

COVID-19 Scientific Advisory Group

Rapid Evidence Report

Topic: Self-collection of samples for SARS-CoV-2 RT-PCR testing

1. What are the different methods, completion rates, and costs for self-collected samples for SARS-CoV-2 RT-PCR?
2. What are the testing characteristics of self-collected samples for SARS-CoV-2 RT-PCR?

Context

- Self-collected samples for SARS-CoV-2 RT-PCR has been identified as a potential strategy to reduce the burden of sample collection on the health care system, saving resources (staff time at assessment centres or pharmacies, personal protective equipment) and reducing potential exposures to health care workers (HCWs)
- Self-collected samples have been identified as a potential option for asymptomatic patients who have not had a close contact, for whom testing is not time-sensitive
- Novel approaches for self-collection samples for SARS-CoV-2 RT-PCR have been proposed based upon research in other infectious diseases (such as influenza and chlamydia/gonorrhoea).
- From the Interim Order (IO) (dated March 18, 2020) from the Minister of Health, Government of Canada “At this time, Health Canada does not consider that the benefits of using home test (self-testing) kits outweigh the risks. In accordance with section 5 of the IO, applications for authorization for these types of medical devices will be rejected without compelling new evidence to the contrary.” Therefore, home self-testing kits are excluded from this rapid review.
- This review may be used to inform a potential pilot self-collection strategy for asymptomatic patients across Alberta

Key Messages from the Evidence Summary

- Several methods for self-collection of samples for SARS-CoV-2 RT-PCR have been recently presented in the literature including: nasal swab, oropharyngeal swab, tongue/buccal swab, saliva sampling, and throat washings for RT-PCR as well as dried blood spots for serologic testing, which will not be included in this review.
- In the largest study comparing self-swabbing (n=530) the sensitivity for detecting SARS-CoV-2 in patient-collected tongue, nasal, and mid-turbinate samples was 89.8% (95% CI: 80.2 -100.0), 94.0 (95% CI: 84.6-100.0) and 96.2 (95% CI: 87.7-100.0), respectively, suggesting that nasal and mid-turbinate samples may be the most promising to evaluate. However, optimal self collection instruction and operationalization of lab processes remain crucial but are not fully addressed in this literature.
- There is little evidence related to completion rates and costing data, however extant information suggests favorable completion of self collection without undue cost with possible reduction of resource use, and reduction in potential exposure of health care workers (HCWs) during COVID-19 sample collection.
- Extrapolating from influenza like illness (ILI) data, self-collection of samples is potentially feasible, effective and timely. In a meta-analysis of ILI self-collection methods compared to professional collection methods pooled sensitivity was 87% (95% CI: 80%, 92%) and specificity 99% (95% CI: 98%, 100%). Further research is required to establish the most appropriate approach to self-collection of samples for SARS-CoV-2 RT-PCR, however the initial data is promising.

Recommendations

1. A pilot of self-collection of samples for SARS-CoV-2 RT-PCR to assess test performance, process feasibility, and return rates is reasonable and would be required to assess appropriateness of self-collection to expand COVID-19 diagnostic testing access in Alberta.

Rationale: Optimal processes in care contexts in Alberta need to be developed to evaluate potential program performance. Priority uses of a self collection program may include expanding access geographically, to individuals that are not able to readily access current testing centres, and reducing turnaround time of testing for HCW or others who need timely sample collection to support Public Health/Workplace Health and Safety based decision making processes in specified workplaces.

2. Pilot design should be informed by evolving evidence and may include sample site comparisons: while there is emerging interest in the use of saliva samples and throat washings as methods amenable to self-collection, nasal, mid turbinate, or oropharyngeal swab self-collection is most consistent with current standard of practice. However, it is important to note that the use of self-collection methods may result in a decrease in test sensitivity. Evaluation of the sensitivity parameters required to support the testing rationale in the population under assessment requires careful consideration.

Rationale: Many of the available studies report <90% agreement and are underpowered to fully address the sensitivity of testing comparisons. Testing programmes may have different rationales which could include a role of lesser sensitivity testing in populations in a designed approach.

Practical Considerations

While data is limited on completion rates, some research suggest self-collection is a viable option for collecting samples for SARS-CoV-2 RT-PCR, particularly in the event of the existing model of limitations of testing related to test collection and transportation. Additionally, it is suggested that self-collection may use less resources, reduce the potential exposure of HCWs and is considered favorably by patients. However, detailed assessment of whether there is a decrease in sensitivity related to insufficient sampling, and analysis of resources that would be required to support community based self-testing protocols would be required to assess sustainability of such a program.

Strength of Evidence

Information was identified through a rapid review. A total of 12 observational or cross sectional cohort studies specific to SARS-CoV-2 RT-PCR were included. Given the rapid development of SARS-CoV-2 literature, many of the studies included are currently in pre-print status. Additionally, the study sample sizes are generally small, and suggest additional research is required to further substantiate the data. Three review articles were included, only one of which a meta-analysis of influenza data-the remaining two reviews were a summary of the literature. Lastly, three grey literature documents (government sources) were incorporated. It should be noted that different collection methods, swabs and media are used in various reports which affects comparability of studies.

Limitations of this review

Due to the nature of a rapid review the following limitations apply:

- Rapid turnaround time resulted in a limited time to conduct a thorough search of the research and grey literature.
- Given the limited research on this topic and rapidly developing body of evidence, several of the included research studies are pre-prints (not yet peer reviewed) and studies presented include small sample sizes.

