HIV Point-of-Care Testing (POCT) in Canada: Action Plan 2015-2020

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REACH 2.0

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Purpose

The overarching purpose of this Action Plan is to help establish recommended actions in relation to greater equity and support in building our national HIV testing response, including, but not limited to, an increase in awareness, access to and uptake of HIV point-of-care-testing (POCT) in Canada by 2020, and the development of expected outcomes or progress indicators towards these actions. To achieve these, both leadership and collaboration with and by government, community, research, industry, health care and government partners, including the provincial health authorities and provincial laboratories, will be required to advocate for change. This Action Plan is therefore meant to be used as an advocacy tool to advance these key issues.

Scope

While this Action Plan is focused primarily on the issues of awareness, access to and uptake of HIV POCT testing in Canada, we also appreciate the need to look toward other testing innovations such as multiplex testing platforms and self-testing, which are not currently available. In addition, we recognize the ongoing national shift toward integrated approaches to sexually transmitted blood borne infections (STBBIs) and a move away from HIV as a standalone issue. We believe this shift may help in 'normalizing' testing for HIV and other STBBIs, however, issues of social stigma surrounding testing, gender-based barriers to testing, as well as other social and structural determinants of testing need to be addressed in moving forward.

Although a thorough discussion on issues related to testing policies in Canada is beyond the scope of this document, we believe issues of informed consent, appropriate counselling and confidentiality of test results must be recognized as core elements in our approaches to testing in the face of new testing technologies and approaches. As such, this current action plan is meant only to offer a snapshot of issues related to awareness, access to and uptake of HIV POCT in Canada as of 2015, and to propose 10 expected outcomes or progress indicators to assess the trajectory of progress over the proposed five-year period of this Action Plan from 2015 to 2020.

Target audience

This Action Plan is directed primarily at individuals and organizations responsible for funding, designing, planning and delivering HIV testing in a variety of settings such as clinical, public health and community-based settings. The intention of this Action Plan is to offer an advocacy document for these audiences so they may use this information to help shape the changes required to realize the expected outcomes leading up to 2020.

1.0 Introduction

The issues of variable access to HIV testing information, access to and uptake of HIV POCT by province, by region, by community, and by population remain significant challenges in getting ahead of the epidemic in Canada. In other words, not everyone in Canada is being reached with our current approaches to HIV awareness and testing. In fact, approximately 25% of people in Canada living with HIV are unaware of their HIV status (Public Health Agency of Canada, 2012). This is an important issue in that new infections, often with accompanying high viral loads, may account for approximately 50% of onward transmissions of HIV (Brenner et al., 2007). Offering increased opportunities for individuals to become aware of the importance of HIV testing, and to be offered testing in a manner that ensures the appropriate consent, counselling and confidentiality procedures are followed, are crucial elements in the national approach to testing. This increased awareness may also help ensure those who test positive for HIV can benefit from advances in care and treatment, which in turn can play an important role in the public health goal of reducing the onward transmission of HIV. Increased opportunities for HIV testing may also provide important opportunities for ongoing prevention efforts in that a negative test result can lead to a conversation that reinforces risk reduction and safer sex strategies and can help link individuals to other services where appropriate.

While HIV testing rates differ across populations and locations in Canada, current testing approaches do not permit us to take full advantage of the individual and public health benefits of these innovations to prevent and treat HIV. Issues of awareness about HIV testing, as well as access to and uptake of testing are complicated by a variety of structural issues including proximity to testing sites and availability of testing options such as anonymous testing or access to appropriate follow-up services (Arthur, Beausoleil, Guay, & Gahagan, 2013). Late diagnosis of HIV infection, and late initiation of HIV antiretroviral medications, remain ongoing challenges. Increasing awareness about HIV testing options, and improving access to and uptake of testing innovation such as HIV POCT, are crucial components in an effective response to HIV in Canada.

