



## Rapid Strep A Antigen Test

### Features

- **Overall positive agreement = 97.1%**  
**Overall negative agreement = 99.4%**  
\*Compared to Culture
- **Results in 5 minutes**
- **Quality Controls included**



### STREP A

Streptococcus pyogenes is a non-motile gram-positive coccus carrying the Lancefield group A antigen.

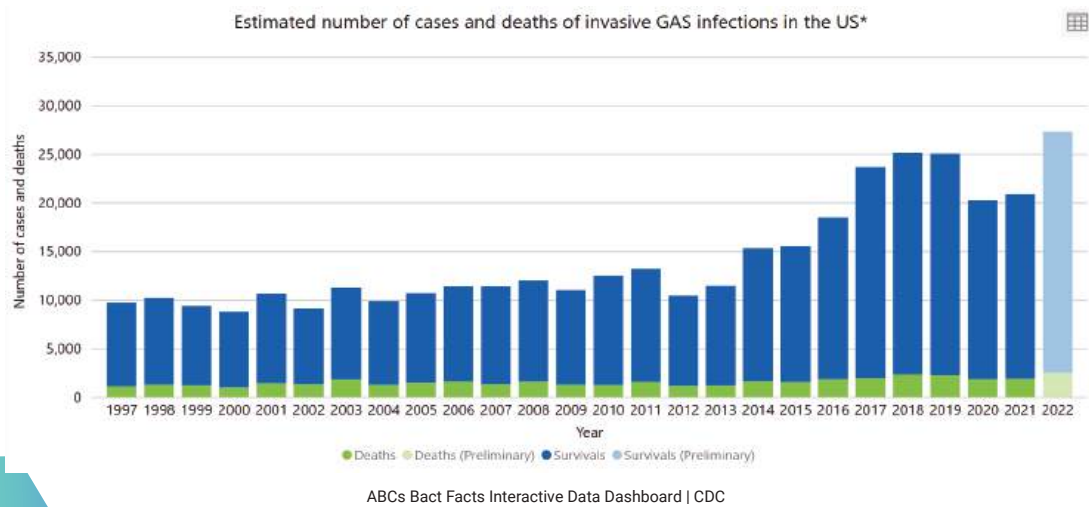
Antibiotics are prescribed to manage Streptococcus A infections, underscoring the critical need for accurate bacterial infection testing amidst rising antibiotic resistance.

Accurate testing helps physicians in making informed treatment decisions, especially when symptoms mimic other respiratory illnesses.

This bacteria may cause a spectrum of serious infections, such as:

- Pharyngitis
- Respiratory infections
- Impetigo
- Endocarditis
- Meningitis
- Puerperal sepsis
- Arthritis
- Rheumatic fever
- Peritonsillar abscess

The rising incident rate of Streptococcus A infections below highlights the growing prevalence each year.



## 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 |
| Healgen® Rapid COVID-19 Antigen Test                                    | GCCOV-502a-NA  | 20 tests                                    |
| COVID-19 Antigen Control Kit  | GCCOV(Ag)-PN10 | 5 each negative and positive control swabs  |
|   | GCCOV(Ag)-PN20 | 10 each negative and positive control swabs |
| RapidCheck RSV Antigen Test   | GCRSV-502b-PBS | 20 Tests/Kit                                |
| Rapid Strep A Antigen Test  | GCSTR-501Ca    | 25 Tests/Kit                                |

## Test Smarter, Breathe Better

\*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.

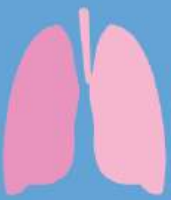
The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.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

Tel: +1 713-733-8088  
Fax: +1 713-733-8848  
Website: [www.healgen.com](http://www.healgen.com)

Healgen Scientific Limited Liability Company  
Address: 3818 Fuqua Street, Houston, TX 77047, USA.

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## Respiratory



COVID-19

FLU A/B

RSV

STREP A

COMBO

Highly contagious viruses such as COVID-19, influenza, and RSV, along with bacterial infections like Strep A, are continuously circulating in the environment. The similarity in patient symptoms can make diagnosing these respiratory illnesses challenging, underscoring the importance of differential testing for healthcare providers. Accurate and timely diagnosis is crucial for appropriate treatment to be administered, ultimately improving patient outcomes and reducing the spread of infection.

As a global IVD company, Healgen Scientific has developed several tests to assist in the differential diagnosis of respiratory illnesses, providing significant benefits to patients. Early and precise identification of the causative pathogen enables targeted therapies, which can shorten the duration of illness, minimize complications, and enhance recovery. Furthermore, rapid testing can reduce unnecessary antibiotic use, thus combating antibiotic resistance and preserving the effectiveness of essential medications.

