Oncosem

Turkey

Discover
the potential

cat
antigen
Covid Rapid Test

COVID-19
ANTIGEN
RAPID
SCREENING
EMERGENCY
RESPONSE TEST

OUR PRODUCT

cat antigen
Covid Rapid Test

15 MINUTES DETECTION TIME

With a swab sample taken from the throat and / or nose

CE

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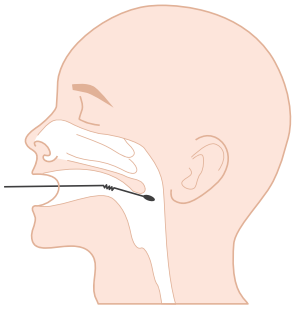
CAT ANTIGEN

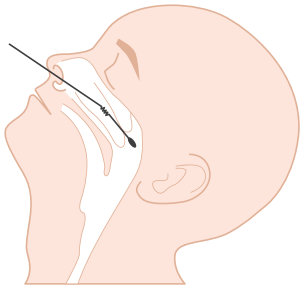
USE OF

Step 1 Specimen Collection

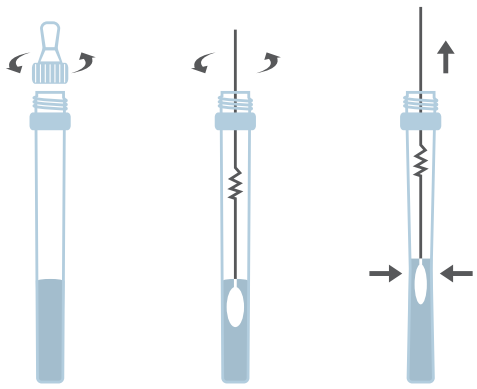
Oropharyngeal Swab



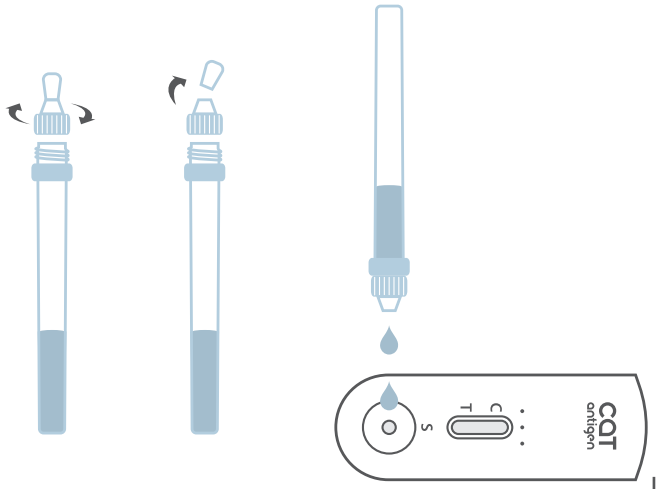
Nasal Swab



Step 2 Solution Preparation



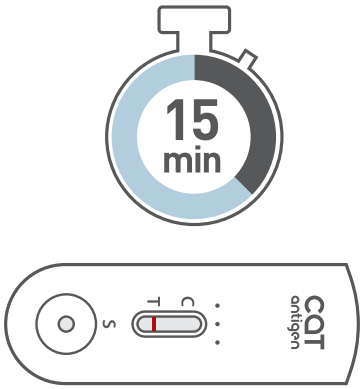
Prepare the specimen



Apply the extracted specimen

Step 3 Detection

Read the test result



CAT Benefits

- **Easy to use.**
- Affordable.
- Highly portable, requiring no instrumentation.
- Reliable, with 97.59% sensitivity and 98.43% specificity.
- **Fast, with results in 15 minutes.**

cat antigen
Covid Rapid Test

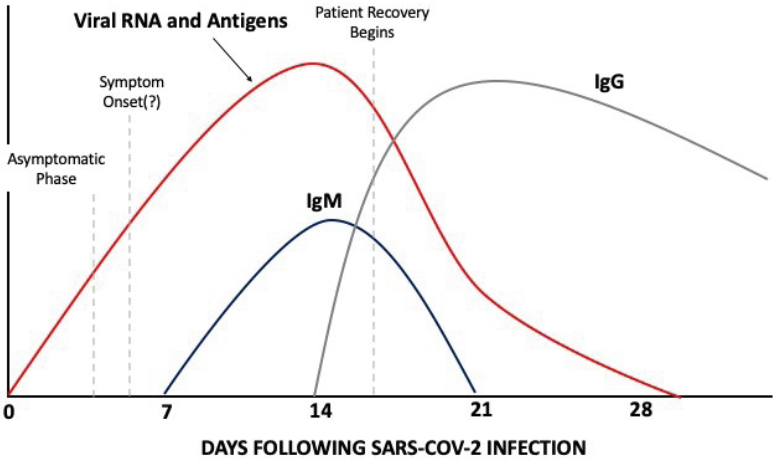
COVID-19 RAPID TEST

Interpretation of result

	Result	Interpretation
Antigen Test	Positive	Most likely *you DO currently have an active COVID-19 infection.
	Negative	Most likely *you DO NOT currently have an active COVID-19 infection.

