

BC HIV Point of Care Test Site Operations Manual 2018-12-03 Page 1 of 3



Purchasing and Inventory Control

INSTI™ HIV Test Kits

The BC Program arranges for the purchase of HIV POC test kits for participating locations in BC. Costs for HIV POC test kits are paid from the BC Program budget; kit orders are placed on a quarterly basis, but contingency stock is available through the BC Program if a location needs kits between order periods.

Health Authorities who require more HIV POC test kits than the BC Program can supply may be required to purchase these test kits independently. All questions regarding ordering HIV POC test kits can be directed to the BC HIV POC Testing Program.

Quality Control (QC) Materials and Other Supplies

Costs for Quality control samples and related supplies are paid from the BC HIV POCT Program budget and ordered through the BC Program. Other testing supplies such as extra lancets, quality control storage materials and temperature monitors can also be ordered through the BC Program.

- Quality control samples are distributed as a set of 2 bottles (known HIV-negative and known weak anti-HIV-1 positive).
- QC samples are stored in the refrigerator until they expire (1 year post-production).
- QC samples may be frozen, but once thawed, they are refrigerated until expiry.
- DO NOT freeze/thaw/refreeze the samples as it may weaken the reactivity.
- QC samples remain OK for up to 8 days at room temperature.
- QC samples should be at room temperature before testing.
- QC samples are handled and disposed as biohazard waste.

Proficiency Test Yearly Subscriptions

Proficiency test yearly subscriptions are paid per test location from the BC HIV POCT Program budget and ordered through the BC Program. A subscription usually includes the testing of 2 unknown samples sent to all participants for the test event. There are usually 3 test events per year.

Proficiency test samples should be refrigerated upon receipt, warmed to room temperature for testing, then stored in the fridge or freezer until the performance report is received. If the results are OK, then the samples should be discarded as biohazard waste.

Inventory Control

HIV POC test kits are shipped to participating test locations. It is the responsibility of each test location to reconcile the number of test kits received against the number of tests performed. This is usually monitored with the Monthly Report. Missing kits or reports are recorded as Waste, and are flagged as an error.

When test kits and quality control samples are received, it is recommended that each test location notify the BC Program of the following:

- number of HIV POC tests or quality control samples received
- lot number and expiry dates of test kits and quality control samples
- status of supplies (any damage)



BC HIV Point of Care Test Site Operations Manual 2018-12-03 Page 2 of 3



MASTER LOT NUMBER and EXPIRY:

Problems with test kits and QC materials are referred back to the MASTER LOT NUMBER. This is the number on the back of the outer foil packet that links the contents of the packet to a single "batch".



Returning Unsuitable Supplies

Unsuitable supplies include those that are expired, improperly stored, or damaged. Contact the BC HIV POC Testing Program to request pick-up/return/disposal of unsuitable supplies.

It is dangerous to keep expired kits at the test location as there is a high probability that someone will use them for a client test by mistake.

Determine the supply destination according to the table below.

If the supply involves:	Action:
Expired INSTI™ HIV Test kits	 DO NOT use for client tests – Quarantine from in-date stock. Notify the BC HIV POC Testing Program with number and consult to prevent recurrence. DO NOT keep expired kits on-site - someone will use them. Note: Monthly report kit expiry dates are monitored so that near-expiry kits can be replaced and transferred to a high use location prior to expiry.
Expired quality control or Proficiency Test samples	Discard as biohazard waste.
Improperly stored INSTI™ HIV test kit or quality control samples	 STOP client tests until an investigation is done. Quarantine the materials at the correct storage temperature while an investigation is underway. Report incident to the POC Test location Lead and BC HIV POC Testing Program. Consider this as an opportunity to determine why this occurred and to prevent reoccurrence.
Improperly shipped/received or damaged materials	 DO NOT use for client tests until investigation is completed. Report incident to POC Test location Lead. Contact the BC Program for instructions on how to proceed.



BC Centre for Disease Control

BC HIV Point of Care Test Site Operations Manual 2018-12-03 Page 3 of 3

PHSA Laboratories

BCCDC Public Health Laboratory

A service of the Provincial Health Services Authority

If the supply involves:	Action:
Defective materials in kits or quality control samples	 STOP client tests until you know if this is random error or something broader. Report incident to the POC Test location Lead and the BC HIV POC Testing Program. Save the original material(s) in the event it needs to be sent to the BC Program. Take a picture of a defective or problematic test membrane and send to the Location and BC Program Leads, if possible. Report on logs so that the kit "use" is recorded as waste for the monthly report.
Recalled INSTI™ HIV Test kits or quality control samples	 Remove affected supplies, and place so that they cannot be used for any tests. Report incident to POC Test location Lead and BC Program. Complete recall form and fax to BC Program. Follow BC Program instructions for return or disposal.

The following information related to inventory can be found in the following manual documents:

- Temperature
- Outreach or Mobile Testing Conditions
- Sharing Kits