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

Serological (antibody) testing for COVID-19 infection: what are the current issues and challenges?

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IN A NUTSHELL

Anti-SARS-CoV-2 virus antibody tests are abundant on the market[6]. In Ireland, HIQA caution that as yet none of the rapid antibody tests have been independently validated and there are no CE-marked antibody tests for self-testing available[1]. Several manufacturers are selling rapid, point-of-care tests based on antibody detection, but the World Health Organization does not recommend these tests because of accuracy concerns in the absence of validation studies[8]. The WHO does however encourage the continuation of work to establish their usefulness in disease surveillance and epidemiologic research[3].

Serological tests based on antibodies could be very helpful, but individual studies measuring the accuracy of the various tests are usually underpowered and inconsistent[11]. The serological tests have been developed rapidly and under urgent market demands, and are poorly validated with clinical samples in everyday practice. Within several studies, these tests show divergence in sensitivity and specificity from data that the manufacturers report. Also, the technology is new and the evidence for its accuracy in coronavirus is still being evaluated[9].

To date, no study has evaluated whether the presence of antibodies to SARS-CoV-2 confers immunity to subsequent infection by this virus in

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humans[3]. It should be emphasized that SARS-CoV-2 antibody detection tests have limited usefulness for early COVID-19 diagnosis as it can take 10 days or more after onset of symptoms for patients to become positive for detectable antibodies, and because the antibodies persist long after the infection has cleared[4]. It is however argued that in those patients presenting with a discrepancy between clinical or radiological features and the molecular test, rapid antibody detection might be an additional element helping the clinician to make a correct diagnosis[15].

Antibody tests could prove essential for performing large-scale sero-epidemiological population surveys for assessing the immune status of workers and as one of the elements guiding de-escalation strategies when the pandemic is under control[6]. Lateral antibody tests are critical for assessing population spread of the virus and the level of 'herd' immunity in the population. This is important for understanding the potential consequences of lifting or enforcing measures to control the virus such as quarantine, social distancing and school or workplace closures[9]. However, studies evaluating the specificity of serologic tests in a broad population are lacking; in particular, the rate of cross-reactivity with other coronaviruses is a potential concern, and IgM tests are prone to false-positive results[8]. Further longitudinal investigations of virus-specific antibodies' functions and their protective efficacy over time are needed[16].

Antibody-based testing is of paramount importance in identifying health workers who may have recovered from initial infection in order to ascertain suitability to return to frontline health services. Testing may also help to inform public health strategies at the end of periods of lockdown or as social distancing restrictions are relaxed[10].

IRISH AND INTERNATIONAL GUIDANCE

What does the Health Information and Quality Authority (Ireland) say?
[Health Information and Quality Authority (2020). Rapid health technology assessment of alternative diagnostic testing approaches for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)[1]](#)
The Health Information and Quality Authority caution that as yet, no rapid antibody tests have been independently validated; and, to date, there are no CE-marked antibody tests for self-testing available.

What does the World Health Organization say?
[World Health Organization (8 April 2020) [WHO Scientific Brief]. Advice on the use of point-of-care immunodiagnostic tests for COVID-19[2]](#)
The WHO does not recommend the use of antibody-detecting rapid diagnostic tests for patient care but encourages the continuation of work to establish their usefulness in disease surveillance and epidemiologic research.

[World Health Organization (24 April 2020) [WHO Scientific Brief]. 'Immunity passports' in the context of COVID-19[3]](#)
There is currently no evidence that people who have recovered from COVID-19 and have antibodies are protected from a second infection. The WHO continues to review the evidence on antibody responses to SARS-CoV-2 infection. To date, no study has evaluated whether the presence of antibodies to SARS-CoV-2 confers immunity to subsequent infection by this virus in humans.

What does the European Centre for Disease Prevention and Control say?
[European Centre for Disease Prevention and Control (2020) [Technical Report]. An overview of the rapid test situation for COVID-19 diagnosis in the EU/EEA[4]](#)
There are many [60+] CE-marked rapid SARS-CoV-2 antibody tests and more continue to be placed on the market. Research groups have also developed and are validating in-house antibody detection tests for SARS-CoV-2, which may serve as potential platforms for commercial tests in the near future. It should be underlined that SARS-CoV-2 antibody detection tests have limited usefulness for early COVID-19 diagnosis as it can take 10 days or more after

onset of symptoms for patients to become positive for detectable antibodies and because the antibodies persist long after the infection has cleared.

