

Quality approved by SD BIOSENSOR / For in vitro diagnostics use only

**EN** **STANDARD Q COVID-19 Ag**

STANDARD™ Q COVID-19 Ag Test

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

**KIT CONTENTS**

Test device (individually in a foil pouch with desiccant)

Extraction buffer tube

Nozzle cap

Sterile swab

Paper stand

Instructions for use

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4. Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.

5. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

6. Press the nozzle cap tightly onto the tube.

7. Apply 3 drops of extracted specimen to the specimen well of the test device.

8. Read the test result in 15-30 minutes.

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history and other data available.

**EXPLANATION AND SUMMARY**

**[Introduction]**

Coronavirus S is a single-stranded positive-sense RNA virus with an envelope of about 80 to 120 nm in diameter. Its genetic material is the largest of all RNA viruses and is an important pathogen of many domestic animals, pets, and human diseases. It can cause a variety of acute and chronic diseases. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. The 2019 new coronavirus, or "SARS-CoV-2 (COVID-19)", was discovered because of Wuhan Viral Pneumonia cases in 2019, and was named by the World Health Organization on January 12, 2020, confirming that it can cause colds and the Middle East Respiratory Syndrome (MERS) and more serious diseases such as acute respiratory syndrome (SARS). This kit is helpful for the auxiliary diagnosis of coronavirus infection. The test results are for clinical reference only and cannot be used as a basis for confirming or excluding cases alone.

**[Intended use]**

STANDARD Q COVID-19 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 present in human nasopharynx. This test is for administration by healthcare workers and labs only, as an aid to early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms with SARS-CoV-2 infection. It provides only an initial screening test result. More specific diagnosis methods should be performed in order to obtain the confirmation of SARS-CoV-2 infection.

**[Test principle]**

STANDARD Q COVID-19 Ag Test has two pre-coated lines. "C" Control line, "T" Test line on the surface of the nitrocellulose membrane. Both the control line and test line in the result window are not visible before applying any specimens. Mouse monoclonal anti-SARS-CoV-2 antibody is coated on the test line region and mouse monoclonal anti-Chicken IgG antibody is coated on the control line region. Mouse monoclonal anti-SARS-CoV-2 antibody conjugated with color particles are used as detectors for SARS-CoV-2 antigen detection. During the test, SARS-CoV-2 antigen in the specimen interact with monoclonal anti-SARS-CoV-2 antibody conjugated with color particles making antigen-antibody color particle complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the mouse monoclonal anti-SARS-CoV-2 antibody. A colored test line would be visible in the result window if SARS-CoV-2 antigens are present in the specimen. The intensity of colored test line will vary depending upon the amount of SARS-CoV-2 antigen present in the specimen. If SARS-CoV-2 antigens are not present in the specimen, then no color appears in the test line. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

**[Kit contents]**

1. Test device (individually in a foil pouch with desiccant)
2. Extraction buffer tube
3. Nozzle cap
4. Sterile swab
5. Paper stand
6. Instructions for use

**KIT STORAGE AND STABILITY**

Store the kit at 2-30°C / 36-86°F out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze the kit.

**WARNINGS AND PRECAUTIONS**

1. Do not use the test kit.

2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use the extraction buffer tube of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.
9. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
10. Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating desiccant beads change from yellow to green, the test device in the pouch should be discarded.

**SPECIMEN COLLECTION AND PREPARATION**

1. To collect a nasopharyngeal swab specimen, insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
2. Using gentle rotation, push the swab until resistance is met at the level of the turbinate.
3. Rotate the swab a few times against the nasopharyngeal wall.
4. Remove the swab from the nostril carefully.
5. Specimen should be tested as soon as possible after collection.
6. Do not use transport media, use the collected specimen and extraction buffer immediately. Be careful of contamination.
7. Specimens may be stored at room temperature for up to 1 hours or at 2-8°C/ 36-46°F for up to 4 hours prior to testing.

