OCSP SCREENING TEST- CERVICAL/ENDOCERVICAL/VAGINAL IN THINPREP COLLECTION

Specimen Anatomic Source

Cervical/Endocervical/Vaginal collected in ThinPrep specimen container

REQUISITIONS: See Testing Indications for specific test to be requested

For Cervical Screening

- ***HPV Test***
- ***Cytology only (Pap only)***

Colposcopy for Follow -Up of Cervical Screening-Related Abnormalities

- ***Co-Test (HPV test and Cytology)***
- ***HPV test only***
- ***Cytology test only (Pap only)***

For information regarding the HPV Cervical/Endocervical collection and testing please refer to:
www.lifelabs.com/healthcare-providers/requisition & collection instructions

Specimen Labeling

All specimens should be clearly labeled **BEFORE** being sent to the laboratory 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

Requisition Information:

Specimens submitted for testing will have the correct Clinical Indication as per Ontario Cervical Screening Guidelines (OCSP) accompanied by the correct requisition. The following information must be provided in a **legible format**:

1. The requester information (requester type, CPSO number, billing number full name address and phone number).
2. Complete the copy to information (full name, billing number, address, billing number and phone number).
3. Full name of patient in the same format as indicated on OHIP card (full name, date of birth, sex, OHIP number with version code
4. Patient complete address with postal code and phone number

5. Correct clinical Indication as per Ontario Cervical Screening Program guidelines
   IMPORTANT: **SELECT THE MOST APPROPRIATE INDICATION**
6. Specimen site, pertinent clinical information, collection and other clinical information
7. Requester signature
8. Date the test is requested

Ontario Health
Cancer Care Ontario

Human Papillomavirus (HPV) and Cytology Tests Requisition – For Cervical Screening

Lab Use Only

- **Eligibility Criteria:** People with a cervix age 25 and older who have ever been sexually active and have a valid OHIP number.
- Ontario Cervical Screening Program's cervical screening recommendations and cessation criteria can be found at ontariohealth.ca/OCSP-recommendations.
- **Immunocompromised populations include** people who are living with HIV/AIDS (regardless of CD4 cell count), congenital (primary) immunodeficiency, systemic lupus erythematosus (regardless of whether they are receiving immunosuppressant treatment), renal failure and require dialysis, transplant recipients (solid organ or allogeneic stem cell transplants) or people requiring treatment (either continuously or at frequent intervals) with medications that cause immune suppression for 3 years or more.
- Referral to a specialist is required for any visible cervical abnormalities.

Requester Information Requester type (check ONE):
☐ Physician ☐ Midwife ☐ Nurse practitioner

CPSO or CNO number:
Practitioner billing number: 1
Last name:
Middle name: (optional)
First name:
Address:
Fax: ( ) Phone: ( )

Copy to: Primary care provider
Last name:
First name: 2
Address: (optional)
Fax: ( ) Phone: ( )

Patient Identification (Enter information as indicated on OHIP card. Can be replaced by a sticker.)
Last name:
Middle name: (optional) 3
First name:
Date of birth: yyyy / mm / dd Sex: ☐ Male ☐ Female
OHIP number: OHIP version:

Patient Contact (Mailing address for result letters and other correspondence. Verify with patient.)
Building / Street number: Street name:
Apt./Unit number: City: 4
Province: Postal Code:
Phone: ( ) Extension: (optional)
Type: ☐ Home ☐ Work ☐ Cell

Testing Indication for Cervical Screening (check ONE):

A. HPV test (includes reflex cytology if HPV-positive) 5
- ☐ Average risk screening: every 5 years
- ☐ Immunocompromised screening: every 3 years
- ☐ HPV-positive (other high-risk types) with normal or low-grade (NILM/ASCUS/LSIL) cytology: 2-year follow-up (moderate risk)
- ☐ More frequent screening post-colposcopy: 2-year follow-up (moderate risk)
- ☐ People with histologic evidence of dysplasia in the cervix at the time of hysterectomy and people with a history of early cervical cancer: 1-time post-hysterectomy vaginal vault testing

B. Cytology test only
- ☐ Repeat after a previous HPV-positive (other high-risk types) with unsatisfactory cytology result

Specimen
Site: ☐ Cervical/endocervical ☐ Vaginal ☐ Double cervix

Special considerations for cytology interpretation: 6
- ☐ Intrauterine device (IUD)
- ☐ Menopausal hormone therapy (MHT)
- ☐ Post-menopausal
- ☐ Postpartum
- ☐ Pregnancy
- ☐ Subtotal hysterectomy
- ☐ Transition-related hormone therapy

Specimen collection date: (yyyy/mm/dd)
Last menstrual period (first day): (yyyy/mm/dd)

