





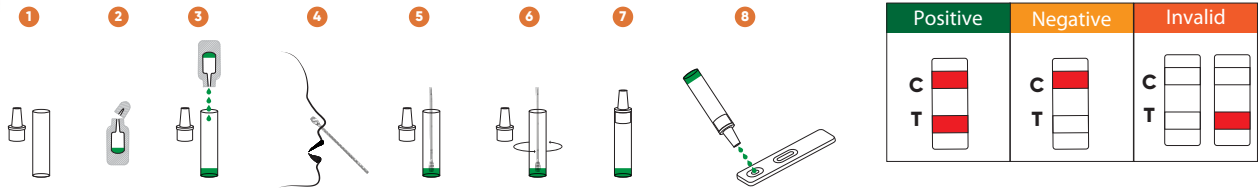
Antigen Test Kit

Softec is used for in vitro qualitative detection of SARS-CoV-2 antigen. Its a lateral flow sandwich assay, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in oropharyngeal (OP) nasal (NS) nasopharyngeal (NP) swab specimens directly.

Softec Ag Test Kit can detect SARS-CoV-2 particles within 15 minutes with 96.38 % sensitivity and 99.17% specificity. Softec provides fast and reliable results for you and your loved ones.

Softec doesn't need any special equipment or laboratory environment. The test can be managed anytime, anywhere by trained professionals.





Do not use test kit after the expiration date. Bring specimen and test components to room temperature if needed (15-30 °C) and use the appropriate personal protective equipment.

1. Gently rotate the swab several times over the surface of the oropharyngeal and posterior nasopharynx and gently remove.
2. Add 15 drops (~ 300 µL) buffer into upright extraction tube using the stand provided.
3. Roll the swab 10+ times within tube, squeeze against inside of tube, let stand for 1 minute and squeeze several more times.
4. Safely remove and discard the swab and insert dropper tip into tube containing the specimen.
5. Lay cassette flat and add 3 drops (~ 100 µL) of the test sample into the sample well. Read results at 5-15 minutes. Used materials should be discarded as biohazardous waste in accordance with local regulations.

Performance

Sensitivity: 96.38 %
Specificity: 99.17 %

Clinical study details: 1224 subjects
Testing by the developer (across a number of sites, clinic environments and operators) demonstrated high quality performance data.

Materials Provided

25 test cassetts
25 sterile swabs
25 extraction tubes ,caps
25 extraction solutions
1 workstation
1 package insert

Specifications

Test time: 15 minutes
Sample type: oropharyngeal, nasopharyngeal
Storage: room temperature or refrigerated (2 / 30 ° C)
Shelf life: 18 months from date of manufacture

Catalog Numer	ZET01A	ZET25A
Product Format	Cassette	Cassette
Sample Type	Oropharyngeal, Nasal and Nasopharyngeal Swab	Oropharyngeal, Nasal and Nasopharyngeal Swab
Product Number	1	25
Extra materials	Steril Swab Extraction Tube, Tip and Extraction Reagent Package Insert	Steril Swab Extraction Tube, Tip and Extraction Reagent Package Insert

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Zet Medikal Ltd. Şti.

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Saliva Test Kit

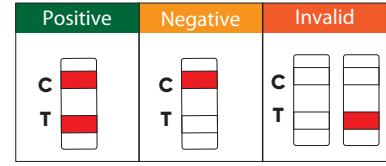
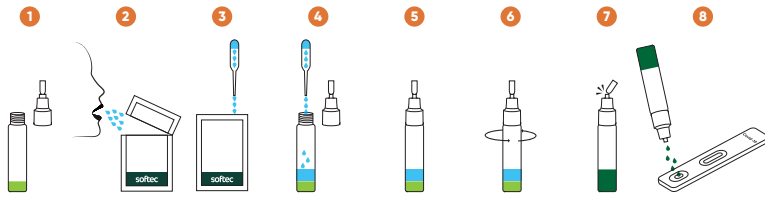
Softec is used for in vitro qualitative detection of SARS-CoV-2 antigen. Its a lateral flow sandwich assay, intended for the qualitative detection of the nucleocapsid protein antigen form SARS-CoV-2 in saliva specimens directly.

Softec Ag Test kit can detect SARS-CoV-2 particles within 15 minutes with 96.8% sensitivity and 99.9% specificty. Softec provides fast and reliable results for you and your loved ones. Softec doesn't need any special equipment or laboratory everonment.





Must be at least 2 hours after eating or drinking used to achieve 95% accuracy.



