

COVID-19 Antigen Point of Care Testing

August 2021



Rapid Antigen Tests

Rapid antigen tests are intended for use at the point of care (POC) to detect the presence of viral protein from SARS CoV 2 and may be used in the detection and screening of SARS-CoV-2 infection in a symptomatic people.

The Onsite COVID-19 antigen rapid test is intended for use with nasopharyngeal, throat or nasal swabs and testing should be performed by trained staff in accordance with the manufacturer's instructions for use.

While rapid antigen tests can provide a result within 15-30 minutes, they are generally considered to be less sensitive than a PCR test which is still currently the gold standard in SARS-CoV-2 diagnosis.

Rapid antigen tests are best performed within the early stages of acute infection, when viral load is at its highest levels (i.e. within the first 5-7 days from symptom onset), after which antigen levels may drop significantly. In conjunction with clinical findings, a positive result is generally considered to be accurate, however further testing by PCR may be required to confirm infection. A negative result in a symptomatic patient, would require further confirmatory testing via PCR testing.

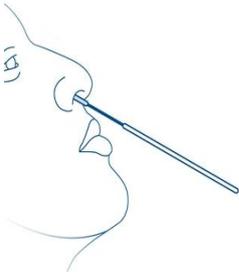
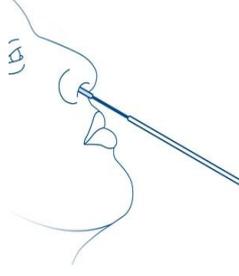
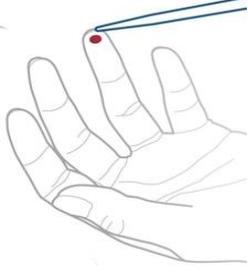
Utilising Antibodies and Antigens in Diagnostics

When a person is infected with a pathogen such as SARS-CoV-2, the body produces antibodies that bind specifically to the antigens to help eliminate the pathogen. This binding can be harnessed to develop antibody and antigen based diagnostic tests.

An antibody test reveals if a person has already been exposed to an infection, by detecting antibodies in their blood or serum. Antibody tests are not usually used to diagnose current infection as it takes the body some time to produce antibodies. Antibody tests are useful to help track the spread of a disease, identify those who should be prioritized for vaccinations, and highlight potential donors for convalescent plasma therapy.

An antigen test reveals if a person is currently infected with a pathogen. Once the infection has gone, the antigen disappears Unlike nucleic acid based tests such as PCR, which detect the presence of genetic material, antigen tests detect proteins, such as those found on the surface of a virus.

The three main types of SARS-CoV-2 tests are:

Nucleic acid detection tests	Rapid antigen tests	Rapid IgM/IgG tests and serology tests
		
to detect SARS-CoV-2 viral (Ribonucleic acid) RNA	to detect antigen viral proteins from the SARS-CoV-2 virus	to detect IgM and/or IgG antibodies against SARS-CoV-2

Screening and Testing COVID-19

The purpose of this document is to provide a current evaluation of the different testing strategies for COVID 19 within Healthcare and related industries and to recommend a possible Point of Care (POC) screening framework that may benefit the response to the COVID 19 pandemic.

COVID-19 POC testing is a rapidly developing field and the use cases and scenarios presented in this report will change in the light of new evidence and the emerging research base.

For COVID-19, the ideal scenario would be a rapid and sensitive POC and/or a test for the virus responsible for COVID 19. This would be available to:

- screen individuals to identify if they have the virus (i.e. an infectious phase)
- detect if individuals have already been exposed to SARS CoV 2 and therefore can't be infected again (the evidence base for the duration of immunity for COVID 19 is evolving).
- Identify asymptomatic carriers of the virus who are not eligible for PCR testing

Unfortunately, there is no single test that can determine both if a person is currently infected (now done via the PCR test) or has been infected in the past (now done via antibody test). PCR based testing is the best currently available testing technology for acute symptomatic individuals during the COVID 19 pandemic. ^{1,2,3,4}

