

COVID-19 Antigen Rapid Test Cassette (Nasal Swab)**Package Insert (For Self-testing)**

English

A rapid test for the qualitative detection of COVID-19 antigen in Nasal Swab in symptomatic individuals.

[INTENDED USE]

The COVID-19 Antigen Rapid Test Cassette(Nasal Swab) is a rapid chromatographic immunoassay for the qualitative detection of COVID-19 antigen in Nasal Swab in symptomatic individuals. The identification is based on the monoclonal antibodies specific for the Nucleocapsid (N) protein of SARS-CoV-2. It is intended to aid in the rapid differential diagnosis of current COVID-19 infections.

[SUMMARY]

The novel coronavirus belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

[PRINCIPLE]

The COVID-19 Antigen Rapid Test Cassette (Nasal Swab) is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in Nasal Swab. In this test, antibody specific to the N protein of SARS-CoV-2 is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to N protein of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N protein of SARS-CoV-2 on the membrane and generate one colored line in the test region. The presence of this colored line of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

[REAGENTS]

The test cassette contains anti-SARS-CoV-2 antibodies, anti-SARS-CoV-2 antibody for gold conjugate, purified antibodies from goat, purified antibodies from rabbit for gold conjugate.

[PRECAUTIONS]

Please read all the information in this package insert before performing the test.

1. Do not use after the expiration date.

2. The test should remain in the sealed pouch until ready to use.

3. Wash hand before and after the test.

4. All specimens should be considered potentially hazardous and handled in the same manner as an infection agent.

5. The used test should be discarded according to the local regulations.

6. Avoid using bloody samples.

7. Wear protective gloves when handling the samples, avoid touching the reagent membrane and sample well.

8. Wear a face covering when collecting nasal swab from children or others.

9. Avoid touching the swab head when handling the swab.

[STORAGE AND STABILITY]

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch.

The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

[SPECIMEN COLLECTION AND PREPARATION]

The COVID-19 Antigen Rapid Test Cassette (Nasal Swab) can be performed using Nasal Swab specimens.

The quality of specimens obtained is of extreme importance. Detection of COVID-19 Antigen requires a vigorous and thorough collection technique that provides COVID-19 Antigen rather than just body fluids.

● Nasal swab Specimen:

• Use the nasal swab supplied in the kit. Prior to collecting the nasal swab, blow your nose before sampling. To collect a nasal swab sample, insert the entire absorbent tip of the nasal swab (usually ½ to 1 of an inch (1.5 to 2.5 cm)) into the nose and firmly sample the nasal wall by rotating the swab in a circular motion along the nasal wall at least 5 times. Take approximately **15 seconds** to collect the sample per nostril. Be sure to collect any nasal drainage that may be present on the swab. **Sample both nostrils with the same swab before testing**.

Do not return the Nasal swab to the original paper packaging.

• For best performance, direct Nasal swabs should be tested as soon as possible after collection.

[MATERIALS]

Materials Provided

	Quantity(pcs)
Test Cassette	1T 2T 5T 25T
Extraction Buffer Tube	1 2 5 25
Sterile Nasal Swab	1 2 5 25
Disposal Bag	1 2 5 25
Quick Reference Guide	1 1 1 1
Tube Holder	/ / / 1
Package Insert	1 1 1 1

Materials required but not provided

• Timer

[DIRECTIONS FOR USE]

Allow the test, specimen, extraction buffer tube to equilibrate to room temperature (15-30°C) prior to testing.

1. Wash your hands before starting your test. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after removing the foil pouch.

2. Tear the aluminum foil on the extraction buffer tube. See illustration 1.

3. Place the swab specimen in the extraction buffer tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the extraction buffer tube to release the antigen in the swab. See illustration 2.

4. Remove the swab while squeezing the swab head against the inside of the individual tube as you remove it to expel as much liquid as possible from the swab. See illustration 3.