Do not use test kit after the expiration date. Bring specimen and test components to room temperature if needed (15-30 °C) and use the appropriate personal protective equipment.

1. Pour your saliva to the saliva collection bag
 2. Take the saliva until saliva fills the pipette
 3. Release the saliva into the buffer tube with already filled with extraction buffer
 4. Close the cap tightly and mix the solution 10 times by shaking up and down
 5. Lay cassette flat and add 3 drops (~100 µL) of the test sample into the sample well by using upper opening of the cap. Read results at 5-15 minutes.
- Used materials should be discarded as biohazardous waste in accordance with local regulations.

Performance

Sensitivity: 96.8 %
Specificity: 99.6 %

Clinical study details: 609 subjects Testing by the developer (across a number of sites, clinical environments and operators) demonstrated high quality performance data.

Materials Provided

1 tube including extraction buffer
1 collecting bag
1 pasteur pipette
1 test cassette
1 package insert

Specifications

Test time: 15 minutes
Sample type: Saliva
Storage: Room temperature of refrigerated (2 / 30 °C)
Shelf life : 18 months from date of manufacture

Catalog Numer	?????	?????
Product Format	Cassette	Cassette
Sample Type	Saliva	Saliva
Product Number	1	25
Extra materials	Extraction Tube Collection Bag Package Insert	Extraction Tube Collection Bag Package Insert

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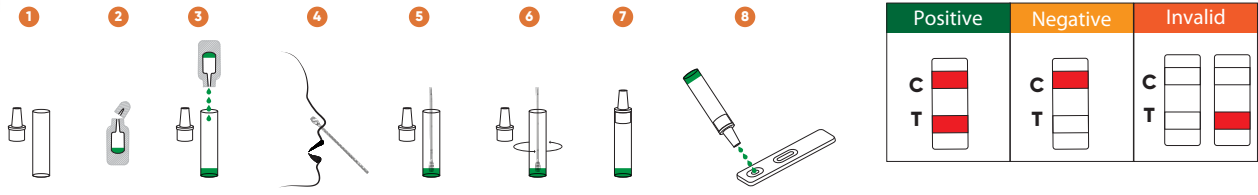
Nasal Antigen Test Kit

Softec is used for in vitro qualitative detection of SARS-CoV-2 antigen. Its a lateral flow sandwich assay, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal (NS) swab specimens directly.

Softec Nasal Antigen Test Kit can detect SARS-CoV-2 particles within 15 minutes with 97,5 % sensitivity and 99,4 % specificity. Softec provides fast and reliable results for you and your loved ones.

Softec doesn't need any special equipment or laboratory environment. The test can be managed anytime, anywhere by trained professionals.





Do not use test kit after the expiration date. Bring specimen and test components to room temperature if needed (15-30 °C) and use the appropriate personal protective equipment.

1. Gently rotate the swab several times over the surface of the oropharyngeal and posterior nasopharynx and gently remove.
2. Add 15 drops (~ 300 µL) buffer into upright extraction tube using the stand provided.
3. Roll the swab 10+ times within tube, squeeze against inside of tube, let stand for 1 minute and squeeze several more times.
4. Safely remove and discard the swab and insert dropper tip into tube containing the specimen.
5. Lay cassette flat and add 3 drops (~ 100 µL) of the test sample into the sample well. Read results at 5-15 minutes. Used materials should be discarded as biohazardous waste in accordance with local regulations.

Performance

Sensitivity: 97.5 %
Specificity: 99.4 %

Clinical study details: 585 subjects
Testing by the developer (across a number of sites, clinic environments and operators) demonstrated high quality performance data.

Materials Provided

25 test cassetts
25 sterile swabs
25 extraction tubes ,caps
25 extraction solutions
1 workstation
1 package insert

Specifications

Test time: 15 minutes
Sample type: Nasal Swab
Storage: room temperature or refrigerated (2 / 30 ° C)

Catalog Numer	ZET01NA	ZET25NA
Product Format	Cassette	Cassette
Sample Type	Nasal Swab	Nasal Swab
Product Number	1	25
Extra materials	Steril Swab Extraction Tube, Tip and Extraction Reagent Package Insert	Steril Swab Extraction Tube, Tip and Extraction Reagent Package Insert

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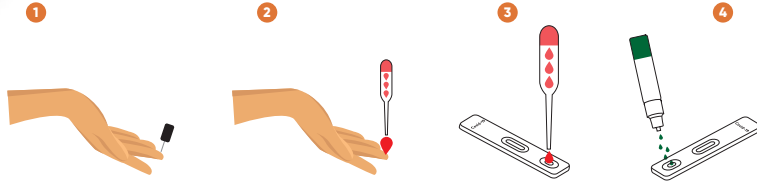
Antibody Test Kit

Softec SARS-CoV-2 Rapid IgG/IgM Test is a colloidal gold enhanced, rapid immunoassay for the qualitative detection of SARS-CoV-2 IgG and IgM antibody in serum, plasma and whole blood samples from patients with suspected SARS-CoV-2 infection.

