CRT

Covid-19 Rapid Test

Oncosem

COVID-19
RAPID SCREENING
EMERGENCY
RESPONSE
TEST

CE

OUR PRODUCT

CRT
Covid-19 Rapid Test

15 MINUTES DETECTION TIME

One drop of finger stick blood

Turkey
Discover the potential

HOW IT WORKS?

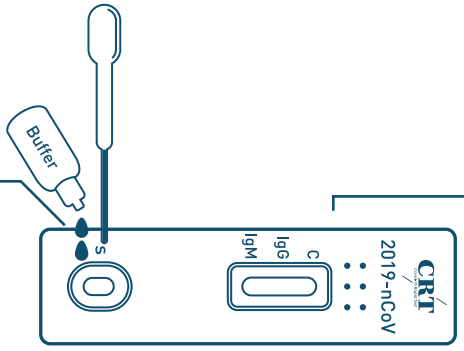
CRT
Covid-19 Rapid Test

PRE-SCREENING

CE certified

Concerned Citizen

Self-conducted Pre-screen Test



If symptoms show positive

Lab test conducted

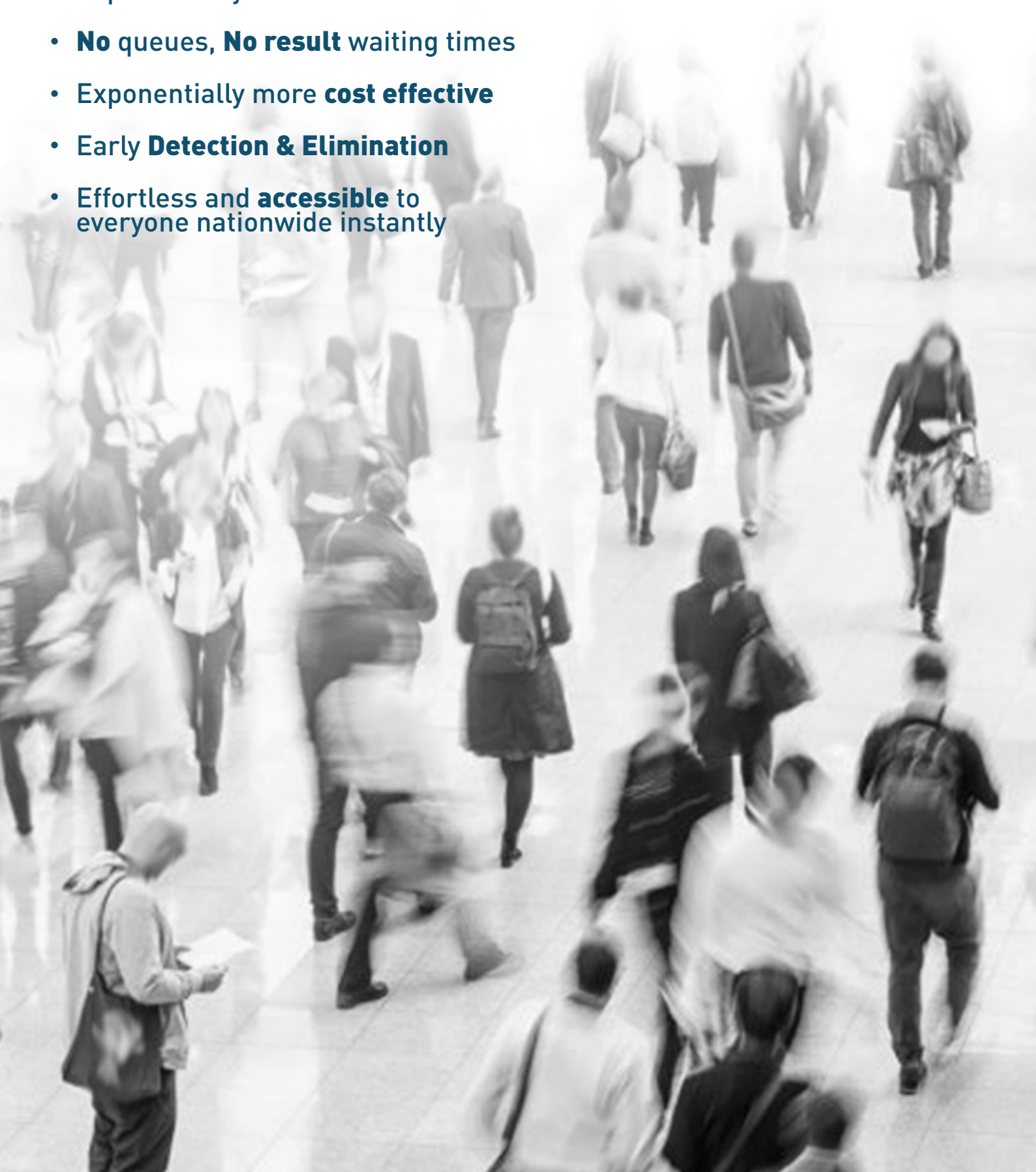
clinical examination

Final Results Positive or Negative

BENEFITS
of pre-screening

CRT
Covid-19 Rapid Test

- Exponentially **faster**
