The following information resources have been selected by the National Health Library and Knowledge Service Evidence Virtual Team in response to your question. The resources are listed in our estimated order of relevance to practicing healthcare professionals confronted with this scenario in an Irish context. In respect of the evolving global situation and rapidly changing evidence base, it is advised to use hyperlinked sources in this document to ensure that the information you are disseminating to the public or applying in clinical practice is the most current, valid and accurate. For further information on the methodology used in the compilation of this document—including a complete list of sources consulted—please see our National Health Library and Knowledge Service Summary of Evidence Protocol.

YOUR QUESTION

What is the false negative rate for swab tests for COVID-19 and are there more reliable ways of testing? Are rectal swab tests effective in detecting COVID-19 for patients presenting with gastrointestinal problems?

IN A NUTSHELL

The diagnosis of COVID-19 is made by detection of SARS-CoV-2 RNA by reverse-transcription polymerase chain reaction (RT-PCR)[5]. The CDC recommends collection of a nasopharyngeal (NP) swab specimen to test for SARS-CoV-2[4]. Oropharyngeal, nasal mid-turbinate, or nasal swabs of both nares are acceptable alternatives for symptomatic patients if nasopharyngeal swabs are unavailable[5]. A positive test for SARS-CoV-2 generally confirms the diagnosis of COVID-19 but false-negative tests from upper respiratory specimens have been well documented[5].
It is unclear the exact percentage of tests that produce false negatives but evidence from China proposes that this could be as high as 30% [6, 14, 15]. The sensitivity of testing depends on the type of specimen obtained, the quality of the specimen, the duration of illness at the time of testing and on the precise RT-PCR assay.

For upper respiratory tract samples, sample quality depends greatly on the operation of the collectors. To get enough virus infected cells, swabs must be inserted deep enough. In detail, nasopharyngeal (NP) swab must be inserted through the nares parallel to the palate, and oropharyngeal (OP) swab needs to be inserted into posterior pharynx and tonsillar areas[4] .

The duration of the illness at the time of testing is crucial if initial testing is negative, but if the suspicion for COVID-19 remains, it is suggested to repeat the test which decreases the chances of failing to identify infected individuals [5, 7, 10]. In such cases it is recommended to test lower respiratory tract (LRT) specimens, if possible [2, 4, 5].

Care must be taken when interpreting RT-PCR tests for SARS-CoV-2 infection, particularly if performed early in the course of infection, and when using results as a basis for removing precautions intended to prevent onward transmission.
Clinical judgement should be used in the case of patients returning negative tests if patients are thought likely to be infected [8, 15]. Chest CT scans have been suggested for screening for SARS-CoV-2 especially if swab tests are negative for patients thought to be infected [6, 9, 10]. Long et al suggest that patients with typical CT findings but negative rRT-PCR results should be isolated, and rRT-PCR should be repeated to avoid misdiagnosis[10].

Some patients may present with gastrointestinal problems as their chief complaint such as abdominal pain, nausea or vomiting [5, 13]. Ng et al[12] suggest that rectal swabs have an important part to play in confirming SARS-CoV-2 infection. Prolonged faecal shedding in infected patients, even after viral clearance in the respiratory tract, suggests that stool testing should be considered in patients with COVID-19 and appropriate transmission precautions for hospitalised patients who remain stool positive. Some patients test positive on rectal swabs in the very first days of COVID-19 onset which points toward the usefulness of rectal swabs at the very onset of the disease to confirm or even diagnose COVID-19 [11]. SARS-CoV-2 RNA was reported to be detected in anal swabs even when not detected in oral swabs[13] Thus, it might be an optional way to improve the diagnosis rate of SARS-CoV-2 infection by testing stool samples when LRT specimens are unavailable.

Serologic tests—as soon as generally available and adequately evaluated—should be able to identify patients who have either a current or a previous infection, but a negative PCR test [5]. In cases where nucleic acid amplification tests (NAAT) assays are negative and there is a strong epidemiological link to COVID-19 infection, paired serum samples in the acute and convalescent phase could support diagnosis once validated serology tests are available [3].

IRISH AND INTERNATIONAL GUIDANCE

What does the Health Protection Surveillance Centre (Ireland) say?

