After completing this unit you will be able to :

FOR COMPLETION OF THE NOMINAL TEST FORM

- Accurately complete the form that you will submit to the Public Health Ontario Laboratories (PHOL) for HIV rapid POC test results and additional HIV testing requests
- Use the stickers provided by the Ministry of Health to notify PHOL of HIV rapid testing results and request additional testing
- Complete the daily testing log to maintain the quality of testing at your site

Record Keeping is Essential

Every time you do an POC HIV test for a client, you MUST:

- Complete an HIV Serology Requisition form. These can be downloaded from https://www.publichealthontario.ca/
- Make a log entry for the test on your site's daily log

These record-keeping steps are essential to provide accurate results for your clients and to maintain quality standards at your testing site.

Errors in this record keeping would be an incident that requires an investigation at your site. Ultimately effective record-keeping is necessary to maintain approval for testing at your site.

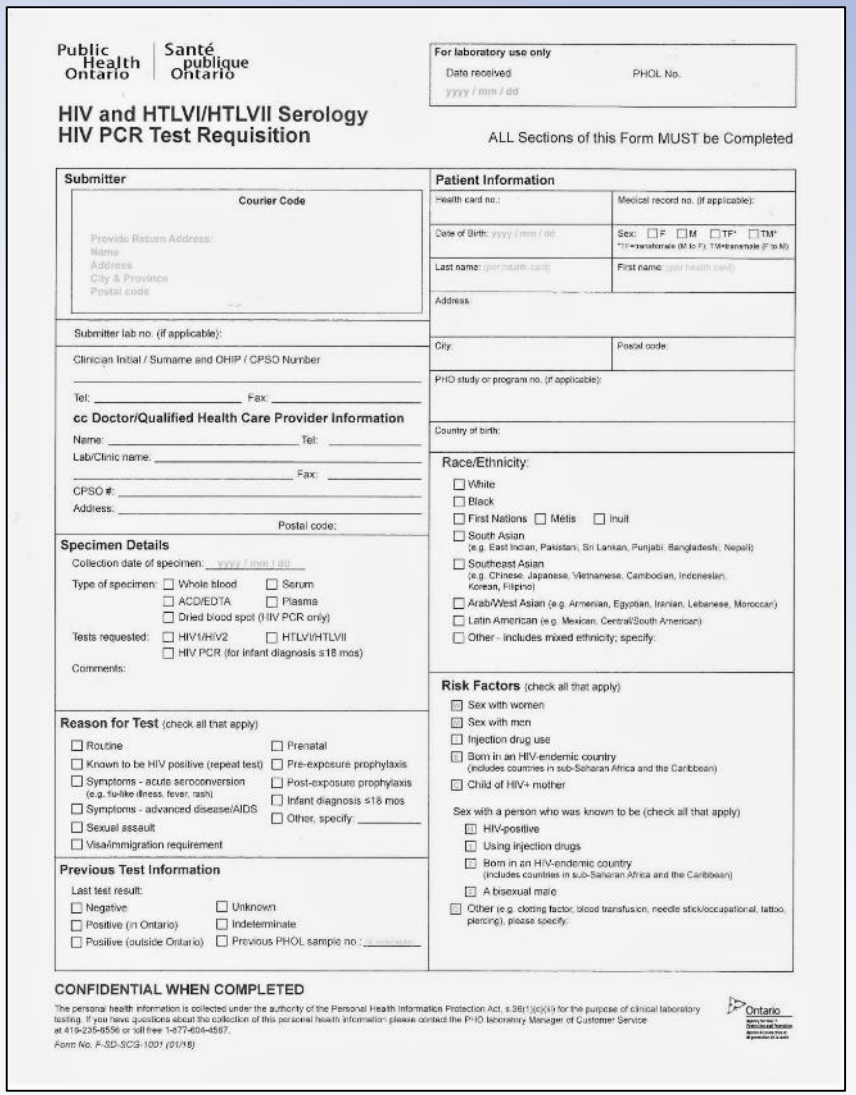
HIV Serology Requisition

This form is used when a client is requesting:

- Rapid POC testing done at your site
- Laboratory testing from the Public Health Ontario Laboratory (PHOL)

Whenever you do a valid POC test, you must submit a form to PHOL. Be sure to complete the form and **all of its fields** in full.

You only submit **ONE** form for each client, even if you are reporting a POC test result and requesting a follow-up test for confirmation or further window period screening.



Public Health Ontario | Santé publique Ontario

For laboratory use only
Date received (yyyy / mm / dd) PHOL No.

HIV and HTLVI/HTLVII Serology
HIV PCR Test Requisition

ALL Sections of this Form MUST be Completed

Submitter
Courier Code
Provide Return Address:
Name
Address
City & Province
Postal code
Submitter lab no. (if applicable):
Clinician Initial / Surname and OHIP / CPSO Number
Tel: Fax:
cc Doctor/Qualified Health Care Provider Information
Name: Tel:
Lab/Clinic name:
Fax:
CPSO #:
Address:
Postal code:

Specimen Details
Collection date of specimen: (yyyy / mm / dd)
Type of specimen: ☐ Whole blood ☐ Serum ☐ ACD/EDTA ☐ Plasma ☐ Dried blood spot (HIV PCR only)
Tests requested: ☐ HIV1/HIV2 ☐ HTLVI/HTLVII ☐ HIV PCR (for infant diagnosis ≤18 mos)
Comments:

Reason for Test (check all that apply)
☐ Routine ☐ Prenatal
☐ Known to be HIV positive (repeat test) ☐ Pre-exposure prophylaxis
☐ Symptoms - acute seroconversion (e.g. flu-like illness, fever, rash) ☐ Post-exposure prophylaxis
☐ Symptoms - advanced disease/AIDS ☐ Infant diagnosis ≤18 mos
☐ Sexual assault ☐ Other, specify:
☐ Visa/immigration requirement

Previous Test Information
Last test result:
☐ Negative ☐ Unknown
☐ Positive (in Ontario) ☐ Indeterminate
☐ Positive (outside Ontario) ☐ Previous PHOL sample no.:

Patient Information
Health card no.: Medical record no. (if applicable):
Date of Birth: (yyyy / mm / dd) Sex: ☐ F ☐ M ☐ TF* ☐ TM*
*TF = transfeminine (M to F); TM=transmale (F to M)
Last name: (per health card) First name: (per health card)
Address
City: Postal code:
PHO study or program no. (if applicable):
Country of birth:

