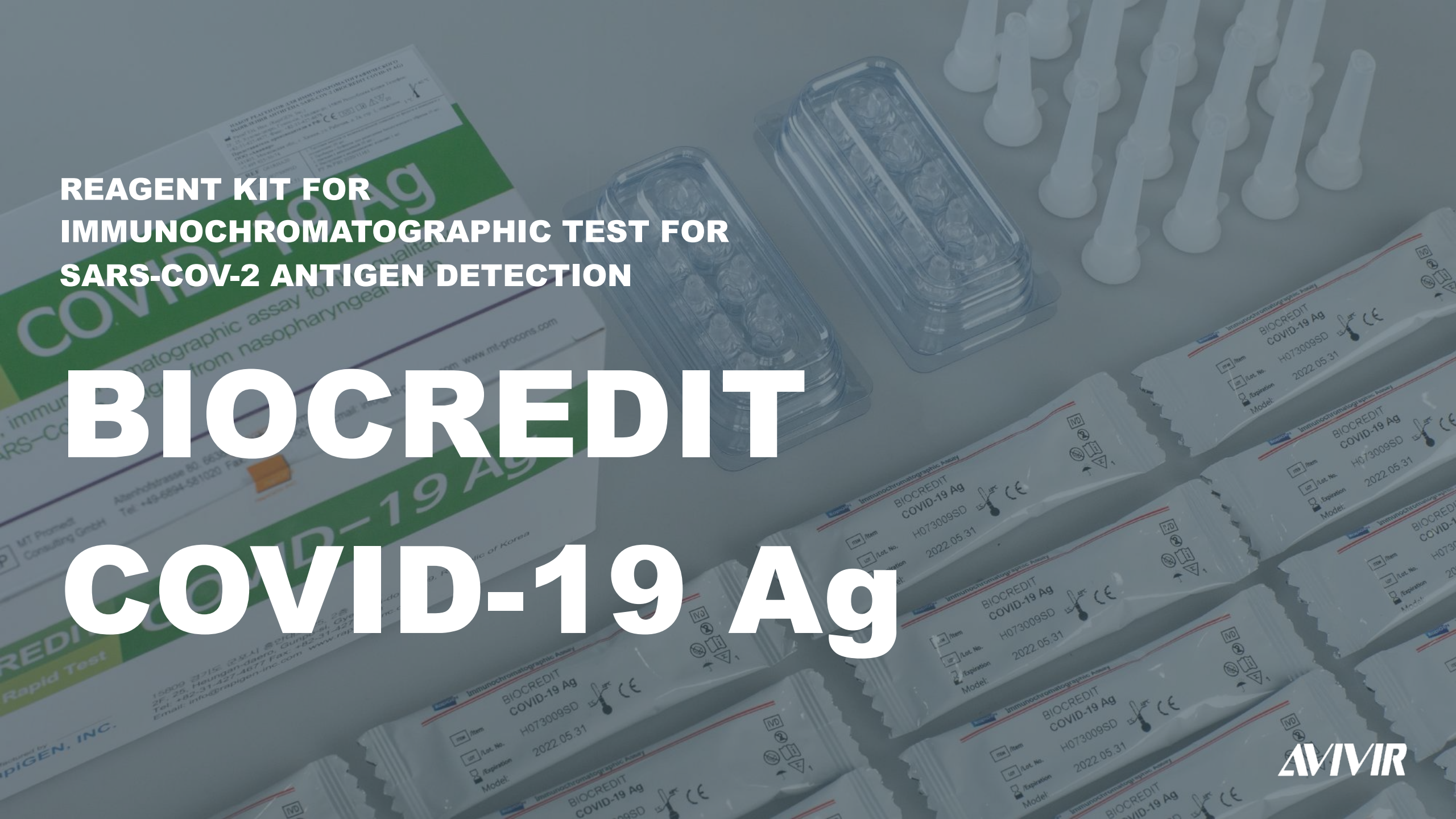

REAGENT KIT FOR
IMMUNOCHROMATOGRAPHIC TEST FOR
SARS-COV-2 ANTIGEN DETECTION
BIOCREDIT
COVID-19 Ag
BIOCREDIT
COVID-19 Ag
H073009SD
2022.05.31
AVIVIR

MEDICAL DEVICE PURPOSE

Designed for qualitative detection of
SARS-CoV-2 antigen in a nasopharyngeal swab.

