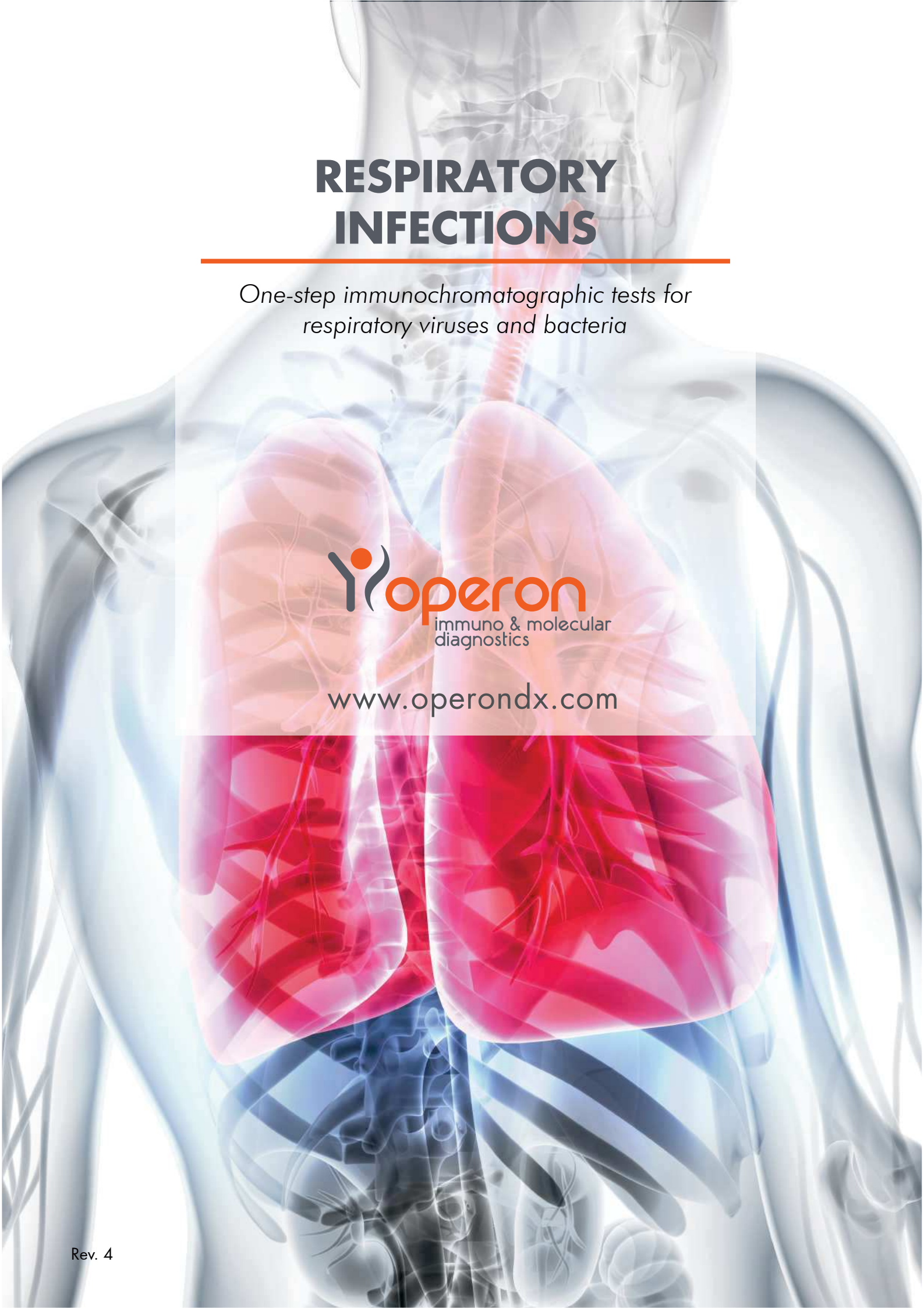
RESPIRATORY INFECTIONS

One-step immunochromatographic tests for respiratory viruses and bacteria



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RESPIRATORY INFECTIONS

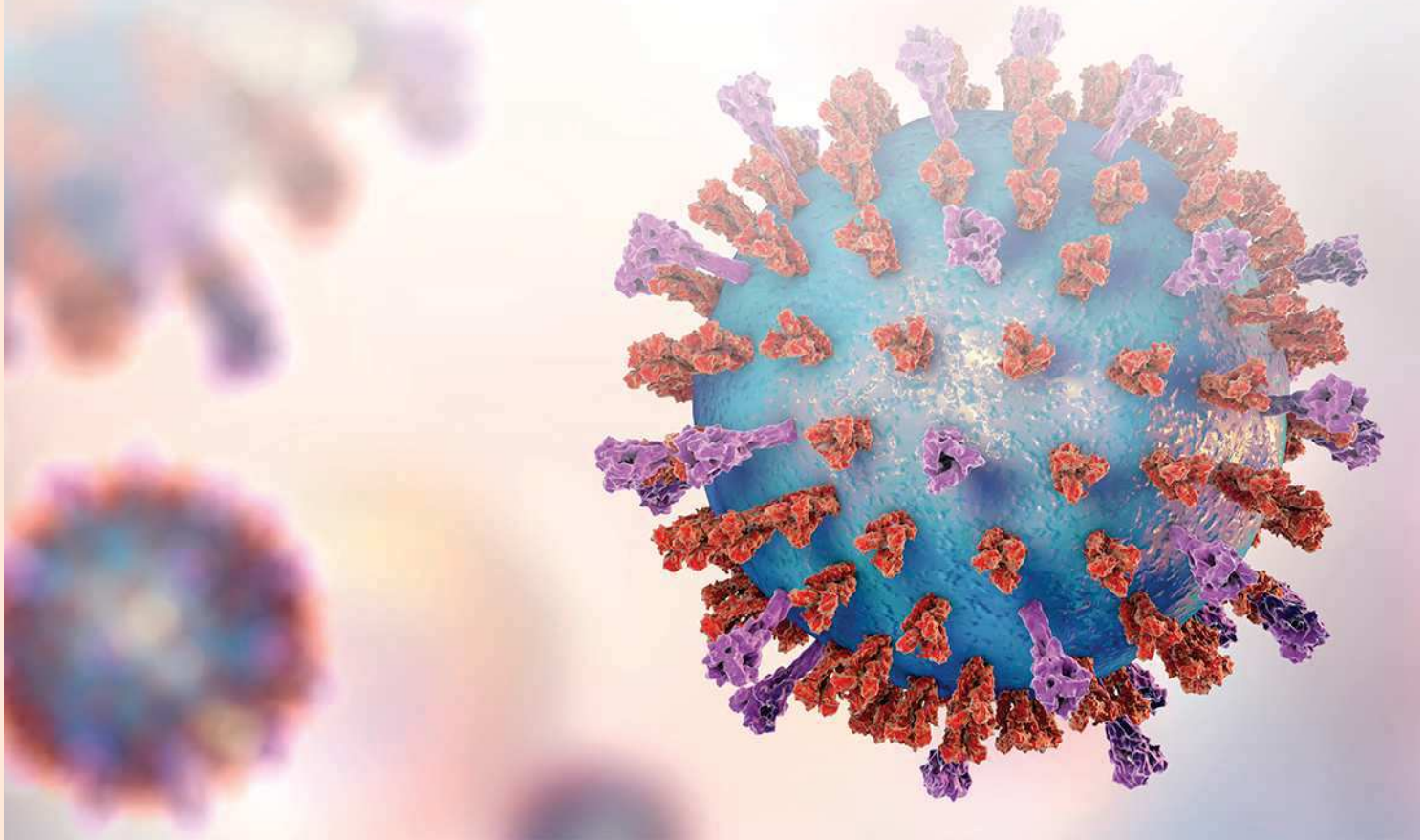
Respiratory tract infections include both upper tract infections, such as the common cold; and lower tract infections, such as pneumonia, bronchitis, bronchiolitis, and exacerbation of asthma. Lower respiratory tract infections cause substantial morbidity and mortality and are a leading cause of hospitalization, especially for infants, the elderly, and immunocompromised individuals.

