After completing this unit you will be able to :

- Understand the purpose of Quality Assurance, the role of the Quality Assurance Lead at your site and how you will support these activities
- Understand how test kits are ordered, stored and evaluated; support ordering and inventory management
- Perform positive/negative quality control testing of new kits
- Understand the ongoing quality assurance processes done at each site and the documentation required

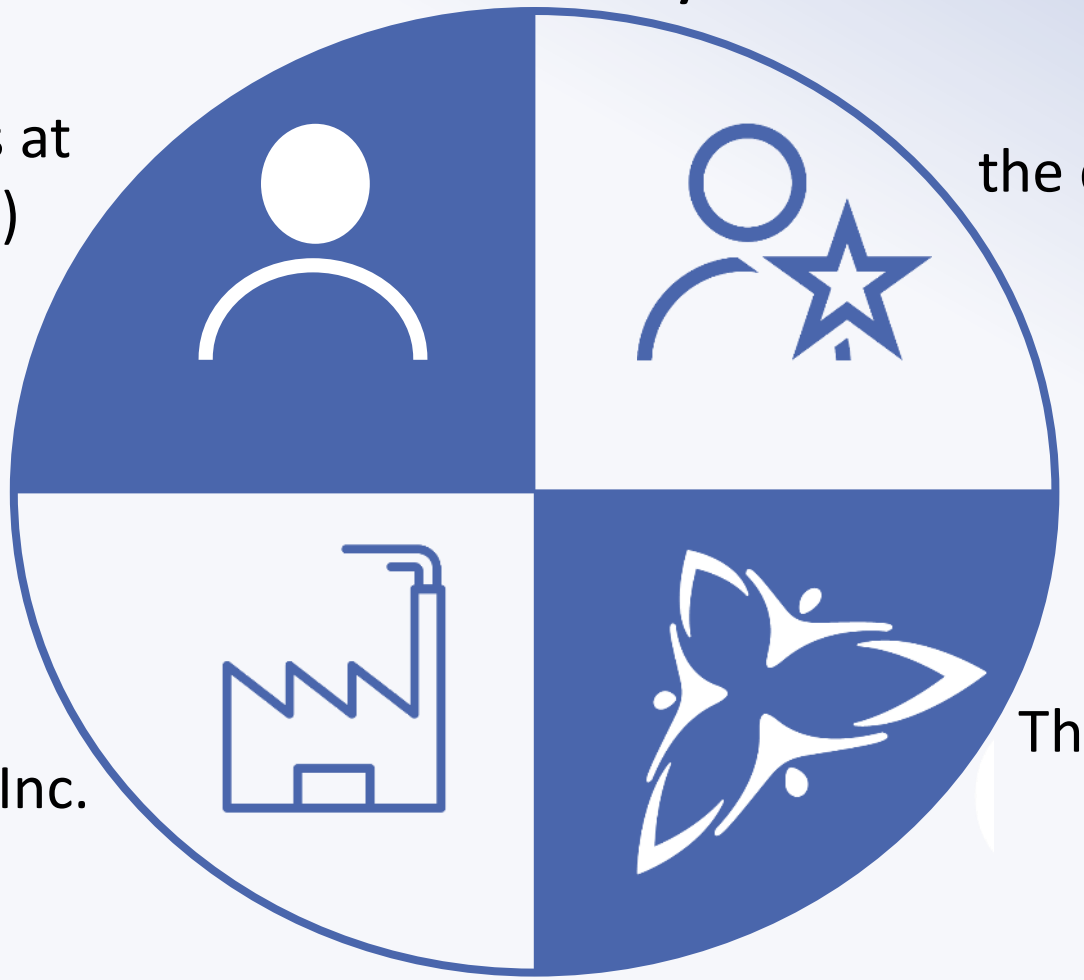
Why is Quality Assurance important?

