WHO Emergency Use Assessment SARS-CoV-2 IVDs
PUBLIC REPORT

Product: STANDARD Q COVID-19 Ag Test
Manufacturer: SD Biosensor, Inc.
EUL Number: EUL 0563-117-00
Outcome: Accepted

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and the Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:


STANDARD Q COVID-19 Ag Test, product codes 09COV30D, 09COV31D, 09COV32D, 09COV33D and 10COVC11 (COVID-19 Ag Control swab), CE-mark regulatory version, manufactured by SD Biosensor, Inc., 4th and 5th, 16 Deogyeong-daero, 1556 beon-gil Suwon-si, Geonggi-do, 16690, Republic of Korea, was listed on 22 September 2020.

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the EUL product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the table below.

<table>
<thead>
<tr>
<th>Version</th>
<th>Summary of amendment</th>
<th>Date of report amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>Addition of a warning that STANDARD COVID-19 Ag Control (product code: 10COVC10) was not assessed with STANDARD Q COVID-19 Ag Test and is not part of EUL.</td>
<td>6 November 2020</td>
</tr>
<tr>
<td>3.0</td>
<td>Correction of the warning added in version to read as, “STANDARD COVID-19 Ag Control (product code: 10COVC10) was assessed and found not acceptable.”</td>
<td>18 November 2020</td>
</tr>
<tr>
<td>4.0</td>
<td>Change the outside packaging box in the public report to align with the approved IFU.</td>
<td>15 January 2021</td>
</tr>
<tr>
<td>5.0</td>
<td>1. Changed the shape of the plastic container cover for the nozzle cap (Blister - flat).</td>
<td>29 June 2022</td>
</tr>
</tbody>
</table>
2. Addition of a new buffer tube rack.
3. Addition of a new manufacturing site.
4. Addition of a new warehousing site.
5. Addition of new suppliers for components.
6. Change the Site plan of BioNote.
8. Addition of a specimen type (Nasal swab).
9. Change of the product IFU and addition of new IFUs.
10. Change of the product package and addition of new packages.

Intended use

According to the claim of intended use from SD Biosensor, Inc., “STANDARD Q COVID-19 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigens of SARS-CoV-2 present in human nasopharyngeal specimens. This product is intended for healthcare professionals at the clinical setup and point of care sites, as an aid to early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms of SARS-CoV-2 infection. It provides only an initial screening test result. This product is strictly for medical professional use only and not intended for personal use. The administration of the test and the interpretation of the results should be done by a trained health professional. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required.”

Specimen types that were validated
Nasopharyngeal and nasal swab specimens (please pay attention to the product codes).

Test kit contents:

<table>
<thead>
<tr>
<th>Component</th>
<th>25 tests (product code 09COV30D)</th>
<th>25 tests (product code 09COV31D)</th>
<th>25 tests (product code 09COV32D)</th>
<th>25 tests (product code 09COV33D)</th>
<th>10 tests/kit COVID-19 Ag Control swab (product code 10COVC11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test device (individually in a foil pouch with desiccant)</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>N/A</td>
</tr>
<tr>
<td>Extraction buffer tube</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>N/A</td>
</tr>
<tr>
<td>Nozzle cap</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>N/A</td>
</tr>
<tr>
<td>Sterile swab (Nasopharyngeal)</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>N/A</td>
</tr>
<tr>
<td>Sterile swab (Nasal)</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>N/A</td>
</tr>
<tr>
<td>Negative and Positive control swabs</td>
<td>N/A</td>
<td>N/A</td>
<td>1 of each</td>
<td>1 of each</td>
<td>10 of each</td>
</tr>
<tr>
<td>Instructions for use</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
Items required but not provided

- Personal Protective Equipment per local recommendations (i.e. gown/lab coat, face mask, face shield/eye goggles and gloves)
- Timer
- Biohazard container
- STANDARD F Analyzer

Storage
2-30°C.

Shelf-life upon manufacture
24 months for STANDARD Q COVID-19 Ag Test (real-time stability studies are ongoing).
30 months for STANDARD COVID-19 Ag Control Swab.

Warnings/limitations:
STANDARD COVID-19 Ag Control (product code:10COVC10) was assessed and found not acceptable.

Product dossier assessment

SD Biosensor, Inc. submitted a product dossier for the STANDARD Q COVID-19 Ag Test for detecting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as per the “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid and rapid diagnostics tests detecting SARS-CoV-2 antigens (PQDx_0347 version 4)”. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

Post listing commitment for EUL

As a commitment to listing, the manufacturer is required to:
1. Provide the real-time stability studies report by 31 July 2022. The commitment is under review.
2. Submit the final transport and real-time stability studies report of the new quality control swab as part of the next EUL renewal application.
3. Submit nasal swab storage stability studies at -20°C for 4 months and -70°C for 6 months as part of the next EUL renewal application.
4. Submit the results of the accelerated stability testing up to week 20 as part of the next EUL renewal application.
5. Amend the IFU’s font size to make it more user-friendly in the following IFU review.
   Submit the amended version of the IFU as part of the next EUL renewal application.