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

[Centers for Disease Control and Prevention (2020). Serology testing for COVID-19](#)[5]

At present, the Centers for Disease Control and Prevention are evaluating commercially manufactured serologic tests in collaboration with the Biomedical Research and Development Authority, the Food and Drug Administration, the National Institutes of Health, the Department of Defense, and the White House Office of Science and Technology Policy.

What does the European Union say?

[European Union (2020). Guidelines on COVID-19 in vitro diagnostic tests and their performance](#)[6]

Anti-SARS-CoV-2 virus antibody tests are abundant on the market. They do not give a definite answer on the presence or absence of the SARS-CoV-2 virus and thus they are not suitable to assess if the tested individual may be contagious for others. Nevertheless, antibody tests could prove essential for performing large-scale sero-epidemiological population surveys for assessments such as the immune status of workers and as one of the elements for guiding de-escalation strategies when the pandemic is under control.

POINT-OF-CARE TOOLS

What does BMJ Best Practice say?

[Coronavirus disease 2019 (COVID-19) Investigations. Emerging tests: serology](#)[7]

Serological testing is becoming increasingly available for use; however, while rapid antibody detection kits have been approved in Europe and the US for the qualitative detection of SARS-CoV-2 IgG/IgM antibodies in serum, plasma, or whole blood, the WHO does not recommend the use of these tests outside of research settings as they have not been validated as yet. It typically takes 1 to 2 weeks after symptom onset for antibodies to develop to

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SARS-CoV-2. Serum samples can be stored to retrospectively define cases when validated serology tests become available.

What does UpToDate say?

[UpToDate (2020). Coronavirus disease 2019 (COVID-19): Epidemiology, virology, clinical features, diagnosis, and prevention[8]](#)
Several manufacturers are selling rapid, point-of-care tests based on antigen testing or antibody detection, but the WHO does not recommend these tests because of accuracy concerns in the absence of validation studies. The accuracy and time to antibody detection vary with the particular test used. Studies evaluating the specificity of serologic tests in a broad population are lacking; in particular, the rate of cross-reactivity with other coronaviruses is a potential concern, and IgM tests are prone to false-positive results.

INTERNATIONAL LITERATURE

What does the international literature say?

[Green et al. Oxford University Centre for Evidence Based Medicine (2020a) What tests could potentially be used for the screening, diagnosis and monitoring of COVID-19 and what are their advantages and disadvantages? [9]](#)
Lateral flow antibody tests can be completed rapidly and the tests can be produced cheaply, so multiple diagnostics companies are working hard to develop lateral flow tests for SARS-CoV-2. Antibody tests provide a hugely important ability to detect past infection with virus to identify people who were asymptomatic, people who have cleared the virus and so no longer risk being infected or spreading the virus to others. In addition, antibody tests are critical for assessing population spread of the virus and the level of 'herd' immunity in the population. This is important for understanding the potential consequences of lifting or enforcing measures to control the virus such as quarantine, social distancing, and school or workplace closures. However, the technology is new and the evidence for its accuracy in coronavirus diagnosis is still being evaluated. So far, available lateral flow tests can only determine if a patient has at some point been infected with COVID-19. Further testing would be needed to check if a patient is currently infected. Future

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versions of this technology might allow clinicians to detect current infections.

Green et al. Oxford University Centre for Evidence-Based Medicine (2020b) Molecular and antibody point-of-care tests to support the screening, diagnosis and monitoring of COVID-19[10]

The characteristics of five antibody-based tests are summarised in this document. Antibody-based testing is of paramount importance in identifying healthcare workers who may have recovered from initial infection, to ascertain suitability to return to frontline health services. Testing may also help to inform public health strategies at the end of periods of lockdown or as social distancing restrictions are relaxed.

Kontou et al (2020) Antibody tests in detecting SARS-CoV-2 infection: a meta-analysis[11]

This systematic review and meta-analysis aims to summarize the available evidence on the performance of all available antibody-tests for SARS-CoV-2. Serological tests based on antibodies could be very helpful, but individual studies measuring the accuracy of the various tests are usually underpowered and inconsistent. The serological tests have been developed rapidly and under urgent market demands, and are poorly validated with clinical samples in everyday practice. Within several studies, these tests show divergence in sensitivity and specificity that may deviate from data that the manufacturers report.

