High Study Levels of Accuracy, Usability, and Acceptance by Observed Participants Lead to Health Canada Licensing of the First HIV Self-Test in Canada

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Introduction

- Unlike other G7 countries, Canada is not seeing a reduction in the overall number of new people being diagnosed with HIV
- Using HIV self-testing to reach the undiagnosed particularly amongst key and hard to reach populations are needed to achieve Canada's original UNAIDS commitment to all three of the 90-90-90 targets
- In 2016, the WHO recommended HIV self-testing as an alternative to conventional facility-based testing, however Canada has yet to finalize a national policy
- Having a licensed HIV self-test in Canada provides new opportunities to increase the access, uptake and frequency of HIV testing and more effectively reach the undiagnosed
- The objectives of this study were to:
    1. Evaluate the INSTI HIV Self-Test (bioLytical Laboratories, Richmond, BC) performance compared to laboratory reference testing
    2. Document if intended users can perform the steps to use the self-test device
    3. Document if intended users can successfully interpret contrived positive, negative, and invalid results

Methods

- The study used a cross-sectional design and recruited 767 consenting adults from four community sites across Ontario, Québec, and Manitoba between August 2019 and March 2020
- Each participant self-collected a fingerstick blood specimen and performed the INSTI HIV Self-Test, including result interpretation, according to the manufacturer's instructions for use
- Each self-test performance was directly observed by a trained healthcare professional (observer) who noted errors and other observations about the participant's test performance
- The INSTI HIV Self-Test results were compared with results of the Abbott Architect HIV Ag/Ab Combo test
- Usability information was captured on instructions for use, pre-self-test preparation, self-collecting blood sample, self-test procedure, and follow-up procedures
- A subset of participants were provided contrived "mock" result membrane cartridges and asked to interpret the results

Figure 1 INSTI HIV Self-Test Package (image courtesy of bioLytical Laboratories)

Results

Table 1. Participant characteristics for Primary Efficacy Analysis (n=678)

	n	%
Gender		
Male	410	60.6%
Female	247	36.5%
Other	20	3.0%
Age Range		
18-25	139	20.5%
26-35	277	40.9%
36-45	106	15.6%
46-55	95	14.0%
>55	61	9.0%
Race/Ethnicity		
White	296	43.7%
African/Caribbean/Black	113	16.7%
Indigenous	95	14.0%
Asian	106	15.6%
Latin American	46	6.8%
Other/Mixed	22	3.2%
Employment Status		
Employed	307	45.4%
Unemployed	153	22.6%
Student	87	12.9%
Retired	16	2.4%
Prefer not to answer	113	16.7%
Highest Education Level		
Primary	16	2.4%
Secondary	184	27.1%
College	156	23.0%
University or Higher	322	47.5%
Experience with HIV Testing		
Yes	500	74.2%
No	174	25.8%

- Primary efficacy analysis on 678 completed HIV self-tests revealed a positive percent agreement of 100% and a negative percent agreement of 99.5% with the comparator method (see Table 2)
- A total of 6 previously undiagnosed participants were identified through completed study testing and linked to care and treatment
- The overall percent agreement between participant and observer for the self-test results was 93.5%
- The overall “invalid” rate for the HIV self-test was 5.6%

Table 2. Positive and Negative Percent Agreement with Laboratory Results (Abbott Architect) based on 678 completed HIV Self-Tests

True Positive	6
False Negative	0
True Negative	669
False Positive	3
Positive Percent Agreement*	5/5 = 100% (95% CI: 43.6-97.0%)
Negative Percent Agreement**	614/617 = 99.5% (95% CI: 98.6-99.8%)

* One additional HIV positive subject had a positive Abbott Architect result, but an invalid self-test result due to wiping the fingertip on the rim of bottle 1 then dropped the bottle and spilled most of the contents before adding the remainder to the membrane unit. This invalid was not used in the calculation.

