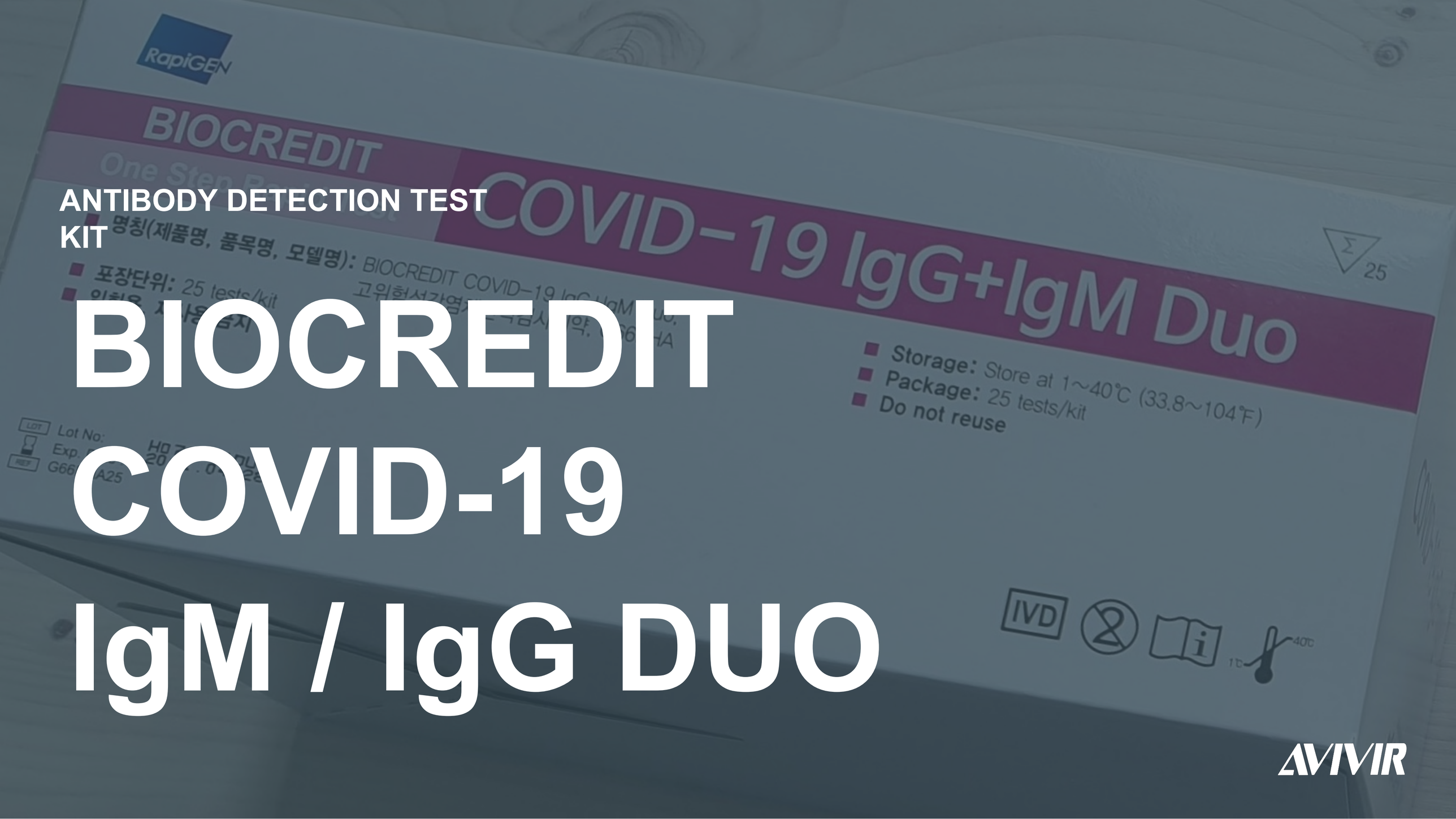


ANTIBODY DETECTION TEST KIT

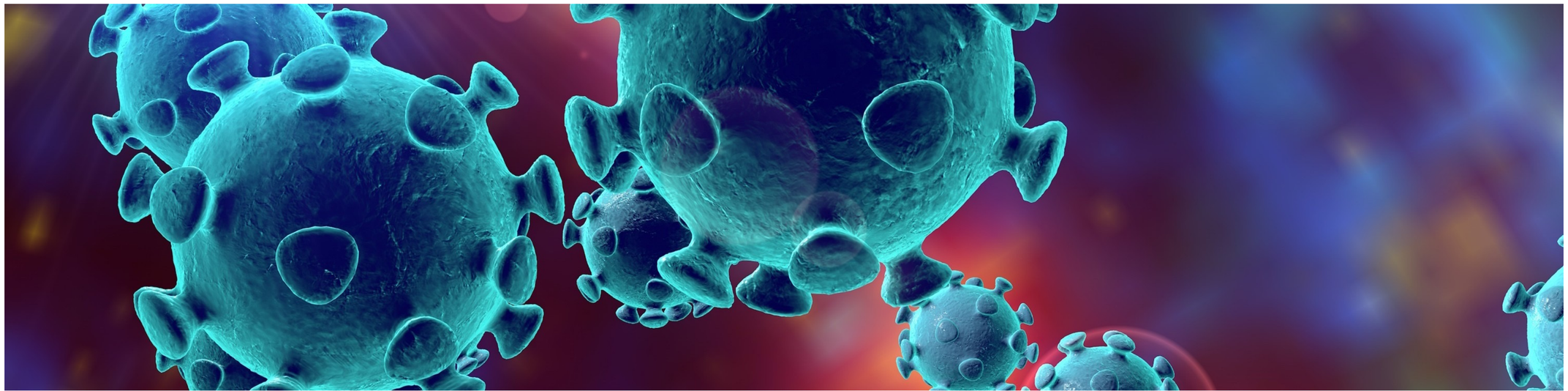
BIOCREDIT COVID-19 IgM / IgG DUO

AVIVIR

VIRUS AND VIRUS DIAGNOSTICS

According to the statistics of **Rospotrebnadzor** almost **30%** of those infected with coronavirus in Russia **are asymptomatic**.