The kit is suitable for in vitrouse only.

INDICATIONS

For the qualitative detection of the SARS-CoV-2 antigen in nasopharyngeal swab specimens from individuals with respiratory disease signs and symptoms who are suspected of COVID-19.

CONTRAINDICATIONS

- Expired test.
- Damaged container with the device.
- Inadequate product storage and transportation.
- There are no other contraindications unless the specimen cannot be taken for medical reasons.

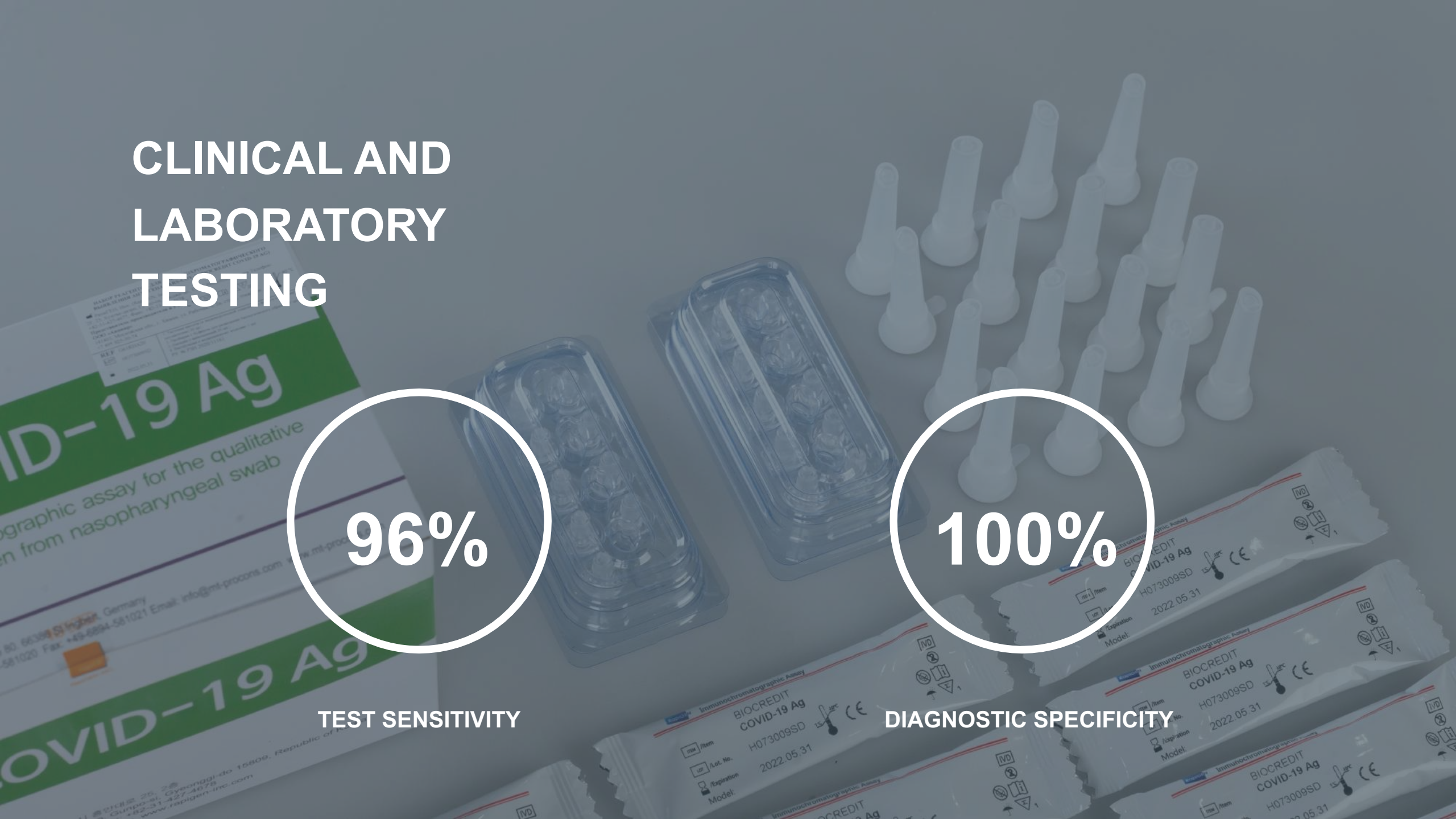
REAGENT KIT FEATURES

BIOCREDIT COVID-19 Ag Reagent Kit is designed for the qualitative and rapid detection of the COVID-19 antigen in nasopharyngeal swab.

