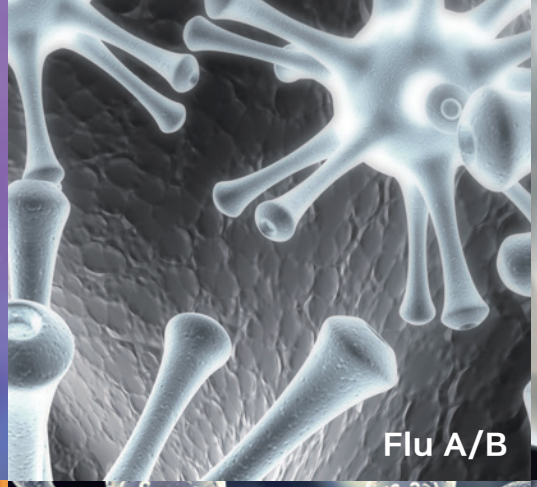

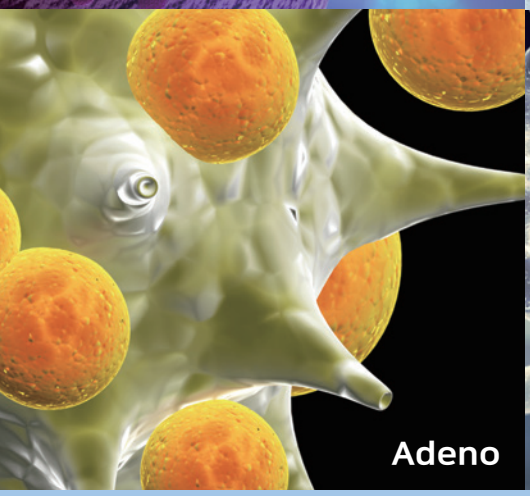

ichroma™
Broad-spectrum Respiratory Solutions

Virus SARS-CoV-2, Influenza A+B, RSV, Adenovirus

Bacteria Strep A, Mycoplasma

Trustworthy test
The trustworthy test is provided with performance similar to the golden standard.

On-site testing
Test results are provided within minutes through a simple method after collecting a sample with a swab.

Broad-spectrum
Single test – COVID-19 Ag, Influenza A+B, RSV, Strep A, Adeno, Mycoplasma
Combo test – COVID-19/Flu Ag, Influenza A+B/RSV, COVID-19/Flu A+B/RSV Ag

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Similar but different

Symptoms for most pathogens of respiratory infections overlap with each other.

Respiratory Infections	Virus				Bacteria	
	COVID-19	Flu A/B	RSV	Adeno	Mycoplasma	Strep A
Upper Respiratory Tract Infection (URTI)						
Common cold	●	●	●	●	●	
Otitis media	●	●	●	●		●
Tonsillitis & Pharyngitis	●	●		●	●	●
Laryngitis	●	●		●		●
Croup cough	●	●	●	●		
Lower Respiratory Tract Infection (LRTI)						
Bronchitis	●	●	●	●	●	
Bronchiolitis	●	●	●	●	●	
Pneumonia	●	●	●	●	●	●

* Infections of the Respiratory System CH. 93, Medical Microbiology. 4th edition

Viral and bacterial infections must be treated differently.

- **Bacterial Infections:** Antibiotics are typically used for treatment. It's crucial to choose the right antibiotic for the specific bacterial type.
- **Viral Infections:** Antibiotics don't work on viruses. Prevention is best achieved through vaccines, antivirals can halt viral growth, and symptomatic treatment is used when no cure is available.