Mass testing of the population for COVID-19 which is recommended by the World Health Organization is a proven and effective infection-control tool.

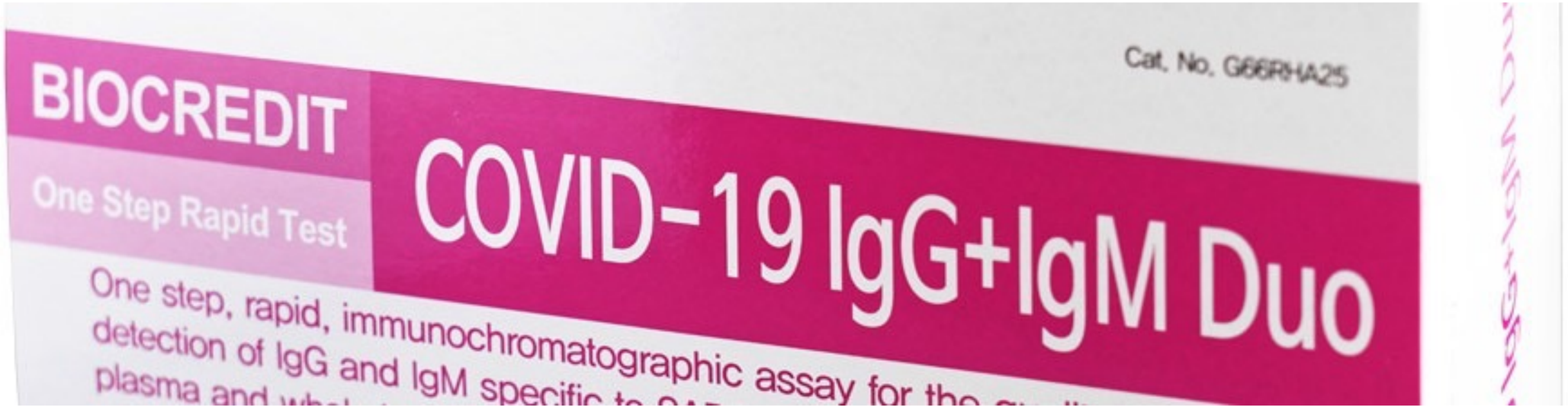


MEDICAL DEVICE PURPOSE

Designed for qualitative detection ofIgM and IgG antibodies to COVID-19 coronavirusin the whole blood, serum or plasma samples.