Clinical information

Requester Verification
Requester signature: 7
Date: (yyyy/mm/dd) 8

Need this information in an accessible format? 1-877-280-8538, TTY 1-800-855-0511, info@ontariohealth.ca.
Document disponible en français en contactant info@ontariohealth.ca

Ontario Health
Cancer Care Ontario

Human Papillomavirus (HPV) and Cytology Tests Requisition – Colposcopy for Follow-Up of Cervical Screening-Related Abnormalities

Lab Use Only

- Please follow the Ontario Cervical Screening Program testing recommendations for colposcopy episodes of care. Recommendations can be found at ontariohealth.ca/OCSP-colposcopy.
- This requisition is not for people with cervical cancer symptoms who are referred to colposcopy for non-screening indications.
- For cervical screening or vaginal vault testing performed in gynecology, use the cervical screening requisition.
- Do not repeat HPV or cytology test at initial colposcopy.

Colposcopist Information

CPSO number:

Practitioner billing number:

Last name: 1

Middle name: (optional)

First name:

Address:

Fax: ( ) Phone: ( )

Copy to: Primary care provider

Last name:

First name: 2

Address: (optional)

Fax: ( ) Phone: ( )

Patient Identification (Enter information as indicated on OHIP card. Can be replaced by a sticker.)

Last name:

Middle name: (optional)

First name: 3

Colposcopy referral date: yyyy / mm / dd

Date of birth: yyyy / mm / dd Sex: ☐ Male ☐ Female

OHIP number: OHIP version:

Patient Contact (Patient mailing address and phone number.)

Building / Street number: Street name:

Apt./Unit number: City: 4

Province: Postal Code:

Phone: ( ) Extension: (optional)

Type: ☐ Home ☐ Work ☐ Cell

Testing Indication for Colposcopy and Tests Required (check ONE):

A. Co-test (HPV test and cytology)

- ☐ Co-testing 12 months after initial colposcopy where high-grade squamous intraepithelial (HSIL) lesion was not detected
- ☐ Co-testing during post-treatment follow up for HSIL or adenocarcinoma in situ (AIS)
- ☐ Co-testing for vaginal vault investigation 5
- ☐ Co-testing after invalid HPV test result with no or unsatisfactory cytology

B. HPV test only

- ☐ Invalid HPV test result with satisfactory cytology

C. Cytology test only

- ☐ Referred with no cytology results in the previous 6 months or after valid HPV test result with unsatisfactory cytology

Specimen

Site: ☐ Cervical/endocervical ☐ Vaginal ☐ Double cervix

Special considerations for cytology interpretation:

- ☐ Intrauterine device (IUD)
- ☐ Menopausal hormone therapy (MHT)
- ☐ Post-menopausal
- ☐ Postpartum
- ☐ Pregnancy
- ☐ Subtotal hysterectomy
- ☐ Transition-related hormone therapy

6

Specimen collection date: (yyyy/mm/dd)

Last menstrual period (first day): (yyyy/mm/dd)

Clinical information

Requester Verification

Requester signature: 7

Date: (yyyy/mm/dd) 8

Need this information in an accessible format? 1-877-280-8538, TTY 1-800-855-0511, info@ontariohealth.ca.
Document disponible en français en contactant info@ontariohealth.ca

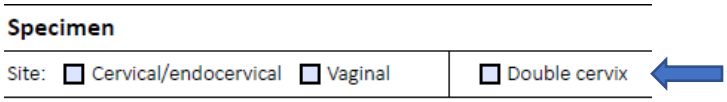
Specimen Exclusions:

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

- Conventional spray fixed Paps (Direct Smears)
- Specimens collected in SurePath® vials
- Paps collected using expired ThinPrep® collection vials
- Specimen collection device (brush or broom) should NOT be included in sample container. **Samples containing brush or broom head will be rejected** due to contamination risk as per Ontario Health Guidance
- Samples that leaked are rejected due to contamination risk

Specimen Handling and Transportation:

- Specimens collected from multiple sites should be collected in separate vials with the specimen source identified. Check the double cervix box.



- Each specimen must be placed into a polybag.
- A completed Cytopathology requisition must accompany each specimen.
- 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.
- Minimum volume is 5 ml.

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 cytological evaluation

Packing Your Specimens:

Specimens in individual poly bags can be packed into the supplied LifeLabs transport bags labeled as ‘Cyto’ or ‘HPV’ testing and provided to your LifeLabs courier as per the prearranged pickup schedule.

Use of a specimen manifest is highly recommended to ensure that samples contained in the bag can be verified upon receipt at the testing location.