** Participants with invalid self-test results (n=37) and who indicated “do not know” for the self-test result (n=18) are not included in the calculation

Results

- Of the 708 participants who took part in the usability study,
  - 92.4% successfully performed the steps determined to be "critical" for successful completion of the test,
  - 96.7% found the instructions easy to follow, and
  - 95% indicated that they would use the test again
- Of the 404 participants who interpreted the strong positive, weak positive, negative and invalid contrived results, successful interpretation ranged from 90.4% (for weak positive) to 99.0% (for negative) (see Table 3)

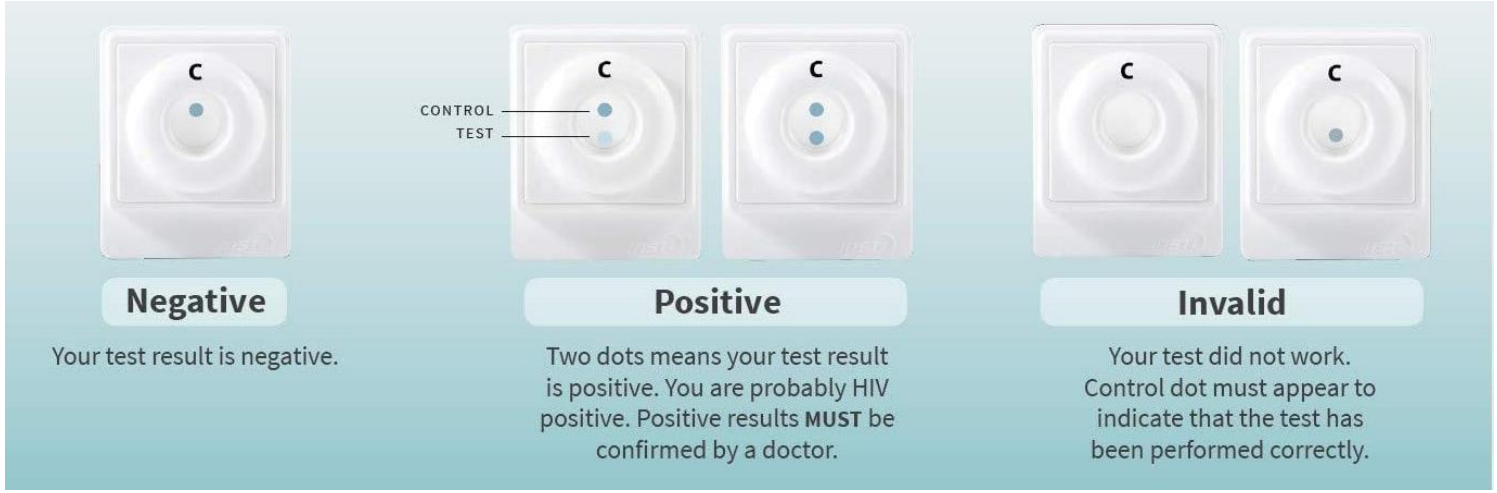

Figure 2 Reading negative, weak positive, strong positive, and invalid INSTI HIV Self-Test results (image courtesy of bioLytical Laboratories)

Table 3. Mock Results Interpretation (n=414)

	n	%
Strong Positive		
Positive	398	97.8%
Negative	3	0.7%
Invalid	5	1.2%
Do not know	1	0.2%
Weak Positive		
Positive	367	90.4%
Negative	8	2.0%
Invalid	28	6.9%
Do not know	3	0.7%
Negative		
Positive	3	0.7%
Negative	404	99.0%
Invalid	1	0.2%
Do not know	0	0.0%
Invalid (no control, no test)		
Positive	1	0.2%
Negative	2	0.5%
Invalid	397	97.8%
Do not know	6	1.5%
Invalid (no control, with test)		
Positive	9	2.2%
Negative	12	2.9%
Invalid	381	93.4%
Do not know	6	1.5%

Discussion

- Data from this study was submitted as evidence of the safety and efficacy of the INSTI HIV Self-Test to Health Canada as part of a device license application
- The overall specificity in this study (negative percent agreement) of 99.5% met the threshold of ≥99% set by Health Canada for Rapid Diagnostic Tests
- To mitigate some of the reasons for invalid results, revisions to the package insert were made to provide clearer instructions on the proper use of the lancet and subsequent blood drop collection, as well as alerting the self-tester that even a faint dot intensity is considered valid
- Acceptance of the INSTI HIV Self-Test by intended users in this study was very high with participants indicating preferences for using the test both at home and at a clinic, suggesting that both assisted and unassisted self-testing strategies will be useful for access and uptake

Conclusions

- This study showed high levels of accuracy, usability and acceptance by participants, leading to the license of the INSTI HIV Self-Test by Health Canada on November 3, 2020
- REACH NEXUS is leading a national implementation science project (I'm Ready to Know) that will provide 50,000 free INSTI HIV Self-Tests to participants across Canada starting in May 2021