

# Rapid Point of Care HIV Testing

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## Hassle Free Clinic

- Community-based clinic in downtown Toronto providing medical and counselling services in all areas of sexual health
- Approximately 25,000 patient visits per year with 12 counsellors and part-time physicians
- Canada's largest Anonymous HIV test site, conducting approximately 5,000 tests annually
- Pioneered AT starting in 1985; illegally for 7 years

## Testing

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- Estimated there are 10,000 to 15,000 people living with HIV in Canada who don't know their status
- Testing very important as part of our response to HIV/AIDS
- Positive people knowing their status allows them to access treatment, care and support
- Negative testers; anxiety relief and strategize around prevention

## Testing

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- Authorities around the world calling for more widespread HIV testing
- When people know their status, less likely to transmit to others
- Calls for more "routine" rather than Voluntary Counselling and Testing (VCT) model
- Not the approach we've taken in Ontario
- Regardless of philosophy, rapid point of care testing (POC) is seen as an important tool in the scale-up of testing

## History

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- First rapid POC test was approved by Health Canada in March of 2000
- First Class IV medical device approved for point of care use
- Recalled in April of 2002 after questions were raised in BC about test accuracy, specifically false negatives
- Hassle Free had been using the tests for six months when the recall occurred
- Fast forward three years.....

## History

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- Extensive clinical trials, with a new device from bioLytical (Vancouver) approved in October 2005
- At Hassle Free, as experienced testers, we felt it was important to start using the rapid point of care test to establish protocols, procedures and standards of care
- Started using the test in April, 2006

## Standard vs. Rapid Point of Care

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- Patients have a choice between tests
- Standard Test - A venous sample is taken, sent to the Public Health Lab
- Follow their testing algorithm; send us the result
- The patient returns to the Clinic in one to two weeks for result and post test counselling

## Rapid Point of Care vs. Standard

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- POC – a finger prick, perform test out of room
- If negative, give patient immediate result – post test counselling
- If reactive, give result, obtain informed consent – draw blood for confirmatory testing at the lab
- Patient returns for confirmatory result in about one week, more post test counselling

## Benefits of POC Testing

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- Client satisfaction; 99% of patients choose POC; 98% report complete satisfaction with testing experience, including those who ultimately test positive
- Test results are easier to give because a relationship with the client is established in the pre-test counselling
- Builds capacity by eliminating separate appointments or drop-ins for results

## Benefits of POC Testing

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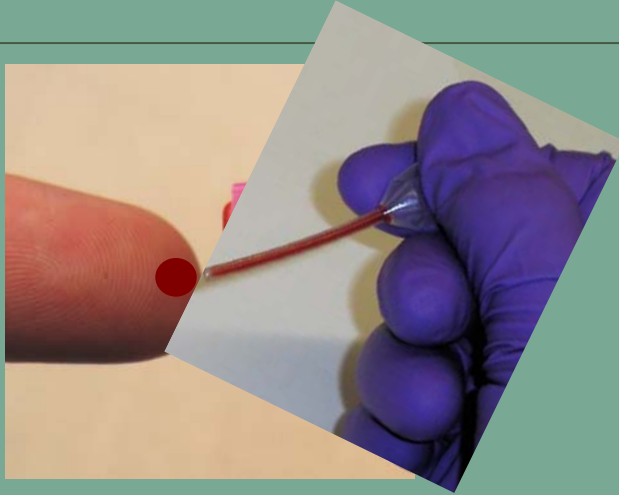
- Everybody gets results (though AT sites have high rates of return)
- Potential to increase access to testing, especially in non-urban settings
- Allows communities to set up their own programs
- Better post test counselling due to two opportunities

## Science of the Test

- Utilizes unique recombinant proteins for HIV-1 (gp-41) and HIV-2 (gp-36).
- 8 years in Research and Development
- 2 years in clinical trial process with Health Canada, over 16,000 tests with matching blood, plasma, serum on 3,500 patients. Sensitivity (fingerstick) 99.6%
- Specificity (fingerstick) 99.3%



