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Scale Up COVID-19 Antigen Testing

Panbio™ COVID-19 Ag Rapid Test Device

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Introduction

COVID-19

COVID-19: Coronavirus Infectious Disease-2019

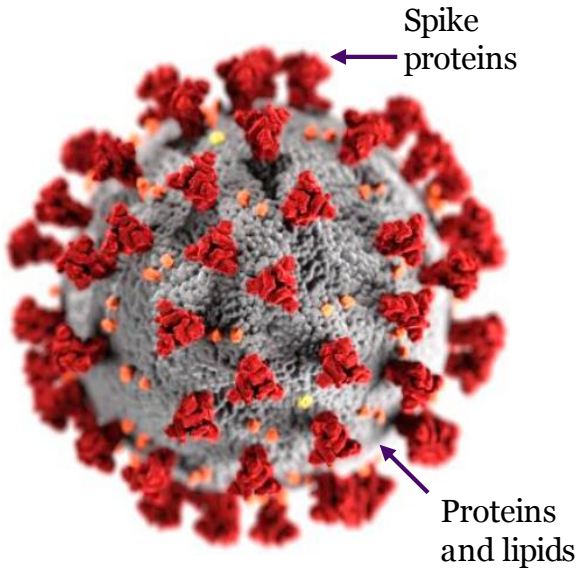
- Caused by SARS-CoV-2
- Declared a pandemic by the WHO on 11-Mar-2020

Six other types of Coronavirus are known to infect humans[1]

- Some cause common cold
- Two caused previous outbreaks: SARS and MERS

Attributes:

- Named after the crownlike spikes on the surface[1]
- Virus is enveloped in bubble of oily lipid molecules
- Oily membrane falls apart on contact with soap[2]



1. CDC Human Coronavirus Types 2020. https://www.cdc.gov/coronavirus/types.html
2. https://www.nytimes.com/interactive/2020/03/11/science/how-coronavirus-hijacks-your-cells.html?
Photo credit: CDC Public Domain https://phil.cdc.gov/Details.aspx?pid=23312

Transmission and Infection

Respiratory droplets enter the body through the nose, mouth or eyes[1]

Attaches to cells in airway that express the ACE2 receptor protein

- Virus infects a cell by fusing its oily membrane
- Hijacks the cell, assembles new copies of the virus and releases millions of copies

Clinical Presentation (& rate of occurrence)[2]

- *Mild to Moderate cases* (81%)
  - mild symptoms up to mild pneumonia
- *Severe cases* (14%)
  - Dyspnea, hypoxia, or >50% lung involvement on imaging)
- *Critical cases* (5%)
  - respiratory failure, shock, or multiorgan system disfunction

High Risk Patient Population[2]

- Elderly, Cardiovascular Disease, Diabetes, Hypertension

1. CDC How COVID19 Spreads 2020. https://www.cdc.gov/coronavirus/2019-ncov/prepare/transmission.html
2. CDC Management of Patients with Confirmed 2019-nCoV June 2020. https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html

The role of Antigens in COVID-19 testing

Suggested Use Cases for Ag (FIND)[1]

