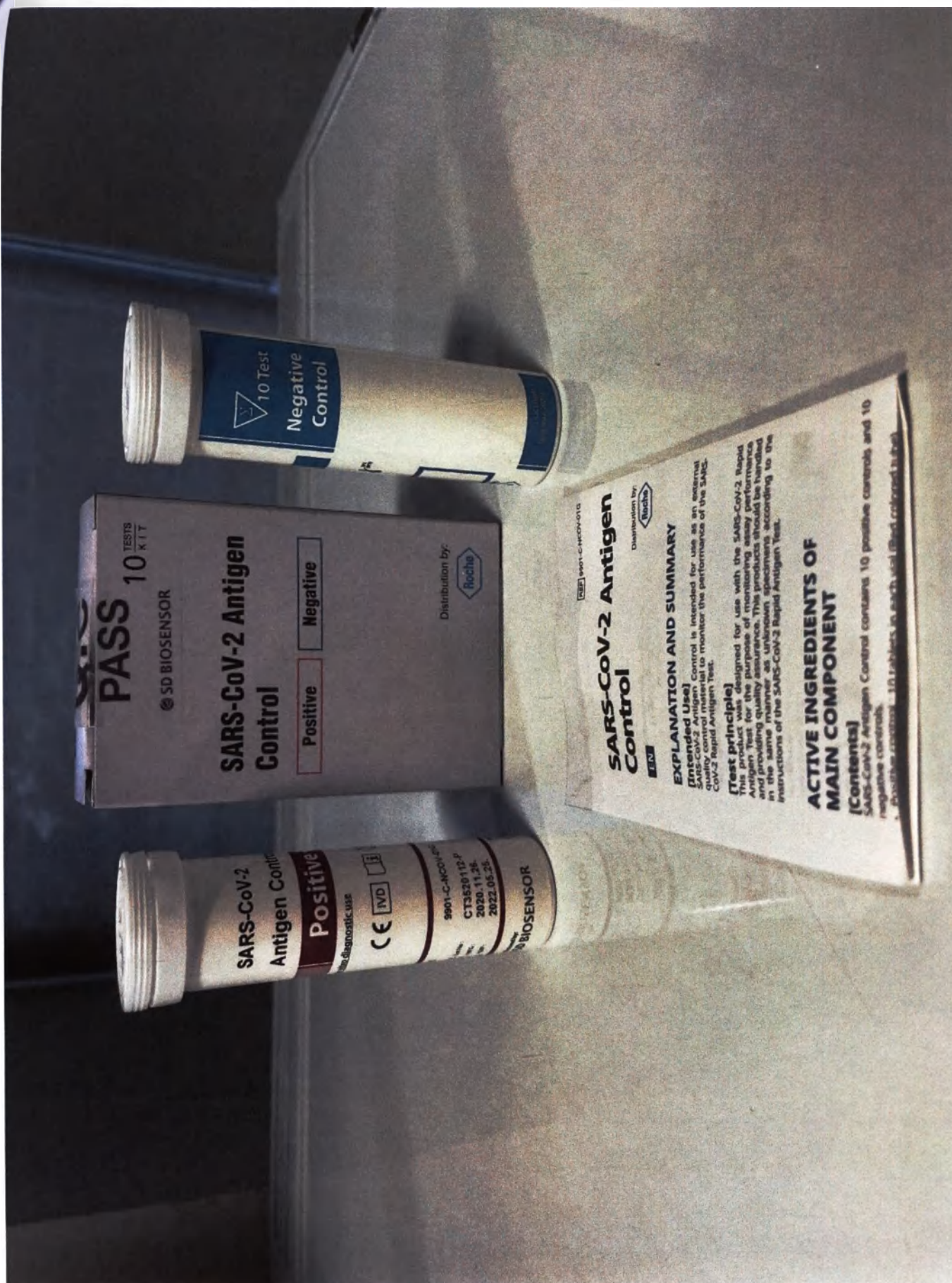


Фотографические изображения

« Набор контрольных материалов для контроля качества экспресс определения специфических антигенов SARS-CoV-2 в мазке со слизистой оболочки носоглотки и мазках со слизистой оболочки носоглотки и ротоглотки человека, помещенных в одну пробирку, иммунохроматографическим методом (SARS-CoV-2 Antigen Control)»

