on the sample vial label using indelible ink

Cytology Requisition Information:

All specimens must be submitted for testing with a completed Cytology & HPV Testing Requisition. The following information must be provided in a **legible format**:

1. The submitting client information (full name, address and billing number).
2. Complete the copy to - physician information (**full name and address** must be provided).
3. Full name of patient (in the same format as patient health card. Health Card Number and Date of birth. Patient address and phone number must be provided for billing purposes
4. Date of collection. Site and specimen collection method (e.g. Cervex-Brush® or Cytobrush™).
5. Select the type of HPV testing to be performed.
6. The specimen collection date.
7. Sign to authorize the request.
8. Inform the patient the laboratory will require payment for HPV testing and ask the patient to sign the requisition.

Missing physician and patient signatures will delay processing the request.

CYTOLOGY & HPV TESTING REQUISITION

LifeLabs

Requesting Clinician/Practitioner

Name

Address

1

Clinician/Practitioner Billing Number

Laboratory Use Only

Clinician/Practitioner Phone Number

3

Patient Chart Number

Health Card Number (HCN)

Sex ☐ M ☐ F

Date of Birth YYYY MM DD

Copy to Clinician(s)/Practitioner(s) *(fill in all fields)*:

Name Billing #

Address

2

Name Billing #

Address

Province

Other Province's Registration Number

Patient Phone Number

Patient Last Name *(as per Health Card)*

Patient First Name & Middle Names *(as per Health Card)*

Patient Address *(including postal code)*

GYNECOLOGIC CYTOLOGY (PAP TEST)

Clinical Indication *(check one)*:

- ☐ Pap screening according to Ontario Cervical Screening Guidelines
- ☐ Pap for follow-up of a previous abnormal test result *(specify below)*
- ☐ Pap during colposcopic exam
- ☐ Patient Pay *(none of the above; the patient has been informed that payment to LifeLabs is required.)*

Specimen Collection Date: YYYY MM DD

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Last Menstrual Period *(first day)*: YYYY MM DD

Site: ☐ Cervical/Endocervical ☐ Vaginal ☐ Other *(specify below)*

Cervix: ☐ Normal ☐ Abnormal *(specify below in Clinical History/Remarks)*

Clinical Status:

- ☐ Pregnancy
- ☐ Post Partum
- ☐ Post Menopausal
- ☐ Post Menopausal Bleeding
- ☐ IUD
- ☐ Hormone Replacement Therapy
- ☐ Irradiation
- ☐ Other *(specify below in Clinical History/Remarks)*

Hysterectomy: ☐ Sub-total (cervix present) ☐ Total (no cervix)

NON-GYNECOLOGIC CYTOLOGY

☐ OHIP/Insured ☐ Third Party/Uninsured ☐ WSIB

Specimen Collection Date: YYYY MM DD

# of Specimens Submitted # of Slides Submitted

Urine: ☐ Voided ☐ Catheterized ☐ Bladder Wash

Respiratory: ☐ Sputum ☐ Bronchial Brush ☐ Bronchial Wash

Site/Side *(if applicable)*:

Fluids: ☐ Pleural ☐ Peritoneal ☐ CSF ☐ Other *(specify)*

Site/Side *(if applicable)*:

Thyroid: ☐ Left ☐ Right ☐ Cyst ☐ Nodule ☐ Single ☐ Multiple

Breast: ☐ Left ☐ Right ☐ Cyst fluid ☐ FNA of Mass ☐ Nipple Discharge

Fine Needle Aspiration Biopsy: ☐ Left ☐ Right ☐ Kidney ☐ Salivary Gland ☐ Lung ☐ Liver ☐ Lymph Node *(specify)* ☐ Pancreas ☐ Other *(specify)*:

Other Site *(specify)*

Clinical History/Remarks:

Inadequate clinical information may hinder diagnosis. For accurate and timely cytologic diagnosis, provide all information required.

HPV TESTING

HPV testing can be ordered, at the patient's request, on the same sample that is submitted for a Pap test
HPV testing can be useful in the management of women over the age of 30. HPV testing under the age of 30 is not recommended.
HPV testing is not currently funded by the MOH. An invoice will be sent to the patient with instructions on how to make the payment. The patient is responsible to pay the current price as of date of collection. Visit LifeLabs.com/test/hpv-testing/ for pricing.

☐ Reflex HPV test only if ASCUS or LSIL

☐ HPV and Cytol… SurePath sample

☐ HPV DNA test only (NO cytol… this SurePath sample)

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Specimen Collection Date: YYYY MM

7

Physician signature:

By signing I acknowledge that I will be invoiced for, and required to pay the current price to LifeLabs for the HPV test.

Patient signature:

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Cyto-HPV Req

Specimen Exclusions:

The following samples are not accepted for HPV testing at LifeLabs:

- Conventional spray fixed Paps (Direct Smears)
- Specimens collected in vials that are not SurePath® or ThinPrep® (Digene, Qiagen)
- Paps collected using expired SurePath® or ThinPrep® collection vials
- Specimens where the collection date to receive date in the laboratory is beyond 30 days
- Non-cervical samples (penile, skin lesions, throat, etc.)
- Vaginal Vault samples
- Bloody specimens

Specimen Handling and Transportation:

- Each specimen must be placed into a polybag and a completed Cytopathology requisition
- Specimens requiring expedited service must be clearly marked as such by the health care provider taking the sample. The typical designation is: ASAP.
- For optimal results transport the specimens to the laboratory as soon as possible after collection

Optimal Patient Conditions for Screening Cytology:

- Patient has not douched the vagina for 48 hours prior to examination
- Patient has avoided the use of contraceptive creams or jellies for 48 hours prior to examination
- Mid-cycle smears are optimal for testing
- Avoid sending samples with blood as this will interfere with molecular testing

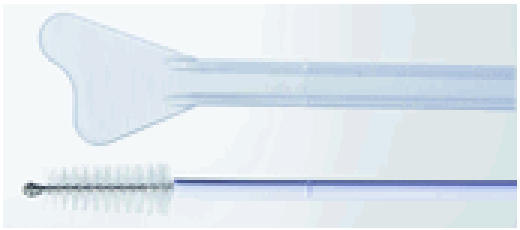
SPECIMEN COLLECTION KIT FOR HPV TESTING (USE THE SUREPATH PAP KIT)

Collection Kit Information:

- Pap kit components are ordered separately:
  - Liquid based collection vial with 10 mL of cytology preservative
  - Cytology requisition
  - Polybag
  - Collection device (two are available):

1. Pap Collection Broom Kit: Cervex-Brush® can sample the ectocervix and endocervix in one procedure.
   ***Note**: The Cervex-Brush® is latex free.*

2. Pap Brush/Spatula Collection Kit: Cytobrush™ & plastic spatula used to collect cells from the endocervix and ectocervix respectively by two separate collection procedures.



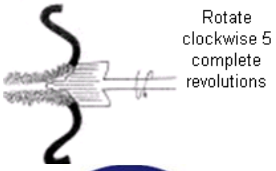
CAUTION: SurePath® Preservative Fluid contains an aqueous solution of denatured ethanol and small amounts of methanol and isopropanol. Do not ingest. If swallowed, do not induce vomiting. Call a physician immediately. Give plenty of water to drink. Never give anything by mouth to an unconscious person. If inhaled, remove person to fresh air. In case of contact, immediately flush skin with water; immediately flush eyes with plenty of water for at least 15 minutes. Flammable; keep away from heat, sparks & open flame. Avoid contact with eyes.

***NOTE**: ThinPrep Pap are accepted but kit is not supplied by LifeLabs*

Collection Instructions Using the Cervex-Brush®

Note: If used in pregnancy the collection technique should be modified (see below).

1. Label a SurePath® collection vial with the required identifiers and complete a cytology requistion.
2. Insert a speculum into the vagina. (Warm water may be used to lubricate the speculum but lubricant jellies should be avoided).
3. Identify the cervical os.
4. Insert the central (longest) bristles of the Cervex-Brush® into the endocervical canal.
5. Apply gentle pressure until the shorter side bristles bend from contact with the ectocervix.
6. While maintaining gentle pressure sufficient to keep the side bristles bent, rotate the Cervex-Brush® through five complete (360º) clockwise revolutions.



7. Using a gloved thumb and forefinger immediately push the head of the Cervex-Brush® from the stem into the larger opening of the labelled container containing cytology preservative. Discard the stem.

8. Re-cap the vial and tighten the lid securely.
9. Place the labeled vial into a polybag with a completed cytology requisition (including patient and healthcare provider information; and pertinent clinical information).
10. Keep the preserved specimen at room temperature or refrigerated (2-8ºC). It is recommended to return the specimen to the laboratory as soon as possible after collection.
11. Store and transport the specimen at room temperature to the laboratory within 24 hours of collection.

Pregnant Patients:
The Cervex-Brush® may be used on pregnant patients up to the 10-week mark. The Cervex-Brush® can be used in a manner similar to spatula. The central bristles of the Cervex-Brush® should not be inserted deep into the canal but by firm pressure and rotation in a clockwise direction, the device may be used to sample the external os and ectocervix. A vaginal pool sample may also be obtained.

Minimum Specimen Volume: 4 ML

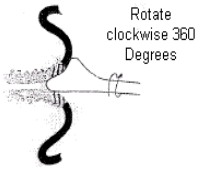
Collection Instructions Using the Cytobrush™ & Plastic Spatula

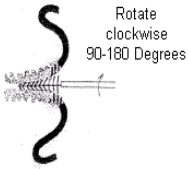
Note:

- The Cytobrush™should not be used on pregnant patients or for endometrial sampling.
- Place the heads of both collection devices into the same collection vial.

1. Label a SurePath® collection vial with the required identifiers and complete a cytology requistion.
2. Insert a speculum into the vagina. (Warm water may be used to lubricate the speculum but lubricant jellies should be avoided).
3. Identify the cervical os.
4. Insert the longer tip of the plastic spatula into the endocervical canal.
5. Rotate the spatula through 1 complete revolution (360 degrees) while maintaining tight contact with the cervix.
6. Using gloved hands, break off the tip of the spatula at the score line and deposit it into the larger opening of the collection container with preservative. Discard the stem.

7. Insert the Cytobrush™ into the endocervical canal (keeping the last row of bristles visible). Slowly rotate the Cytobrush™ clockwise 90 to 180°, excessive rotation will distort the cells.





8. Using gloved hands, break off the tip of the Cytobrush™ at the score line and deposit it into the larger opening of the collection container with preservative. Discard the stem.

9. Re-cap the vial and tighten the lid securely.
10. Place the labelled vial into a polybag with a completed cytology requisition (including patient and healthcare provider information; and pertinent clinical information).
11. Store and transport the specimen at room temperature to the laboratory within 24 hours of collection.

Minimum Specimen Volume: 4 ML

Reference:

SurePath Collection Poster BD 2014, 980-0566-00 REV E 09/14