Quality Control (QC)

Quality Control (QC) provides objective proof that test results are accurate, and proactively detects random variation in the kits, among test providers or within the testing environment.

QC samples are produced by the manufacturer (bioLytical). QC checks the stability and function of the test kit, the test provider's eyes and the lighting conditions in which the test is run. Since the result is a visual colour, it is critical that each test provider is able to detect a weak reactive result and to distinguish between a nonreactive and a weak reactive result in the lighting conditions of the test environment.

Currently in BC, a set of vials /bottles are tested each time that QC is run. Each set includes a bottle of HIV negative and anti-HIV-1 positive human sera.

- Each vial/bottle should be sufficient to conduct 15-20 tests.
- The samples are shipped at ambient temperature and should be stored in the fridge upon receipt by the test location.
- The materials will last up to one year post-production if they are stored in the fridge.
- Samples are warmed to room temperature (approximately five minutes) and gently inverted a few times to mix before use.

QC samples are made from human sera and should be treated as a biohazard risk, albeit, a low risk. Test locations should follow biosafety rules regarding storage, handling and disposal of QC samples.

It is recommended that the vials/bottles be stored in a refrigerator in a labeled, leak-proof container (eg: a urine collection bottle).

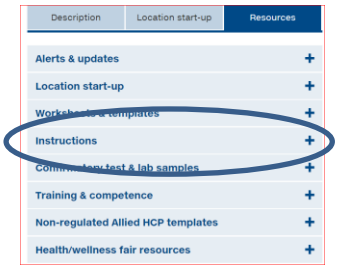
When performing QC testing, it is recommended that test locations rotate test providers each time QC is done, or follow a "View or Do" model for quality control.

The "View or Do" model encourages those performing QC testing to show the results to their colleagues so that test providers are reminded of what a weak positive result looks like, without using a large number of test kits.

Contact the BC HIV POCT Program for suggestions as to how this may be done at a test location.

Performing a Quality Control Test

QC samples are run similar to a client test, BUT using a different pipette to collect the 50 uL sample. Detailed instructions are found on the BC Program webpage – Resources- Instructions section.



Both samples are always tested for each QC test.
It is recommended that both samples be discarded at the same time (i.e. – don't hold onto one sample if the other is discarded).

QC Frequency of Use

It is a BC HIV POCT Program expectation that all test locations will test QC samples per manufacturer's recommendations, but at a minimum of once per month. Test locations take on risks associated with not meeting this minimum expectation.

If QC fails, the accuracy of results since the last QC success is in doubt. Test locations must balance how often QC samples are tested with the number of clients who would have to be retested in the event of a problem with the test kits.

For test locations doing few tests per month (0-10), the once per month minimum is reasonable as the number of clients that would need to be retested is minimal.

For test locations that do many (25 or more) tests per month, regular use of QC samples may be increased (e.g. once per week).

QC Samples - Indications for Use

The manufacturer recommends that QC be run at the following times:

- for newly trained test providers prior to actually using the HIV POC test kit on clients
- when a test location receives a new shipment of HIV POC test kits
- when there is a change in test kit lot number
- when a test location receives a new shipment of quality controls
- if the temperature of the storage or testing area falls outside of the manufacturer's specified temperature range (less than 2°C or greater than 30°C)
- when two consecutive invalid results occur with the same client in the same test session

Indications for when to run QC samples are included at the bottom of the QC Log. It is recommended that the reason for testing should be included on the log to aid the identification of potential opportunities for improvement.

When QC samples do not provide the expected results and it has been determined that there is a problem with the test kits, or QC failures are unresolved, none of the tests used since the last time QC samples were used with correct results can be considered valid.

Contact the BC HIV POCT Program immediately as client retests, or a product recall, may be required.

Documentation of Quality Control Results

Test locations are required to document the results of all quality control tests performed, including:

- The type of quality control material (e.g., HIV negative, anti-HIV-1 positive)
- Quality control lot number and expiry date on each vial
- HIV POC test lot number (on the back of the test kit foil kit packet)
- HIV POC test result (reactive, non-reactive, invalid)
- If the result is invalid, then the log should show that QC was retested and passed. Inclusion of the reason (or probable reason) for the invalid result is good practice, and helps the person who completes the Monthly Inventory Report.

It is recommended that a separate QC Log be kept and that the reason to run QC is included in the record. This makes it easier for the person gathering information for the Monthly Inventory Report to assess if an opportunity exists for improvement, or for preventive action, or if QC is being run at an appropriate level. Often, the QC Log is kept with test kits so that test providers can easily check that the kits are OK to use.

QC Failure

When the QC results do not agree with the expected result, QC is determined to have "failed" and an investigation into what caused the problem is necessary. This event should be reported in the test location's error/accident/corrective action reporting system, and to the BC Program Lead.

In the event of a QC failure, record the QC result and inform the POC Test location Lead as soon as possible.

Client HIV POC testing must be stopped immediately, until the cause of the failure is found and corrected.

It is important to review the testing environment for factors that could have caused the QC failure.

Do not continue to use QC samples until you get a "correct result".

It is a good practice to start an investigation by excluding more-common errors such as mix-up of control materials, reagents, pipettes and missed steps in the use of QC.

Other important areas to investigate are:

- recent changes to the test or testing environment
- QC storage conditions
- QC expiry date/contamination
- pipette used for testing

Suggested Actions if QC Fails:

FIRST – assess why the failure occurred, then repeat use of QC samples from the SAME vial if the assessment suggests a procedural error.

If QC fails again,	repeat test using a different test kit lot, if available
if QC fails again,	there may be a problem with the test kit lot. STOP CLIENT TESTING. Notify the POC Test location Lead and the BC Program Lead IMMEDIATELY.

The BC Program Lead has additional QC and test kit master lots to troubleshoot this problem. It may be necessary to send kits from the "failing" lot to the BC Program or to the vendor as part of the investigation.

If the results of the investigation suggest that there is a problem with the test kits, or QC failure is unresolved, none of the tests used since the last time QC samples were used with correct results can be considered valid.

The BC Program Medical Director will determine if all clients tested since the last use of QC samples with correct results will need to be called back and retested (unless a confirmatory test was ordered). A recall of the test kit or control products may be indicated.