

## LABORATORY TESTING FOR COVID19: CURRENT STATUS

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- At PRHC (through Kingston Health Sciences Center's lab and Peterborough Public Health lab), the assays used have 99% analytical sensitivity when there is virus in the sample.

- False negatives are difficult to quantify and usually due to sample failure, not test failure (there is no virus or not enough virus in the sample to be detected).

- Reasons for false negatives include: incorrect nasopharyngeal (NP) swabbing, low viral shedding in NP, not enough media, swab defects, transportation defects, or other. **MANY FACTORS CAN CONTRIBUTE TO A FALSE NEGATIVE, BUT IN GENERAL THESE ARE NOT TEST FACTORS. THE TESTS ARE EXCELLENT.**

- **A FALSE POSITIVE IS VERY UNLIKELY.**

**Only nucleic acid based tests which detect viral RNA are approved for primary diagnosis of COVID19.**

- **The newer antibody detection tests are currently NOT for primary diagnosis.**

They can tell us who may or may not have past exposure to SARS-CoV-2, identify who may have neutralizing antibodies for experimental convalescent serum therapy, and facilitate epidemiologic and public health studies.

- For these reasons you should never rely just on the test for determining the likelihood a patient has COVID19 and clinical suspicion is critical for appropriate decision making.

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The recent announcement of a rapid, mobile test for diagnosing COVID19 by **Spartan Bioscience** is exciting but it is really the tiny, quick DNA testing device

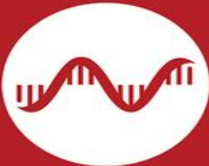

that is the real development. Like the current approved methods, it is a nucleic acid based test.

The emerging **serologic tests (IgM/IgG antibody tests)** will be helpful in understanding the antibody response to SARS-CoV-2/COVID19 but currently are **NOT recommended for primary diagnosis** as more information is needed on how to interpret the results. It is uncertain at this point exactly how the antibody response to COVID19 works, or whether it means you are immune (protected by those newly made antibodies) or for how long. An antibody test must be specific for COVID19 and not cross react with other viruses, (including other corona viruses). If the test is specific for SARS-CoV-2, we only know that finding the antibodies in a patient's serum means that they have likely been exposed to the SARS-CoV-2/COVID19.

#### References:

1. <https://doi.org/10.1128/mBio.00722-20>. Patel R et al. Report from the American Society for Microbiology COVID-19 International Summit, 23 March 2020: Value of diagnostic testing for SARS-CoV-2/COVID19
2. <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html#wb-auto-5>
3. <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>
4. <https://images.app.goo.gl/cY3ZVdTFgGTVVvg69>

# Tests for SARS-CoV-2/COVID-19 and Potential Uses

Type of Test	Measure	Value	Beneficiary
 <b>Nucleic acid amplification test for viral RNA</b> <i>(nasopharyngeal swab, oropharyngeal swab, sputum, bronchoalveolar lavage fluid, others)</i>	Current infection with SARS-CoV-2	<ul style="list-style-type: none"><li>• Inform individual of infection status so they can anticipate course of illness and take action to prevent transmission</li><li>• Inform patient management and actions needed to prevent transmission</li><li>• Inform actions needed to prevent transmission</li></ul>	<ul style="list-style-type: none"><li>• Individual</li><li>• Healthcare or long-term care facility</li><li>• Public health</li></ul>
 <b>Antibody detection</b>	Past exposure to SARS-CoV-2	<ul style="list-style-type: none"><li>• Detect susceptible individuals (antibody negative) and those previously infected</li><li>• Identify individuals with neutralizing antibodies</li><li>• Facilitate contact tracing and surveillance</li></ul>	<ul style="list-style-type: none"><li>• Identify those potentially immune to SARS-CoV-2 (if tests can detect protective immunity, individuals could be returned to work)</li><li>• Healthcare facilities: Experimental therapy</li><li>• Public health</li></ul>

Ref 4: Schematic of how RT-PCR generally works to detect SARS-CoV-2. Targets for identifying SARS-CoV-2 are recommended by the WHO, and the assay generally includes an internal control to ensure viral material is present. Other nuclei acid based testing methods exist that involve similar principles for detection but different methods. It is always important to ask about the performance characteristics of your lab's diagnostic testing.