Respiratory tract infections are caused by a wide variety of pathogens, which include several viral and bacterial agents.

Although the specific microorganisms responsible for illness differ according to season and age of patient, symptoms and seasons are similar for many respiratory pathogens.

Acute respiratory infections are the most common reason for oral antibiotic prescriptions in Western countries. Recent data suggest that approximately 30% of antibiotics used in the outpatient setting are inappropriate, largely driven by misuse of antibiotics for viral upper respiratory tract infections. Overuse of antibiotics has been linked to several negative outcomes, including development of antibiotic resistance, antibiotic-associated infections, increased costs, and drug toxicities. Antibiotic stewardship programs focus on guiding clinicians to use antibiotics for upper respiratory tract infections only when adequate evidence for bacterial infection exists.

Therefore, early and accurate laboratory diagnosis to identify the etiologic agent of a respiratory infection is important to ensure appropriate antimicrobial therapy and for the effective implementation of isolation precautions and patient cohorting.



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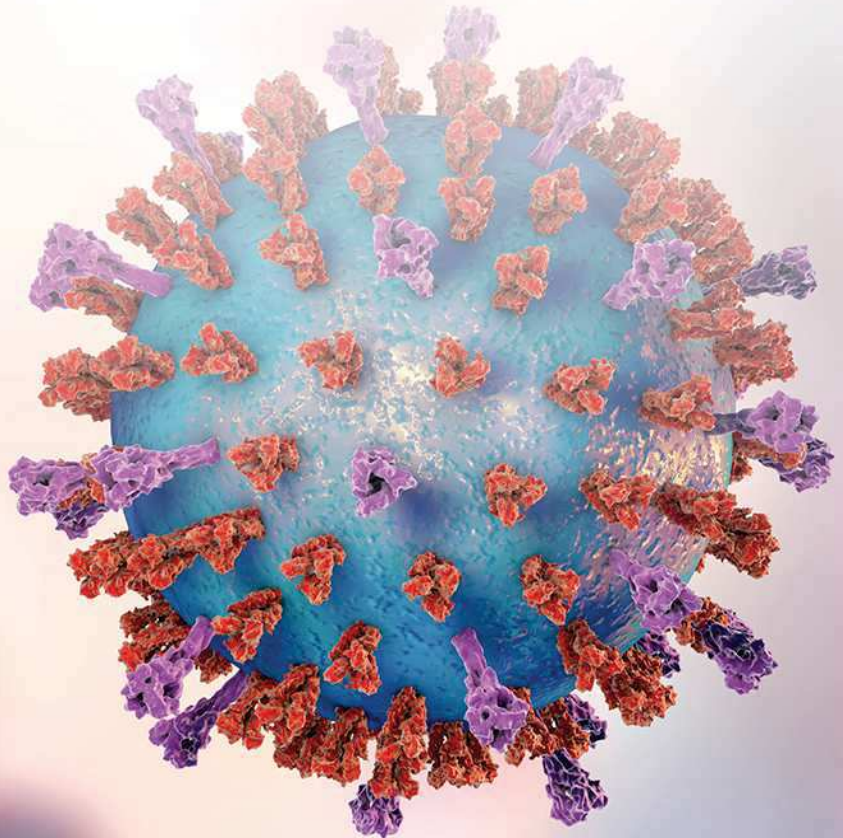
VIRUSES

BACTERIA



SIMPLE/STICK AG SARS-COV-2

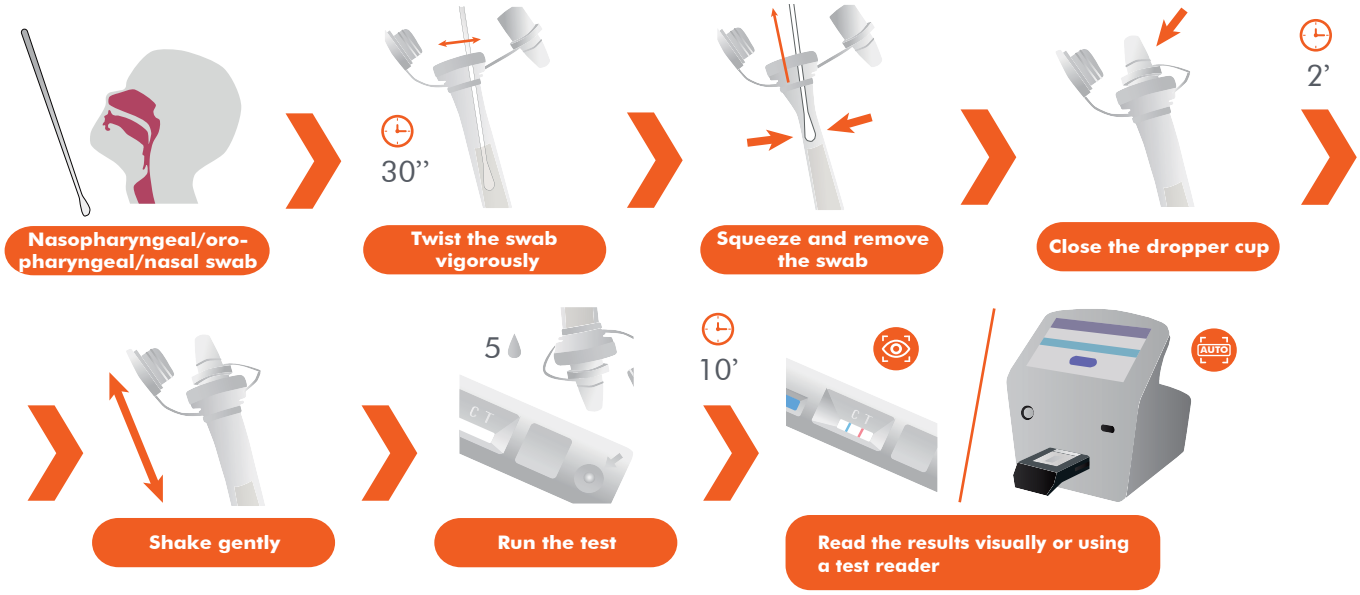
One-step immunochromatographic test for the qualitative detection of the antigen of the virus SARS-CoV-2 in nasopharyngeal, oropharyngeal and nasal samples

A new severe respiratory syndrome caused by a coronavirus was first observed in Wuhan (China) in December 2019. The infection has spread all over the world and, consequently, on March 2020, the disease was declared a pandemic by the WHO. The new virus was called SARS-CoV-2, causing COVID-19 disease.

