

# Three Respiratory Viruses – One Test

Respiratory



COVID-19

FLU A/B

RSV

STREP A

COMBO

## Healgen® COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab)

For Emergency Use Authorization (EUA) Only.\*  
For Prescription Use Only.

### Description



The Healgen® COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from **anterior nasal swab specimens of individuals with signs and symptoms of respiratory infection consistent with COVID-19 by their healthcare provider within the first 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests.** Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

Positive results do not rule out bacterial infection or co-infection with other viruses.

### Features & Benefits



**Detect Three Respiratory Viruses Simultaneously from a Single Sample**  
Faster diagnosis for improved patient care and cost-effectiveness



**Simple and Effective**  
CLIA Waived testing at the point-of-care for use with minimally trained healthcare professionals



**Rapid Detection**  
Results available in 15 minutes



**External Quality Controls Available**  
Facilitates routine quality procedures



**Excellent Test Performance (comparator method RT-PCR)**



**Shelf Life that Spans Viral Seasonality**  
16 months from date of manufacture at room temperature storage

Test	Positive Percent Agreement	Negative Percent Agreement
SARS-CoV-2	90.2%	99.1%
Flu A	90.0%	99.9%
Flu B	91.2%	100.0%

\*The Healgen® COVID-19/Flu A&B Ag Combo Rapid test Cassette (Swab) is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been cleared or approved.

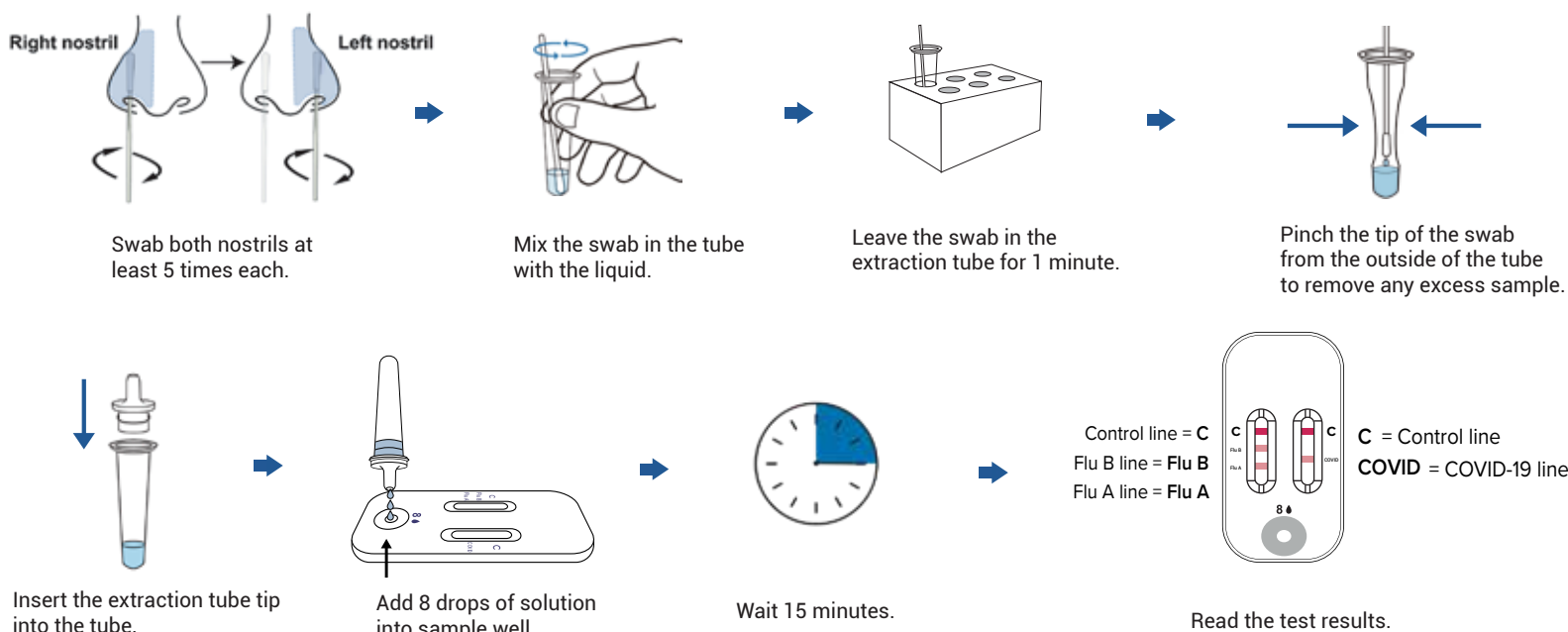
## Kit Content

25 Sealed Test Cassettes  
 25 Sterile Nasal Swabs  
 25 Pre-filled Extraction Tubes  
 25 Extraction Tube Tips  
 2 Tube Holders  
 1 Healthcare Provider Instructions for Use  
 1 Healthcare Provider Fact Sheet  
 1 Patient Fact Sheet  
 1 Quick Reference Guide (QRG)

## Specifications

Time to result	15 minutes
Storage	2-30°C/36-86°F
Shelf Life	16 months
Specimen Type	Nasal Swab

## Test Procedures



## Ordering Information

Product	REF/Catalog #	Quantity
Healgen® COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab)	GCFC-525Sa	25 Tests
External Controls: COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab)	GCFC-PN2	1 each negative and positive control swabs
	GCFC-PN20	10 each negative and positive control swabs