- **No** queues, **No result** waiting times
- Exponentially more **cost effective**
- Early **Detection & Elimination**
- Effortless and **accessible** to everyone nationwide instantly



HOW IT WORKS?

CRT
Covid-19 Rapid Test

15 MINUTES Detection Period

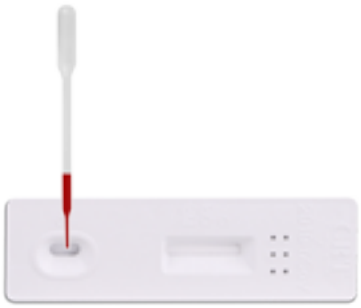
No special storage and transportation conditions required

Works with finger stick and venipuncture
(whole blood serum and plasma)

Tests for 2 antibodies IgM and IgG simultaneously

Faster population screening

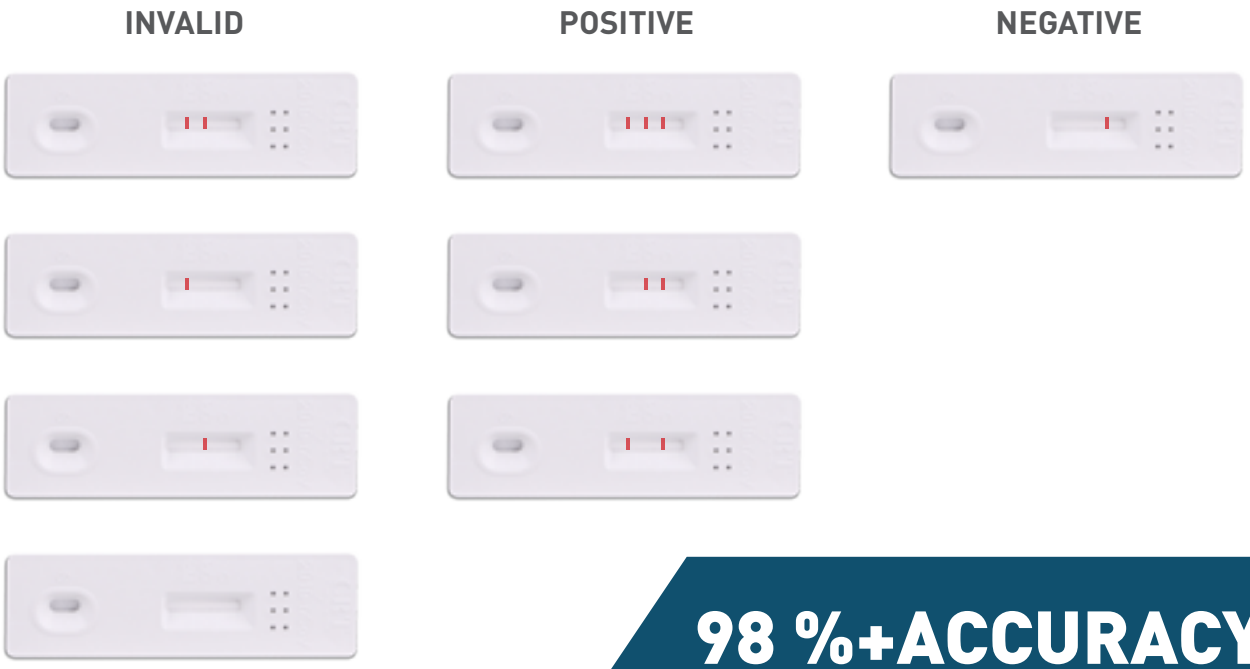
Step 1
One drop of sample
(whole blood, serum of plasma)