Health Protection Surveillance Centre (2020). Laboratory guidance for COVID-19[1]

Sample types accepted for SARS-CoV-2 testing:

- combined swab for oropharyngeal and nasopharyngeal samples [one swab to test both is sufficient] in ambulatory patients; or
- bronchoalveolar lavage or endotracheal aspirate or sputum if produced is preferred in cases of severe illness

Health Protection Surveillance Centre (2020). COVID-19 assessment and testing pathway for use in a hospital setting[2]

If virus is not detected in an upper respiratory tract sample, clinical suspicion for COVID-19 should be maintained in patients with severe respiratory disease that is not readily explained. Testing of lower respiratory tract samples can be considered if available.

What does the World Health Organization say?

World Health Organization (2020) Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases[3]

If a negative result is obtained from a patient with a high index of suspicion for COVID-19 virus infection, particularly when only upper respiratory tract specimens were collected, additional specimens, including from the lower respiratory tract if possible, should be collected and tested.

Serological Testing

Serological surveys can aid investigation of an ongoing outbreak and retrospective assessment of the attack rate or extent of an outbreak. In cases where NAAT assays are negative and there is a strong epidemiological link to COVID-19 infection, paired serum samples in the acute and convalescent phase could support diagnosis once validated serology tests are available. Serum samples can be stored for these purposes.

What do the Centers for Disease Control and Prevention (United States) say?

Centers for Disease Control and Prevention (2020) Interim guidelines for collecting, handling and testing clinical specimens from persons for Coronavirus Disease 2019 (COVID-19)[4]

For initial diagnostic testing for SARS-CoV-2, CDC recommends collecting and testing an upper respiratory specimen. CDC also recommends testing lower respiratory tract specimens, if available. Nasopharyngeal specimen is the preferred choice for swab-based SARS-CoV-2 testing. When collection of a nasopharyngeal swab is not possible, the following are acceptable alternatives:

- an oropharyngeal (OP) specimen collected by a healthcare professional; or
- a nasal mid-turbinate (NMT) swab collected by a healthcare professional or by onsite self-collection using a flocked tapered swab; or
- an anterior nares nasal swab (NS) specimen collected by a healthcare professional or by onsite self-collection using a flocked or spun polyester swab; or
- nasopharyngeal wash/aspirate or nasal aspirate (NA) specimen collected by a healthcare professional

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POINT-OF-CARE TOOLS

What does UpToDate say?

Coronavirus disease 2019 (COVID-19): Epidemiology, virology, clinical features, diagnosis, and prevention[5]

The diagnosis of COVID-19 is made by detection of SARS-CoV-2 RNA by reverse-transcription polymerase chain reaction (RT-PCR). In the United States, the CDC recommends collection of a nasopharyngeal swab specimen to test for SARS-CoV-2. An oropharyngeal swab can be collected but is not essential; if collected, it should be placed in the same container as the nasopharyngeal specimen. Oropharyngeal, nasal mid-turbinate, or nasal swabs of both nares are acceptable alternatives for symptomatic patients if nasopharyngeal swabs are unavailable. Expectorated sputum should be

collected from patients with productive cough; induction of sputum is not recommended. A lower respiratory tract aspirate or bronchoalveolar lavage should be collected from patients who are intubated.
The accuracy and predictive values of SARS-CoV-2 testing have not been systematically evaluated, and the sensitivity of testing depends on the precise RT-PCR assay, the type of specimen obtained, the quality of the specimen and duration of illness at the time of testing. If initial testing is negative but the suspicion for COVID-19 remains and determining the presence of infection is important for management or infection control, we suggest repeating the test. In such cases, the WHO also recommends testing lower respiratory tract specimens, if possible.
Serologic tests, as soon as generally available and adequately evaluated, should be able to identify patients who have either current or previous infection but a negative PCR test.

INTERNATIONAL LITERATURE

What does the international literature say?

Fang et al (2020) Sensitivity of Chest CT for COVID-19: Comparison to RT-PCR[6]

In our series, the sensitivity of chest CT was greater than that of RT-PCR (98% vs 71%, respectively, p<.001). The reasons for the low efficiency of viral nucleic acid detection may include: 1. immature development of nucleic acid detection technology; 2. variation in detection rate from different manufacturers; 3. low patient viral load; or 4 improper clinical sampling. Our results support the use of chest CT for screening for COVD-19 for patients with clinical and epidemiologic features compatible with COVID-19 infection particularly when RT-PCR testing is negative.

