



Roles and Responsibilities

This document summarizes the roles and responsibilities of the Test provider, the Health Authority/Test location, the BC HIV POC Test Program and service providers such as bioLytical and the proficiency testing service provider. Collaboration of all of these groups is critical to the success of this HIV test program. The BC HIV Point of Care Test Program has created supporting recommendations and operations documents; test locations/Health Authorities are responsible for a review and any adaptations to these tools to meet their specific needs and operational policies/procedures during implementation.

Activity	Test provider (approved by test location and/or Health Authority)	Test location / Health Authority* These items may be the responsibility of the Health Authority or test location and are to be determined at a regional level.	BC Program	Service Provider: bioLytical (manufacturer of INSTI™ test kit)
Testing Process	<ul style="list-style-type: none"> • Provide pre and post discussions, including informed consent, to clients according to established process and procedures. • Perform client testing and interpret results according to established procedures. • Deliver test results to client according to established procedures. • Obtain venous blood sample for confirmatory testing as applicable and arrange for follow up with client regarding confirmatory test results. • Record usage and results of each test kit on client testing log used at test location (including those used for quality controls, wasted, training etc.) • Follow test location policies regarding confidentiality of records. • Report concerns/problems with the test kit performance to POC test location lead and BC Program as applicable. 	<ul style="list-style-type: none"> • Allocate sufficient clinic, material and human resources to implement, operate, review and maintain the use of HIV POC testing within each test location. • Ensure necessary equipment is available for testing (i.e. gloves, sharps containers, Band-Aids). • Report all reactive results to Medical Health Officer according to established regional procedures for communicable disease reporting. • Collaborate with test providers to ensure appropriate implementation of HIV POC testing. • Report concerns/problems with the test kit performance to BC Program. 	<ul style="list-style-type: none"> • Prepare, maintain and report budget status and requirements to the appropriate committees and management teams. • Provide monthly summaries of POC test kit usage by Health Authority and provincially to the appropriate committees and management teams. • Provide data regarding test kit usage to Health Authority/Test location quarterly or as requested. • Provide support to test locations performing HIV POC testing including training, procurement, distribution and trouble shooting. • Follow up with test locations on queries about reported test usage. • Report concerns/problems with the test kit performance to appropriate BCCDC managers and to bioLytical. • Collaborate with test providers, Health Authority/test location to ensure optimal implementation of HIV POC testing at test location, health authority and provincial levels. • Disseminate product information and 	<ul style="list-style-type: none"> • Provide advice regarding usage and specifications of test kit. • Follow up on concerns/problems related to test kit performance and provide direction on the use of kits.



Activity	Test provider (approved by test location and/or Health Authority)	Test location / Health Authority* These items may be the responsibility of the Health Authority or test location and are to be determined at a regional level.	BC Program	Service Provider: bioLytical (manufacturer of INSTI™ test kit)
			feedback to Health Authorities/Test locations if concerns have been raised and subsequently addressed by bioLytical.	
Training <ul style="list-style-type: none"> • Competency • Continuing education/ refresher training 	<ul style="list-style-type: none"> • Participate in POC as well as HIV pre and post-test discussion training programs. • Successfully complete competency assessment before testing clients in collaboration with POC test location lead. • Participate in periodic refresher training and continuing education. • Participate in additional training as identified during Test location Approval Process. 	<ul style="list-style-type: none"> • Schedule staff training in collaboration with approved trainers. • Verify that trained staff members have successfully completed competency assessment before testing clients. • Retain training and competency records for all staff (tracked, filed and retained for 10 years). • Schedule periodic refresher training and continuing education for test providers. • Identify additional non-HIV training requirements. • Verify new test providers have completed all HIV and non-HIV training / competency requirements. 	<ul style="list-style-type: none"> • Develop training materials such as presentations, checklists etc. • Coordinate, participate and deliver content for training as requested by and in collaboration with Health Authorities/test locations. • Develop continuing education materials and coordinate continuing education sessions in collaboration with Health Authority/Test location as needed. • Cooperate with appropriate trainers in the development and presentation of associated non-HIV training materials. 	