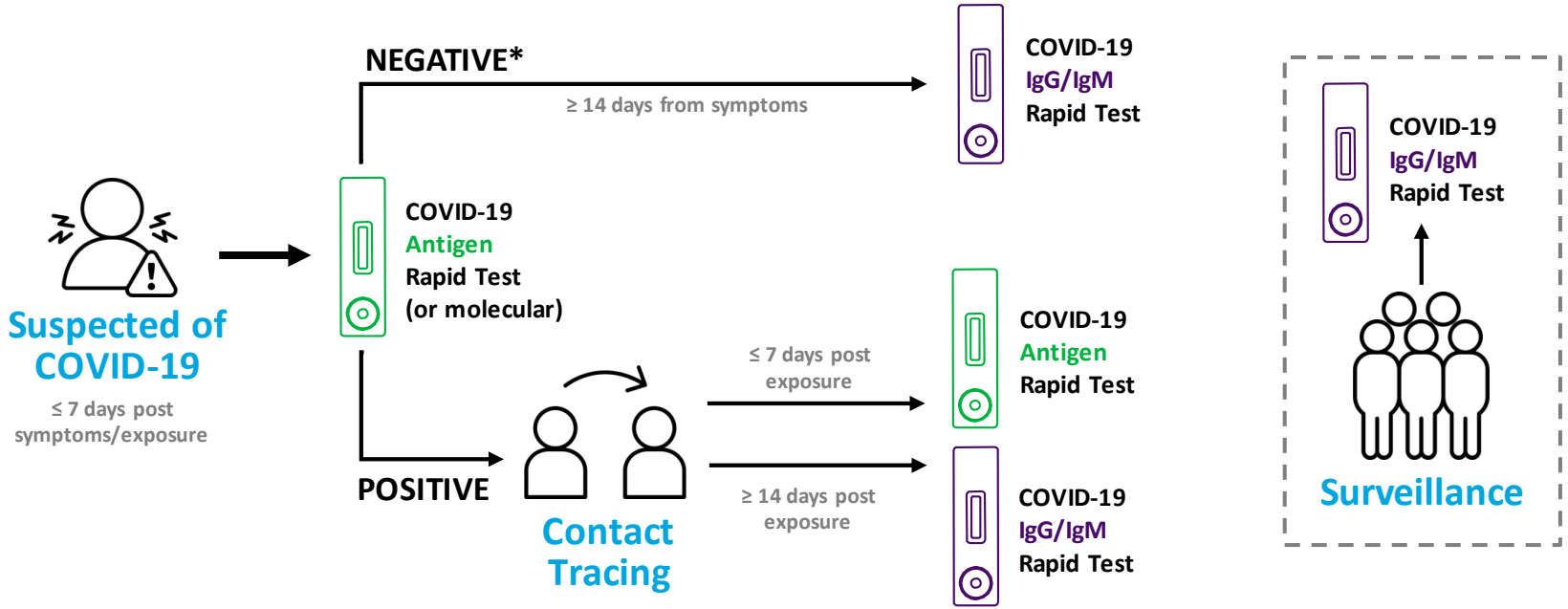
- Ag tests are useful for detection of COVID-19 active infection.
- Ag RDTs should be prioritized for case management to enable decentralized testing, especially when access to PCR testing is limited.

Use Cases:

- Triage suspect cases
- Confirm active infection
- Contact tracing

1. FIND Rapid Diagnostic Tests for COVID-19, 18 May 2020. https://www.finddx.org/wp-content/uploads/2020/05/FIND_COVID-19_RDTs_18.05.2020.pdf

COVID-19 Testing of Suspected Individuals[1,2,3]

