REAGENT KIT

SGTI-FLEX COVID-19 Ag

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.

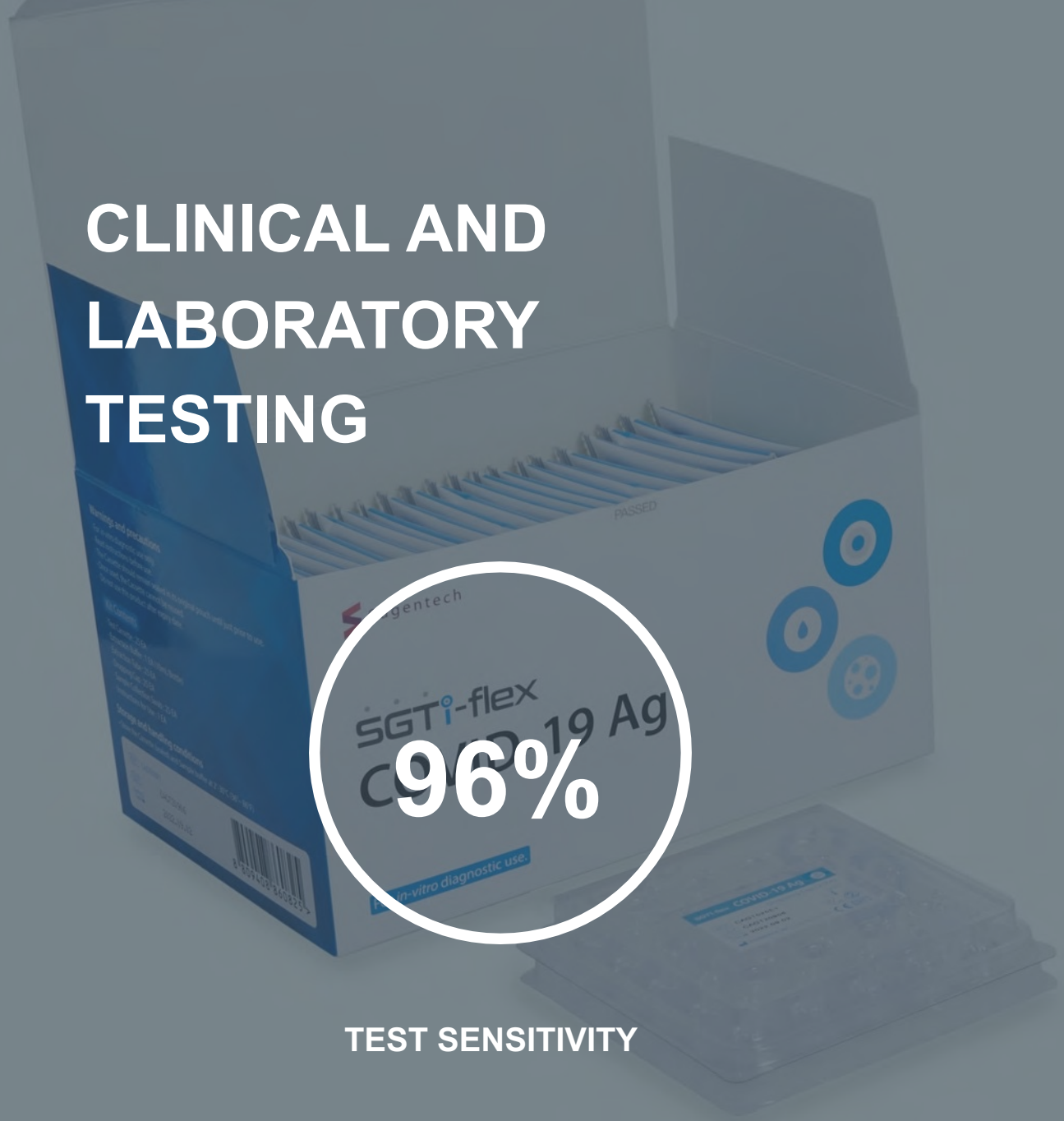
REAGENT KIT FEATURES

The SGTi-flex COVID-19 Ag Reagent Kit is designed for the qualitative rapid detection of the COVID-19 in nasopharyngeal swab.

Easy-to-use test strips.

Testing time 20-30 minutes.