Activity	Test provider (approved by test location and/or Health Authority)	Test location /Health Authority* These items may be the responsibility of the Health Authority or test location and is to be determined at a regional level.	BC Program	Service Provider: bioLytical (manufacturer of INSTI™ quality control samples)
Quality Control Samples	<ul style="list-style-type: none"> • Store and use quality control samples according to manufacturer’s instructions. • Use quality control samples as per recommendations. • Record quality control sample results and notify POC test location lead of any unexpected results. • Contact POC test location lead/BC Program if quality control samples fail to give the result expected. 	<ul style="list-style-type: none"> • Order quality control samples through the BC Program. • Assume responsibility for integrity of quality control samples in health authority/test location. • Ensure quality control samples are stored as per manufacturer’s instructions and contact BC Program if there is a concern with storage. • Review HIV POC test kit usage log sheets and take corrective action as required. • Contact BC Program in the event of a problem with quality control samples. 	<ul style="list-style-type: none"> • Purchase quality control samples for test locations. • Provide guidance around the use of quality control samples and training. • Act as a resource for quality control sample problems/concerns. • Contact the manufacturer as needed. 	<ul style="list-style-type: none"> • Manufacture and ship quality control samples. • Respond to any issues related to quality control samples.



Activity	Test provider (approved by test location and/or Health Authority)	Test location /Health Authority* These items may be the responsibility of the Health Authority or test location and is to be determined at a regional level.	BC Program	Service Provider: bioLytical (manufacturer of INSTI™ test kit)
Inventory	<ul style="list-style-type: none"> Track test kit usage on daily log of client POC test results, and Quality Control Log, or test location system/documents. Report when kit inventory is low or close to expiration date to POC test location lead. Store test kits and materials as recommended. 	<ul style="list-style-type: none"> Evaluate test location needs for each upcoming order cycle. Collaborate with BC Program to order test kits and required supply inventory. Assume responsibility for test kits at test location/in health authority. Forward testing Monthly Summary Report to BC Program. Participate in kit redistribution to optimize utilization and eliminate wastage in such instances as kits being near expiration date. 	<ul style="list-style-type: none"> Initiate renewal of contract with kit vendor. Order test kits on behalf of test locations and organize distribution and delivery. Verify Certificate of Analysis for each lot number received. Retain the original Certificate of Analysis for each kit lot number and provide a copy to test locations on request. Verify performance of new lot. Verify ongoing performance of each lot. Order and distribute supplies such as quality controls, extra lancets, pipets and temperature monitors. Disseminate information regarding inventory changes to test locations in a timely manner. Coordinate redistribution of limited date kits in collaboration with Health Authorities/test locations to enhance utilization. 	<ul style="list-style-type: none"> Inform the BC HIV POC Program of any product updates or changes related to test kits, quality controls samples or other associated testing materials in a timely manner. Supply test kits and quality control samples with the maximum expiry date possible. Provide the Certificate of Analysis for each kit lot with each shipment



Activity	Test provider (approved by test location and/or Health Authority)	Test location /Health Authority* These items may be the responsibility of the Health Authority or test location and is to be determined at a regional level.	BC Program	Service Provider: bioLytical (manufacturer of INSTI™ test kit)
Storage of INSTI Test Kits	<ul style="list-style-type: none"> Complete daily temperature logs for all areas where test kits are stored, and notify POC test location lead of any temperature outside the accepted range. Move stock as needed if temperature goes out of range. Run QC to ensure kits are acceptable for client use if temperature ranges are exceeded. 	<ul style="list-style-type: none"> Ensure temperature logs are maintained regularly for all areas where test kits are stored and take corrective action as required. Assume responsibility for storage of test kit materials and supplies. 	<ul style="list-style-type: none"> Provide test locations with temperature monitors as needed or recalibrate existing monitors as scheduled. 	
Documentation and Reference Material	<ul style="list-style-type: none"> Complete and retain all documentation as recommended, and/or per test location/HA requirements. Use most recent version BC Program templates, documents and manufacturer's instructions. Provide feedback to BC Program on suggestions for new documents, or revisions of current documents. 	<ul style="list-style-type: none"> Maintain all documentation as required. Review Client and QC logs at least monthly. Ensure the most recent version of documents and instructions are being used by test providers. 	<ul style="list-style-type: none"> Liaise with test providers and Health Authority/Test location supervisors to update documents and reference materials as required. 	<ul style="list-style-type: none"> Notify BC Program regarding changes to product documents.



