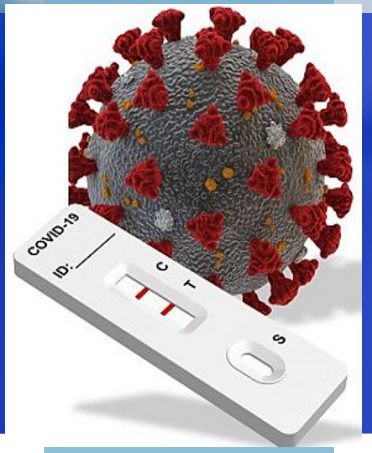
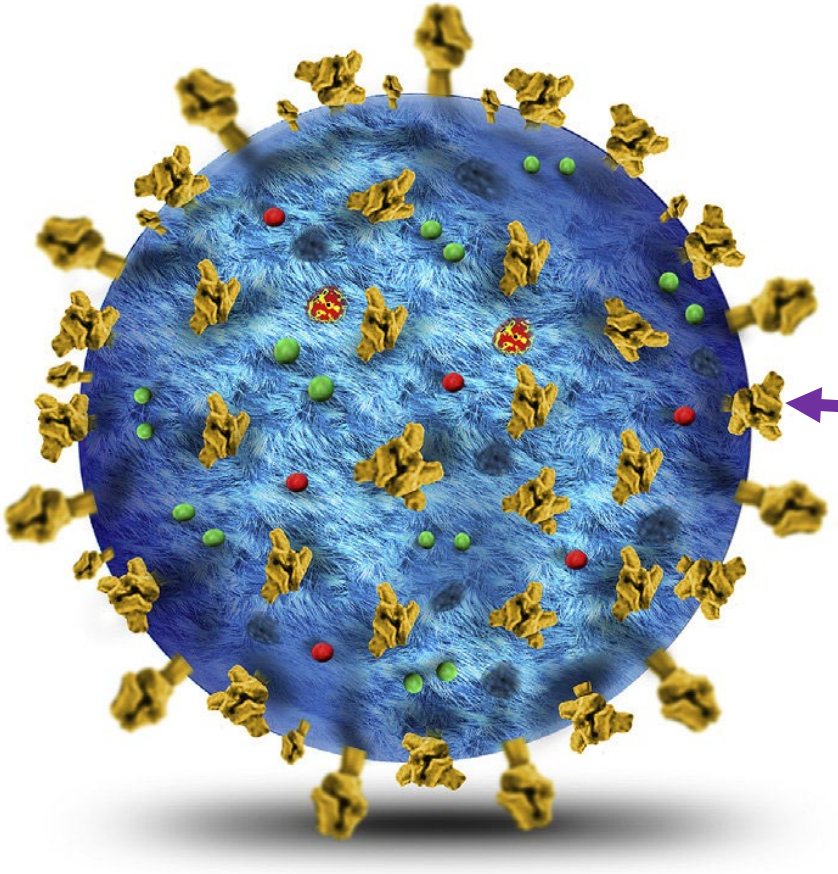


