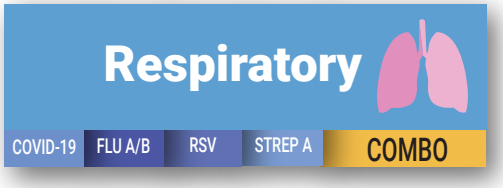
Three Respiratory Viruses – One Test



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)

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%

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

*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.

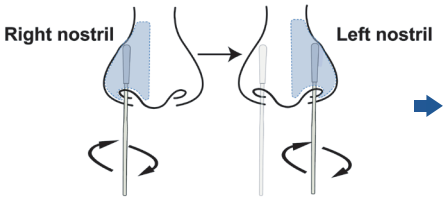
Kit Contents

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)

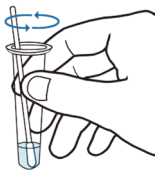
Specifications

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

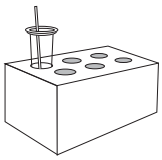
Test Procedures



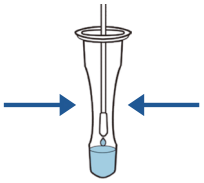
Swab both nostrils at least 5 times each.



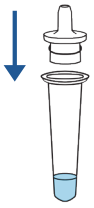
Mix the swab in the tube with the liquid.



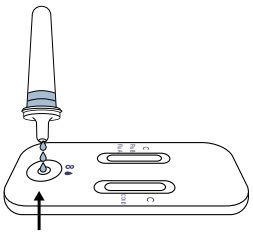
Leave the swab in the extraction tube for 1 minute.



Pinch the tip of the swab from the outside of the tube to remove any excess sample.

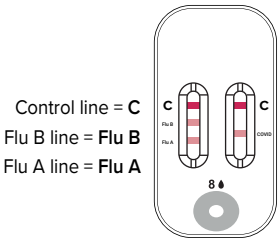


Insert the extraction tube tip into the tube.



Add 8 drops of solution into sample well

Wait 15 minutes.



Read the test results.

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

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MRK240005 Ver. 2
Rev. 2024-07-22