RAPID POINT OF CARE HIV TESTING IN ONTARIO, CANADA 2007 - 2011

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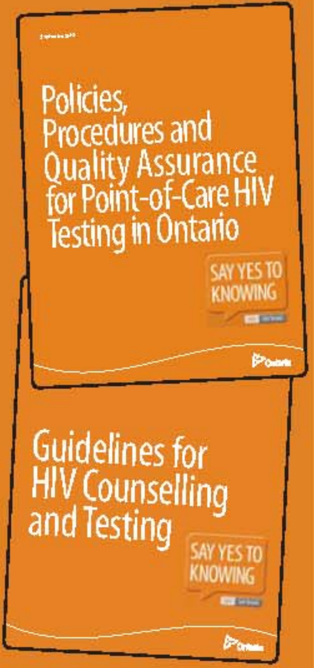
BACKGROUND

In 2007, the **Ontario Ministry of Health and Long-Term Care** launched an HIV POC testing program to increase access to testing for at risk and vulnerable populations. The program was developed by a steering committee consisting of community, public health, program and policy stakeholders. Through a partnership between the Public Health Laboratories and the AIDS Bureau, HIV POC testing was made available in 46 sexual health and community health centres across the province and has more than 200 trained POC test providers. Most sites offer anonymous HIV testing (39/46) and some offer outreach services with vans or multiple locations to attract hard-to-reach clients. A comprehensive quality assurance program was developed to ensure that POC testing would produce consistent and reliable test results.

Our QA program includes all the elements required for medical laboratory accreditation as follows:

- Guidebooks describing the program policies and procedures and counselling guidelines
- Training – initial (4-6 hours), plus yearly refresher course
- Each trained provided must pass a competency assessment by testing a blinded panel of 6 samples provided by the manufacturer
- Kit lot batch validation – by a third party laboratory against a panel of difficult samples
- Kit lot validation is performed independently by each site on receipt of each batch of kits
- Daily/weekly quality control – once every 25 tests, or at a minimum once weekly, and a maximum of once daily, detailed instructions on how to proceed when there is an incorrect control result
- Temperature monitoring of areas where kits are stored
- Inventory control – ie last in, first out
- Parallel laboratory testing – all POC reactives and potential window period POC non reactive samples are forwarded to the Public Health Laboratories for standard laboratory testing
- External quality assessment (EQA) – the organization providing EQA to all licensed HIV laboratories in Ontario, provides the same panel of 4 samples, twice per year. On a rotating basis, up to 10 test providers at each site participate.



The INSTI HIV Assay (bioLytical Laboratories, Richmond, BC) is used for POC testing. Counselling and testing is provided by the same test provider (nurse or other allied health worker under a medical directive). All reactive POC results are confirmed by whole blood tested at the PHL. In addition, any POC non-reactive clients likely to be recently infected and therefore, in the window period are advised to submit a whole blood sample for supplemental testing, including p24 antigen. Counsellors complete a PHL HIV laboratory requisition with demographic and risk data for all POC tests and for samples for confirmatory testing. Data are entered into the PHL information system and the data are analyzed for positivity rates by gender, exposure category and test performance.

RESULTS

Graph 1. Uptake of POC Testing 2007-2011

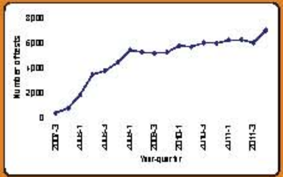


Table 1. Overall Test Results

Total POC tests: 84,085

- **Reactive: 777 (0.92%)**
- **Non-reactive: 83,308**
  - **Window period: 707**

Table 2. Reactive POC Tests

Reactive tests: 777

No sample available: 55

Sent for confirmatory testing: 722

- **Confirmed HIV-positive: 547 (76%)**
- **Confirmed HIV-negative: 162 (22%)**
- **Inconclusive: 13 (2%)**

Table 3. Supplemental Testing of POC Non-Reactive Window Period Samples

Sent for confirmatory testing: 707

- **Confirmed HIV-positive: 0**
- **Confirmed HIV-negative: 696**
- **Inconclusive: 11**