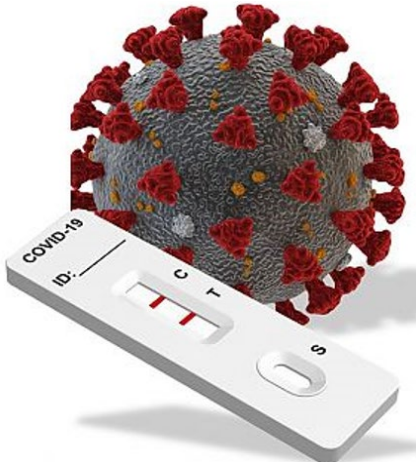
OnSite® COVID-19 Ag Rapid Test

Covid-19 - Positive or Negative in 15 minutes

MD SOLUTIONS
AUSTRALASIA

Human Coronavirus



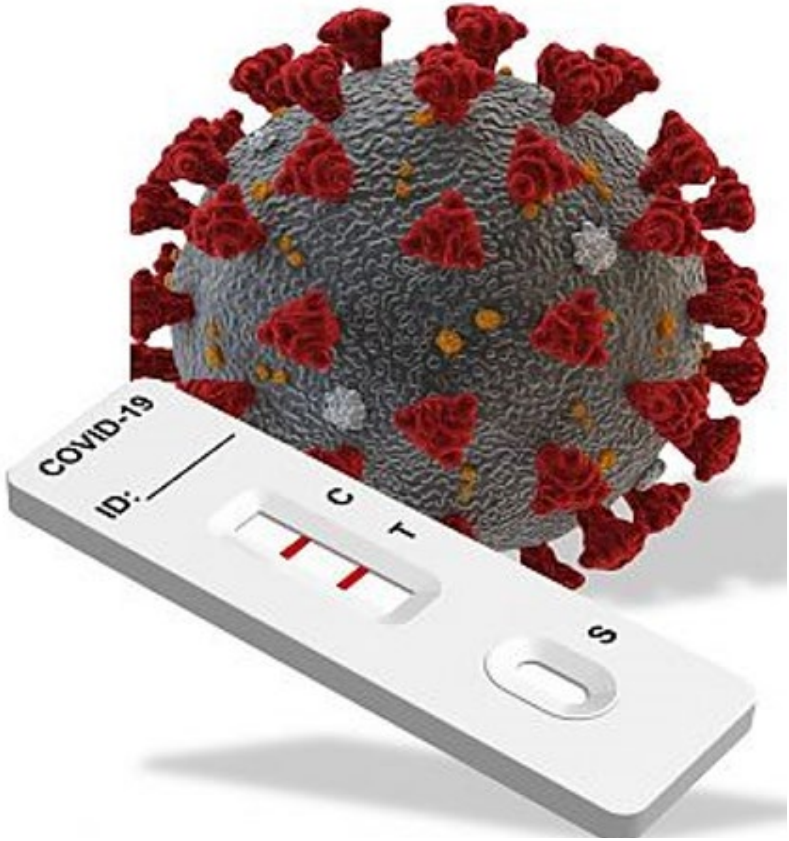


Viral proteins detected by Rapid Antigen Tests

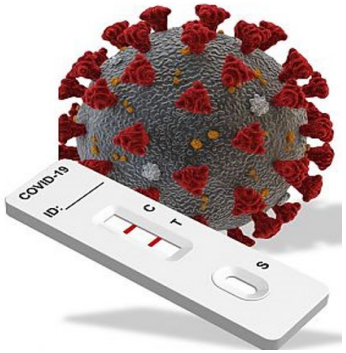
- **Rapid Antigen tests target the 'spike protein' that studs the surface of the coronavirus.**

OUTLINE

- Principles
- Specimen requirements
- Safety
- Benefits
- Kit Information
- Assay Procedure, Results Interpretation and Follow-up
- Performance characteristics
- Storage
- Quality of the test



PRINCIPLES



- ***What is a Rapid Antigen Test (RAT)?***

RAT stands for rapid diagnostic test. **RAT**s are easy-to-perform tests that may be used out of **laboratory settings** and typically give results in **15–20** minutes.

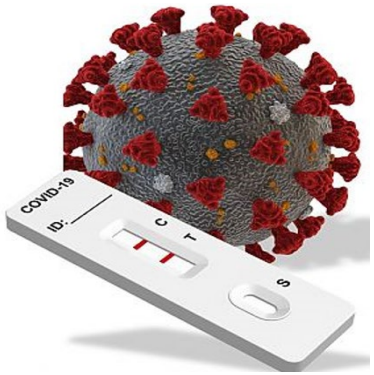
- ***What is the difference between rapid antigen testing and PCR?***

PCR detects the SARS-CoV-2 viral genetic material **(RNA),** whereas antigen tests detect SARS-CoV-2 **specific antigens/proteins** in a person's body. Both tests are used to detect active infection with SARS-CoV-2.