2.0 HIV point-of-care testing (POCT)

The HIV POCT as a testing innovation has, where available, greatly expanded access to and uptake of testing and of HIV diagnosis (Asghari et al., 2015; Broeckaert & Challacombe, 2015). In addition, HIV POCT has the ability to test individuals and to offer a test result in the same visit. Those who have a reactive test result using HIV POCT can be referred for confirmatory HIV testing and appropriate counseling and supports in a timely manner. In addition, HIV POCT has the potential to be performed outside clinical or hospital settings, including in non-urban settings where clinical testing opportunities may not exist. In the findings of a recent scoping review of testing in non-urban centres, it was found that innovative approaches and non-traditional models of HIV POCT have a number of public health benefits that are particularly relevant to populations in rural settings (Gahagan, Minichiello, & Swab, 2015). However, testing innovations such as HIV POCT in non-urban communities require additional research in order to understand how best to 'fit' and scale up novel approaches in contexts with limited or no access to testing currently.

In Canada, the only HIV POCT currently approved for use is the HIV-1-HIV-2 Antibody Test (the INSTI test). This HIV POCT was developed by BioLytical Laboratories and was approved by the Medical Devices Bureau of Health Canada in 2005. This particular HIV POCT can be used to detect HIV-1 and HIV-2 using a small amount of blood obtained through a finger-prick. This process takes approximately one minute. Through clinical trials, the sensitivity and specificity of the INSTI HIV POCT have been shown to be over 99% (Galli, 2015; Galli et al., 2013). Another Canadian company, MedMira, produces several multiplex tests which can detect STBBIs including HIV, hepatitis C

(HCV), and syphilis using a single sample of blood, again obtained through a finger-prick. These multiplex POCT platforms have not yet been brought forward to the Medical Devices Bureau of Health Canada and therefore are not currently approved for use in Canada, although they are widely used around the world. In addition, there are currently no HIV POCTs approved for home use in Canada.

Research has demonstrated that many populations considered to be at "high risk" for HIV infection prefer HIV POCT over HIV testing methods that require taking blood in the standard blood draw methods used in clinical settings (i.e. venous puncture). These populations include persons who use injection drugs (Pant Pai et al., 2014) and men who have sex with men (Yang et al., 2014). HIV POCT may also be more useful than conventional testing for reaching individuals who have never been tested for HIV, and for those who have HIV but are unaware of their status (Broeckaert & Challacombe, 2015). A pilot study conducted in Halifax, Nova Scotia has indicated that a multiplex HIV and HCV POC test may appeal to persons who inject drugs more than a stand-alone HIV test (Gahagan, Condran, Sharma, & Hatchette, 2015). HIV POCT also has the potential to extend HIV testing to non-urban settings, particularly in remote and isolated communities, where pre-existing testing infrastructures, knowledge of HIV/AIDS, and clinical and organizational structures are not present and where concerns related to HIV stigma and confidentiality may prevent individuals from seeking testing (Broeckaert & Challacombe, 2015; Ha et al., 2014; Lewis, Gahagan, & Stein, 2013).

3.0 Current access to HIV POCT in Canada

Given that as of 2015, INSTI remains the only HIV rapid test to have obtained a license from Health Canada that allows it to be marketed in Canada for use outside the laboratory setting, we are using INSTI data to illustrate our key points about awareness, access to and uptake of HIV POCT in this Action Plan. While Health Canada has granted licenses to other HIV rapid tests, under the terms of those licenses their use is restricted to laboratory settings. Therefore, these Canadian-made tests are not yet approved for use outside of laboratory settings in Canada. During the period 2011 to 30 June 2015, Biolytical distributed INSTI test kits to British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Quebec and the Yukon. During the same time period Biolytical did not distribute any test kits in the four Atlantic Provinces (Nova Scotia, New Brunswick, Newfoundland and Labrador, and Prince Edward Island), the Northwest Territories, or Nunavut. This suggests that many health care providers and patients cannot access HIV POCT and this may be related to decisions among health authorities not purchase the test kits, not to cover the cost, or due to the lack of a billing code.

4.0 Key Actions and Expected Outcomes 2015-2020

TABLE 1 provides an overview of the key actions and expected outcomes in advancing HIV POCT in Canada. Achieving these key actions by 2020 will require partnerships between government, community, research and industry sectors..