Li et al (2020) Development and clinical application of a rapid IgM-IgG combined antibody test for SARS-CoV-2 infection diagnosis[12]

Li et al developed a rapid point-of-care lateral flow immunoassay to detect immunoglobulin M (IgM) and IgG antibodies simultaneously against COVID-19 virus in human blood within 15 minutes, which can detect patients at different infection stages. They conducted clinical studies of the test kit to validate its clinical efficacy. The IgM-IgG combined assay has better utility and sensitivity compared with a single IgM or IgG test. They recommend it be used for the rapid screening of COVID-19 carriers, symptomatic or asymptomatic, in hospitals, clinics and test laboratories.

Hoffman et al (2020) Evaluation of a COVID-19 IgM and IgG rapid test: an efficient tool for assessment of past exposure to SARS-CoV-2[13]

Hoffman et al evaluated the commercially available test described by Li et al[12]. The results revealed a sensitivity of 69% and 93.1% for IgM and IgG, respectively, based solely on PCR-positivity due to the absence of a serological gold standard. The assay specificities were shown to be 100% for IgM and 99.2% for IgG. This indicates that the test is suitable for assessing previous virus exposure, although negative results may be unreliable during the first weeks after infection. More detailed studies on antibody responses during and post infection are urgently needed. In contrast to Li et al, Hoffman found fewer indications for using this test for clinical diagnosis. Nevertheless, it might contribute to detecting potential asymptomatic infections as well as getting a notion of the magnitude of the spread in different geographical areas, which might be a key to taking the appropriate decisions and policies forward. The high negative predictive value indicates that the rapid test will be useful for detecting past infections and possible immunity, which may be crucial for restoring social functions after lockdown.

Haveri et al (2020) Serological and molecular findings during SARS-CoV-2 infection: the first case study in Finland, January to February 2020[14]

This case study describes the timeline of events around the first COVID-19 case imported to Finland, and summarises the clinical, molecular and serological data. After better understanding the kinetics, specificity and sensitivity of the assays in development, the serological testing may help contact tracing of clusters and have a role in diagnosing acute and past SARS-CoV-2 infections.

Spicuzza et al (2020) Reliability and usefulness of a rapid IgM-IgG antibody test for the diagnosis of SARS-CoV-2 infection: a preliminary report[15]

This study assessed the reliability of the 2019-nCoV IgG/IgM Antibody Rapid Test Kit (Beijing Diagreat Biotechnologies) in patients with confirmed COVID-19 and in a small sample of patients with suspected disease. This test has the advantage of being a point-of-care test that gives a response within minutes. In those patients presenting with a discrepancy between the clinical/radiological feature and the molecular test, the rapid antibody detection might be an additional element helping the clinician to make a correct diagnosis. Further studies are needed to investigate both the diagnostic and the screening value of this test.

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Padoan et al (2020) IgA-Ab response to spike glycoprotein of SARS-CoV-2 in patients with COVID-19: a longitudinal study[16]

Validation studies of serological antibody tests must be properly designed for clinical, epidemiological and public health objectives such as confirmation of suspected COVID-19 cases, certification of seroconversion after infection, and epidemiological surveillance. Further longitudinal investigations of virus-specific antibodies' functions and their protective efficacy over time are needed.

Infantino et al (2020) Serological assays for SARS-CoV-2 infectious disease: benefits, limitations and perspectives[17]

Though there is limited and contrasting data available on the utilisation of antibody testing, they may provide a mirror of how immunity is acting, giving clinicians a valid prognostic as well as diagnostic tool. There must be strong evidence of a test's reliability, its accuracy, precision, specificity and sensitivity.

Zhao et al (2020) Antibody responses to SARS-CoV-2 inpPatients of novel coronavirus disease 2019[18]

In this study, Zhao et al investigate the dynamics of total antibody (Ab), IgM and IgG antibody against SARS-CoV-2 in serial blood samples collected from 173 confirmed COVID-19 patients. They provide discussion on the clinical value of antibody testing and conclude that the antibody detection offers vital clinical information during the course of SARS-CoV-2 infection. Their findings provide strong empirical support for the routine application of serological testing in the diagnosis and management of COVID-19 patients.