5. Fit the dropper tip on top of the extraction buffer tube. Place the test cassette on a clean and flat surface. Do not move the test cassette during the test. See illustration 4.

6. Hold the tube vertically and transfer 3 drops of the sample solution (approx.80µL) to the sample well and then start the timer. Read the result at 10 minutes. Do not interpret the result after 20 minutes.

7. Please dispose off the swab, extraction buffer tube and test cassette in the disposal bag provided inside the test kit package. Wash your hand after the test.

COVID-19 Antigen Rapid Test Cassette (Nasal Swab)**Package Insert (For Self-testing)**

The COVID-19 Antigen Rapid Test Cassette(Nasal Swab) is a rapid chromatographic immunoassay for the qualitative detection of COVID-19 antigen in Nasal Swab in symptomatic individuals. The identification is based on the monoclonal antibodies specific for the Nucleocapsid (N) protein of SARS-CoV-2. It is intended to aid in the rapid differential diagnosis of current COVID-19 infections.

[SUMMARY]

The novel coronavirus belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

[PRINCIPLE]

The COVID-19 Antigen Rapid Test Cassette (Nasal Swab) is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in Nasal Swab. In this test, antibody specific to the N protein of SARS-CoV-2 is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to N protein of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N protein of SARS-CoV-2 on the membrane and generate one colored line in the test region. The presence of this colored line of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

[REAGENTS]

The test cassette contains anti-SARS-CoV-2 antibodies, anti-SARS CoV-2 antibody for gold conjugate, purified antibodies from goat, purified antibodies from rabbit for gold conjugate.

[PRECAUTIONS]

Please read all the information in this package insert before performing the test.

1. Do not use after the expiration date.

2. The test should remain in the sealed pouch until ready to use.

3. Wash hand before and after the test.

4. All specimens should be considered potentially hazardous and handled in the same manner as an infection agent.

5. The used test should be discarded according to the local regulations.

6. Avoid using bloody samples.

7. Wear protective gloves when handling the samples, avoid touching the reagent membrane and sample well.

8. Wear a face covering when collecting nasal swab from children or others.

9. Avoid touching the swab head when handling the swab.

[STORAGE AND STABILITY]

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch.

The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

[SPECIMEN COLLECTION AND PREPARATION]

The COVID-19 Antigen Rapid Test Cassette (Nasal Swab) can be performed using Nasal Swab specimens.

The quality of specimens obtained is of extreme importance. Detection of COVID-19 Antigen requires a vigorous and thorough collection technique that provides COVID-19 Antigen rather than just body fluids.

● Nasal swab Specimen:

• Use the nasal swab supplied in the kit. Prior to collecting the nasal swab, blow your nose before sampling. To collect a nasal swab sample, insert the entire absorbent tip of the nasal swab (usually ½ to 1 of an inch (1.5 to 2.5 cm)) into the nose and firmly sample the nasal wall by rotating the swab in a circular motion along the nasal wall at least 5 times. Take approximately **15 seconds** to collect the sample per nostril. Be sure to collect any nasal drainage that may be present on the swab. **Sample both nostrils with the same swab before testing**.

Do not return the Nasal swab to the original paper packaging.

• For best performance, direct Nasal swabs should be tested as soon as possible after collection.

[MATERIALS]

Materials Provided

	Quantity(pcs)
Test Cassette	1T 2T 5T 25T
Extraction Buffer Tube	1 2 5 25
Sterile Nasal Swab	1 2 5 25
Disposal Bag	1 2 5 25
Quick Reference Guide	1 1 1 1
Tube Holder	/ / / 1
Package Insert	1 1 1 1

Materials required but not provided

• Timer

[DIRECTIONS FOR USE]

Allow the test, specimen, extraction buffer tube to equilibrate to room temperature (15-30°C) prior to testing.

1. Wash your hands before starting your test. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after removing the foil pouch.