Risk-benefit assessment is acceptable.
Quality Management Systems Review

To establish eligibility for WHO procurement, SD Biosensor, Inc. was asked to provide up-to-date information about the status of its quality management system.

Based on the review of the submitted quality management system documentation by WHO staff, it was established that sufficient information was provided by SD Biosensor, Inc. to fulfil the requirements described in the “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid and rapid diagnostics tests detecting SARS-CoV-2 antigens (PQDx_347 version 4)”.

Quality management documentation assessment is acceptable.

Plan for Post-Market Surveillance

Post-market surveillance, including monitoring all customer feedback, detecting and acting on adverse events, product problems, non-conforming goods and processes is a critical component of minimizing potential harm of an IVD listed for emergency use.

The following post-EUL activities are required to maintain the EUL listing status:
1. Notification to WHO of any planned changes to a EUL product, in accordance with “WHO procedure for changes to a WHO prequalified in vitro diagnostic” (document number PQDx_121); and

SD Biosensor, Inc. is also required to submit an annual report that details sales data and all categories of complaints in a summarized form. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents.

The manufacturer has committed to ensuring that post-emergency use listing safety, quality and performance monitoring activities are in place in accordance with WHO guidance “WHO guidance on post-market surveillance of in vitro diagnostics”. ¹

Scope and duration of procurement eligibility

STANDARD Q COVID-19 Ag Test, product codes 09COV30D, 09COV31D, 09COV32D, 09COV33D and 10COVC11 (COVID-19 Ag Control swab), manufactured by SD Biosensor, Inc. is considered to be eligible for WHO procurement until further notice. The assay may be used

¹ Available on the web page
to detect the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) antigens. This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO prequalified.

As part of the ongoing requirements for listing as eligible for WHO procurement, SD Biosensor, Inc. must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality and performance requirements. SD Biosensor, Inc. is required to notify WHO of any complaints, including adverse events related to the use of the product, within 7 days and any changes to the product.

WHO reserves the right to rescind eligibility for WHO procurement if additional information on the safety, quality, and performance during post-market surveillance activities and if new data becomes available to WHO that changes the risk-benefit balance.
Labelling

1.0  Labels

2.0  Instructions for Use (IFU)
1.0 Product labels
1.1 Outside box labels
1.1.1 Product code 09COV30D
CONTENIDO
1) Dispositivo de prueba (individualmente en una bolsa de aluminio con desecante)  x 25
2) Tubo de diluyente de extracción x 25
3) Tapa de nozzel x 25
4) Hisopo esterilizado x 25
5) Instrucciones de uso x 1

ES
-25 PRUEBAS/KIT-

CONTEÚDO
1) Dispositivo de teste (individualmente em uma bolsa de alumínio com dessecante) x 25
2) Tubo buffer de extração x 25
3) Tampa do bico x 25
4) Zaragatoa estéril x 25
5) Instruções de uso x 1

PT
-25 TESTES/KIT-

CONTENU
1) Dispositif de test (emballage individuel dans un sachet en aluminium avec un desiccant) x 25
2) Tube de solution tampon d'extraction x 25
3) Capuchon de buse x 25
4) Écouvillon stérile x 25
5) Mode d'emploi x 1

FR
-25 TESTS/KIT-

CONTENUTI
1) Dispositivo di test (confezione individuale in un sacchetto di alluminio con un essiccante) x 25
2) Provetta con tampone di estrazione x 25
3) Tappo con dell'ugello x 25
4) Tampone sterile x 25
5) Istruzioni per l'uso x 1

IT
-25 TESTGERÄT/KIT-

INHALT
1) Testgerät (einzeln in einem Folienbeutel mit Trocknemittel) x 25
2) Extraktionspuffer-röhrchen x 25
3) Düsenkappe x 25
4) Steriler Tupfer x 25
5) Gebrauchsanweisung x 1

DE
1.1.2 Product code 09COV31D
STANDARDQ COVID-19 Ag Test

CONTENIDO
1) Dispositivo de prueba (individualmente en una bolsa de aluminio con desecante) x 25
2) Tubo de diluyente de extracción x 25
3) Tapa de nozzel x 25
4) Hisopo esterilizado x 25
5) Instrucciones de uso x 1

ES - 25 PRUEBAS/KIT-

CONTEÚDO
1) Dispositivo de teste (individualmente em uma bolsa de alumínio com dessecante) x 25
2) Tubo buffer de extração x 25
3) Tampa do bico x 25
4) Eletcro de estéril x 25
5) Instruções de uso x 1

PT - 25 TESTES/KIT-

CONTENU
1) Dispositif de test (emballage individuel dans un sachet en aluminium avec un desiccant) x 25
2) Tube de solution tampon d'extraction x 25
3) Capuchon de buse x 25
4) Écouvillon stérile x 25
5) Mode d'emploi x 1

FR - 25 TESTS/KIT-

CONTENUTI
1) Dispositivo di test (confezione individuale in un sacchetto di alluminio con un essiccante) x 25
2) Provetta con tampone di estrazione x 25
3) Tappo con dell'ugello x 25
4) Tampone sterile x 25
5) Istruzioni per l'uso x 1