Step 2
One-two drops of buffer solution

Step 3 Wait for 15 min

Step 4 Result

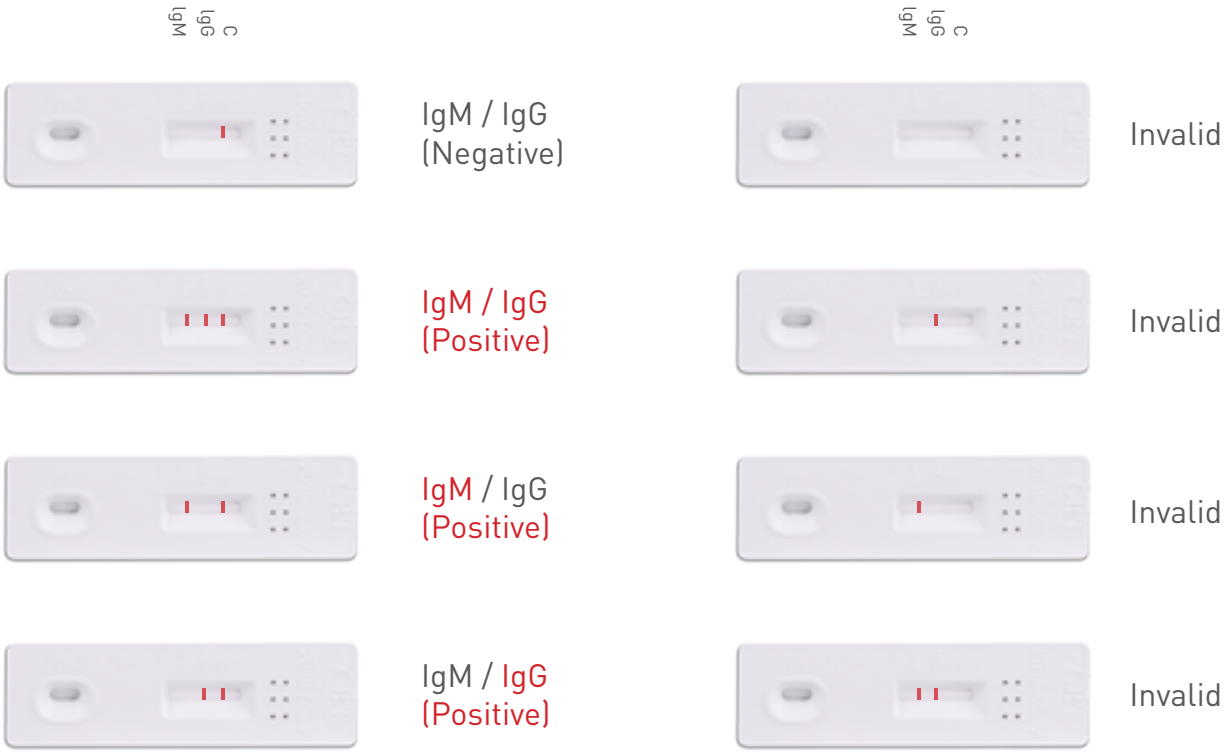


98 %+ACCURACY

CE certified

HOW IT WORKS?

CRT
COVID-19 Rapid Test



Results	Interpretation
IgM, IgG	Suspected recent infection of 2019-nCoV
IgM, IgG	Suspected recent infection of 2019-nCoV
IgM, IgG	Patient Suspected to have past infection
IgM, IgG	Antibody for COVID-19 Virus undetected or Low IgG/IgM level below limit of detection