DIAGNOSTIC PROCESS

Antigen-detection diagnostic tests are designed to directly detect SARSCoV-2 proteins produced by replicating virus in respiratory secretions and have been developed as both laboratory-based tests, and for near-patient use, socalled rapid diagnostic test.



TECHNICAL REVIEW

COVID-19 IVD Solution

Lateral Flow

COVID-19 Antigen Test (CAT) named Rapid SARS-CoV-2 Antigen Test is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of SARS-CoV-2 virus antigen in nasopharyngeal / oropharyngeal swabs from individuals suspected of COVID-19 within the first seven days of symptom onset.

	RT-qPCR	ECLIA	Colloidal Gold Method (CRT)	Lateral Flow Method (CAT)
Detection substance	Nucleic Acid	Antibody	Antibody	Antigen
Type of sample	Nasopharyngeal swabs, sputum, alveolar lavage fluid	Serum/ Plasma	Serum/ Plasma / Whole blood	Nazofaringeal Orofaringeal swab
Time to get result	2 hrs	20 min	Within 15 minutes	Within 15 minutes
Instrument needed or not	Yes	Yes i 3000, i 1000	Not needed	Not needed
Laboratory requirement	High	Relatively high	Low	Low

2019-nCoV Antigen Rapid Test Kit

For the Qualitative Assessment of SARS-CoV-2 Virus Antigen in Nasopharyngeal Swab Specimens

For In Vitro Diagnostic Use Only

INTENDED USE
2019-nCoV Antigen Rapid Test Kit is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of SARS-CoV-2 virus antigen in nasopharyngeal swab specimens. 2019-nCoV Antigen Rapid Test Kit cannot be used as the basis to diagnose or exclude SARS-CoV-2 infection.

SUMMARY
COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection, asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main symptoms include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE
2019-nCoV Antigen Rapid Test is an immunochromatographic lateral flow device that employs the principle of double antibody sandwich method. Colloidal gold conjugated anti-SARS- CoV-2 antibodies are dry-immobilized on the test device. When the specimen is added, it migrates by capillary diffusion through the strip to re-hydrate the gold conjugate complexes. If present at or above the limit of detection, SARS-CoV-2 viral antigens will react with the gold conjugate complexes to form particles, which will continue to migrate along the strip until the Test Zone (T) where they are captured by the immobilized anti-SARS-CoV-2 antibodies to form a visible red line. If there are no SARS-CoV-2 viral antigens in the specimen, no red line will appear in the Test Zone (T). The gold conjugate complexes will continue to migrate alone until being captured by immobilized antibody in the Control Zone (C) to form a red line, which indicates the validity of the test.

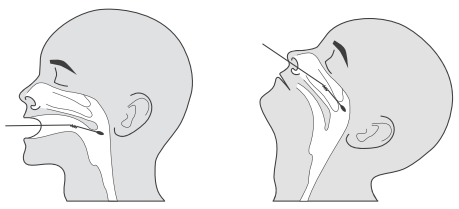
MATERIALS PROVIDED
Box Contents
1.2019-nCoV Antigen Rapid Test Kit
2.Sterile swab
3.Sample extraction buffer in tube
4.Instructions for use

MATERIALS REQUIRED BUT NOT SUPPLIED
Clock or timer, specimen collection container, biohazard waste container. personal protection equipment.

STORAGE
1.Store the test device at 4 to 30 ℃ in the original sealed pouch. Do Not Freeze.
2.Kit contents are stable until the expiration date printed on the outer box based on the proper storage conditions.
3.The test device should remain in its original sealed pouch until ready for use. After opening, the test device should be used immediately. Do not reuse the device.

PRECAUTIONS
1.For professional in vitro diagnostic use only.
2.The product is strictly for medical professional use only and not intended for personal use.
3.Do not use the product beyond the expiration date.
4.Do not use the product if the pouch is damaged or the seal is broken.
5.Handle all specimens as potentially infectious.
6.Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infectious material.
7.Inadequate or inappropriate specimen collection, storage, and transport may yield inaccurate test results.