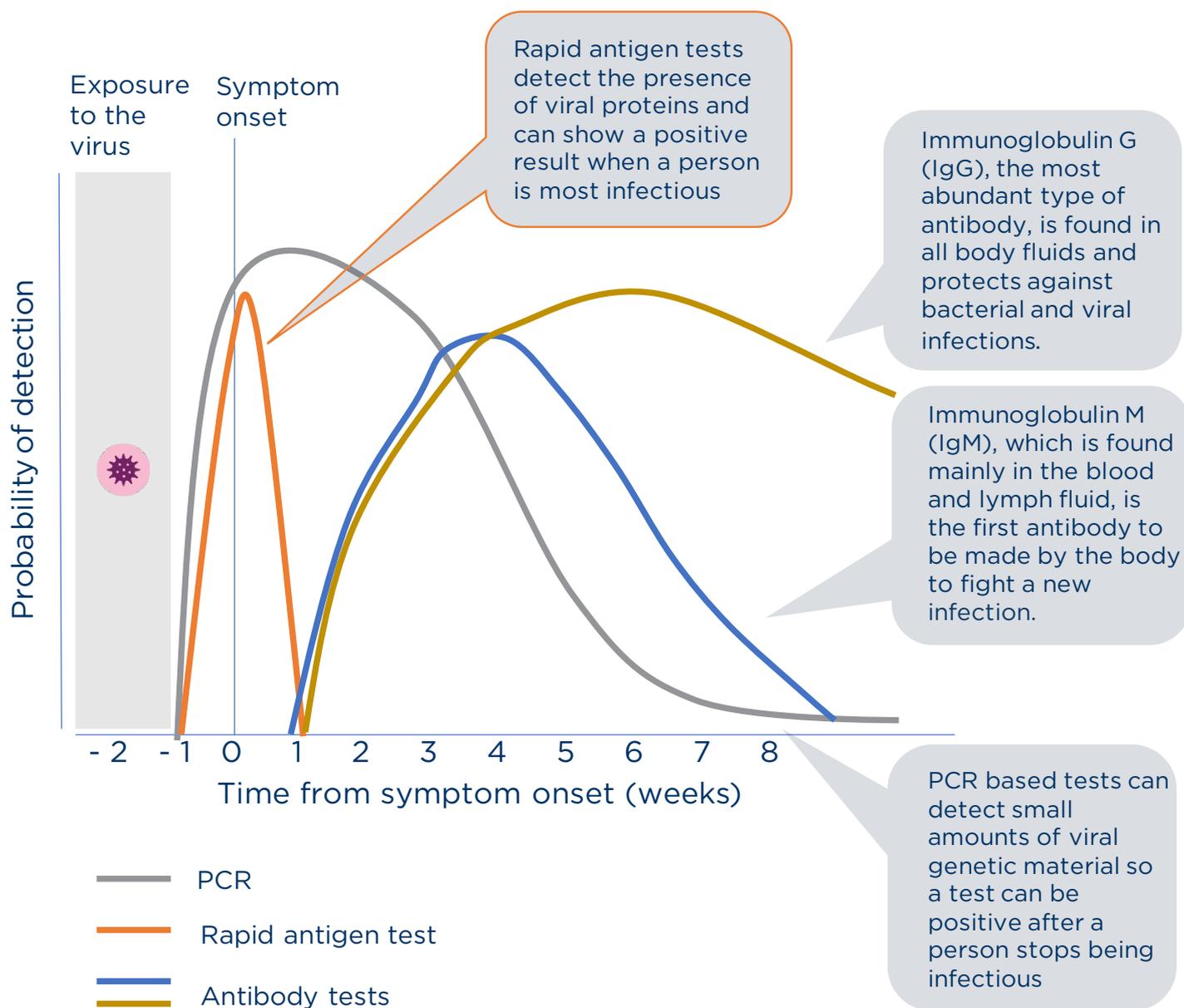
The current available tests are:

Summary of Differences between PCR Tests and Rapid Antigen Tests

	Nucleic acid detection tests PCR	Rapid antigen tests
Intended Use	Detect current infection	Detect current infection
Analyte Detected	Viral RNA	Viral Antigens
Specimen Type(s)	Nasal Swab, Sputum, Saliva	Nasal Swab
Sensitivity	High	Moderate
Specificity	High	High
Test Complexity	Laboratory	Relatively easy to use
Turnaround Time	Ranges from 15 minutes to >2 days	Approximately 15 minutes
Cost/Test	Moderate	Low

The Infectious period of COVID-19 remains unknown, however there is some evidence to support the occurrence of pre symptomatic or asymptomatic transmission. As a precautionary approach, cases are considered to be infectious 24 hrs prior to onset of symptoms. Cases are considered to pose a risk of onward transmission and require isolation. POC tests due not confirm virus presence but provide evidence of recent infection, this information is useful to establishing transmission risk timelines and when access to PCR testing is limited in pandemic situations.