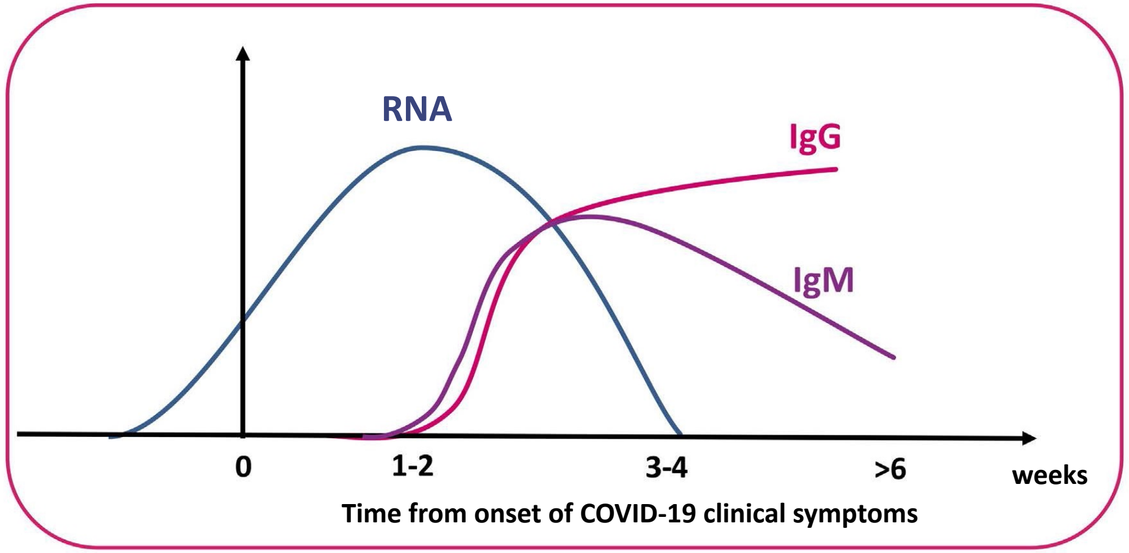
When using the Kit for biological samples testing the results indicating the sample reactivity should be confirmed by alternative test methods.

The kit is suitable for in vitrouse only.



ANTIBODIES TO COVID-19

Graph of the antibodies detection to SARS-CoV-2 with relation to the onset of the disease.



IgM ANTIBODIES

indicate the recent infection and can be used as an auxiliary diagnosis of the early infection.

IgG ANTIBODIES

are produced later and for a longer period and indicate of a previous or a secondary infection.

Source: gemohelp.ru

INDICATIONS

For the qualitative determination of the presence of IgM or IgG antibodies to coronavirus (SARS-CoV-2) in the serum, plasma and whole blood samples in patients with clinical symptoms of respiratory disease with suspected COVID-19 infection, as well as in patients without the signs of colds and not in contact with the COVID-19 patients.

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.

TEST KIT FEATURES

- Run time - 5-10 minutes;
- Auxiliary tool for diagnosis;
- Easy-to-use, test strips (cassettes).
- Identification of those who were ill and acquired immunity.

KIT CONTENTS

BIOCREDIT COVID-19 IgG/IgM DUO kit contains:

- Test cassette (in individual foil package with desiccant material) – 25 pieces (IgG) + 25 pieces (IgM).
- A vial with the solution for biological sample diluting — 1 pc.
- Disposable capillary pipettes – 50 pc.
- Prescribing information - 1 pc.

Materials not included in the scope of supply: protective gloves, protective glasses, micropipette, alcohol soaked wipe, scarifier(lancet), blood sampling tubes.

CLINICAL AND LABORATORY TESTING IGm

Marketing Authorization issued by Roszdravnadzor
Ref. No.2020/10777 dated June 10, 2020.

93.4%

TEST SENSITIVITY

100%

DIAGNOSTIC SPECIFICITY

CLINICAL AND LABORATORY TESTING IGg

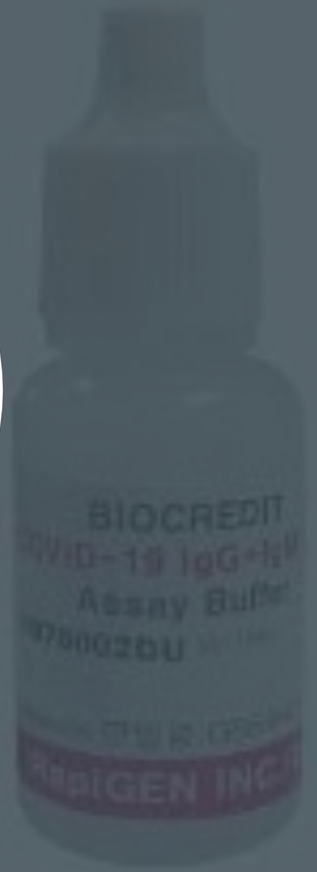
Marketing Authorization issued by Roszdravnadzor
Ref. No.2020/10777 dated June 10, 2020.

