Saskatchewan Health Authority

COVID-19 Testing in Saskatchewan FAQs

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The information provided below is dynamic, and will be updated regularly. Individual situations may warrant additional considerations, and this should not take the place of appropriate consultation.

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Q1. What tests are used to diagnose COVID-19 in Saskatchewan?

All diagnostic testing for COVID-19 in Saskatchewan relies on PCR (polymerase chain reaction). PCR directly detects the SARS-CoV-2 virus in a patient specimen. In Regina and Saskatoon, the labs use a combination of commercial and lab developed tests (LDTs) that are equivalent to the tests performed at the National Microbiology Laboratory (NML), the US Centers for Disease Control and Prevention (CDC), and other Canadian provincial public health laboratories.

The Cepheid GeneXpert™ is a point of care laboratory-based instrument that also uses PCR to directly detect the virus in a patient specimen. The GeneXpert COVID-19 test is Health Canada approved, and has been validated by the NML and Canadian provincial public health laboratories. Saskatchewan has GeneXpert instruments either currently or soon to be in use in 19 different communities across the province[1], and will be using them for COVID-19 diagnostic testing as their kits become available.

Q2. What is the sensitivity/specificity of the test?

There are 2 different kinds of sensitivity/specificity: analytic and clinical. Analytic sensitivity/specificity indicates how well a test can detect the virus when it is present and distinguish between SARS-CoV-2 and other viruses. The analytic performance of both the LDT and commercial testing used in Saskatchewan (including the GeneXpert PCR) is excellent, with 100% accuracy compared to reference tests.

However, what is more relevant is clinical sensitivity/specificity. This indicates the real-world application of a test and how well it can predict the true state of infection in an individual patient. It depends not only on the analytic performance of the test, but also must consider whether a person is shedding virus at the time and site of specimen collection, and how well the specimen is collected. Accurate estimates of clinical test performance require clinical studies which investigate and follow patients to determine their true infection status. These studies are still taking place, but preliminary results show that the clinical specificity of PCR is excellent; however, the clinical sensitivity is lower than analytic performance and dependent on several patient factors.

Specifically related to the onset of symptoms, the false negative rate (i.e. the probability of getting a negative result in a person truly infected with SARS-CoV-2) of PCR has been estimated[2]:

- On the day before symptom onset 61% (95% CI 18-98%)
- On the day of symptom onset 39% (95% CI 16-77%)
- On day 3 after symptom onset 26% (95% CI 18-34%)

This emphasizes that in a symptomatic individual highly suspected of COVID-19, a single negative test result should not be used to rule out the diagnosis. In asymptomatic individuals, a negative test result has little to no predictive value of true infection state.

Q3. What is the best specimen to submit?

[1] Saskatchewan locations either currently equipped or soon to be equipped with GeneXperts: All Nations Health Hospital, Ile a la Crosse, Kindersley, La Loche, La Ronge, Lloydminster, Meadow Lake, Moose Jaw, Moosimin, North Battleford, Onion Lake, Pelican Narrows, Prince Albert, Regina, Saskatoon, Swift Current, Tisdale, Weyburn, Yorkton

[2] Kucirka et al. pre-publication https://doi.org/10.1101/2020.04.07.20051474

Specimens that are useful to submit for COVID-19 testing include: nasopharyngeal (NP) swabs or aspirates, oropharyngeal (OP) +/- nares swabs, sputum, endotracheal tube aspirates, bronchial wash and bronchoalveolar lavage specimens.

In patients with upper respiratory tract infections, an NP or OP swab is recommended. A swab of the nares alone should not be used as there is evidence this has decreased clinical sensitivity. Initial reports suggested NP swabs were preferable to OP swabs, however, more recent experience is that these are largely equivalent.

In patients with lower respiratory tract infections, specimens from the lower respiratory tract (e.g. sputum, ETT, etc.) are recommended in addition to an upper respiratory tract specimen.

Q4. Are we looking at using serology?