IT - 25 TESTGERÄT/KIT-

INHALT
1) Testgerät (einzeln in einem Folienbeutel mit Trockenmittel) x 25
2) Extraktionspuffer-röhrchen x 25
3) Düsenkappe x 25
4) Steriler tupfer x 25
5) Gebrauchsanweisung x 1

DE - 25 TESTGERÄT/KIT-

Nasal Swab
1.1.3 Product code 09COV32D
CONTENTS
1) Test device (individually in a foil pouch with desiccant) x 25
2) Extraction buffer tube x 25
3) Nozzle cap x 25
4) Sterile swab x 25
5) STANDARD COVID-19 Ag Positive Control swab x 1
6) STANDARD COVID-19 Ag Negative Control swab x 1
7) Instructions for use x 1
1.1.4 Product code 09COV33D
1.1.5 Product code 10COVC11 (COVID-19 Ag Control swab)
CONTENTS

1) STANDARD COVID-19 Ag Positive Control swab x 10

2) STANDARD COVID-19 Ag Negative Control swab x 10

3) Instructions for Use x 1

www.sdbiosensor.com

SD BIOSSENSOR

HEAD OFFICE
C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu,
Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA

MANUFACTURING SITE
74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

SD BIOSSENSOR, INC.

Manufactured Under Good Manufacturing Practices (GMP)
1.2 Testing device label
STANDARD Q
COVID-19 Ag Test

STANDARD™
1.3 Nasopharyngeal swab labels
EZ-FINDER SWABS™
FLOCKED SWABS
Sterile only if peel-pouch is intact
This product is a disposable medical device

Sterile
CE
FDA

Product Code: MFG: EXP: LOT:
Use with caution if allergic to nylon fibre and ABS material.
Use with caution if allergic to nylon fibre and ABS material.
1.4 Nasal swab labels
PEEL DOWN

FA SPONGE SWAB
Specimen Collection Swab
REF: FASPS02

CONTENTS
SINGLE TIP APPLICATORS

- STERILITY ONLY IF PEEL-POUCH IS INTACT
- DISPOSABLE USE
- DESTROYED AFTER USE
- PLEASE DO NOT USE IT IF EXPIRED OR PACKING DAMAGE

USA FDA Registration Number: 3011555966

L. = [Lot]
E. = [EXP.DATE(YYYY-MM)]

MFR.: FA INC.
10-5, Myeonghaksan-danseo-ro, Yeondong-myeon, Sejong-si,
30068 Rep. of KOREA
www.facompany.co.kr

EU Representative:
MT Promedt Consulting GmbH
Aleinholofstrasse 80, 66386 St. Ingbert, Germany
Miraclean Technology Co., Ltd.

No. 18, Longhua Industrial Zone, Tongle Community, Longgang District, Shenzhen, China, 518116

Tel: 86755-26573572
With www.miraclean.com
P/N 93050

Use with caution if allergic to sponge and POM material.
Miraclean Technology Co., Ltd.
No.18, Nonghuaxia Industrial Zone, Tingle Community, Longgang District, Shenzhen, China, 51816
Tel: 86755-40848777
With: www.miraclean.com
P/N: 93050
XX: XXXXXXXXXX
YY: YYYY/MM/DD

Disposable Sampling Swab

Use with caution if allergic to sponge and POM material.

Share Info Consultant Service LLC
Repräsentanzbüro Heerdter
Lohweg 83, 40549 Düsseldorf

FDA Registered

2C

30C
Miraclean Technology Co., Ltd.

Room 301, Building A, No. 18, Rongshuxia Industrial Zone, Tongxin Community, Longgang District, Baolong Street, Longgang District, Shenzhen, Guangdong, P.R. China

Tel: 0755-2547 7788
With www.miraclean.com
P/N: 93050L

Use with caution if allergic to sponge and POM material.

Disposable Sampling Swab
Miraclean Technology Co., Ltd.

Room 301, Building A, No. 18, Rongshuxia Industrial Zone, Tongxin Community, Longgang District, Shenzhen, 518116, Guangdong, P. R. China

Tel: +44 (0) 20 837 56 00
With: www.miraclean.com
Fax: +44 (0) 20 837 56 00
P/N: 93050L
M/N: XXXXXXXXXX
YY/MM/DD

Disposable Sampling Swab 1000pc

Use with caution if allergic to sponge and POM material.

Share Info Consultant Service LLC
Repräsentanzbüro Heerdter
Lohweg 83, 40549 Düsseldorf

FDA Registered

2 C

30 C
1.5 Controls pouch label
STANDARD COVID-19 Ag Negative Control swab
195mm x 50
STANDARD COVID-19 Ag Positive Control swab
195mm x 50
1.6 Extraction tube label
Extraction Buffer Tube

STANDARD Q COVID-19 Ag Test

LOT No. : XXXXXXXXXXX
MFG DATE : YYYY.MM.DD.
EXP DATE : YYYY.MM.DD.
Quantity : 25pcs
1.7 Nozzle label
Nozzle cap
80 x 12

80mm x 12mm

@ SD BIOSENSOR

Issue date: 2021.01
Nozzle cap

80 x 12

80mm x 12mm
2.0 Instructions for use

2 English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.
Performances were calculated from a study of patients within 24 days of onset of symptoms.