TABLE 1: Key Actions and Expected Outcomes 2015-2020		
Actions	**Key Partners**	**Expected outcomes**
1. AWARENESS Increase awareness of importance of HIV POCT, and related testing innovations such as testing settings, delivery methods, programs approaches, and multiplex and self-test technologies in Canada.	Federal, Provincial Territories AIDS (FPT AIDS), Public Health Agency of Canada (PHAC), Health Canada's First Nations and Inuit Health Branch, Ministerial Council on the Federal Initiative to Address AIDS (MAC-FI), Canadian Public Health Association (CPHA), Canadian Medical Association (CMA) provincial laboratory managers, national and provincial AIDS Service Organizations (ASOs), community health organizations, sexual health organizations, harm reduction organizations (CHOs, SHOs, HROs), Health Canada, Public Health Units	Increased number of Canadians aware of HIV POCT and other testing innovations available in Canada.
2. ACCESS Increase access to POCT in Canada, particularly in regions where it is not currently available and among populations who could benefit from access.	FPT AIDS, provincial laboratory managers, ASOs, CHOs, SHOs, HROs, government/public health funding bodies.	Increased partnerships between government, community, researchers, and industry to ensure availability of HIV POCT to people at highest risk of HIV without cost throughout each province and territory in Canada.
3. BILLING Offer a billing code for POCT in all Canadian jurisdictions.	FPT AIDS, Public Health Agency of Canada, Health Canada.	All provinces and territories will have a billing code in place for HIV POCT.
4.TRAIN Provide training and education to medical, pharmacy, nursing, social, work and other allied health professions, and lay providers/lay testers including those living with HIV (as peer testers)	FPT AIDS, provincial regulatory bodies for health professions, faculties of health professions at Canadian colleges and universities, Canadian Public Health Association, ASOs, SHOs, HROs.	Increased number of people who are involved in the prevention, treatment, and support of Canadians infected or affected by STBBIs who are trained and have clear standards on HIV POCT.

TABLE 1: Key Actions and Expected Outcomes 2015-2020		
Actions	**Key Partners**	**Expected outcomes**
5. TEST Increase testing rates among high-risk populations through HIV POCT and other testing innovations.	Provincial laboratories, ASOs, CHOs, SHOs, HROs.	Increased numbers of high-risk populations accessing HIV POCT and other testing innovations.
6. STANDARDS Promote standardization of POCT in Canada.	FPT AIDS, MAC-FI, PHAC, Health Canada, CPHA, ASOs/CBAOs.	Canada develops, updates, and promotes standardization of POCT through increased intersectoral collaboration.
7. EDUCATE Increase education and support for people living with HIV about the prevention of the onward transmission of HIV, about the programs and services for people living with HIV, and about related supports.	FPT AIDS, PHAC, CPHA, faculties of health professions, community-based health care organizations, ASOs/ CBAOs, CHOs, HROs.	Increased number of training and educational opportunities for Canadian health care providers, allied health professionals, community-based health workers, and health trainees on the needs of those living with HIV in relation to HIV transmission.
8. COLLABORATE Strengthen collaboration between urban, suburban, and rural POCT sites for high-risk populations.	FPT AIDS, MAC-FI, Health Canada, PHAC, ASOs, CHOs, SHOs, HROs	Technology is creatively and effectively used to bridge information sharing between urban and rural POCT sites in Canada.
9. REMIND Increase awareness about HIV POCT through reminders to high-risk populations as per current epidemiological data for Canada for sustained awareness.	FPT AIDS, Health Canada, PHAC, CPHA, provincial public health associations, public health units, ASOs, CHOs, SHOs, HROs .	High-risk populations are tested earlier and more regularly. Standards are set to ensure clear practice testing guidelines, including guidelines related to consent, counseling and confidentiality.
10. INNOVATE Increase research on and approval of processes on testing innovation in Canada, including multiplex testing, self-testing options when such test kits are approved, peer based models, settings where testing is offered, and STBBI integration	FPR AIDS, Health Canada, PHAC, Industry, public health units, ASOs, CHOs, SHOs, HROs, health researchers.	Expand options for HIV POCT, multiplex and self-testing for HIV, HCV, and other blood borne infections.

5.0 Conclusions

HIV POCT and other POCT innovations such as multiplex testing platforms, self-testing and non-urban testing outreach offer examples of promising new approaches to increasing awareness about testing, as well as access to and uptake of not only HIV POCT but also STBBI POCT. However, the issue of variable access by province, by region, by community and by population remain significant challenges in getting ahead of the epidemic in Canada. Given the current shift to an integrated approach to STBBIs, more must be done to ensure increased collaboration and partnerships within and across government, community, research and industry sectors to fully realize the potential of POCT and related testing innovations in Canada.