- Ensures that your clients get accurate results and high-quality care
- Ensures that your site is able to perform accurate testing – necessary to maintain approval for testing at your site
- Ensure that all sites in Ontario provide consistent results
- Allows the Ministry to monitor the reliability of the kits it purchases

All Ontario laboratories perform Quality Assurance testing by law, these procedures have been adapted for point of care testing sites by the Ministry

Quality Assurance is Everyone's Responsibility!

HIV test counsellors at your site (like you)



the quality assurance lead at your site (may be a supervisor or some other designated individual)

the manufacturer bioLytical Laboratories Inc.

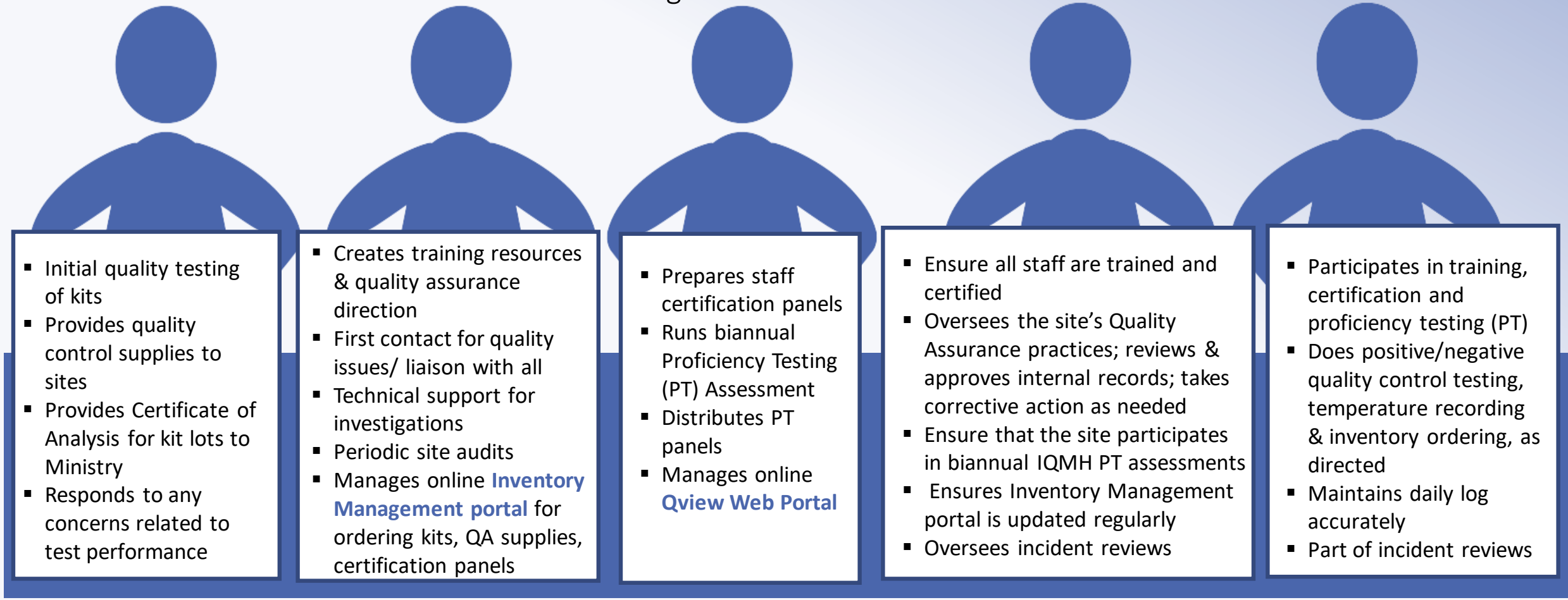
The Ministry of Health and Long-term Care

What does Quality Assurance Involve:

- Training and updating of staff skills
- Monitoring of how test kits are ordered, received, stored and used
- Regular evaluation of test kits to make sure they are working properly
- Regular assessment of the proficiency of the staff and procedures at your site to ensure correct results

In every case, careful record-keeping is essential!

