Dual HIV-syphilis rapid test approved for use in Canada

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Dr. Sean B. Rourke. Credit: Eduardo Lima

Federal regulators have approved the licensure of an all-in-one rapid device that allows Canadians to simultaneously be tested for HIV and syphilis. Canada is the first country to approve and implement a dual-

target device in North America that can produce results in as little as 60 seconds.

The approval was made possible, in part, by the results of a two-year clinical trial led by researchers at the University of Alberta and St. Michael's Hospital, a site of Unity Health Toronto, which have been published in *Clinical Microbiology and Infection*. The results were included as part of the device manufacturer's submission to Health Canada and were necessary for the regulators' review and approval.

A recent report by the Public Health Agency of Canada showed spiking rates of syphilis in the country, primarily among young women. From 2017 to 2021, rates of syphilis among females increased by 729%, compared with 96% among males. Syphilis infection can increase the risk of HIV acquisition and transmission, and co-infection creates a high risk of neurological problems. Cases of congenital syphilis—which is present at birth—are at crisis levels for young mothers, particularly those from persons of First Nations ethnicity. Ninety-six cases of congenital syphilis were reported in 2021, compared with seven cases in 2017.

"We need urgent actions to mobilize testing, treatment and connections to care for syphilis and HIV that are culturally appropriate, and that can reach and meet people where they are. They won't come to us because the health and public health system has failed them—we need to go to them," says Dr. Sean B. Rourke, a scientist at MAP Center for Urban Health Solutions, a world-leading research center housed at St. Michael's Hospital, and the Director of REACH Nexus, a national research group working on how to address access and treatment for HIV, Hepatitis C and other sexually transmitted and blood-borne infections.

Rourke spearheaded the cross-Canada clinical trial which evaluated and proved the accuracy of HIV-self tests. Health Canada approved the tests for use in November 2020 based on the results of the trial.

The Point of care Tests for Syphilis and HIV (PoSH) Study launched in August 2020 and analyzed two different test devices among over 1,500 participants in clinical settings in Edmonton and northern Alberta. The study found both devices to be 100% accurate in identifying HIV infection, and more than 98% accurate in detecting active syphilis. Both test kits provide a test result in under five minutes using a fingerstick blood specimen.

Among the study participants, 24 tested positive for HIV on both devices and were confirmed by a lab test—four of those were new diagnoses. Acting on the device's instantaneous nature, connecting participants to care and early treatment was a key priority of the study. Of the 20 people previously diagnosed with HIV, nine were on antiretroviral therapy, and all 24 participants were linked or relinked to care. There were 202 cases of infectious syphilis and the majority (87.4%) were treated immediately following point of care test positive results. An additional 32 of 34 (94.1%) participants with infectious syphilis who did not receive treatment at the test visit were treated within a median of four days.

"These extremely rapid point of care tests for the diagnosis of syphilis and HIV are much needed and a game changer for Canada. We were able to save costs associated with an additional clinic visit, reducing the number of cases lost to follow up, and prevent ongoing disease transmission," says Dr. Ameeta Singh, the study's principal investigator and an infectious disease physician with the University of Alberta.

Health Canada is approving the INSTI Multiplex HIV-1/2 Syphilis Antibody Test, which is manufactured by bioLytical Laboratories Inc. in British Columbia. To do the test, a health provider obtains a fingerstick blood specimen, places a single drop of blood with the materials provided in the kit, follows the simple procedure instructions provided in the package, and reads the result in as little as one minute. The health

provider can then offer treatment or linkage to care based on the test result. In February 2023, a dual-target device that produces results in 15 minutes was approved in the United States.

More information: Ameeta E. Singh et al, Sensitivity and specificity of two investigational Point of care tests for Syphilis and HIV (PoSH Study) for the diagnosis and treatment of infectious syphilis in Canada: a cross-sectional study, *Clinical Microbiology and Infection* (2023). DOI: 10.1016/j.cmi.2023.02.015

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