The currently gold standard for the detection of SARS-CoV-2 relies on viral RNA amplification by real-time RT-PCR, but it requires few hours before results release. In addition, the pandemic highlighted the limits of production and trade for molecular tests. There are increasing amounts of data to support the use of antigen tests as screening tests to detect or exclude active COVID-19, and to determine whether a person who previously was diagnosed with COVID-19 remains infectious. Antigen tests can be used at the point of care, as they are user friendly, returning results in just few minutes.

Ag SARS-CoV-2 rapid test, in conjunction with confirmatory testing, might be an important tool for accurate and prompt clinical management of patients with suspected COVID-19 and for preventing transmission. Furthermore, it may be helpful to relieve the workload in diagnostic hospitals and laboratories and to improve the turn-around time.

Procedure



*Also available in Stick format
**Positive control available

Results

Negative | Positive | Invalid

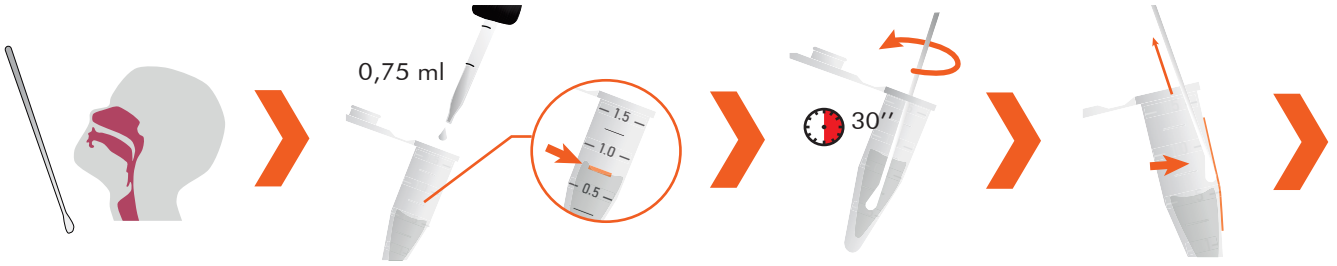
SIMPLE/STICK FLU A+B

One-step immunochromatographic test for the qualitative detection of the Influenza virus types A and B (in separate bands), from respiratory samples such as nasopharyngeal and oropharyngeal swabs, washes and aspirates

The Influenza virus is a serious and highly contagious infection of the respiratory tract. It causes one third of all upper respiratory infections and may develop into serious complications in risk groups that can lead to death. Influenza type A viruses are usually more frequent than type B viruses and are associated with the most severe flu epidemics. Influenza has a significant load in terms of morbidity, mortality and monetary cost. So, prevention, early diagnosis, and treatment of influenza are heavily prioritized in developed countries.

Simple/Stick Flu A+B allows the early and differential detection of Influenza virus types A and B in the physician's office. So, it is a helpful tool to improve outcomes in influenza patients and to prevent unnecessary testing and treatment reducing healthcare expenses and development of antimicrobial resistance.

Procedure



Nasopharyngeal/ Oropharyngeal swab

Dispense the sample dilution buffer until the third mark

Twist the swab vigorously

Remove the swab, pressing it against the microtube walls

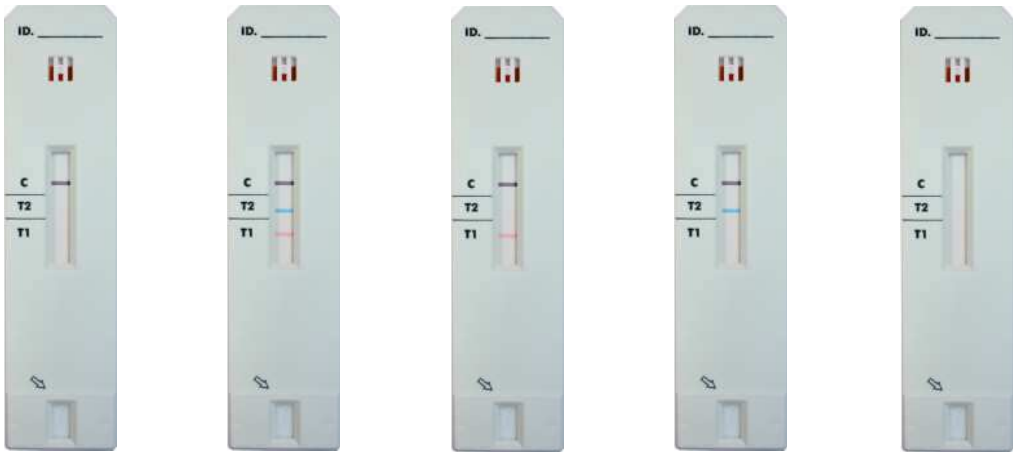
Add 7 drops to the sample addition zone

Wait 15 minutes

Read the results visually or using a test reader

*Also available in Stick format
**Compatible with swab samples in transport medium, washes and aspirates
***Positive control available

Results



Negative | Flu B + Flu A + | Flu B - Flu A + | Flu B + Flu A - | Invalid

SIMPLE/STICK RSV

One-step immunochromatographic test for the qualitative detection of Respiratory Syncytial Virus (RSV) from respiratory samples such as nasopharyngeal and oropharyngeal swabs, washes and aspirates

Respiratory Syncytial Virus (RSV) is the leading cause of acute lower respiratory tract infections in infants and young children worldwide. RSV can also become a serious problem in the elderly or immunocompromised adults and is considered as one of the main cause of nosocomial infection. The clinical diagnosis of RSV is hampered by the mostly unspecific symptoms of RSV infection.

SIMPLE/STICK RSV is a rapid test for a prompt recognition of RSV infection. It is useful to optimize care management, minimize unnecessary antibiotic use and provide targeted infection control for children hospitalized with RSV infection. In addition, it is important for timely antiviral treatment in severely sick children.