- ***What is the underlying technology for the test?***

The underlying technology for the test is lateral flow immuno-chromatography

SPECIMEN REQUIREMENTS



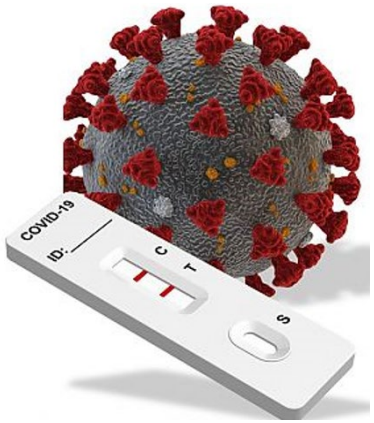
- ***What samples can I test using antigen tests?***

Nasopharyngeal swabs are the often-preferred sample for testing using SARS-CoV-2 Antigen RATs. As new tests become available, other sample types are being used, such as **nasal swabs.** Always refer to the kit's Instructions for Use (IFU) which will specify the type of samples to use.

- ***How long can samples be stored after collection before testing?***

Some test samples should be tested **within 8 hours** of collection when stored at ambient temperature.

SPECIMEN REQUIREMENTS



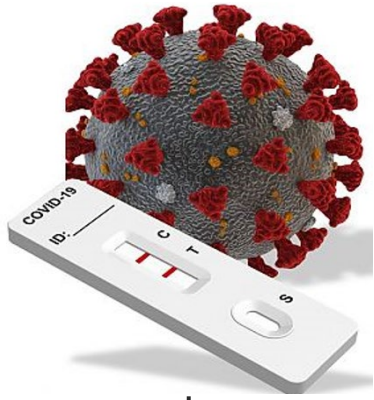
- ***How should samples be stored while awaiting testing or during shipment?***

Follow the manufacturer's instructions for use. In some cases, samples can be **stored at 4–30°C** prior to testing. If the ambient temperature is **over 30°C**, samples should be stored in a **refrigerator or cool box** during transportation and prior to testing.

- ***The sample is bloody, can I still use it for testing?***

Yes. Samples that contain traces of blood can still be used for testing with an antigen test.

SAFETY



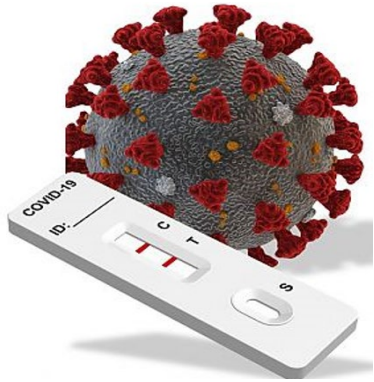
- ***What safety requirements are needed for collecting samples and performing RATs?***

Personal protective equipment **(PPE),** including gloves, eye protection, medical mask and gown, must be worn while collecting samples from persons and while performing RAT.

- ***How should I dispose of waste (e.g., used tests, sample containers, etc.)?***

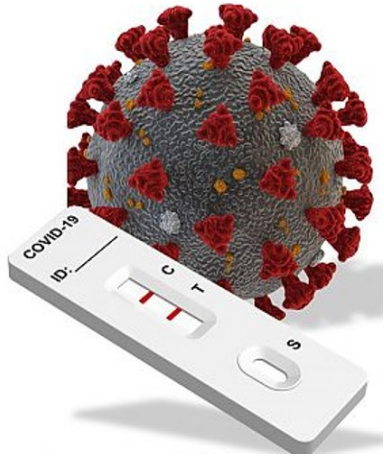
All waste generated from the testing of specimens from suspected or confirmed COVID-19 cases should be classified as **biohazardous waste** and should be handled according to applicable local state guidelines.

