

BACKGROUNDER

INSTI HIV Self Test Clinical Study Findings

A ground-breaking Canadian study of the blood-based INSTI HIV Self Test was led by Dr. Sean B. Rourke and his team at the MAP Centre for Urban Health Solutions and the CIHR Centre for REACH at St. Michael's Hospital.

The INSTI HIV Self Test, manufactured by the Canadian company bioLytical Laboratories Inc. of British Columbia, was tested with the support of regional teams in three provinces:

- Toronto (Hassle Free Clinic and Women's Health in Women's Hands)
- Winnipeg (Nice Circles Community Health Centre)
- Montreal (Clinique Médicale L'Actuel)

This study conducted the necessary real-world "intended user" trial required by Health Canada as part of the application to license the INSTI HIV Self Test for use in Canada. The clinical trial began in August 2019 and was completed in March 2020.

The objective of the study was to provide data on the performance, acceptance, and usability of the HIV self-test in the hands of intended users in Canada. Study participants were >18 years of age, and were from a cross section of ethnicities and population groups including those who are found to be at higher risk of HIV infection.

Participants were enrolled at the study sites during their visits for standard HIV testing, and asked to administer the self-test on their own using only the English or French instructions for use provided by the manufacturer. A non-interactive health care professional observed and documented how well the participant was able to conduct the self-test on their own without assistance.

There were three main components of the study:

1. The performance of the device (sensitivity, specificity, and overall accuracy) compared to a licensed laboratory HIV antigen/antibody combo test.
2. Examination if the intended users (i.e., persons who were inexperienced in HIV self-testing but known to be at higher risk for acquiring HIV) can successfully perform the steps to use the HIV self-test device without product demonstration.
3. Evaluation if intended users can successfully interpret "mock" test results, including invalid results.

Main Findings

1. Overall, the study results indicated that the self-test is highly accurate (> 99%), acceptable, and easy to use by self-testers from diverse backgrounds and locations.
2. Overall usability was found to be close to 100% for individual ease of use attributes, and over 95% of study participants indicated they would use the self-test again, and recommended it to their partners, family, and friends.
3. Intended users were able to interpret "mock" test results with a high degree of success for positive, weak positive, negative and invalid results.

The final study results were submitted by the manufacturer to Health Canada in April 2020 as part of the license application approval of the INSTI HIV Self-Test for use in Canada.

Scientific findings have been submitted to a peer-reviewed journal for publication.

For more information, contact: Sean B. Rourke, PhD, FCAHS – sean.rourke@utoronto.ca