Summary of Evidence

Evidence from secondary and grey literature

The Centers for Disease Control (CDC) (2020) recommend an upper airway specimen to test for SARS-CoV-2, including the following self-collection method in the home without supervision:

- A nasal mid-turbinate swab collected by a healthcare provider or by a supervised onsite self-collection (using a flocked tapered swab).¹

¹ A flocked swab has fibers with an adhesive-coated surface that aims to more effectively capture samples

The BC Centre for Disease Control and the BC Public Health Laboratory created interim guidance for diagnosis of acute COVID-19 infection in settings where health services for obtaining provider-collected NP swabs are not accessible in June, 2020 (British Columbia Government, 2020). They suggest mouth rinse samples, throat swab, and nasal swabs as possible approaches in settings where health services for obtaining provider-collected NP swabs are not accessible.

Evidence from the primary literature

Evidence from Influenza Like Illness (ILI) Research

Given the limited research specific to SARS-CoV-2 RT-PCR, self-collection of samples in influenza literature was explored. Seaman and colleagues (2019) completed a meta-analysis comparing diagnostic accuracy of self-collected to professional-collected nasal swabs with inclusions of 9 studies. Comfort and acceptability was assessed in 6 studies, (three assessed flocked mid turbinate swabs, 2 used foam nasal swabs and one did not specify). In all studies symptomatic individuals were tested for influenza. All of the included studies advocated for the use of self-collection swabs, citing reasons such as patient comfort, acceptability (simple and comfortable to complete). Children indicated they preferred to have their parents complete the swab, rather than a HCW. Pooled sensitivity was 87% (95% CI: 80%, 92%) and specificity 99% (95% CI: 98%, 100%) compared to professional collected swabs. Viral loads from self-collected versus professional collected swabs were compared in 6 studies, with no difference in 4, a slightly higher viral load in professional collected swab in one study, and a 10 fold higher viral load in self-collected swabs in one study of foam nasal swabs in children with CF for viral diagnostics, predominantly involving rhinovirus and with home swabs done 2.3 days earlier in illness.

Completion rates for self-administered (submitted via postal service) for ILI conducted in the UK to assess feasibility found that 51 of 66 (77%) completed the self-swab kit (Wenham, et al, 2018). In Ontario, a one-year pilot study of a self-swabbing surveillance system was created to capture data from influenza - approximately 90 % of the specimens received at the laboratory with a swab collection date reported were received within 8.0 days, and 25 % were received within 3.0 or less days (McGolrick et al, 2020). The mailed package included: a flocked swab, labels, packaging materials, an information letter, instructions, a questionnaire, postage paid packaging (for return) and a consent form. An overall response rate was not presented. During the H1N1 pandemic a UK based study assessed 6,043 self-administered nasal swabs sent to individuals by mail and 1,146 clinician administered swabs - there was no evidence of a difference in Ct values between clinician-based sampling and community self-sampling ($p = 0.93$) (Elliot, et al, 2015). Included in the mailed package to the patient was: a letter, a patient information book, an instructional sheet, a dry swab, a vial of virus transport medium (VTM), a demographic/symptom questionnaire, and a postage paid envelope for return of the swab. ILI research suggest that self-collection of samples may be a viable option for the effective and timely diagnosis during the current COVID-19 pandemic, however also acknowledge that it requires infrastructure to support implementation. It is unclear if these jurisdictions have continued to implement self-swab and mail-based testing.

Evidence from SARS-CoV-2 Research

Mawaddah and colleagues (2020) conducted a literature review (no pooled results) of the present evidence on upper respiratory tract sampling in COVID-19. A total of 12 papers were included, and the authors noted that the research had not all completed the peer review process to date. The viral load of SARS-CoV-2 RNA in the upper respiratory tract was significantly higher during the first week and peaked at 4-6 days after onset of symptoms. Nasal cavity swab specimens have demonstrated higher viral load than oropharyngeal swabs, best seen at 0-9 days after the onset of illness, with higher sensitivity (73.3% versus 60% and 63% versus 32% respectively in two studies), although another study showed no difference in (paired NP and OP swabs (Wolfel)). Patient self-collected throat washing have been shown to contain higher viral load than nasopharyngeal or oropharyngeal swab of 11 subjects, with significantly higher sensitivity in late testing (48-57 days post onset) when compared with paired nasopharyngeal swab-however this was based on a single small sample study (Guo, 2020). A total of 24 paired nasopharyngeal and throat washing samples were compared-17 pairs were negative for SARS-CoV-2 for both tests, one pair was positive for both, and 6 were positive for throat washing only.

Research Question 1: What are the different methods, completion rates, and costs for self-collected samples for SARS-CoV-2 RT-PCR?

Methods

1. Oral/Nasal/Tongue swab

Kojima (2020) described the method of self-administered nasal swab (with supervision) as the patient inserts the swab into one nostril (to the depth of 3-4 cm), rotate the swab for 10 seconds, and then return the swab to the collection tube. Invert the tube 3-5 times, and return the tube to the collection bag.

Tu et al (2020) provided the following guidance for nasal samples with foam swab:

- 1) gently inserting the swab into nasal passage until there is gentle resistance,
- 2) leave the swab in place for 10-15 seconds, rotating the swab, and
- 3) repeat the procedure on the other side with the same swab.

Tongue samples collected with a nylon flocked swab according to the following

- 1) Extend the tongue, and
- 2) firmly but gently brushing the swab along the length of the anterior 2/3 of the tongue for 10 seconds (Tu et al, 2020).