Easy-to-use test strips.

Testing time 5 minutes.

CLINICAL AND LABORATORY TESTING



PRINCIPLES OF THE TEST

The reagents kit for SARS-CoV2 antigen detection (BIOCREDIT COVID-19 Ag) is designed for rapid and quality immunochromatographic assay.

T LINE

Antibodies specific to the SARS-CoV-2 coronavirus antigen were preliminarily applied to the membrane strip of reagent T Line. If the test biological sample contains the SARS-CoV-2 coronavirus antigen, a visible black strip appears along the line at the result of testing.

C LINE

C Control line is provided in the test system to provide integration of the correct test execution procedure. If the test procedure is performed correctly, control line C should be colored under all circumstances, regardless of the test results.

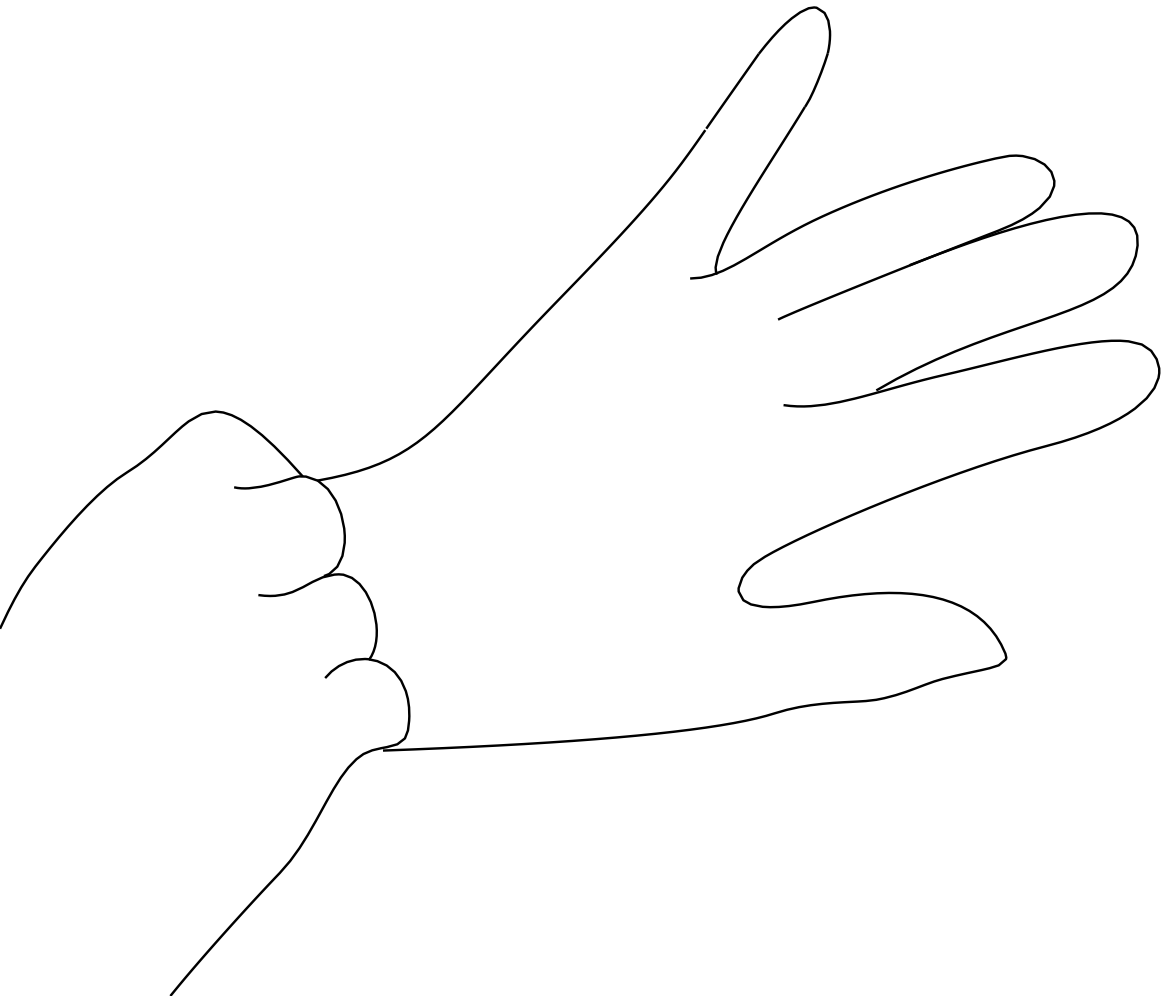
KIT CONTENTS

The product is a reagent kit containing:

- Test cassette (together with a desiccant in individual foil package) - 20 pcs.
- A test tube with a buffer for biological sample diluting - 20 pcs.
- Dropper cap - 20 pcs.
- Prescribing information - 1 pc.

The following materials are not provided: protective gloves, safety goggles.

SAMPLE COLLECTION