**LIMITATION OF TEST**

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. The test should be used for the detection of SARS-CoV-2 antigen in human nasopharyngeal swab specimens.
3. Neither the quantitative value nor the rate of SARS-CoV-2 antigen concentration can be determined by this qualitative test.
4. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
5. A negative test result may occur if the level of a extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained.
6. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
7. The test result must always be evaluated with other data available to the physician.
8. A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or an molecular assay or ELISA.
9. Positive test results do not rule out infections with other pathogens.
10. Negative test results are not intended to rule in other coronavirus infection except SARS-CoV-1.
11. Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.

Calidad aprobada por SD BIOSENSOR / Sólo para uso en diagnóstico in Vitro

**ES**

**STANDARD Q COVID-19 Ag**

STANDARD™ Q COVID-19 Ag Test

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

**KIT CONTENTS**

Test device (individually in a foil pouch with desiccant)

Extraction buffer tube

Nozzle cap

Sterile swab

Paper stand

Instructions for use

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Qualidade aprovada pela SD BIOSENSOR / Somente para uso de diagnóstico *in vitro*

**PT** REF: Q-NCOV-01G

**STANDARD Q COVID-19 Ag**  
STANDARD™ Q COVID-19 Ag Test  
LEIA COM ATENÇÃO ANTES DE REALIZAR O TESTE

**CONTEÚDO DO KIT**



#### PREPARATION AND TEST PROCEDURE

##### [Preparação]

- Leia as instruções atentamente antes de usar o Teste STANDARD Q COVID-19 Ag.
- Verifique a data de validade na parte traseira da bolsa de alumínio. Não use se a data de validade tiver passado.
- Verifique o dispositivo de teste e o pacote de dessecante dentro da bolsa de alumínio.



##### [PROCEDIMENTO DE TESTE]

- Inserir um swab estéril na narina do paciente, atingindo a superfície da nasofaringe posterior.



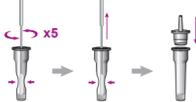
- Passar o swab sobre a superfície da nasofaringe posterior.



- Retirar o swab estéril da cavidade nasal.



- Inserir a pipeta Spoit em um tubo com tampão de extração. Gire o swab pelo menos cinco vezes.
- Remova o swab enquanto aperta os lados do tubo para extrair o líquido do swab.
- Pressione a Tampa do bico firmemente no tubo.



- Aplicar quatro gotas da amostra extraída no poço de amostras do dispositivo de teste.
- Leia os resultados do teste em 30 minutos.



##### INTERPRETAÇÃO DO RESULTADO DO TESTE

\* "C" Control Line | "T" Test Line

**Negativo**

Only one band at "C" control line in the result window indicates a negative result.

**Positivo**

Both bands appeared in each of "C" control line and "T" test line indicate COVID-19 Ag positive.

**Inválido**

NO band at "C" control line is considered as invalid result. The directions may not have been followed correctly or the test may have deteriorated. Re-test with a new specimen and a new test device.

- Uma banda colorida aparecerá na seção superior da janela de resultados para mostrar que o teste está funcionando adequadamente. Essa banda é a linha de controle (C).
- Uma banda colorida aparecerá na seção inferior da janela de resultados. Essa banda é a linha de teste do antígeno COVID-19 (T).
- Mesmo se a linha de controle for fraca ou a linha de teste não for uniforme, o teste deverá ser considerado realizado adequadamente e o resultado deverá ser interpretado como positivo.