MODULE: Quality Assurance and Inventory Management



Manufacturer

- Initial quality testing of kits
- Provides quality control supplies to sites
- Provides Certificate of Analysis for kit lots to Ministry
- Responds to any concerns related to test performance

The Ministry

- Creates training resources & quality assurance direction
- First contact for quality issues/ liaison with all
- Technical support for investigations
- Periodic site audits
- Manages online **Inventory Management portal** for ordering kits, QA supplies, certification panels

IQMH
Institute for Quality Management in Health

- Prepares staff certification panels
- Runs biannual Proficiency Testing (PT) Assessment
- Distributes PT panels
- Manages online **Qview Web Portal**

Site Supervisor/ QA Lead

- Ensure all staff are trained and certified
- Oversees the site's Quality Assurance practices; reviews & approves internal records; takes corrective action as needed
- Ensure that the site participates in biannual IQMH PT assessments
- Ensures Inventory Management portal is updated regularly
- Oversees incident reviews

HIV Test Counsellor

- Participates in training, certification and proficiency testing (PT)
- Does positive/negative quality control testing, temperature recording & inventory ordering, as directed
- Maintains daily log accurately
- Part of incident reviews

See the Ontario HIV Testing Program website for a complete table of responsibilities.

Training and Updating of Staff Skills

Your Responsibilities

- ✓ Participate in new staff training, including these training modules, practical training and mentorship at your site, etc.
- ✓ Complete a **certification testing panel** after your training is complete to fully qualify as a tester.
- ✓ Take part in refresher training, after any prolonged absence. Annual refreshers are recommended, particularly for lower volume sites.
- ✓ Keep track of the records of your training and make sure you submit them to be placed in your HR file.

It is the responsibility of your site and your quality assurance lead to make sure you are trained appropriately.

Certification Testing

HIV testing sites in Ontario can order certification panels for new HIV test counsellors through the Ministry's **Inventory Management portal**. Once you have completed your training, you will participate in this testing.

What happens:

1. You receive a panel of samples for HIV testing. The panel is prepared by the Institute for Quality Management in Healthcare (IQMH) Neither you, nor anyone else at your site will know what the results of these tests should be.
2. You will test the samples according to the package instructions.
3. Results of the testing will be available to the administrators of your testing site and through the ministry. If your findings were acceptable, you will be certified as an HIV testing counsellor.

Certification panels are not positive/negative quality controls or Proficiency Testing panels. Each of these forms of quality assurance testing has a different purpose and process.

Supplies and Inventory

Different supplies are ordered from different locations:

Inventory Management portal (www.HIVPOCT.ca) – Kits, positive/negative quality controls, and certification panels

AIDS Bureau – Additional capillary pipettes, bulb pipettes and tracking stickers to prioritize and direct samples referred to the Public Health Ontario Laboratory (PHOL).

Public Health Ontario Laboratory (PHOL) – Standard HIV Testing Requisition (online) and Anonymous HIV Testing Requisition (by phone)

A quick reference table included with the training materials describes where all needed supplies can be ordered.

We'll talk more about testing requisitions and tracking stickers in the Test Requisition Module.

Inventory Management & Supplies

Maintaining supplies and ensuring their quality is one of the primary responsibilities of your Quality Assurance Lead. However it is also useful for you to know how these supplies are managed. Alert the lead about damaged supplies, or low supplies of kits or positive/negative quality controls.