Biological samples should be taken by trained healthcare professionals. Biological samples should be handled with caution due to the risk of infection.

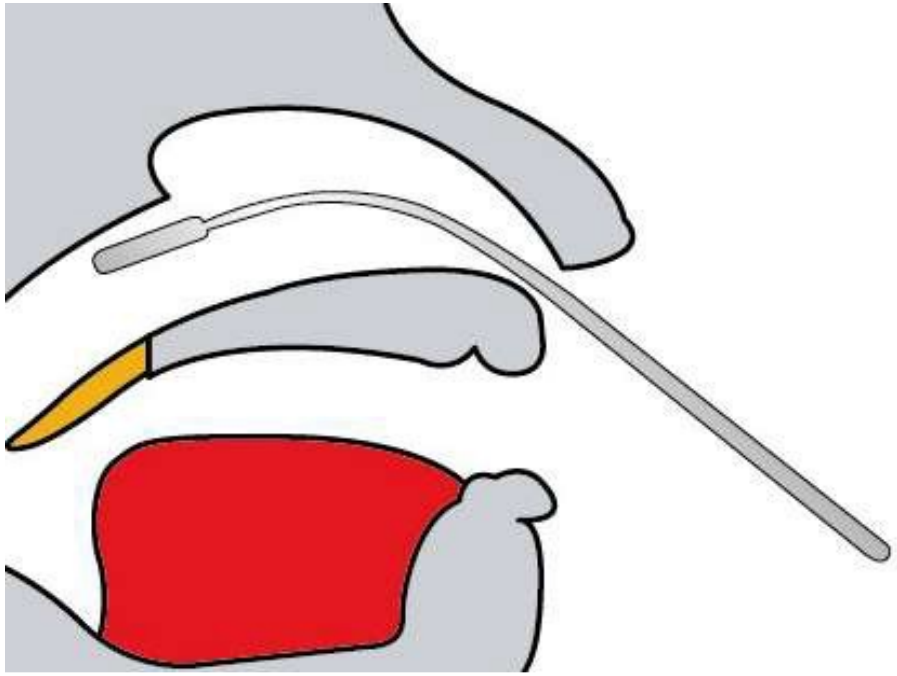
Handling of biological samples requires special care; any violation of prescribed procedures may adversely affect the specimen and lead to inaccurate test results.

In order to obtain more accurate test results, it is advisable to take a biological sample from several areas of the nasopharyngeal.

IMPORTANT

Test should be performed immediately as soon as a sample is taken. If this is not possible, a swab with the sampled material may be stored for a maximum 12 hours in a refrigerator, at a temperature within 2 - 8°C, or for a maximum of 24 hours in a freezer at -20°C.

NASOPHARYNGEAL SWAB COLLECTION



To collect a biological sample from the nasopharyngeal area, carefully insert a swab on a stick into the nasal cavity.
Keep gently inserting the tampon until resistance is encountered in the nasal turbinate.

Gently rotate the swab around its axis several times with your fingers and remove it from the nasal cavity. Visually verify that the tip of the swab is wet.

TEST PROCEDURE

PREPARATORY STEP

Ensure that the biological sample and all Kit components are at room temperature before performing the test.