TECHNICAL REVIEW

2019-nCoV IVD Solution

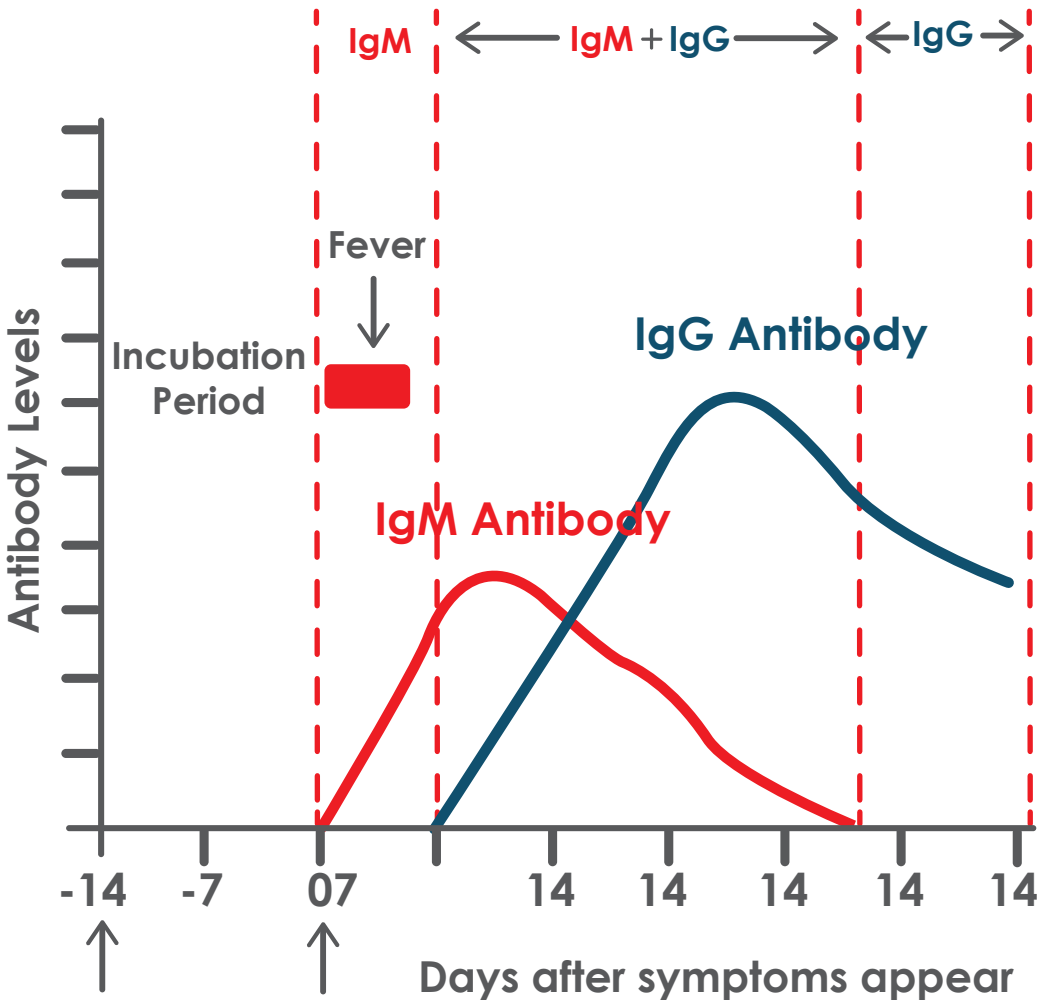
Colloidal Gold Method:
The 2019-nCoV IgG/IgM Rapid Test Device using this Method is a rapid chromatographic immunoassay for the qualitative detection of IgG & IgM antibody of Coronavirus in human whole blood, serum or plasma

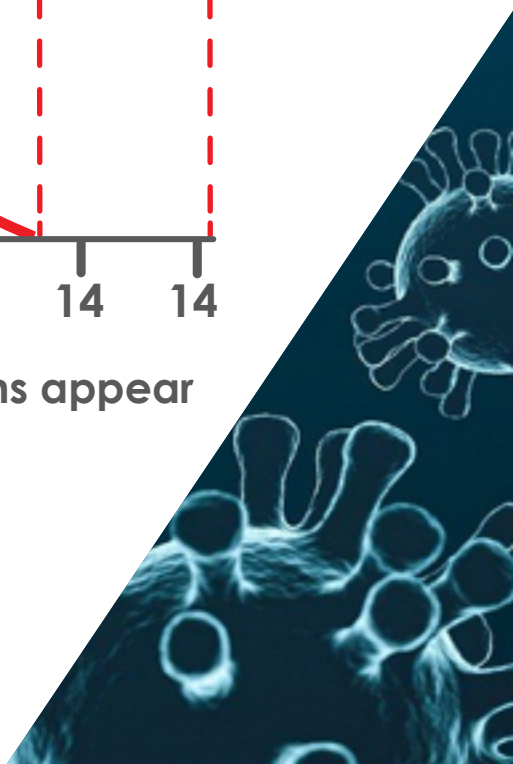
	RT-qPCR	ECLIA	Colloidal Gold Method (CRT)
Detection substance	Nucleic Acid	Antibody	Antibody
Type of sample	Nasopharyngeal swabs, sputum, alveolar lavage fluid	Serum/ Plasma	Serum/ Plasma / Whole blood
Time to get result	2 hrs	20 min	Within 15 minutes
Instrument needed or not	Yes	Yes i 3000, i 1000	Not needed
Laboratory requirement	High	Relatively high	Low
Product usage	Confirming diagnosis	Nucleic acid negative sample reviewing or high-volume sample detection	Nucleic acid negative sample reviewing or basic hospital sample testing

DIAGNOSTIC PROCESS

CRT
Covid-19 Rapid Test

It is widely accepted that IgM provides the first line of defence during viral infections, followed by the generation of adaptive, high anity IgG responses for long term immunity and immunological memory. The refore testing of COVID-19 IgM and IgG antibodies is an efective method for the rapid diagnosis of COVID-19 infection. Furthermore, detection of COVID-19 IgM antibodies tends to indicate a recent exposure to COVID-19, whereas detection of COVID-19 IgG antibodies indicates a later stage of infection. Thus, this combined antibody test could also provide information on the stage of infection.