контрольных материалов для контроля качества экспресс определения специфических антигенов SARS-CoV-2 в мазке со слизистой оболочки носоглотки и мазках со слизистой оболочки ротоглотки человека, помещенных в одну пробирку, иммунохроматографическим методом (SARS-CoV-2 Antigen Control)

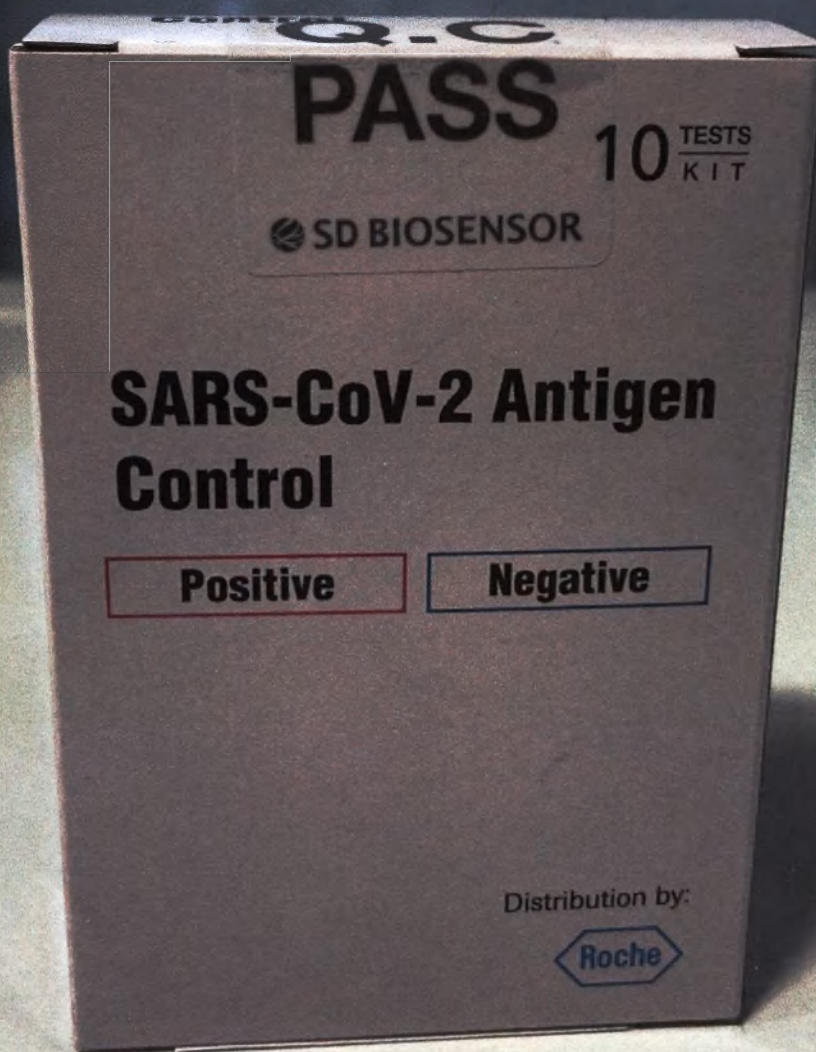


ES -10 PRUEBAS/KIT-
CONTENIDO

- 1) SARS-CoV-2 Antigen
Control Positivo x 10
- 2) SARS-CoV-2 Antigen
Control Negativo x 10
- 3) Instrucciones de uso x1

FR -10 TESTS/KIT-
CONTENU

- 1) SARS-CoV-2 Antigen
Contrôle Positif x 10
- 2) SARS-CoV-2 Antigen
Contrôle Négatif x 10
- 3) Mode d'emploi x 1



SARS-CoV-2 Antigen Control

CONTENTS

- 1) SARS-CoV-2 Antigen Positive Control x 10
- 2) SARS-CoV-2 Antigen Negative Control x 10
- 3) Instructions for use x 1



SD BIOSENSOR

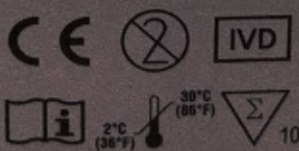
Head office: C-4th&5th, T6, Deogyong-daero 1556beon-gil,

