

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



For in vitro Diagnostic Use Only.  
For Professional Use Only.  
De Novo Authorized.

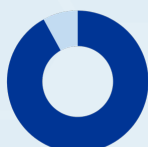
The **Healgen® Rapid Check® COVID-19/Flu A&B Antigen Test Pro** is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from 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 use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

## Features & Benefits:

### SARS-COV-2

Positive Percent Agreement



92.0%

Negative Percent Agreement



99.0%

### Flu A

Positive Percent Agreement



92.5%

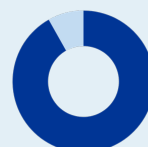
Negative Percent Agreement



99.9%

### Flu B

Positive Percent Agreement



90.5%

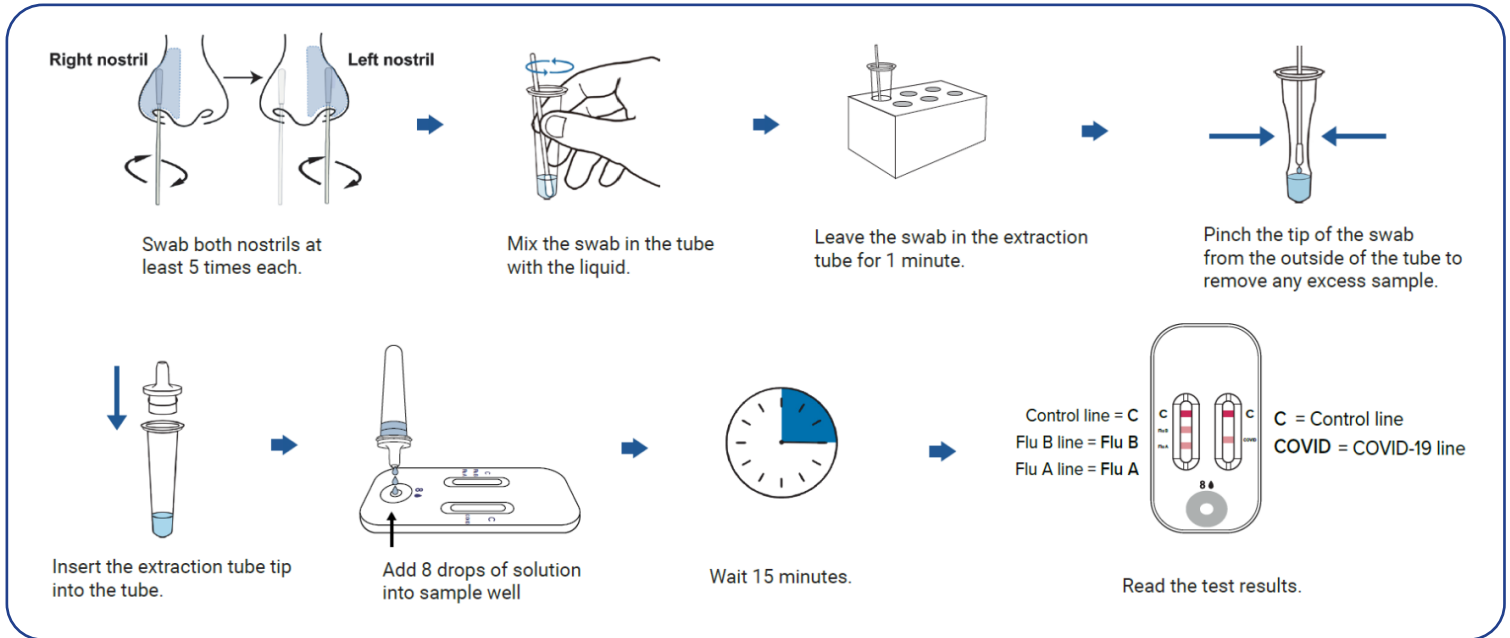
Negative Percent Agreement



99.9%

- Excellent test performance (comparator RT-PCR)
- Rapid detection - results available in 15 minutes
- Simultaneously detects 3 viruses at once (SARS-CoV2, Flu A&B)
- External control availability - fits all QC testing scenarios
- Easy readability - two result windows 24 month expiration
- Store between 36°F - 86°F (2°C - 30°C)

## Test Procedure:



## Kit Contents:

- 25 Sealed Test Cassettes
- 25 Sterile Nasal Swabs
- 25 Pre-filled Extraction Tubes
- 25 Extraction Tube Tips
- 2 Tube Holders
- 1 Instructions For Use (IFU)
- 1 Quick Reference Instructions (QRI)

Learn more about  
this product online,  
just scan the QR Code!



## Ordering Information:

| Product Name                                                               | Catalog No.     | Kit Size                                | Regulatory Status |
|----------------------------------------------------------------------------|-----------------|-----------------------------------------|-------------------|
| Healgen® Rapid Check® COVID-19/Flu A&B Antigen Test Pro                    | GCFC-525SKa-10T | 10 Test/Kit                             | De Novo           |
|                                                                            | GCFC-525SKa-25T | 25 Test/Kit                             |                   |
| External Controls: Healgen® Rapid Check® COVID-19/Flu A&B Antigen Test Pro | GCFC-PNK2       | 1 Positive & 1 Negative Control Swab    | FDA Exempt        |
|                                                                            | GCFC-PNK20      | 10 Positive & 10 Negative Control Swabs |                   |
|                                                                            | GCFC-PNK40      | 20 Positive & 20 Negative Control Swabs |                   |