

Coronavirus Ag Rapid Test Cassette (Swab)

SARS-CoV-2 antigen detection in nasal or nasopharyngeal swab specimens for diagnosis of COVID-19 infection

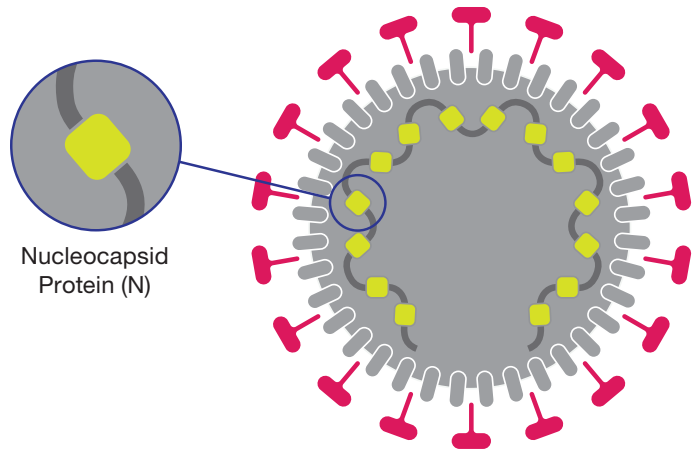


Simple Test, Rapid Results for SARS-CoV-2 Ag Detection

Qualitative detection of SARS-CoV-2 antigen for rapid diagnosis of COVID-19

As COVID-19 continues to spread globally, rapid testing has become more important for diagnosing patients infected with SARS-CoV-2. When timely decisions are needed or when RT-PCR testing is inaccessible, this RDT COVID Ag test complements RT-PCR testing in laboratory and point-of-care settings.¹

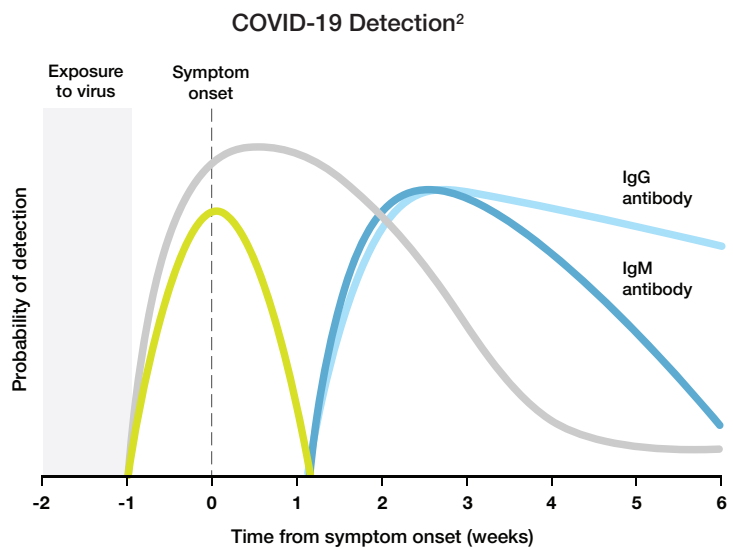
Bio-Rad, as part of its COVID-19 portfolio, offers this rapid, *in vitro* immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 nasal or nasopharyngeal swab specimens.



Detection of SARS-CoV-2 Nucleocapsid Protein

Sensitive detection of COVID-19 disease in specimens taken at early symptom onset

The Coronavirus Ag Rapid Test is sensitive enough to detect patient cases with a high viral load. This includes, for example, pre-symptomatic and early symptomatic cases or low RT-PCR cycle threshold cases, which likely account for a significant number of transmissions.¹



Adapted from Guglielmi G 2020

- Rapid antigen tests** detect the presence of viral proteins and can return positive results when a person is most infectious.
- PCR-based tests** can detect small amounts of viral genetic material, so a test can be positive long after a person stops being infectious.
- Antibody tests** detect the body's immune response to the virus and are not effective at the earliest phase of infection.

Addressing the need for rapid, reliable SARS-CoV-2 testing results

Rapid antigen tests offer multiple benefits in comparison to RT-PCR tests for the detection of SARS-CoV-2.¹

The Coronavirus Ag Rapid Test offers an advantage over RT-PCR with rapid 15 minute time to results and the ability to bring testing closer to patients tested, and facilitate quick patient clinical care decisions.

