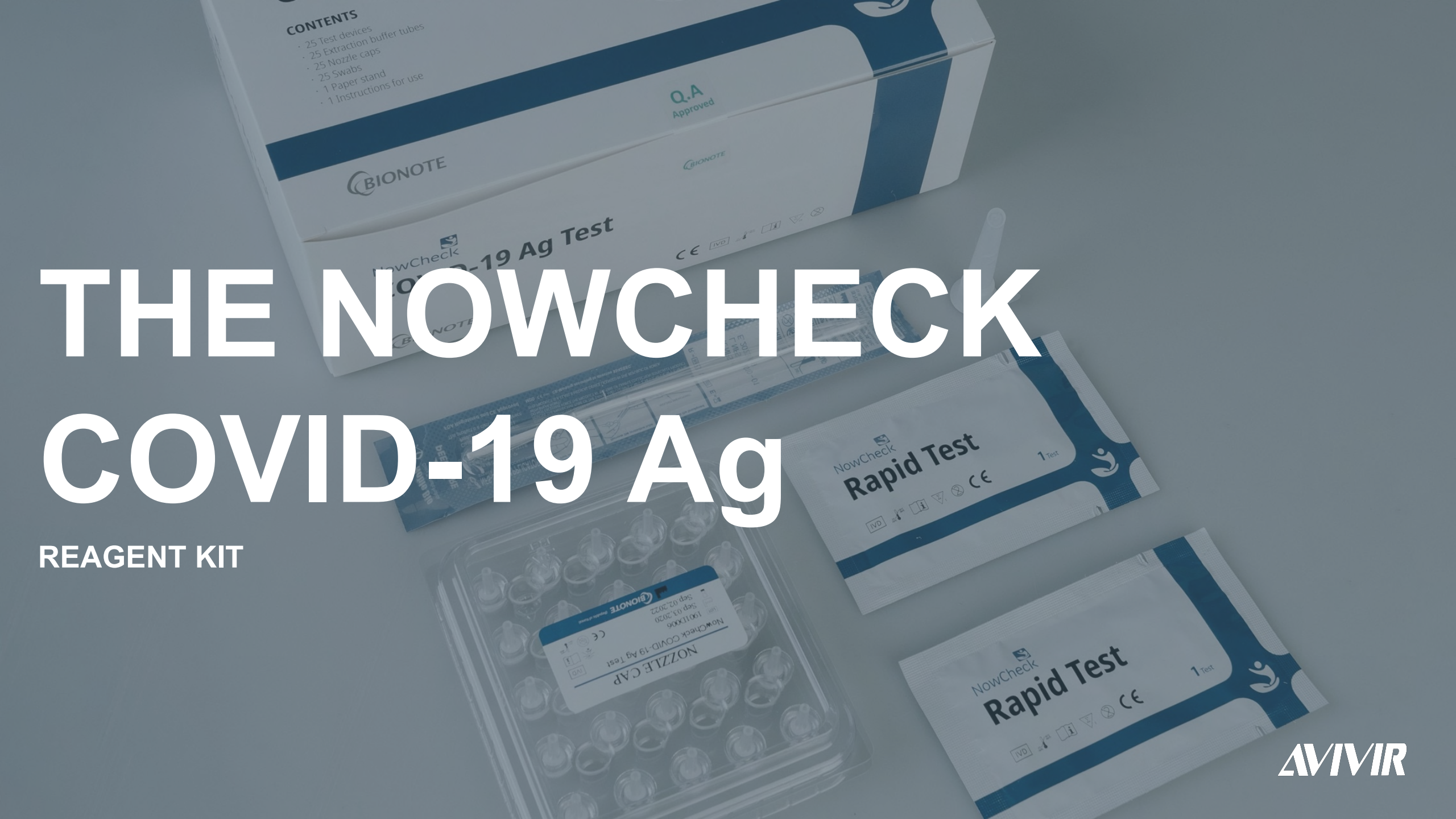


THE NOWCHECK COVID-19 Ag

REAGENT KIT

AVIVIR

MEDICAL DEVICE DESIGNATION

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

The kit is only suitable for in vitro use.

