

Three Respiratory Viruses – One Test



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	92.0%	99.0%
Flu A	92.5%	99.9%
Flu B	90.5%	99.9%

*The Healgen® COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories.

This product has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

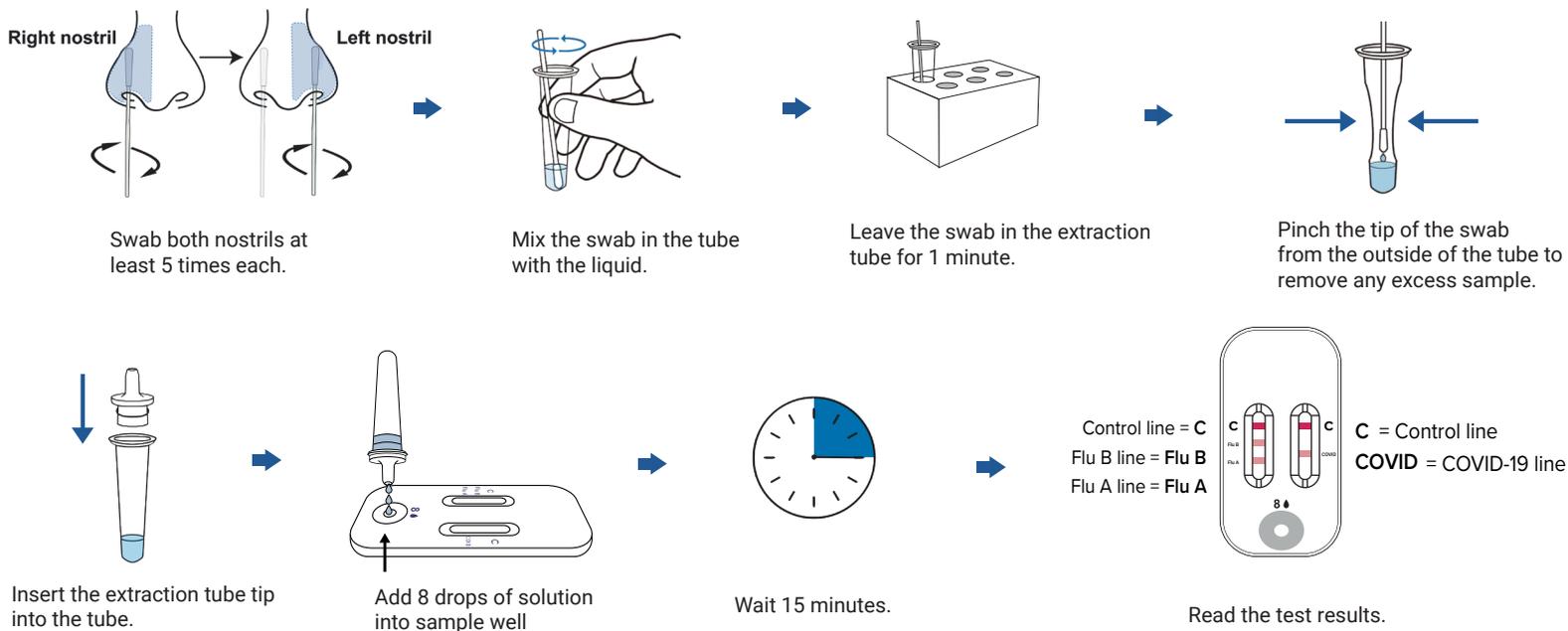
Kit Contents

- 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