



Cervical Cancer Screening Lab (CCSL)

About the Cervical Cancer Screening Laboratory

The Cervical Cancer Screening Laboratory (CCSL) is funded by the Provincial Health Services Authority (PHSA) to provide cervix screening testing to all eligible women and people with a cervix in British Columbia. The laboratory distributes cervix screening test sampling supplies to health care practitioners at no cost (see Appendix A). CCSL s accredited by the College of American Pathologists and by the Diagnostic Accreditation Program of College of Physicians and Surgeons of British Columbia (ISO 15189).

Contact us:

Phone: 1-877-747-2522 (1-877-PHSA LAB)

8:00am – 4:00pm Mon-Fri (except Statutory holidays)

Current Cervix Cancer Screening Guidelines

Cervix Screening guidelines are developed by the BC Cancer Cervix Screening Program. Current guidelines can be found on the BC Cancer website at <u>www.bccancer.bc.ca/screening/health-</u>professionals/cervix/resources.

Provider registration

Cervical cancer screening testing can be performed by:

- 1) Members of the BC College of Physicians and Surgeons
- Members of the BC College of Nurses and Midwives: professionals who carry out pelvic exams or cervical cancer screening must possess the competencies established by their scope of practice: www.bccnm.ca/Pages/Default.aspx
- 3) Members of the Association of Naturopathic Physicians of BC -- for provider-collect LBC samples only

To request registration as a new provider, please contact the laboratory at: <u>CCSLClientServices@phsa.ca</u>

Specimen types

Patient-collect vaginal swabs

A FLOQSwab[®] can be collected by the patient or with the

assistance of a healthcare practitioner. The standard CCSL lab requisition can be used if collected in-clinic (ensure collection method "Vaginal swab: provider-collect" is ticked) or if the swab is collected by the patient (select collection method "Vaginal swab: patient-collect", and ensure mandatory requisition elements are completed for patient).

Provider-collect vials – liquid-based (LBC) for HPV and/or Cytology

The current collection kits provided by CCSL is the Hologic Preservcyt[®] LBC vial with spatula/cytobrush collection devices. Provider-collected samples will be triaged at the laboratory to either primary HPV testing or cytology, depending on the patient's screening/clinical history and/or age. Starting January 29, 2024 the age of eligibility for primary HPV on provider-collect samples is 55 year old, with a step down approach to include younger age groups in time. This step-down approach is



FLOQSwabs

important to ensure the laboratory operations and colposcopy clinics are not overwhelmed and can continue to deliver quality patient care.

- In the primary cytology stream, any provider-collect sample that has any cytologic atypia will be reflexed for HPV testing on the same vial.
- In the primary HPV stream, any positive HPV test result will have cervical cytology testing performed from the same vial.

Cervix Self-Screen or LBC Sample Collection Algorithm can be found here.

Specimen collection

Patient-collect FLOQSwabs®

Please follow the instructions received in the self-collect kit for detailed instructions on collection of vaginal swabs for HPV testing. Once collected, a swab can remain at room temperature and does not need to be refrigerated. It should be sent to the Lab as soon as possible to ensure the Lab has time to re-suspend the swab in preservative prior to 28 days after collection.

Download swab collection instructions here.

Provider-collect Preservcyt[®] vials

1. Labeling

The specimen vial should be labeled prior to collection of the sample. Proper and legible labeling of the vial, that matches the requisition and the BC Services Card exactly, will ensure there are no issues or delays with sample processing.

All specimen vials must be labeled with a minimum of two patient identifiers:

- Patient's LAST NAME and DATE OF BIRTH or
- Patient's LAST NAME and PHN (Personal Health Number)

Note: A pre-printed patient label may be used (affix along manufacturer's label), or patient identifiers may be clearly handwritten.



A sample will be rejected when the last name and DOB or PHN are not on the vial, or when there is a major discrepancy in the spelling of the last name, or the date of birth.

2. Prepare for collection of cervical material

When possible, the sample should be obtained at mid-cycle as applicable.

