Reference Document – Testing 101

Infographic section	Content	Reference
Sample collection	A swab is taken from the inside of the nose or back of the throat	World Health Organization. Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases. March 19, 2020. <u>https://www.who.int/publications/i/item/10665-331501</u>
Processing	Molecular tests detect whether there is genetic material from the virus	World Health Organization. Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases. March 19, 2020. https://www.who.int/publications/i/item/10665-331501
True positive	You are currently infected	BC Centre for Disease Control. Interpreting the results of Nucleic Acid Amplification testing (NAT; or PCR tests) for COVID-19 in the Respiratory Tract. April 30, 2020. <u>http://www.bccdc.ca/Health- Professionals-</u> <u>Site/Documents/COVID19_InterpretingTesting_Results_NAT_PCR.</u> <u>pdf</u>
	Almost all positive results are true positives	Public Health Ontario. COVID-19 Laboratory Testing Q&As. https://www.publichealthontario.ca/-/media/documents/lab/covid-19- lab-testing-faq.pdf?la=en
False positive	You are not infected but test positive (very rare)	Centers for Disease Control and Prevention Fact Sheet for Patients— CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. June 12, 2020. https://www.cdc.gov/coronavirus/2019-ncov/downloads/Factsheet-for- Patients-2019-nCoV.pdf Public Health Ontario. COVID-19 Laboratory Testing Q&As. https://www.publichealthontario.ca/-/media/documents/lab/covid-19- lab-testing-faq.pdf?la=en
True negative	You are not currently infected. There is no risk of infecting others.	Centers for Disease Control and Prevention Fact Sheet for Patients— CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. June 12, 2020. https://www.cdc.gov/coronavirus/2019-ncov/downloads/Factsheet-for- Patients-2019-nCoV.pdf
False negative	You are infected, but test negative. Can happen when the test is done too early to detect the disease or when sample collection is poor.	Centers for Disease Control and Prevention Fact Sheet for Patients— CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. June 12, 2020. https://www.cdc.gov/coronavirus/2019-ncov/downloads/Factsheet-for- Patients-2019-nCoV.pdf Woloshin et al. False Negative Tests for SARS-CoV-2 Infection— Challenges and Implications. NEJM. August 6, 2020. https://www.nejm.org/doi/pdf/10.1056/NEJMp2015897?articleTools=tr ue

		BC Centre for Disease Control. Interpreting the results of Nucleic Acid Amplification testing (NAT; or PCR tests) for COVID-19 in the Respiratory Tract. April 30, 2020. <u>http://www.bccdc.ca/Health- Professionals-</u> <u>Site/Documents/COVID19_InterpretingTesting_Results_NAT_PCR.</u> <u>pdf</u>
Positive test result	Individual isolates	Government of Canada. Updated: Public health management of cases and contacts associated with COVID-19. April 10, 2020. https://www.canada.ca/en/public-health/services/diseases/2019- novel-coronavirus-infection/health-professionals/interim-guidance- cases-contacts.html
False negative test result	Unaware of their infection and could infect others	Centers for Disease Control and Prevention Fact Sheet for Patients— CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. June 12, 2020. https://www.cdc.gov/coronavirus/2019-ncov/downloads/Factsheet-for- Patients-2019-nCoV.pdf
Test accuracy	Worst: Days 0-2 Best: Days 4-8	He <i>et al.</i> Temporal dynamics in viral shedding and transmissibility of COVID-19. Nature Medicine, Volume 26, pages 672–675 (2020). <u>https://www.nature.com/articles/s41591-020-0869-5</u> ,
	Based on a 5- day incubation period from exposure to symptoms	Lauer <i>et al.</i> The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. May 5, 2020. <u>https://www.acpjournals.org/doi/10.7326/M20-0504</u>
Initial exposure	Days 0-2 Very low virus	He <i>et al.</i> Temporal dynamics in viral shedding and transmissibility of COVID-19. Nature Medicine, Volume 26, pages 672–675 (2020). <u>https://www.nature.com/articles/s41591-020-0869-5</u>
	~98% not detected	Lauer <i>et al.</i> The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. May 5, 2020. https://www.acpjournals.org/doi/10.7326/M20-0504
		It is estimated that fewer than 2.5% of infected persons will show symptoms within 2.2 days of exposure. The test's sensitivity is estimated to be 80% among symptomatic individuals (80% of the 2.5% of subjects testing positive at 2.2 days are actually positive = 2% are true positives = approximately 98% failure rate).
		Centers for Disease Control and Prevention Fact Sheet for Patients— CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. June 12, 2020.