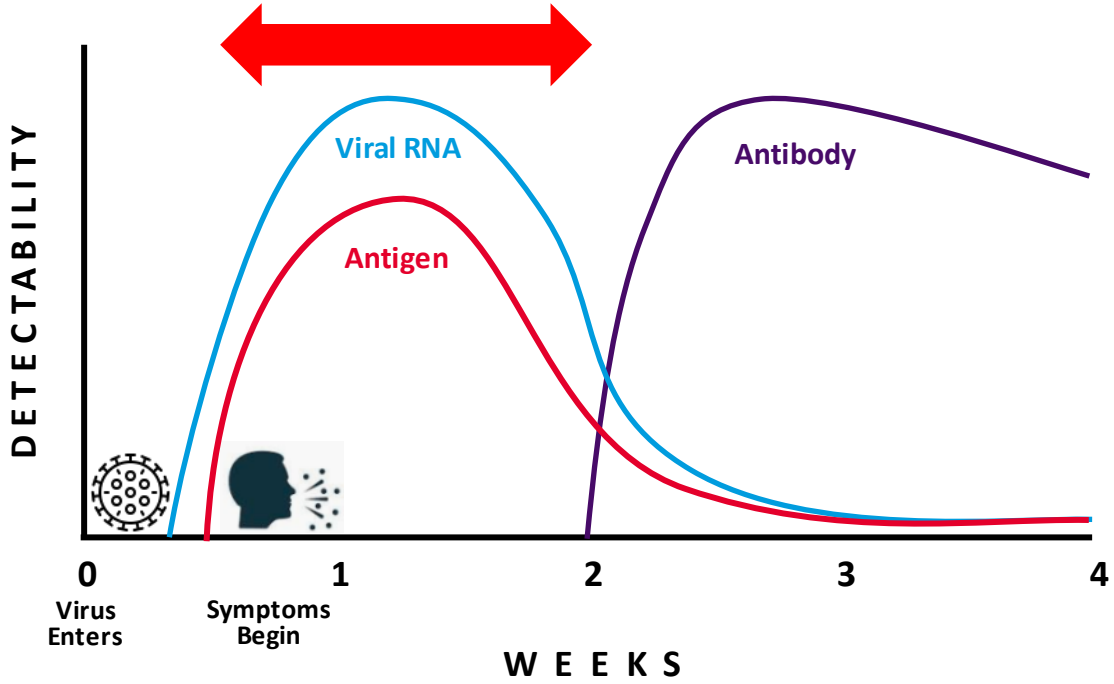


***Note: Negative results must be combined with clinical observations, patient history, and epidemiological information. Can potentially consider Molecular testing, but this is NOT a requirement with the Panbio™ COVID-19 Ag Antigen test.**

This illustration is adapted from guidelines published by FIND, Africa CDC, and IDSA and is intended for informational purpose only. Customers are solely responsible for designing and implementing testing strategies and for making any decisions based on test results.

1. FIND. Rapid Diagnostic Tests for COVID-19. (18 May 2020). https://www.finddx.org/wp-content/uploads/2020/05/FIND_COVID-19_RDTs_18.05.2020.pdf
2. Africa CDC Interim Guidance on use of Rapid Antibody Tests for COVID-19. (June 2020). https://africacdc.org/download/interim-guidance-on-the-use-of-rapid-antibody-tests-for-covid-19-response
3. Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19 Serologic testing https://www.idsociety.org/practice-guideline/covid-19-guideline-serology/#:~:text=s1%2Ds5).-,Recommendation%201%3A%20Serologic%20testing%20during%20first%20two%20weeks%20after%20symptom,very%20low%20certainty%20of%20evidence).

When to Test for Antigen[1,2,3]



1. Sethuraman, N., Jeremiah, SS., Ryo, A. Interpreting Diagnostic Tests for SARS-CoV-2. JAMA. 6 May 2020. doi: 10.1001/jama.2020.8259
2. Theel ES, The role of antibody testing for SARS-CoV-2: is there one? J Clin Microbiol 58:e00797-20. 2020. https://doi.org/10.1128/JCM.00797-20.
3. CDC Symptom-Based Strategy to Discontinue Isolation for Persons with COVID-19. Decision Memo. May 3, 2020

Diagnostic Tests Types and Use[1,2]

	Molecular Test	Immunoassay Tests (Current infection)		Non-disease specific test
		Antigen Test (Current infection)	Antibody Test (Past exposure to virus)	
How does it work?	Detects viral genetic material through a technique called polymerase chain reaction (PCR) to amplify sample	Detects antigen through an enzyme linked immunosorbent assay (ELISA) or lateral flow test.	Detects antibodies through ELISA test. Or lateral flow test, for example	Detects symptoms or signs of disease through scans, imaging or observation
Where is the test taken?	Typically performed in lab although samples may be taken outside of the lab.	May be performed in laboratory or point of care	May be performed in laboratory or point of care	In a hospital, clinic, or point of care depending on equipment required
What is it typically used for?	Testing suspected cases of COVID-19	Testing suspected cases of COVID-19 or candidates for further testing (like PCR)	Assessing infection and/or exposure rates in a community	Screening or triage for further testing
What does a positive result indicate?	Confirms a case of SARS-CoV-2 infection	Confirms a case of SARS-CoV-2 infection or potential infection	Previous exposure to SARS-CoV-2 or potential of previous SARS-CoV-2 infection	Further testing is needed if results suggest possible SARS-CoV-2 infection

1. Kelly-Cirino, C. Special COVID-19 ECHO Session #2 Webinar from African Society of Laboratory Medicine. (06 May 2020). https://aslm.org/wp-content/uploads/2020/04/COVID-19_FIND_ECHO-session-30.03.2020-FINAL.pdf
2. Patel, R., Babady, E., Theel, ES., et. al. Report from the American Society for Microbiology COVID-19 International Summit, 23 March 2020: Value of Diagnostic Testing for SARS–CoV-2/COVID-19. https://mbio.asm.org/content/11/2/e00722-20