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 package.
- Inadequate product storage and transportation.
- There are no other contraindications unless the specimen cannot be taken for medical reasons.

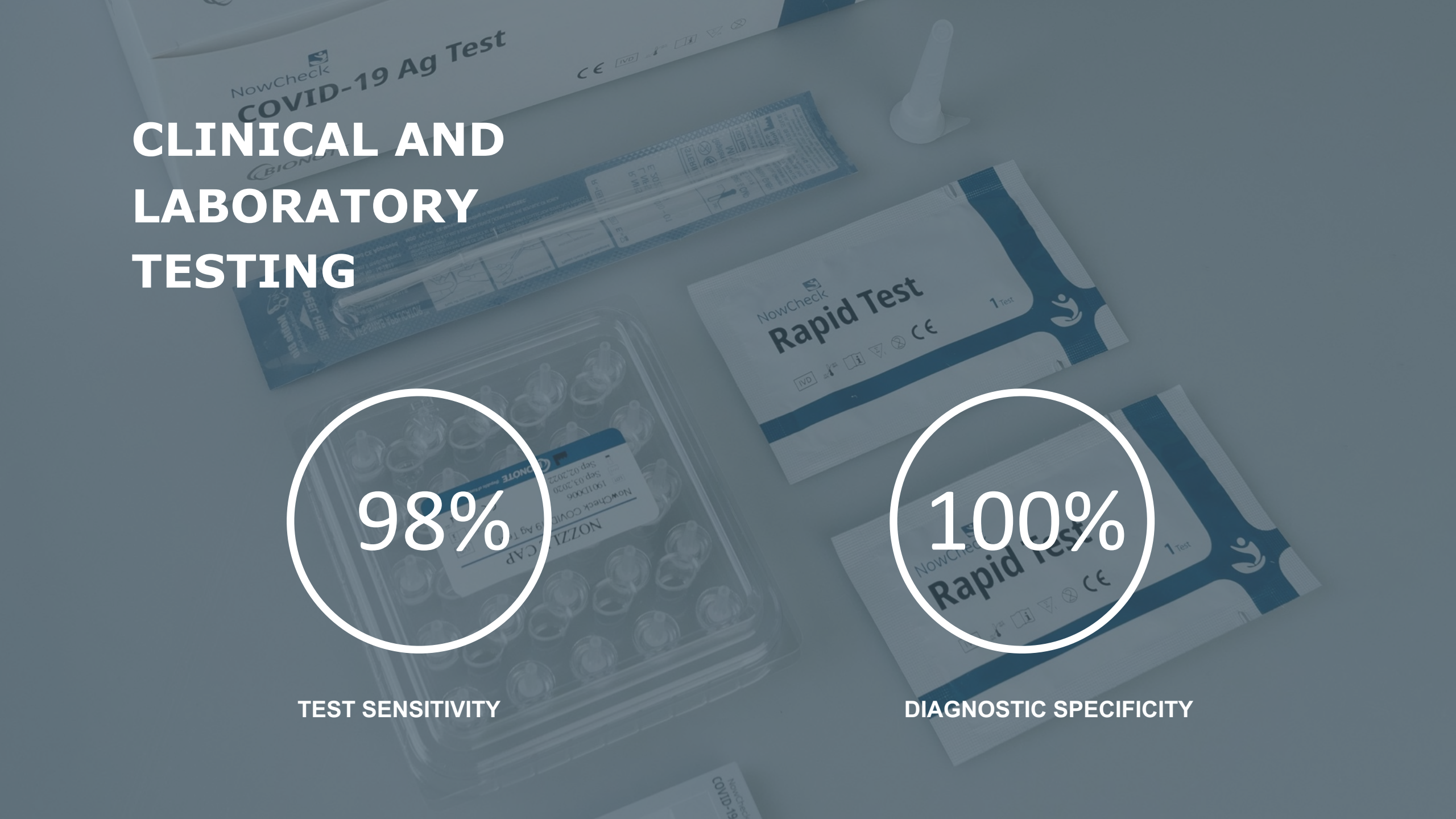
REAGENT KIT FEATURES

The NOWCHECK COVID-19 Ag Reagent Kit
is designed for the qualitative detection of the SARS-CoV-2 antigen in nasopharyngeal swab.