Activity	Test provider (approved by test location and/or Health Authority)	Test location /Health Authority* These items may be the responsibility of the Health Authority or test location and is to be determined at a regional level.	BC Program	Service Provider: bioLytical (manufacturer of INSTI test kit)
Risk Management	<ul style="list-style-type: none"> Report abnormal/unexpected errors/outcomes to the POC test location lead. 	<ul style="list-style-type: none"> Retain and store client log sheets in case of a future need to communicate problem with test kit to clients. Investigate unexpected outcomes, record actions and ensure implementation of corrective actions. Report abnormal/unexpected results to the BC Program. 	<ul style="list-style-type: none"> Discuss abnormal/unexpected results with Health Authority/test location supervisors. Report to advisory and steering committees as required. Relay information on changes or problems with test kits to all test locations as applicable. Report abnormal/unexpected results to appropriate BCCDC management and to vendor as applicable. 	<ul style="list-style-type: none"> Respond to any concerns regarding kit performance and provides guidance as to how to proceed.
Recall Process	<ul style="list-style-type: none"> Respond to recall alert messages from BC Program. Review current stock for recalled product. Quarantine recalled product and follow instructions from Test location Lead and contact BC Program regarding outcomes. Re-test clients as recommended by BC Program. 	<ul style="list-style-type: none"> Ensure recalled product has been identified and quarantined for all test locations Communicate with test locations, BC Program and bioLytical throughout entire process. Lead process for client retesting as necessary. Retain all documents related to the recall event 	<ul style="list-style-type: none"> Facilitate communication between POC Test location Leads/test locations and vendor. Determine if client retest is needed and facilitate process as needed. 	<ul style="list-style-type: none"> Initiate recall process. Liaise with BC Program throughout the recall process. Provide clear instructions of expectations to BC Program and test locations.



Activity	Test provider (approved by test location and/or Health Authority)	Test location /Health Authority* These items may be the responsibility of the Health Authority or test location and is to be determined at a regional level.	BC Program	Service Provider: Proficiency Testing provider	Service Provider: bioLytical (manufacturer of INSTI test kit)
Proficiency Testing	<ul style="list-style-type: none"> Participate in proficiency testing as requested. 	<ul style="list-style-type: none"> Work with BC Program to enroll test locations in proficiency testing program. Schedule staff participation in proficiency testing events. Review proficiency testing results with staff, and follow up concerns accordingly. Maintain proficiency testing records. 	<ul style="list-style-type: none"> Initiate and manage contract with proficiency testing provider on behalf of the test locations. Act as the contact for test locations if concerns or questions arise. Analyze provincial proficiency testing data results in aggregate form and report on results as part of the BC Program evaluation. Offer support/assistance (i.e. training) for those test locations that discover errors as a result of their participation in the proficiency testing program. 	<ul style="list-style-type: none"> Manufacture and distribute the proficiency testing materials to test locations. Respond to issues regarding shipments or testing schedule. Analyze data from all participating test locations. Create and distribute reports to participating test locations. 	<ul style="list-style-type: none"> Respond to any proficiency testing issues related to kit performance.
Evaluation	<ul style="list-style-type: none"> Participate in BC Program evaluation if requested. Participate in location evaluation if requested 	<ul style="list-style-type: none"> Participate in BC Program evaluation if requested. Define and assess HA or location evaluation criteria and process. 	<ul style="list-style-type: none"> Coordinate evaluation of the BC Program. 		