SPECIMEN COLLECTION
Proper specimen collection, storage, and transport are critical to the performance of this test. Specimens should be tested as soon as possible after collection. The training in specimen collection is highly recommended because of the importance of specimen quality. The sample is swabbed through the nose or throat and nose. For optimal test performance, use the swabs supplied in the kit.

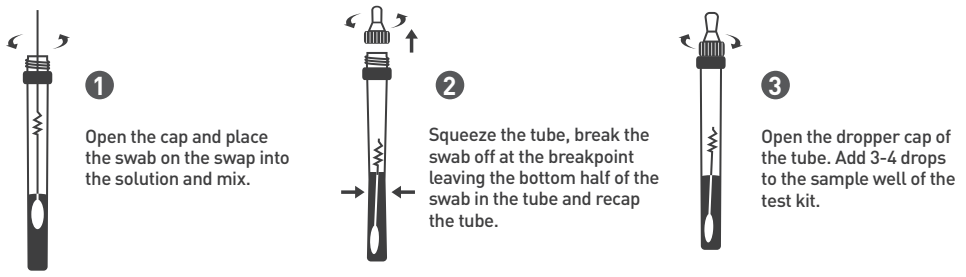


1.Carefully insert the swab into the mouth and nose nostrils separately for the patient, reaching the surface of posterior nasopharynx that presents the most secretion.

2.Swab over the surface of the posterior nasopharynx. Rotate the swab several times.

3.Withdraw the swab from the nasal cavity.

SPECIMEN PREPARATION
1.Place the swab with specimen into the extraction tube. Roll the swab three to five (5) times. **Leave the swab in the extraction buffer for 1 minute.**
2.Pinch the extraction tube with fingers and remove the solution from the swab as much as possible. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
3.Return the cap assembly to the extraction tube. Use extraction solution as test specimen.



Note: Results after 20 minutes may not be accurate.

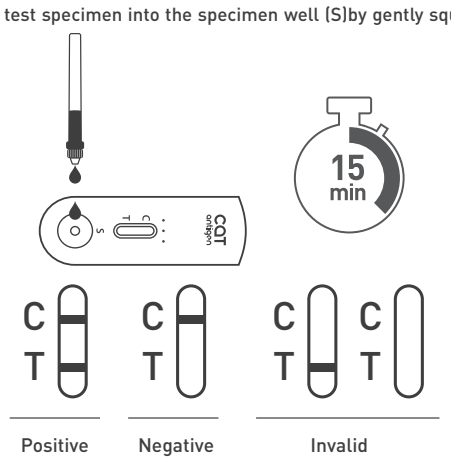
PROCEDURE
1.Bring the kit components to room temperature before testing.
2.Open the pouch and remove the card. Once opened, the test card must be used immediately. Label the test card with patient identity.
3.Invert the extraction tube and add **3-4 drops (70-110 µL)** of test specimen into the specimen well (S)by gently squeezing the extraction tube.
4.Read the results at **15 minutes.**

INTERPRETATION OF RESULTS

POSITIVE : If two colored bands appear within 15 minutes with one colored band in the Control Zone (C) and another in the Test Zone (T), the test result is positive and valid. No matter how faint the colored band is in the Test Zone (T), the result should be considered as positive. A positive result does not rule out co-infections with other pathogens.

NEGATIVE : If one colored band appears in the Control Zone (C) and no colored band appears in the Test Zone (T)within 15 minutes, the test result is negative and valid. A negative result does not exclude SARS- CoV-2 viral infection and should be confirmed by molecular diagnostic method if COVID-19 disease is suspected.

INVALID : The test result is invalid if there is no colored band in the Control Zone (C) within 15 minutes. Repeat the test with a new test device.



Add 3-4 drops of the prepared extraction solution to the CAT Antigen Rapid Test and wait 15 minutes

QUALITY CONTROL
1.The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2.Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which are not provided with this test kit are commercially available

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity
The limit of detection (LoD) for the Rapid SARS-CoV-2 Antigen Test Card was established in an analytical sensitivity study performed with one virus strain and one recombinant nucleocapsid protein. The LoD was confirmed in the following table

Item	Limit of Detection
SARS-CoV-2, Virus	1.3 x10^2 $TCID_{50}$/mL
SARS-CoV-2, Recombinant nucleocapsid protein	1 ng/mL

Cross Reactivity
1.The cross reactivity of the 2019-nCoV Antigen Rapid Test Kit was evaluated with a total of 29 microorganisms. None of the microorganisms tested in the following table gave a positive result.