Race/Ethnicity:
☐ White
☐ Black
☐ First Nations ☐ Métis ☐ Inuit
☐ South Asian (e.g. East Indian, Pakistani, Sri Lankan, Punjabi, Bangladeshi, Nepali)
☐ Southeast Asian (e.g. Chinese, Japanese, Vietnamese, Cambodian, Indonesian, Korean, Filipino)
☐ Arab/West Asian (e.g. Armenian, Egyptian, Iranian, Lebanese, Moroccan)
☐ Latin American (e.g. Mexican, Central/South American)
☐ Other - includes mixed ethnicity; specify:

Risk Factors (check all that apply)
☐ Sex with women
☐ Sex with men
☐ Injection drug use
☐ Born in an HIV-endemic country (includes countries in sub-Saharan Africa and the Caribbean)
☐ Child of HIV+ mother

Sex with a person who was known to be (check all that apply)
☐ HIV-positive
☐ Using injection drugs
☐ Born in an HIV-endemic country (includes countries in sub-Saharan Africa and the Caribbean)
☐ A bisexual male
☐ Other (e.g. clotting factor, blood transfusion, needle stick/occupational, tattoo, piercing), please specify:

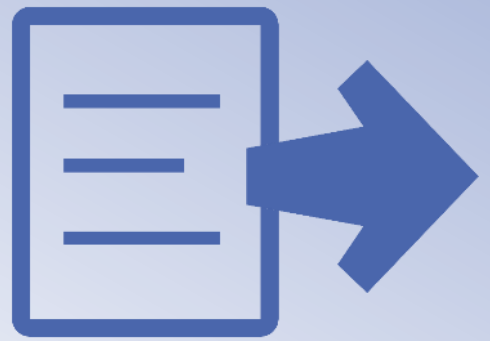
CONFIDENTIAL WHEN COMPLETED

The personal health information is collected under the authority of the Personal Health Information Protection Act, s.36(1)(c)(ii) for the purpose of clinical laboratory testing. If you have questions about the collection of this personal health information please contact the PHO laboratory Manager of Customer Service at 416-235-6556 or toll free 1-877-604-4567.

Form No. F-SD-SCS-1001 (01/18)

Ontario

Anonymized forms



In this module, we will discuss several scenarios that may occur when submitting a serology form to PHOL. Sometimes you will submit a form, but not a sample. This happens when:

- You did a POC test and it was nonreactive; there is no reason to request further follow-up testing
- There is a reason to recommend follow-up testing, but your client does not consent to submit a specimen to PHOL

In these circumstances, your client **should not be identified** to PHOL, and information like the client's name and date of birth should be excluded from the form (an ***anonymized form***). However you must still submit a record of the test and information about the reason for the test and the client's risk factors.

Workflow and the Serology Requisition

- Complete all sections as fully as possible.
- Complete the sections:
  - Reason for testing
  - Previous testing information
  - Race/Ethnicity
  - Risk factors

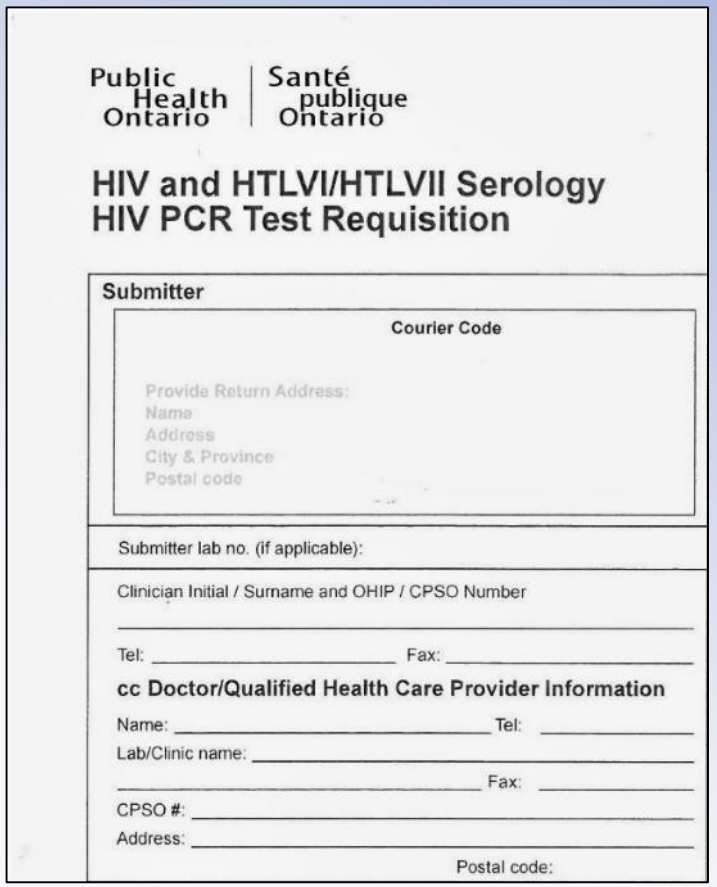
  …while speaking with your client, during the HIV testing counselling appointment

Do not complete the patient information section of the form until POC testing is complete.
The outcomes of the POC testing will determine whether or not you need to anonymize this information.

The Serology Requisition

- Your clinic will most often have pre-printed HIV Serology forms with this portion complete.
- If you need to complete it by hand, the doctor's name is the person who holds your site's medical directive and their CPSO# is used.

Where do you get forms when you need them (or more when you run out)? Ask about the practice at your site.