1. Carefully read instructions for using the STANDARD Q COVID-19 Ag Test.
2. Verify the kit expiration date and check the lot number against the details on the carton. Store the kit at 2-30°C / 36-86°F out of direct sunlight. Kit materials are stable until the expiration date indicated on the box. Do not freeze.
3. If the test device and the desiccant pack in the foil pouch are damaged, do not use the kit. Do not use this kit if the foil pouch is damaged or the desiccant pack is not in place. Each kit contains two calibrated test devices.

**PROCEDURE OF PREPARATION AND TESTING**

1. For sampling, use a sterile swab to turn over the plunger of the extraction buffer tube. Insert the swab into an extraction buffer tube. While holding the swab, press the plunger of the extraction buffer tube firmly. While holding the swab, press the plunger of the extraction buffer tube firmly.
2. Pour 3 mL of extraction buffer into a sterile plastic tube and add the mixture. Close the tube tightly after adding the mixture. Close the tube tightly after adding the mixture.
3. Run the mixture through the test device. Run the mixture through the test device. Run the mixture through the test device.
4. The test result must always be evaluated with other data available to the clinician for confirming the presence of COVID-19. The result of this test is not intended for use in clinical decision-making or to establish the cause of the suspected symptoms.
5. The test result must always be evaluated with other data available to the clinician for confirming the presence of COVID-19. The result of this test is not intended for use in clinical decision-making or to establish the cause of the suspected symptoms.

**LIMITATION OF TEST**

The test result must always be evaluated with other data available to the clinician for confirming the presence of COVID-19. The result of this test is not intended for use in clinical decision-making or to establish the cause of the suspected symptoms.
**INTRODUÇÃO**

Este kit de teste de antígeno COVID-19 é um método de detecção rápido de anticorpos e antígenos de SARS-CoV-2. O kit é indicado para uso em laboratórios e em ambientes hospitalares.

**CONTROLES DE QUALIDADE**

- **Certificado de Qualidade**
- **Caixa do kit**
- **Imagens do kit**
- **Instruções de uso**

**PREPARAÇÃO E PREPARAÇÃO DO TESTE**

1. **Preparação do kit**
   - Abra a caixa do kit e retire a amostra para teste.
   - Insira a pipete Spoit em um tubo buffer de extração. Gire uniformemente.
   - Separe a zaragatoa e armazene em buffer de extração.

2. **Preparação do teste**
   - Para uma diluição mínima do material a ser testado, use 3 gotas de amostra.
   - Coloque a amostra e o conta-corpos na superfície da nitrozeloce em um ambiente 4°C.

**APLICAÇÃO E REAÇÕES**

- **Teste em T**
  - Para identificar a presença de anticorpos contra SARS-CoV-2.

**RESULTADO DO TESTE**

1. **Interpretação do resultado**
   - O resultado pode ser positivo ou negativo.
   - Se o resultado for positivo, a área de teste não se colorirá.
   - Se o resultado for negativo, a área de teste se colorirá.

**AVERTIMENTOS E PRECAUÇÕES**

- **Alinhamento da janela do teste**
  - Certifique-se de que a janela do teste esteja alinhada corretamente.

**MANUTENÇÃO**

- **Manuseio cuidadoso**
  - Manuseie o kit com extremo cuidado.

**ANÁLISE DE AMOSTRA**

- **Amostra a ser testada**
  - A amostra deve ser coletada com a janela do teste correta.

**AMIGOS DE VIDA**

- **Animais e plantas**
  - Este kit é destinado para amostras humanas.

**ENVIO DE AMOSTRAS**

- **Condução do teste**
  - O kit deve ser enviado para o laboratório em um meio de transporte virale em 4°C.

**CONSERVAÇÃO DO KIT**

- **Estabilidade do kit**
  - O kit deve ser mantido em 4°C até a data de validade.

**PERFIL II**

- **Perfis de amOSTRAS**
  - O kit deve ser mantido em 4°C até a data de validade.

**CONSERVAÇÃO DO KIT**

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**PERFIL II**

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  - O kit deve ser mantido em 4°C até a data de validade.
COVID-19 Ag Test

INFORMATION ON TEST RESULTS

1. **Negative**
   - The test line (T) and control line (C) appear.
   - The test line (T) appears fainter than the control line (C).

2. **Weakly Positive**
   - The test line (T) appears fainter than the control line (C).

3. **Positive**
   - The test line (T) and control line (C) appear.
   - The test line (T) appears darker or equal to the control line (C).

INTERPRETATION OF TEST RESULTS

**Positive**

- SARS-CoV-2 infection. It provides only an initial screening test result. This product is not a substitute for a confirmatory test using a different method.

**Negative**

- Suspect negative result. If there is still clinical suspicion, collect another sample and retest. Consider performing a confirmatory test using a different method.

**Weakly positive**

- Further testing is recommended to confirm the result. Consider performing a confirmatory test using a different method.

**No result**

- No test line (T) appears. The test must be repeated using a new kit.