Procedure

Nasopharyngeal/ Oropharyngeal swab

Dispense the sample dilution buffer until the third mark

Twist the swab vigorously

Remove the swab, pressing it against the microtube walls

Add 7 drops to the sample addition zone

Wait 15 minutes

Read the results visually or using a test reader

*Also available in Stick format
**Compatible with swab samples in transport medium, washes and aspirates
***Positive control available

Results

Negative

Positive

Invalid

SIMPLE/STICK RESPIRADENO

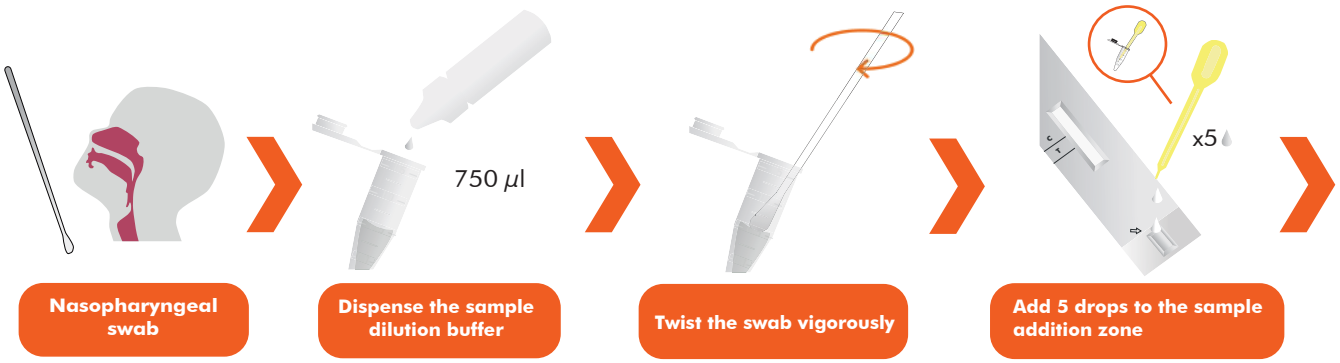
One-step immunochromatographic test for the qualitative detection of Respiratory Adenovirus from respiratory samples such as nasopharyngeal swabs, washes and aspirates

Adenovirus is a contagious agent causing from 5-24% of respiratory infections in children under 5 years old. Normally, those infections are mild except in immunosuppressed patients where it may be life threating.

Adenovirus symptoms are similar to those from a common cold.

Since the virus is highly contagious, a rapid diagnosis using Simple/Stick RespirAdeno allows the optimal management of the patient, having also a positive effect on the public health system.

Procedure



1. Nasopharyngeal swab
2. Dispense the sample dilution buffer
3. Twist the swab vigorously
4. Add 5 drops to the sample addition zone
5. Wait 15 minutes
6. Read the results visually or using a test reader

*Also available in Stick format
**Compatible with swab samples in transport medium, washes and aspirates
***Positive control available

Results

Negative | Positive | Invalid

SIMPLE AG SARS-COV-2 / FLU A+B

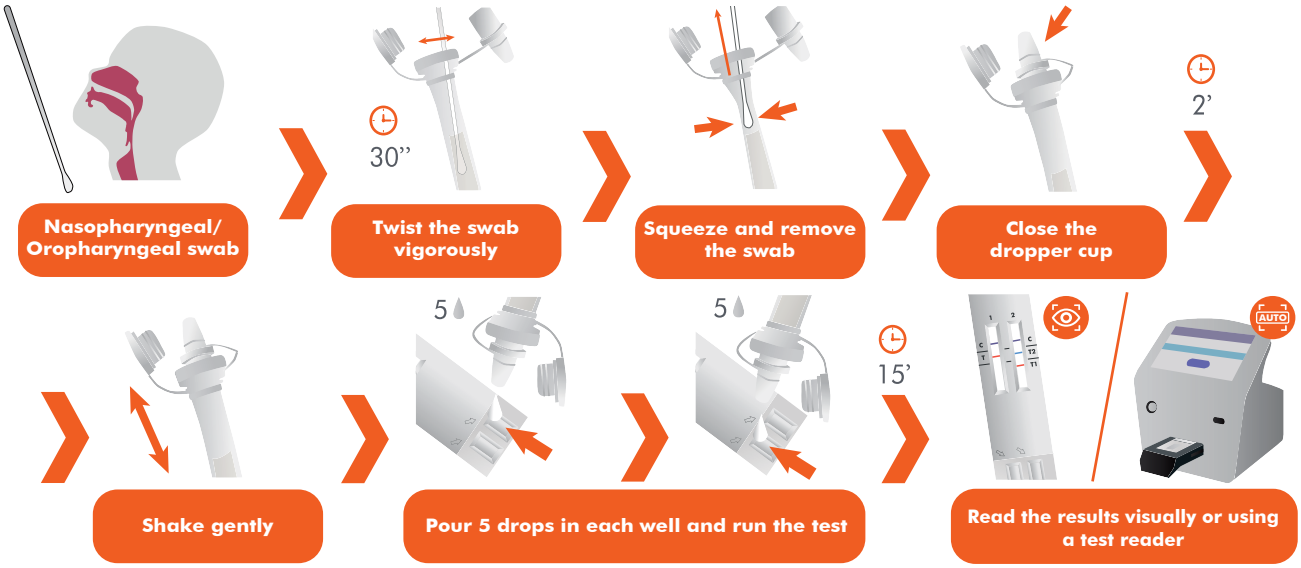
One-step immunochromatographic test for simultaneously detecting SARS-CoV-2, Influenza A and Influenza B virus antigens in nasopharyngeal and oropharyngeal swab type human respiratory samples

The currently gold standard for the detection of SARS-CoV-2 relies on viral RNA amplification by real-time RT-PCR, but it requires few hours before results release. In addition, the pandemic highlighted the limits of production and trade for molecular tests. There are increasing amounts of data to support the use of antigen tests as screening tests to detect or exclude active COVID-19, and to determine whether a person who previously was diagnosed with COVID-19 remains infectious. Antigen tests can be used at the point of care, as they are user friendly, returning results in just few minutes.

Influenza A and B virus infection is also mainly a respiratory condition, coursing with similar symptoms to COVID-19, thereby supporting their separate simultaneous detection using this test. The WHO estimates that annual flu epidemics cause approximately 3 to 5 million cases of serious disease, and 300,000 to 500,000 deaths.

The Ag SARS-CoV-2 / Flu A+B test can detect both the SARS-CoV-2 virus nucleoprotein, and the Influenza A and B virus nucleoproteins in the same sample, using separate strips in a double cassette. In conjunction with confirmatory testing, this might be an important tool for accurate and prompt clinical management of patients with suspected COVID-19 or Flu, and for preventing transmission. Furthermore, it may be helpful to relieve the workload in diagnostic hospitals and laboratories and to improve the turn-around time.