Yes, we are investigating several potential uses of serology for COVID-19. However, none of the tests currently available has been shown to be sufficiently accurate for these uses yet and should only be used in research settings. Situations where serology may be of benefit include:

- Evidence of prior infection: after we are infected with a virus, we typically develop antibodies to that virus which can be measured in our blood.
    - By surveying the population for these antibodies, we can estimate how many people have been exposed to the virus whether or not they were diagnosed with the infection at the time.
    - This can also be used for public health investigations when a clear source of transmission is not identified for an index case (i.e. to uncover previously unidentified infections).
- Evidence of immunity: sometimes the antibodies we develop after an infection help protect us from getting that infection again (i.e. we are immune). If it is found that SARS-CoV-2 infection results in protective immunity, these tests may be able to predict whether a person remains susceptible to reinfection.

Q5. I hear we are getting Spartan tests. What will they be used for?

The Spartan Bioscience Cube™ is a point of care instrument that also uses PCR to directly detect the virus in a patient specimen. The Spartan COVID-19 test is Health Canada approved, but has not yet been validated by Canadian laboratories. Saskatchewan has committed to purchase 50 of these devices to improve access to testing in the province, but it has not yet been confirmed when they will become available. The specific ways they will be distributed and used will depend upon the results of more comprehensive evaluations of their performance, which are currently ongoing.

Q6. I was diagnosed with COVID-19 but have now recovered. Can I get tested to prove I am clear to go back to work?

Repeat PCR testing after a positive result is not recommended, and cannot be used to indicate clearance of the virus. In these situations neither a positive result nor a negative result can be interpreted.

A positive PCR result does not mean a person remains infectious. It has been found that individuals recovering from SARS-CoV-2 infection can shed remnants of the virus for extended periods of time. These remnants are not infectious, but the PCR test cannot tell that. Current evidence indicates that in people who experienced a mild course of illness, they are no longer infectious by approximately day 8 after symptom onset[3]. It is recommended that people remain isolated for 14 days after they develop symptoms, and continue to isolate beyond that if their symptoms persist.[4]

A negative PCR result does not rule out infectivity, as described above in answer to Q2.

Q7. What is the role of testing asymptomatic people?

There are situations where testing asymptomatic people are being considered:

- Enhanced Case Finding: testing asymptomatic contacts of cases, asymptomatic individuals linked to outbreaks, or other asymptomatic individuals with significant risk factors for being infected
- Surveillance: testing randomly in the population (or in specific groups of the population) to estimate the prevalence of asymptomatic cases

Strategies to deploy testing of asymptomatic people for these purposes are being considered, and may be implemented in the future.

Testing an asymptomatic person cannot be used to 'clear' an asymptomatic person for work or other activities. A negative result, especially before the onset of symptoms, cannot be used to rule out infection (see answer to Q2).

Q8. What is the turnaround time of results?

Once a specimen is taken and submitted to a local laboratory, it generally needs to be sent either to Regina or Saskatoon for testing. The time it takes to travel from the point of collection to the laboratories in Regina or Saskatoon varies depending on where in the province you are. Once it arrives at the laboratories in either Regina or Saskatoon, results are available within 24 hours. Results are immediately accessible on the eHealth Viewer and on MySaskHealthRecord.

Q9. What does 'point of care' mean?

The GeneXpert is being used as a 'lab-based point of care' test. This means it is used within an existing community laboratory, but does not require infrastructure for molecular laboratory testing and its results are available in <1 hour. Depending on the community, their instruments will be able to run between 2 and 16 tests at a time.

The Spartan Cube also does not require molecular laboratory infrastructure and its results are available <1 hour. We do not yet know how the Spartan devices will best be used. They may be appropriate for use outside of community labs, for deployment at testing sites or clinics.

[3] Wolfel, et al. *Nature* (2020). https://doi.org/10.1038/s41586-020-2196-x
[4] Refer to Saskatchewan Communicable Disease Manual:
https://www.ehealthsask.ca/services/Manuals/Documents/cdc-section2.pdf#page=12