Do not open an individual test cassette packaging until all preliminary manipulations are completed and test procedure is ready for immediate performance.

TEST STAGES

Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer.

Place a swab with a smear from the nasopharyngeal area into the extraction vial with a buffer and press the swab tip against inner wall or bottom of the vial to release biological sample and transfer it to the buffer medium.

While continuing to press the swab tip against the wall or bottom, make 5 – 10 circular movements.

Press the tip of the swab against the inner wall to release the liquid, then remove the swab from the vial and dispose it in accordance with the hazardous biological waste disposal requirements.

Securely close the vial using the dropper cap from the kit.

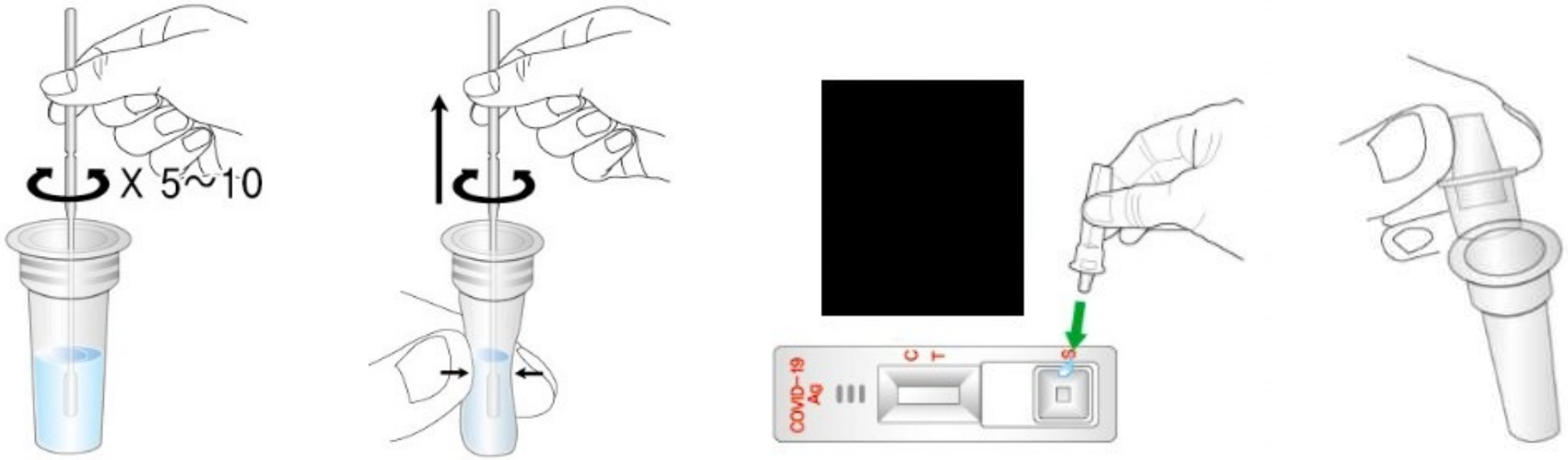
Remove the test cassette from the individual package. Place the cassette on a dry, flat surface.

TEST STAGES

Turn down the vial with the buffer and biological sample and press lightly on the sides to dispense 3 - 4 drops (90 - 150 µl). Obtained volume should be placed in the center of the sample well on the surface of the test cassette, marked with the letter S. Ensure that an adequate volume of buffer containing biological sample is used for the test.

Insufficient or excessive sample volume, as well as insufficient or excessive buffer volume, can lead to inaccurate (invalid or distorted) test results.

Read the test result in 5 - 8 minutes.

