

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.

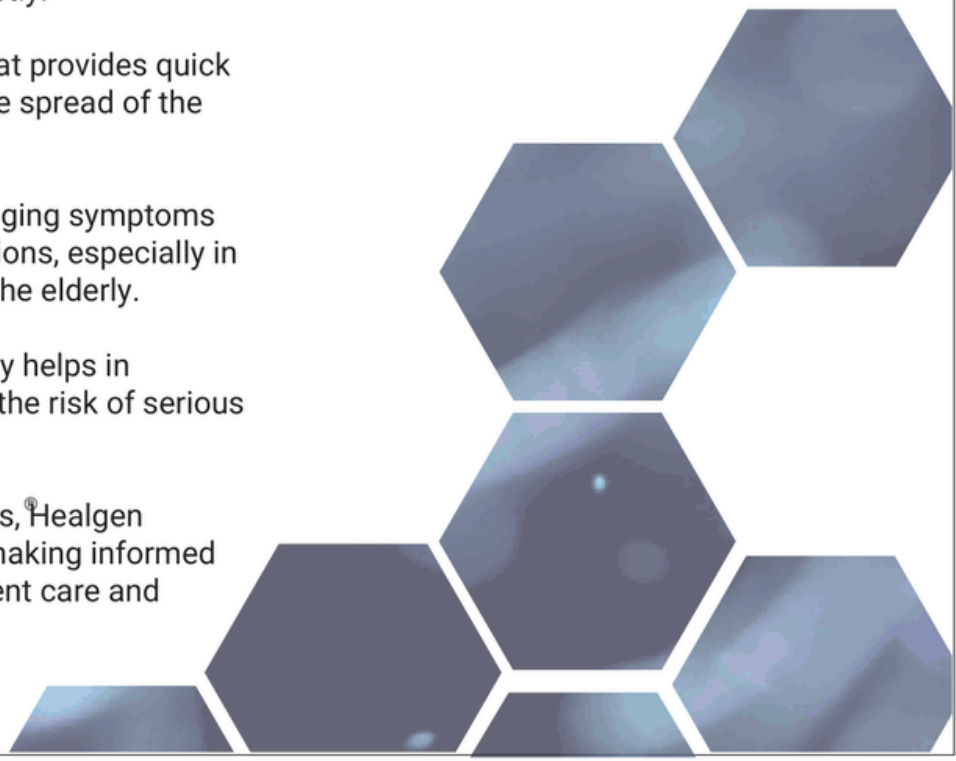
RSV: Early detection of RSV is vital for managing symptoms and preventing severe respiratory complications, especially in vulnerable populations such as infants and the elderly.

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, Healgen Scientific supports healthcare providers in making informed clinical decisions, ultimately enhancing patient care and improving health outcomes.



Rapid Testing for Respiratory Pathogens

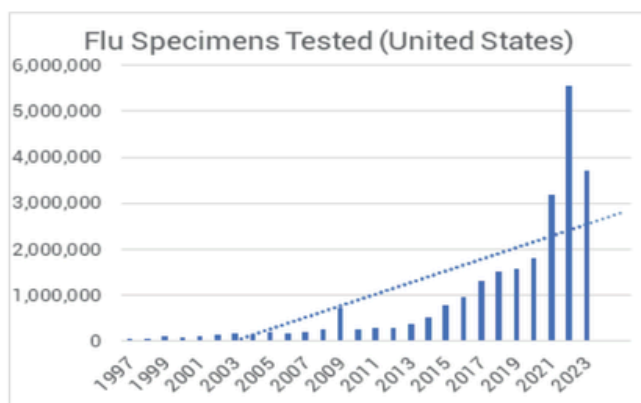


Test for Three Viruses Simultaneously from One Sample



Features

- Results in 15 minutes
- 16 months Shelf Life
- CLIA Waived Testing
- External Quality Controls Available