Xie et al (2020) Characteristics of patients with coronavirus disease (COVID-19) confirmed using an IgM-IgG antibody test [19]

To increase the sensitivity of COVID-19 diagnoses, Xie et al developed an IgM-IgG combined assay and tested it in patients with suspected SARS-CoV-2 infection. Their findings suggest that patients who develop severe illness might experience longer virus exposure times and develop a more severe inflammatory response. Xie et al conclude that the IgM-IgG test is an accurate and sensitive diagnostic method. A combination of nucleic acid and IgM-IgG testing is a more sensitive and accurate approach for diagnosis and early treatment of COVID-19.

Xiang et al (2020) Antibody detection and dynamic characteristics in patients with COVID-19 [20]

A serologic test to identify antibody dynamics and response to COVID-19 was developed. The authors conclude the antibodies against COVID-19 can be detected in the middle and later stage of the illness. Antibody detection may play an important role in the diagnosis of COVID-19 as a complement approach for viral nucleic acid assays.

Stadlbauer et al (2020) SARS- CoV- 2 seroconversion in humans: a detailed protocol for a serological assay, antigen production, and test setup [21]

Serological assays are urgently needed to conduct serosurveys, to understand the antibody responses mounted in response to the virus and to identify individuals who are potentially immune to re-infection. Here, the authors describe a detailed protocol for expression of antigens derived from the spike protein of SARS-CoV-2 that can serve as a substrate for immunological assays, as well as a two-stage serological enzyme-linked immunosorbent assay (ELISA). These assays can be used for research studies and for testing in clinical laboratories.

Liu et al (2020) Diagnostic indexes of a rapid IgG/IgM combined antibody test for SARS-CoV-2 [22]

The aim of this study was to evaluate diagnostic indexes of a rapid IgG/IgM combined antibody test for SARS-CoV-2. Although the sensitivity and specificity of the IgG/IgM combined test kit were adequate, it cannot replace SARA-CoV-2 nucleic acid RT-PCR. It could however serve as a complementary option for RT-PCR. The combination of RT-PCR and IgG-IgM combined test kit could provide further insight into SARS-CoV-2 infection diagnosis.

Bendavid et al (2020) COVID-19 antibody seroprevalence in Santa Clara County, California [23]

The purpose of this study is to provide new and well-measured data for informing epidemic models, projections and public policy decisions. In April 2020, the researchers, using a lateral flow immunoassay, measured the seroprevalence of antibodies to SARS-CoV-2 in a community sample drawn from Santa Clara County. Results from the study suggest that the infection may be much more widespread than indicated by the number of confirmed cases. More studies are needed to improve precision of prevalence

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estimates. Locally-derived population prevalence estimates should be used to calibrate epidemic and mortality projections.

Pang et al (2020) Potential rapid diagnostics, vaccine and therapeutics for 2019 novel coronavirus (2019-nCoV): A systematic review [24]

Pang et al systematically review the potential of interventions to guide policymakers globally on their prioritisation of resources for research and development. Comparison between the molecular test and serological test showed that the molecular test has better sensitivity and specificity.

Patel et al (2020) Report from the American Society for Microbiology COVID-19 International Summit, 23 March 2020: Value of diagnostic testing for SARS–CoV-2/COVID-19 [25]

Antibody testing is a useful tool for research studies to determine the sensitivity of PCR assays for detecting infection. Testing can be employed retrospectively to determine the true scope of the pandemic and assist in the calculation of statistics, including the case fatality rate.

Dohla et al (2020) Rapid point-of-care testing for SARS-CoV-2 in a community screening setting shows low sensitivity [26]

Dohla et al evaluated a rapid antibody IgG/IgM–based testing system in the community setting for its ability, specificity and sensitivity to reliably identify infected individuals. Their results indicate the rapid test was substantially inferior to the RT-qPCR testing and should therefore neither be used for individual risk assessment nor for decisions on public health measures. As there is an urgent need for a sufficient rapid testing system for COVID-19, an antigen-based system may therefore be more appropriate.