- i. Ensure direct visualization of the cervix, if present.
- ii. Gently insert a sterile, pre-warmed speculum to visualize cervix.

Please note: use of lubricants during sampling is discouraged when at all possible as it will interfere with sample processing and yield an unsatisfactory result with liquid-based cytology (LBC) and may interfere with PCR HPV testing. Please use warm water.

If a lubricant is required (e.g. in post-menopausal patients) then a tiny amount of lubricant may be used on the lower bill or posterior sides of the speculum (avoid the tip). The FDAapproved lubricant for use with LBC is the water-soluble, **carbomer-free** lubricant Surgilube[®].

See Appendix A for more information.

- iii. Gently cleanse the cervix with cotton pledget if obscured with discharge or secretions.
- iv. Identify extent of transformation zone and probable squamocolumnar junction.

Variation in Cervical Transformation Zone

The transformation zone is the region lying between the columnar epithelium of the endocervix and the mature squamous epithelium of the ectocervix. It is this region that is highly susceptible to HPV infections that cause cervical dysplasia and carcinoma.

Cautions

- If a clinically suspicious lesion is seen, biopsy immediately or refer for colposcopy without waiting for cervix screening results.
- A screening test is not needed for colposcopy referral and may be expedited if clinical suspicion is high.
- If the patient is menstruating or infection is present reschedule the exam.
- Irregular bleeding may be a symptom of gynecological malignancy. Pelvic examination with lower genital tract and appropriate investigation is indicated.
- Use of the cytobrush is not recommended in pregnant women.

The location of the squamocolumnar junction is dependent on the individual's age, parity, hormonal status and any previous surgery. Generally, during the reproductive years, the transformation zone lies on the ectocervix. Post-menopausally, it recedes within the endocervix.

Sampling both the endocervix and the ectocervix improves the likelihood of sampling the transformation zone, however absence of the transformation zone in the sample alone does not warrant earlier rescreening.

Reference:

Polanco Jacome EC, Maerki J, Chau K, Akerman M, Sajjan S, Klein M, Gimenez C, Laser A, Das K. Lack of transformation zone in cervical Pap tests, should it be a concern? A quality assurance initiative. Diagn Cytopathol. 2018 Jul;46(7):584-588. doi: 10.1002/dc.23955. Epub 2018 May 2. PMID: 29722175.

https://onlinelibrary.wiley.com/doi/10.1002/dc.23955

3. Obtaining the sample

The spatula/cytobrush collection device combo was chosen as the preferred collection combination over the broom, do the increased cellular yield obtained. Vials received with a broom or brush left in the vial will be rejected.

A. Sampling ectocervix and endocervix

Spatula: Insert the plastic spatula into the
cervical os and rotate 360° whileCyrmaintaining tight contact with the
ectocervixthe

Cytobrush: Insert the cytobrush into the cervix until only the bottom-most fibers are seen, then slowly rotate ¼ or ½ turn



<u>Rinse the spatula as quickly as possible</u> into the Preservcyt[®] vial by swirling vigorously at least 10 times. Discard the spatula.



<u>Rinse the brush as quickly as possible</u> into the Preservcyt[®] vial by rotating the device at least 10x while pushing against the vial wall. Discard the brush.

B. Sampling the vaginal vault (e.g. after total hysterectomy or for those with DES exposure)

Spatula: Insert the spatula to the top of the vagina and rotate while maintaining contact with the vaginal vault.

4. Prepare the vial for transport

Tighten the vial cap securely and ensure the black line on the cap passes the black line on the vial. Place in a plastic bag (with absorbent pad if feasible), along with the completed requisition.

Refrigeration of the sample is not required.



Download a single-page PDF of the LBC collection instructions <u>here</u>.

Laboratory Requisition

To ensure the patient's demographics are up-to-date, the laboratory requires:

- Current and correct spelling of the first, middle, last names. The name on the requisition and the name on the specimen vial must match exactly.
- Personal Health Number (PHN) if available
- Date of birth (day/month/year) on the requisition and on the specimen vial must match exactly.
- Gender: options are Female, Male, Unknown, X (non-binary). Please note gender other than Female/Male will be reflected on the report as 'U' (unknown) due to limitations of the laboratory information system.