Although as of 2015 no increase in availability of HIV POCT test kits is being offered for provinces and territories with no access, consideration must be given to making HIV POCT available in these regions of Canada. Additional research in determining if and how the appropriateness of testing innovation such as HIV POCT is matched with the needs of the community is warranted in an effort to ensure the approach to scaling up testing is in keeping with the needs of particular communities and populations in these regions. This must include careful consideration of the interrelated and complex issues of consent, appropriate counseling and confidentiality.

In an effort to maximize the potential of POCT for STBBIs, we are looking to all partners to show leadership in advancing and supporting equity in access to HIV POCT as outlined in the **10 Key Actions and Expected Outcomes between 2015 and 2020**.

These **Actions and Outcomes** include:

- increase **awareness** of and **access** to testing innovations such as HIV POCT;
- address current issues related to **billing codes** for HIV POCT;
- offer additional **training opportunities** in the use of HIV POCT;
- provide venues to make **testing more accessible** to those who currently do not have HIV POCT;
- develop **national and provincial standards** for incorporating HIV POCT through intersectoral collaboration;
- increase **educational opportunitie**s for those working with populations at risk for HIV as well as those living with HIV;
- **strengthen urban-rural collaboration** in utilizing HIV POCT;
- offer regular **testing reminders** about the importance of testing;
- and mobilize **testing innovations**, including HIV POCT, multiplex testing, and self-testing opportunities. Between 2015 and 2020 structural change is needed to ensure all Canadians at risk for HIV can benefit from HIV POCT, as well as other testing innovations and related care, treatment and support interventions.

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APPENDICES

TABLE 2 displays the number of tests distributed to each province/territory annually since 2011. It should be noted that these data do not offer a break down related to test kits that are designated for quality assurance purposes and therefore cannot offer a definitive indication of how many test kits were used for actual screening. However, the data in Table 2 also compare the number of INSTI tests delivered to each province in 2013 with the number of HIV-infected individuals diagnosed during the same year through any form of HIV testing. While the highest ratio of test kits to HIV cases appears to be the Yukon, this is due to only a single case of HIV being identified in 2013 while 96 test kits were delivered in this same year. Among the Canadian provinces, Ontario had the highest ratio, while British Columbia had the second highest.

TABLE 2: INSTI Test Kits and HIV-infected individuals by province/territory in Canada: 2011-2015

Name	Number of distributed INSTI Test Kits						HIV-infected individuals in 2013**	Test Kits per each HIV-infected individual in 2013
	2011	2012	2013	2014	2015*	Total		
Quebec (QC)	2,142	8,561	8,141	10,108	5,894	34,846	457	17.83
Nova Scotia (NS)	0	0	0	0	0	0	16	0
Saskatchewan (SK)	4,536	1,920	3,984	4,080	996	15,516	126	31.59
Alberta (AB)	384	3,816	4,104	4,344	3,502	16,150	260	15.76
Newfoundland & Labrador (NL)	0	0	0	0	0	0	7	0
British Columbia (BC)	8,976	12,466	15,840	16,8740	10,474	64,630	270	58.59
New Brunswick (NB)	0	0	0	0	0	0	6	0
Prince Edward Island (PEI)	0	0	0	0	0	0	2	0
Yukon (YT)	48	48	96	48	48	288	1	97.68
Manitoba (MB)	120	1,784	2,572	2,974	9,282	9,732	116	22.09
Ontario (ON)	53,975	39,874	57,166	43,437	19,197	213,649	827	69.16
Nunavut (NU)	0	0	0	0	0	0	0	0
Northwest Territories (NT)	0	0	0	0	0	0	1	0

* The reported numbers represent the distributed INSTI Test Kits between January 1st, 2015 and June 30th, 2015.

** Data were obtained from Public Health Agency of Canada. HIV and AIDS in Canada: Surveillance Report to December 31, 2013. Minister of Public Works and Government Services Canada; 2014

FIGURES 1 THROUGH 5 provide a visual representation of the distribution of the INSTI tests in Canada.