B30COVC92MLR0
Issue date: 2020.10

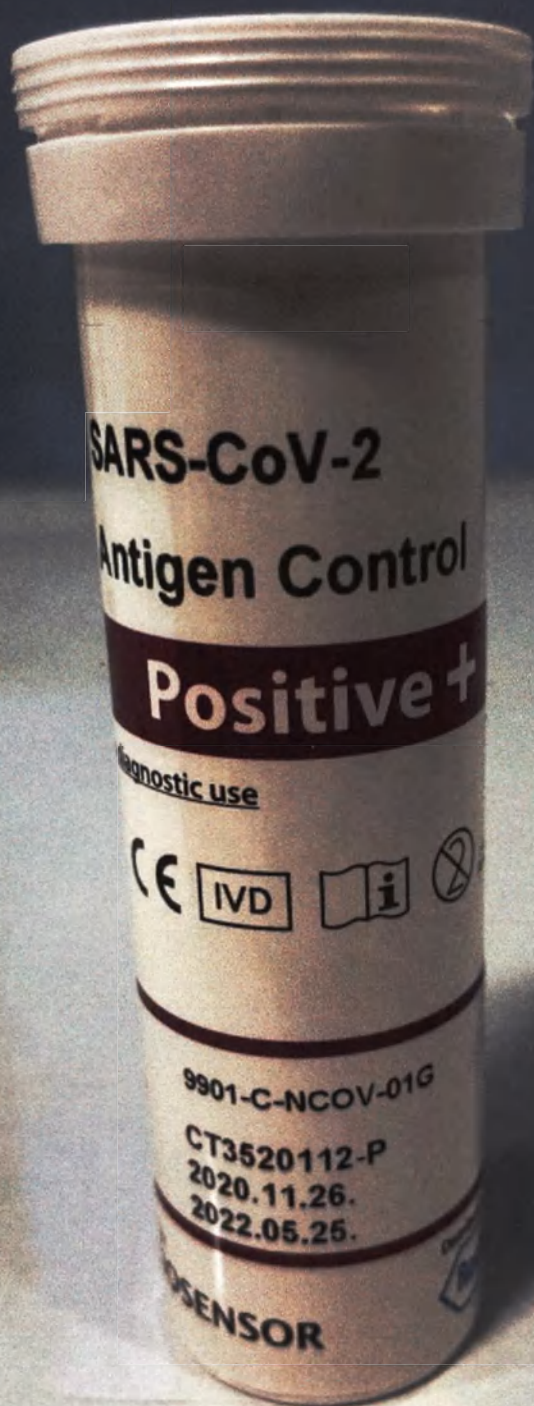
Q.C

PT -10 TESTES/KIT-
CONTEÚDO

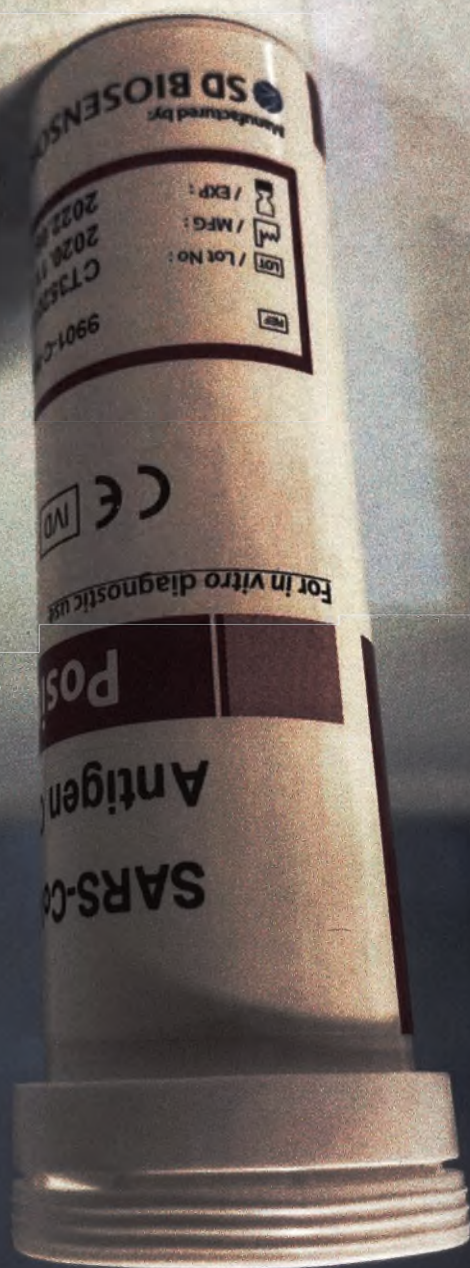
- 1) SARS-CoV-2 Antigen
Controle Positivo x 10
- 2) SARS-CoV-2 Antigen
Controle Negativo x 10
- 3) Instruções de uso x1

