Wikramaratna et al (2020) Estimating false-negative detection rate of SARS-CoV-2 by RT-PCR[7]

Reverse transcription-polymerase chain reaction (RT-PCR) assays are used to test patients and key workers for infection with the causative SARS-CoV-2 virus. RT-PCR tests are highly specific and the probability of false positives is low, but false negatives can occur if the sample contains insufficient quantities of the virus to be successfully amplified and detected. The amount

of virus in a swab is likely to vary between patients, sample location — nasal, throat or sputum — and through time as infection progresses.
On its own, testing throat and nasal swabs by RT-PCR is not guaranteed to yield a positive result for SARS-CoV-2 infection and this probability decreases with time since the onset of symptoms. In other words, the longer the time from the onset of symptoms until a suspected case is tested, the more likely a false-negative result. Repeat testing of suspected but RT-PCR negative infections drastically decreases the chances of failing to identify infected individuals by this method, but may not always be feasible.
In countries that do not currently have mass testing, there are calls for testing to be expanded to the population at large with the aim of determining how many people have, or have recently had, infection. While RT-PCR testing of key workers will be of great importance, particularly those working with vulnerable groups, our results suggest that there may be some benefit to testing indiscriminately; conducting a single test on someone who had symptoms 10 days ago will have a nearly 33% false negative rate using a nasal swab; 52.89% for a throat swab. As a means of determining population level exposure to SARS-CoV-2, serological tests are far more likely to provide an accurate profile.
In conclusion, we demonstrate how the sensitivity of the RT-PCR assay for detecting SARS-CoV-2 infection depends on the time from the onset of symptoms in symptomatic individuals, and show how nasal swabs appear more sensitive than throat swabs.

Kucirka et al (2020) Variation in False Negative Rate of RT-PCR Based SARS-CoV-2 Tests by Time Since Exposure[8]

SARS-CoV-2 RT-PCR based tests are being used to rule out infection among high-risk individuals such as exposed inpatients and healthcare workers. It is critical to understand how the predictive value of the test varies with time from exposure and symptom onset in order to avoid being falsely reassured by negative tests.
We used previously published data on RT-PCR sensitivity on samples derived from nasal swabs by day since symptom onset (n=633) and fit a cubic polynomial spline to calculate the false negative rate by day since exposure and symptom onset. Over the four days of infection prior to the typical time of symptom onset (day 5) the probability of a false negative test in an infected individual falls from 100% on day one (95% CI 69-100%) to 61% on day four (95% CI 18-98%), though there is considerable uncertainty in these numbers. On the day of symptom onset, the median false negative rate was

39% (95% CI 16-77%). This decreased to 26% (95% CI 18-34%) on day 8 (3 days after symptom onset), then began to rise again, from 27% (95% CI 20-34%) on day 9 to 61% (95% CI 54-67%) on day 21. Care must be taken when interpreting RT-PCR tests for SARS-CoV-2 infection, particularly if performed early in the course of infection, when using these results as a basis for removing precautions intended to prevent onward transmission. If there is high clinical suspicion, patients should not be ruled out on the basis of RT-PCR alone and the clinical and epidemiologic situation should be carefully considered.

Li et al (2020) Stability issues of RT- PCR testing of SARS- CoV- 2 for hospitalized patients clinically diagnosed with COVID- 19[9]

In this study, we collected a total of 610 hospitalized patients from Wuhan between February 2, 2020, and February 17, 2020. We reported a potentially high false negative rate of RT-PCR testing for SARS-CoV-2 in the 610 hospitalized patients clinically diagnosed with COVID-19 during the 2019 outbreak. We also found that the RT-PCR results from several tests at different points were variable from the same patients during the course of diagnosis and treatment of these patients. Our results indicate that in addition to the emphasis on RT-PCR testing, clinical indicators such as computed tomography images should also be used not only for diagnosis and treatment but also for isolation, recovery, discharge and transferring for hospitalized patients clinically diagnosed with COVID-19 during the current epidemic. These results suggested the urgent needs for the standard of procedures of sampling from different anatomic sites, sample transportation, optimization of RT-PCR, serology diagnosis/screening for SARS-CoV-2 infection, and distinct diagnosis from other respiratory diseases such as influenza infections.