Procedure



*Compatible with swab samples in transport medium
**Positive controls available

Results

Negative | Ag SARS-CoV-2 + Flu A - / Flu B - | Ag SARS-CoV-2 - Flu A + | Ag SARS-CoV-2 - Flu B + | Invalid

SIMPLE RSV-FLU A+B

One-step immunochromatographic test for the qualitative and differential detection of RSV and Flu A and B virus antigen in respiratory samples such as nasopharyngeal and oropharyngeal swabs, washes and aspirates

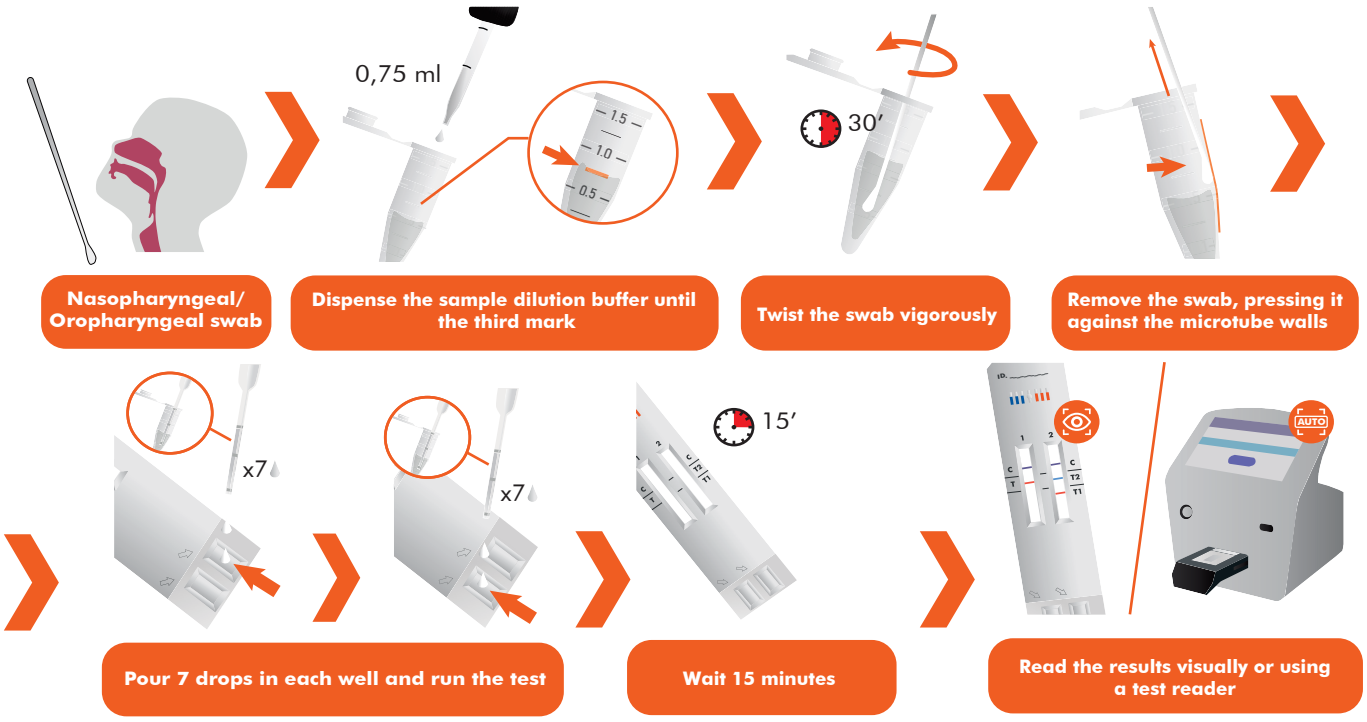
Respiratory Syncytial Virus (RSV) is the leading cause of emergency department visits and hospitalisation for acute lower respiratory tract infections in infants and young children worldwide. In addition, its infective characteristics have made RSV one of the leading causes of nosocomial infection.

Influenza virus is a serious and highly contagious infection of the respiratory tract. Influenza type A viruses are generally more common than type B viruses and are associated with the most severe influenza epidemics.

The similar seasonality of RSV and Influenza viruses support joint detection. Although RSV tends to appear before Influenza (at the beginning of autumn as opposed to flu during the winter months), both viruses coexist during the winter months with incidence highest for around a 5 month period, before they completely disappear when spring arrives.

The Simple RSV-Flu A+B test can detect both the RSV virus fusion protein (from subtype A and B) and Influenza A and B virus nucleoproteins in the same sample.

Procedure

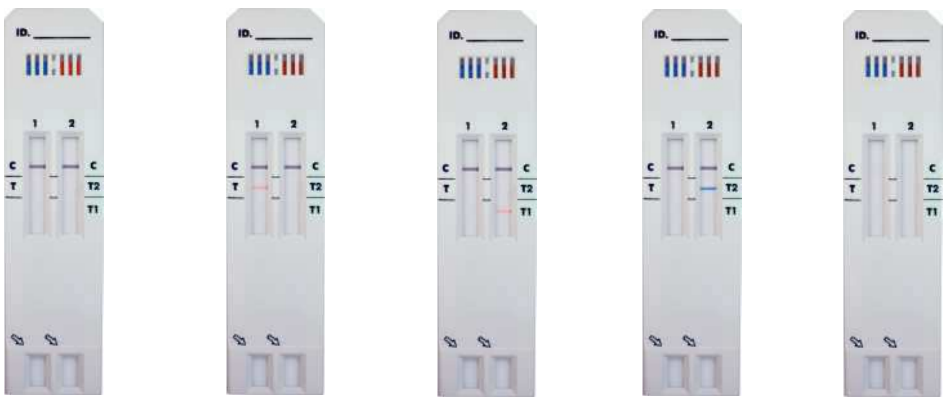


1. Nasopharyngeal/ Oropharyngeal swab
2. Dispense the sample dilution buffer until the third mark
3. Twist the swab vigorously
4. Remove the swab, pressing it against the microtube walls
5. Pour 7 drops in each well and run the test
6. Wait 15 minutes
7. Read the results visually or using a test reader