Globally, WHO estimates that **only 50%** of antibiotics are used correctly. [1]

CDC – Antibiotic resistance Threat & data report, 2019

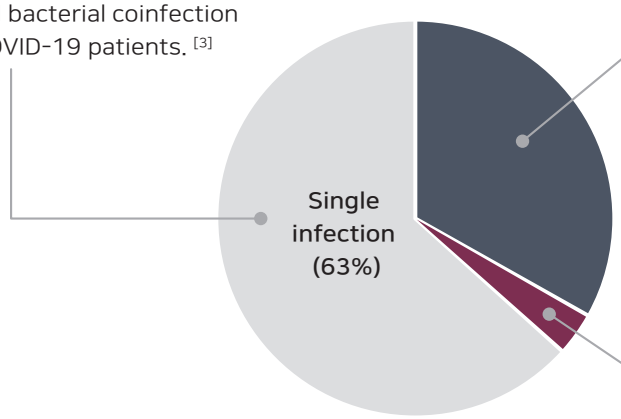
1,270,000 deaths were the direct result of drug resistant bacterial infection

4,950,000 deaths were associated bacterial resistance globally [2]

CDC estimates that U.S. doctor's offices and departments prescribe about 47 million antibiotic courses each year for infections that don't need antibiotics.

Bacterial and viral coinfections in the SARS-CoV-2-positive populations

Numerous meta-analysis reports have confirmed viral and bacterial coinfection in about 35% of COVID-19 patients. [3]



Bacterial coinfection (33%)

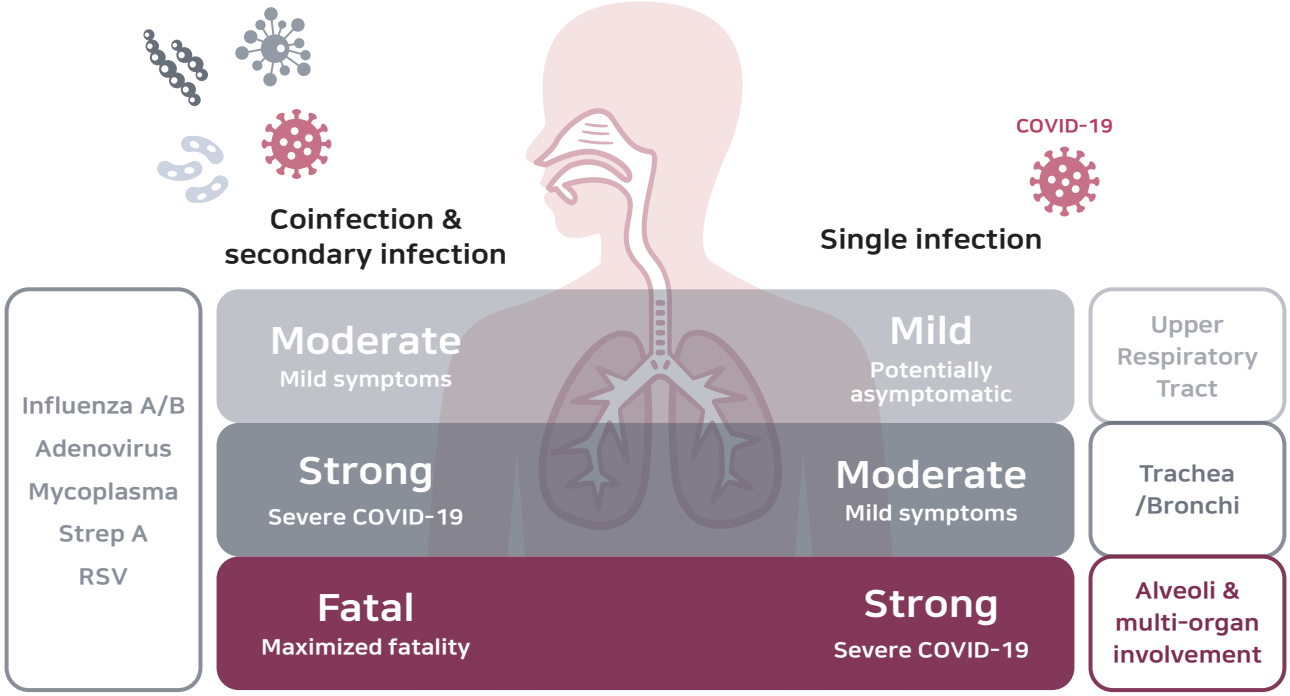
Mycoplasma	9.7%
Strep A	0.1%

Viral coinfection (4%)