FIGURE 1

Trends in the number of distributed INSTI Test Kits by province/territory in Canada: 2011-2014

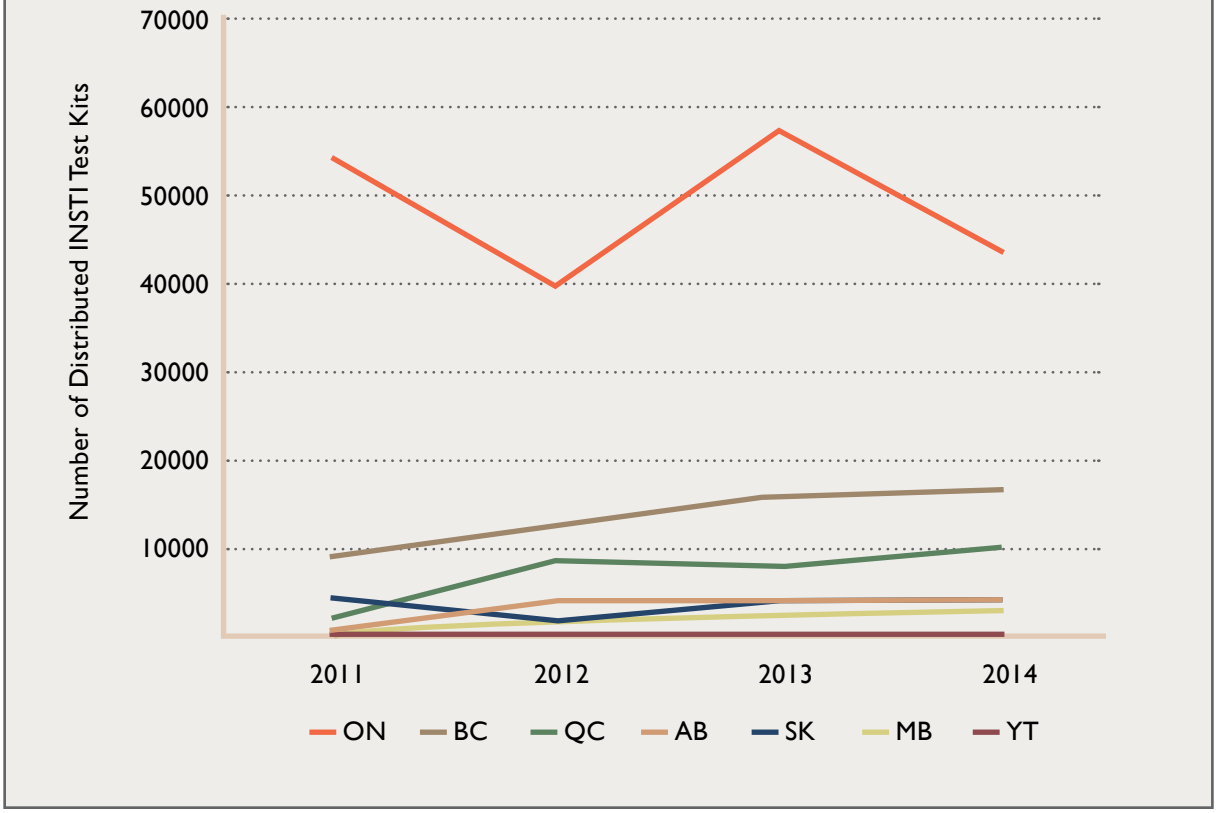

FIGURE 1 illustrates the trend in distribution for each province and territory where it is available: with the exception of Ontario, the number of INSTI tests provided to each province has increased since 2011. However, Ontario has received the greatest number of INSTI tests over the period between 2011 and 2014.

FIGURE 2 (below) provides the overall number of HIV cases identified in each province/territory in 2013, whereas **FIGURE 3** illustrates the number of distributed test kits by province/territory in the same year. **FIGURE 4** shows the total number of distributed tests per each HIV-infected individual by province/territory in Canada. Quebec received fewer test kits per HIV cases identified than British Columbia, Saskatchewan or Manitoba even though during 2013 more HIV cases were identified in Quebec than any other province except Ontario. **FIGURE 5** demonstrates the overall number of distributed test kits by province/territory over the period between 2011 and 2015. As shown in Figure 5, most of the test kits were distributed in Ontario.