COVID-19 Antigen Test

- **How does it work?**
  - Directly detects the presence of the virus, indicating **active infection** (i.e. replication of the virus)
- **Where and who performs?**
  - Trained healthcare workers, wearing appropriate personal protective equipment (PPE) at decentralized points of need
- **Benefits**
  - Enables fast, **decentralized access to direct testing** for the virus, relieving the burden on the laboratory testing system
  - If used for contact tracing, provides an **objective marker to define chains of transmission**

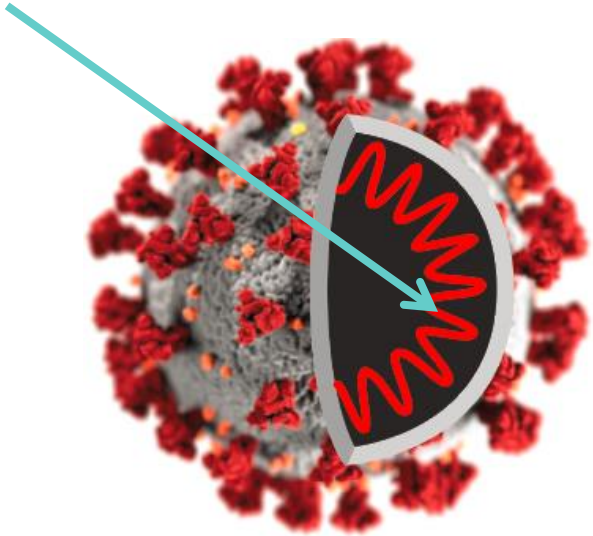
Introducing the Panbio™ COVID-19 Rapid Test Device

Panbio™ COVID-19 Ag Rapid Test Device

- Abbott's Panbio COVID-19 Ag Rapid Test Device is intended for the detection of the SARS-CoV-2 virus in people suspected of having COVID-19
- Requires no instrumentation and provides results in 15-20 minutes, making it a valuable tool for mass testing in decentralized settings
- Designed to offer an accessible, portable, and scalable option for COVID-19 testing
- May also be a very useful tool for supporting public health strategies, such as contact tracing and large-scale testing of people suspected of having an active infection

Panbio™ COVID-19 Ag Rapid Test Device

- *In vitro* diagnostic rapid test for qualitative detection of SARS-CoV-2 antigen (Ag)
- Detects nucleocapsid protein inside the SARS-CoV-2 virus



Intended Use

Panbio™ COVID-19 Ag Rapid Test Device is an *in vitro* diagnostic rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasopharyngeal swab specimens from individuals who meet COVID-19 clinical and / or epidemiological criteria.

Panbio™ COVID-19 Ag Rapid Test Device is for professional use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.

The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The test is not intended to be used as a donor screening test for SARS-CoV-2.