**Invalid**

- The control line (C) is not visible. The test must be repeated using a new kit.

PREPARATION AND PROCESSING OF SAMPLE

**Procedure**

1. Place a sterile swab by applying pressure to the left and right nostrils.
2. Read the test result in 15-30 minutes.

**Limitations of test**

- If the sample is positive, nucleic acid amplification testing is recommended.
- It is important to consider the clinical information in the patients.

**Materials required but not provided**

- Disinfectant
- Adhesive tape
- Paper towel
- Antiviral medication
- Alcohol spray
- Surgical mask
- Goggles
- Face mask
- Cuffs
- PPE kit
- Antivirus spray
- Antiseptic
- Antimicrobial solution
- Antiseptic spray

**Specimen collection and preparation**

- **Sputum** (initially by a healthcare professional, collected by the patient or family in the appropriate container).
- **Nasopharyngeal aspirate** by a healthcare professional (initially by a healthcare professional, collected by the patient or family in the appropriate container).
- **Bronchoalveolar lavage fluid** by a healthcare professional (initially by a healthcare professional, collected by the patient or family in the appropriate container).
- **Sputum** (self-collected by the patient or family).
- **Nasopharyngeal aspirate** by the patient or family.
- **Blood** by a healthcare professional.

**Precautions**

- **Data**
- **vaccination history**
- **symptoms**
- **comorbidities**
- **contact history**
- **travel history**
- **occupational exposure history**
- **other relevant medical history**

**Reference**

- **Caution**: Use only in accordance with local guidelines and regulations.
- **Note**: The test is not recommended for use in individuals with a history of self-limiting respiratory tract infections.
### COVID-19 Ag Test

**INTRODUÇÃO**

O STANDARD™ Q COVID-19 Antigen Test (Ag Test) foi desenvolvido para detectar o antígeno SARS-CoV-2 em amostras nasais humanas ou nasofaríngeas.

**IDEIA-CHAUS**

- **Fase de pré-teste**: O testador deve ler as instruções com atenção antes de realizar o teste.
- **Fase de teste**: A amostra deve ser testada o mais rápido possível após a recolha.
- **Fase pós-teste**: Os resultados devem ser interpretados e o dispositivo de teste deve ser descartado adequadamente.

**PREPARAÇÃO E PROCEDIMENTO DE TESTE**

**1. Preparação da amostra**

Lembre-se que o teste depende fortemente da qualidade da amostra. A amostra deve ser transportada a uma temperatura de 2-8°C. Adicione o tampão de transporte à amostra.

**2. Aplicação da amostra**

Deixe a amostra agir por 15-30 minutos. Remova o tampão de transporte e infiltre a solução de transporte nas aberturas do tubo de reação. Dê várias voltas ao redor de cada abertura para garantir a absorção total.

**3. Interpretação dos resultados**

- **Positivo**: Presente uma área de pigmentação ou uma faixa na seção de controle (C).
- **Negativo**: A seção de controle (C) é clara, mas a seção de teste (T) é clara.
- **Inespecífico**: Visível tanto na área de pigmentação como na área de controle.

**NOTA**

Certifique-se de que o teste foi realizado de acordo com as instruções do fabricante e que os kits de teste foram conservados corretamente.

**INTERPRETAÇÃO DE RECEPÇÃO**

- **Verde**: Não é um resultado válido.
- **Amarelo**: É um resultado válido.
- **Preto**: Não é um resultado válido.

**VÍRUS**

SARS-CoV-2 é um vírus de RNA filamentoso com um invólucro proteico, encontrado no sistema respiratório humano.

**LIMITAÇÕES DO TESTE**

- O teste deve ser realizado em laboratórios com equipamento e pessoal capacitado.
- A presença de outros antígenos pode causar resultados falsos positivos.
- A técnica de diagnóstico por imunocromatografia pode ter limitações em relação à sensibilidade e especificidade.

**MATERIAIS**

- **Dispositivo de teste**
- **Tampão de transporte**
- **Etiquetas de identificação**
- **Acessórios de segurança**

**PRECAUÇÕES E VERIFICAÇÕES**

- **Precauções**
  - Use equipamentos de proteção (ovos, máscaras, luvas).
  - É importante considerar as precauções de biosegurança.

- **Verificações**
  - Certifique-se de que o teste foi realizado adequadamente.
  - Verifique a validade da amostra e do kit de teste.

**CONCLUSÃO**

O STANDARD™ Q COVID-19 Antigen Test (Ag Test) é um teste rápido e confiável para detectar o antígeno SARS-CoV-2 em amostras nasais humanas ou nasofaríngeas. É recomendado para uso em laboratórios e centros de saúde para o diagnóstico de infecções por SARS-CoV-2.

**RECOMENDAÇÕES**

- **Higiene**: Mantenha as mãos limpas antes e depois de realizar o teste.
- **Decontaminação**: Use equipamentos de proteção adequados e siga as regras de biosegurança.