This brochure highlights the following lateral flow assays:

**COVID-19/Flu A&B:** This combined test differentiates between COVID-19 and influenza types A and B, ensuring patients receive the correct treatment promptly.

**COVID-19:** A dedicated test for COVID-19 that provides quick and reliable results, crucial for controlling the spread of the virus.

**RSV:** Early detection of RSV is vital for managing symptoms and preventing severe respiratory complications, especially in vulnerable populations such as infants and the elderly.

**Strep A:** Identifying Strep A infections swiftly helps in administering the right antibiotics, reducing the risk of serious complications like rheumatic fever.

By providing these advanced diagnostic tools,<sup>®</sup> Healgen Scientific supports healthcare providers in making informed clinical decisions, ultimately enhancing patient care and improving health outcomes.



## Rapid Testing for Respiratory Pathogens



Test for Three Viruses  
Simultaneously from One Sample



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

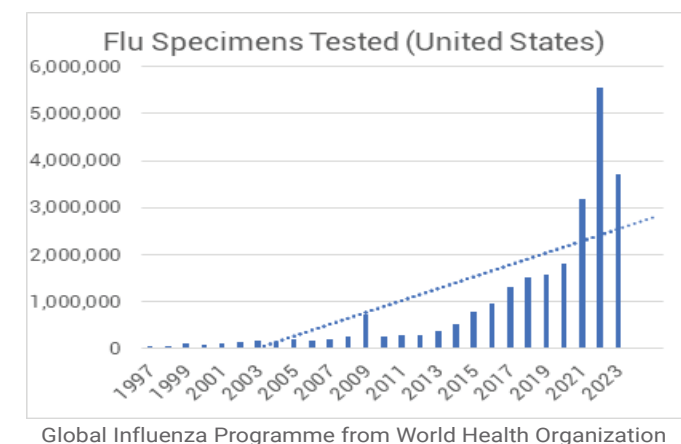
COMBO

Similar symptoms between influenza A, influenza B and COVID-19 pose challenges in differentiations. Influenza A and B are common viruses responsible for seasonal flu outbreaks and annual epidemics, while COVID-19, caused by a coronavirus, shares similar symptoms, posing challenges in differentiation.

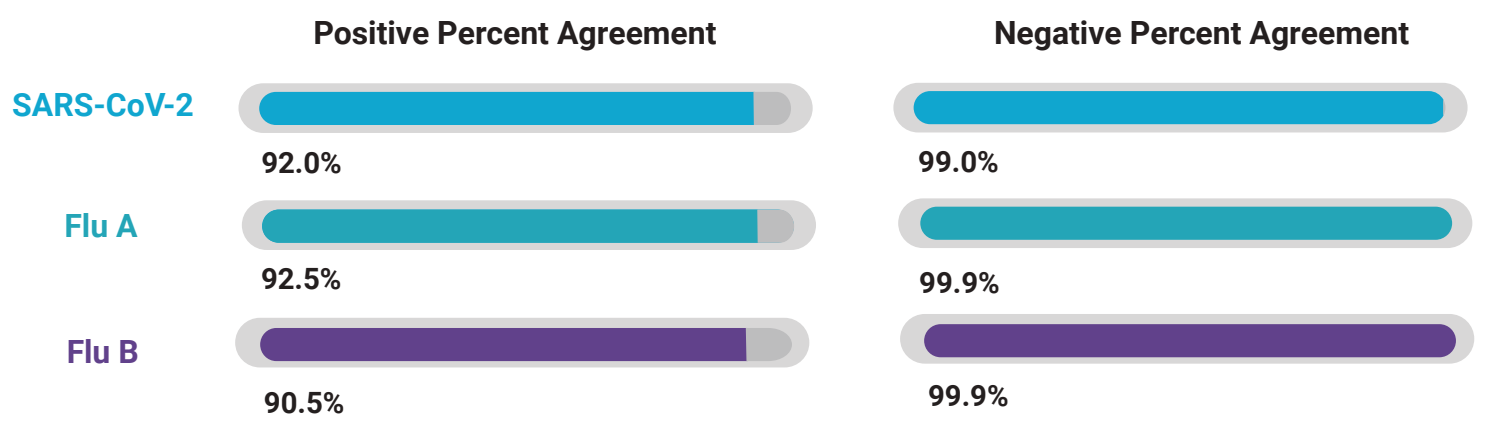
- Certain high-risk groups include:
- Individuals aged 65 years and older
  - Young children
  - People with specific health conditions

Rapid testing kits are crucial for detecting and distinguishing infections by SARS-CoV-2, influenza A, and influenza B viruses, aiding in effective management and treatment.

The graph depicts a consistent rise in flu tests conducted in the U.S.