Use case examples¹:

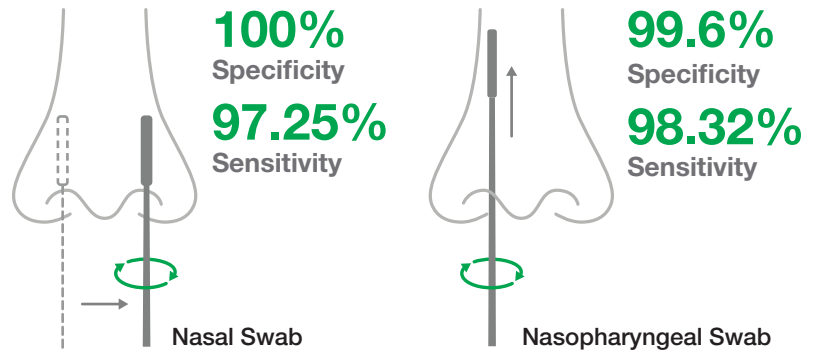
- Early detection and isolation for triage and mitigation of infection
- Prompt clinical management of COVID-19 patient cases
- Control of transmission
- Identification of clusters or outbreaks

Coronavirus Ag Rapid Test Cassette (Swab) Performance

Highly specific and sensitive, easy-to-read results

The Coronavirus Ag Rapid Test demonstrated high performance for specificity and sensitivity in a study with “real-world” patients. The rigorous evaluation at seven test sites included a total of 237 fresh nasal swab specimens and 865 fresh nasopharyngeal swab specimens collected and tested in a randomized, blinded study.

Using highly sensitive, FDA Emergency Use Authorized RT-PCR comparator tests, each test site obtained performance results well above the WHO minimum requirements.³

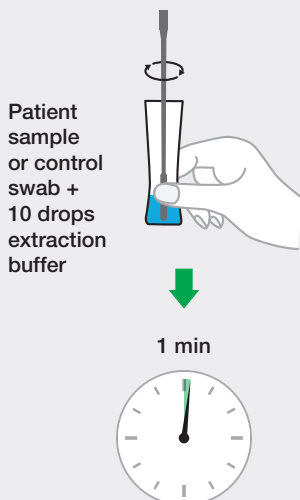


Limit of Detection
 1.15×10^2 TCID₅₀/ml

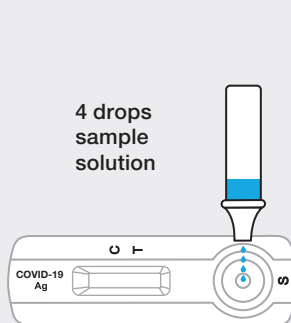
3 Quick Steps

In just three steps, the Coronavirus Ag Rapid Test detects the presence or absence of SARS-CoV-2 antigen in specimens collected at the first onset of symptoms.

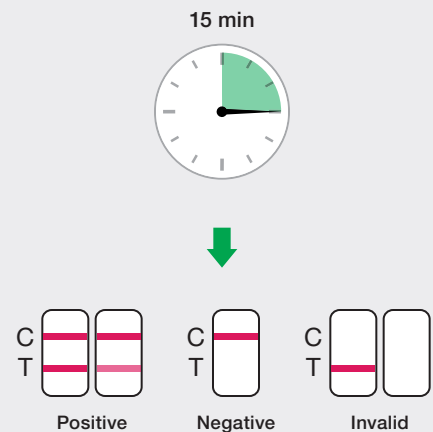
1. Short sample preparation



2. Fast test procedure



3. Easy result interpretation



For more detailed instructions, please refer to the IFU.

Coronavirus Ag Rapid Test Cassette (Swab) Kit

The Coronavirus Ag Rapid Test is a rapid test for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasal or nasopharyngeal swab specimens.

Complete Kit Provided

Everything you need to perform the test is included in each kit: cassettes, buffer, sterile swabs, extraction tubes, and nozzles with filters.

A workstation for tubes and buffer is provided for convenient and secure sample handling and processing. No instrumentation is needed.

Dedicated Control Swabs Kit

This set of controls for the Coronavirus Ag Rapid Test (Swab) Kit is a separate external qualitative quality control kit. This test can be used in accordance with your laboratory needs and local requirements (e.g., to validate a new test kit, new test lot, new operator, etc.).



Key Product Information

The CE marked Coronavirus Ag Rapid Test provides a quick and easy tool for detecting SARS-CoV-2 antigen in the early stages of COVID-19 infection while offering a robust level of performance.

Coronavirus Ag Rapid Test Cassette (Swab)	
Authorization	CE marked
Time to Result	15 minutes
Storage	+2 to +30°C
Specimen Type	Nasal or nasopharyngeal
Shelf Life	24 months
Kit Size	20 tests/kit
External Quality Controls	Control kit (order as needed)

REFERENCES

1. European Centre for Disease Prevention and Control (2020). Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK. ECDC Stockholm.
2. Guglielmi G (2020). Fast coronavirus tests: what they can and can't do. Nature 585, 496-498. doi: <https://doi.org/10.1038/d41586-020-02661-2>.
3. WHO (2020). Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays: Interim guidance. <https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays>. Accessed December 18, 2020.

Visit [bio-rad.com/diagnostics](https://www.bio-rad.com/diagnostics) for more information.

Ordering Information

Catalog No.	Description	Units
12015553	Coronavirus Ag Rapid Test Cassette (Swab)*	20 units
12016147	COVID-19 Antigen Control Kit (10 Positive + 10 Negative Control Swabs)*	20 swabs

* Not available in the U.S.

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