**CÓDIGO DA REFERÊNCIA**

- **Nº de lote**: hw-b-s-23-041-01-000001
- **Data de validade**: 30/06/2023
- **Emissor**: STANDARD™ Q COVID-19 Antigen Test (Ag Test)

**SÍMBOLO**

- **Símbolo de perigo**: Alerta de perigo
- **Símbolo de advertência**: Caution

**EMBALAGEM**

- **Confeção**: Plain Box
- **Material de embalagem**: EVA Foam Box

**CERTIFICADO**

- **Até 30/06/2023**: Certificado de conformidade CE

**DISTRIBUIDOR**

- **SD Biosensor, Inc.**, Foshan, China

**FAX**

- **+86-757-87350296**

**E-MAIL**

- **sales@sdbiosensor.com.cn**

**PHONE**

- **+86-757-87350296**

**WEB**

- www.sd biosensor.com.cn
**COVID-19 Ag Test**

**CONTENTS OF THE KIT**

- **Negative Control**
- **Positive Control swab**
- **Test principle**
- **Urine specimen**
- **Sample collection and preparation**
- **Equipment needed**
- **Advisories and precautions**
- **TEST PROCEDURE**

**TEST PROCEDURE**

1. **Equipment needed**
   - Tube of solution
   - **Mask**
   - **Gloves**
   - **Face shield**
   - **Eye goggles**

2. **Advisories and precautions**
   - In case of a positive result, a medical review and management should be performed according to the local guidelines.
   - In case of a negative result, a medical review and management should be performed according to the local guidelines.

3. **TEST PROCEDURE**

   a. **Equipment needed**
   - Tube of solution
   - **Mask**
   - **Gloves**
   - **Face shield**
   - **Eye goggles**

   b. **Advisories and precautions**
   - In case of a positive result, a medical review and management should be performed according to the local guidelines.
   - In case of a negative result, a medical review and management should be performed according to the local guidelines.

4. **TEST PROCEDURE**

   a. **Equipment needed**
   - Tube of solution
   - **Mask**
   - **Gloves**
   - **Face shield**
   - **Eye goggles**

   b. **Advisories and precautions**
   - In case of a positive result, a medical review and management should be performed according to the local guidelines.
   - In case of a negative result, a medical review and management should be performed according to the local guidelines.

5. **TEST PROCEDURE**

   a. **Equipment needed**
   - Tube of solution
   - **Mask**
   - **Gloves**
   - **Face shield**
   - **Eye goggles**

   b. **Advisories and precautions**
   - In case of a positive result, a medical review and management should be performed according to the local guidelines.
   - In case of a negative result, a medical review and management should be performed according to the local guidelines.

6. **TEST PROCEDURE**

   a. **Equipment needed**
   - Tube of solution
   - **Mask**
   - **Gloves**
   - **Face shield**
   - **Eye goggles**

   b. **Advisories and precautions**
   - In case of a positive result, a medical review and management should be performed according to the local guidelines.
   - In case of a negative result, a medical review and management should be performed according to the local guidelines.

7. **TEST PROCEDURE**

   a. **Equipment needed**
   - Tube of solution
   - **Mask**
   - **Gloves**
   - **Face shield**
   - **Eye goggles**

   b. **Advisories and precautions**
   - In case of a positive result, a medical review and management should be performed according to the local guidelines.
   - In case of a negative result, a medical review and management should be performed according to the local guidelines.

8. **TEST PROCEDURE**

   a. **Equipment needed**
   - Tube of solution
   - **Mask**
   - **Gloves**
   - **Face shield**
   - **Eye goggles**

   b. **Advisories and precautions**
   - In case of a positive result, a medical review and management should be performed according to the local guidelines.
   - In case of a negative result, a medical review and management should be performed according to the local guidelines.

9. **TEST PROCEDURE**

   a. **Equipment needed**
   - Tube of solution
   - **Mask**
   - **Gloves**
   - **Face shield**
   - **Eye goggles**

   b. **Advisories and precautions**
   - In case of a positive result, a medical review and management should be performed according to the local guidelines.
   - In case of a negative result, a medical review and management should be performed according to the local guidelines.

10. **TEST PROCEDURE**

    a. **Equipment needed**
    - Tube of solution
    - **Mask**
    - **Gloves**
    - **Face shield**
    - **Eye goggles**

    b. **Advisories and precautions**
    - In case of a positive result, a medical review and management should be performed according to the local guidelines.
    - In case of a negative result, a medical review and management should be performed according to the local guidelines.

11. **TEST PROCEDURE**

    a. **Equipment needed**
    - Tube of solution
    - **Mask**
    - **Gloves**
    - **Face shield**
    - **Eye goggles**

    b. **Advisories and precautions**
    - In case of a positive result, a medical review and management should be performed according to the local guidelines.
    - In case of a negative result, a medical review and management should be performed according to the local guidelines.

12. **TEST PROCEDURE**

    a. **Equipment needed**
    - Tube of solution
    - **Mask**
    - **Gloves**
    - **Face shield**
    - **Eye goggles**

    b. **Advisories and precautions**
    - In case of a positive result, a medical review and management should be performed according to the local guidelines.
    - In case of a negative result, a medical review and management should be performed according to the local guidelines.