Long et al (2020) Diagnosis of the Coronavirus Disease (COVID-19): rRT-PCR or CT?[10]

Purpose: To evaluate the diagnostic value of computed tomography (CT) and real-time reverse-transcriptase-polymerase chain reaction (rRT-PCR) for COVID-19 pneumonia.
Methods: This retrospective study included all patients with COVID-19 pneumonia suspicion who were examined by both CT and rRT-PCR at initial presentation. The sensitivities of both tests were then compared. For patients with a final confirmed diagnosis, clinical and laboratory data in addition to CT imaging findings were evaluated.

Results: A total of 36 patients were finally diagnosed with COVID-19 pneumonia. 35 patients had abnormal CT findings at presentation, whereas 1 patient had a normal CT. Using rRT-PCR, 30 patients were tested positive, with 6 cases initially missed. Amongst these 6 patients, 3 became positive in the second rRT-PCR assay after 2 days, 2 days and 3 days respectively; and the other 3 became positive only in the third round of rRT-PCR tests after 5 days, 6 days and 8 days respectively. At presentation, CT sensitivity was therefore 97.2%, whereas the sensitivity of initial rRT-PCR was only 83.3%. Conclusion: rRT-PCR may produce initial false negative results. We suggest that patients with typical CT findings but negative rRT-PCR results should be isolated, and rRT-PCR should be repeated to avoid misdiagnosis.

Tozzi et al (2020) Rectal Swabs For COVID-19 Diagnosis[11]

Oropharyngeal specimen negativity been described together with anal swab positivity up to 28 days after the onset of symptoms also in in children. These findings suggest that some patients with SARS-CoV-2 infection have viral RNA or live infectious virus in feces well after the negativization of oropharyngeal specimens.
Apart from the inference that patients test positive on rectal swabs even after nasopharyngeal swabs become negative, another deduction can be drawn that is even more important by an operative standpoint. Indeed, the available data suggest that some patients test positive on rectal swabs in the very first days of COVID-19 onset. To take a few examples, in a review article, Tian et al reported fecal PCR positivity 2-5 days after sputum in in 36%-53% of patients, while Xiao et al found that 39/73 hospitalized patients had viral RNA in their feces from 1 to 12 days. Therefore, the occurrence of oro-fecal route points towards the usefulness of rectal swabs at the very onset of the disease to confirm or even diagnose COVID-19.

Ng and Tilg (2020) COVID-19 and the gastrointestinal tract: more than meets the eye[12]

These studies provide new insights into our understanding of the prevalence, aetiology and potential mechanisms of COVID-19 in the GI tract crucial for defining prevention measures, clinical care and treatment strategies. Unanswered questions and challenges remain, such as the significance of virus detection in the stool/rectal swabs of asymptomatic subjects, whether ACE2 is a direct mediator for SARS-CoV-2 entry into the GI tract and how the virus could survive passage through extreme pH environment of the digestive system. Currently, prolonged fecal shedding in

infected patients even after viral clearance in respiratory tract suggests that stool testing should be considered in patients with COVID-19 with appropriate transmission precautions for hospitalised patients who remain stool positive.

Hindson (2020) COVID-19: faecal–oral transmission? [13]

The SARS-CoV-2 infection is typically characterized by respiratory symptoms, which indicates droplet transmission. However, several case studies have reported gastrointestinal symptoms and/or evidence that some patients with SARS-CoV-2 infection have viral RNA or live infectious virus present in faeces, which suggests that another possible route might be faecal–oral transmission.

In a clinical characterization of ten paediatric patients with SARS-CoV-2 infection in China, none of whom required respiratory support or intensive care and all of whom lacked signs of pneumonia, eight tested positive on rectal swabs, even after nasopharyngeal testing was negative. The details were published as a Brief Communication in Nature Medicine. The patients, whose ages ranged from 2 months to 15 years, initially tested positive after being screened by nasopharyngeal swab real-time reverse transcription PCR (RT–PCR). Next, the researchers conducted a series of nasopharyngeal and rectal swabs to investigate the pattern of viral excretion. Eight patients had real-time RT–PCR-positive rectal swabs. “The findings suggest that we also need to use rectal swabs to confirm diagnosis of COVID-19,” says Kang Zhang, a corresponding author of the study.

There had been earlier reports, particularly in adults, of gastrointestinal symptoms and of the possibility of a faecal–oral route of transmission. In a cohort of 1,099 patients with COVID-19 from 552 hospitals in China, published in the New England Journal of Medicine, 5.0% of patients presented with nausea or vomiting and 3.8% presented with diarrhoea. Also, preliminary findings published in the American Journal of Gastroenterology found that of 204 patients with COVID-19 (mean age 54.9 years) who presented to three hospitals in China, 99 (48.5%) patients presented with digestive symptoms as their chief complaint.