2. Saliva

In a review article, Harikrishnan and colleagues (2020) identified three approaches to saliva collection for testing of SARS-CoV-2 including coughing, saliva swabs and directly from salivary gland duct. To (2020) indicated that saliva samples were more acceptable to patients and HCWs. Saliva samples require little instruction, are easy to self-collect and are postulated to reduce HCW risk (by limiting exposure) (Harikrishnan, 2020). Kojima (2020) described the method of collection as coughing deeply 3-5 times collecting any phlegm or secretions in the mouth, rub the swab on cheeks, above and below the tongue, gums, and on the palate for 20 seconds. Then place the swab into the tube, secure the lid, invert the tube 3-5 times, and place the tube into a bag provided. Alternatively Ngura-Ikeda suggested self-collection can be conducted by simply spitting into the tube, with no restrictions on timing or food intake. Saliva studies may inadvertently include sputum samples if collection technique is sub-optimal, however it is unclear if this would have a negative impact on the test results.

3. Throat wash-requires patients to oscillate over the posterior pharyngeal wall with sterile normal saline for up to 10 seconds, then to spit the saline in a sterile container (Guo, 2020). The procedure is non-invasive and does not require the assistance of a HCW.

Completion Rates

Guest and colleagues (2020) evaluated a telehealth approach to self-collection for oropharyngeal swabs, saliva samples and dried blood samples, having patients complete tests via video with a HCW to determine rate of kit return and sufficiency for testing for SARS-CoV-2 in the United States. A total of 153/159 (96.2%) testing kits were returned. Observers assessed that of the samples collected, 147/153 (96.1%) of the saliva samples, 146/151 (96.7%) of the oropharyngeal samples, and 135/145 (93.1%) of the dried blood samples were of sufficient quality for submission for laboratory testing; 100% of the oropharyngeal samples and 98% of the saliva samples had cycle threshold values for RNase P <30, as a putative markers of sample adequacy (ie contained sufficient nucleic acid for RNA-PCR testing for SARS-CoV-2). However, human genes may not be an adequate maker of effectiveness of sample collection.

Note: while cost/benefit evidence was not identified in this rapid review, it was suggested that self-collection may be resource saving as it would require fewer staff, and may potentially conserve PPE (Harikrishnan, 2020; Miller, 2020; Nundy & Patel, 2020; Pasomsub et al, 2020)-although unclear if it would require additional laboratory support to troubleshoot collection errors. At home kits are estimated to be less than \$15 USD/sample (Won, 2020), although this may vary widely by jurisdiction. However, resources to manage the shipping and handling of specimens would have to be considered in feasibility of broad adoption.

Research Question 2: What are the testing characteristics of self-collected samples for SARS-CoV-2 RT-PCR?

Please see Table 1 for a review of the testing characteristics of the 12 described studies.

1. Nasal swab self-collection

Altamirano and team (2020) compared the diagnostic equivalence of self-collection swab of lower nasal to HCW collected oropharyngeal swabs (clinical standard) and the HCW lower nasal swab during a single visit. A total of 30 individuals participated in the study with equivalence across the three collection methods (sensitivity of the patient collected specimens was 100% (95%CI, 72%-100%), and the specificity was 95% (95%CI, 74%-100%)). Clinician-supervised self-collected nasal swab specimens detected 23 (85%) of 27 infected individuals, clinician-collected posterior nasopharyngeal swab specimens detected 23 (79%) of 29 infected individuals in the Kojima and colleagues (2020) study. All samples were collected in the patient's home within a 30 minute time period.

Waghmare et al (2020) assessed the self-administration of foam and flocked nasal swabs (no comparison to HCW collection) in 15 subjects. Foam and flocked swabs were concordant for viral detection in 22/30 samples (73.3%). Among the 12 samples positive by flocked swab, 3 were negative by foam swab. Among 14 samples positive by foam swab, 5 were negative by flocked swab. In a larger study, Wehrhahn and colleagues (2020) compared self-collected nasal/throat swabs to HCW collected. Of 236 patients sampled, 25 had SARS-CoV-2 (24 by HCW and 25 by self-administered) and 63 had other respiratory viruses (56 by HCW and 58 by self-administered). Self-administered sample results were highly concordant with HCW collected ($\kappa=0.890$) for all viruses including SARS-CoV-2 (Wehrhahn, 2020).

2. Nasal, tongue and mid turbinate

In another study of 530 symptomatic patients, swabs from the nasopharynx and at least one other site were collected in clinic, and patients' self-collected tongue, nasal and mid turbinate swabs. In 504 patients, self-collection specimens were compared to HCW collection of nasopharyngeal swab as a gold standard. The patient was provided instructions on the three self-collection methods and asked to complete all three tests prior to the HCW collection of the nasopharyngeal swab. The sensitivity for detecting SARS-CoV-2 in patient-collected tongue, nasal, and mid-turbinate samples was 89.8% (95% CI: 80.2 -100.0), 94.0 (95% CI: 84.6-100.0) and 96.2 (95% 38 CI: 87.7-100.0), respectively. The HCW collected nasopharyngeal swabs were positive in 50 of 504 individuals. In positive results, cycle threshold (Ct) 39 values (a measure of viral load) had correlation coefficients of 0.48, 0.78, and 0.86 between the 40 nasopharyngeal samples and the tongue, nasal, and mid-turbinate samples (Tu et al, 2020). Flocked MT swabs have been found to be sensitive for the diagnosis of multiple respiratory viruses and offer a simple approach to self-collection of samples (Larios et al, 2011).