Global Influenza Programme from World Health Organization

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

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

COMBO

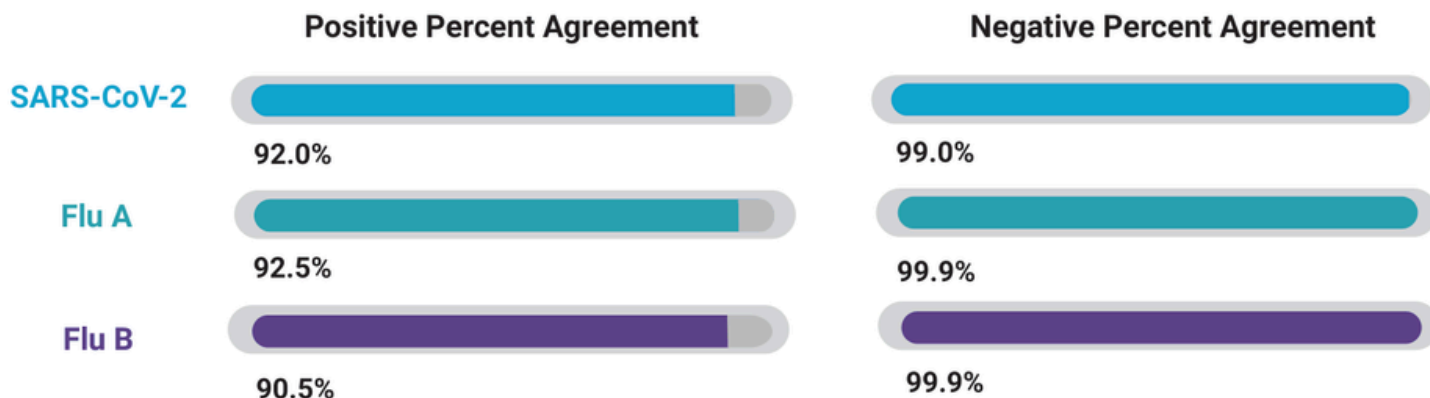
Similar symptoms between influenza A, influenza B and COVID-19 pose challenges in differentiations. Influenza A and B are common viruses responsible for seasonal flu outbreaks and annual epidemics, while COVID-19, caused by a coronavirus, shares similar symptoms, posing challenges in differentiation.

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.

Excellent Test Performance (comparator method RT-PCR)





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.

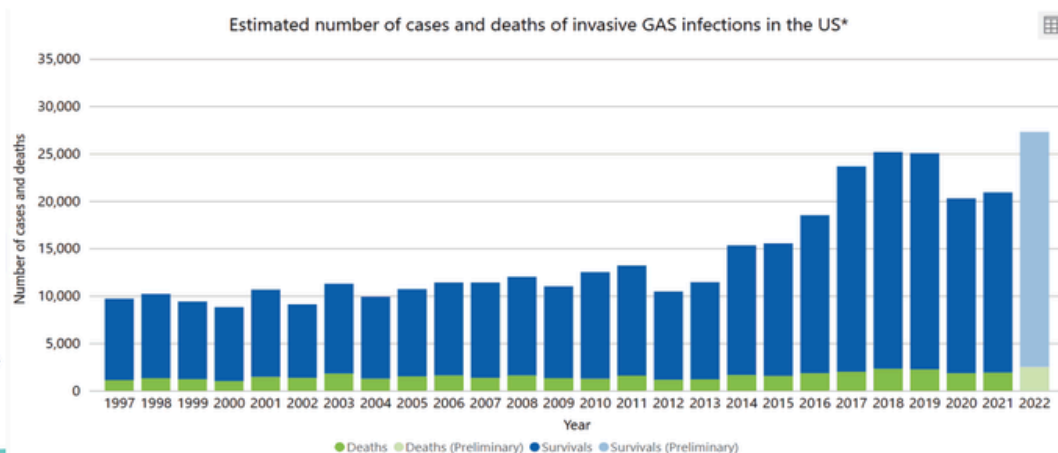
Antibiotics are prescribed to manage Streptococcus A infections, underscoring the critical need for accurate bacterial infection testing amidst rising antibiotic resistance.