**\*A presença de qualquer linha, não importa o quão fraca, é considerada um resultado positivo.**

**\*Os resultados positivos devem ser considerados em conjunto com o histórico clínico e outros dados disponíveis.**

#### EXPLICAÇÃO E RESUMO

##### [Introdução]

O coronavírus é um vírus de RNA de sentido positivo e fita simples com um envelope de cerca de 80 a 120 nm de diâmetro. Seu material genético é o maior de todos os vírus de RNA e um patógeno importante de muitos animais domésticos, animais de estimação e doenças humanas. Pode causar uma série de doenças agudas e crônicas. Os sinais comuns de uma pessoa infectada por um coronavírus incluem sintomas respiratórios, febre, tosse, falta de ar e diarreia. Nos casos mais graves, a infecção pode causar pneumonia, síndrome respiratória aguda grave, insuficiência renal e até mesmo a morte. O novo coronavírus de 2019, ou "COVID-19", foi descoberto por causa dos casos de pneumonia viral ocorridos em Wuhan em 2019 e foi assim denominado pela Organização Mundial da Saúde em 12 de janeiro de 2020, quando se confirmou que esse vírus pode causar resfriados, síndrome respiratória do Oriente Médio (MERS) e doenças mais graves, como a síndrome respiratória aguda (SARS). Este kit é útil para auxiliar no diagnóstico de infecção por coronavírus. Os resultados do teste são apenas para referência clínica e não podem ser utilizados isoladamente como base para confirmação ou exclusão de casos.

##### [Indicações de uso]

O Teste STANDARD Q COVID-19 Ag é um imunoenso cromatográfico rápido para a detecção qualitativa de anticorpos específicos contra COVID-19 presentes na nasofaringe humana. É um teste de diagnóstico precoce *in vitro* para uso profissional e foi desenvolvido como uma ajuda para o diagnóstico da infecção por COVID-19 em pacientes com sintomas clínicos de infecção por COVID-19. Fornece apenas o resultado de uma triagem inicial. Métodos diagnósticos alternativos mais específicos devem ser utilizados para a confirmação final da infecção do COVID-19.

##### [Princípio do teste]

O teste STANDARD Q COVID-19 Ag tem duas linhas pré-revestidas, linha de controle "C", linha de teste "T" na superfície da membrana de nitrocelulose. Nem a linha de controle nem a linha de teste ficam visíveis na janela de resultados antes da aplicação de quaisquer amostras. Anticorpo monoclonal anti-COVID-19 de camundongo reveste a região da linha de teste e o anticorpo anti-IgY de galinha monoclonal de camundongo reveste a região da linha de controle. Anticorpos monoclonais anti-COVID-19 de camundongo conjugados com partículas coloridas são usados como detectores para o dispositivo antígeno COVID-19. Durante o teste, o antígeno COVID-19 na amostra interage com o anticorpo monoclonal anti-COVID-19 conjugado com partículas coloridas, formando o complexo antígeno-anticorpo-partícula colorida. Esse complexo migra ao longo da membrana, por ação capilar, até a linha de teste, onde será capturado pelo anticorpo monoclonal anti-COVID-19 de camundongo. Uma linha de teste colorida ficará visível na janela de resultados se houver antígenos contra COVID-19 na amostra. A intensidade da linha de teste colorida varia dependendo da quantidade de antígeno de COVID-19 presente na amostra. Se antígenos de COVID-19 não estiverem presentes na amostra, então nenhuma cor aparecerá na linha de teste. A linha de controle é usada para controle de procedimento e deve aparecer sempre se o procedimento de teste for realizado da forma correta e os reagentes de teste da linha de controle estiverem funcionando.

##### [Conteúdo do kit]

- Dispositivo de teste (individualmente em uma bolsa de alumínio com dessecante)
- Tubo com tampão de extração
- Tampa do bico
- Swab estéril
- Suporte de papel
- Instruções de uso

#### ARMAZENAMENTO E ESTABILIDADE DO KIT

Armazene o kit em temperatura ambiente, a 2-30°C / 36-86°F longe da luz solar direta. Os materiais do kit são estáveis até a data de validade impressa na caixa. Não congele o kit.

#### ADVERTÊNCIAS E PRECAUÇÕES

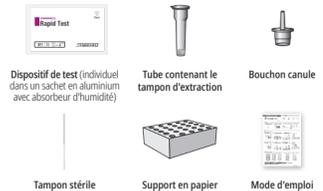
- Não reutilize o kit de teste.
- Não use o kit de teste se a bolsa estiver danificada ou se o selo estiver quebrado.