Specifications

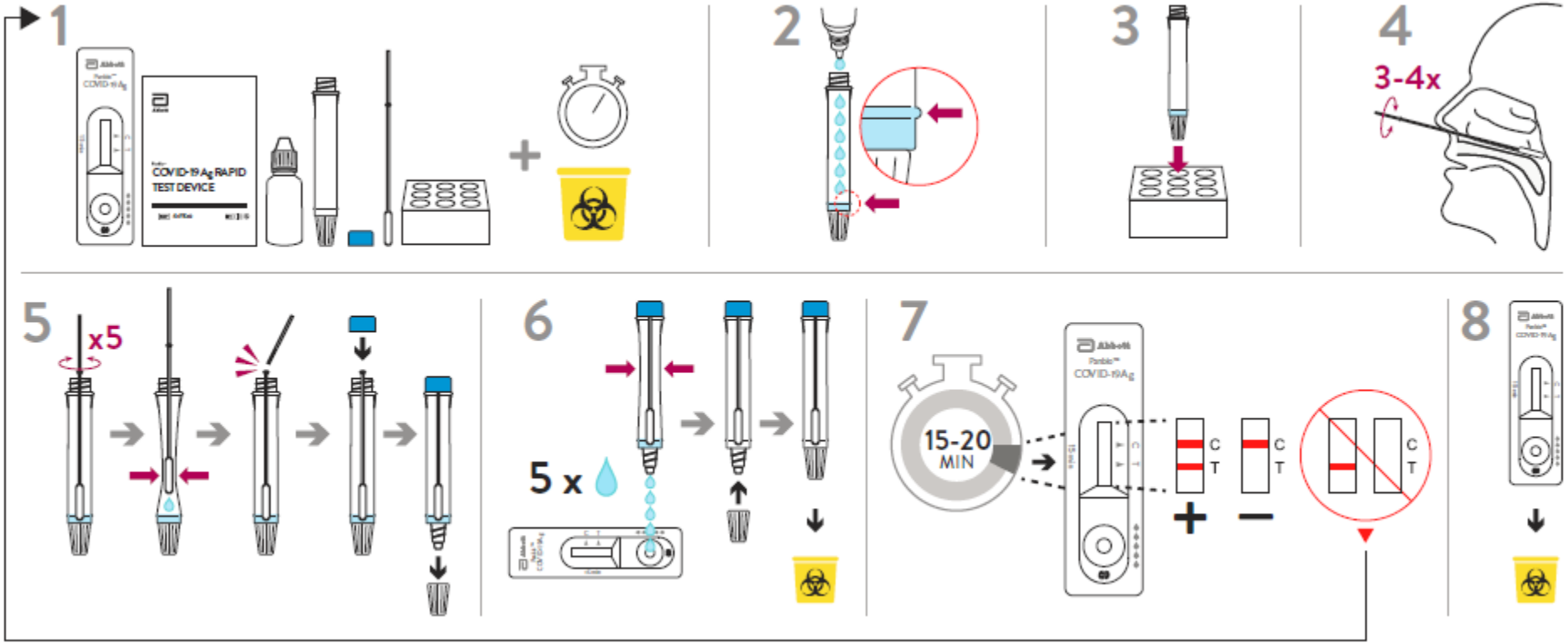
Performance

- Sensitivity: 93.3% (98.2% for samples with Ct values ≤33)
- Specificity: 99.4%

Specifications

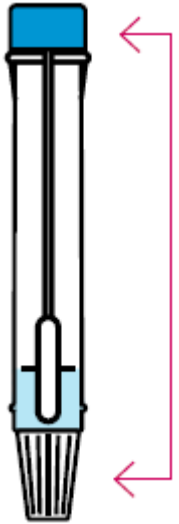
- Test time: 15–20 minutes
- Storage: 2°C–30°C
- CE Mark
- Sample Type: Nasopharyngeal swab

Test Procedure



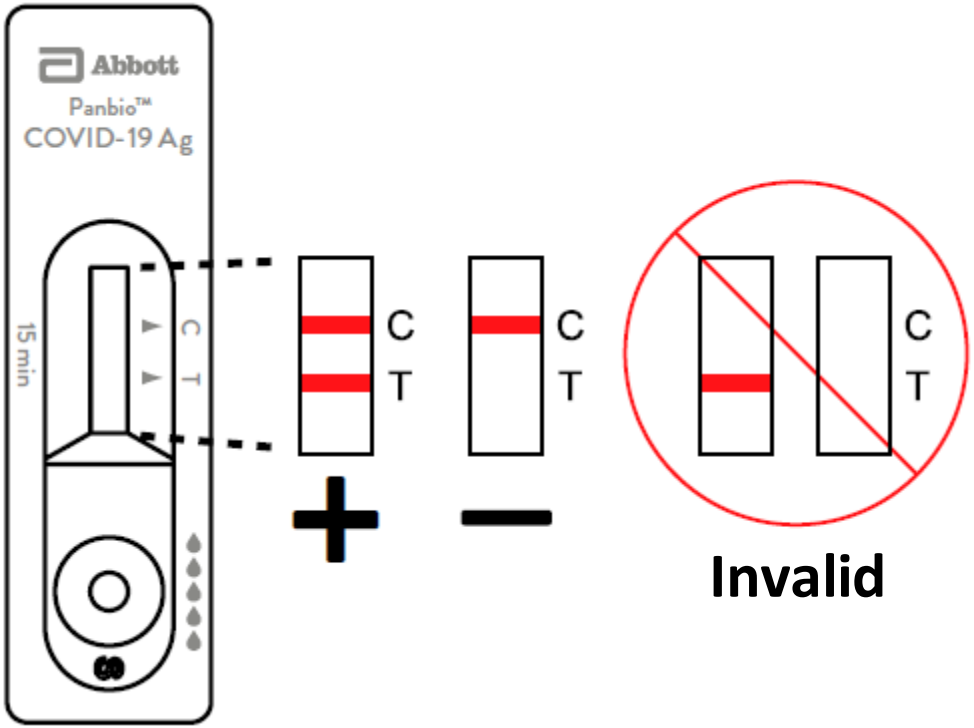
Biohazard Containment Features Help Protect Staff