OTHER

Watson and Whiting (2020) [Website]. Coronavirus: how accurate are coronavirus tests? [14]

There are two main types of COVID-19 tests. SWAB TESTS — which usually take a sample from the throat or nose to detect viral RNA; these determine if you currently have COVID-19. BLOOD TESTS — which detect antibodies; can determine if you have had COVID-19 and are therefore [presumed] immune.
No test is 100% accurate. Although tests can perform well in ideal laboratory conditions, in real life lots of other factors affect accuracy including the timing of the test, how the swab was taken and the handling of the specimen.
Early on in the novel coronavirus outbreak, doctors started reporting cases of people who had coronavirus which had been missed by swab tests — also known as false negatives. We don't know for sure how often these false negatives occur in the UK, but evidence from China suggests up to 30 out of every 100 people with coronavirus might test negative. Antibody blood tests are also being developed. These could help us find out who has had coronavirus previously and is therefore presumed to be immune. This could help inform decisions about lifting lockdowns to allow people to go back to work safely.
But before these are rolled out, we need to know how accurate they are. This time we need to be confident that the antibody test doesn't falsely reassure people that they are immune, as this could worsen the spread of infection. At the moment we don't have enough information on these tests to be able to answer these questions. The very limited data available suggests they have fewer false negative results than swab tests, but more false positive results. This means there is a possibility that you could test positive without being immune and so these tests may not be as helpful as people are hoping.

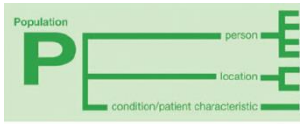
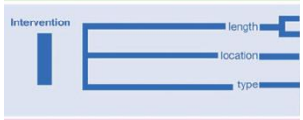
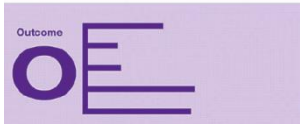
Krumholz (2020) [News Article] If You Have Coronavirus Symptoms, Assume You Have the Illness, Even if You Test Negative[15]

False-negative test results — tests that indicate you are not infected, when you are — seem to be uncomfortably common. Increasingly, and disturbingly, I hear a growing number of anecdotal stories from my fellow doctors of patients testing negative for coronavirus and then testing positive or people who are almost certainly infected who are testing negative.

Unfortunately, we have very little public data on the false-negative rate for these tests in clinical practice. Research coming out of China indicates that the false-negative rate may be around 30 percent. Some of my colleagues, experts in laboratory medicine express concerns the false-negative rate in this country could be even higher. Even as better tests emerge, we should always put the test result in the context of the other information we have. It's a lesson that endures throughout medicine: look at the big picture, not a single piece of data. Triangulate on the truth, using all the sources of information you have, no matter how good a single test. And don't be shy about questioning a conclusion that doesn't fully fit the facts.

Produced by the members of the National Health Library and Knowledge Service Evidence Team†. Current as at 30 April 2020. This evidence summary collates the best available evidence at the time of writing and **does not replace clinical judgement or guidance**. Emerging literature or subsequent developments in respect of COVID-19 may require amendment to the information or sources listed in the document. Although all reasonable care has been taken in the compilation of content, the National Health Library and Knowledge Service Evidence Team makes no representations or warranties expressed or implied as to the accuracy or suitability of the information or sources listed in the document. This evidence summary is the property of the National Health Library and Knowledge Service and subsequent re-use or distribution in whole or in part should include acknowledgement of the service.

The following PICO(T) was used as a basis for the evidence summary:

	PATIENTS WITH SUSPECTED COVID-19
	SWAB TESTS
	OTHER TESTS SUCH AS RECTAL TESTS
	

The following search strategy was used:

FALSE NEGATIVE RESULT* OR FALSE NEGATIVE RATE* OR FALSE NEGATIVE OR FALSE NEGATIVE RESULT* OR FALSE NEGATIVE TEST* OR SPECIFICITY OR NEGATIVE PREDICTIVE VALUE* AND COVID-19 OR CORONAVIRUS OR "CORONA VIRUS" OR WUHAN NEAR/3 VIRUS OR (("2019-NCOV" OR "2019 NCOV")) OR "SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2" OR "2019 NOVEL CORONAVIRUS" OR "2019 NEW CORONAVIRUS"

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