2019-nCoV IgG/IgM Rapid Single Use Test
(Fingerstick Whole Blood) Instruction For Use

INTENDED USE
The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by 2019-nCoV The test provides preliminary test results. Negative results don't preclude 2019-nCoV infection and they cannot be used as the sole basis for treatment or other management decision. Negative results don't preclude COVID-19 infection. Positive results may arise due to past or present infection with non-SARS-CoV-2 coronavirus strains (such as coronavirus HKU1, NL63, OC43, or 229E.). For in vitro diagnostic use only. For healthcare professional use only.

SUMMARY
Corona Virus Disease 2019 (2019-nCoV) is an acute infectious disease caused by 2019 novel coronavirus (2019-nCoV). The incubation period of the disease is infectious and ranges from 1-14 days (mostly 3-7 days). Asymptomatic infections may also be the source of infection. Respiratory droplets and contact are the main routes of transmission. The initial symptoms of the patients include fever, fatigue and coughing, which gradually develops into dyspnea and other serious manifestations. Most of the patients have a good prognosis. Some of the severe cases may have acute respiratory distress syndrome or septic shock, or even death. At present, there is no specific treatment for the disease.

There are several days of incubation period after infection with 2019-nCoV. IgM antibodies can be detected soon after the incubation period and remain for a short time. IgM positive in blood samples can be an indicator of acute infection. IgG antibodies appear after a few days of incubation period and remain for a long time. IgG positive in blood samples can be an indicator of present or previous infection.

PRINCIPLE
This Test Card utilizes the principle of immuno-chromatography. Mouse anti- human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. The IgM line in the test window is closer to the sample well followed by IgG line. As the test sample flows through the membrane within the test device, the colored 2019-nCoV recombinant antigen-colloidal gold conjugate forms complexes with specific antibodies (IgM and/or IgG) to 2019 novel coronavirus, if present in the sample.

This complex moves further on the membrane to the test region where it is captured by the anti-human IgM and/or human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test is performed properly, regardless of the presence or absence of anti-2019 novel coronavirus antibodies in the specimen.

PRECAUTION
1.This kit is for in vitro diagnostic use only.
2.All specimens should be treated as capable of transmitting diseases. Use appropriate precautions in the collection, handling, storage and disposal of patient samples and used kit contents. And follow biosafety level 2 or higher guidelines.
3.Wear appropriate personal protective equipment (e.g. gowns, gloves, eye protection) when handling the contents of this kit.
4.Proper specimen collection storage and transport are critical to the performance of this test.
5.Discard after first use. The test cannot be used more than once.
6.Do not touch the reaction area of test strip.
7.Do not use test kit beyond the expiration date.
8.Do not use the kit if the pouch is punctured or not well sealed.
9.Testing should be applied by professionally trained staff working in certified laboratories or clinics where the sample(s) is taken by qualified medical personnel.
10.The test result should be interpreted by the physician along with clinical findings and other laboratory test results.
11.DISPOSAL OF THE DIAGNOSTIC: All specimens and used-kits have infectiob risk. The process of disposing the diagnostics must follow the local infectious disposal laws or laboratory regulations.

MATERIALS
Materials Provided:
1.1 Individual sealed pouches, each pouch contains: 1 x Test cassette, 1 x desiccant pouch
2.1 disposable droppers
3.Detection buffer (1*1mL)
4.Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED
1.Specimen collection containers or lancet for finger stick
2.Centrifuge (for serum/plasma samples)
3.Timer
4.Personal protective equipment, such a protective gloves, medical mask, goggles and lab coat.
5.Appropriate biohazard waste container and disinfectants.
6.Serum, plasma or blood samples from COVID-19 diagnosed patients to be used as positive control. It is recommended that the samples are taken from the patient at least 15 days after first symptoms appear and either of the samples are COVID-19 positive by any other (like ELISA) serological tests.
7.Samples taken form COVID-19 negative patients can be used as negative controls.