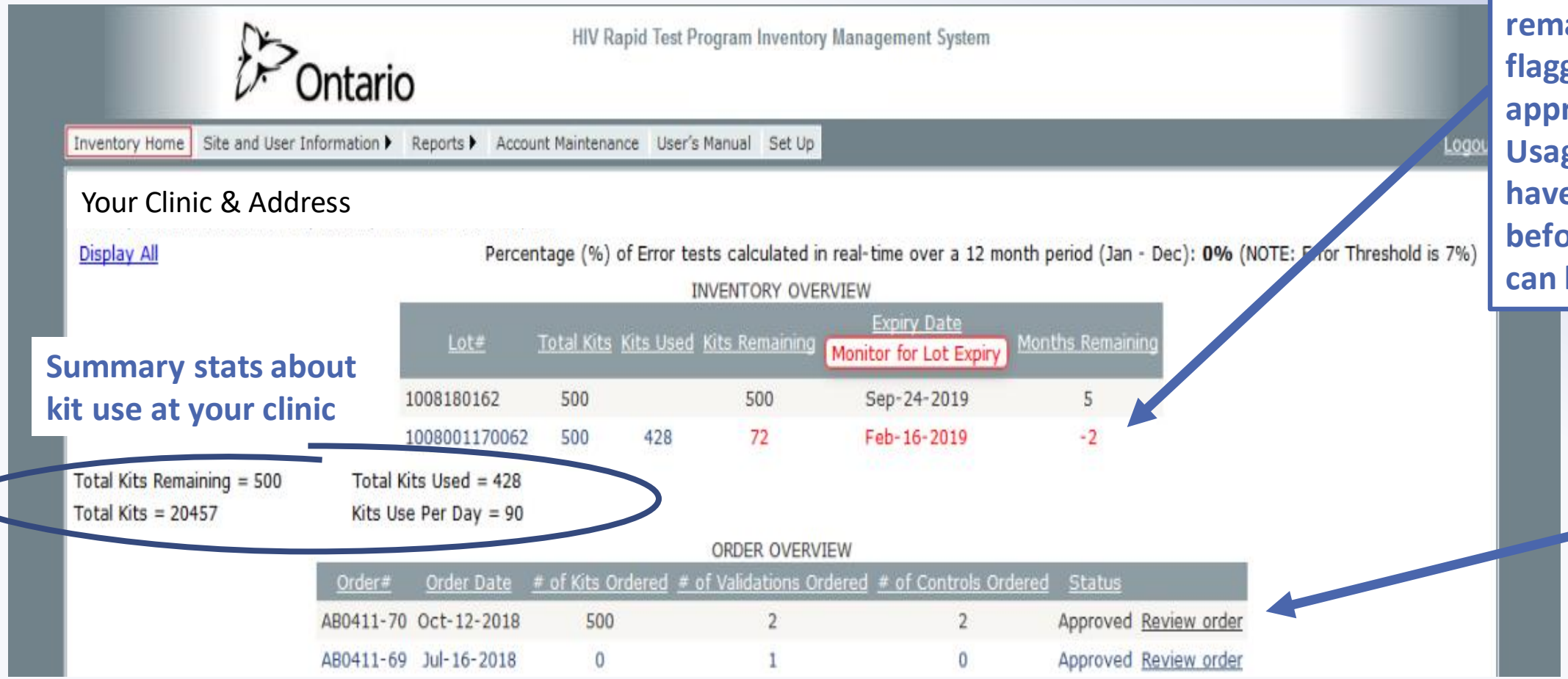
Your site has a secure user name and password for the www.HIVPOCT.ca portal, which is used to manage your inventory. The portal allows your site to:

1. Order supplies (kits, positive/negative quality controls, certification panels)
2. Confirm shipment of new kits (not necessary for positive/negative quality controls or certification panels).
3. Enter kit usage information prior to ordering new kits. The necessary information is collected in the monthly summary done by your QA Lead.
4. Review reports of past/current orders and kit usage.

Kit usage reports help the Ministry track how many kits are needed and any problems or errors that may be occurring.

Invalid results should be reported as damaged.

Inventory Management Portal



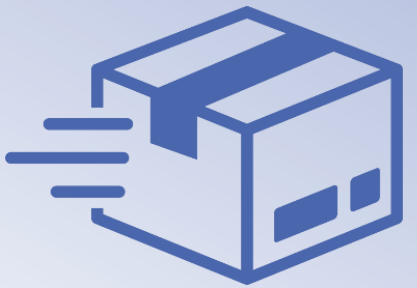
When 500 new kits were ordered in Oct; 72 of the old lot remained. These are flagged as approaching expiry. Usage of kits will have to be updated before any new kits can be ordered

Summary stats about kit use at your clinic

Kits, Controls, & Certification Panels last ordered Oct 12, 2018

Test Kits – Receiving an Order

- ✓ Make sure that new orders of test kits are stored in the storage area away from any existing kits, until they can be tested with positive/negative quality controls; all existing lot of kits should be used before starting the new ones.
- ✓ Check to make sure the new kits have not been frozen or damaged.
- ✓ If asked to do so by the Quality Assurance Lead, test new kits with the positive/negative quality controls



Ensure that new kits are not left unattended and that you know who to notify about a new shipment.