2. Tear the aluminum foil on the extraction buffer tube. See illustration 1.

3. Place the swab specimen in the extraction buffer tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the extraction buffer tube to release the antigen in the swab. See illustration 2.

4. Remove the swab while squeezing the swab head against the inside of the individual tube as you remove it to expel as much liquid as possible from the swab. See illustration 3.

5. Fit the dropper tip on top of the extraction buffer tube. Place the test cassette on a clean and flat surface. Do not move the test cassette during the test. See illustration 4.

6. Hold the tube vertically and transfer 3 drops of the sample solution (approx.80µL) to the sample well and then start the timer. Read the result at 10 minutes. Do not interpret the result after 20 minutes.

7. Please dispose off the swab, extraction buffer tube and test cassette in the disposal bag provided inside the test kit package. Wash your hand after the test.

COVID-19 Antigen Schnelltestkassette (Nasenabstrich)**Verpackungsbeilage (Für Selbsttest)**

Ein Schnelltest für die qualitative Detektion von COVID-19-Antigen in Nasenabstrichen bei symptomatischen Individuen.

[BESTIMMTE VERWENDUNG]

Die COVID-19-Antigen-Schnelltestkassette (Nasenabstrich) ist ein chromatographischer Immunoassay zur qualitativen Detektion von COVID-19-Antigen-Nasenabstrichen von symptomatischen Individuen. Die Identifizierung basiert auf den monoklonalen Antikörpern, die spezifisch für die Nucleocapsid(N)-Protein von SARS-CoV-2 sind. Es soll bei der schnellen Differentialdiagnose aktueller COVID-19-Varianten.

[ZUSAMMENFASSUNG]

Die neuartigen Coronaviren gehören der Gattung β an. COVID-19 ist eine akute respiratorische Infektionskrankheit. Menschen sind im Allgemeinen empfänglich. Gegenwärtig sind die Patienten, die mit dem neuartigen Coronavirus infiziert sind, die Hauptinfektionsquelle; asymptotisch infizierte Personen können ebenfalls eine Infektionsquelle sein. Auf der Grundlage der aktuellen epidemiologischen Untersuchung beträgt die Inkubationszeit 1 bis 14 Tage, meist 3 bis 7 Tage. Zu den Hauptmanifestationen gehören Fieber, Müdigkeit und trockener Husten. Nasenverstopfung, laufende Nase, Halsbeschwerden, Myalgie und Durchfall werden in einigen wenigen Fällen festgestellt.

[GRUNDSATZ]

Die COVID-19-Antigen-Schnelltestkassette (Nasenabstrich) ist ein qualitativer Lateral-Flow-Immunoassay für die Detektion des N-Proteins von SARS-CoV-2 in Nasenabstrichen. Bei diesem Test wird ein für das N-Protein von SARS-CoV-2 spezifischer Antikörper separat auf die Testlinien der Testkassette aufgetragen. Während des Tests reagiert die extrahierte Probe mit dem Antikörper gegen das N-Protein von SARS-CoV-2 oder der Antikörper aufgetragen wird. Das Gemisch wandert die Membran hinauf, um mit dem Antikörper gegen das N-Protein von SARS-CoV-2 an der Membran zu reagieren und eine farbige Linie in den Testregionen zu erzeugen. Das Vorhandensein dieser farbigen Linie in der Testregionen zeigt ein positives Ergebnis an. Um als Verfahrenskontrolle zu dienen, erscheint immer eine farbige Linie in der Kontrollregion, wenn der Test ordnungsgemäß durchgeführt wurde.

[REAGENS]

Die Testkassette enthält Anti-SARS-CoV-2-Antikörper, Anti-SARS-CoV-2-Antikörper für Goldkonjugat, gereinigte Antikörper von Ziege, gereinigte Antikörper von Kaninchens für Goldkonjugat.

[GRUNDZÄTTEN]

Bitte lesen Sie alle Informationen in dieser Verpackungsbeilage, bevor Sie den Test durchführen.