*Compatible with swab samples in transport medium, washes and aspirates

**Positive control available

Results



Negative | RSV + Flu A - / Flu B - | RSV - Flu A + | RSV - Flu B + | Invalid

SIMPLE RSV-RESPIRADENO

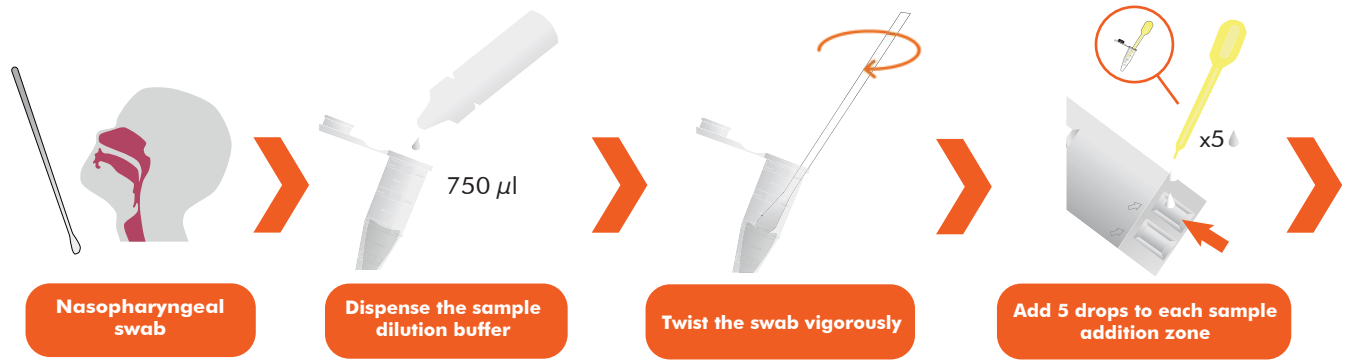
One-step immunochromatographic test for the qualitative and differential detection of RSV and Respiratory Adenovirus in respiratory samples such as nasopharyngeal swabs, washes and aspirates

Respiratory Syncytial Virus (RSV) is the leading cause of emergency department visits and hospitalisation for acute lower respiratory tract infections in infants and young children worldwide. In addition, its infective characteristics have made RSV one of the leading causes of nosocomial infection.

Adenovirus is a virus of the Adenoviridae family. The symptoms of Adenovirus infections are similar to a common cold, but unlike other respiratory viruses such as influenza or RSV, it is not seasonal and is detectable throughout the year.

The Simple RSV-RespirAdeno test allows the simultaneous and differential detection of Respiratory Sincitial Virus and respiratory Adenovirus, two of the viruses that most frequently cause respiratory infections in children. Both viruses are highly contagious, so a rapid detection of them8,9 facilitates and improves the control of the infection and optimizes the use of health resources.

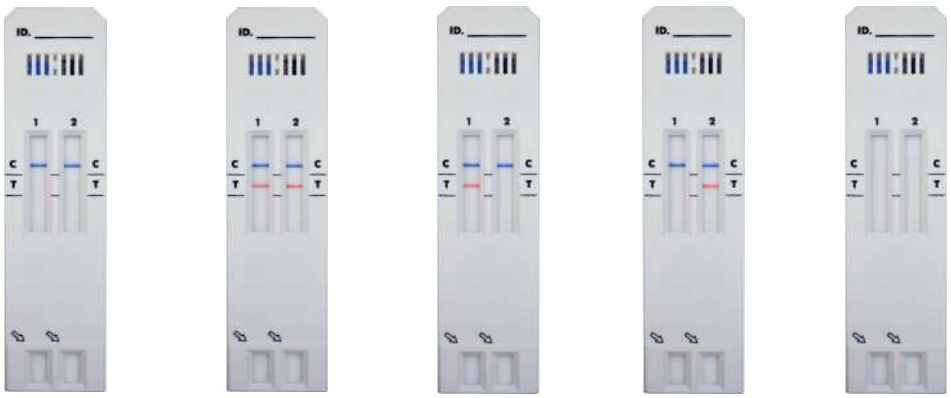
Procedure



1. Nasopharyngeal swab
2. Dispense the sample dilution buffer
3. Twist the swab vigorously
4. Add 5 drops to each sample addition zone
5. Add 5 drops to each sample addition zone
6. Wait 15 minutes
7. Read the results visually or using a test reader

*Compatible with swab samples in transport medium, washes and aspirates
**Positive control available

Results



Negative | RSV + Adeno + | RSV + Adeno - | RSV - Adeno + | Invalid

SIMPLE/STICK STREP PNEUMO

One-step immunochromatographic test for the detection of the Streptococcus pneumoniae soluble antigen in human urine

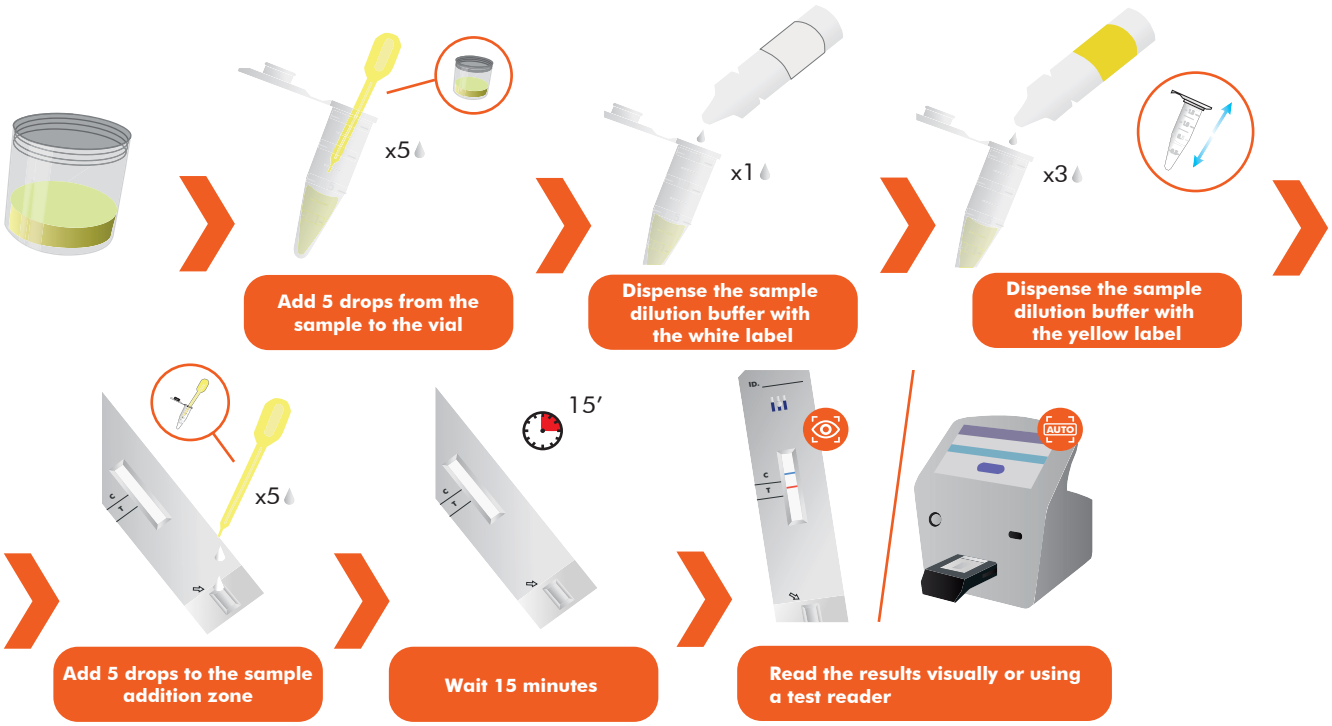
Streptococcus pneumoniae is the main pathogen responsible for community-acquired and hospital-acquired pneumonia in adults and children. It is the second most frequent cause of bacterial meningitis, and a common cause of bacteremia.