Qualité approuvée par SD BIOSENSOR / Uniquement destiné aux diagnostics *in vitro*

**FR** REF: Q-NCOV-01G

**STANDARD Q COVID-19 Ag**  
STANDARD™ Q COVID-19 Ag Test  
VEUILLEZ LIRE ATTENTIVEMENT LA PAGE AVANT DE LANCER LE TEST

**CONTENUS DU KIT**



#### PREPARATION AND TEST PROCEDURE

##### [Préparation]

- Veillez lire attentivement le mode d'emploi pour utiliser le STANDARD Q COVID-19 Ag Test.
- Vérifiez la date d'expiration à l'arrière du sachet en aluminium. N'utilisez pas le kit, si la date d'expiration est dépassée.
- Vérifiez le dispositif de test et le paquet avec l'absorbreur d'humidité dans le sachet en aluminium.



##### [PROCÉDURE DE TEST]

- Insérer le tampon stérile dans la narine jusqu'à atteindre l'arrière du nasopharynx.



- Tamponner la surface de l'arrière du nasopharynx.



- Retirer le tampon stérile de la cavité nasale.



- Insérer le tampon dans le tube contenant le tampon d'extraction. Remuez le tampon plus de 5 fois, tout en pressant sur le tube.
- Retirez le tampon tout en appuyant sur les côtés du tube pour en extraire le liquide.
- Vissez fermement le bouchon canule sur le tube.



- Versez 3 gouttes de l'échantillon prélevé dans le puits d'échantillons du dispositif de test.
- Lisez le résultat du test au bout de 15/30 minutes.



##### INTERPRÉTATION DES RÉSULTATS DE TEST

\* Ligne de contrôle "C" | Ligne de test "T"

**Négatif**

Only one band at "C" control line in the result window indicates a negative result.

**Positif**

Both bands appeared in each of "C" control line and "T" test line indicate COVID-19 Ag positive.

**Invalide**

NO band at "C" control line is considered as invalid result. The directions may not have been followed correctly or the test may have deteriorated. Re-test with a new specimen and a new test device.

- Une bande colorée apparaîtra en haut de la fenêtre de résultats pour montrer que le test fonctionne correctement. Cette bande est la ligne de contrôle (C).
- Une bande colorée apparaîtra dans la partie basse de la fenêtre de résultats. Cette bande est une ligne de test de l'antigène SARS-CoV-2 (T).
- Même si la ligne de contrôle est faible, ou si la ligne de test n'est pas uniforme, le test devra être considéré comme fonctionnant correctement et le résultat de test devra être interprété comme un résultat positif.

**\*Le résultat doit être considéré comme positif dès qu'une ligne est présente, même floue ou peu visible.**

**\*Les résultats positifs doivent être pris en compte par rapport à l'historique clinique et d'autres données mises à la disposition du médecin.**

#### EXPLICATION ET RÉSUMÉ

##### [Introduction]

Le Coronavirus est un virus à ARN simple brin de polarité positive avec une enveloppe de 80 à 120 nm de diamètre. Son matériel génétique est le plus grand de tous les virus à ARN et est un pathogène important des maladies chez de nombreux animaux domestiques, de compagnie et chez les humains. Il peut provoquer de nombreuses maladies aiguës ou chroniques. Les symptômes indiquant qu'une personne est infectée par le coronavirus sont les suivants : problèmes respiratoires, fièvre, toux, souffle court et dyspnée. Dans les cas les plus graves, l'infection peut entraîner une pneumonie, le syndrome respiratoire aigu sévère, des défaillances rénales et même la mort. Le nouveau coronavirus 2019, ou "SARS-CoV-2 (COVID-19)", a démarré à Wuhan en 2019 par des cas de pneumonies virales. L'Organisation mondiale de la santé l'a nommé ainsi le 12 janvier 2020, en confirmant qu'il peut provoquer des rhumes et le Syndrome Respiratoire du Moyen-Orient (MERS), ainsi que des maladies plus graves comme le syndrome respiratoire aigu sévère (SARS). Ce kit aide à effectuer un diagnostic auxiliaire de l'infection par le coronavirus. Les résultats du test servent uniquement comme référence clinique et ne peuvent pas être utilisées comme base pour confirmer ou exclure des cas seuls.