Different types of COVID-19 tests can detect the presence of SARS-CoV-2 virus or when the body responds to the infection. The likelihood of a positive result depends on which test is used and at what time that test is used during the days and weeks after infection.



COVID-19 Ag Rapid Test

Point of Care Testing Guide

1 Set Up

Clinical staff undertaking POC test must be trained and knowledgeable regarding use of PPE for screening



Collection of specimens must be performed with accurate identification of the patient or client and ensuring traceability of the specimen to the report.

- correct test
- correct patient
- correct patient preparation
- correct collection technique and processing

2 Take the sample

THROAT SWAB



To collect a throat swab specimen, rub the sterile swab on both tonsil surfaces and the posterior pharynx.

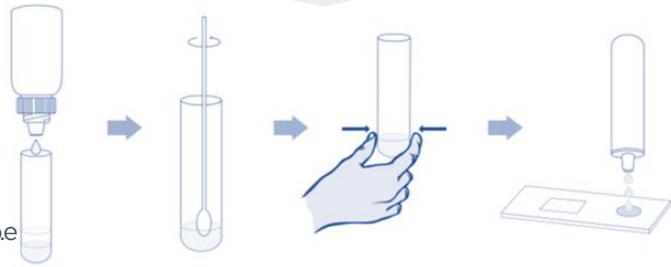
NOSE SWAB



Insert the sterile swab into the Nostril. Using gentle rotation, push the swab until resistance is met. Rotate the swab a few times against the nasopharyngeal wall.

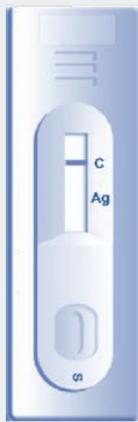
3 Process the sample using the POC test kit

Add **0.5 mL** of the sample extraction buffer into the extraction tube up to the **lower marked line**. Insert swab into extraction tube. Invert tube and add 3 drops of test sample into sample well by gently squeezing the tube. Start timer for **15 mins**

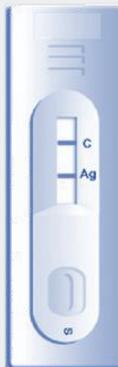


4 Interpret Results

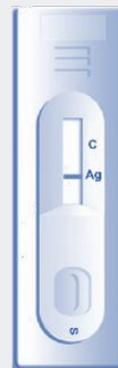
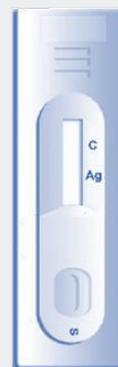
NEGATIVE RESULT: C LINE ONLY
the test indicates that no detectable SARS-CoV-2 virus is present in the specimen. The result is negative or non-reactive.



POSITIVE RESULT: C LINE and AG LINE
the test indicates the presence of SARS-CoV-2 virus. The result is COVID-19 positive or reactive.