Influenza A	14.8%
Influenza B	2.8%
Adeno	6.0%
RSV	2.2%

- **Single infection:** one pathogen, one host
- **Coinfection (mixed infection):** when two or more antigenically distinct pathogens infect one host

- Secondary bacterial infection is a notable complication associated with worse outcomes in COVID-19 than influenza co-infected patients. Careful surveillance and prompt antibiotic treatment may benefit patients. [4]
- Coinfection can rise the difficulties of diagnosis, treatment, progression of COVID-19 and even increase the disease symptom and mortality. [5]



Increased risk of coinfection of COVID-19 with other respiratory infections

ichroma™ broad-spectrum Respiratory Solutions Effectively solve these challenges

Misdiagnosis

If it is misdiagnosed due to lesions and symptoms similar to those of respiratory diseases, timely and appropriate treatment is not possible.

Increased mortality

COVID-19 co-infected patients have a mortality rate of 5.92 times higher than those of negative people and 2.27 times higher than those with a single infection. [6]

Contagion

Due to the delayed judgment for quarantine, the time to block the spread of the disease may be missed.

Single test

Respiratory panels	COVID-19 Ag	Influenza A+B	RSV	Adeno	Mycoplasma	Strep A
Principle	Time-resolved fluorescent lateral flow assay (TRF-LFIA)					
Reaction time	12 min	10 min				5 min
Sample type	Nasopharyngeal swab				Throat swab	
Output data	Positive(+), Negative(-), or invalid					
Analyzer	ichroma™ II, ichroma™ III, ichroma™ M2					

Clinical Performance							
	COVID-19 Ag	Flu A	Flu B	RSV	Adeno	Mycoplasma	Strep A
Sensitivity (%)	91.1	98.6	96.0	91.3	93.0	81.9	93.4
Specificity (%)	98.8	100	100	100	98.0	98.8	97.9

Combo test

Respiratory panels	COVID-19/Flu Ag	Influenza A+B/RSV	COVID-19/Flu A+B/RSV Ag
Principle	Time-resolved fluorescent lateral flow assay (TRF-LFIA)		
Reaction time	20 min	10 min	20 min
Sample type	Nasopharyngeal swab		
Output data	Positive(+), Negative(-), or invalid		
Analyzer	ichroma™ II, ichroma™ III, ichroma™ M2*		

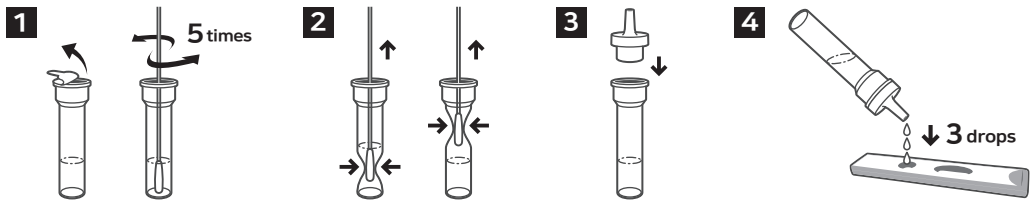
Clinical Performance									
	COVID-19 Ag	Flu A	Flu B	Flu A	Flu B	RSV	COVID-19 Ag	Flu A	Flu B	RSV
Sensitivity (%)	100	93.8	93.8	96.0	98.7	96.0	95.0	95.0	91.4	95.0
Specificity (%)	98.3	100	100	100	100	99.1	99.4	98.8	100	99.4