Lastly, Luvira (2020) studied 26 samples from three COVID cases with pneumonia in Bangkok, Thailand. Cycle threshold values of RT-PCR for SARS-CoV-2 was followed over time in 3 patients, with 26 clinical specimens collected by HCW from the upper (nasopharyngeal and throat swabs) and self-collected lower (sputum) respiratory tract specimens. Higher concentration of virus was found in sputum from the same day was noted. Viral RNA could be detected for longer time in sputum (during > 2–6 weeks) than swab specimens in two of three. They suggest that higher SARS-CoV-2 RNA concentration and longer time for detection make self-collected (expectorated) sputum an appropriate specimen for the diagnosis of COVID-19 pneumonia.

3. Saliva

Wyllie et al (2020) evaluated SARS-CoV-2 detection in paired nasopharyngeal swabs and saliva samples collected from COVID-19 inpatients and asymptomatic healthcare workers at risk of COVID-19 exposure. They determined from positive samples tested of the inpatient cohort (n = 46 nasopharyngeal, 37 saliva), geometric mean virus titers from saliva were approximately five times higher than nasopharyngeal swabs (p < 0.05). Of 98 asymptomatic HCW with saliva and/or nasopharyngeal swabs on average every 2.9 days (range = 1-8 days), SARS-CoV-2 has been detected in saliva from two

HCWs that were negative by nasopharyngeal swabs. Similarly, Azzi (2020) found saliva to be reliable and consistent with nasopharyngeal swab collection in the diagnosis of SARS-CoV-2. Kojima (2020) found clinician-supervised self-collected oral swab specimens detected 26 (90%) of 29 infected individuals and unmonitored self-collected oral swab specimens detected 19 (66%) of 29 infected individuals. This latter study raises important questions concerning self-collection of oral swab specimens.

Miller and colleagues (2020) studied self-administered saliva testing for detection of SARS-CoV2, compared to clinical standard nasopharyngeal swab testing methods. Three RNA extraction methods were evaluated yielding a sensitivity of 97.1% and 96.5-98.2% specificity compared nasopharyngeal swab in 34 positive patients and 57 negative patients, with saliva picking up 1 -2 positives in NP negative patients depending on extraction technique, and 1 NP positive patient negative on salivary testing. The reduced specificity may have been an artifact of using an imperfect method as the 'gold standard'.

Nagura-Ikeda (2020) evaluated self-collected saliva samples from 103 patients with confirmed COVID-19. Of the 103 samples, viral RNA was detected in 50.5–81.6% of the specimens by molecular diagnostic tests and an antigen was detected in 11.7% of the specimens by the rapid antigen test. Viral RNA was detected at a significantly higher percentage (65.6–93.4%) in specimens collected within 9 d of symptom onset compared to that of specimens collected after at least 10 d of symptom onset (22.2–66.7%) and in comparison to that of asymptomatic patients (40.0–66.7%).

Pasomsub and colleagues (2020) evaluated 200 pairs of samples using nasopharyngeal and throat swab RT-PCR as the reference standard, compared with saliva sample through self-collection. The prevalence of COVID-19 diagnosed by nasopharyngeal and throat swab RT-PCR was 9.5% (n=19). The sensitivity and specificity of the saliva sample RT-PCR were 84.2% (95% CI 60.4%e96.6%), and 98.9% (95% CI 96.1% -99.9%), respectively (saliva tested positive for an additional two cases, and tested negative for three of the confirmed positives). An analysis of the agreement between the two specimens showed 97.5% observed agreement (k coefficient 0.851, 95% CI 0.723e0.979; $p < 0.001$).

4. Throat wash

Only one study reported the use of self-administered throat washing as described above. A series of 24 paired throat washings and NP swab specimens were evaluated, and determined throat washing to be significantly superior to NP swabs for its higher positive detection rate of SARS-CoV-2 nucleic acid. As previously described a total of 24 paired nasopharyngeal and throat washing samples were compared-17 pairs were negative for SARS-CoV-2 for both tests, one pair was positive for both, and 6 were positive for throat washing only. Notably this study was carried out > 40 days from symptom onset and results may not be extrapolatable to early infection (Guo, 2020).