Microorganisms	Concentrations	Microorganisms	Concentrations
Human coronavirus 229E	2.0x10^5 CID_{50}/mL	MERS-coronavirus	2.0 x 10^5 $TCID_{50}$/mL
Human coronavirus OC43	2.0x10^5 $TCID_{50}$/mL	Chlamydia pneumoniae	2.0 x 10^6 IFU/mL
Human coronavirus NL63	2.0x10^5 $TCID_{50}$/mL	Streptococcus pneumoniae	2.0 x 10^6 CFU/mL
Parainfluenza virus 1	2.0 x 10^6 $TCID_{50}$/mL	Streptococcus pyogenes	2.0 x 10^6 CFU/mL
Parainfluenza virus 2	2.0 x 10^6 $TCID_{50}$/mL	Bordetella pertussis	2.0 x 10^6 CFU/mL
Parainfluenza virus 3	2.0 x 10^6 $TCID_{50}$/mL	Mycobacterium tuberculosis	2.0 x 10^6 CFU/mL
Parainfluenza virus 4	2.0 x 10^6 $TCID_{50}$/mL	Legionella pneumophila	2.0 x 10^6 CFU/mL
Enterovirus EV71	2.0 x 10^6 $TCID_{50}$/mL	Mycoplasma pneumoniae	2.0 x 10^6 U/mL
Respiratory syncytial virus	9×10^5 $TCID_{50}$/ mL	Haemophilus influenzae	2.0 x 10^6 CFU/mL
Rhinovirus	2.0 x 10^6 $TCID_{50}$/mL	Candida albicans	2.0 x 10^6 CFU/mL
Influenza A virus (H1N1)	2.0 x 10^6 $TCID_{50}$/mL	Staphylococcus aureus	2.0 x 10^6 CFU/mL
Influenza A virus (H3N2)	2.0 x 10^6 $TCID_{50}$/mL	Pseudomonas aeruginosa	8.7×10^7 CFU/mL
Influenza B virus (Yamagata)	2.0 x 10^6 $TCID_{50}$/mL	Escherichia coli	2.0 x 10^6 CFU/mL
Influenza B virus (Victoria)	2.0 x 10^6 $TCID_{50}$/mL	SARS-coronavirus	2.0 x 10^6 $TCID_{50}$/mL
Adenovirus C1 Ad. 71	2.0 x 10^6 $TCID_{50}$/mL	Pooled human nasal wash (Normal Flora)	

Interference
2. Rapid SARS-CoV-2 Antigen Test Card has tested samples with common microorganism.
The results showed that these microorganisms had no effect on the specificity of the assay up to the listed concentration.

Microorganisms	Concentrations	Microorganisms	Concentrations
Human coronavirus 229E	2.0x10^5 CID_{50}/mL	MERS-coronavirus	2.0 x 10^5 $TCID_{50}$/mL
Human coronavirus OC43	2.0x10^5 $TCID_{50}$/mL	Chlamydia pneumoniae	2.0 x 10^6 IFU/mL
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Parainfluenza virus 3	2.0 x 10^6 $TCID_{50}$/mL	Mycobacterium tuberculosis	2.0 x 10^6 CFU/mL
Parainfluenza virus 4	2.0 x 10^6 $TCID_{50}$/mL	Legionella pneumophila	2.0 x 10^6 CFU/mL
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Influenza A virus (H3N2)	2.0 x 10^6 $TCID_{50}$/mL	Pseudomonas aeruginosa	8.7×10^7 CFU/mL
Influenza B virus (Yamagata)	2.0 x 10^6 $TCID_{50}$/mL	Escherichia coli	2.0 x 10^6 CFU/mL
Influenza B virus (Victoria)	2.0 x 10^6 $TCID_{50}$/mL	SARS-coronavirus	2.0 x 10^6 $TCID_{50}$/mL
Adenovirus C1 Ad. 71	2.0 x 10^6 $TCID_{50}$/mL	Pooled human nasal wash (Normal Flora)	

ACCURACY

2019-nCoV Antigen Rapid Test Kit	RT-PCR		
	Positive	Negative	Total
Positive	162	4	166
Negative	4	251	255
Total	166	255	421

Sensitivity = 162/166 x 100 % = 97.59 % (95% CI: 95.26% - 99.92 %)
Specificity = 251/255 x 100 % = 98.43 % (95% CI: 96.91% - 99.96%)
Accuracy = 413/421 x 100 % = 98.10 % (95% CI: 96.80 % - 99.40 %)

Endogenous Substances
Rapid SARS-CoV-2 Antigen Test Card has tested samples with common endogenous substances. The results showed that these substances had no affect on the specificity of the assay up to the listed concentration.