Easy-to-use test strips.

Testing time 15–30 minutes.

CLINICAL AND LABORATORY TESTING



98%

TEST SENSITIVITY

100%

DIAGNOSTIC SPECIFICITY

PRINCIPLES OF THE TEST

The reagents kit for SARS-CoV2 antigen detection (NOWCHECK COVID-19 Ag) is designed for rapid and high-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

Control line C is provided in the test system as a means of integrating the correct test procedure performing.
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) — 25 pcs.

Test tube with biological sample extraction buffer — 25 pcs.

Dropper cap — 25 pcs.

Sterile swab for specimen collection – 25 pcs.

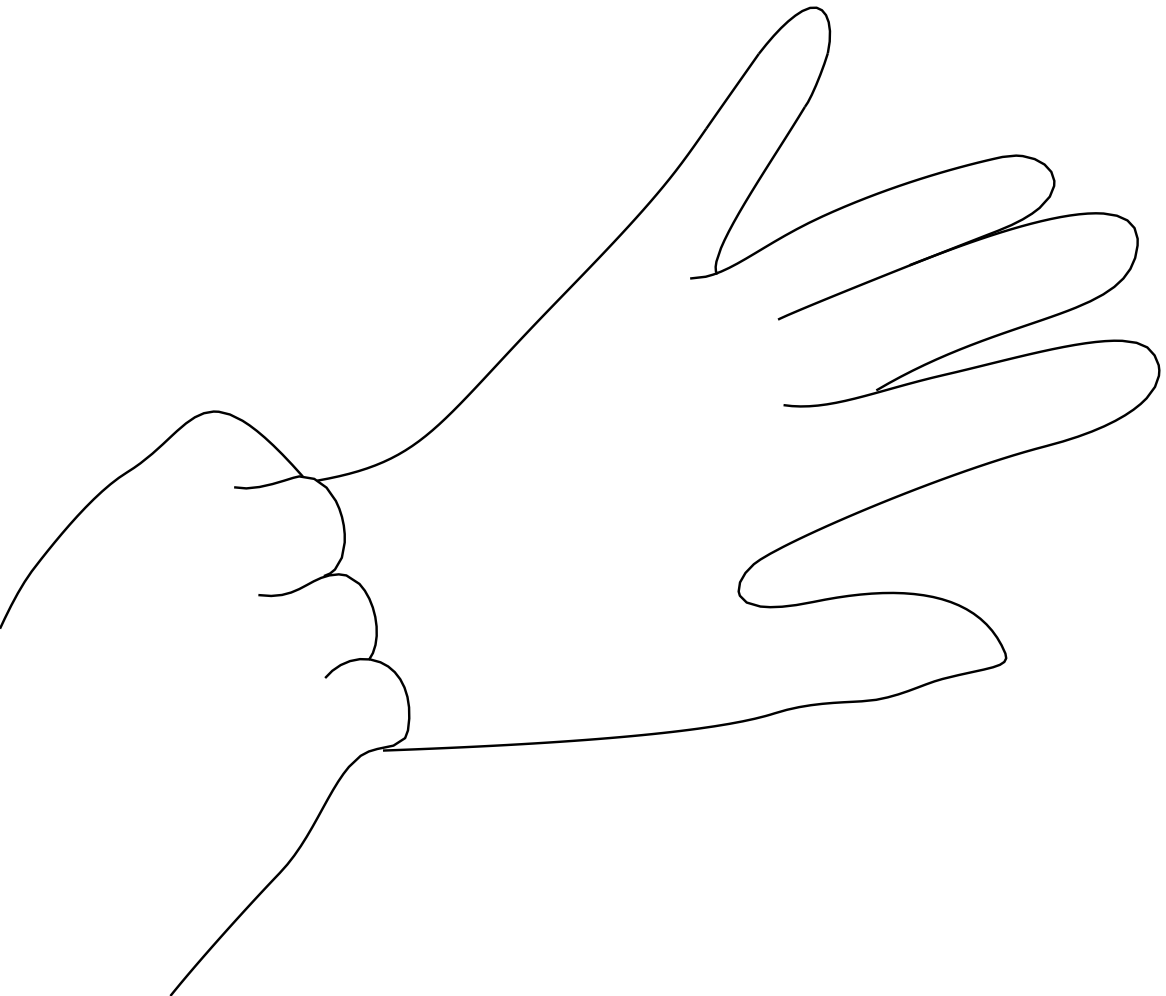
Cardboard stand — 1 pc.