CLINICAL AND LABORATORY TESTING



96%

TEST SENSITIVITY

100%

DIAGNOSTIC SPECIFICITY

PRINCIPLES OF THE TEST

The reagents kit for SARS-CoV-2 antigen detection (SGTi-flex 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

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.;

Extraction buffer - 1 pc.; Sample extraction tubes - 25 pcs.;

Dropper cap - 25 pcs.;

Sterile swab for specimen collection - 25

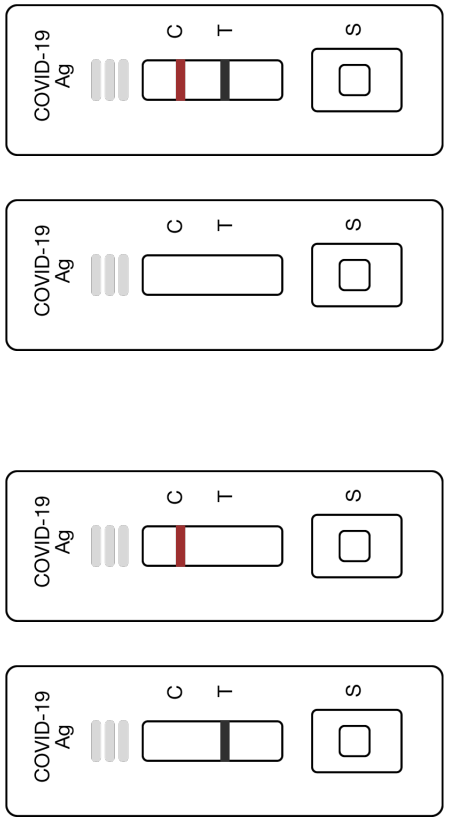
pcs.Cardboard stand - 1 pc.;

Prescribing information - 1 pc.

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

INTERPRETATION OF RESULTS

Note: strip width or color intensity are irrelevant.