BENEFITS



- Getting a quick result within 15-20 minutes – no need for a follow-up to discuss
- Easy handling which does not require specific training
- No instrument required
- Does not need to be run by laboratory/medical personnel
- Facilitates patient treatment decisions quickly
- Simple, time-saving procedure
- All necessary reagents provided

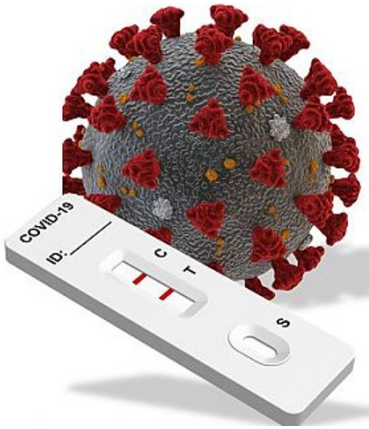
KIT INFORMATION



The following components are needed for a test and included in the kit:

- 20 Test cassettes (individually in a foil pouch with desiccant)
- Prefilled Extraction buffer tube
- Nozzle cap
- Sterile swab
- Instructions for use
- 1 workstation

SAMPLE COLLECTION



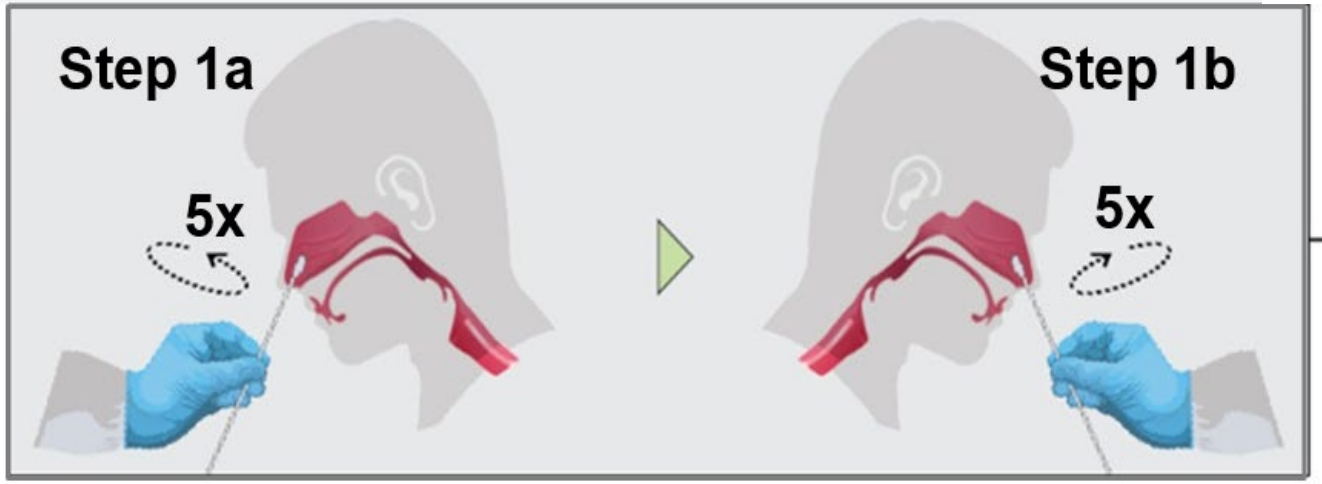


Figure 1 (Nasal Swab)