Mandatory fields ...

Prevent delays or rejection of samples by ensuring <u>all</u> mandatory sections highlighted in yellow on the requisition are completed.

To ensure optimum evaluation of specimens, the laboratory requires:

- Sample collection date
- Date of the patient's last menstrual period (LMP) – for LBC vials only
- Collection method (e.g. LBC vial or vaginal swab)
- Reason for test e.g. asymptomatic screening, follow-up of self-collect HPV positive, etc
- Relevant clinical information e.g., IUD, DES exposure, immunocompromised status, medications.
- Relevant past history, such as the reason for total hysterectomy procedures or out of province histologically proven cervical abnormalities. This information helps determine appropriate follow-up recommendations.
- Please print clinical comments clearly on requisitions to ensure they are legible.

To ensure accurate report delivery, the laboratory requires:

- Practitioner or clinic responsible for follow-up, with full address & MSP number
- Sample collector, if different from above.

Download the most up-to-date CCSL requisition here.

Specimen Transportation

To ensure that the specimens arrive at the Cervical Cancer Screening Laboratory:

Provider-collect vials

- The clearly labeled vials, with last name and date of birth (or PHN) as the minimum specimen labeling should be placed in plastic bag provided.
- The completed CCSL requisition should be folded and inserted into the plastic bag with the tightly-closed vial, along with a small piece of absorbent material if feasible in case there is specimen leakage (e.g. paper towel, gauze, etc).

Note: ensuring the vial cap is tightly closed will prevent any leakage

- Samples requiring expedited processing due to clinical concerns should be marked URGENT on the sample's outer packaging using a red marker in addition to writing URGENT on the requisition.
- Refrigeration is not required
- Package up to 25 individual vials in outer packaging
 Refer to: CCSL LBC Packaging & Shipping Instructions here
- The vial and requisition should be sent by courier or Canada Post addressed to the laboratory

Note: please do not keep vials in clinic for more than a few short days to allow adequate time for processing (vials must be processed no later than 6 weeks post collection)

Vaginal swabs

- The clearly labeled swabs, with last name and date of birth (or PHN) as the minimum specimen labeling should be placed in an envelope or plastic bag.
- The completed requisition either the 'At-Home' requisition provided in the kit mailed to the patient, or the standard CCSL requisition – should be included in the envelope or bag, or securely fastened around the swab.
- Refrigeration is not required

Did you know ...

The Cervical Cancer Screening Lab validation of the FLOQSwab® for HPV testing confirmed stability over a temperature range of -80 degrees to +50 degrees Celsius

- There are no restrictions on how many swabs can be bundled together and sent to the lab.
- Please send to the Lab in a timely manner to ensure the laboratory has sufficient time to transfer the cells into the preservative no more than 28 days after collection.
- The swab can be sent to the Lab using already established courier delivery or via Canada Post

DELIVER ALL SAMPLES TO:

Cervical Cancer Screening Laboratory c/o Central Processing and Receiving 655 West 12th Avenue Vancouver, BC V5Z 4R4

Unacceptable Samples and Sample Rejection

Cervical Cancer Screening samples will be rejected for reporting for the following reasons:

- 1) Samples that lack the appropriate labelling of patient identifiers or are labelled with discrepant identifiers
- 2) Requisition forms lacking patient identifiers or containing discrepant information
- 3) Samples not accompanied by an appropriate requisition form
- 4) Samples that exceeded a reasonable time period between the sampling date and the sample received date
- 5) Leaking vials that have insufficient sample remaining or that leak and cause patient identifiers on the vial label to be illegible
- 6) Sample vials or swabs that are used beyond expiry date (vials have a 2 year expiry date)
- 7) Swab containers damaged or improperly closed
- 8) Swabs received more than 28 days from date of collection
- 9) Sample vials received more than 3 months from date of collection
- 10) Specimens submitted using an unapproved collection method/device
- 11) Specimens submitted when cervix screening is not suitable for the patient (i.e. HPV tests in those under age 25)

Health care providers are advised when a new sample needs to be collected.