##### [Utilisation prévue]

Le STANDARD Q COVID-19 Ag Test est un test par immunochromatographie qui permet d'identifier les anticorps spécifiques au SARS-CoV-2 présents dans le nasopharynx humain. Ce test est uniquement destiné aux laboratoires et services de santé. Il a pour objectif d'aider à diagnostiquer les infections par le SARS-CoV-2 chez des patients qui présentent des symptômes cliniques d'une infection par le SARS-CoV-2. Il fournit seulement un résultat de test de dépistage initial. Il faudra passer par des méthodes diagnostiques plus spécifiques pour avoir une confirmation de l'infection par le SARS-CoV-2.

##### [Principe du test]

Le STANDARD Q COVID-19 Ag Test comprend deux lignes recouvertes, "C" (ligne de contrôle) et "T" (ligne de test) sur la surface de la membrane en nitrocellulose. Ces deux lignes (contrôle et test) situées dans la fenêtre de résultats ne sont pas visibles avant d'y avoir introduit des échantillons. Des anticorps anti-SARS-CoV-2 monoclonaux de souris recouvrent la zone de la ligne de test et des anticorps IgY anti-poulet monoclonaux de souris recouvrent la zone de la ligne de contrôle. Les anticorps anti-SARS-CoV-2 monoclonaux de souris conjugués aux particules de couleur sont utilisés comme des détecteurs pour le dispositif antigène SARS-CoV-2. Lors du test, les antigènes SARS-CoV-2 dans l'échantillon interagissent avec les anticorps anti-SARS-CoV-2 monoclonaux conjugués aux particules de couleur pour former un complexe de particules de couleur anticorps-antigènes. Ce complexe migre sur la membrane par action capillaire jusqu'à la ligne de test où il sera capturé par les anticorps anti-SARS-CoV-2 monoclonaux de souris. Une ligne de test colorée devrait apparaître dans la fenêtre de résultats si les antigènes SARS-CoV-2 sont présents dans l'échantillon. L'intensité de la ligne de test colorée variera en fonction de la quantité d'antigènes SARS-CoV-2 présents dans l'échantillon. Si aucun antigène SARS-CoV-2 n'est présent dans l'échantillon, aucune couleur n'apparaîtra sur la ligne de test. La ligne de contrôle est utilisée en guise de contrôle procédural et doit toujours apparaître si la procédure de test est lancée correctement et que les réactifs de test de la ligne de contrôle sont valides.

##### [Contenu du kit]

- Dispositif de test (individuel dans un sachet en aluminium avec absorbreur d'humidité)
- Tube contenant le tampon d'extraction
- Bouchon canule
- Tampon stérile
- Support en papier
- Mode d'emploi

#### KIT DE STOCKAGE ET STABILITÉ

Stockez le kit à une température entre 2 et 30 °C (36 - 86 °F), à l'abri de la lumière directe du soleil. Les matériaux du kit sont stables jusqu'à leur date d'expiration indiquée à l'extérieur de la boîte. Ne pas congeler le kit.

#### AVERTISSEMENTS ET PRÉCAUTIONS

- Né pas réutiliser le kit de test.
- Né pas utiliser le kit de test si le sachet est endommagé ou ouvert.

