CADTH COVID-19 PANDEMIC

Saliva-Based Testing as an Alternative to Traditional COVID-19 Testing Techniques

Key Messages:

- Testing using saliva samples (also known as saliva-based testing) has been proposed as a less invasive solution to the long wait times characterized by widespread traditional COVID-19 tests.
- Evidence on the accuracy and reliability of testing for COVID-19 using saliva samples is currently limited in quality and quantity.
- While there is evidence to support the use of testing using saliva samples for COVID-19, some studies have found conflicting results between different sample specimens collected from the same individual and between individuals.
- International scientific literature is changing rapidly and there are currently several ongoing research trials, including those in Canada, to determine the diagnostic accuracy of COVID-19 testing using a saliva sample.

With cases on the rise and no known cure for the novel coronavirus disease 2019 (COVID-19), many jurisdictions have increased their COVID-19 testing capacity. Testing allows for earlier detection, treatment, and contained spread through identification, isolation, and contact tracing. Traditional testing requires a sample specimen to be collected via a nasopharyngeal, deep nasal, or throat swab from suspected individuals. The sample is then tested for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) — the virus that causes COVID-19. Certain challenges are posed by traditional sample collection methods, including potential supply shortages when demand is high, discomfort to the individual being tested, long wait times, and difficulty for health care workers (HCWs) performing the tests due to their invasive nature.

Testing using saliva samples (also known as saliva-based testing) has been proposed as an alternative to traditional sample collection methods because it is less invasive, uses different supplies and reagents, and may alleviate long wait times as an adjunct to standard testing. Saliva samples have previously been used to detect diseases of the upper respiratory tract and are currently being investigated for use against SARS-CoV-2. In a recent issue of <u>Health Technology Update</u>, CADTH looked at the latest research on testing using saliva samples to detect active SARS-CoV-2.

CADTH is an independent agency that finds, assesses, and summarizes the research on drugs, medical devices, tests, and procedures. The CADTH *Health Technology Update* newsletter describes new and emerging health technologies that are likely to have a significant impact on health care in Canada.

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What Type of Test is Used in Saliva-Based Testing?

There are three broad categories of COVID-19 tests:

- 1. **Reverse transcriptase-polymerase chain reaction (RT-PCR) test:** This tests for the genetic material of the virus (e.g., DNA, ribonucleic acid) and is used in common practice.
- 2. Antigen test: This tests for the proteins found on the surface of the virus.
- 3. Serological test: This tests an individual's immune response to the virus (e.g., antibodies).

Each of these tests require a sample for testing. The RT-PCR test can use a variety of different sample specimens, including saliva. Examples of RT-PCR tests that can use saliva as the sample specimen include the Infinity BiologiX TaqPath SARS-CoV-2 Assay (formerly known as the Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 assay) and the Curative-Korva SARS-CoV-2 Assay. Both of these RT-PCR tests can use saliva or oral fluid (the mixture of saliva with other constituents in the mouth) in addition to other types of sample specimens. The Infinity BiologiX test uses the Spectrum Solutions LLC SDNA-1000 saliva collection device, which the individual suspected of being infected with SARS-CoV-2 can spit directly into. With the Curative-Korva test, the sample is collected by swabbing the inside of the individual's cheeks. According to each tests' Emergency Use Authorization by the US FDA, sample specimens can be self-collected; however, a trained HCW must be present to supervise. Samples of each company's respective tests are analyzed in their respective lab within 24 to 48 hours of collection.

Read more about the differences between the various types of tests in the CADTH Horizon Scan.

Advantages of Testing Using Saliva Samples

Potential advantages of integrating testing using saliva samples into standard testing practices include:

- increased testing accessibility by easing medical supply shortages during high demand; testing using saliva samples requires different supplies to collect the sample specimen than traditional nasopharyngeal swabs.
- less invasive procedure; saliva samples can be self-collected at home, which also limits HCW exposure to suspected SARS-CoV-2-infected individuals.
- **better user experience**; it is easier and faster to complete the saliva sample collection and it is more comfortable and less stressful for the individual undergoing the test.

What Is the Evidence?

Evidence from cross-sectional studies has been mixed regarding the accuracy of saliva sampling. Some research has shown that saliva samples have the potential to result in similar or higher SARS-CoV-2 detection rates with RT-PCR than with nasopharyngeal sampling. However, other evidence has shown saliva sampling to be less accurate, particularly in non-hospitalized patients. Some studies have also reported conflicting results between different sample types collected from the same individual. Evidence suggests that the results of saliva-based tests are more accurate when conducted early in the morning before eating or brushing one's teeth. Several ongoing clinical trials, including those in Canada, are being conducted to evaluate tests that use saliva to detect SARS-CoV-2.

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Current Practice in Canada

As of early December 2020, testing using saliva samples had not been authorized for use by Health Canada. However, if a testing method is developed and administered within a lab for research purposes rather than being marketed for sale, the same authorization is not required. An example of this is the "swish-and-spit" test, developed by a research group from British Columbia, with the aim of eliminating the need for the use of swabs during sample collection. Intended for school-aged children, the sample is collected by first having the child swish a sterile saline solution for five seconds and gargle it for another five seconds. The process is repeated for a total of three swish-and-gargle cycles and then finally the solution is spat into a collection tube and used for testing. This swish-and-spit saliva-based test is now available in British Columbia.

For a full list of Health Canada-authorized testing devices, please visit the Health Canada website.

Bottom Line

Testing using saliva samples may result in safer and more comfortable testing for HCWs and those being tested. Evidence is currently unclear given the accuracy of this testing method; however, research is rapidly evolving during the pandemic and several studies are currently being conducted to determine its diagnostic accuracy. Despite unclear evidence, saliva samples may still have a place in COVID-19 testing given their feasibility and simplicity of use. The ability for self-collection would be especially beneficial for those in remote locations, who are unable to access COVID-19 testing centres. Overall, increasing testing methods allows for greater capacity to test large groups of people with or without COVID-19 symptoms — a necessary part of a public health strategy to manage the pandemic.

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