13. **TEST PROCEDURE**

    a. **Equipment needed**
    - Tube of solution
    - **Mask**
    - **Gloves**
    - **Face shield**
    - **Eye goggles**

    b. **Advisories and precautions**
    - In case of a positive result, a medical review and management should be performed according to the local guidelines.
    - In case of a negative result, a medical review and management should be performed according to the local guidelines.

14. **TEST PROCEDURE**

    a. **Equipment needed**
    - Tube of solution
    - **Mask**
    - **Gloves**
    - **Face shield**
    - **Eye goggles**

    b. **Advisories and precautions**
    - In case of a positive result, a medical review and management should be performed according to the local guidelines.
    - In case of a negative result, a medical review and management should be performed according to the local guidelines.

15. **TEST PROCEDURE**

    a. **Equipment needed**
    - Tube of solution
    - **Mask**
    - **Gloves**
    - **Face shield**
    - **Eye goggles**

    b. **Advisories and precautions**
    - In case of a positive result, a medical review and management should be performed according to the local guidelines.
    - In case of a negative result, a medical review and management should be performed according to the local guidelines.
1. Uma banda roxa aparecerá na seção inferior da janela de resultados. Essa banda é da zaragatoa, insira a zaragatoa estéril na narina do rinofaringe.

2. Imatéis de transportamento dos testes para zaragatoa. Use uma técnica de aspiração de zaragatoa para aspirar 350 μl da zaragatoa estéril para aspirar.

3. Depois de aspirar o tampon, torça suavemente os lados da provetta para extrair o líquido da zaragatoa.

4. Empurre a tampa com segurança para o tubo, siga a orientação correta e os reagentes de teste da linha de teste (T), a linha de controle "C" pode ser visível.

5. A interação entre o RNA e o antígeno permite a formação de uma reação de fluorescência. Isso ocorre quando os reagentes de teste da linha de teste (T) e a linha de controle "C" reagem com o RNA para produzir uma fluorescência detectável.

6. A presença de uma fluorescência detectável indica a presença de zaragatoa no teste. A ausência de fluorescência detectável indica a ausência de zaragatoa no teste.
**STANDARD Q COVID-19 Ag Test**

**Materials Required but Not Provided**
- Buffer Solution
- Wash Solution
- Control Solution
- Removable Cap
- Laminated Contact Window

**Recommended for**
- Rapid detection of SARS-CoV-2

**Operating Principle**
- A monoclonal antibody that specifically recognizes an epitope of the SARS-CoV-2 viral spike protein

**Principle of the Test**
- The SARS-CoV-2 antigen reacts with the monoclonal antibodies conjugated to the gold particles present on the nitrocellulose membrane. If SARS-CoV-2 antigen is present in the sample, it will bind to the monoclonal antibodies and form a complex that will be captured by the gold particles. This complex will then be visible as a blue band on the test strip.

**Performance Characteristics**

<table>
<thead>
<tr>
<th>Product</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>STANDARD Q COVID-19 Ag Test</td>
<td>≥95%</td>
<td>≥95%</td>
</tr>
</tbody>
</table>

**Important Precautions**
- The test must be performed under sterile conditions.
- The test is not intended for use in patients with known allergies to any component of the test kit.
- The test is not intended for use in pregnant women.

**Interpretation of Control Test Result**

<table>
<thead>
<tr>
<th>Control Test Result</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>A blue band should appear on the control line (C) and the test line (T)</td>
</tr>
<tr>
<td>Negative</td>
<td>Only a blue band should appear on the control line (C)</td>
</tr>
</tbody>
</table>

**Interpretation of Result**

- A blue band on the control line (C) indicates that the test was performed correctly.
- A blue band on the test line (T) indicates a positive result.
- A negative result is indicated by the absence of a blue band on the test line (T).

**Explain the significance of the results**

- A positive result is indicative of the presence of SARS-CoV-2 antigen in the sample.
- A negative result does not rule out the presence of SARS-CoV-2, as the test may not detect all positive samples.

**Further Information**

- For more information, please refer to the manufacturer’s instructions for use.

**Technical Support**
- Contact the manufacturer for technical support.

**References**

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**Specimen Collection and Preparation**

1. Incline la cabeza del paciente ligeramente hacia atrás.
2. Inserte el hisopo girándolo hasta una profundidad máxima de una pulgada.
3. Remueva el hisopo mientras presiona los lados del tubo de buffer de extracción.
4. Repita en la otra fosa nasal empleando el mismo hisopo.

**Priming and Procedure of Prueba Control**

<table>
<thead>
<tr>
<th>Description</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Priming</td>
<td>Inserte el hisopo en el tubo de buffer de extracción. Presione los costados del tubo de buffer para extraer el líquido.</td>
</tr>
</tbody>
</table>

**Priming and Procedure of Prueba**

<table>
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<tr>
<td>Priming</td>
<td>Inserte el hisopo en el tubo de buffer de extracción. Presione los costados del tubo de buffer para extraer el líquido.</td>
</tr>
</tbody>
</table>

**Interpretation of the Result**

- A blue band on the control line (C) indicates that the test was performed correctly.
- A blue band on the test line (T) indicates a positive result.
- A negative result is indicated by the absence of a blue band on the test line (T).