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.





The Healgen Rapid COVID-19 Antigen Test

Features

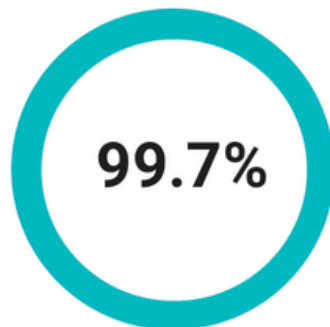
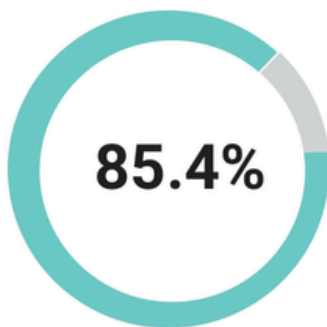
- Use within the first 6 days of symptom onset
- No age restrictions for testing
- External Control Kit Available
- Premier Test Performance (comparator PT-PCR)

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.

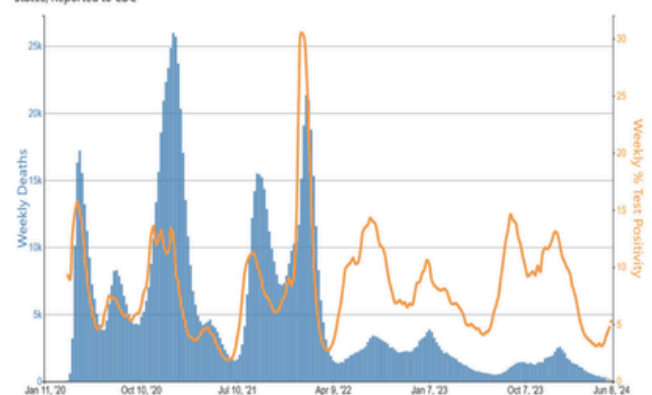
The graph below demonstrates weekly mortality rates and the percentage of positive tests, highlighting ongoing outbreaks and emphasizing the need for rapid testing.

Positive Percent Agreement Negative Percent Agreement



Limit of Detection (TCID₅₀/mL) = 5.75×10^3

Provisional COVID-19 Deaths and COVID-19 Nucleic Acid Amplification Test (NAAT) Percent Positivity, by Week, in the United States, Reported to CDC



Centers for Disease Control and Prevention, COVID Data Tracker, Atlanta, GA U.S. Department of Health and Human Services, CDC 2024, June 18, <https://covid.cdc.gov/covid-data-tracker>

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



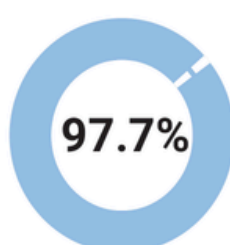
Features

- **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**

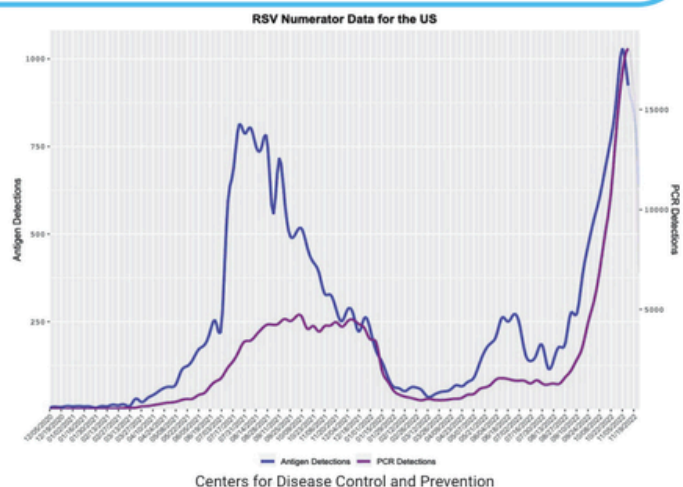
Overall Positive Performance



Overall Negative Performance



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®.



Centers for Disease Control and Prevention

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.