Your site is responsible for maintaining an ongoing inventory of your kits at www.hivpoct.ca.

Test Kits – Storage of Kits

Test kits may be stored in a refrigerator or at room temperature, as long as the temperature never exceeds 30° C. The temperature must be recorded daily and range between 2-30° C.

- Your temperature gauge should record the high and low temperature each day as well as the current temperature
- Because low temperature storage is acceptable, kits can be refrigerated to protect them in hot environments. When kits are being moved to an outreach site, be aware of the temperature; kits should never sit out in the sun, or be left in a car trunk in winter.

The store room temperature must be checked daily

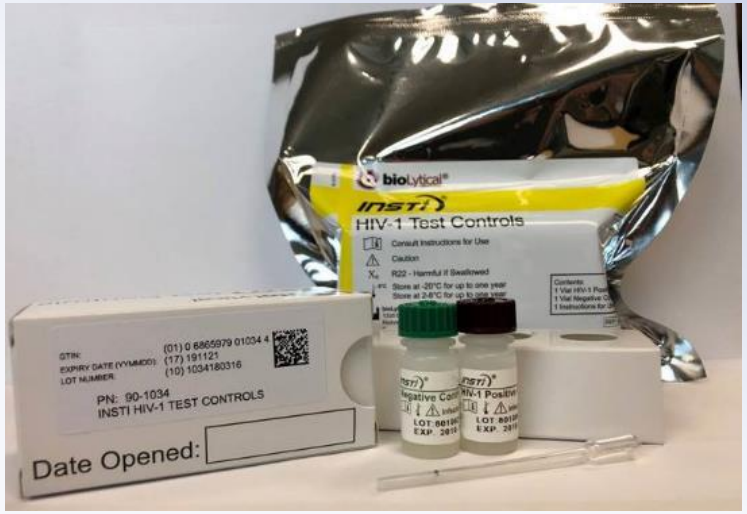
If a temperature outside 2-30°C is recorded, **quality control** testing of all stored lots must be done, before further client testing can continue.

Evaluating Kits with Positive/Negative Quality Controls

Your site should have two vials of quality control material: one HIV-positive and one negative. The positive control is only weakly positive. A reactive test demonstrates that the kits at your site are working in an optimal way. Controls are ordered at www.hivpoct.ca.

Control testing should be done:

- When the kits are first received before any kits are used (this is sometimes referred to as validating the kits)
- If a temperature reading is recorded outside the 2-30°C range
- Monthly on existing kits or every 125 tests completed (not more than once a week for high-volume sites)



Controls may be kept frozen or refrigerated for up to a year. Which ever way they are stored, **use the expiry date as written**!

Evaluating Kits with Positive/Negative Quality Controls

1. Take two test kits from the lot you are testing, unwrap the **first kit** and open vial one as normal
2. Use a bulb pipette to withdraw 50 µl of control from the negative control (up to the pipette's black line), and add it to vial one; complete testing as normal
3. To test the **second kit**, use a <u>different</u> bulb pipette to withdraw 50 µl of control from the positive control, and add it to vial one; test as normal
4. It is recommended that the results be recorded on both the Daily Log and the Quality Control Log

What if Positive/Negative Quality Control Testing fails?

Immediately

1. If the positive is not positive, or the negative is not negative, don't discard the test material (membrane, etc.) Take a picture. Both may be used to investigate.
2. Alert the **Quality Assurance Lead** and/or **Supervisor** (not required at all sites).
3. Record what happened in the **incident log** including the expected result, the result obtained and subsequent efforts to resolve the cause of this incident.