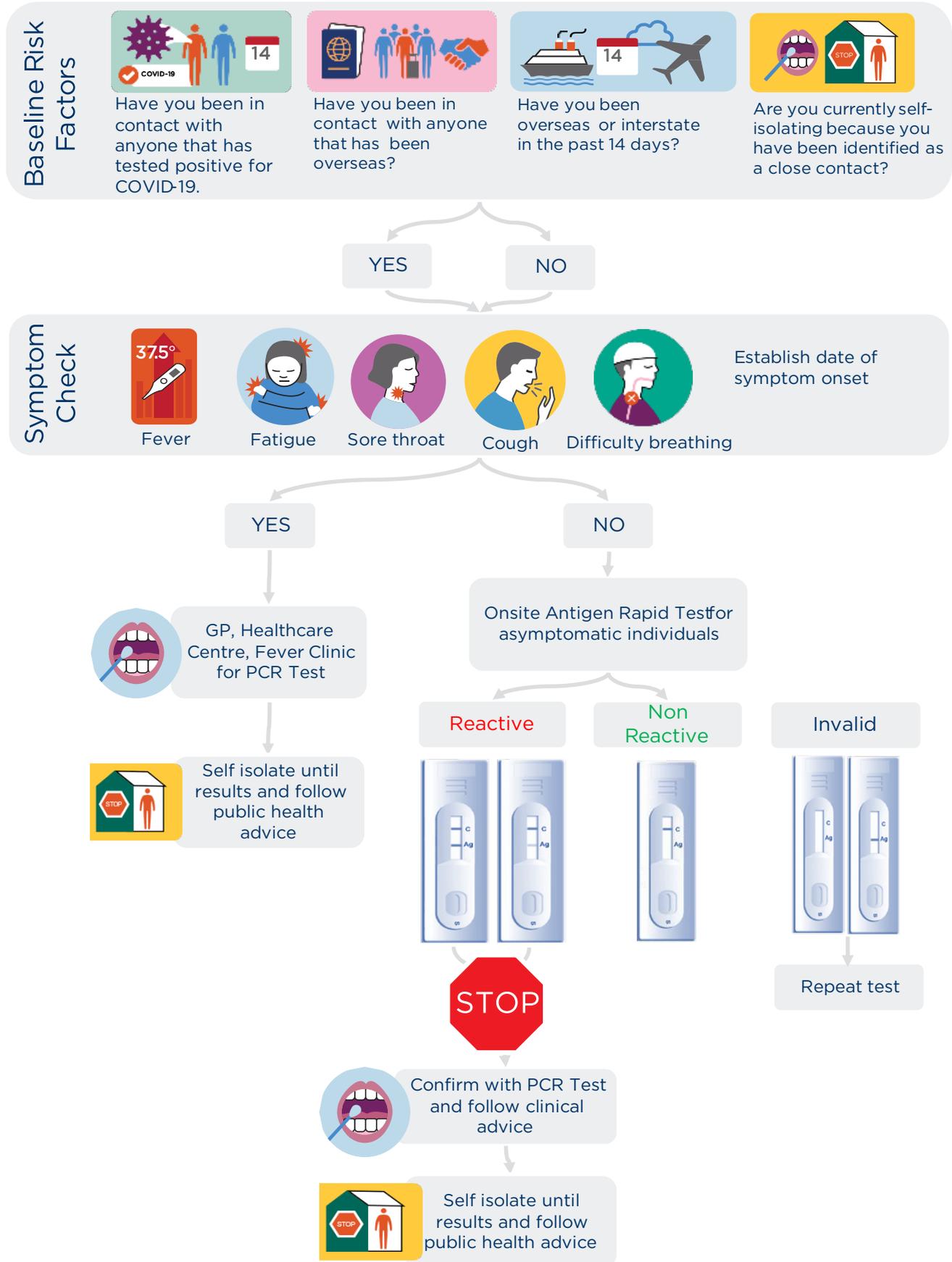


INVALID:
If no C line develops, the assay is invalid regardless of colour development on the Ag line. Repeat the assay with a new device.



COVID-19 Ag Rapid Test

Point of Care Testing Flowchart



Key Terms

Antibody	A protein made by your body to combat infection by virus. Antibodies to the SARS-CoV-2 virus are likely to help protect the body from re-infection as they can neutralise the virus. [comment: reinfection has only been shown in a single study in macaques with 2 animals and no testing as to role of antibody-hedging text added here]
Antibody test	Is a test to see if a patient has generated antibodies (see IgG and IgM) to the SARS-CoV-2 virus.
Antigen test	Is a test for the SARS-CoV-2 virus that detects surface proteins of the virus rather than the viral RNA (see PCR).
COVID-19	The name given to the disease pandemic caused by the SARS-CoV-2 virus which arose in the Wuhan Province in China in late 2019.
ELISA	Enzyme-linked immunosorbent assay. In the context of COVID-19, this is a test conducted inside a diagnostic laboratory to test for antibodies (see IgG and IgM) to coronavirus. It may be used as a measure of immune response to the virus.
False positive	When a test for COVID-19 comes up as positive when in fact the patient is not carrying the virus or been previously exposed.
False negative	When a test for COVID-19 comes up as negative when in fact the patient is carrying the virus.
IgG	A type of antibody that is typically generated late in the SARS-CoV-2 infection.
IgM	A type of antibody that is typically generated early in the SARS-CoV-2 infection.
PCR	Polymerase Chain Reaction is a test by which RNA (or DNA) is replicated and then detected. This is the core test for SARS-CoV-2 virus as it is very sensitive and specific.
POC	Point-of-Care - a test that is typically a 'yes/no' answer that is conducted rapidly at the patient's bedside, at a workplace or in a clinic.
RNA	The form of genetic material that the SARS-CoV-2 virus and related viruses use as opposed to many other viruses and humans that use DNA.
SARS-CoV-2	The virus that is responsible for the COVID-19 epidemic.
Serological	A term used to describe how our body fluids respond to the virus, for example the formation of antibodies.
Validation	The process by which a test for COVID-19 is assessed to see how reliable it is. Test validation takes many forms but centres around how well a test performs in terms of sensitivity and precision.

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