The mortality rates are up to 30%, depending on the bacteraemia, age, and latent diseases.

Many non-bacteraemic pneumonia cases remain undetected using traditional respiratory or blood sample culture methods.

Simple/Stick S. pneumo enables a quick and reliable diagnosis. This allows the administration of the most suitable antibiotic treatment at the early stages of the disease.

Procedure



*Also available in Stick format
**Positive control available

Results

Negative | Positive | Invalid

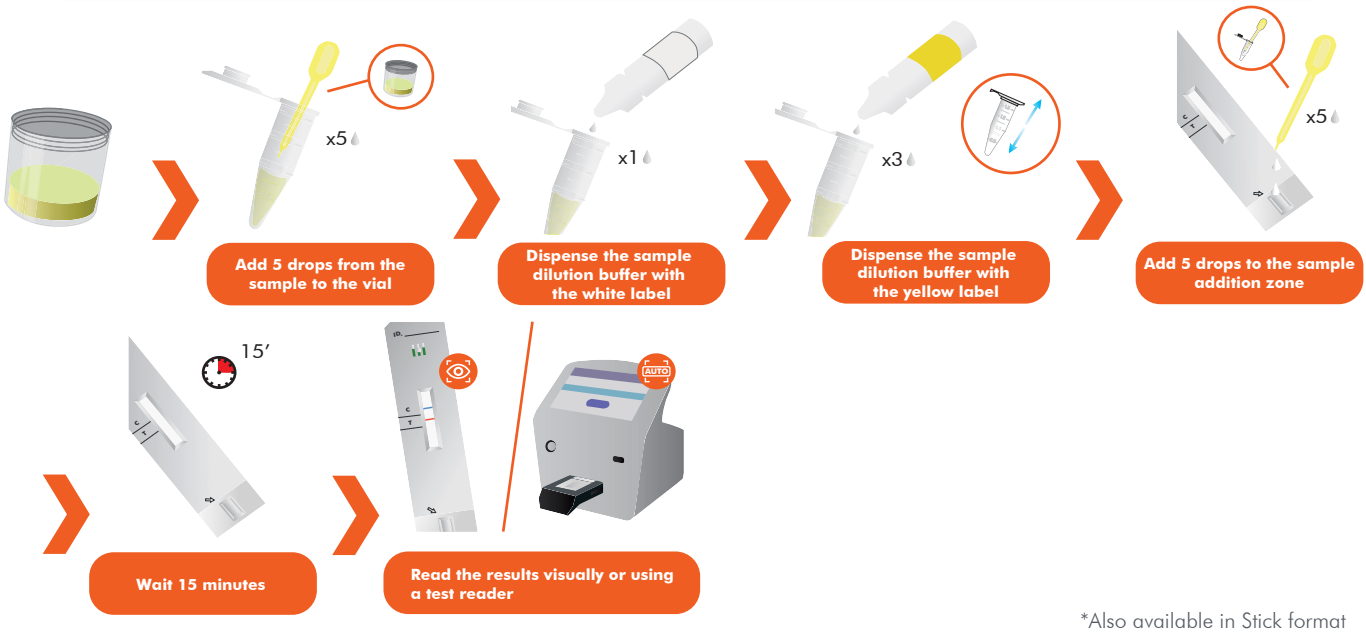
SIMPLE/STICK LEGIO PNEUMO

One-step immunochromatographic test for the detection of the Legionella pneumophila serogroup 1 soluble antigen in human urine

Infection by Legionella or legionellosis can take on two different clinical forms. These are lung infection, or "Legionnaires' disease", which is known for pneumonia accompanied with a high fever, and the non-pneumonia form known as "Pontiac fever", with symptoms of acute fever with a mild prognosis, which doesn't normally require treatment. The incidence of L. pneumophila induced pneumonia varies, accounting for 2 to 15% of community-acquired pneumonia cases requiring hospitalisation. It occurs more frequently among adults aged 40 to 70 years old. It occurs two to three times more often in males compared to females. Legionella can be acquired in two domains, community-acquired with a 3 % mortality rate, and hospital-acquired, where it affects high risk patients and has a mortality rate of 10 to 30 %, presenting as outbreaks and in isolated or sporadic cases.

Simple/Stick S. Legio is a helpful tool for the early diagnosis and treatment of "Legionnaires' disease", notably reducing its mortality. In addition, it facilitates the early recognition of epidemic outbreaks favouring a quick response when applying disease preventive and control measures.