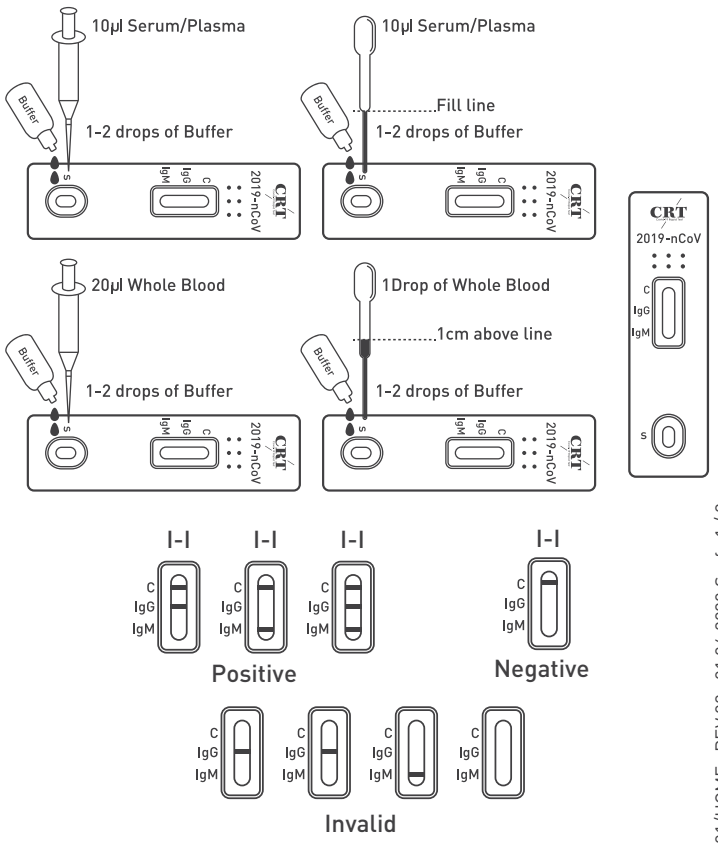
STORAGE AND STABILITY
1.Store at 2ºC~30ºC in the sealed pouch up to the expiration date printed on the package. Do not freeze
2.The test cassette should be used within 1 hour after taking out from the foil envelope. Buffer solution should be re-capped in time after use.
3.Keep away from sunlight, moisture and heat.

SPECIMEN COLLECTION AND PREPARATION
The 2019-nCoV IgG/IgM Rapid Single Use Test can be performed using whole blood, serum and plasma specimens. Both fingerstick whole blood and venipuncture whole blood can be used

For whole blood:
1.Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (containing EDTA, Heparin or Citrated sodium). Other anticoagulants have not been validated and may give incorrect results.
2.It is recommended that whole blood specimen is tested at the time of specimen collection. If the specimens are not tested immediately, they may be stored at 2ºC□8ºC for up to 7 days. Prior to testing, mix the blood by gentle inversion several times, do not freeze or heat whole blood specimens
3.To collect fingerstick whole blood specimens:
• Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
• Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger
• Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
• Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

For Serum and Plasma:
1.Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma, use a blood collection tube containing suitable anticoagulant (containing EDTA, Heparin or Citrated sodium). Other anticoagulants have not been validated and may give incorrect results.
2.Centrifuge whole blood and separate the plasma from red blood cell as soon as possible to avoid hemolysis.
3.Test should be performed within 8 houres after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum or plasma specimens may be stored at 2ºC□8ºC for up to 3 days prior to testing. Serum or plasma specimens may be stored at -20ºC for up to 9 days.
Note:Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Severe hemolytic or heat inactivated specimens are not recommended.

TEST PROCEDURE
Please read the instruction for use carefully before performing the test.
1.Allow the device, buffer and specimen to equilibrate to room temperature (10ºC ~30ºC) prior to testing.
2.Remove a test cassette from the foil pouch by tearing at the notch and place it on a level surface.
3.Transfer 10 µL serum or 10 µL plasma or 20 µL of whole blood specimen to the sample well "S" and then add 1~2 drops (50 µL) of buffer solution to the Sample well "S".
4.As the test begins to work, you will see purple color move across the result window in the center of the test device.
5.Wait for 15 minutes and read the results. Do not read results after 20 minutes.



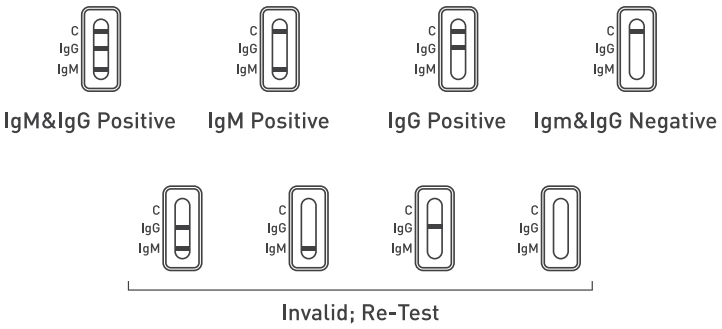
Note: the rightmost window on the cassette shows the product abbreviation "nCoV" to identify this product.