Table 1. Testing Characteristics

Study	Population	N	Method of Self-Collection	Comparator	Results
Altamirano (2020)	outpatients with a reverse transcriptase–polymerase chain reaction test that was positive for SARS-CoV-2 in March 2020	30	Lower nasal	HCW oropharyngeal and HCW lower nasal swab	Equivalence across the three collection methods (sensitivity of the patient collected specimens was 100% (95%CI, 72%-100%), and the specificity was 95% (95%CI, 74%-100%)).
Kojima (2020)	individuals recently tested for SARS-CoV-2 infection through a “drive-through” testing program	45	Oral fluid, supervised mid-turbinate swab	Nasopharyngeal swab	Clinician-supervised self-collected nasal swab specimens detected 23 (85%) of 27 infected individuals, clinician-collected posterior nasopharyngeal swab specimens detected 23 (79%) of 29 infected individuals
Waghmare (2020)	COVID + Individuals within 3 days after symptom onset	15	self-administration of foam and flocked nasal swabs	none	Foam and flocked swabs were concordant for viral detection in 22/30 samples (73.3%). Among the 12 samples positive by flocked swab, 3 were negative by foam swab. Among 14 samples positive by foam swab, 5 were negative by flocked swab
Wehrhahn (2020)	Patients presenting at lab for testing	236	Nasal/throat swabs	HCW collected nasal/throat swabs	25 had SARS-CoV-2 (24 by HCW and 25 by self-administered) and 63 had other respiratory viruses (56 by HCW and 58 by self-administered). Self-administered sample results were highly concordant with HCW collected ($\kappa=0.890$) for all viruses including SARS-CoV-2
Tu (2020)	Symptomatic patients	504	self-collected tongue, nasal and mid turbinate swabs	HCW collection of nasopharyngeal swab	501 patients had a result for both the tongue and NP samples, 498 had a result for the nasal and NP samples, and 504 had results for both the MT and NP samples. The nasopharyngeal swabs were positive in 50 of 504 individuals. The sensitivity for detecting SARS-CoV-2 in patient-collected tongue, nasal, and mid-turbinate samples was 89.8% (95% CI: 80.2 -100.0), 94.0 (95% CI: 84.6-100.0) and 96.2 (95% 38 CI: 87.7-100.0), respectively. In positive results, cycle threshold (Ct) 39 values (a measure of viral load) had correlation coefficients of 0.48, 0.78, and 0.86 between the 40 nasopharyngeal samples and the tongue, nasal, and mid-turbinate samples
Luvira (2020)	SARS CoV-2 positive hospitalized patients	3 (26 samples)	Lower sputum samples	Upper (nasopharyngeal and throat swabs)	Higher concentration of virus was found in sputum from the same day was noted. Viral RNA could be detected for longer time in sputum (during > 2–6 weeks) than swab specimens in two of three.
To (2020)	patients with laboratory-confirmed COVID-19 in two hospitals in Hong Kong	23	saliva		Median viral load in posterior oropharyngeal saliva or other respiratory specimens at presentation was $5.2 \log_{10}$ copies per mL (IQR 4.1–7.0) for 23 subjects. Salivary viral load was highest during the first week after symptom onset and subsequently declined with time (slope -0.15 , 95% CI -0.19 to -0.11 ; $R^2=0.71$)

Study	Population	N	Method of Self-Collection	Comparator	Results
Wyllie (2020)	Inpatients and HCWs	44 inpatients; 121 HCW	Saliva	Nasopharyngeal	From positive samples tested of the inpatient cohort (n = 46 nasopharyngeal, 37 saliva), geometric mean virus titers from saliva were approximately five times higher than nasopharyngeal swabs (p < 0.05). Of 98 asymptomatic HCW with saliva and/or nasopharyngeal swabs on average every 2.9 days (range = 1-8 days)- SARS-CoV-2 has been detected in saliva from two HCWs that were negative by nasopharyngeal swabs
Miller (2020)	34 patients positive for SARS CoV-2 and 57 negative patients	91	Saliva testing	Nasopharyngeal	Three RNA extraction methods were evaluated yielding a sensitivity of 97.1% and 96.5-98.2% specificity compared nasopharyngeal swab in 34 positive patients and 57 negative patients.
Nagura-lkeda (2020)	SARS CoV-2 positive patients	103	Saliva samples		Viral RNA was detected in 50.5–81.6% of the specimens by molecular diagnostic tests and an antigen was detected in 11.7% of the specimens by the rapid antigen test. Viral RNA was detected at a significantly higher percentage (65.6–93.4%) in specimens collected within 9 d of symptom onset compared to that of specimens collected after at least 10 d of symptom onset (22.2–66.7%) and in comparison to that of asymptomatic patients (40.0–66.7%).
Pasomsub (2020)	persons seeking care at an acute respiratory infection clinic	200	Saliva sample	nasopharyngeal and throat swab RT-PCR	The prevalence of COVID-19 diagnosed by nasopharyngeal and throat swab RT-PCR was 9.5% (n=19). The sensitivity and specificity of the saliva sample RT-PCR were 84.2% (95% CI 60.4%e96.6%), and 98.9% (95% CI 96.1% - 99.9%), respectively (saliva tested positive for an additional two cases, and tested negative for three of the confirmed positives). An analysis of the agreement between the two specimens showed 97.5% observed agreement (k coefficient 0.851, 95% CI 0.723e0.979; p < 0.001).
Guo (2020)	SARS CoV-2 positive patients	11	Throat washing	nasopharyngeal	A total of 24 paired nasopharyngeal and throat washing samples were compared-17 pairs were negative for SARS-CoV-2 for both tests, one pair was positive for both, and 6 were positive for throat washing only

Evolving Evidence

As noted, many of the SARS-CoV-2 research regarding self-collection of samples for diagnostic testing is new, requiring further research with larger study samples. The evidence will continue to be assessed as new information is provided.

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(If applicable) Date of re-assessment:

Authorship and Committee Members

This report was written by Heather Sharpe and scientifically reviewed by Nathan Zelyas, Lynora Saxinger (co-chair), and Braden Manns (co-chair).