Procedure



*Also available in Stick format
**Positive control available

Results

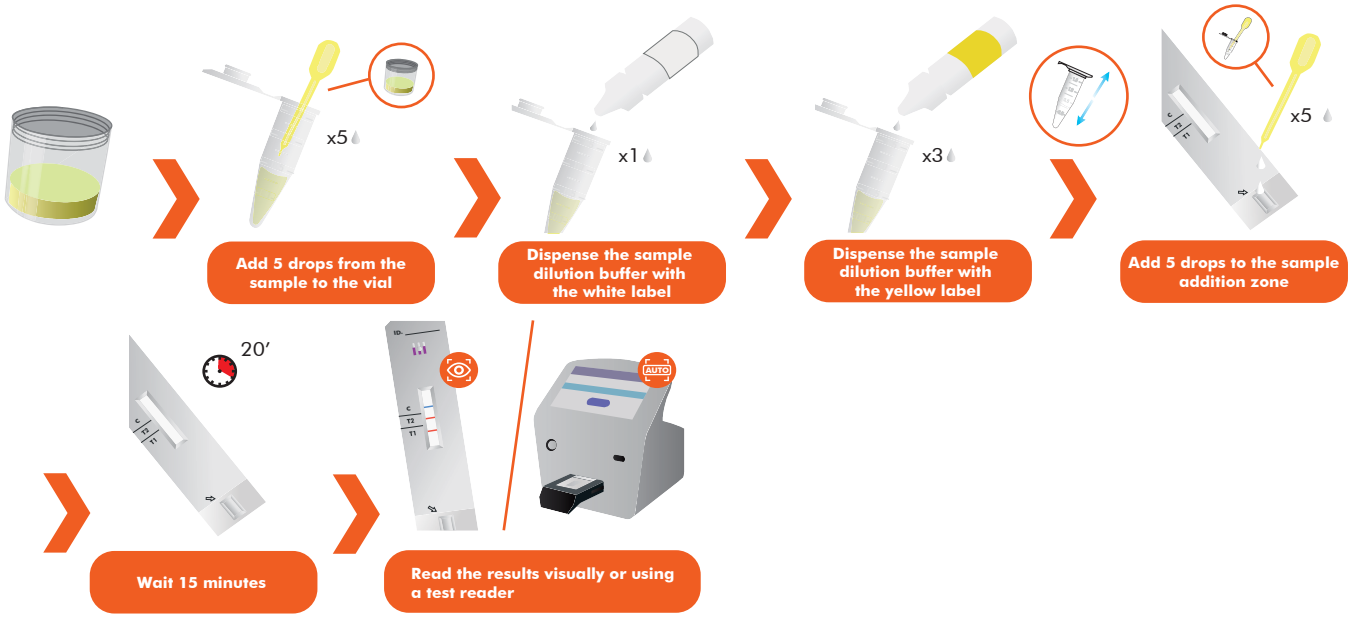
Negative | Positive | Invalid

SIMPLE/STICK STREP PNEUMO-LEGIO

One-step immunochromatographic test for the detection of the Streptococcus pneumoniae and Legionella pneumophila serogroup 1 soluble antigen in human urine.

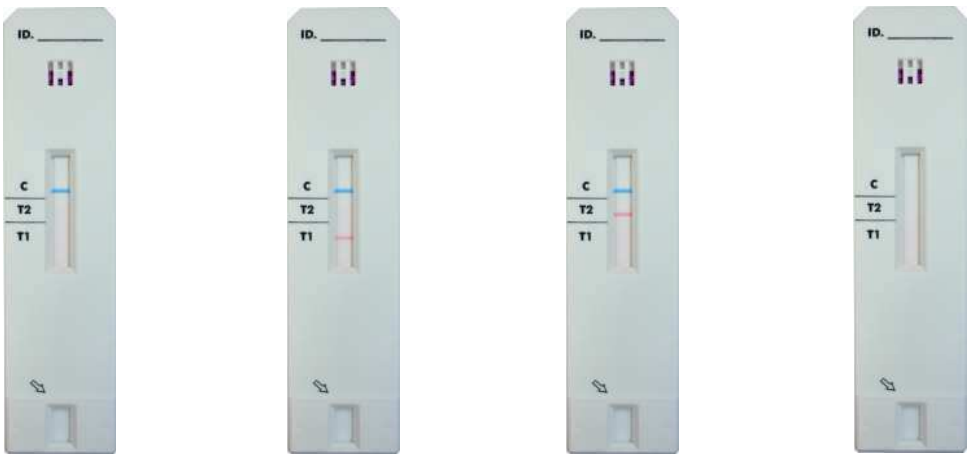
Simple/Stick Strep pneumo-Legio rapid test for *Streptococcus pneumoniae* and *L.pneumophila* serogroup 1 soluble antigens released during the course of pneumococcus-derived pneumonia or "Legionnaire's disease", enables the early and differential diagnosis of both diseases, and the use of the most suitable antibiotic treatment during the early stages of both diseases.

Procedure



*Also available in Stick format
**Positive control available

Results



Negative

L. pneumo -
S. pneumo +

L. pneumo +
S. pneumo -

Invalid

SIMPLE STREP A

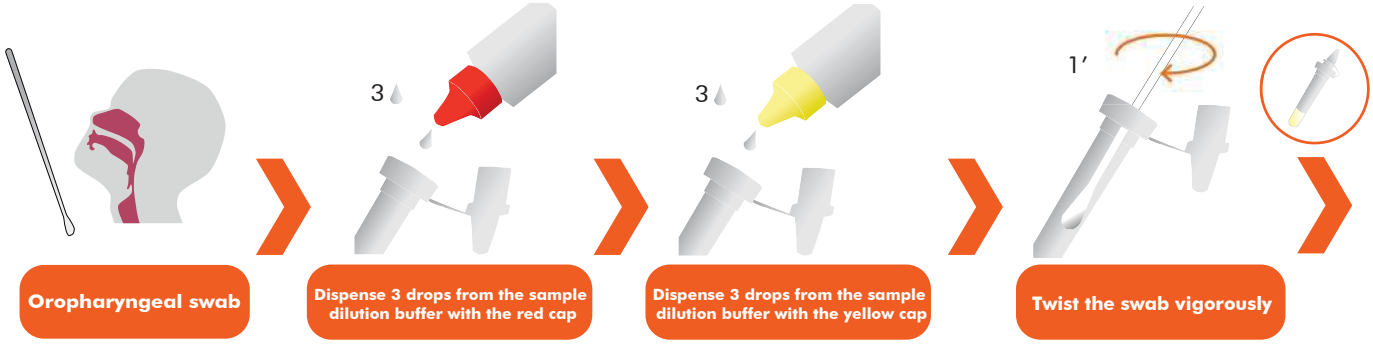
One-step immunochromatographic test for the detection of Group A Streptococcus in oropharyngeal swabs, other type of swabs (ear, ulcers...) and bacteria cultures

Group A Streptococcus is a major cause of upper respiratory infections in human, being the most significant pathogen causing pharyngitis. In the paediatric population, it is estimated that 30% of pharyngitis are caused by Group A Streptococcus. The symptoms may become more severe if not treated and the patient can develop complications such as rheumatic fever, toxic-shock like syndrome and glomerulonephritis. So, a rapid identification to initiate an antibiotic treatment can prevent these complications.

Conventional methods used to identify Group A Streptococcus involve 24-48 h culture of throat swabs specimens and its confirmation of beta-hemolytic colonies as Group A Streptococcus.

The Simple /Stick Strep A test is a rapid immunochromatographic method which employs specific antibodies against an antigen (a carbohydrate present in the wall cell) unique to Group A Streptococcus. To perform the test, a throat specimen is collected and the antigen is extracted with Sample Diluent Buffers 1 and 2 that has to be mixed previously before the addition of the swab. The test detects either viable or non viable organism directly from throat swabs or culture colonies within 10 minutes (or less in the case of high positive samples).

Procedure



*Also available in Stick format
**Compatible with swab samples in transport medium, other type of swabs (ears, ulcers...) and bacteria culture
***Positive control included

Results

Negative | Positive | Invalid

HIGHLIGHTS

- All formats: Stick/Simple, Single/Combo
- Ready to use
- Reliable: highly accurate results
- Long shelf-life: 24 months
- Flexible: different sample types for virus rapid tests
- Efficient: one common patient sample for various related rapid tests
- Safe: minimal sample manipulation
- Easy: limited hands-on-time
- Fast: results in minutes
- Easy interpretation of the visual results: different coloured bands
- Automatic reading available with the OPERON lateral flow reader
- Positive Controls available
- Actionable: Valuable information before hospital admission to control the spread of infection
- Reassuring: optimal patient management before leaving the doctor's office

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