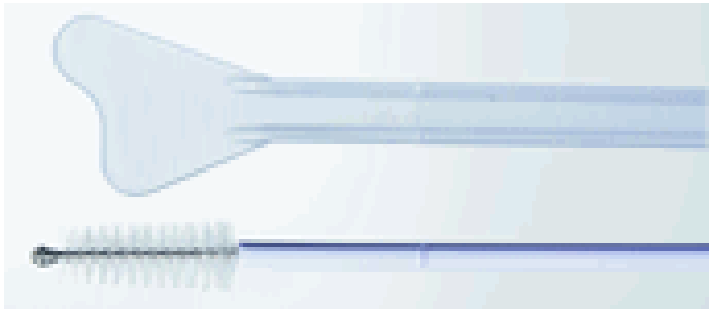
Collection Kit Information:

- Pap kit components are ordered separately:
  - ThinPrep collection vial with 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: ThinPrep® 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.

Ontario Cervical Screening Program (OCSP): How to Collect a Cervical Sample

The ThinPrep® System

The Ontario Cervical Screening Program (OCSP) uses the ThinPrep® system for cervical sample collection in cervical screening and colposcopy. Many providers will be familiar with the devices and methods used in the ThinPrep® system. The same sample collection processes are used for all of the tests involved in the OCSP: human papillomavirus (HPV) testing with reflex cytology, cytology testing only, and HPV and cytology co-testing (in colposcopy settings only).

Collection Device Options

There are two collection device options: a broom-like device and an endocervical brush-spatula combination. Choose one of these options based on your preference.

Broom-like device (page 2)

Endocervical brush-spatula combination (page 3)

For warnings, contraindications and limitations associated with sample collection, refer to the manufacturer instructions provided with the collection device.

Tips for Collecting Cervical Samples

Do not leave any part of the collection device, including the head of the broom, the head of the endocervical brush or the spatula, in the vial: Unlike some other systems for cervical sample collection, the ThinPrep® system does not allow any collection devices to be left in collection vials. Samples with devices left inside the vial will be rejected by the laboratory.

Avoid certain types of lubricant or use water to lubricate: Using too much lubricant or using lubricants that contain carbomer or Carbopol® polymers (thickening agents) may cause an invalid test result. To minimize the risk of an invalid test result:

- Use lukewarm water to warm and lubricate the speculum
- If a lubricant gel needs to be used for patient comfort:
  - Use a dime-sized amount of water-soluble and carbomer-free gel lubricant[1,2]
  - Apply the lubricant only to the outer sides of the speculum blades, avoiding contact with the tip and inner sides of the speculum
  - A list of lubricant brands that have been validated by Hologic, Inc. for use with the ThinPrep® system can be found in the ThinPrep® Pap Test Lubricant Compatibility List[3] at hologic.com

Remember to label all samples with the patient's full legal name (first and last), date of birth and the date of specimen collection: If the patient's legal name and date of birth on the label do not match the requisition, testing may be delayed or the sample may be rejected by the laboratory. A pre-printed label is preferred.

Remember to check the expiry date of the collection vial before you collect a sample: Cervical samples collected using expired medium will be rejected by the laboratory.

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How to Use the Broom-Like Device for Collection

1 **Write the patient's legal name (first and last), their date of birth and the date of specimen collection on the vial, or attach a pre-printed label.**

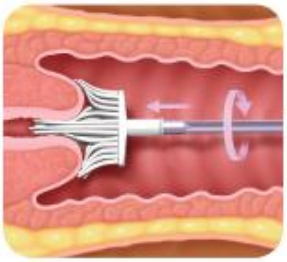
Fill out the appropriate OCSP requisition form (i.e., the form for cervical screening or the form used in colposcopy for the follow-up of cervical screening-related abnormalities).

If the information on the label does not match the requisition, testing may be delayed or the sample may be rejected by the laboratory.

2 **Collect a sample from the cervix using the broom.**

Insert the central bristles of the broom into the endocervical canal, ensuring that the shorter bristles fully contact the ectocervix.

Push gently until you see the bristles bend outward. Rotate the broom all the way around five times (i.e., five complete 360-degree turns).



3 **Insert the broom into the vial.**

Push the broom into the bottom of the vial, forcing the bristles apart, 10 times.

Keep rotating the broom back and forth as you remove it from the vial to release additional cellular material.

Discard the broom.

Do not leave the head of the broom in the vial or the laboratory will reject the sample.

4 **Tighten the cap so that the torque line on the cap passes the torque line on the vial. Leaking samples may be rejected or may cause invalid results.**

Put the vial and requisition into a leak-proof sample bag for mailing to the laboratory.