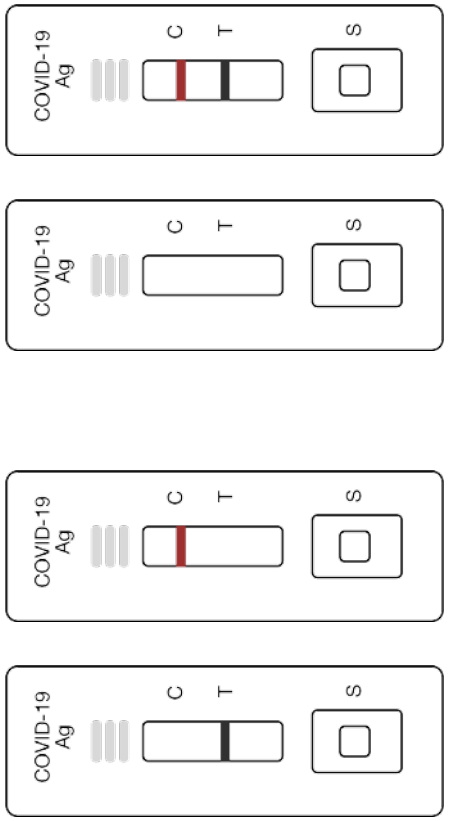


TESTING PROCEDURE SCHEME

Read the test result in 5 - 8 minutes.

INTERPRETATION OF RESULTS

Note: strip width or color intensity are irrelevant.



If only the control line (C) is colored red in the result window: the test is negative for the presence of the coronavirus antigen.

If the control line (C) is colored red and the test line (T) turns black in the result window: the test is positive for the presence of the coronavirus antigen.

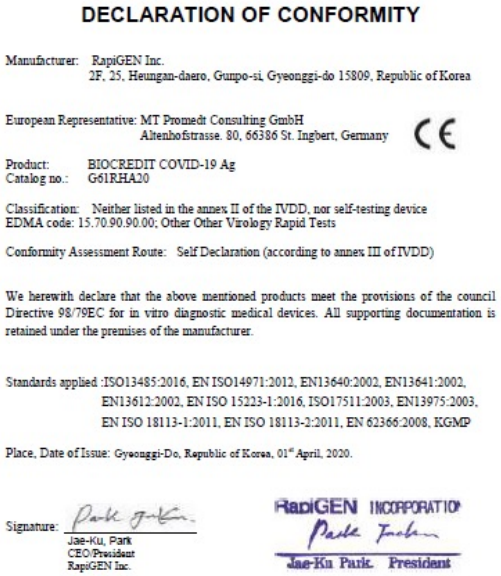
If there is no red-colored control line (C) in the result window, the test result is considered invalid. The reason for such a result could be a violation of the biological sample collection and/or analysis procedures or the failure of the test cassette(test system) used.

LIMITATIONS

The test result can be negative if the coronavirus content (titer) in the biological sample is below the detection limit.

A negative test result does not rule out the presence of infection in cases of recent infection.

CERTIFICATES



DECLARATION OF CONFORMITY

Manufacturer: RapiGEN Inc.
2F, 25, Heungan-daero, Gunpo-si, Gyeonggi-do 15809, Republic of Korea

European Representative: MT Promedt Consulting GmbH
Altenhofstrasse. 80, 66386 St. Ingbert, Germany CE

Product: BIOCREDIT COVID-19 Ag
Catalog no.: G61RHA20

Classification: Neither listed in the annex II of the IVDD, nor self-testing device
EDMA code: 15.70.90.90.00; Other Other Virology Rapid Tests

Conformity Assessment Route: Self Declaration (according to annex III of IVDD)

We herewith declare that the above mentioned products meet the provisions of the council Directive 98/79EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied :ISO13485:2016, EN ISO14971:2012, EN13640:2002, EN13641:2002, EN13612:2002, EN ISO 15223-1:2016, ISO17511:2003, EN13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 62366:2008, KGMP

Place, Date of Issue: Gyeonggi-Do, Republic of Korea, 01st April, 2020.

Signature:
Jae-Ku, Park
CEO/President
RapiGEN Inc.

RapiGEN INCORPORATION
Jae-Ku Park President

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ (РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 02 июля 2020 года № РЗН 2020/11161

Действительно до 1 января 2021 г.

На медицинское изделие
Набор реагентов для иммунохроматографического выявления антигена SARS-CoV-2 (BIOCREDIT COVID-19 Ag), Lot No: H073009SD

Настоящее регистрационное удостоверение выдано
Обществу с ограниченной ответственностью "АВИВИР" (ООО "Авивир"), Россия, 141401, Московская область, г. Химки, ул. Рабочая, д. 2а, стр. 1, этаж 2, пом. 7

Производитель
"РапиГЕН, Инк.", Республика Корея,
RapiGEN, Inc., 3-4F, 16, LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do 14119, Republic of Korea

Место производства медицинского изделия
RapiGEN, Inc., 3-4F, 16, LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do 14119, Republic of Korea