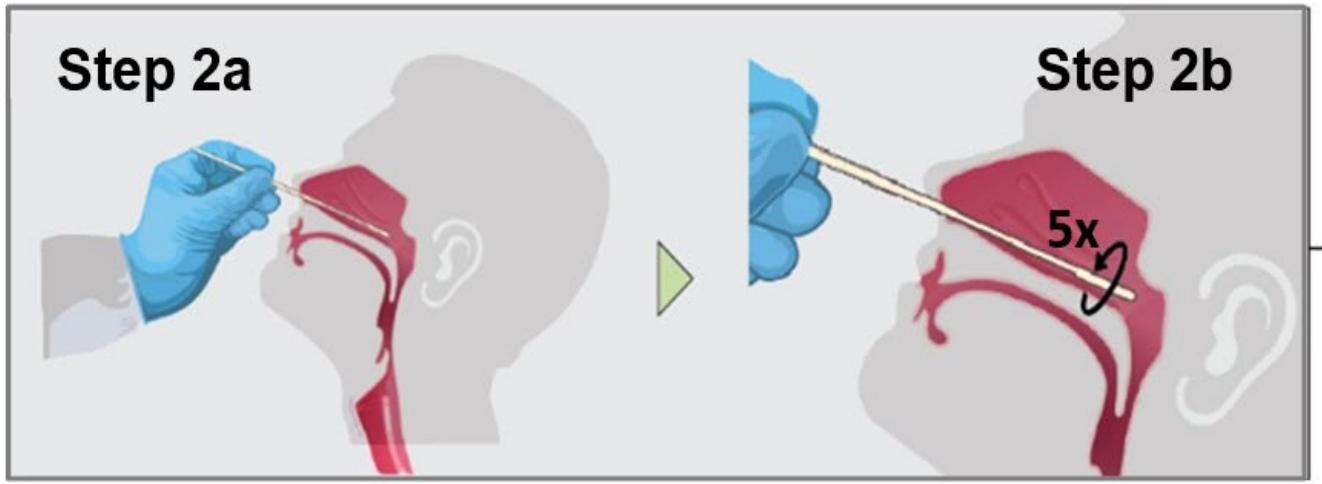
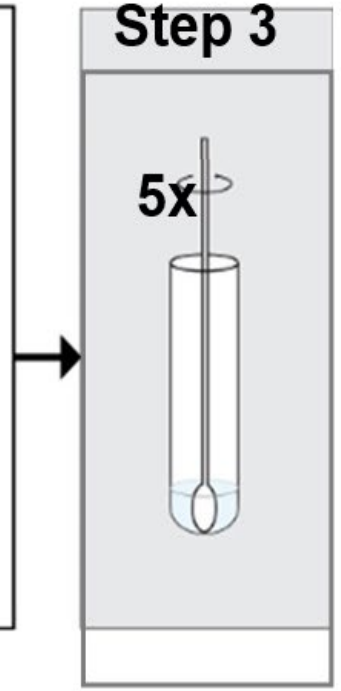