Table 4. HIV Positivity Rate by Year and Exposure Category

	MSM		IDU		HIV-endemic		High risk hetero		Low risk hetero		Other/unknown		Total	
	T	%	T	%	T	%	T	%	T	%	T	%	T	%
2007	[illegible]	2.07%	3	0.00%	11	0.00%	[illegible]	0.00%	844	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
2008	[illegible]	[illegible]	[illegible]	2.14%	141	[illegible]	[illegible]	[illegible]	8,170	[illegible]	974	[illegible]	[illegible]	0.84%
2009	[illegible]	[illegible]	[illegible]	1.97%	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1,740	[illegible]	[illegible]	[illegible]
2010	[illegible]	1.70%	[illegible]	1.35%	[illegible]	1.55%	411	0.73%	[illegible]	0.11%	2,117	0.57%	[illegible]	[illegible]
2011	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1.04%	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Total	[illegible]	[illegible]	[illegible]	1.77%	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	0.10%	[illegible]	[illegible]	[illegible]	[illegible]

Table 5. Test Performance – Specificity by Year

Year	Non-reactive POC	"False reactives"	"False reactives" per 1,000 HIV-negative tests
2007	1,085	0	0.0
2008	15,078	58	2.9
2009	20,569	56	2.7
2010	25,069	45	1.9
2011	25,199	25	0.9
Total	87,955	162	1.9

Table 6. Test Performance – Positive Predictive Value

	POC reactive	Confirmed HIV-positive	PPV (%)
MSM-IDU	5	5	100%
MSM	442	415	93%
IDU	30	23	77%
HIV-endemic	21	13	62%
HR Hetero	26	18	69%
LR Hetero	147	49	33%
Other/unknown	33	24	73%
Total	709	547	77%

Table 7. External Quality Assessment Experience

Survey #	# Sites	# Sites with Errors	# Tester Errors / # Testers	% Correct
[illegible]	43	6	11/755	98.5%
[illegible]	43	2	9/799	98.9%
[illegible]	43	3	3/675	99.2%
[illegible]	43	0	0/535	100%

All EQA discordant results were investigated. To date, the most common cause of error is from testing the wrong survey panel. There have been occasional incidents of carryover and contamination of a survey sample during testing. EQA results have improved over time.

Sites are advised to report any issues related to testing to the AIDS Bureau who in turn communicates with the manufacturer. There have been several issues related to the physical appearance of the POC test. While these did not affect performance, on occasion, they have caused anxiety for testers and clients.

The bulb pipettes used exclusively for controls, validation panels and EQA presented challenges to staff, as they are difficult to control for non-laboratory personnel. Although it is a simple assay to run, the minor variations in technique may occur which can affect performance (delaying the addition of vials), so it is important to ensure the procedure is followed precisely. Maintaining good communication with all sites at all times has ensured rapid response to all testing issues.

Table 8. Test Performance Issues*

Yellow smudges on cassette

- **Do not affect performance**

Bulls eye IgG control spot

- **Does not affect performance**

White flecks on cassette

- **Do not affect performance**

Defective lancets

- **Does not affect performance**

*Technical performance may not have been affected but site and client confidence in test result compromised

Table 9. Lessons Learned

Bulb pipettes (QC/EQA/Validation)

Technique can drift….

EQA is not perfect (150+ testers)

Communication with sites is KEY!

CONCLUSIONS AND DISCUSSION

The HIV POC program has been successful in attracting high risk clients for testing.

32% of clients were high risk compared to 16% in standard testing.

Overall positivity rates were 3 times higher than standard testing (0.65% vs 0.22% with highest rates in MSM (1.9%), IDU (1.8%) and people from endemic areas (1.4%). These findings are consistent with rates from our anonymous testing program which has been operating since 1992.

Test performance has been excellent with specificity at least as good as the manufacturer specifications (99.8% vs 99.7%) and no evidence of "missed" HIV infections during the window period.

More than 99% of clients receive a non-reactive result immediately, providing relief from waiting time anxiety and ensuring higher client through-put in our clinics.

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