REF 9901-C-NCOV-01G

SARS-CoV-2 Antigen Control

EN

Distribution by:



EXPLANATION AND SUMMARY

[Intended Use]

SARS-CoV-2 Antigen Control is intended for use as an external quality control material to monitor the performance of the SARS-CoV-2 Rapid Antigen Test.

[Test principle]

This product was designed for use with the SARS-CoV-2 Rapid Antigen Test for the purpose of monitoring assay performance and providing quality assurance. This product should be handled in the same manner as unknown specimens according to the instructions of the SARS-CoV-2 Rapid Antigen Test.

ACTIVE INGREDIENTS OF MAIN COMPONENT

[Contents]

SARS-CoV-2 Antigen Control contains 10 positive controls and 10 negative controls.

- Positive control: 10 tablets in each vial (Red colored tube)
- Negative control: 10 tablets in each vial (Transparent tube)
- Instructions for use



[Materials required but not provided]

SARS-CoV-2 Rapid Antigen Test (REF: 9901-NCOV-01G)

STORAGE AND STABILITY

1. Store the SARS-CoV-2 Antigen Control at 2-30° C/ 36-86° F.
2. Kit materials are stable until the expiry date printed on the outer box.
3. Do not use kit materials if the expiry date has passed.

WARNINGS AND PRECAUTIONS

1. Discard the control if there is evidence of microbial contamination in the reconstituted 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.

CONTROL TEST PROCEDURE

This product should be handled the same as patient specimens in accordance with the instructions accompanying the kit being used.

Run positive and negative controls:

- Once for each new lot
- Once for each untrained operator
- Once for each new shipments of test kits
- As required by test procedures in these instructions and in accordance with local, state, and federal regulations.

[Preparation]

1. Begin bringing the SARS-CoV-2 Rapid Antigen Test and SARS-CoV-2 Antigen Control to room temperature (15-30°C/59-86°F) prior to use.
2. Carefully read the instructions for use.
3. Check the expiry date of the control on the bottle and of the test device on the pouch. Do not use expired controls or test devices.



[Preparing the control]

1. Open the bottle of the SARS-CoV-2 Antigen Control and take a tube out of the bottle.



2. Insert a positive or negative control tablet into an extraction buffer tube of the SARS-CoV-2 Rapid Antigen Test.



3. Press the nozzle cap tightly onto the tube.



4. Mix the control tablet and extraction buffer using vortex or hand swirling.



[Test procedure]

1. Apply 3 drops of the prepared control mixture into the specimen well of the test device.



2. Interpret the results in accordance with the instructions for use accompanying the SARS-CoV-2 Rapid Antigen Test.

Набор контрольных материалов для контроля качества экспресс определения специфических антигенов SARS-CoV-2 в мазке со слизистой оболочки носоглотки и мазках со слизистой оболочки носоглотки и ротоглотки человека, помещенных в одну пробирку, иммунохроматографическим методом (SARS-CoV-2 Antigen Control), в составе:

1. Материал контрольный положительный (SARS-CoV-2 Antigen Control Positive+), 10 таблеток во флаконе
2. Материал контрольный отрицательный (SARS-CoV-2 Antigen Control Negative-), 10 таблеток во флаконе
3. Инструкция по применению.

Регистрационное удостоверение № _____ от _____

Срок годности см. на упаковке

Температура хранения см. на упаковке

Номер лота см. на упаковке

Производитель: «SD Biosensor, Inc.» ("СД Биосенсор, Инк."), C-4th&5th, 16, Deogyong-daere 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, Republic of Korea, Республика Корея

Изделие предназначено только для диагностики in vitro

Уполномоченный представитель производителя на территории РФ:

Общество с ограниченной ответственностью «Рош Диагностика Рус» (ООО «Рош Диагностика Рус»), 107031, Москва,

Трубная площадь, д.2

Тел: +7 495 229-69-99, факс: +7 495 229-62-64

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Кат. номер 09338322190

Виз



Визировано

по доверенности
от 04.02.2021