**Further Information**

- For more information, please refer to the manufacturer’s instructions for use.

**Technical Support**
- Contact the manufacturer for technical support.

**References**
**COVID-19 Ag Test**

**CONTENTS OF THE KIT**

- Glass test tube
- Absorbent swab
- Absorbent swab pack
- Aerosol* 25 x 2
- Desiccant
- Test device
- Aluminium bag

**PREPARATION OF THE KIT AND PROPER HANDLING**

- Clean and dry hands before opening the kit.
- Read the instructions below carefully before using the kit.
- In the event that the test procedure, precautions and interpretation of results deviate, consult an专业eat.

**INTERPRETATION OF THE RESULTS OF THE TEST**

- Positive 4
- Negative
- Invalid test

**TEST PROCEDURE**

1. Open the test kit and remove the glass tube and absorbent swab pack.
2. Insert the absorbent swab into the patient’s nasal passage and rotate 5 times to extract the sample.
3. Add 4 drops of nasal fluid to the test line for 30 minutes.
4. Read the result after 15-30 minutes.

**INTERPRETATION OF THE TEST RESULTS**

- Positive: A purple line appears in the test line area, indicating the presence of SARS-CoV-2 antigens.
- Negative: No line appears in the test line area, indicating the absence of SARS-CoV-2 antigens.
- Invalid: The control line is not present, indicating a failed test.

**LIMITATIONS OF THE TEST**

- The test is not suitable for use with children under 3 years old.
- The test is not suitable for use with pregnant women.
- The test is not suitable for use with individuals undergoing immunosuppressive therapy.

**CONSIDERATIONS AND VITAMIN HINTS**

- Results should be correlated with the patient’s medical history and symptoms.
- The test is intended for use by healthcare professionals.
- The test is not suitable for use by individuals with a known allergy to antigens.

**DISCLOSURE**

- This information is subject to change without notice. For the most up-to-date information, please refer to the package insert.

**AUTHORIZATION REPRESENTATIVE**

- SD Biosensor, Inc.

**REPRESENTATION OF THE LEGAL TEXT**

- The legal text is not included in this document but can be found in the package insert.
STANDARD COVID-19 Ag Control swab

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

EXPLANATION AND SUMMARY

■ Intended use
STANDARD COVID-19 Ag Control swab is intended for use as an external quality control material to monitor the performance of STANDARD COVID-19 Ag products. It is important to perform control tests with positive and negative control materials to assure STANDARD COVID-19 Ag testing system is working properly.

■ Principle
This product was designed for use with STANDARD COVID-19 Ag products for purpose of monitoring assay performance and maintaining quality assurance.

KIT CONTENTS
STANDARD COVID-19 Ag Control swab is contained 10 Positive control swabs and 10 Negative control swabs.

MATERIALS REQUIRED BUT NOT PROVIDED
• STANDARD COVID-19 Ag Products

PREPARATION AND CONTROL TEST PROCEDURE
This product should be treated the same as patient specimens and run in accordance with instruction accompanying the instrument and kit being used. It is recommended that positive and negative controls be run:
• Once for each new lot,
• Once for each untrained operator,
• Once for each new shipments of test kits,
• As required by test procedures in this instructions and in accordance with local, state and federal regulations of accreditation requirements.

■ Preparation
1. Check the expiry date at the label of a STANDARD COVID-19 Ag Control swab package and Front of the foil pouch of a STANDARD COVID-19 Ag Control swab. Use another lot, if it has expired.
2. Insert the positive or negative control swab into an extraction buffer tube which is in the STANDARD COVID-19 Ag products. Stir the swab at least five times.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from swab. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
4. Press the nozzle cap tightly onto the tube.
5. Testing and interpreting in accordance with the instruction accompanying the STANDARD COVID-19 Ag products.

■ Test procedure
1. Test should be run following the instructions for use provided by the test kit for unknown specimens.
2. Results should be determined in the same manner as used for unknown specimens when tested using the test kits.
3. Results may vary among methodologies, among products, and among different lots of the same kit.

INTERPRETATION OF TEST RESULTS
Test should be interpreted following the instructions for use provided by the test kit for unknown specimens.

STORAGE AND STABILITY
Store the STANDARD COVID-19 Ag Control swab at 2-30°C/36-86°F. Kit materials are stable until expiration date printed on the outer box.

WARNINGS AND PRECAUTIONS
1. If there is evidence of microbial contamination in the reconstituted control, discard the control.
2. Wear protective clothing and gloves when handling specimens or reagents.
3. Clean any spillage by immediately and thoroughly wiping up with a suitable disinfectant such as 1% sodium hypochlorite solution.
4. Handle and dispose of all specimens, controls and materials used in testing as though they contain infectious agents.
5. Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact the local distributor of SD Biosensor, Inc.
LIMITATIONS

1. This product is provided for quality assurance purposes and must not be used for calibration or as primary reference preparations in any test procedure.
2. Adverse storage conditions or use of outdated reagents may produce erroneous results.
3. This product should not be used past the expiration date.
4. Alterations in physical appearance may indicate instability or deterioration of this product. If there is evidence of microbial contamination in this product, discard it.