2. Nach dem Verpackungsabnehmen nicht verwenden.

3. Vor und nach dem Test die Hände waschen.

4. Alle Proben sollten als potenziell gefährlich betrachtet und wie ein Infektionserreger gehandhabt werden.

5. Der verwendete Test sollte entsprechend den örtlichen Vorschriften entsorgt werden.

6. Vermeiden Sie die Verwendung blutiger Proben.

7. Tragen Sie bei der Handhabung der Proben Einweghandschuhe und vermeiden Sie es, die Reagenzmembran und die Probenvertiefung zu berühren.

8. Tragen Sie einen Gesichtsschutz, wenn Sie Nasenabstriche von Kindern oder anderen Personen entnehmen.

9. Vermeiden Sie es, den Tupferkopf zu berühren, wenn Sie den Tupfer handhaben.

[LAGERUNG UND STABILITÄT]

Verpackt bei Raumtemperatur oder gekühlt (2-30 °C) lagern. Der Test ist bis zu dem auf dem versiegelten Beutel aufgedruckten Verfallsdatum stabil. Der Test muss bis zur Verwendung in dem versiegelten Beutel bleiben. NICHT EINFRIERN. Nach Ablauf des Verfallsdatums nicht mehr verwenden.

[PROBENSAMMLUNG UND -PRÄPARATION]

Die COVID-19-Antigen-Schnelltestkassette (Nasenabstrich) kann mit Nasenabstrichproben durchgeführt werden. Die Qualität der entnommenen Proben ist von äußerster Wichtigkeit. Die Detektion von COVID-19-Antigen erfordert eine energetische und gründliche Entnahmetechnik, die nicht nur Körperfunktionen, sondern auch COVID-19-Antigen liefern.

[SPEZIFISCHE PRÄZISION]

• Verwenden Sie den im Kit enthaltenen Nasenab

tal individuo.
9. C'è una rara probabilità di un risultato positivo falso per la presenza dei ceppi del coronavirus non-SARS-CoV-2 come HKU1, NL63, OC43 o 229E. Test possono essere eseguiti per tali patogeni respiratori ad un certo livello alto per escludere la possibilità di risultati falsi per la loro presenza a livelli moderati. Tuttavia, non viene escluso un risultato falso imputabile alla presenza di tali patogeni a livelli elevati rispetto al test.

10. Risultati del test dell'antigene non vengono usati come la sola base per diagnosticare ed escludere l'infezione da SARS-CoV-2 od informare lo stato infettivo.

11. Tampone d'estrazione più dissipativo soltanto il virus in misura limitata e non viene usato come un agente anti-virus per trattare la spazzatura dopo lo smaltimento. Tutti i materiali inclusi nel tampone d'estrazione usato nel test vengono ritenuti potenzialmente infettivi e quindi smaltiti nel sacchetto della spazzatura a corredo del test come rifiuti bio-pericolosi.

12. La performance della COVID-19 Cassetta del Test Rapido dell'Antigene (Tampone Nasale) si basa sulla valutazione del numero limitato di campioni clinici. Performance clinica è stata stabilita con tutti i varianti di circolazione, ma è anticipata di riflettere i varianti prevalenti in circolazione al momento e la posizione della valutazione clinica. Performance al momento di test varierebbe in funzione dei varianti in circolazione, inclusi emergenti ceppi di SARS-CoV-2 e la loro prevalenza che varierebbero nel tempo.

INFORMAZIONI AGGIUNTIVE

1. A chi è applicabile il test?

I maggiorenne 18 anni e più possono completare il test da solo. Adolescenti di 13/17 anni possono completare il test con l'assistenza di un adulto. Bambini di età inferiore di 13 anni devono tenersi dagli adulti. Lo studio è stato eseguito con la minima fascia d'età di 3/13 anni. Nessun studio è stato eseguito su bambini di non oltre 3 anni. Quindi non si consiglia l'uso del test per i bambini inferiori di 3 anni. Interrrompe il test in caso di difficoltà di comunicazione dei bambini.