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Reference List

1. Adeniji, A. A. (2020). **'Self-collected upper respiratory tract swabs for COVID-19 test': A feasible way to increase overall testing rate and conserve resources in South Africa.** *African Journal of Primary Health Care & Family Medicine*, 12(1), 4.
2. Altamirano, J., Govindarajan, P., Blomkalns, A. L., Kushner, L. E., Stevens, B. A., Pinsky, B. A., & Maldonado, Y. (2020). **Assessment of sensitivity and specificity of patient-collected lower nasal specimens for sudden acute respiratory syndrome coronavirus 2 testing.** *JAMA Network Open*, 3(6), e2012005.
3. Centers for Disease Control and Prevention. (2020). **Interim guidelines for collecting, handling, and testing clinical specimens from persons under investigation (PUIs) for coronavirus disease 2019 (COVID-19).** *Covid-19*, Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>
4. Elliot, A. J., Bermingham, A., Charlett, A., Lackenby, A., Ellis, J., Sadler, C., . . . Zambon, M. (2015). **Self-sampling for community respiratory illness: A new tool for national virological surveillance.** *Euro Surveillance: Bulletin Europeen Sur Les Maladies Transmissibles = European Communicable Disease Bulletin*, 20(10), 21058.
5. Guest, J. L., Sullivan, P. S., Valentine-Graves, M., Valencia, R., Adam, E., Luisi, N., . . . Sanchez, T. H. (2020). **Suitability and sufficiency of telehealth clinician-observed, participant-collected samples for SARS-CoV-2 testing: The iCollect cohort pilot study.** *JMIR Public Health and Surveillance*, 6(2), e19731.
6. Guo, W., Jiang, Q., Ye, F., Li, S., Hong, C., Chen, L., & Li, S. (2020). **Effect of throat washings on detection of 2019 novel coronavirus.** *Clinical Infectious Diseases*, doi:10.1093/cid/ciaa416
7. Harikrishnan, P. (2020). **Saliva as a potential diagnostic specimen for COVID-19 testing.** *The Journal of Craniofacial Surgery*, doi:10.1097/SCS.00000000000006724
8. Karp, D. G., Danh, K., Seftel, D., Robinson, P., & Tsai, C. (2020). **A serological assay to detect SARS-CoV-2 antibodies in at-home collected finger-prick dried blood spots.** *MedRxiv : The Preprint Server for Health Sciences*, doi:<https://dx.doi.org/10.1101/2020.05.29.20116004>
9. Kojima, N., Turner, F., Slepnev, V., Bacelar, A., Deming, L., Kodeboyina, S., & Klausner, J. D. (2020). **Self-collected oral fluid and nasal swabs demonstrate comparable sensitivity to clinician collected nasopharyngeal swabs for covid-19 detection.** *medRxiv*, Retrieved from <https://www.medrxiv.org/content/medrxiv/early/2020/04/15/2020.04.11.20062372.full.pdf>
10. Larios OE, Coleman BL, Drews SJ, Mazzulli T, Borgundvaag B, Green K, et al. (2011) Self-Collected Mid-Turbinate Swabs for the Detection of Respiratory Viruses in Adults with Acute Respiratory Illnesses. *PLoS ONE* 6(6): e21335. <https://doi.org/10.1371/journal.pone.0021335>
11. Luvira, V., Jittmittraphap, A., Muangnoicharoen, S., Chantawat, N., Janwitthayanan, W., & Leangwutiwong, P. (2020). **Temporal change of SARS-CoV-2 in clinical specimens of COVID-19 pneumonia patients.** *The American Journal of Tropical Medicine and Hygiene*, doi:10.4269/ajtmh.20-0551
12. McGolrick, D., Belanger, P., Richardson, H., Moore, K., Maier, A., & Majury, A. (2016). **Evaluation of self-swabbing coupled with a telephone health helpline as an adjunct tool for surveillance of influenza viruses in Ontario.** *BMC Public Health*, 16(1), 1-9.
13. Mawaddah, A., Gendeh, H. S., Lum, S. G., & Marina, M. B. (2020). **Upper respiratory tract sampling in COVID-19.** *Malaysian Journal of Pathology*, 42(1), 23-35.