- Né pas utiliser le tampon de outro lote.
- Né pas fumer, néo beba e néo coma enquanto estiver manipulando a amostra.
- Use equipamentos de proteção pessoal, como luvas e aventais de laboratório quando estiver manuseando os reagentes do kit. Lave bem as mãos depois de terminar os testes.
- Limpe completamente os respingos usando um desinfetante apropriado.
- Manuseie todas as amostras como se elas contivessem agentes infecciosos.
- Observe as precauções estabelecidas contra riscos microbiológicos durante os procedimentos de teste.
- Descarte todas as amostras e todos os materiais utilizados para realização do teste como resíduos biológicos perigosos. Os resíduos químicos de laboratório e resíduos biológicos perigosos devem ser manuseados e descartados de acordo com os regulamentos municipais, estaduais e federais.
- O dessecante na bolsa de alumínio serve para absorver a umidade e evitar que ela afete os produtos. Se os grânulos de dessecante mudarem de cor de amarelo para verde indicando umidade, o dispositivo de teste na bolsa deverá ser descartado.

#### COLETA E PREPARAÇÃO DA AMOSTRA

- Para coletar uma amostra de swab nasofaríngeo, insira um swab estéril na narina do paciente, atingindo a superfície da nasofaringe posterior. Gire o swab delicadamente, empurrando-o até encontrar resistência na altura do osso turbinado (concha nasal).
- Esfregue o swab na parede da nasofaringe algumas vezes com movimentos circulares.
- Remova o swab da narina cuidadosamente.
- A amostra deve ser testada o mais rápido possível após a coleta.
- Não use meios de transporte, use a amostra coletada e o tampão de extração imediatamente. Tenha cuidado com a contaminação.
- As amostras podem ser armazenadas em temperatura ambiente por até 1 hora ou a 2-8°C/36-46°F por até 4 horas antes do teste.

##### LIMITAÇÃO DO TESTE

- O procedimento de teste, as precauções e a interpretação dos resultados devem ser seguidos estritamente.
- O teste deve ser utilizado para a detecção de antígenos da COVID-19 em amostras em swab de nasofaringe humana.
- Nem o valor quantitativo nem a taxa de concentração de antígenos COVID-19 podem ser determinados por este teste qualitativo.
- Não seguir corretamente o procedimento de teste e interpretação dos resultados pode prejudicar o desempenho do teste e/ou produzir resultados inválidos.
- Um resultado negativo pode ocorrer se o nível de antígenos extraídos em uma amostra estiver abaixo da sensibilidade do teste ou se a amostra for de má qualidade.
- Para saber sobre o estado imune com maior precisão, recomenda-se realizar testes adicionais de acompanhamento usando outros métodos laboratoriais.
- O resultado do teste deve ser avaliado sempre em conjunto com outros dados disponíveis para o médico.
- Pode ocorrer um resultado negativo se a concentração de antígeno ou anticorpo em uma amostra estiver abaixo do limite de detecção do teste ou se a amostra foi coletada ou transportada incorretamente, portanto, um resultado negativo não elimina a possibilidade de SARS-CoV-2, e deve ser confirmada por cultura viral ou ensaio molecular ou ELISA.
- Os resultados positivos dos testes não descartam co-infecções com outros patógenos.
- Os resultados negativos dos testes não se destinam a excluir outras infecções por coronavírus, exceto o SARS-CoV-1.
- As crianças tendem a lançar vírus por períodos mais longos do que os adultos, o que pode resultar em diferenças de sensibilidade entre adultos e crianças.

- Ne pas utiliser le tube avec le tampon d'extraction d'un autre lot.
- Ne pas fumer, boire ou manger pendant la manipulation des échantillons.
- Porter un équipement de protection individuelle, comme des gants et une blouse de laboratoire lors de la manipulation des kits de réactifs. Se laver les mains minutieusement une fois les tests achevés.
- Tout déversement doit être nettoyé rigoureusement à l'aide d'un désinfectant adapté.
- Manipuler tous les échantillons avec les mêmes précautions que s'ils contenaient des agents infectieux.
- Respecter les précautions établies contre les dangers microbiologiques pendant toute la procédure.
- Éliminer tous les échantillons et les matériaux utilisés pour effectuer le test en les considérant comme des déchets dangereux. Manipuler et éliminer les déchets dangereux et échantillons biologiques conformément aux réglementations locales, régionales et nationales.
- L'absorbreur d'humidité dans le sachet en aluminium absorbe l'humidité pour l'empêcher d'affecter les produits. Si le voyant lumineux indiquant le taux d'humidité passe de jaune à vert, le dispositif de test dans le sachet doit être jeté.