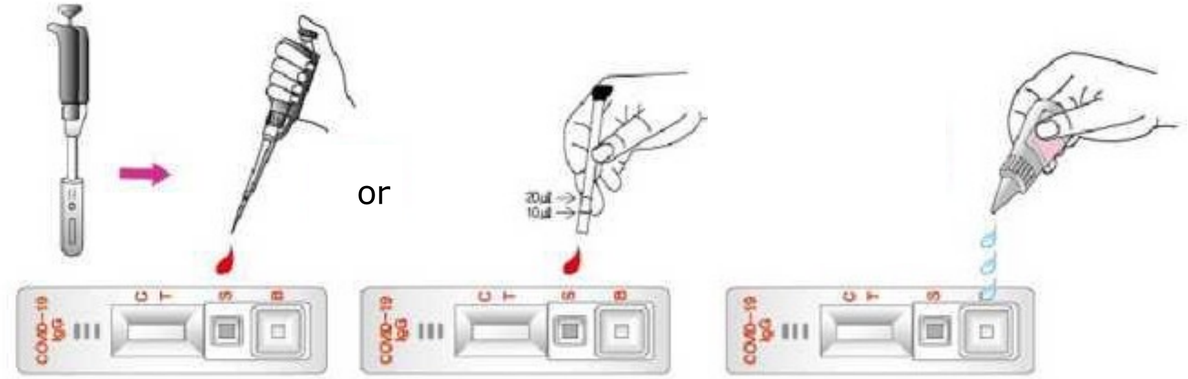
95.1%

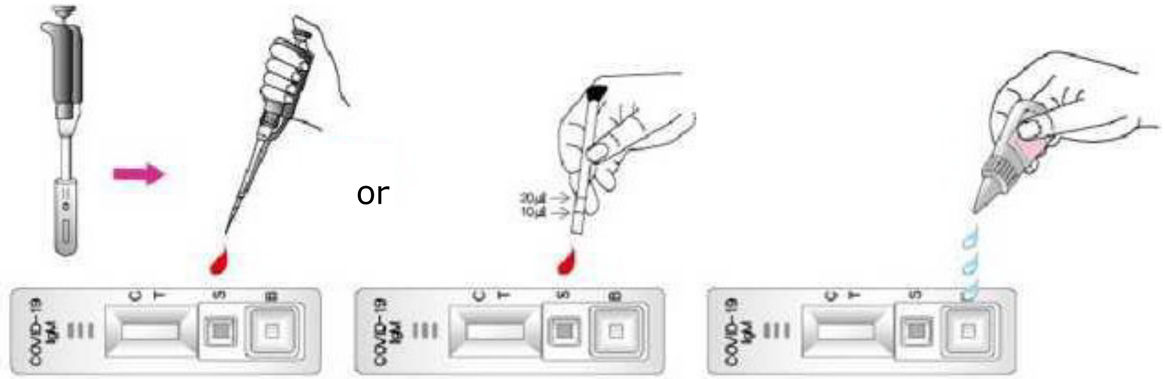
TEST SENSITIVITY

95.3%

DIAGNOSTIC SPECIFICITY







TESTING PROCEDURE SCHEME

1. Add 10 µl(serum or plasma) or 20 µl (whole blood) of the sample to sample well (S), using the capillary pipette or micropipette included in the set.

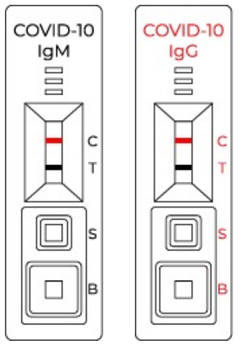
2. Add 3 drops of the diluent for analyses to buffer well (B) of the device.

3. Read the result during 5~10 minutes.

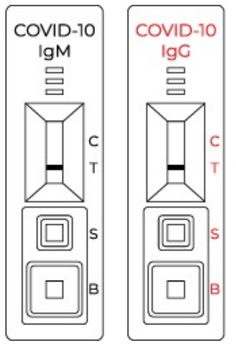
INTERPRETATION OF RESULTS

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.



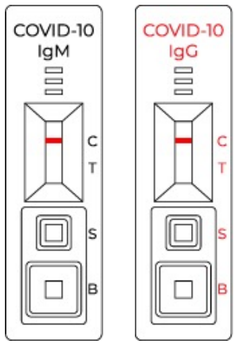
Positive



Negative

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.



Invalid

CERTIFICATES

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

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.: 74956286

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 • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 18 ноября 2020 года № РЗН 2020/12583

Действительно до 1 января 2021 г.

На медицинское изделие
Набор реагентов для иммунохроматографического выявления антител IgM/IgG к вирусу SARS-CoV-2 в образцах цельной крови, сыворотки или плазмы (BIOCREDIT COVID-19 IgG+IgM Duo), Lot № H078012DU

Настоящее регистрационное удостоверение выдано
Общество 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., 2F, 25, Heungan-daero, Gunpo-si, Gyeonggi-do 15809, Republic of Korea

Номер регистрационного досье **№ РД-37406/83557 от 09.11.2020**

Класс потенциального риска применения медицинского изделия **2б**

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

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 18 ноября 2020 года № 10747
допущено к обращению на территории Российской Федерации.

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

0052951

OUR CLIENTS


ГАЗПРОМ


PRODO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Клинический институт
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медицины


Р-ФАРМ
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KINROSS


Severstal


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MOSCOW


ВитаМед


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современной
педиатрии


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GROUP OF COMPANIES
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