* COVID-19/Flu A+B/RSV Ag is not available

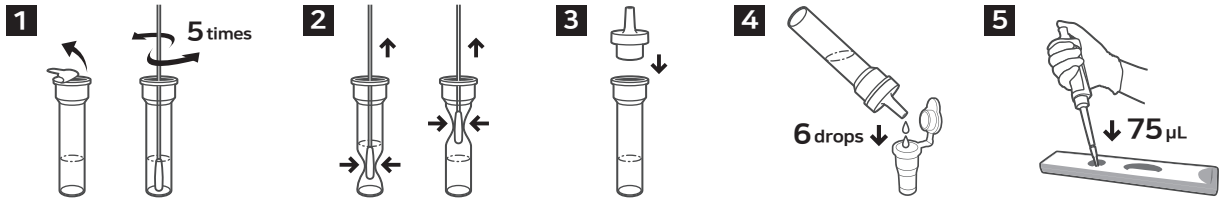
- **Reference tests**
  - RT-PCR: COVID-19 Ag, Influenza A+B, RSV, Adenovirus, Mycoplasma
  - Culture method: Strep A

Procedures (ichroma™ II, ichroma™ III, ichroma™ M2)

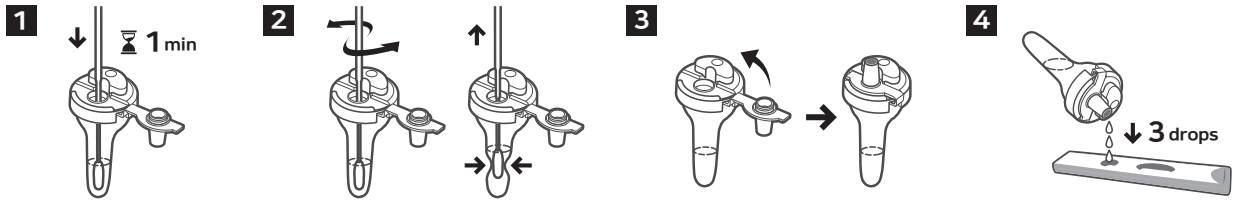
ichroma™ Influenza A+B, RSV, Mycoplasma, Adeno, influenza A+B/RSV



ichroma™ COVID-19 Ag, COVID-19 Ag/Flu Ag, COVID-19/Flu A+B/RSV Ag



ichroma™ Strep A



Measurement

Ordering information

Product	Cat.No	Contents	Shelf life
Analyzer			
ichroma™ II	FPRR021	Set	-
ichroma™ III	FPRR037	Set	-
ichroma™ M2	FPRR031	Set	-
Single test			
ichroma™ COVID-19 Ag	CFPC-115	25 T/box	20 months
ichroma™ Influenza A+B	CFPC-61	25 T/box	18 months
ichroma™ RSV	CFPC-88	25 T/box	18 months
ichroma™ Adeno	CFPC-96	25 T/box	18 months
ichroma™ Mycoplasma	CFPC-94	25 T/box	18 months
ichroma™ Strep A	CFPC-74	25 T/box	18 months
Combo test			
ichroma™ COVID-19/Flu Ag	CFPC-117	25 T/box	20 months
ichroma™ Influenza A+B/RSV	CFPC-80	25 T/box	18 months
ichroma™ COVID-19/Flu A+B/RSV Ag	CFPC-138	25 T/box	20 months

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References

1) Jonas, Olga B, et al, Drug-Resistant Infection: a threat to our economic future, World Bank Group, 2017
2) Antimicrobial Resistance Collaborators, Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis, Lancet, 2022
3) Singh V et. al., SARS-CoV-2 respiratory co-infections: Incidence of viral and bacterial co-pathogens (2021). Int J Infect Dis. 105: 617. doi: 10.1016/j.ijid.2021.02.087. Epub 2021 Feb 25. PMID: 33640570
4) Shafran N et. al., Secondary bacterial infection in COVID-19 patients is a stronger predictor for death compared to influenza patients (2021). Sci Rep. 11(1): 12703. doi: 10.1038/s41598-021-92220-0. PMID: 34135459
5) Chen X et. al., The microbial coinfection in COVID-19 (2020). Appl Microbiol Biotechnol. 104(18): 7777. doi: 10.1007/s00253-020-10814-6. Epub 2020 Aug 11. PMID: 32780290
6) Iacobucci G. Covid-19: Risk of death more than doubled in people who also had flu, English data show. BMJ. 2020 Sep 23;370:m3720. doi: 10.1136/bmj.m3720. PMID: 32967850.

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