	unaware of infection and may infect others.	https://www.cdc.gov/coronavirus/2019-ncov/downloads/Factsheet-for- Patients-2019-nCoV.pdfWoloshin et al. False Negative Tests for SARS-CoV-2 Infection— Challenges and Implications. NEJM. August 6, 2020. https://www.nejm.org/doi/pdf/10.1056/NEJMp2015897?articleTools=tr ueBC Centre for Disease Control. Interpreting the results of Nucleic Acid Amplification testing (NAT; or PCR tests) for COVID-19 in the Respiratory Tract. April 30, 2020.
Incubating	Days 0-5 Virus multiplying	Lauer <i>et al.</i> The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. May 5, 2020. https://www.acpjournals.org/doi/10.7326/M20-0504
	~50% not detected	 *Expert opinion Assuming an incubation period distribution of mean 5.2 days from a separate study of early COVID-19 cases, we inferred that infectiousness started from 2.3 days (95% CI: 0.8 to 3.0 days) before symptom onset and peaked at 0.7 days (95% CI: -0.2 to 2.0 days) before the onset of symptoms (Fig 1c). The estimated proportion of presymptomatic transmission (area under the curve) was 44% (95% CI: 25 to 69%). He <i>et al.</i> Temporal dynamics in viral shedding and transmissibility of COVID-19. Nature Medicine, Volume 26, pages 672–675 (2020). https://www.nature.com/articles/s41591-020-0869-5
Symptoms	Day 5+ Virus plentiful ~10 % not detected	Lauer <i>et al.</i> The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. May 5, 2020. <u>https://www.acpjournals.org/doi/10.7326/M20-0504</u> Based on a sensitivity of 70 to 90 % among symptomatic individuals. Infectious Diseases Society of America. Guidelines on the Diagnosis
		of COVID-19. May 6, 2020. <u>https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics/</u> "Several studies with small sample sizes have been published, and have estimated that the first test done has a sensitivity of 70% to 90% for detecting SARS-CoV-2." Public Health Ontario. COVID-19 Laboratory Testing Q&As. <u>https://www.publichealthontario.ca/-/media/documents/lab/covid-19-lab-testing-faq.pdf?la=en</u> "A statistic commonly quoted is that there is a 30% chance of a false negative result for a NAT test in a patient with

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		COVID-19 infection (i.e. a 70% sensitivity)."
		BC Centre for Disease Control. Interpreting the results of Nucleic Acid Amplification testing (NAT; or PCR tests) for COVID-19 in the Respiratory Tract. April 30, 2020. <u>http://www.bccdc.ca/Health- Professionals-</u> <u>Site/Documents/COVID19_InterpretingTesting_Results_NAT_PCR.</u> <u>pdf</u>
Footnote	*Based on preliminary data and expert opinion. Some do not develop symptoms, test accuracy for asymptomatic cases is unclear as it is not known where they are in their disease progression.	 "SARS-CoV-2 has been detected in cases with a range of disease severity, including prior to symptom onset and in asymptomatic cases. At present, there is only a single study regarding the viability of the virus in presymptomatic and asymptomatic cases." Public Health Ontario. COVID-19 – What We Know So Far AboutViral Detection. May 7, 2020. https://www.publichealthontario.ca/-/media/documents/ncov/covid-wwksf/2020/05/what-we-know-viral-detection.pdf?la=en "It is presumed that the large majority of patients included in this analysis were symptomatic. The sensitivity in patients with milder forms of illness, including asymptomatic patients, is likely very different, and has not been well elucidated. Available data suggests that patients with more severe illness have higher viral loads than those with milder illness. When testing asymptomatic patients, a negative test does not rule out infection, as it could be early in the incubation period before the virus is actively replicating at a level that can be detected by PCR assays. At this time, there is not enough data to know the sensitivity, specificity, and predictive values of testing in asymptomatic persons. This would also require a large cohort of patients tested in a controlled fashion, with clinical follow up and repeat retesting at intervals." Public Health Ontario. COVID-19 Laboratory Testing Q&As. https://www.publichealthontario.ca/-/media/documents/lab/covid-19-lab-testing-faq.pdf?la=en
Recovering	Day 15+ Virus decreasing	Lauer <i>et al.</i> The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. May 5, 2020. https://www.acpjournals.org/doi/10.7326/M20-0504

	May not be infectious to others. May take longer to recover from severe disease.	Government of Canada. Coronavirus disease (COVID-19): Summary of assumptions. April 13, 2020. <u>https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/health-professionals/assumptions.html</u> Government of Canada. Coronavirus disease (COVID-19): Summary of assumptions. April 13, 2020. <u>https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/health-professionals/assumptions.html</u>
Serological (blood) test	Blood tests detect antibodies to the virus that usually start to appear when a person is recovering.	
	The blood test is not used to diagnosed active COVID-19	World Health Organization. Advice on the use of point-of-care immunodiagnostic tests for COVID-19. Scientific Brief. April 8, 2020. <u>https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19</u> Alberta Health Services. COVID-19 Scientific Advisory Group Rapid Evidence Report—Topic: Can people with previous COVID-19 infection become re-infected by the SARS-CoV-2virus? [updated May 12, 2020]. <u>https://www.albertahealthservices.ca/assets/info/ppih/if- ppih-covid-19-reinfection-rapid-review.pdf</u>
	Research is underway to find out whether antibodies protect you from future infections.	World Health Organization. "Immunity passports" in the context of COVID-19—Scientific Brief. April 24, 2020. <u>https://www.who.int/news-room/commentaries/detail/immunity- passports-in-the-context-of-covid-19</u> Government of Canada. Testing devices for COVID-19: Overview. <u>https://www.canada.ca/en/health-canada/services/drugs-health- products/covid19-industry/medical-devices/testing.html</u>
		CADTH. Serological Tests for COVID-19. May 28, 2020. <u>https://cadth.ca/sites/default/files/covid-19/eh0085-serology-for-covid-</u> <u>tests-final.pdf</u> Canada Communicable Disease Report. Canadian Public Health Laboratory Network Best Practices for COVID-19. Volume 46-5, May 7, 2020: Nosocomial infection surveillance. <u>https://www.canada.ca/en/public-health/services/reports-</u> <u>publications/canada-communicable-disease-report-ccdr/monthly-</u> <u>issue/2020-46/issue-5-may-7-2020/covid-19-health-professional-</u> <u>cphln.html</u>