2. Come funziona la cassa di test?

La COVID-19 Carta di Test Rapido dell'Antigene (Tampone Nasale) è un rapido test immunologico chromatografico per il rilevamento qualitativo dell'antigeno COVID-19 nel Tampone Nasale. È progettato per assistenza nella rapida diagnosi differenziale delle infezioni da COVID-19.

3. Quanto preciso è il test?

Una valutazione clinica è stata condotta confrontando i risultati ottenuti utilizzando la cassetta per il test rapido dell'antigene COVID-19 (tampone nasale) con la PCR. I tamponi nasali sono stati raccolti e testati utilizzando la cassetta COVID-19 Antigen Rapid Test (Nasal Swab), i campioni sono stati considerati positivi se la PCR indicava un risultato positivo.

Per 103 casi positivi alla PCR, 96 casi positivi sono stati testati con COVID-19 Antigen Rapid Test Cassette(Nasal Swab), la sensibilità relativa della COVID-19 Antigen Rapid Test Cassette(Nasal Swab) è del 93.2%(96/103), (95%CI: 86.5% - 97.2%).

Per 250 casi di PCR negativa, 248 casi negativi sono stati testati con COVID-19 Antigen Rapid Test Cassette(Nasal Swab), la specificità relativa della COVID-19 Antigen Rapid Test Cassette(Nasal Swab) è 99.2%(248/250), (95%CI: 97.1% - 99.9%).

4. Commenti di confidenza

4. Come altre malattie influiscono sul risultato?

Nessuna reattività incrociata è stata osservata nel test nei campioni positivi per i seguenti patogeni respiratori/orofaringei comuni:- Virus dell'influenza A, virus dell'influenza B, adenovirus, virus Coxackie, virus parainfluenza tipo1, virus parainfluenza tipo2, virus parainfluenza tipo3, virus parainfluenza tipo4, enterovirus, virus della parotite, virus respiratorio sincitiale, Rhinovirus, Bordetella pertussis, Haemophilus parainfluenzae, Staphylococcus aureus, Streptococcus agalactiae, Neisseria meningitidis, Streptococcus sp. gruppo A, Streptococcus sp. gruppo B, Streptococcus sp. C, Candida albicans, Metapneumovirus umano (hMPV), Legionella pneumophila, Mycobacterium tuberculosis, Mycoplasma pneumoniae, Pneumocystis jirovecii(PJP)-S cerevisiae Recombinate, Pseudomonas aeruginosa, Staphylococcus epidermidis, Streptococcus salivarius, Streptococcus pneumoniae, Streptococcus suis, coronavirus NL63, MERS-coronavirus. Tuttavia, non viene escluso un risultato falso imputabile alla presenza di tali organismi a livello elevato rispetto al test.

5. Altre sostanze interferenti influenzano il risultato?

Nessuna reattività incrociata è stata osservata durante il test con le seguenti sostanze - Ambroxol Hydrochloride compresse, Momentasone furato spray nasale, Nin Jiom Pei Pa Kao lozione per la tosse, Desmofenofene idrossidola soluzione orale, Mucoolvan/Ambroxol Hydrochloride soluzione orale, soluzione di pulizia nasale (NaCl), Hyland's 4 Kids Cold Cough Liquid Safe Natural Relief, Durham's Canker-Rid, collutorio Listerine, collutorio Scope, antibiotico nasale (polimurofina), Oxymetazolina Hydrochloride Spray, Beclometasone Dipropionate Nasal Aerosol, Triamcinolona Acetonide Nasal Spray, Azelastina Hydrochloride Nasal Spray, Fluticasone Propionate Nasal Spray, Physiological Seawater Nasal Spray, Tobramycin Eye Drops, Whole blood, Mucin.

