



## Description

The Healgen® Rapid COVID-19 Antigen Test is a lateral flow immunochromatographic assay intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in **anterior nasal swabs specimens from individuals with signs and symptoms of upper respiratory infection within the first six (6) days of symptom onset**. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the Healgen® Rapid COVID-19 Antigen Test and followed with a molecular test.

Positive results do not rule out co-infection with other respiratory pathogens.



## Features & Benefits

### Rapid Detection and Patient Management

Results available in 15 minutes

### Simple and Effective

Low complexity testing at the point-of-care for use with minimally trained healthcare professionals

### Strong Test Performance (comparator method RT-PCR)

Positive Percent Agreement: 85.4%

Negative Percent Agreement: 99.7%

### External Quality Controls Available

Facilitates routine quality procedures

### Shelf Life that Spans Viral Seasonality

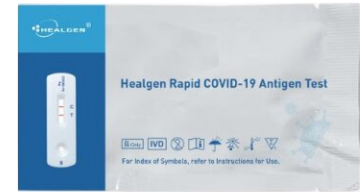
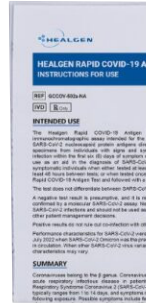
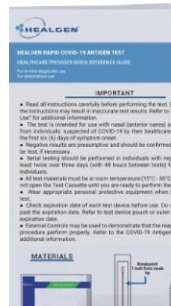
24 months from date of manufacture at room temperature storage

## Specifications

Time to result	15 minutes
Storage	2-30°C/36-86°F
Shelf Life	24 months
Specimen Type	Nasal Swab

## Kit Content

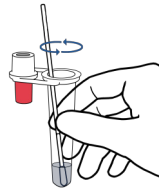
- 20 Test Cassettes
- 20 Sterile Swabs
- 20 Pre-filled buffer tubes with flip-top
- 2 Tube Holders
- 1 Instructions for Use
- 1 Quick Reference Guide



## Test Procedures



Swab both nostrils at least 5 times each.



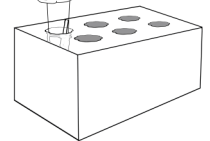
Mix the swab in the tube with the liquid.



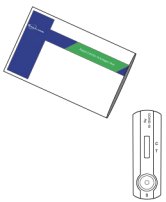
Gently break the swab at the breakpoint.



Close the tube.



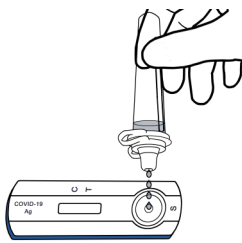
Place the tube in the holder for at least 1 minute but no more than 30 minutes.



Open the test device pouch and take out the test device.



Remove the red cap from the tube.



Add 4 drops into the test device.



Wait 15 minutes.



Read the test results.

## Ordering Information

Product	REF/Catalog Number	Quantity
Healgen® Rapid COVID-19 Antigen Test	GCCOV-502a-NA	20 tests
COVID-19 Antigen Control Kit	GCCOV(Ag)-PN10	5 each negative and positive control swabs
	GCCOV(Ag)-PN20	10 each negative and positive control swabs