FIGURE 2

Number of HIV-infected Individuals by province/territory in Canada, 2013

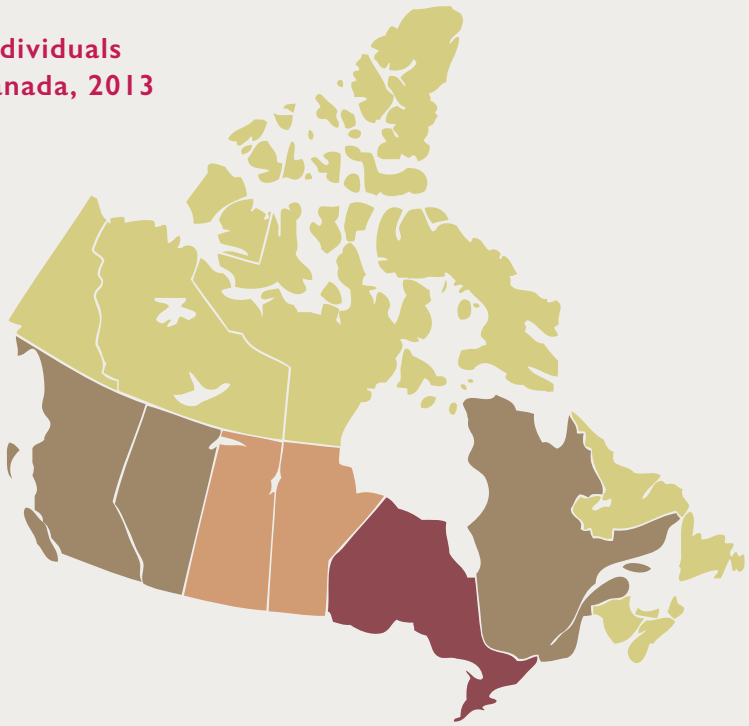

FIGURE 3

Number of distributed INSTI Test Kits by province/territory in Canada, 2013

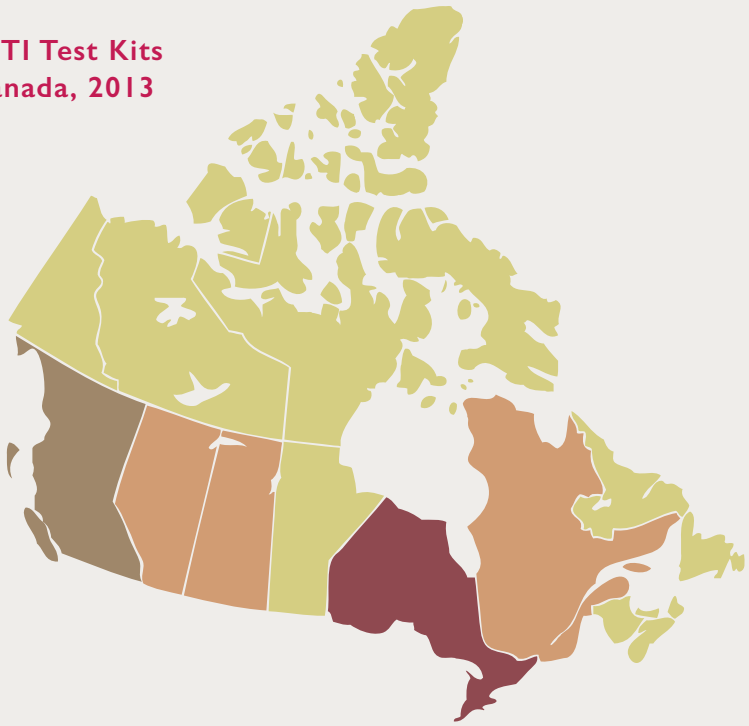

FIGURE 4

Number of distributed INSTI Test Kits per each HIV-infected Individual by province/territory in Canada, 2013