Excellent Test Performance (comparator method RT-PCR)

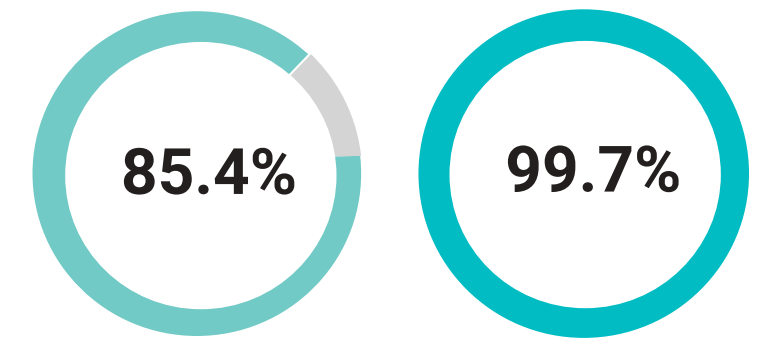


The Healgen Rapid COVID-19 Antigen Test

Features

- Use within the first 6 days of symptom onset
- No age restrictions for testing
- External Control Kit Available
- Premier Test Performance (comparator PT-PCR)

Positive Percent Agreement      Negative Percent Agreement

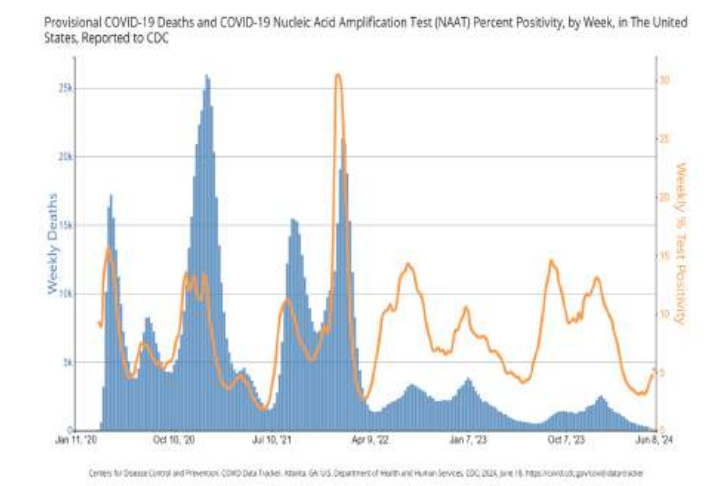


Limit of Detection (TCID<sub>50</sub>/mL) = 5.75x10<sup>3</sup>

COVID-19

COVID-19 is caused by Severe Acute Respiratory Syndrome Coronavirus 2(SARS-CoV-2). The virus typically has an incubation period between 1 to 14 days with symptoms appearing within 2 to 14 days after exposure.

The graph below demonstrates weekly mortality rates and the percentage of positive tests, highlighting ongoing outbreaks and emphasizing the need for rapid testing.



Respiratory Syncytial Virus (RSV)

Common respiratory infection affecting the nose, throat, lungs, and airways

Leading cause of hospitalization among infants in their first year of life

0.5% mortality rate in lower respiratory tract cases

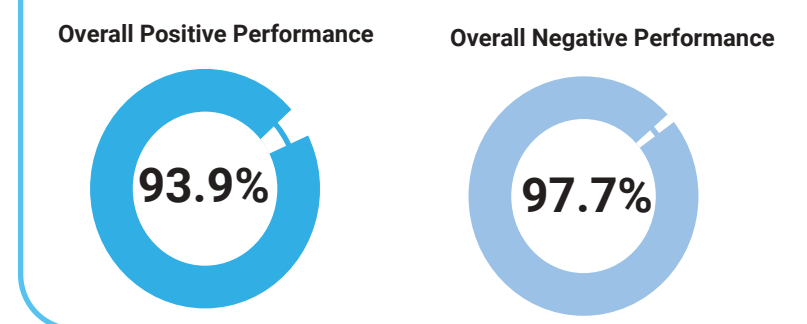
Higher cases of hospitalization and fatality for elderly individuals aged 65 years and older

Rapid Check™ RSV  
Antigen Test Cassette



Features

- Tests suitable for children less than 6 years old and adults over the age of 60.
  - Clinical data age of the patients ranged from 2 days to 100 years
- Excellent Test Performance
  - \*compared to Tissue Culture, EIA and Direct Fluorescent Antibody
- Results in 15 minutes
- Nasopharyngeal swab and Nasal aspirate specimens
- Quality Controls Included



The accompanying graph illustrates the frequency of antigen and PCR detections over weeks, underscoring the widespread prevalence of this virus and emphasizing the importance of rapid testing through the Healgen Rapid Check™ RSV Antigen Test Cassette.