Номер регистрационного досье **№ РД-34267/43486 от 02.07.2020**

Класс потенциального риска применения медицинского изделия **3**

Код Общероссийского классификатора продукции по видам экономической деятельности **21.20.23.110**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 02 июля 2020 года № 3621
допущено к обращению на территории Российской Федерации.
Руководитель Федеральной службы по надзору в сфере здравоохранения **А.В. Сивойлова**

0050968

DAkkS

Certificate
No. Q5 053740 0007 Rev. 00

Holder of Certificate: RapiGEN, Inc.
3-4F, 16, LS-ro 91beon-gil, Dongan-gu
Anyang-si, Gyeonggi-do 14119
REPUBLIC OF KOREA

Facility(ies): RapiGEN, Inc.
3-4F, 16, LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do
14119, REPUBLIC OF KOREA

Certification Mark:

Scope of Certificate: Design, Development, Production and Distribution of In Vitro Diagnostic Medical Device - Immunochromatographic assay

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 74060290
Valid from: 2020-06-14
Valid until: 2023-06-13

Date, 2020-04-16
Christoph Dicks
Head of Certification/Notified Body

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstaße 65 • 80339 Munich • Germany TÜV®

2ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

«РапиДЖЕН, Инк.» (RapiGEN INC.)
2F, 25, Хеунган-дэаро, Гунпо-си, Джинети-до, 15809, Республика Корея (2F, 25, Heungan-daero, Gunpo-si, Gyeonggi-do 15809, Republic of Korea)
Тел.: +82-31-427-4677 факс: +82-31-427-4678 Эл. Почта : info@rapigen-inc.com www.rapigen-inc.com

СЕРТИФИКАТ АНАЛИЗА

Название продукта: Экспресс-тест BIOCREDIT COVID-19 Ag

Производитель: «РапиДЖЕН, Инк.» (RapiGEN INC.)

2F, 25, Хеунган-дэаро, Гунпо-си, Джинети-до, 15809, Республика Корея

Номер по каталогу: G61RHA20

Номер серии: H073009SD

Дата производства: 30 мая 2020 г.

Годен до: 31 мая 2022 г.

Дата выдачи: 12 июня 2020 г.

Компоненты	Результаты
1) 20 тестовых кассет, запечатанных в упаковки из фольги в комплекте с осушителем	Соответствует
2) 20 пробирок для отбора проб, содержащих аналитический буфер	Соответствует
3) 20 насадок с капельницей	Соответствует
4) 20 стерильных тампонов	Соответствует
5) Инструкция по применению	Соответствует

Результаты испытания продукта

Испытание	Нормы спецификации	Результаты	Соответствует/ не соответствует
Положительный	0,4 нг/мл	Контрольная линия + Линия появляется согласно нормам спецификации	Соответствует
Отрицательный	0	Только контрольная линия проявляется согласно нормам спецификации	Соответствует
Заключение			Соответствует

Испытание было проведено на вышеуказанных компонентах, и можно сделать вывод, что продукт отвечает внутреннему стандарту контроля качества. Данный продукт используется только в целях диагностики in vitro.

Подписан **12 июня 2020 г., и действителен в течение 2 лет со дня производства.**

Подпись: Джа-сук Джан
подпись
Отдел обеспечения качества в «РапиДЖЕН, Инк.»

F807-3 (ред.1)

PUBLICATIONS IN MEDIA

MEDRUSSIA.ORG portal- a **rapid test for SARS-CoV-2 antigen detection has appeared in Russia: Biocredit from RapiGEN.**

GOVORIT MOSKVA radio station- **Moscow ambulances will be equipped with an innovative Korean test for coronavirus detection**

ARGUMENTY I FAKTY- **Yelena Malysheva: "Know your coronavirus test in 5 minutes"**

VADEMECUM - **THE MINISTRY OF HEALTH RECOMMENDED TO USE EXPRESS TESTS FOR COVID-19 "AT THE PATIENT'S SIDE" AND MORE**

MEDVESTNIK.RU portal- **according to Korean system**

VADEMECUM - **SOUTH KOREAN RAPIGEN EXPRESS TEST FOR COVID-19 OBTAINED MARKETING AUTHORIZATION IN RUSSIA**