Public Health Ontario | Santé publique Ontario

HIV and HTLVI/HTLVII Serology
HIV PCR Test Requisition

Submitter

Courier Code

Provide Return Address:
Name
Address
City & Province
Postal code

Submitter lab no. (if applicable):

Clinician Initial / Surname and OHIP / CPSO Number

Tel: _____ Fax: _____

cc Doctor/Qualified Health Care Provider Information

Name: _____ Tel: _____

Lab/Clinic name: _____

_____ Fax: _____

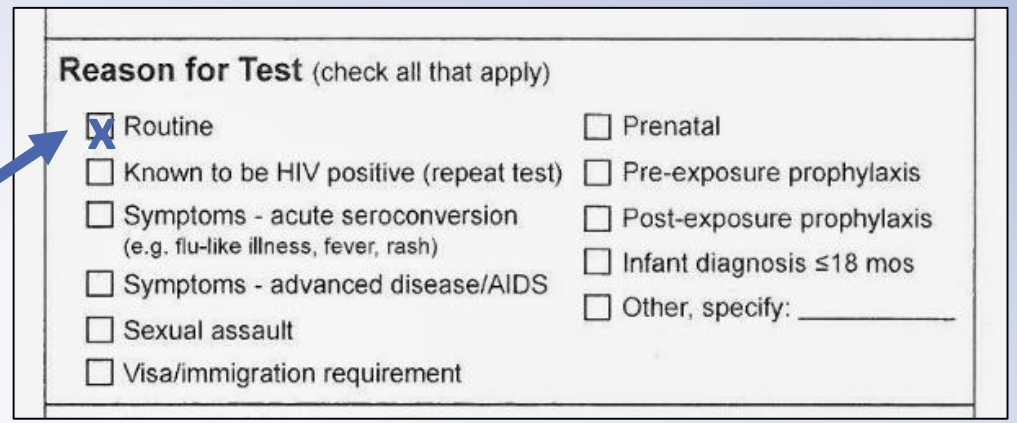
CPSO #: _____

Address: _____

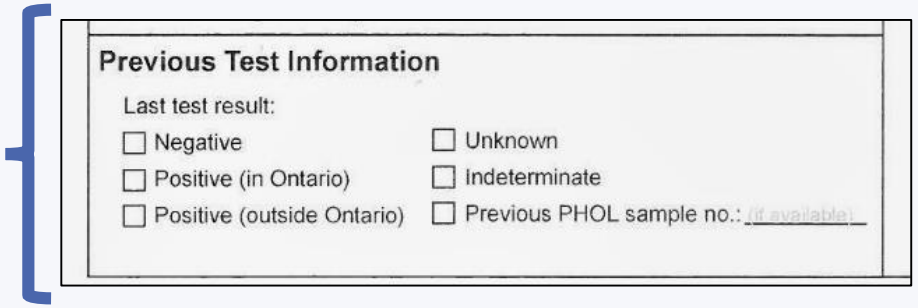
Postal code:

Required Fields

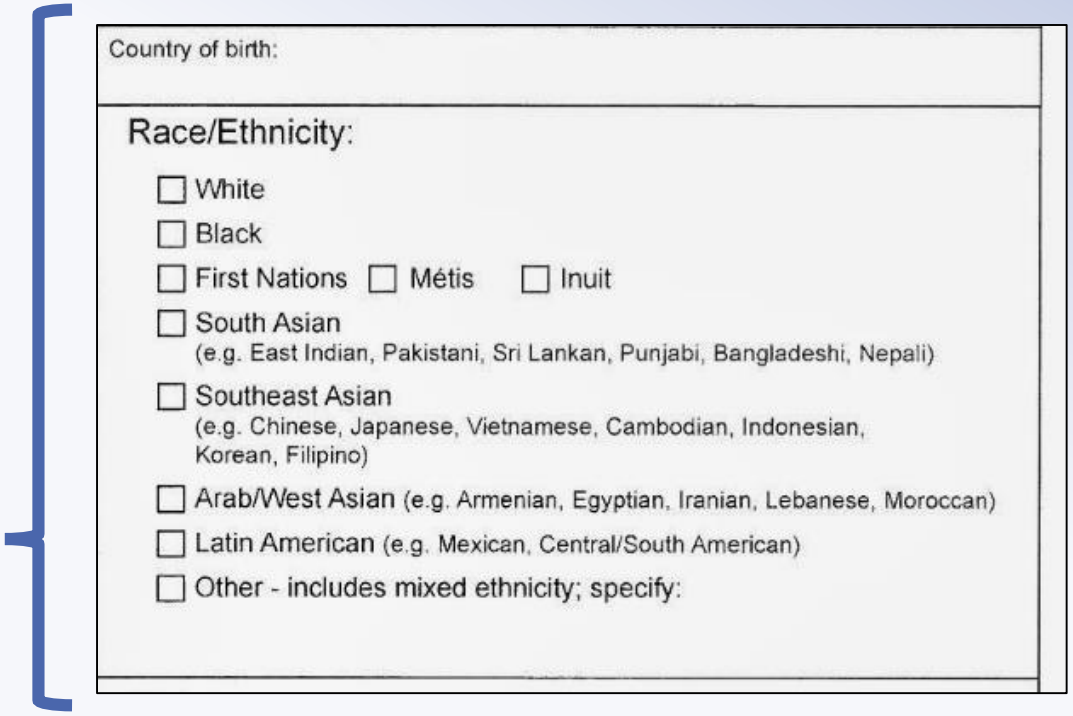
Most tests will be **routine** – although you may identify additional reasons for testing, such as sexual assault or symptoms of acute HIV infection, when speaking with the client.



Complete this section based on your site's records of this client OR what the client tells you about their history.