How to Use the Endocervical Brush-Spatula Combination for Collection

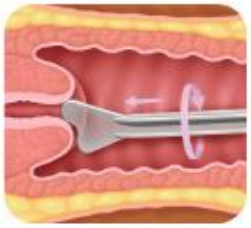
1 **Write the patient's legal name (first and last), their date of birth and date of specimen collection on the vial or attach a pre-printed label.**

Complete the appropriate OCSP requisition form (i.e., form used for cervical screening or in colposcopy for the follow-up of cervical screening-related abnormalities).

If the information on the label does not match the requisition, testing may be delayed or the sample may be rejected by the laboratory.

2 **Collect a sample from the ectocervix using the plastic spatula.**

Rotate the spatula once all the way around (a full 360-degree turn) while maintaining steady, but light, contact with the ectocervical surface. It does not matter what direction you rotate the spatula.



3 **Insert the spatula into the vial.**

Rotate the spatula back and forth in the vial 10 times.

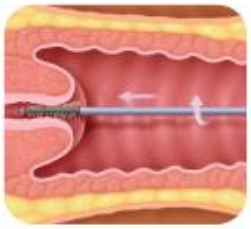
Discard the spatula.

Do not leave the head of the spatula in the vial or the laboratory will reject the sample.

4 **Collect a sample from the endocervix using the endocervical brush.**

Insert the brush into the cervix until you can see only the bottom-most fibres.

Slowly rotate the brush one-quarter to one-half turn in one direction only.



Do not over-rotate the brush or it can cause bleeding.

5 **Insert the brush into the same vial you inserted the spatula.**

Rotate the brush back and forth in the vial while pushing it against the wall of the vial 10 times.

Keep rotating the brush back and forth as you remove it from the vial to release additional cellular material.

Discard the brush.

Do not leave the head of the brush in the vial or the laboratory will reject the sample.

6 **Tighten the cap so that the torque line on the cap passes the torque line on the vial. Leaking samples may be rejected or may cause invalid results.**

Put the vial and requisition into a leak-proof sample bag for mailing to the laboratory.

3

Additional Instructions

How to collect a sample from someone who is pregnant

People who are pregnant can be screened in the OCSP if they are otherwise eligible for cervical screening. Cervical sampling is safe, but instruments should not enter the cervical canal, which means the endocervical brush should not be used to collect a sample from someone who is pregnant.

Options for collecting a sample from someone who is pregnant include:

- Using the broom as instructed (follow instructions on page 2), or
- Using the plastic spatula only (steps 3 and 4 on page 3) and do not use the endocervical brush (skip steps 5 and 6)

For patient comfort, cervical screening is usually avoided after 24 weeks. Cervical screening can be resumed as early as six weeks postpartum.

How to collect and label samples from people with a double cervix

Collect one sample from each cervix in people with a double cervix. Use a new collection device for each cervical sample, but make sure both samples are collected using the same type of device (broom or endocervical brush-spatula combination). Each sample should be placed in a separate vial that identifies which cervix they are from (i.e., right or left cervix). Both samples should be submitted using a single requisition form.

How to collect a sample from the vaginal vault

Some people who have had their cervix removed as part of a hysterectomy may need a single HPV test of the vaginal vault*. When collecting a sample from the vaginal vault, use either:

- The broom, or
- The plastic spatula only (i.e., do not use the endocervical brush)

The sample should be collected from the top of the vaginal vault in a back and forth, horizontal (i.e., left to right) sweeping motion five times. The broom or spatula should make full contact with the top of the vaginal vault during collection.

The Ontario Cervical Screening Program Guidance for Vaginal Vault testing is available at: ontariohealth.ca/Vaginal-vault

References

1. Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition (Clinical and Laboratory Standards Institute GP15-A3).

2. Hologic internal study, data on file.

3. ThinPrep® Pap Test Lubricant Compatibility List. MISC-04037-001. Marlborough, MA: Hologic, Inc.; 2020.

*The use of the HPV test is approved by Health Canada for health care provider-collected cervical samples but has not been reviewed or authorized by Health Canada for use in the vaginal vault. HPV test performance has not been specifically evaluated for detecting vaginal precancer/cancer in relevant populations, therefore risks to the patient may include, but are not limited to, a decrease in testing accuracy. The Ontario Cervical Screening Program Guidance for Vaginal Vault Testing has been developed by Ontario Health in consultation with a multidisciplinary, international expert panel. Other Canadian and international jurisdictions also provide guidance on using the HPV test in the vaginal vault. The information provided by Ontario Health is not intended to serve as a substitute for a clinician's professional experience, independent judgment and decision making. Ontario Health assumes no liability whatsoever for any errors or omissions associated with the information provided herein and furthermore assumes no liability for any decision or action taken by the clinician or others in reliance on the information contained in these materials.

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