2019-nCoV IgG/IgM Rapid Single Use Test
(Fingerstick Whole Blood) Instruction For Use

CRT
Covid-19 Rapid Test

RESULT INTERPRETATION
Positive Results: Colored bands appear at both test line (IgG/IgM) and control line (C). It indicates a positive result for the SARS-CoV-2 antibodies in the specimen.
•Both IgG/IgM Positive: Control line and both test lines appear.
•IgM Positive/IgG Negative: Both control line and the second test line (the lower test line which is closer to the sample well) appears. It indicates the possibility of primary infection.
•IgM Negative/IgG Positive: Both control line and the second test line (the higher test line) appears. It indicates the possibility of secondary infection or past infection.

Negative Result
Colored band appears at control line (C) only. It indicates that the concentration of the SARS CoV-2 antibodies is zero or below the detection limit of the test.
Invalid Result
No visible colored band appears at control line after performing the test. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



QUALITY CONTROL
A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS
1.This test has not been reviewed by the FDA
2.Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
3.Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
4.Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
5.Not for the screening of donated blood
6.This reagent is designed to detect antibodies against SARS-CoV-2 in human whole blood, plasma, serum sample.
7.This reagent is a qualitative assay. It is not designed to determine the quantitative concentration of SARS-CoV-2 antibodies.
8.The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, or repeated freezing and thawing of the sample will affect the test results.
9.The test results of this test are for clinical reference only, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.
10.Limited by the method of antibody detection reagents, for negative test results, it is recommended to use nucleic acid detection or virus culture identification methods for review and confirmation.
11.In the early stage of infection, if IgM and IgG antibodies are not produced or the titer is very low, false negative results will occur.
12.Positive test results do not rule out co-infections with other pathogens. A negative result of this test can be caused by:

-Improper sample collection, improper sample transfer or handing, too low IgM/IgG titer in the sample;
-The level of SARS-CoV-2 antibodies is below the detection limit of the test.
-Variations in viral genes may cause changes in antibody determinants.

PERFORMANCE CHARACTERISTICS
Analytical Sensitivity and Precision Study
1. With 100% agreement, performance on all control levels, which meets the acceptance criteria, study results demonstrate that the 2019-nCoV IgG/IgM Rapid Single Use Test sensitivity is accurate and determined properly.
2. Based on the precision and reproducibility study, the results indicate high agreements of within-day, between-day, between lots and between human visual effects.
3. With the fact that no invalid result was reported, human error has been minimized so that 2019-nCoV IgG/IgM Rapid Single Use Test can be used easily.

Accuracy
A total of 74 specimens from confirmed patients were tested, the results showed that 65 specimens were IgM positive and/or IgG positive, and the clinical sensitivity was 87.8%. A total of 305 specimens from healthy persons were tested, the results showed that 302 specimens were both IgM and IgG negative, 1 specimen was IgM positive, 2 specimens were IgG positive, and the clinical specificity was 99.0%. The accuracy was 96.8%.

Assay Specificity

1.Other infectious diseases
Rapid 2019-nCoV IgG/IgM Rapid Single Use Test has tested samples that were infected by the following diseases: Influenza A Virus, Influenza B Virus, Adenovirus, Rotavirus and Mycoplasma Pneumoniae. All the samples showed no effect on the specificity of the assay.

2.Blood compounds
2019-nCoV IgG/IgM Rapid Single Use Test has tested samples with high Rheumatoid Factor (RF), Bilirubin, Triglyceride and Hemoglobin. The results showed that these compounds had no effect on the specificity of the assay up to the listed concentration.
Rheumatoid Factor: 80 IU/mL
Bilirubin: 342 μmol/L
Triglyceride: 37 mmol/L
Hemoglobin : 10 mg/mL

3.Common drugs
2019-nCoV IgG/IgM Rapid Single Use Test has tested samples with common drugs. The results showed that these drugs had no effect on the specificity of the assay.
Histamine Hydrochloride, Interferon-α, Zanamivir, Ribavirin, Oseltamivir, Peramivir, Lopinavir, Ritonavir, Arbidol, Levofloxacin, Azithromycin, Ceftriaxone, Meropenem, Tobramycin.