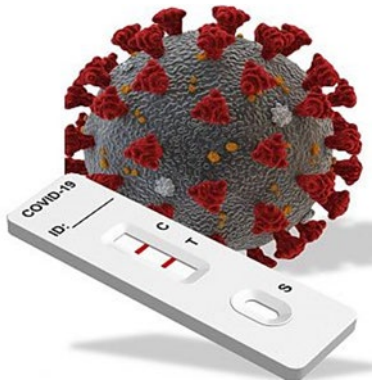
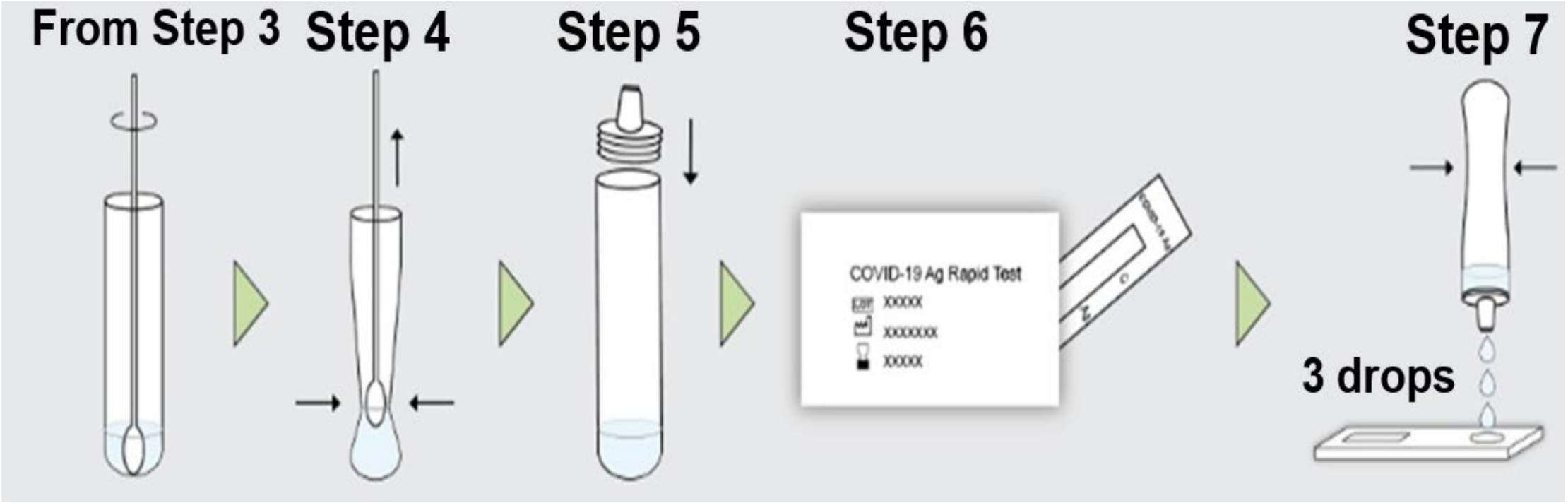