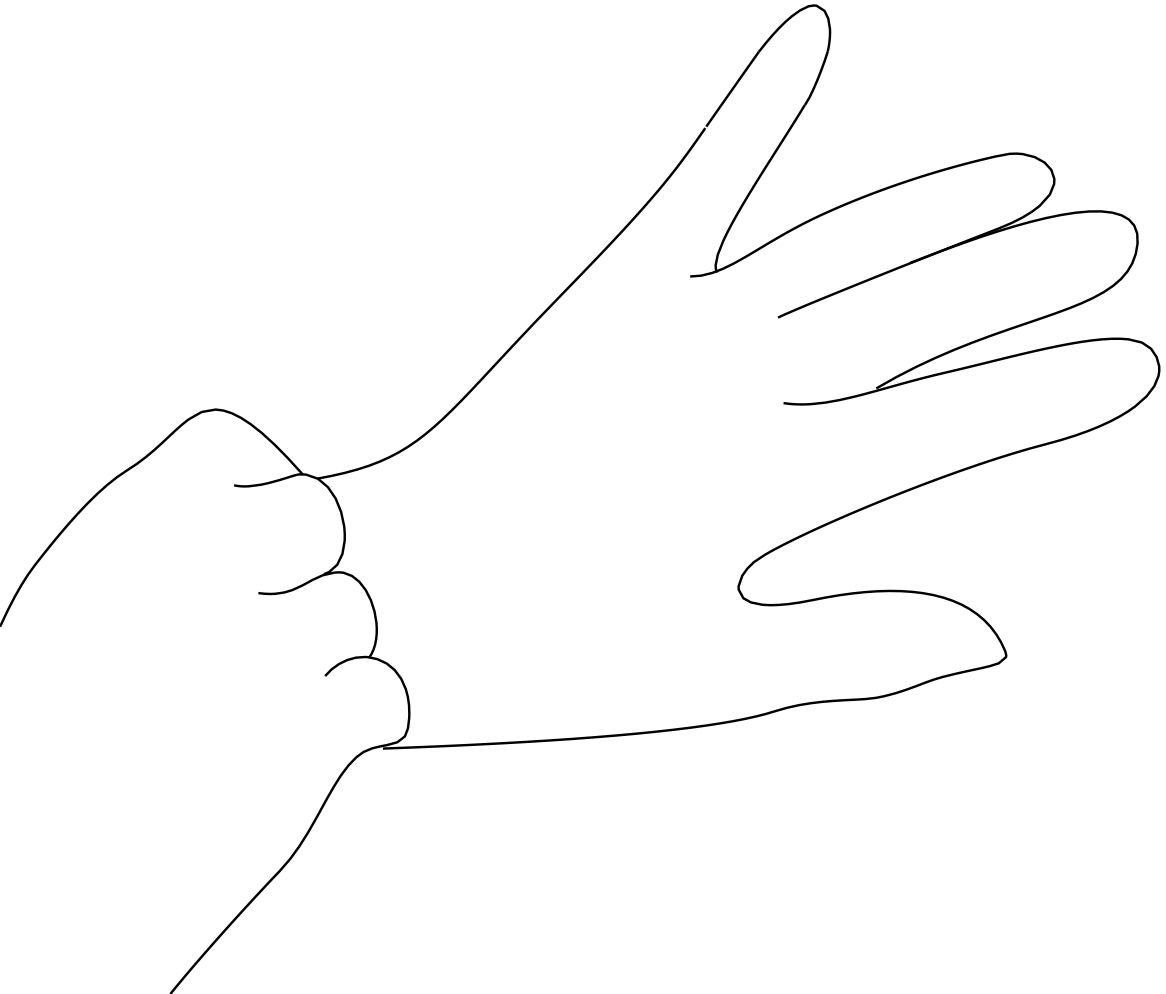


If only the control line (C) is colored red in the result window: the test is negative for the presence of the coronavirus antigen.

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.

SAMPLE COLLECTION

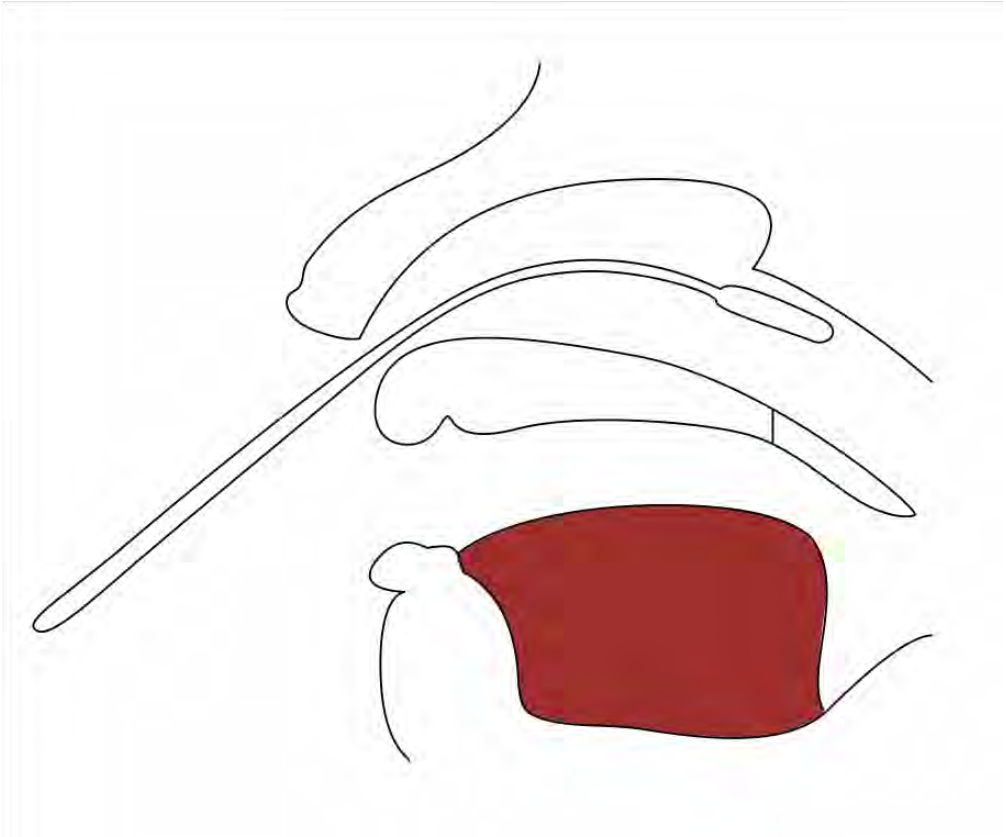


Biological samples should be taken by trained healthcare professionals. Biological samples should be handled with caution due to the risk of infection.

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.

NASOPHARYNGEAL SWAB COLLECTION



1. Gently insert a swab into the nasal cavity in order to collect a biological sample from the nasopharyngeal. Keep gently inserting the tampon until resistance is encountered in the nasal turbinate.
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

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.