Special “break off” swab stays contained in tube, minimizing staff exposure



Safely dispose the fully enclosed extraction tube

Simple Results Interpretation

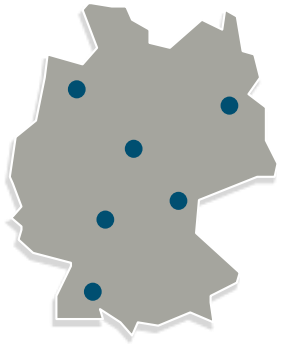


Deploy at Point of Care

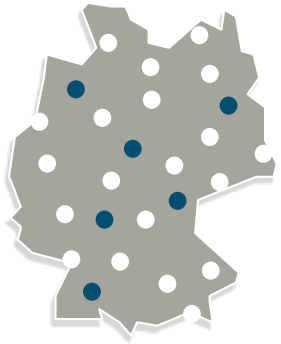
- Portable format allows fast setup of decentralized testing sites
- Deploy in lab and non-lab decentralized locations
- Samples are taken and directly applied to test at point of care
- No requirement to ship samples

Extend Capacity of Lab Testing

- Relieve burden on busy labs
- Mass testing becomes achievable
- Extend geographic coverage
- Test can be run outside lab setting
- Deploy where lab PCR is unavailable/inconvenient



Lab Only



Lab + POC

Faster Answers for Patients

- Test is run at point of care
- Answers in 15-20 minutes, while patients wait
- Fewer follow up calls to patients
- Fast alternative if lab PCR unavailable
- Fewer bottlenecks on throughput
- Help reduce overall community transmission

Accessible Solution

- Less costly than molecular
- No capital equipment required
- No pre-installed instrumentation required
- Fewer infrastructure needs
- Simplified training

Kit Contents: Everything Needed to Run a Test

Materials Provided

- 25 Test devices with desiccant in individual foil pouch
- 1 Buffer (1 x 9 ml/bottle)
- 25 Extraction tubes
- 25 Extraction tube caps
- 1 Positive control swab
- 1 Negative control swab
- 25 Sterilized nasopharyngeal swabs for sample collection
- 1 Tube rack
- 1 Quick reference guide (Nasopharyngeal)
- 1 Instructions for use

Required But Not Provided

- Personal protective equipment (PPE)
- Protective gloves
- Timer
- Biohazard container

Ordering Information

- Cat No: 41FK10
- 25 Tests per Kit Box

Languages

- English
- German
- Spanish
- French
- Italian
- Portuguese
- Russian

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Appendix

Supporting documents - FIND

FIND Rapid Diagnostic Tests for COVID-19, 18 May 2020.

Suggested Uses for Ag and Ab Detection

https://www.finddx.org/wp-content/uploads/2020/05/FIND_COVID-19_RDTs_18.05.2020.pdf

SUGGESTED USES FOR Ag- AND Ab-DETECTION RDTs GIVEN OUR CURRENT UNDERSTANDING

- **Ag RDTs** should be prioritized for **case management** to enable decentralized testing, especially when access to PCR testing is limited.
- **Ab RDTs** should be prioritized for **seroprevalence surveys** to inform public health measures and testing of contacts to establish previous spread of the virus.