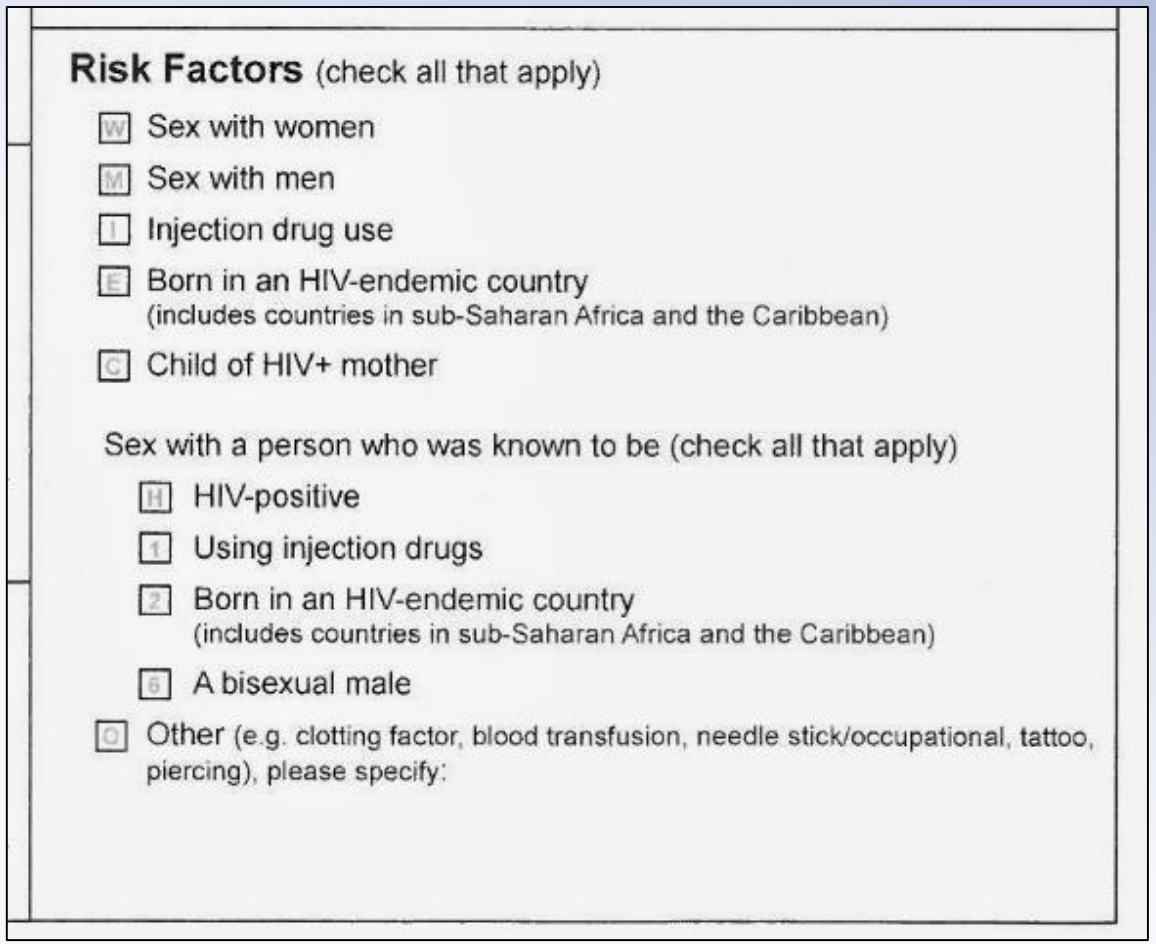
This information is often collected on your site's intake form. Some sites are able to print this information from their electric medical record as part of the patient identification sticker.



Required Fields

Collected during your risk assessment of the client

All <u>required</u> sections of the form are important for provincial planners to understand where more HIV prevention and care services are needed. They are not used to "track" individual patients.



Risk Factors (check all that apply)

- [W] Sex with women
- [M] Sex with men
- [I] Injection drug use
- [E] Born in an HIV-endemic country (includes countries in sub-Saharan Africa and the Caribbean)
- [C] Child of HIV+ mother

Sex with a person who was known to be (check all that apply)

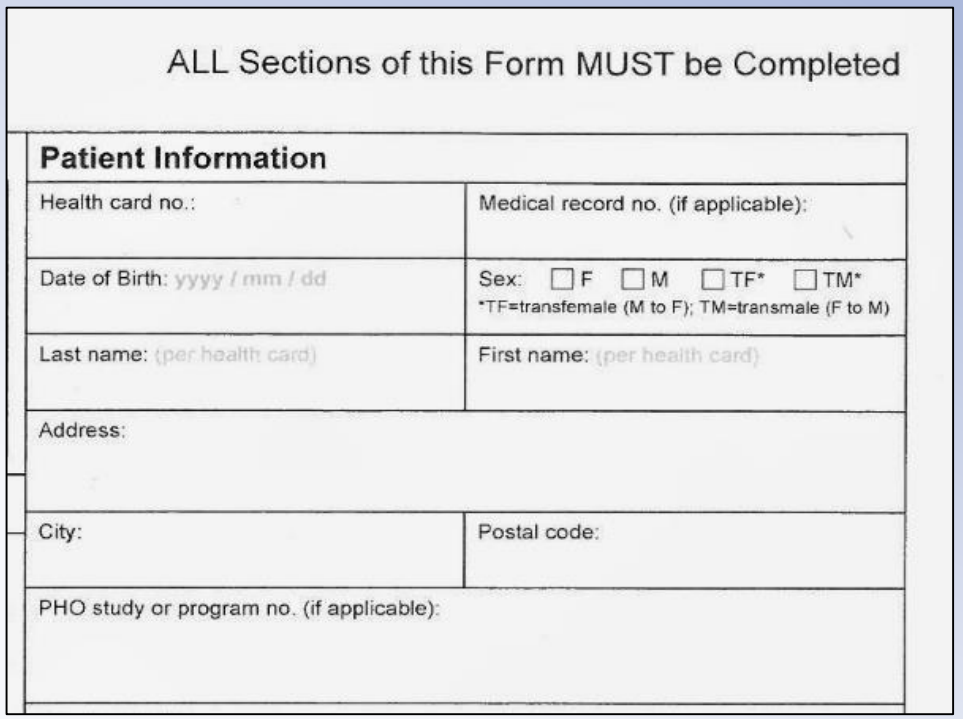
- [H] HIV-positive
- [1] Using injection drugs
- [2] Born in an HIV-endemic country (includes countries in sub-Saharan Africa and the Caribbean)
- [B] A bisexual male

[O] Other (e.g. clotting factor, blood transfusion, needle stick/occupational, tattoo, piercing), please specify:

Do not complete the patient information section of the form until POC testing is complete.