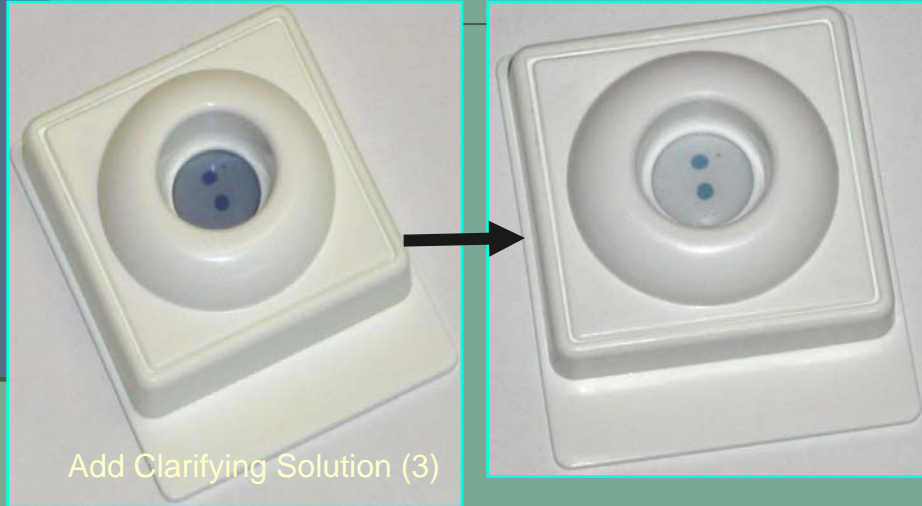
INSTI Procedure:



INSTI Procedure...



## STI Procedure...



## Rapid POC HIV antibody testing

Interpreting the results:

- the top dot is the control dot and the bottom dot is the test dot
- **1 blue dot = non-reactive (negative)**
- **2 blue dots = reactive (positive)** and indicates the specimen has HIV-1 antibodies
- **No dots or partial rings/dots = invalid or indeterminate**



Results in 60 Seconds or Less

## Ontario's Program

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- Targeted Testing Program to at-risk populations
- New best-practice Counselling and Testing Guidelines
- Approximately 50 Anonymous test sites
- Approximately 50 POC sites (lots of overlap)
- Extensive Quality Assurance/Quality Control Program

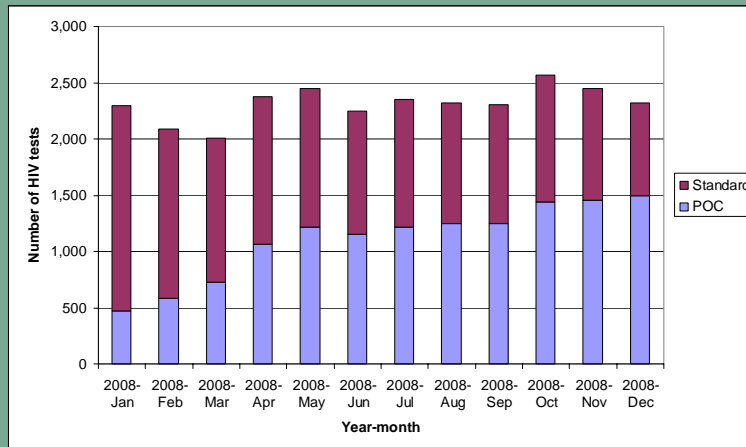
## Ontario's Program

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- High uptake and high degree of client satisfaction (98%, including positive testers)
- Ongoing training for those offering POC
- No loss of epi data, as all information still goes to Public Health Lab

## As of December 31, 2008

- 41 POC Sites, Total POCT= 13,772



## POC Testing Details

- | Status                                | Number         |
|---------------------------------------|----------------|
| Non-Reactive                          | 13,452         |
| Window Period<br>(all neg POCs in wp) | 143            |
| confirmed as neg                      | 100% Sensitive |
| Reactive                              | 177            |
| Confirmed HIV +                       | 130            |

## Specificity

Total False Reactive	39
Total Negative POC Tests	13,595
Overall Specificity	99.71%

## Window Period Results N=143

■ Confirmed HIV +	0	0%
■ Confirmed HIV -	137	99.3%
■ Inconclusive (no follow-up)	1	.72%
■ No sample provided	5	3.73%

## Good News

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- AT/POC Testing Program is working well
- Attracting at risk populations
- No false Negatives – Sensitivity 100%
- High positivity rates – compared to other testing (0.91% vs 0.29%)
- No “incidents” or missed cases among window period testers.
- High proportion of early HIV infections diagnosed.

## Country-Wide

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- B.C. – Pilots in downtown east-side Vancouver and Prince George
- Alberta – Finished pilots with pregnant women, occupational health exposures and ER patients with acute illnesses
- Saskatchewan – Using in outreach testing programs, primarily in north
- Manitoba – Nine Circles Community Health Centre (1,000 to 1,500 tests annually)

## Country wide

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- Quebec – Finishing translation of guidelines through National Institute of Public Health
- Nothing east of Quebec

## Conclusions

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- Rapid HIV Point of Care Testing is an important tool to encourage testing
- Ontario's Program demonstrates:
  - - excellent test performance (including window period)
  - - high positivity rate; attracting high risk groups
  - - increased capacity; fewer return visits
  - - better post test counselling; two opportunities

## Acknowledgements

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