#### PRÉLÈVEMENT ET PRÉPARATION DES ÉCHANTILLONS

- Pour prélever l'échantillon d'écouvillon nasopharyngé, insérer le tampon stérile dans la narine jusqu'à atteindre l'arrière du nasopharynx.
- En effectuant délicatement une rotation, pousser le tampon jusqu'à trouver une résistance au niveau du cornet nasal.
- Tourner le tampon plusieurs fois contre les parois nasopharyngées.
- Retirer doucement le tampon de la narine.
- L'échantillon devra être testé dès que possible après le prélèvement.
- N'utiliser aucun moyen de transport, l'échantillon prélevé et le tampon d'extraction doivent être utilisés immédiatement. Attention à toute contamination.
- Les échantillons peuvent être stockés à température ambiante pendant 1 heure maximum ou à 2 - 8 °C (36 - 46 °F) pendant 4 heures maximum avant le test.

##### LIMITES DU TEST

- Les procédures de test, les précautions et l'interprétation des résultats pour ce kit de test doivent être rigoureusement respectés lors du test.
- Ce test doit être utilisé pour détecter les antigènes SARS-CoV-2 dans les échantillons d'écouvillon nasopharyngé humains.
- Ni la valeur quantitative ni le taux de concentration d'antigènes SARS-CoV-2 ne peuvent être établis par ce test qualitatif.
- Le non-respect de la procédure de test et de l'interprétation des résultats de test peuvent nuire à la performance du test et/ou entraîner des résultats de test invalides.
- Un résultat peut être négatif si le taux d'antigènes extrait dans un échantillon est en dessous de la sensibilité du test ou si un échantillon de mauvaise qualité a été fourni.
- Pour plus de précisions sur le statut immunitaire, un test de suivi supplémentaire en utilisant d'autres méthodes de laboratoire est recommandé.
- Les résultats de test doivent toujours être évalués avec d'autres données mises à disposition du médecin.
- Il est possible d'obtenir un résultat négatif si la concentration d'antigènes ou d'anticorps dans un échantillon est inférieure au seuil de détection du test ou si l'échantillon n'a pas été correctement prélevé ou transporté. Par conséquent, un résultat négatif n'implique pas la possibilité d'être infecté par le SARS-CoV-2, et l'infection devra être confirmée par une culture virale, un test moléculaire ou un test ELISA.
- Les résultats positifs n'excluent pas la possibilité d'une coinfecction par d'autres pathogènes.
- Les résultats de test négatifs ne visent pas à confirmer d'autres infections par les coronavirus, sauf par le SARS-CoV-1.
- Les enfants tendent à excréter le virus pendant de plus longues périodes de temps que les adultes. Il peut donc y avoir des différences entre les adultes et les enfants.

#### BIBLIOGRAPHY

- Clinical management of severe acute respiratory infection when novel coronavirus(ncov) infection is suspected. Interim guidance. WHO.2020
- Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR.2020
- Diagnosis and treatment of pneumonia caused by new coronavirus (trial version 4) National Health Commission. 2020

#### SYMBOL

REF	Reference number	Caution	Use by	LOT	Batch code	Consult Instructions for Use	Do not re-use
IVD	In vitro Diagnostics	Note	Manufacturer		Date of manufacture	Contains Sufficient for <=> Tests	Keep away from sunlight
	Indicate that you should keep the product dry		To indicate the temperature limitations in which the transport package has to be kept and handled.	CE	To indicate the requirements of Directive 98/79/EC on in vitro diagnostic medical devices		Do not use if packaging is damaged

EC REP

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