When Submitting a Sample

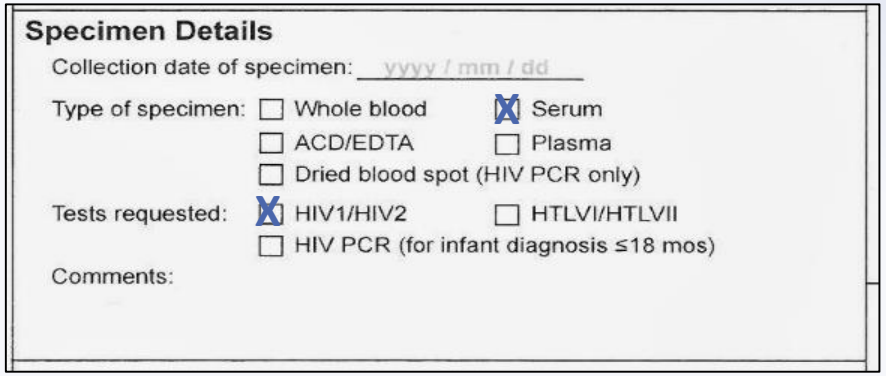
- Be careful to enter the client's OHIP card number correctly and their full date of birth. This information is used by Public Health units to follow-up with clients for contact tracing.
- Make sure that the specimen details are complete. The tube of blood and the form must have the date you drew the blood. Both this date and the person's name must **MATCH.**
- You will usually be submitting serum (red top tube) and requesting a HIV1/HIV2 test



ALL Sections of this Form MUST be Completed

Patient Information

Health card no.:	Medical record no. (if applicable):
Date of Birth: yyyy / mm / dd	Sex: ☐ F ☐ M ☐ TF* ☐ TM* *TF=transfemale (M to F); TM=transmale (F to M)
Last name: (per health card)	First name: (per health card)
Address:	
City:	Postal code:
PHO study or program no. (if applicable):	



Specimen Details

Collection date of specimen: yyyy / mm / dd

Type of specimen: ☐ Whole blood ☒ Serum
☐ ACD/EDTA ☐ Plasma
☐ Dried blood spot (HIV PCR only)

Tests requested: ☒ HIV1/HIV2 ☐ HTLVI/HTLVII
☐ HIV PCR (for infant diagnosis ≤18 mos)

Comments:

When NOT Submitting a Sample

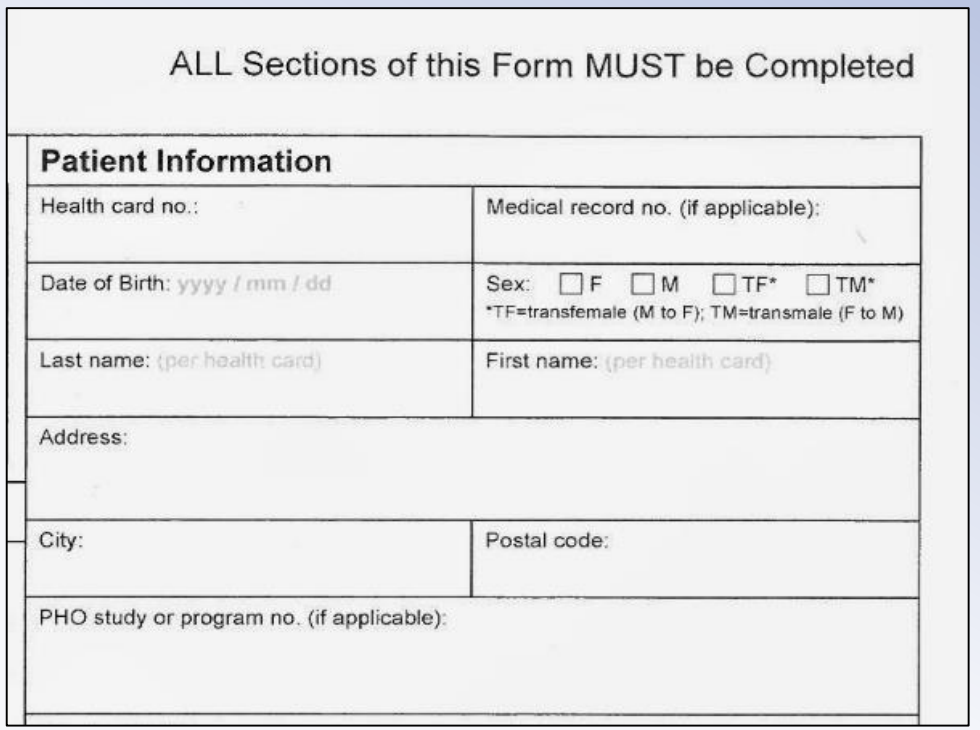
If only POC testing was done, the patient information should be limited. If you are not submitting a sample to PHOL:

- Only put the client's year of birth on the form
- Don't use the client's name, use an identification code

Suggested code

If you saw Jack Smith on July 3, 2019, the code could be:

JS-03072019



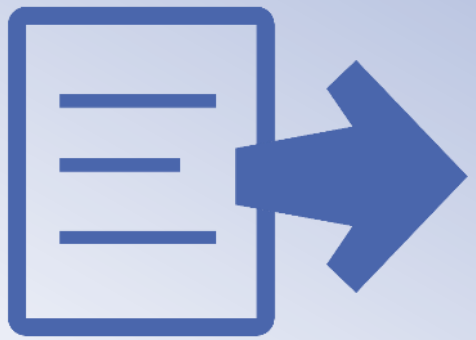
ALL Sections of this Form MUST be Completed

Patient Information	
Health card no.:	Medical record no. (if applicable):
Date of Birth: yyyy / mm / dd	Sex: ☐ F ☐ M ☐ TF* ☐ TM* *TF=transfemale (M to F); TM=transmale (F to M)
Last name: (per health card)	First name: (per health card)
Address:	
City:	Postal code:
PHO study or program no. (if applicable):	

Your site will order stickers from the Ministry to flag forms that are not submitted with samples. We will review the sticker system, as we review possible testing scenarios.

Testing Scenarios

Here are some scenarios you will encounter when testing clients :



1) Your client requests standard testing (You did not do a rapid test.)
2) You perform a rapid POC test - it is non-reactive *and* outside the window period.
3) You perform a rapid POC test and it is non-reactive. However, the client is from a priority population, has had a very recent high risk exposure (in the last 2-4 weeks or with current signs of acute HIV infection).
4) You perform a rapid POC test and it is reactive.
5) Your client has two invalid POC tests, and you are submitting a sample for testing.

1) Standard Testing

Some of your clients will choose to have a standard HIV test instead of a rapid test. After counselling and consent:

- Draw and label a tube of blood (red top tube)
- Complete the form fully, including the client's name and OHIP#
- Ensure that the name and date on the sample matches the name and date on the form.