Suggested use		Ag	Ab
Case management in high prevalence/ active outbreak settings	Triage suspect cases **Positive:** no confirmatory testing required **Negative:** confirmatory testing with PCR recommended, if available	✓	
	Aid diagnosis in symptomatic cases presenting late (≥10 days post-symptom onset) In addition to PCR/Ag, not a replacement		✓
	Monitor active infection	✓	
Public health measures	Screen contacts for infection	✓	
	Screen contacts for previous exposure (≥10 days post exposure)		✓
	Seroprevalence surveys to define levels of population exposure,* including vaccine trial support		✓

* Insufficient data supporting effectiveness of protection or duration of immunity.

Supporting documents – Africa CDC

Africa CDC supports the use of Antibody tests for the following use cases:

- Triage
- Contact Tracing
- Surveillance

At present, the use of antibody-based rapid tests can be considered in the following situations:

a. Triaging symptomatic individuals in healthcare or community settings

Where there is limited or no access to molecular tests, rapid antibody tests provide a means to quickly triage suspect cases of COVID-19 provided the test is highly sensitive and specific for COVID-19. A positive IgM or total antibody test results in symptomatic patients fulfilling the COVID-19 case definition is strongly suggestive of a recent infection with SARS-CoV-2. This approach has allowed a large number of symptomatic individuals to be rapidly tested in the community or healthcare setting, relieving the backlog and waiting time for molecular testing and preventing the healthcare system from being overwhelmed. This approach is relevant specifically if there is evidence of community transmission for which timely laboratory diagnostic is essential. Negative antibody test in individuals with signs and symptoms suggestive of COVID-19 **does not** exclude the disease and a swab should be taken for molecular testing.

b. Testing of contacts of confirmed COVID-19 cases

Testing all close contacts of a confirmed case, who are symptomatic, is critical in interrupting the chain of transmission in the community. Those who test positive by a total antibody test should self-isolate or seek treatment, if warranted. If testing is done within 7–10 days post the exposure event, those who test negative should be swabbed for molecular testing. Additionally unless daily testing is available, contacts who are found to be negative on antibody or molecular tests should be advised to continue to quarantine as they may still become infectious and/or symptomatic.

c. Informing situation analysis and serosurveillance

In countries that have set up syndromic surveillance, such as surveillance for influenza-like illness (ILI) or severe acute respiratory infections (SARI), that collects blood and throat swabs routinely at sentinel sites, these surveillance samples can be tested for COVID-19 using molecular, antigen or antibody tests, either alone or in combination. If any of these samples are positive, it means COVID-19 has been circulating in the community. If serial samples are available, it may be possible to date when COVID-19 established itself in a community or country. For conducting prospective surveys, it may be useful to consider the use of dried blood spot (DBS) for antibody testing and deep saliva samples for molecular or antigen testing. These sample types are less cumbersome and hazardous to collect in the field. Collection of DBS samples followed by testing on a high-volume immunoassay will both enable the use of better performing tests (some laboratory-based immunoassays have high sensitivity and specificity) as well as reduce costs.

In general, antibody tests can be used to determine the true extent of an outbreak, map its geographic distribution, and identify at-risk populations. These could be especially helpful to monitor prevalence in healthcare or other high-risk essential workers and could further inform public health measures and control strategies.

Africa CDC Interim Guidance on use of Rapid Antibody Tests for COVID-19. (June 2020).
https://africacdc.org/download/interim-guidance-on-the-use-of-rapid-antibody-tests-for-covid-19-response

Supporting Documents - IDSA

IDSA Guidelines on Serology Testing

Recommendation 1: The IDSA panel suggests against using serologic testing to diagnose SARS-CoV-2 infection during the first two weeks (14 days) following symptom onset (conditional recommendation, very low certainty of evidence).

Recommendation 6: The IDSA panel suggests using IgG antibody to provide evidence of COVID-19 infection in symptomatic patients with a high clinical suspicion and repeatedly negative NAAT testing (weak recommendation, very low certainty of evidence).

- **Remark** – When serology is being considered as an adjunct to NAAT for diagnosis, testing three to four weeks post-symptom onset maximizes the sensitivity and specificity to detect past infection.

Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19 Serologic testing
https://www.idsociety.org/practice-guideline/covid-19-guideline-serology/#:~:text=s1%2Ds5).-,Recommendation%201%3A%20Serologic%20testing%20during%20first%20two%20weeks%20after%20symptom,very%20low%20certainty%20of%20e vidence).