Set of film labels — 1 pc.

Medical device instructions for use — 1 pc.

The following materials are not provided: protective gloves, timer or stopwatch, micropipettes.

SAMPLE COLLECTION

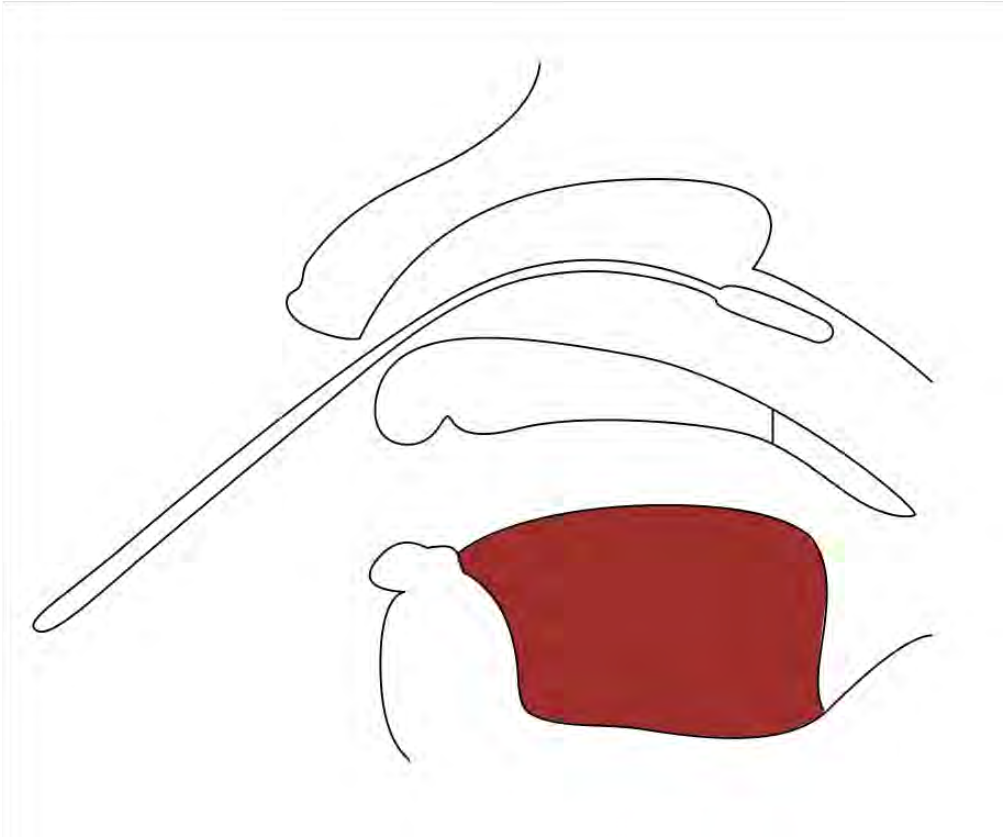


Biological samples should be taken by trained healthcare professionals. Biological samples should be handled with caution due to the risk of infection.