No Sticker necessary

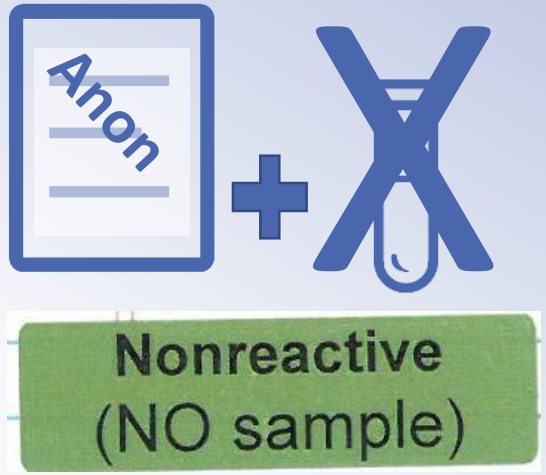
- Submit the tube and requisition; enter the test on the daily log if this is the practice at your site.

Book an appointment in approximately one week for the client to return for their result.

2) A Non-reactive POC Test

After counselling and consent:

- **You perform a POC test; it is non-reactive and the client is not in the window period**
- Complete the patient information section using a code (not the client's name) and their year of birth; attach a GREEN "non-reactive" sticker
- Submit the requisition and enter this test on the daily log



- Complete post-test counselling. Advise client about further testing (follow-up testing on a high risk exposure or routine testing.)

NOTE: PHOL will issue a standard report for this submission, it can be discarded.

3) A Non-Reactive Window Period Test

After counselling and consent, you determine that:

The client is from a priority population and has had a **very recent** high risk exposure (in the last 2-4 weeks or with signs of acute HIV infection).

Nonreactive-Window Period
(INCLUDE sample)

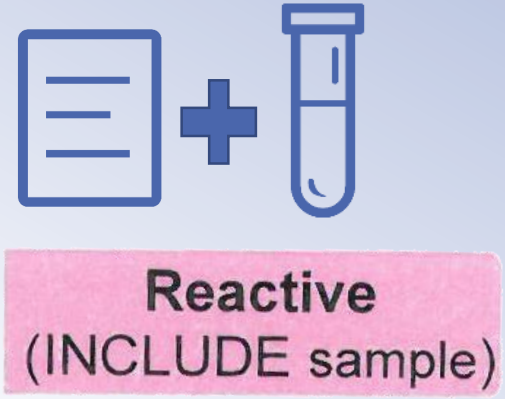
- Perform a POC test; it is non-reactive
- Recommend the client submit a standard test for p24 testing; if the client agrees, draw blood
- Complete the form fully, including the client's name and OHIP#; attach a YELLOW "non-reactive window period" sticker; ensure the name/date on the sample matches the name/date on the form
- Submit the requisition; enter the test on the daily log

Complete post-test counselling. Book an appointment in one week to share results.

4) A Reactive POC Test

After counselling and consent:

- Perform a POC test; it is reactive
- Recommend client submit a standard test to confirm this result; if the client agrees, draw blood
- Complete the form fully, including the client's name and OHIP#; attach a PINK "reactive" sticker. Ensure the name/date on the sample matches the name/date on the form
- Submit the requisition; enter the test on the daily log

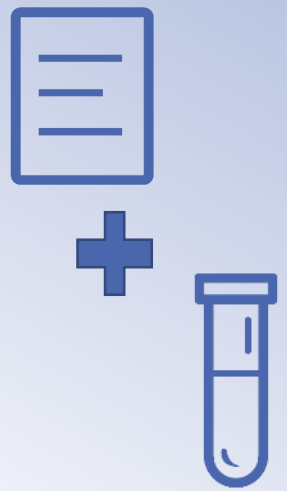


Complete post-test counselling. Book an appointment in one week to confirm result.

5) Two repeated Invalid tests

After counselling and consent:

- Perform a POC test; it is invalid. Repeat the test once; ensure a sufficient sample of blood. If is invalid again, don't throw out the test membranes.
- If TWO invalid tests have occurred, ask the client if you can draw blood for standard testing. Be reassuring, an invalid result, is not caused by the presence of HIV. It can have many underlying causes (most commonly adding too little sample to the test.)
- If the client agrees, draw blood (red top) for testing. Ensure the form is completed fully for standard testing; no sticker is needed. If the client declines standard testing, DO NOT SUBMIT A FORM as a valid test did not occur.
- Enter the record of both POC and standard tests on the daily log as well as an entry in the incident log for the invalid tests. Take a picture of the invalid membranes and notify the AIDS Bureau about the invalid tests.



No Sticker necessary

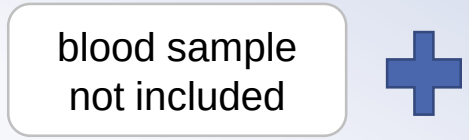
Complete post-test counselling. Book an appointment in one week for results.

Forms without Samples – What Sticker do I use?

The purpose of the priority stickers is to clarify for PHOL staff what further actions to take. When you submit a form to PHOL but **NOT a blood sample,** you need to make it clear that a sample has not been lost.

- The most usual "no sample" situation is a nonreactive test , where the client is not in the window period, and no further testing is needed. Use the **GREEN** sticker.

- In other circumstances, this white sticker is added in addition to another sticker, to make it clear that a sample is intentionally absent:
  - Client had a reactive POC test and declined blood draw (PINK + WHITE)
  - Priority population client, had a very recent high risk exposure (3-4 weeks) and declined a blood draw (YELLOW + WHITE)
  - Priority population client, testing six weeks after a very high risk exposure (YELLOW + WHITE)
  - Client is NOT from a priority population and is in the window period, but has been deferred from blood draw (GREEN + WHITE)



Forms without samples should be <u>anonymized</u> (no name or date of birth; use code/year of birth only)

MODULE: Requisitions and Reporting (Nominal)