6. Quale danno porta il test?

Il tampono nasale non è acuto e non risulta invasivo. Il tampono può essere occasionalmente un po' scomodo o sollecito. Qualora sente il dolore, arrestate il test e interpellate un fornitore di cura sanitaria.

7. Ho sangue dal naso dopo essermi tamponato il naso. Cosa da fare?

Nel caso indesiderato che il Suo naso sanguini, applicare la pressione al Suo naso fino all'emostasi e interpellare una professionista sanitario. Non inserire di nuovo il tampono.

8. Come so che il test si svolge correttamente?

9. Come fare quando il risultato risulta positivo?

Per favore consultare immediatamente il proprio medico curante e informare gli immediati contatti che ha avuto nelle ultime 24 ore. Azioni vengono intraprese in accordo alle linee guida locali per limitare l'ulteriore diffusione dell'infezione. Immediato Test PCR è consigliato e l'auto-isolamento, ogni trattamento medico si basano sul test PCR. Un test laboratoristico con il metodo PCR è consigliato per confermare un risultato positivo.

10. Cosa fare quando il risultato risulta negativo?

Risultati negativi richiederebbero il test aggiuntivo per conferma. Parlare con il Suo fornitore di cura sanitaria qualora necessita del test aggiuntivo. È possibile che non è stato infettato Lei al momento del test. Tuttavia, un risultato negativo non La manleva dal coronavirus. Per favore continuare a seguire la distanza sociale e le norme locali.

11. Può il Test dell'Antigene RightSign® 19 rilevare i varianti di COVID-19?

1. Weiss SR, Leibowitz JL. Patogenesi del Coronavirus. Adv Virus Res 2011;81:85-164.

2. Cui J, Li F, Shi ZL. Origine ed evoluzione dei coronavironi patogeni. Nat Rev Microbiol 2019;17:181-192.

3. Su S, Wong G, Shi W, et al. Epidemiologia, ricombinazione genetica e patogenesi dei coronavironi. TrendsMicrobiol 2016;24:490-502.

Indice dei Simboli

	Consultare istruzioni per uso
	Prova al kit
	Rappresentante Autorizzato
	Per uso diagnostico in vitro
	Usato da
	Conservare tra 2/30 °C
	Non usare qualora l'imballo è danneggiato
	Numero di lotto
	Catalogo #
	Allontanarsi dal sole
	Mantenere asciutto

Cassette di test rapido dell'antigene COVID-19 (Écouillon nasale)

Manuel (Destinati a des autodiagnostic)

Un test rapido per la deteczione qualitativa dell'antigene COVID-19 chez les sujets symptomatiques.

[UTILISATION PRÉVUE]

La cassette di test rapido dell'antigene COVID-19 (écouillon nasal) è un test immunologico chromatografico rapido per la deteczione qualitativa dell'antigene COVID-19 chez les sujets symptomatiques. L'identification est basée sur les anticorps monoclonaux spécifiques à la protéine Nucleocapsid (N) du SRAS-CoV-2. Il vise à faciliter le diagnostic différentiel rapide des infections actuelles à la COVID-19.

[RÉSUMÉ]

Les nouveaux coronavirus appartiennent au genre β . La COVID-19 est une maladie respiratoire infectieuse aiguë. Les gens y sont généralement sensibles. Actuellement, les patients infectés par le nouveau coronavirus sont la principale source d'infection; les personnes infectées asymptomatiques peuvent également être une source infectieuse. Selon l'épidémiologie actuelle, la période d'incubation est de 1 à 14 jours, principalement de 3 à 7 jours. Les principales manifestations comprennent la fièvre, la fatigue et la toux sèche. Congestion nasale, écoulement nasal, maux de gorge, myalgie et diarrhée sont trouvés dans quelques cas.