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 nasopharynx.

NASOPHARYNGEAL SWAB COLLECTION



1. Gently insert a swab into the nasal cavity in order to collect a biological sample from the nasopharynx. Keep gently inserting the tampon until resistance is encountered in the nasal cavity.
2. Gently rotate the swab around its axis several times with your fingers and remove it from the nasal cavity.
3. Visually verify that the tip of the swab is wet.

TEST PROCEDURE

PREPARATION STAGE

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 nasopharynx 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.

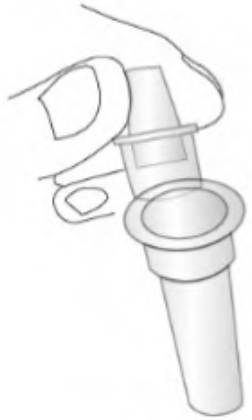
While continuing to press the swab tip against the wall or bottom, make 5–10 circular movements.

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.

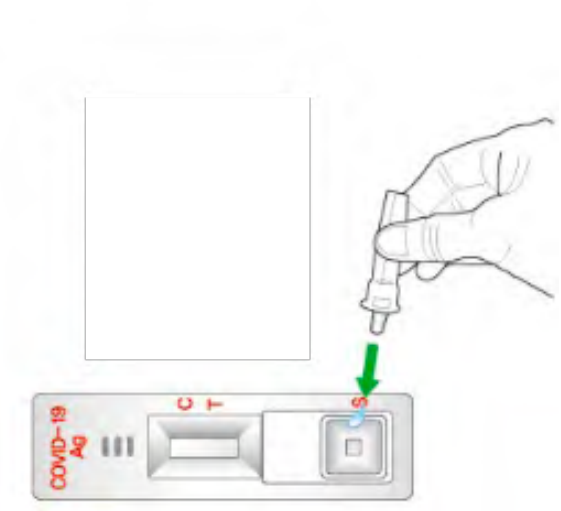
TEST STAGES

1. Insert the swab sample and rotate 5–10 times.

2. Remove the swab by gently squeezing its tip.

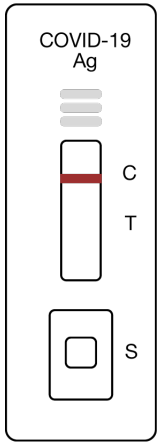


3. Close the assay diluent tube with a filter cap securely.

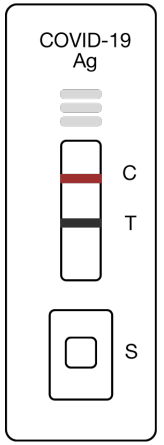


4. Invert the assay diluent tube and squeeze it gently to draw 3 drops into the well.

INTERPRETATION OF RESULTS

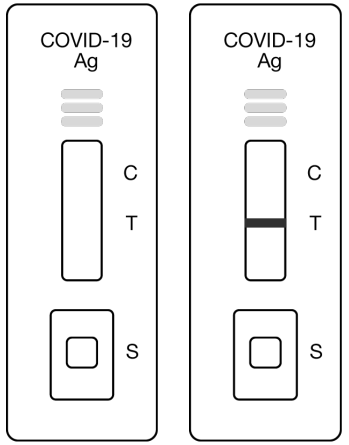


If line (C) turns red:
the test result is considered negative for coronavirus antigen.



If line (C) turns red and line (T) turns black:
the test result is considered positive for coronavirus antigen.

Note: strip width or color intensity are irrelevant.