Summary

HIV Serology Requisition

Complete the form – for all POC tests
add the appropriate sticker

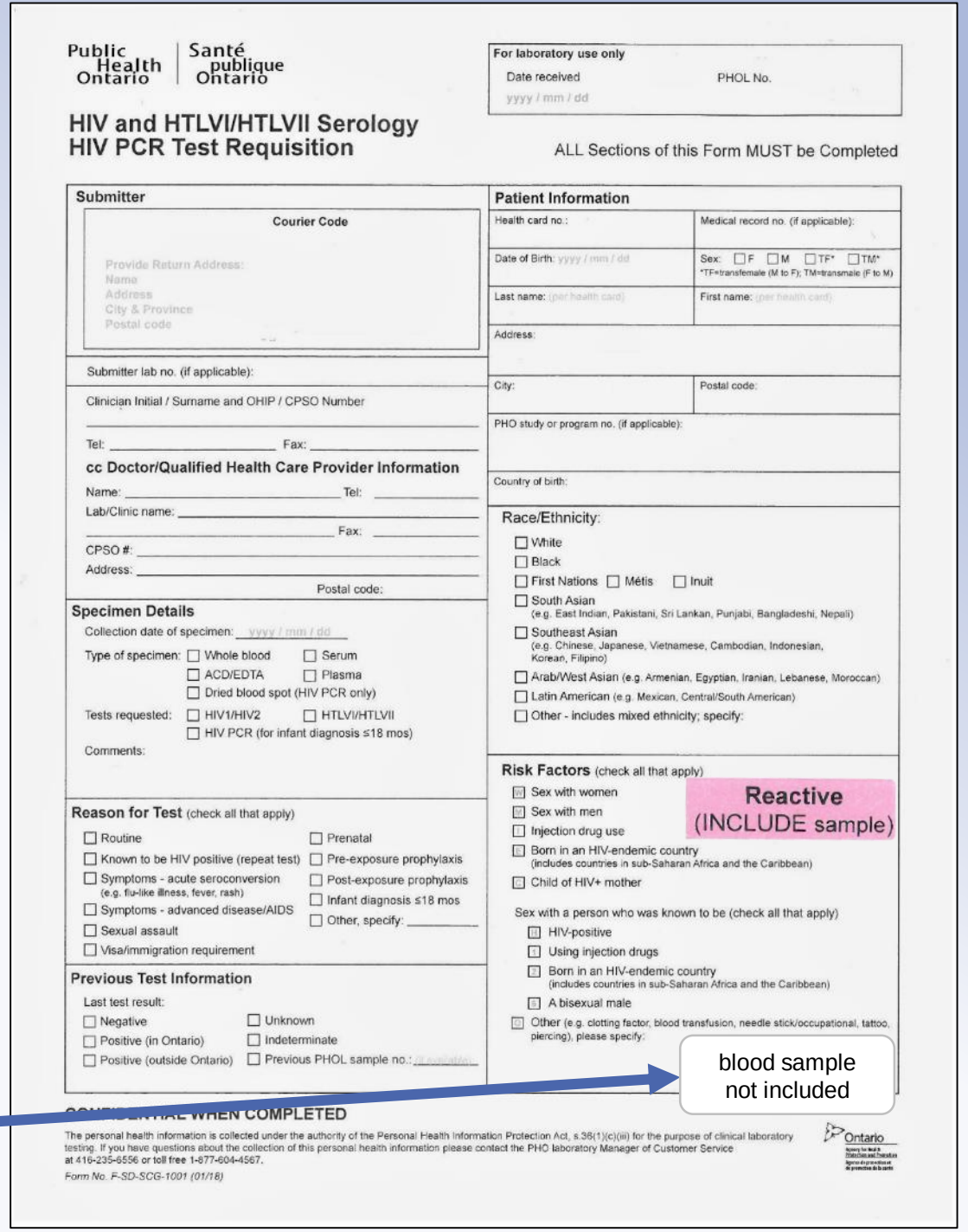
Nonreactive
(NO sample)

Nonreactive-Window Period
(INCLUDE sample)

Reactive
(INCLUDE sample)

blood sample
not included

Put second
white sticker
here if needed



Public Health Ontario | Santé publique Ontario

For laboratory use only
Date received yyyy / mm / dd
PHOL No.

HIV and HTLVI/HTLVII Serology
HIV PCR Test Requisition

ALL Sections of this Form MUST be Completed

Submitter
Courier Code
Provide Return Address:
Name
Address
City & Province
Postal code

Submitter lab no. (if applicable):

Clinician Initial / Surname and OHIP / CPSO Number

Tel: _____ Fax: _____

cc Doctor/Qualified Health Care Provider Information
Name: _____ Tel: _____
Lab/Clinic name: _____
_____ Fax: _____
CPSO #: _____
Address: _____
Postal code:

Specimen Details
Collection date of specimen: yyyy / mm / dd
Type of specimen: ☐ Whole blood ☐ Serum ☐ ACD/EDTA ☐ Plasma ☐ Dried blood spot (HIV PCR only)
Tests requested: ☐ HIV1/HIV2 ☐ HTLVI/HTLVII ☐ HIV PCR (for infant diagnosis ≤18 mos)
Comments:

Reason for Test (check all that apply)
☐ Routine ☐ Prenatal
☐ Known to be HIV positive (repeat test) ☐ Pre-exposure prophylaxis
☐ Symptoms - acute seroconversion (e.g. flu-like illness, fever, rash) ☐ Post-exposure prophylaxis
☐ Symptoms - advanced disease/AIDS ☐ Infant diagnosis ≤18 mos
☐ Sexual assault ☐ Other, specify: _____
☐ Visa/immigration requirement

Previous Test Information
Last test result:
☐ Negative ☐ Unknown
☐ Positive (in Ontario) ☐ Indeterminate
☐ Positive (outside Ontario) ☐ Previous PHOL sample no.: _____

Patient Information
Health card no.: | Medical record no. (if applicable):
Date of Birth: yyyy / mm / dd | Sex: ☐ F ☐ M ☐ TF* ☐ TM* *TF=transfemale (M to F); TM=transmale (F to M)
Last name: (per health card) | First name: (per health card)
Address:
City: | Postal code:
PHO study or program no. (if applicable):
Country of birth:

Race/Ethnicity:
☐ White
☐ Black
☐ First Nations ☐ Métis ☐ Inuit
☐ South Asian (e.g. East Indian, Pakistani, Sri Lankan, Punjabi, Bangladeshi, Nepali)
☐ Southeast Asian (e.g. Chinese, Japanese, Vietnamese, Cambodian, Indonesian, Korean, Filipino)
☐ Arab/West Asian (e.g. Armenian, Egyptian, Iranian, Lebanese, Moroccan)
☐ Latin American (e.g. Mexican, Central/South American)
☐ Other - includes mixed ethnicity; specify:

Risk Factors (check all that apply)
☐ Sex with women
☐ Sex with men
☐ Injection drug use
☐ Born in an HIV-endemic country (includes countries in sub-Saharan Africa and the Caribbean)
☐ Child of HIV+ mother

Sex with a person who was known to be (check all that apply)
☐ HIV-positive
☐ Using injection drugs
☐ Born in an HIV-endemic country (includes countries in sub-Saharan Africa and the Caribbean)
☐ A bisexual male
☐ Other (e.g. clotting factor, blood transfusion, needle stick/occupational, tattoo, piercing), please specify:

Reactive
(INCLUDE sample)

blood sample
not included

CONFIDENTIAL WHEN COMPLETED

The personal health information is collected under the authority of the Personal Health Information Protection Act, s.36(1)(c)(iii) for the purpose of clinical laboratory testing. If you have questions about the collection of this personal health information please contact the PHO laboratory Manager of Customer Service at 416-235-6556 or toll free 1-877-604-4567.

Form No. F-SD-SCG-1001 (01/18)

Ontario

The Daily Log

This is a screen shot of the daily log template. An entry must be made for every test you do.

Point-of-Care (POC) HIV Testing Record - Daily Log

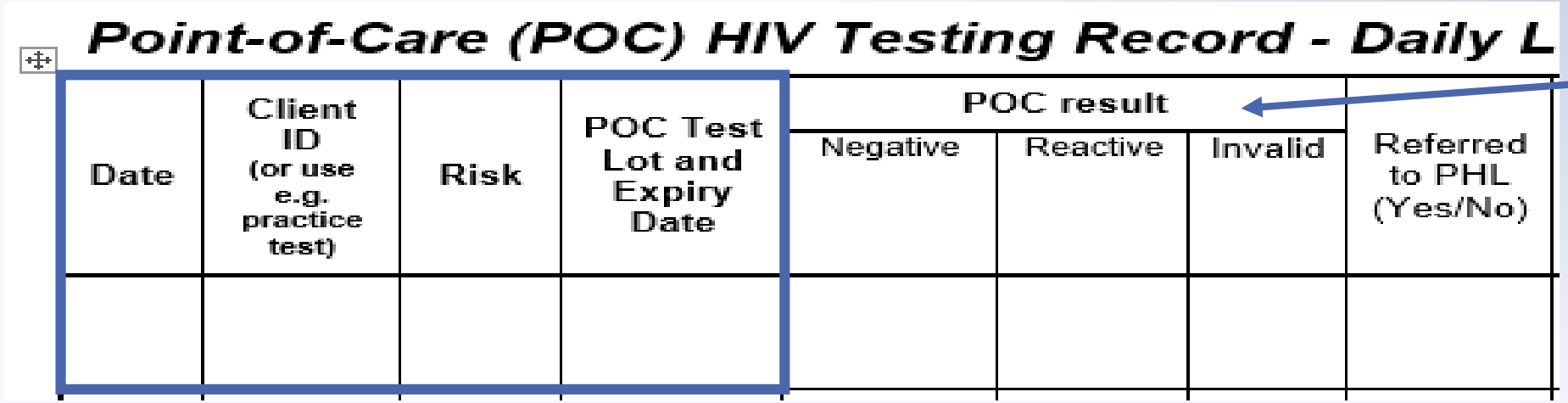
Date	Client ID (or use e.g. practice test)	Risk	POC Test Lot and Expiry Date	POC result			Referred to PHL (Yes/No)	If POC is negative, reason for referral	PHL Result			False Positive		False Negative		Date Reported	Tester's Initials
				Negative	Reactive	Invalid			Ag/Ab combo Screen	HIV1/HIV2 Antibody Confirm	Final Interpretation	No	Yes	No	Yes		

This part of the log is used to make a record of any POC test.

This part of the log is used for follow-up of tests sent to PHOL and analysis of the returned results.

Make sure you sign and date each entry.

The Daily Log – Record of a POC Test



Point-of-Care (POC) HIV Testing Record - Daily L

Date	Client ID (or use e.g. practice test)	Risk	POC Test Lot and Expiry Date	POC result			Referred to PHL (Yes/No)
				Negative	Reactive	Invalid	

Write the result in one of these three fields.

If sending a sample to PHOL say yes in the last field, shown here.

Use these four fields for every test you do:

- When you did the test
- Who you did the test for (most commonly a client name/number)
- The risk factors (usually abbreviated i.e. MSM, ACB, PWID, etc.)
- The lot number and expiry date of the kit you used

For Proficiency Tests, practice testing, or errors/damage, write what the test was used for across these fields

The Daily Log – Record of a Sample Sent to PHOL

Daily Log

Referred to PHL (Yes/No)	If POC is negative, reason for referral	PHL Result			False Positive		False Negative		Date Reported	Tester's Initials
		Ag/Ab combo Screen	HIV1/HIV2 Antibody Confirm	Final Interpretation	No	Yes	No	Yes		

Date and sign.

Say yes if a sample is sent to PHOL

Most commonly you will do this if the client is testing early in the window period

Use the results that return to you from PHOL (1 week) to complete these fields.

Record differences between POC and PHOL results. These fields may be completed by the Quality Assurance Lead at your site when preparing the monthly summary report. **Ask about the practice at your site.**

The Daily Log

Point-of-Care (POC) HIV Testing Record - Daily Log

Date	Client ID (or use e.g. practice test)	Risk	POC Test Lot and Expiry Date	POC result			Referred to PHL (Yes/No)	If POC is negative, reason for referral	PHL Result			False Positive		False Negative		Date Reported	Tester's Initials
				Negative	Reactive	Invalid			Ag/Ab combo Screen	HIV1/HIV2 Antibody Confirm	Final Interpretation	No	Yes	No	Yes		

Record keeping in the Daily Log matters because:

- It lets you track what has been sent to PHOL for testing, to ensure all sent samples have a result returned
- It helps track the number of test kits used at your site, a total required when ordering new kits through the Inventory Management portal (www.hivpoct.ca)
- The log assists with quality assurance at your site, helping to identify any discrepancies between the POC test results you record and PHOL findings