14. Miller, M., Jansen, M., Bisignano, A., Mahoney, S., Wechsberg, C., Albanese, N., . . . Jaremko, M. (2020). **Validation of a self-administrable, saliva-based RT-qPCR test detecting SARS-CoV-2.** *medRxiv*, Retrieved from <https://www.medrxiv.org/content/medrxiv/early/2020/06/09/2020.06.05.20122721.full.pdf>
15. Nagura-Ikeda, M., Imai, K., Tabata, S., Miyoshi, K., Murahara, N., Mizuno, T., . . . Iwata, M. (2020). **Clinical evaluation of self-collected saliva by RT-qPCR, direct RT-qPCR, RT-LAMP, and a rapid antigen test to diagnose COVID-19.** *Journal of Clinical Microbiology*, Retrieved from <https://jcm.asm.org/content/early/2020/07/03/JCM.01438-20.abstract>
16. Nundy, S., & Patel, K. K. (2020). **Self-service diagnosis of COVID-19—Ready for prime time?** *1*(3), e200333.
17. Pasomsub, E., Watcharananan, S. P., Boonyawat, K., Janchompoo, P., Wongtabtim, G., Suksuwan, W., . . . Phuphuakrat, A. (2020). **Saliva sample as a non-invasive specimen for the diagnosis of coronavirus disease 2019: A cross-sectional study.** *Clinical Microbiology and Infection*, doi:10.1016/j.cmi.2020.05.001
18. Seaman, C. P., Tran, L. T. T., Cowling, B. J., & Sullivan, S. G. (2019). **Self-collected compared with professional-collected swabbing in the diagnosis of influenza in symptomatic individuals: A meta-analysis and assessment of validity.** *Journal of Clinical Virology*, *118*, 28-35.
19. To, K. K., Tsang, O. T., Leung, W., Tam, A. R., Wu, T., Lung, D. C., . . . Yuen, K. (2020). **Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: An observational cohort study.** *The Lancet Infectious Diseases*, *20*(5), 565-574. doi:10.1016/S1473-3099(20)30196-1
20. Tu, Y., Jennings, R., Hart, B., Cangelosi, G., Wood, R., Wehber, K., . . . Berke, E. M. (2020a). **Patient-collected tongue, nasal, and mid-turbinate swabs for SARS-CoV-2 yield equivalent sensitivity to health care worker collected nasopharyngeal swabs.** *medRxiv*, Retrieved from <https://www.medrxiv.org/content/medrxiv/early/2020/04/06/2020.04.01.20050005.full.pdf>
21. Tu, Y., Jennings, R., Hart, B., Cangelosi, G. A., Wood, R. C., Wehber, K., . . . Berke, E. M. (2020b). **Swabs collected by patients or health care workers for SARS-CoV-2 testing.** *New England Journal of Medicine*, Retrieved from <https://www.nejm.org/doi/full/10.1056/NEJMc2016321>
22. Waghmare, A., Krantz, E. M., Baral, S., Vasquez, E., Loeffelholz, T., Chung, E. L., . . . Schiffer, J. T. (2020). **Reliability of self-sampling for accurate assessment of respiratory virus viral and immunologic kinetics.** *MedRxiv : The Preprint Server for Health Sciences*, doi:<https://dx.doi.org/10.1101/2020.04.03.20051706>
23. Wehrhahn, M. C., Robson, J., Brown, S., Bursle, E., Byrne, S., New, D., . . . Hadlow, N. (2020). **Self-collection: An appropriate alternative during the SARS-CoV-2 pandemic.** *Journal of Clinical Virology*, 104417. Retrieved from <https://www.sciencedirect.com/science/article/pii/S1386653220301591>
24. Wenham, C., Gray, E. R., Keane, C. E., Donati, M., Paolotti, D., Pebody, R., . . . Edmunds, W. J. (2018). **Self-swabbing for virological confirmation of influenza-like illness among an internet-based cohort in the UK during the 2014-2015 flu season: Pilot study.** *Journal of Medical Internet Research*, *20*(3), e71.
25. Won, J., Lee, S., Park, M., Kim, T. Y., Park, M. G., Choi, B. Y., . . . Lee, C. J. (2020). **Development of a laboratory-safe and low-cost detection protocol for SARS-CoV-2 of the coronavirus disease 2019 (COVID-19).** *Experimental Neurobiology*, *29*(2), 107-119.
26. Wyllie, A. L., Fournier, J., Casanovas-Massana, A., Campbell, M., Tokuyama, M., Vijayakumar, P., . . . Vogels, C. B. (2020). **Saliva is more sensitive for SARS-CoV-2 detection in COVID-19 patients than nasopharyngeal swabs.** *Medrxiv*, Retrieved from <https://www.medrxiv.org/content/10.1101/2020.04.16.20067835v1.full.pdf>

COVID-19 Scientific Advisory Group Rapid Evidence Report

Appendix

List of Abbreviations

AHS: Alberta Health Services

COVID-19: Coronavirus Disease-2019

SAG: Scientific Advisory Group

KRS: Knowledge Resource Services

HCW: Health Care Worker

Search Strategy

The literature search was conducted by Nicole Loroff from Knowledge Resources Services (KRS) within the Knowledge Management Department of Alberta Health Services.

Ovid MEDLINE(R) and In-Process & Other Non-Indexed Citations and Daily 1946 to July 15, 2020

Ovid Healthstar 1966 to May 2020

Search Strategy:

#	Searches	Results
1	exp Coronavirus/ or Coronavirus Infections/ or coronaviru*.mp. or corona viru*.mp. or ncov*.mp. or n-cov*.mp. or novel cov*.mp. or COVID-19.mp. or COVID19.mp. or COVID-2019.mp. or COVID2019.mp. or SARS-CoV-2.mp. or SARSCoV-2.mp. or SARSCoV2.mp. or SARSCoV19.mp. or SARS-Cov-19.mp. or SARSCov-19.mp. or SARSCoV2019.mp. or SARS-Cov-2019.mp. or SARSCov-2019.mp. or severe acute respiratory syndrome coronaviru*.mp. or severe acute respiratory syndrome cov 2.mp. or 2019 ncov.mp. or 2019ncov.mp.	34843
2	(self swab* or self collect* or self service* or self administer* or self test* or self sampl* or patient collect* or patient administer* or at-home test* or home collect* or home test*).mp.	41069
3	1 and 2	69
4	limit 3 to english language	67
5	limit 4 to yr="2020 -Current"	42
6	Respiratory Tract Infections/ or Severe Acute Respiratory Syndrome/ or SARS Virus/ or Middle East Respiratory Syndrome Coronavirus/ or Influenza A Virus, H1N1 Subtype/ or Influenza, Human/	96241
7	(SARS or SARS-CoV or MERS or MERS-CoV or H1N1 or influenza).mp.	127646
8	(respiratory adj1 (infection* or illness* or virus*)).mp.	33068
9	6 or 7 or 8	180094

