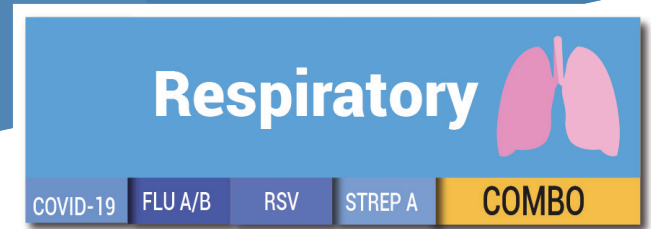


# Healgen® Rapid Check® Covid-19/Flu A&B Antigen Test

For Over the Counter Use  
510(k) cleared



## No Repeat Testing Required

Additional testing in 48 hours not needed for a negative test result.

# One Test, Three Reliable Results

### Excellent Clinical Performance



	PPA (Positive Percent Agreement)	NPA (Negative Percent Agreement)
<b>SARS-CoV-2</b>	92.0%	99.0%
<b>Influenza A</b>	92.5%	99.9%
<b>Influenza B</b>	90.5%	99.9%

### Two result windows for easy readability

### Approved for Ages 2+

Self-collected swabs for ages 14 +  
Adult collected swabs for ages 2-13

### Intended Use

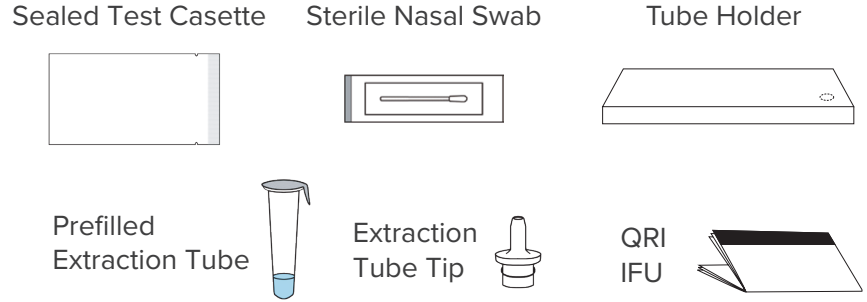
The Healgen® Rapid Check® COVID-19/Flu A&B Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza and SARS-CoV-2 or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should therefore seek follow-up care from their healthcare provider.

Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.

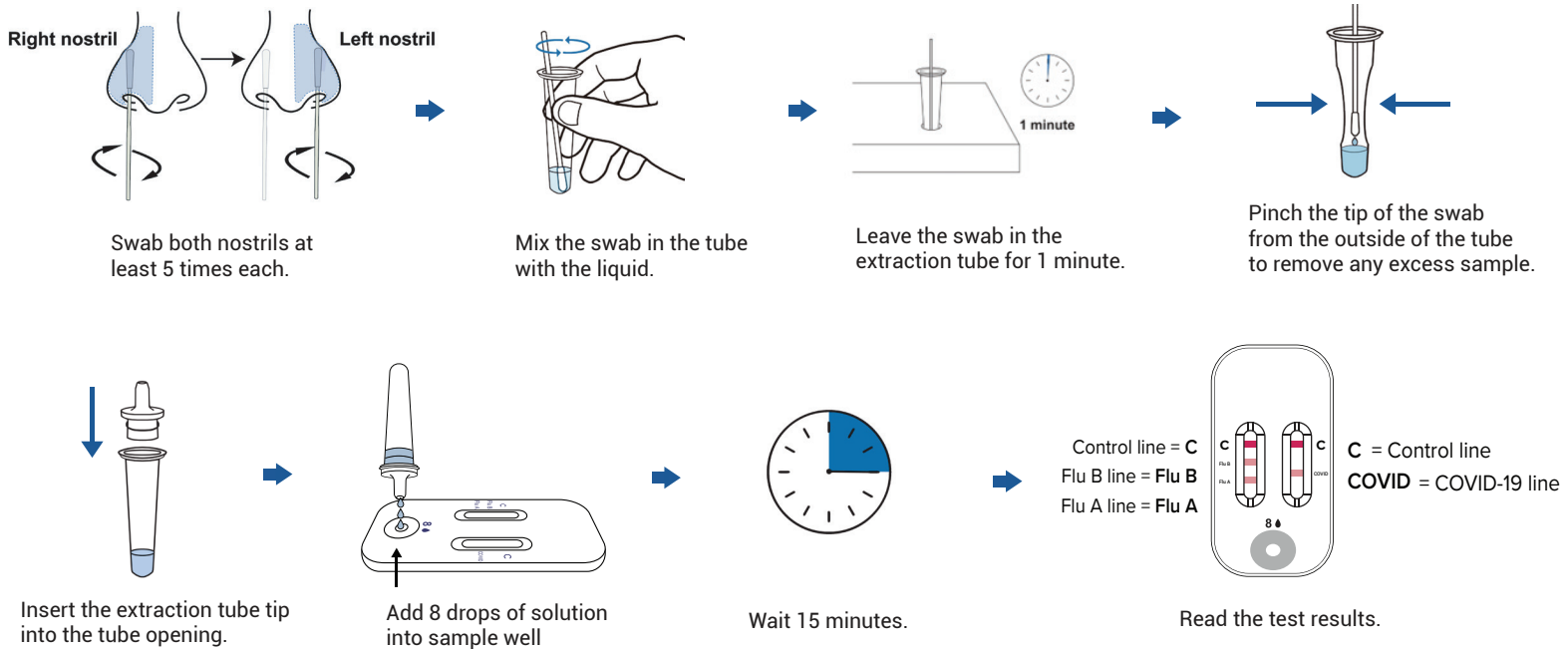
# Kit Contents

- Sealed test cassettes
- Steriles nasal swabs
- Pre-filled extraction tubes
- Extraction tube tips
- Quick Reference Instructions (QRI)
- Instructions for Use (IFU)



# Test procedure\*

\*This is one example of a possible result. To see further result interpretation, please refer to the Quick Reference Instructions.



### Additional Information: Reading Results



Scan QR code for more information on reading results.

Webpage: <https://www.healgen.com/covid19-influenza-a-b-OTC>

# Ordering Information

Description	REF/Catalog Number	Kit Size
Healgen® Rapid Check® COVID-19/Flu A&B Antigen Test	GCFC-525SKa-HX X= kit size.	1/2/4 tests kit