Substances	Concentrations	Substances	Concentrations
Whole Blood	4% v/v	Homeopathic (Alkalol)	10% v/v
Mucin	0.5% w/v	Nostril Nasal Drop(Phenylephrine)	15% v/v
Tobramycin	0.0004% w/v	Illiadin Merck - Oxymetazoline)	15% v/v
Mebucain (Menthol)	0.15% mg/mL	Allergo Comod Nasal Spray (Cromolyn)	15% v/v
VISION PUMP SPREY(Benzocain)	0.15% w/v	Avamys (Fluticasone Propionate)	5% v/v
Mupirocin	10 mg/mL	Zicam	5% w/v
Enfluvir (Oseltamivir Phosphate)	0.5% w/v	DISINOL	Phenol 2 g/10ml
		(Phenol 2 g/10ml, Chlorbutanol 3.5 g/ml)	Chlorbutanol 3.5 g/ml

LIMITATIONS
1.The test is limited to the qualitative detection of SARS-CoV-2 viral antigen in nasopharyngeal swab specimens. The exact concentration of SARS-CoV-2 viral antigen cannot be determined by this assay.
2.Proper specimen collection is critical, and failure to follow the procedure may give inaccurate results. Improper specimen collection, storage or repeated freezing and thawing of specimens can lead to inaccurate results.
3.A negative test result may occur if the level of antigen in a specimen is below the limit of detection of the test.
4.As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
5.Negative test results do not rule out other potential non-SARS-CoV-2 viral infections. Negative results should be confirmed by molecular diagnosis if COVID-19 disease is suspected.
6.Positive test results do not rule out co-infections with other pathogens.
7.Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
8.The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5-7 of illness are more likely to be tested negative compared to a RT-PCR assay.

REFERENCES
1. Wu C, Liu Y, Yang Y, Zhang P, Zhong W, Wang Y, et al. (February 2020). "Analysis of therapeutic targets for SARS-CoV-2 and discovery of potential drugs by computational methods". Acta Pharmaceutica Sinica B. doi:10.1016.

SYMBOL INDEX

IVD — In Vitro Diagnostic Use
See Instruction for Use
Expiry Date
Σ — Tests per Kit
Manufacturing Date
Keep Dry
Manufacturer
LOT — Batch Number
Keep away from Sunlight
4℃ 30 ℃ — Store between 4~30°C
Do not reuse
REF — Catalog#
CE

ONCOSEM Onkolojik Sistemler San. ve Tic. A.Ş.
Mustafa Kemal Mah. 2125 Sokak A Blok No: 6/8 Söğütözü 06520
IFU-CAT-01-EN Rev02 16.12.2020

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 Antigen Rapid Test Kit

Model : Single Use Test Kit
Ref# : CAT-01
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 14971:2019, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2020, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of Issue: Ankara Turkey on October 20th, 2020

NAME: EROL ÇELİK – GENERAL MANAGER

ONCOSEM ONKOLOJİK SİSTEMLER SAN. VE TİC. A.Ş.
Mustafa Kemal Mh. 2125. Sk. A Blok No: 6/8
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Tel: 0312 219 50 33 • Fax: 0312 219 50 73
Mersis No: 0643057054700001
Tic. Sic. No: 250234 • Maltepe V.D.: 643 057 0547

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.

IAS ACCREDITED MSCB125

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

CERTIFICATE OF REGISTRATION

SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

This Certificate has been awarded to

ONCOSEM ONKOLOJİK SİSTEMLER SANAYİ VE TİCARET ANONİM ŞİRKETİ

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

In recognition of the organization's Managements System which complies with

ISO 9001:2015

The scope of activities covered by this certificate is defined below

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, HYGIENE PRODUCTS, MOLECULAR AND IMMUNOCHEMICAL BASED ANALYSIS KITS AND DEVICES, RESPIRATORYADJUANT DEVICE AND VENTILATOR

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

Certificate Number: SISTURQ10202054254
Date of Issue of Orginal Certificate: 26.10.2020
Date of Issue of Latest Certificate: 26.10.2020
Expiry Date: 25.10.2021

Managing Director

SIS CERT

Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.

The Organization's documentation and Implementation has been rewiewed and found to comply with the relevant standard rules. This certificate of Registration is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the revelant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid. This is an accredited certificate isseud by SIS Certifications Pvt. Ltd. sanctioned for issue by International Accreditation Services, 3060 Saturn Street Suite 100 Brea, California 92821-1732, USA.

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Issue No.:01

SIS CERT.

IAS
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Management Systems Certification Body
MSCB - 131

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT
IAF

CAT antigen

Covid Rapid Test

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