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

LIMITATIONS

Test result can be negative if the content (titer) of the coronavirus 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

DAkkS

Certificate

No. Q5 071892 0005 Rev. 00

Holder of Certificate: BioNote, Inc.
22, Samsung 1-ro 4-gil
Hwaseong-si, Gyeonggi-do 18449
REPUBLIC OF KOREA

Facility(ies): BioNote, Inc.
22, Samsung 1-ro 4-gil, Hwaseong-si, Gyeonggi-do 18449,
REPUBLIC OF KOREA

Certification Mark:

Scope of Certificate: Design, Development, Production and Distribution of In Vitro Diagnostic Reagents - Immunochromatographic Assay Kits and ELISA Kits

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.: 74952017

Valid from: 2018-12-01
Valid until: 2021-11-30

Date, 2018-11-12

Stefan Preiß

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

TÜV SÜD ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Osong Health Technology Administration Complex,
187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, Korea, 28159
Tel: +82-43-719-2396, Fax: +82-43-719-1000

No. of Certificate : 20200061996 Date : 2020/05/29

Certificate of Free Sales

Exporting(certifying) country : Republic of Korea
Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in overseas markets.

Manufacturer (Registered No. : IVD-5591)

BioNote, Inc.

22, Samsung 1-ro 4-gil, Hwaseong-si, Gyeonggi-do

Product-License No.	Classification
IVD-20-385	IVD reagents for infectious disease markers|Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than high-risk pathogens, Infectious agents with moderate infectivity| Immunological method |III Product Name : NowCheck COVID-19 Ag Test
IVD-20-386	IVD reagents for infectious disease markers|Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than high-risk pathogens, Infectious agents with moderate infectivity| Immunological method |III Product Name : NowCheck COVID-19 IgM/IgG Test

※Attached : List of Product Classification and Model

Director of High-Tech Medical Devices Division
Department of Medical Device Evaluation
National Institute of Food and Drug Safety Evaluation
Ministry of Food and Drug Safety

Page 1 of 2

promedt CONSULTING

Certificate
of EU product notification

Herewith we confirm that

MT Promedt Consulting GmbH
Altenhofstraße 80
66386 St. Ingbert
Germany

has taken over the function of an European Authorized Representative according to the requirements of Article 10 of the IVDD 98/79/EC for

BioNote, Inc.
22, Samsung 1-ro 4-gil, Hwaseong-si,
Gyeonggi-do 18449
Republic of Korea

MT Promedt Consulting GmbH has made the product notification at the relevant competent authority according to Article 10(3).

The in vitro diagnostic medical devices of the manufacturer, covered by the notification, are listed in Annex I of this certificate.

This certificate does not attest the conformity of the medical devices with the above mentioned directive. The conformity is stated in the respective product-related Declarations of Conformity signed under the sole responsibility of the manufacturer.

8 June 2020

Dr. Michael Rinck
- Managing Director -

Enclosure
Annex I

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 29 октября 2020 года № РЗН 2020/12392

Действительно до 1 января 2021 г.

На медицинское изделие
Набор реагентов для иммунохроматографического выявления антигена SARS-CoV-2 в мазке из носоглотки (NowCheck COVID-19 Ag Test), Lot № 1901D006

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
"БиоНоут, Инк.", Корея,
BioNote, Inc., 22, Samsung, 1-ro 4-gil, Hwaseong-si, Gyeonggi-do 18449, Republic of Korea

Место производства медицинского изделия
BioNote, Inc., 22, Samsung, 1-ro 4-gil, Hwaseong-si, Gyeonggi-do 18449, Republic of Korea

Номер регистрационного досье **№ РД-37046/83167 от 22.10.2020**

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 29 октября 2020 года № 10005
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы по надзору в сфере здравоохранения **А.В. Самойлова**

0052920

OUR CLIENTS


ГАЗПРОМ


ПРОДО


ПЕРВЫЙ КАНАЛ
ВСЕМИРНАЯ СЕТЬ


Клинический институт
репродуктивной
медицины


Р-ФАРМ
Инновационные
технологии
здоровья


KINROSS


Severstal


HADASSAH
Medical
MOSCOW


ВитаМед


Центр
современной
педиатрии


EMC
GROUP OF COMPANIES
EUROPEAN MEDICAL CENTER