Lou et al (2020) Serology characteristics of SARS-CoV-2 infection since the exposure and post symptoms onset [27]

The serology testing provides important complementation to RNA test for pathogenic specific diagnosis and helpful information to evaluate the adapted immunity status of patient. It should be strongly recommended to apply well-validated antibody tests in the clinical management and public health practice to improve the control of COVID-19 infection.

Lassaunière et al (2020) Evaluation of nine commercial SARS-CoV-2 immunoassays[28]

This study evaluated the sensitivity and specificity of nine commercially available serological tests. Overall, the sensitivity of all the tests improved over time, with the highest sensitivity recorded two weeks after symptoms first appeared. The findings of this study may facilitate selection of serological assays for the detection SARS-CoV-2-specific antibodies towards diagnosis as well as sero-epidemiological and vaccine development studies.

Amanat et al (2020) A serological assay to detect SARS-CoV-2 seroconversion in humans[29]

Serological assays are of critical importance to determine seroprevalence in a given population, define previous exposure and identify highly reactive human donors for the generation of convalescent serum as therapeutic. Sensitive and specific identification of coronavirus SARS-Cov-2 antibody titers may, in the future, also support screening of health care workers to identify those who are already immune and can be deployed to care for infected patients minimizing the risk of viral spread to colleagues and other patients.

Vogel (2020) First antibody surveys draw fire for quality, bias[30]

Surveying large swaths of the public for antibodies to the new coronavirus promises to show how widespread undiagnosed infections are, how deadly the virus really is, and whether enough of the population has become immune for social distancing measures to be eased, but the first batch of results has generated more controversy than clarity. The many different academic and commercial tests for coronavirus antibodies are still being refined and validated. They can show whether someone's immune system has encountered the virus. But because no one knows what level of antibodies, if any, confers protection against the new virus, the tests can't tell whether a person is immune to a future infection; and no one knows how long such immunity might last.

Mallapaty (2020) Will antibody tests for the coronavirus really change everything?[31]

Mallapaty addresses some of the key questions in relation to the rapid research and developments in the design and implementation of antibody testing, concluding that despite the challenges, once reliable antibody tests

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are available, they could be important to understanding which groups of people have been infected how to stop further spread of the COVID-19 infection.

FURTHER READING

Abbasi (2020). The promise and peril of antibody testing for COVID-19 [32]

Beeching et al. (2020). Covid-10: testing times [33]

Hu et al (2020). The production of antibodies for SARS-CoV-2 and its clinical implication [34]

Mallapaty (2020). Antibody tests suggest that coronavirus infections vastly exceed official counts [35]

Maxmen (2020). The researchers taking a gamble with antibody tests for coronavirus [36]

Okba et al (2020). Severe acute respiratory syndrome coronavirus 2–specific antibody responses in coronavirus disease 2019 patients [37]

Page (2020). Home testing is no quick fix [38]

Petherick (2020). Developing antibody tests for SARS-CoV-2 [39]

Tang et al (2020). The laboratory diagnosis of COVID-19 infection: current issues and challenges [40]

Yan et al. (2020). Laboratory testing of SARS-CoV, MERS-CoV, and SARS-CoV-2 (2019-nCoV): current status, challenges, and countermeasures [41]

Zhe Du et al (2020). Detection of antibodies against SARS-CoV-2 in patients with COVID-19 [42]

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

Population — person, location, condition/patient characteristic	COVID-19 INFECTION
Intervention — length, location, type	SEROLOGICAL/ANTIBODY TESTING
Comparison — another intervention, no intervention, location of the intervention	
Outcome	

The following search strategy was used:

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covid-19.ab,ti.
coronavirus.ab,ti.
"corona virus".ab,ti.
(Wuhan adj3 virus).ab,ti.
("2019-nCoV" or "2019 ncov").ab,ti.
"severe acute respiratory syndrome coronavirus 2".ab,ti.
("2019" and (new or novel) and coronavirus).ab,ti.
1 or 2 or 3 or 4 or 5 or 6 or 7
exp serology/ or exp immunoassay/ or exp antibody/
serolog*.ab.ti
antibod*.ab,ti.
9 or 10 or 11
8 and 12
limit 13 to yr="2020 -Current"
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BMJ Best Practice

Cochrane Clinical Answers

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