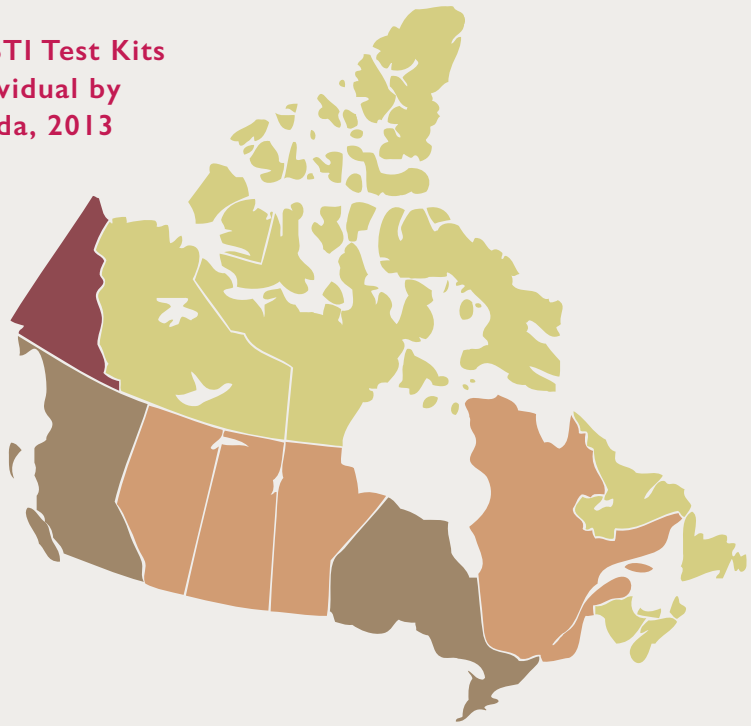

FIGURE 5

Number of distributed INSTI Test Kits by province/territory in Canada, 2011 to 2015

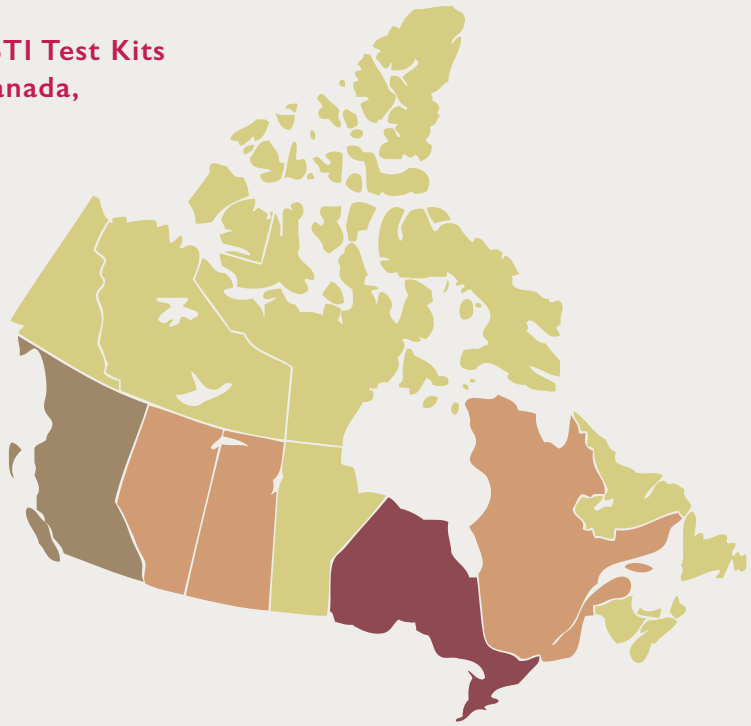

TABLE 3 offers a two-year 'moving average' (a calculation used to analyze data points by creating a series of averages of different subsets of the full data set) of the expected number of distributed INSTI test kits in provinces and territories with current access to HIV POCT in moving forward from 2015 through to the end of 2020 based on current distribution data.

TABLE 3: A two-year moving average of the expected number of distributed INSTI Test Kits over the period between *2015 and 2020*

Name	Number of distributed INSTI Test Kits					
	2015	2016	2017	2018	2019	2020
Quebec (QC)	9,125	9,616	9,370	9,493	9,432	9,463
Nova Scotia (NS)	0	0	0	0	0	0
Saskatchewan (SK)	4,032	4,056	4,044	4,050	4,047	4,049
Alberta (AB)	4,224	4,284	4,254	4,269	4,262	4,265
Newfoundland & Labrador (NL)	0	0	0	0	0	0
British Columbia (BC)	16,357	16,616	16,486	16,551	16,519	16,535
New Brunswick (NB)	0	0	0	0	0	0
Prince Edward Island (PEI)	0	0	0	0	0	0
Yukon (YT)	72	60	66	63	65	64
Manitoba (MB)	2,773	2,874	2,823	2,848	2,836	2,842
Ontario (ON)	50,302	46,869	48,585	47,727	48,156	47,942
Nunavut (NU)	0	0	0	0	0	0
Northwest Territories (NT)	0	0	0	0	0	0