Figure 2 (Nasopharyngeal Swab

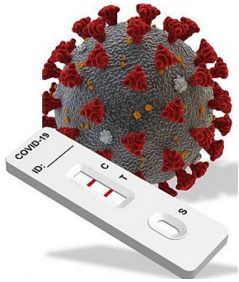


ASSAY PROCEDURE

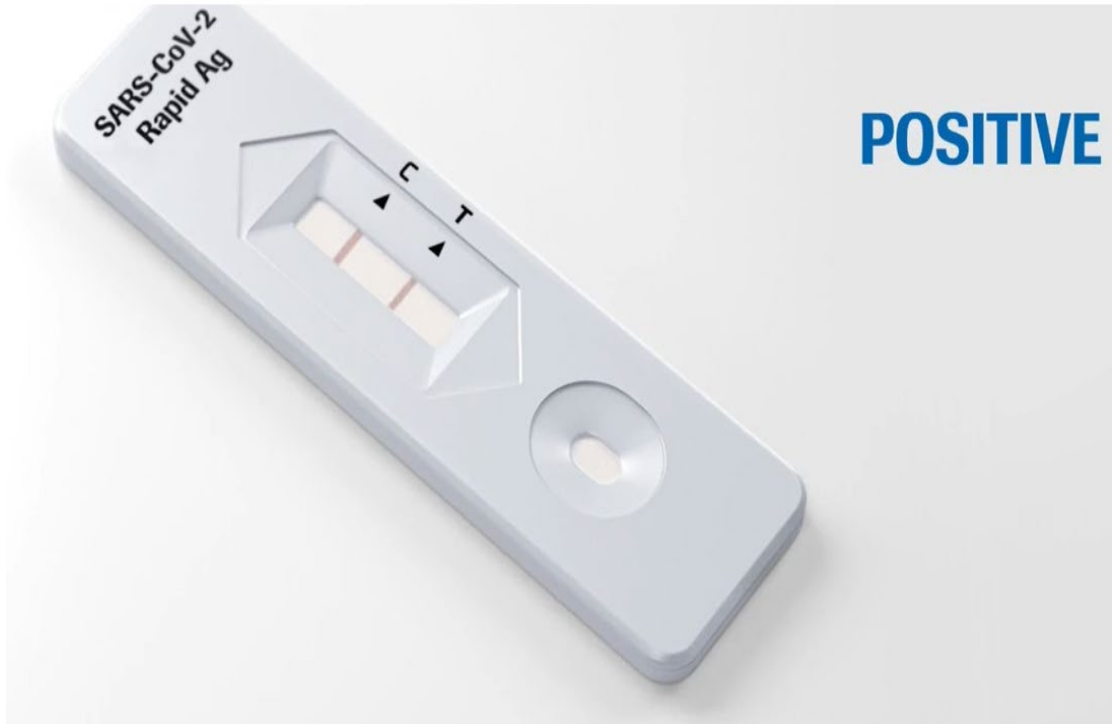


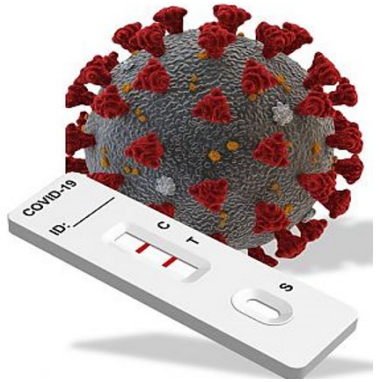


RESULTS INTERPRETATION

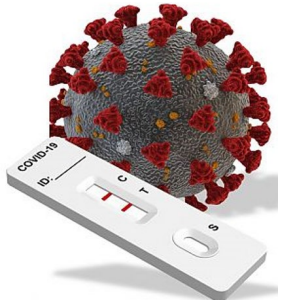


- When the control band is visible, but the test band is not visible, it means the test is negative.



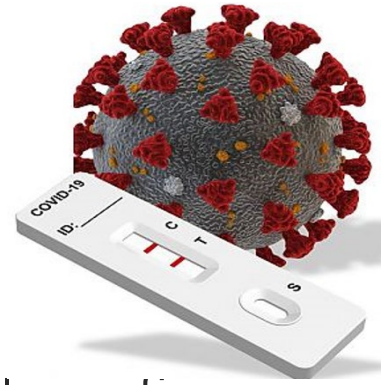


- In case of a positive result, a colored line appears in the lower section of the result window. This is the test line (T).
- Even if the test line is very faint or not uniform, the test result should be interpreted as a positive result.



- A colored line appears in the top section of the result window to show that the test is working properly. This is the control line (C).
- Even if the control line is faint, the test should be considered to have been performed properly.
- If no control line is visible the test is invalid.

FOLLOW UP



- ***If you get a positive test result***

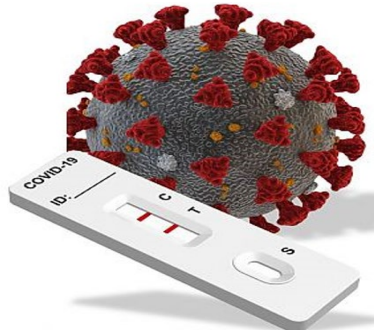
If you get a positive rapid antigen test result, you must

- immediately get a standard COVID-19 test (PCR) at a specified state govt testing clinic to confirm the result of your screening test
- isolate until you get a negative result from your state Health.
- Isolating immediately after your positive result, or if you have symptoms, can help break chains of transmission and limit the spread of COVID-19 at your workplace or school.

- ***If you get a negative test result***

In line with the Rapid antigen testing indicative process - under the supervision of a health practitioner (PDF, 434.47 KB) , where a person receives a negative result, they must have the test result registered with testing supervisor; the person can then check out of rapid antigen testing site and go to their work site.