10	2 and 9	474
11	limit 10 to english language	447
12	limit 11 to "reviews (best balance of sensitivity and specificity)"	11
13	exp Specimen Handling/ or Self-Examination/	349017
14	11 and 13	25
15	Nose/ or Nasal Cavity/ or Saliva/ or Oropharynx/	80028
16	(nose or nasal or nasopharyngeal or oropharyngeal or throat or saliva).mp.	230062
17	15 or 16	272142
18	11 and 17	75
19	exp "Costs and Cost Analysis"/	236829
20	cost*.mp.	692931
21	19 or 20	704260
22	11 and 21	31
23	Patient Compliance/	57588
24	(complet* or adhere* or compliance or comply* or complied or uptake).mp.	2163975
25	23 or 24	2163975
26	11 and 25	179

PubMed

Search Strategy:

#	Searches	Results
1	("COVID-19"[Supplementary Concept] OR "severe acute respiratory syndrome coronavirus 2"[Supplementary Concept] OR COVID-19[tiab] OR COVID19[tiab] OR COVID2019[tiab] OR COVID-2019[tiab] OR SARS-CoV2[tiab] OR SARSCoV2[tiab] OR SARS coronavirus 2[tiab] OR 2019-nCoV[tiab] OR 2019nCoV[tiab] OR nCoV2019[tiab] OR nCoV-2019[tiab] OR ((Wuhan[tiab] OR Hubei[tiab]) AND coronavirus*[tiab]) OR ((2019[dp] OR 2020[dp]) AND (new[tiab] OR novel[tiab] OR pandemic*[tiab] OR epidemic*[tiab]) AND (coronavirus*[tiab] OR corona virus*[tiab])))	33096
2	"self swab*" [Title/Abstract] OR "self collect*" [Title/Abstract] OR "self service*" [Title/Abstract] OR "self administer*" [Title/Abstract] OR "self test*" [Title/Abstract] OR "self samp*" [Title/Abstract] OR "patient collect*" [Title/Abstract] OR "patient administer*" [Title/Abstract] OR "at home test*" [Title/Abstract] OR "home collect*" [Title/Abstract] OR "home test*" [Title/Abstract]	41697
3	1 and 2	76

4	limit 3 to english language	74
5	"respiratory tract infections"[MeSH Terms] OR "severe acute respiratory syndrome"[MeSH Terms] OR "sars virus"[MeSH Terms] OR "middle east respiratory syndrome coronavirus"[MeSH Terms] OR "influenza a virus, h1n1 subtype"[MeSH Terms] OR "influenza, human"[MeSH Terms]	372845
6	"SARS"[Title/Abstract] OR "SARS-CoV"[Title/Abstract] OR "MERS"[Title/Abstract] OR "MERS-CoV"[Title/Abstract] OR "H1N1"[Title/Abstract] OR "influenza"[Title/Abstract] OR "respiratory infection*"[Title/Abstract] OR "respiratory illness*"[Title/Abstract] OR "respiratory virus*"[Title/Abstract]	146176
7	5 or 6	448337
8	2 and 6	748
9	limit 8 to english language	696
10	limit 9 to "reviews"	21
11	specimen handling[MeSH Terms] or self-examination[MeSH Terms]	350389
12	9 and 11	30
13	"nose"[MeSH Terms] OR "nasal cavity"[MeSH Terms] OR "saliva"[MeSH Terms] OR "oropharynx"[MeSH Terms]	145828
14	nose[Title/Abstract] OR nasal[Title/Abstract] OR nasopharyngeal[Title/Abstract] OR oropharyngeal[Title/Abstract] OR throat[Title/Abstract] OR saliva[Title/Abstract]	204030
15	13 or 14	297658
16	9 and 15	113
17	"costs and cost analysis"[MeSH Terms]	236869
18	"cost*"[Title/Abstract]	617773
19	17 or 18	721421
20	9 and 19	57
21	"patient compliance"[MeSH Terms]	76303
22	"complet*"[Title/Abstract] OR "adhere*"[Title/Abstract] OR "compliance"[Title/Abstract] OR "comply*"[Title/Abstract] OR "complied"[Title/Abstract] OR "uptake"[Title/Abstract]	2111952
23	21 or 22	2140605
24	9 and 23	283

TRIP Pro/Google/Google Scholar (first 10 pages screened)

(coronaviru* OR "corona virus" OR ncov* OR n-cov* OR COVID-19 OR COVID19 OR COVID-2019 OR COVID2019 OR SARS-COV-2 OR SARSCOV-2 OR SARSCOV2 OR SARSCOV19 OR SARS-COV-19 OR SARSCOV-19 OR SARSCOV2019 OR SARS-COV-2019 OR SARSCOV-2019 OR "severe acute respiratory syndrome cov 2" OR "severe acute respiratory syndrome coronavirus*" OR "2019 ncov" OR 2019ncov OR Hcov*)

AND (self swab* or self collect* or self service* or self administer* or self test* or self sampl* or patient collect* or patient administer* or at-home test* or home collect* or home test*)from:2020

(SARS or SARS-CoV or MERS or MERS-CoV or H1N1 or influenza or respiratory infection* or respiratory illness* or respiratory virus*) AND (self swab* or self collect* or self service* or self administer* or self test* or self sampl* or patient collect* or patient administer* or at-home test* or home collect* or home test*) and (nose or nasal or nasopharyngeal or oropharyngeal or throat or saliva)

LitCovid/ WHO COVID-19 Research Database/Cochrane Library/medRxiv & bioRxiv/CADTH

self swab* or self collect* or self service* or self administer* or self test* or self sampl* or patient collect* or patient administer* or at-home test* or home collect* or home test*