SYMBOL INDEX

ONCOSEM Onkolojik Sistemler San. ve Tic. A.Ş.
Mustafa Kemal Mah. 2125 Sokak A Blok No: 6/8 Söğütözü 06520
Ankara TURKEY

CE

EC Declaration of Conformity

Manufacturer	**: Oncosem Onkolojik Sistemler San. Ve Tic. A.Ş.**
Address	**:** Mustafa Kemal Mah. 2125 Sokak A Blok No: 6/8 Sogutozu 06520 Ankara - Turkiye
Product Name	**:** 2019-nCoV IgG/IgM Rapid Single Use Test (Fingerstick Whole Blood)
Model	**:** Single Use Test Kit
Classification	**:** Other Device of IVDD 98/79/EC
Conformity Assessment Route	**:** IVDD 98/79/EC Annex III
EDMA Code	**:** 15 70 90 90 00

We, Oncosem Onkolojik Sistemler San. Ve Tic. A.Ş., herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned products meet the transposition into national law, the provsions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General Applicable Directives:
DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 in vitro diagnostic medical devices.

Standard Applied: EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of Issue: Ankara Turkey on March 23th, 2020

NAME: EROL ÇELİK – GENERAL MANAGER

ONCOSEM ONKOLOJİK SİSTEMLER SAN. VE TİC. A.Ş.
Mustafa Kemal Mh. 2125. Sk. A Blok No: 6/8
Söğütözü / ANKARA
Tel: 0312 219 50 35 - Fax: 0312 219 50 73
Mersis No: 0643057054700001
Tic. Sic. No: 250234 • Maltepe V.D.: 643 057 0547

Acknowledgment Letter

5/19/2020

Erol Celik
Oncosem Onkolojik Sistemler San.ve Tic. A.S.
Mustafa Kemal Mah. Kolbay Is Merkezi A Blok No:6/8
Cankaya-ANKARA 06510
TURKEY

Dear Erol Celik:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: EUA201233
Received: 5/19/2020
Applicant: Oncosem Onkolojik Sistemler San.ve Tic. A.S.
Device: CRT (COVID-19 RAPID TEST)

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

CERTIFICATE
of Registration

This is to Certify that the

Medical Devices – Quality Management System

of

ONCOSEM ONKOLOJİK SİSTEMLER SANAYİ VE TİCARET ANONİM ŞİRKETİ

MUSTAFA KEMAL MAH. 2125. SOK. NO:6 A/8
ÇANKAYA / ANKARA / TÜRKİYE

has been independently assessed and is compliant with the requirements of

ISO 13485:2016

This Certificate is applicable to the following product or service ranges:

DESIGN, PRODUCTION, STORAGE, DELIVERY INSTALLATION AND TECHNICAL SERVICES OF IN-VITRO DIAGNOSTIC KITS, PCR KITS, VIRUS TRANSPORT MEDIUM, PATHOGEN KITS, DIAGNOSTICK KITS AND READERS AND ANALYSIS DEVICES, DISINFECTANTS, MOLECULAR AND IMMUNOCHEMICAL BASED ANALYSIS KITS AND DEVICES, RESPIRATORY ADJUANT DEVICE AND VENTILATOR

VÜCUT DIŞINDA KULLANILAN TANI KİTLERİ, PCR KİTLERİ, VİRÜS TAŞIMA ORTAMI, PATOJEN KİTLERİ, TANI-TEŞHİS KİTLERİ İLE OKUYUCULARI VE ANALİZ CİHAZLARI, DEZENFEKTAN, MOLEKÜLER VE İMMÜNOKİMYASAL TABANLI ANALİZ KİTLERİ VE CİHAZLARININ, SOLUNUM DESTEK CİHAZI VE VENTİLATÖR ÜRETİMİ, DEPOLANMASI, TESLİMİ, KURULUMU VE TEKNİK SERVİS HİZMETLERİ

:: Certificate No :: TR51903H

Date of initial registration	**15 April 2020**
Date of this Certificate	**15 April 2020**
Surveillance audit on or before	**14 April 2021**
Recertification Due / Certificate expiry	**14 April 2023**

This Certificate is property of Staunchly Management & System Services Ltd. and remains valid subject to satisfactory surveillance audits.

Director

STAUNCHLY MANAGEMENT & SYSTEM SERVICES LTD.
Suite 48, 88-90 Hatton Garden, London, EC1N 8PN.

COVID-19
RAPID SCREENING
EMERGENCY
RESPONSE
TEST

CRT
Covid-19 Rapid Test

Turkey
Discover
the potential

CRT

Covid-19 Rapid Test

ONCOSEM Onkolojik Sistemler San. Ve Tic. A.Ş.
Mustafa Kemal Mah. 2125. Sok. 6A/8
Çankaya-Ankara/ TÜRKİYE
+90 (312) 219 50 33
info@oncosem.com
oncosem.com