PERFORMANCE CHARACTERISTICS



Nasopharyngeal swab specimens

RT-PCR Test (Reference)	OnSite COVID-19 Ag Rapid Test Result		
	Positive	Negative	Total
Positive	60	5	65
Negative	0	370	370
Total	60	375	435

Nasopharyngeal Swabs

Sensitivity: 92.3%
Specificity: 100%

Nasal swab specimens

RT-PCR Test (Reference)	OnSite COVID-19 Ag Rapid Test Result		
	Positive	Negative	Total
Positive	36	2	38
Negative	0	170	170
Total	36	172	208

Nasal Swabs

Sensitivity: 94.7%
Specificity: 100%

Why us?

Fast:

Result in 15-20 mins

Accurate

Sensitivity 92.3% (Nasopharyngeal Swab)

94.7% (Nasal Swab)

Specificity 100% for both swabs

Easy to use:

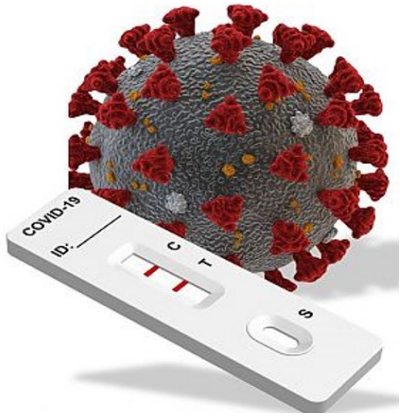
Vial already prefilled with buffer

Early detection:

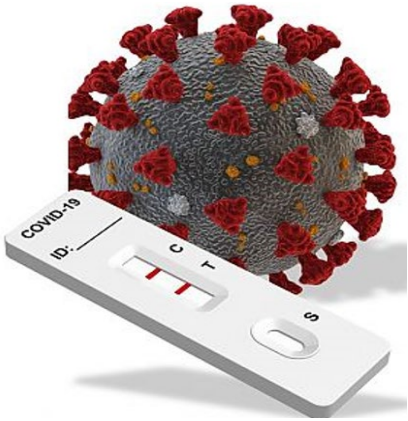
Very low LoD of 280 $TCID_{50}$/mL allows infected people to quarantine BEFORE they become highly contagious

Convenient:

Nasal or Nasopharyngeal swabs



STORAGE



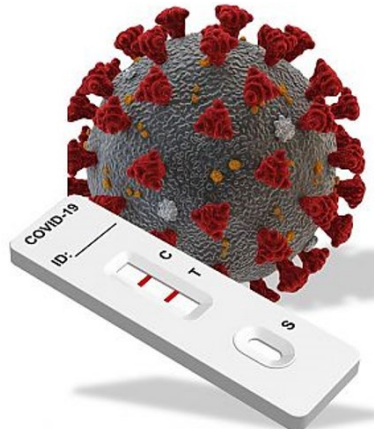
- ***How should I store the kit?***

Follow the manufacturer's instructions, typically found on the side of the box for test kits. Typically, the kit should be stored at **2–30°C out of direct sunlight**.

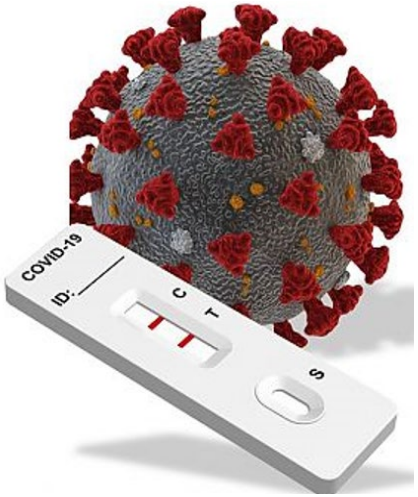
- ***What is the shelf life of the kit?***

Kit materials are stable until the expiration date printed on the outer box. Typically, shelf life is **24 months from the date of manufacture.**

FACTORS AFFECTS THE QUALITY OF THE TEST



- ***What factors can potentially affect the quality of the test?***
  - The quality of the sample
  - Using expired test kits
  - Exceeding the recommended storage conditions for the kits
  - Poor packaging
  - Not following the instructions for use



QUESTIONS?