Criteria for an adequate cervical cancer screening test

A. HPV

The laboratory test for HPV (Roche cobas[®] assay) utilizes human beta-globin DNA as an internal control to confirm sample adequacy and monitor sample preparation and polymerase chain reaction (PCR) processes. Invalid HPV tests are most commonly due to insufficient sampling indicated by an absence of beta-globin but may also rarely indicate a test process or interference error.

B. Cervical cytology

The presence of endocervical cells, metaplastic cells, and squamous cells suggest that the transformation zone has been sampled, which is generally considered optimal. Cervical samples without a transformation zone component show abnormalities at a similar rate of samples without this component, and will still be reported as adequate for interpretation.

Specimens are regarded as unsatisfactory if:

- 75% or more of the cells are obscured by inflammatory exudate or replaced by interfering substances (blood or lubricant)
- Excessive cytolysis (cellular disintegration) is present
- Too few squamous epithelial cells are present o (generally less than 5,000 well-preserved, wellvisualized squamous cells), or the sample consists mainly of endocervical glandular cells (sample mainly from the endocervical canal and not representative of the transformation zone)

Reporting of Results

Cervical Cancer Screening results will be reported through the laboratory information system using the Excelleris distribution system. Reporting directly to Electronic Medical Records is preferred. Results showing significant findings such as features diagnostic or suspicious for invasive carcinoma are faxed in addition to the usual distribution channel.

The healthcare provider identified as responsible for follow up will be considered as the primary provider. Reports will be sent to the follow-up provider, sample provider (unless a locum) and all 'copy to' providers, provided they have a registered address in our system. If the provider has multiple addresses in our system and have not indicated which specific address should be used, the default address will be used. If no provider was entered on the requisition, the patient will be informed directly by registered letter, using the current address identified in the Medical Services Plan patient record. This process does not negate the primary healthcare provider's responsibility to supply accurate contact details.

Patients can access their Cervix Screening test results on <u>Health Gateway</u>. Reports will also be routed to the MyCareCompass portal for those patients who are registered with this service. For normal cytology results, the patient will receive a verbatim copy of the report. For abnormal cytology results the patient will be instructed to contact their provider.

Where supported by the EMR vendor, reports will be flagged for specific review by healthcare provider in the following way:

Interpretation	Recommendation	Flagged
HPV POSITIVE (any)	Repeat Pap or Colposcopy	Y
HPV NEGATIVE (all)	5Y, 3Y, or 1Y	Ν
ASC-H, AGC, HSIL+	Colposcopy	Y
ASCUS, LSIL	6m repeat or Colposcopy	Y
NILM	6m repeat or Colposcopy	Ν
NILM, endometrial cells in a woman >45 years	6m, 12m, or 36m	Ν

Provider Responsibility for Follow-up

It is the provider's responsibility to ensure that a follow-up pathway for recall or follow up to specialist as appropriate is in place.

Find more information on cervix screening test results on the BC Cancer Cervix Screening page:

http://www.bccancer.bc.ca/screening/health-professionals/cervix/resources

Cervix Screening Test Supplies

The Cervical Cancer Screening Lab has an online ordering system for cervix screening collection supplies, including provider-collect liquid-based (LBC) vials for HPV and/or cytology with collection devices (spatula/brush combo), plastic bags, pads of requisitions and FLOQSwabs for patient-collect or provider-collect for HPV.

The steps are as follows:

- 1. Complete the <u>online registration form</u>.
- 2. When you receive your log-in details (usually within one business day, you will be directed to the <u>online ordering system</u>.

Here you will be able to order LBC kits (PreservCyt (R) vials, plastic spatulas and cytobrushes in a plastic bag for shipping) and pads of requisitions (if needed).

If you currently use Canada Post for shipping samples to the lab, you will also be able to order packs of prepaid envelopes.

If you have any questions or issues with the online ordering process, please contact the fulfilment center helpdesk at:

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604-332-4694

helpdesk@silverbacksystems.io