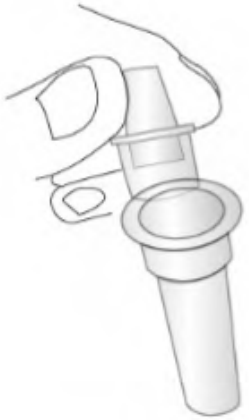
Securely close the vial using the dropper cap from the kit.

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

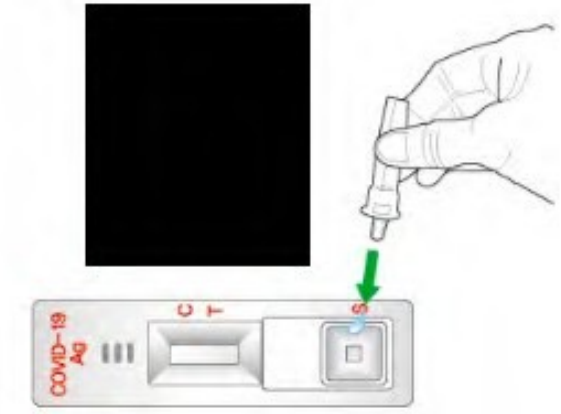
TEST STAGES

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

2. Remove the swab by gently squeezing its tip.

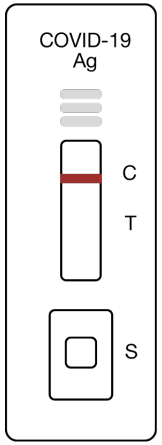


3. Close the assay diluent tube with a filter cap securely.

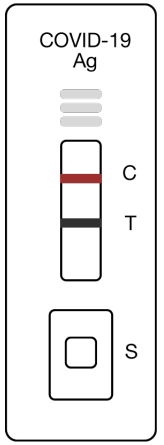


4. Invert the assay diluent tube and squeeze it gently to draw 3 drops into the well.

INTERPRETATION OF RESULTS

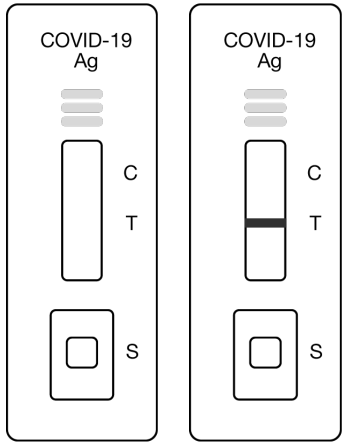


If line (C) turns red: the test result is considered negative for coronavirus antigen.



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

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

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 20 ноября 2020 года № РЗН 2020/12690

Действительно до 1 января 2021 г.

На медицинское изделие
Набор реагентов для иммунохроматографического выявления антигена SARS-CoV-2 в биологическом материале человека (SGTi-flex COVID-19 Ag), Lot № CAGT20002

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
"Сугентех, Инк.", Корея,
Sugentech, Inc., 721-26, Jeongjungyeonje-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do 28161, Republic of Korea

Место производства медицинского изделия
Sugentech, Inc., 721-26, Jeongjungyeonje-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do 28161, Republic of Korea

Номер регистрационного досье **№ РД-37568/91605 от 18.11.2020**

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 20 ноября 2020 года № 10875
допущено к обращению на территории Российской Федерации.

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

0052972

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 20 ноября 2020 года № РЗН 2020/12690

Действительно до 1 января 2021 г.

Лист 1

На медицинское изделие
Набор реагентов для иммунохроматографического выявления антигена SARS-CoV-2 в биологическом материале человека (SGTi-flex COVID-19 Ag), Lot № CAGT20002, в составе:
1. Тестовая кассета (в индивидуальной упаковке из фольги в комплекте с осушителем) - 25 шт.
2. Буфер для экстрагирования - 1 шт.
3. Пробирки для экстрагирования образца - 25 шт.
4. Насадка с капельницей - 25 шт.
5. Стерильный тампон для взятия мазка - 25 шт.
6. Подставка из картона - 1 шт.
7. Инструкция к медицинскому изделию - 1 шт.

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

0068361

OUR CLIENTS


ГАЗПРОМ


ПРОДО


ПЕРВЫЙ КАНАЛ
ВСЕМИРНАЯ СЕТЬ


Клинический институт
репродуктивной
медицины


ФАРМ
Р-ФАРМ
Инновационные
технологии
здоровья


KINROSS


Severstal


HADASSAH
Medical
MOSCOW


ВитаМед


Центр
современной
педиатрии


EMC
GROUP OF COMPANIES
EUROPEAN MEDICAL CENTER