[PRINCIPLE]

La cassette di test rapido dell'antigene COVID-19 (écouillon nasal) est un test immunologique qualitativo di flux laterale pour la détection de la protéine N du SRAS-CoV-2 dans l'écouillon nasal. Dans ce test, l'anticorps spécifique à la protéine N du SRAS-CoV-2 è separé en érobore sur les zones de la ligne di test della cassette di test. Au cours des tests, l'écouillon extrait réagent con l'anticorpo a la protéine N du SRAS-CoV-2 qui è entrerò sur des particules. Le mélange migre vers le haut de la membrane pour réagir con l'anticorpo a la protéine N du SRAS-CoV-2 nella membrane e generare una linea colorata dans les régions di test. La présence de cette ligne colorata des régions de test indique un résultat positivo. Pour servir de contrôle di procedure, una linea colorata apparira toujours dans la région di controllo se il test è stato correttamente déroulé.

[TESTES]

La cassette di test rapido dell'antigene COVID-19 (écouillon nasal) è un test immunologique qualitativo di flux laterale pour la détection de des anticorpi anti-SARS CoV-2, des anticorpi anti-SARS CoV-2 per il conjugato or, des anticorpi purificati de chèvre, des anticorpi purificati de lapin per il conjugato or.

[PRÉCAUTIONS]

Veuillez lire toutes les informazioni de cet encart avant d'effectuer le test.

1. Ne pas insérer après la date d'expiration.

2. Ne pas démonter la cassette scellée jusqu'à ce qu'elle soit prête à être utilisée.

3. Se laver la main avant et après le test.

4. Tous les écouillons doivent être considérés comme potentiellement dangereux et manipulés de la même manière qu'un agent infectieux.

5. Le test utilisé doit être rejeté conformément à la réglementation locale.

6. Éviter d'utiliser des écouillons sanguins.

7. Porter des gants jetables lors de la manipulation des écouillons, éviter de toucher la membrane de réactif et le puits d'échantillonnage.

8. Porter un couvre-visage pour prélever des écouillons nasaux sur des enfants ou d'autres personnes.

9. Éviter de toucher la tête de l'écouillon lors de la manipulation de l'écouillon.

[STOCKAGE ET STABILITÉ]

Conservez come embalato à température ambiente o réfrigéré (2-30°C). Le test è stable jusqu'à la date d'expiration indiquée sur la pochette scellée. Le test doit rester nella pochette scellée jusqu'à l'utilisation. NE PAS GELER. Ne pas utiliser au-delà de la date d'expiration.

[COLLETTA E PRÉPARAZIONE DES ÉCHANTILLONS]

La cassette di test rapido dell'antigene COVID-19 (écouillon nasal) peut è realizzata à l'aide d'échantillons d'écouillon nasal. La qualità des échantillons obtenu è d'une extrême importance.

La détection de l'antigene de la COVID-19 nécessite une technique de collecte rigoureuse et rigoureuse qui fournit de l'antigene de la COVID-19 plutot que seulement des liquides organiques.

• Échantillons de l'écouillon nasal :

• Utilizez l'écouillon nasal fourni dans le kit. Avant de prélever l'écouillon nasal, souffrez votre nez devant l'échantillonnage. Pour prélever un écouillon d'écouillon nasal, insérez la totalité de la pointe absorbante de l'écouillon nasal (habituellamente 1 pouce (de 1.5 a 2.5 cm) à l'intérieur de la narine e écouillonnage fermete la paroi nasale nel moins 5 fois. Prenez environ 15 secondes pour prélever l'écouillon par narine. Assurez-vous de prélever tout drainage nasal qui pourrait être présent sur l'écouillon. Prélvez les deux narines avec le même écouillon avant le test.

Ne retournez pas l'écouillon nasal dans l'emballage en papier d'origine.

• Pour une performance optimale, les écouillons nasaux directs doivent è testés dès que possibile après le prélevement.

Instruction de collecte des échantillons



Instruction de collecte des échantillons



Instruction de collecte des échantillons

Instruction de