Second Test

1. Repeat the testing a second time **using the same lot of test kits and the same controls**. Tests of each control should be done one at a time, not simultaneously.
2. If the results are acceptable (as expected), record them in the quality control log and incident log. Testing at your site can continue as usual.
3. Try to identify why the first test came out wrong (i.e. mix up of materials or a missed step) Record in the incident log.

The failure of two sequential QC tests is cause for serious concern.

If two quality control tests have failed:

Have the quality assurance lead conduct this testing whenever possible.

Test again (3rd test) using a different lot of quality controls

3rd test produces acceptable result; do a fourth test with the same newly-opened quality controls

3rd test result is un-acceptable (unexpected or invalid result)

4th test result is acceptable. The problem was with the controls. Record in the incident log and order new control.

4th test result is un-acceptable (unexpected or invalid result)

All testing at your site must stop. Notify the AIDS Bureau Immediately. An investigation must be conducted.

Test Kits – Use of Kits

- ✓ Record the lot number and expiry date of every kit that you use in the daily log
- ✓ Do not switch back and forth between different lots of kits. The first kits to arrive should be used first
- ✓ Check each kit before use to make sure it has not been damaged bring damaged kits to the attention of the Quality Assurance Lead.
- ✓ Positive and negative quality control need to be used regularly!
- ✓ If a kit does expire, it is sterile. It can be placed in the regular garbage. Please do not use clear garbage bags.

Test Kits – Use of Kits

What if a kit produced an invalid/unreadable test result when testing a client?

When invalid tests happen, don't discard the testing material (membrane, etc.)

Do a second test

If the 2nd test is valid

Record the first and second results in the daily log; counsel the client as normal based on the 2nd test.

Record the first result in the incident log, and carefully consider what may have caused it.

If the 2nd test is invalid

Recommend the client have a standard test. With client consent, draw blood for the testing.

Record the results of both tests on the daily log along with the referral to PHOL.
Record both tests in the incident log, and report to the QA Lead for investigation.

Whenever an invalid test happens, take a picture. This photo should be sent to the AIDS Bureau.

Assessing Testing Processes at Your Site

Rapid testing sites are also expected to evaluate their staff and procedures regularly as follows:

- **Parallel Testing** – Every time a reactive test occurs, clients are advised to confirm the result with standard laboratory testing. This also helps ensure that testing is working well at your site. Report to your Quality Assurance Lead whenever follow-up testing on a reactive rapid test is non-reactive or when a negative sample submitted for standard testing in the window period has a reactive result.

- **Monthly Assessment of Testing Results** – Each month, your Quality Assurance Lead completes a monthly summary of testing at your site including the number of positive, negative and invalid tests done, the number referred to PHOL for further testing, any unanticipated results and kit usage. This information is gathered from the daily log.

- **Proficiency Testing** (next slide)

Proficiency Testing (PT)

The Ministry has established a regular Proficiency Testing Program for rapid testing sites, administered by the **Institute for Quality Management in Healthcare (IQMH).**

- Your site will regularly receive unknown samples from IQMH to test and return for assessment.
- Each of the people who provide testing for clients at your site should participate.
- When the results have been analyzed they will be available through the secure Qview portal managed by IQMH. Your Quality Assurance Lead will have access.

The Ministry monitors the outcomes of this testing, to ensure that errors are investigated and corrective action taken, as needed.

NOTE: Proficiency Testing (PT) samples are NOT positive/negative quality controls or certification panels. Ensure that each package is handled correctly.

Summary of Required Logs and Documentation

Daily tools that all staff interact with and use regularly

- Rapid HIV Testing Record Daily Log
- Environmental Monitoring Log

A monthly summary usually done by your site's Quality Assurance Lead

Records kept as the activities occur

- Quality Control Log
- Incident Log
- Proficiency Testing Records
- Records of Counsellor Training and Certification

These documents might be requested, if an investigation at your site occurred

There is a brief description of each document in your handout; All documentation is stored for 10 years.