



# Rapid COVID-19 Antigen Tests



The Healgen Rapid COVID-19 Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein in direct anterior nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first seven (7) days of symptom onset.

(For professional *in vitro* diagnostic use only)

## FEATURES

- Health Canada Medical Device Authorization (# 353562) Class IV IVD for POC professional use.
- Rapid and accurate results within 15 minutes.
- Strong test performance:
  - Positive Percent Agreement: 84.2%
  - Negative Percent Agreement: 99.7%
- Easy to use, suitable for POC use with minimally trained healthcare professionals.
- Includes an internal procedural control line (C) to confirm proper execution.

## SPECIFICATIONS

Test kits include:

- 20X test devices
- 20X sterile swabs
- 2X tube holders
- 1X instruction for use
- 20X pre-filled buffer tubes with flip-tops
- 1X QRI for HealthCare Providers
- 1X Self-swab collection instructions
- Specimen type: Nasal swab
- Storage: 2-30°C/36-86°F
- Shelf life: 24 months

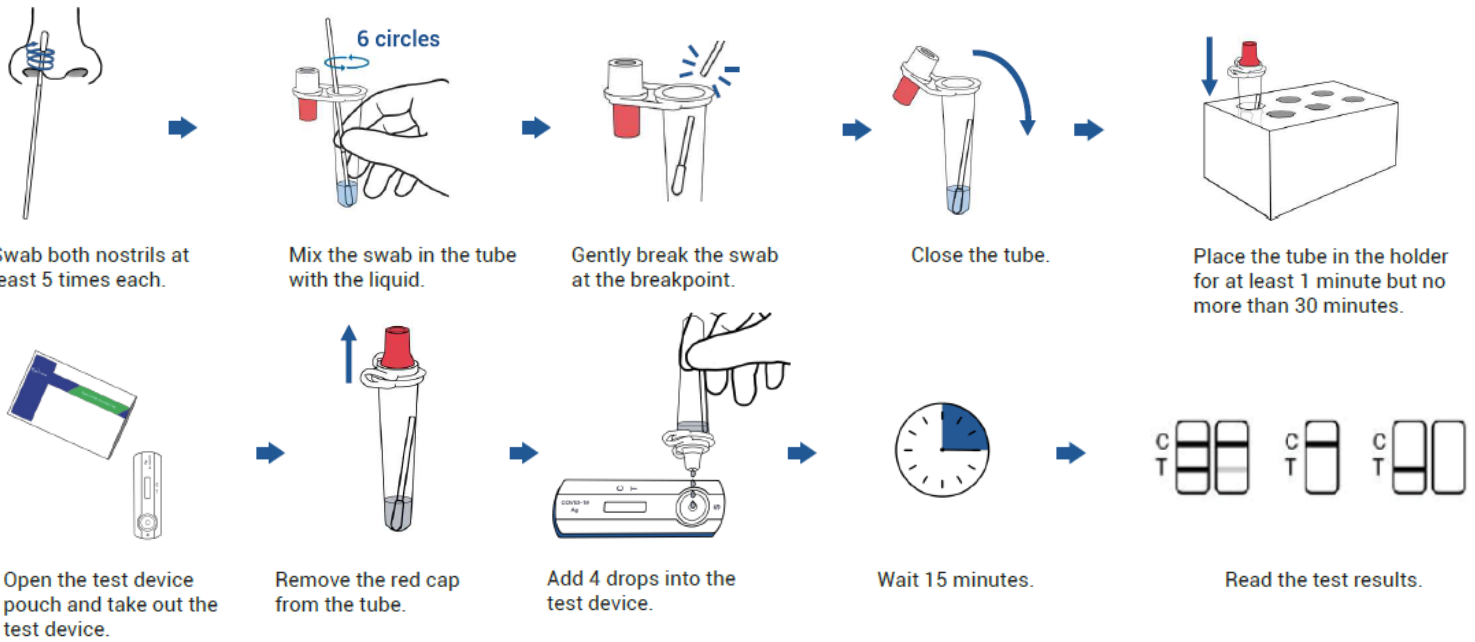




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## Test Procedures (Reference only, please strictly follow IFU):



## Ordering Information

Product Description	Catalog No.	Kit Size
Healgen® Rapid COVID-19 Antigen Test	GCCOV-502a-NA	20 Tests/Kit
COVID-19 Antigen Control Kit	GCCOV(Ag)-PN10	5 negative control swabs + 5 positive control swabs
	GCCOV(Ag)-PN20	10 negative control swabs + 10 positive control swabs