Softec Sars-CoV-2 Rapid IgG/IgM Test Kit detect SARS-CoV-2 particles within 15 minutes with 93.41% sensitivity and 99.42 % specificity for IgG. Softec provides fast and reliable results for you and your loved ones.

Softec doesn't need any special equipment or laboratory environment. The test can be managed anytime, anywhere by trained professionals.





Negative	IgG / IgM Positive	IgG Positive	IgM Positive	Invalid
C IgG IgM	C IgG IgM	C IgG IgM	C IgG IgM	C IgG IgM

Do not use test kit after the expiration date. Bring specimen and test components to room temperature if needed (15-30 C) and use the appropriate personal protective equipment.

1. Use the lancet and pierce the finger for whole blood.
2. Add 1 drop (10 µL) of specimen (whole blood/serum/plasma) to the sample well of the test lay the plastic dropper provided according to the figure.
3. Then add drops (80 µL) of sample diluent to the sample
4. Read results at 5-15 minutes.

Used materials should be discarded as biohazardous waste in accordance with

Performance

Sensitivity: 97.5 %
Specificity: 99.4 %

Clinical study details: 585 subjects
Testing by the developer (across a number of sites, clinic environments and operators) demonstrated high quality performance data.

Materials Provided

25 test cassetts
25 Disposable Droppers
25 solution tubes
25 Alcohol Wipes
25 Lancets
1 Packaging insert

Specifications

Test time: 15 minutes
Sample type: Serum, plasma and whole blood
Storage: Room temperature of refrigerated (2 / 30 °C)
Shelf life: 18 months from date of manufacture

Catalog Numer	ZET01AB	ZET25AB
Product Format	Cassette	Cassette
Sample Type	Serum, Plasma and Whole Blood	Serum, Plasma and Whole Blood
Product Number	1	25
Extra materials	Buffer Tube Disposable Droppers Alcohol Wipes Lancet Package Insert	Buffer Tube Disposable Droppers Alcohol Wipes Lancet Package Insert

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Technical
Universal
Verification



CERTIFICATE

This Certificate has been awarded to:

ZET MEDİKAL TEKSTİL DIŞ TİCARET LİMİTED ŞİRKETİ

CEMİL MERİÇ MAH. İSTİKLAL CAD. NO: 132 - 134 /B ÜMRANIYE
İSTANBUL - TURKEY

In Recognition of the Organisation's Management System which complies with:

ISO 13485 : 2016

For the Scope of Activities described below:

PRODUCTION AND SALES OF SINGLE-USE PERSONAL CASSETTE TESTS (INCLUDING MIDSTREAM), SINGLE USE TESTS (PROFESSIONAL USE), URINE STRIPS, ELISA TEST KITS, GENE ANALYSIS KITS, NOSE SPRAYS AND DROPS, DISINFECTANTS, FIRST AID KIT, ULTRASOUND GEL, ANTISEPTICS, NASAL WASH KIT, HEAD LICE SPRAY TREATMENT SPRAY AND SHAMPOOS, LOZENGES, WOUND CARE PRODUCTS, DISPOSABLE MEDICAL PRODUCTS, ELECTROLYTE SOLUTIONS, MEDICAL DEVICES WITH HERBAL CONTENT, NEBULIZERS, NASAL ASPIRATORS AND SPARE TIPS

Certificate No : 4100
Date of Audit : 15.08.2018
Date of Registration : 04.10.2018

Reissue Date : 23.09.2020
Expiry Date : 03.10.2021

Technical Universal Verification

This document is valid for 3 years provided that the management system is well maintained and surveillance audits are performed regularly. After performing the surveillance audits certificate will be reissued. The current status of this certificate can be viewed via www.techcert.com.tr web site. This certificate is a property of Technical Universal Verification Certification and Training Services Co., Ltd. Thus, this certificate has to be returned if required by property owner. National Accreditation Center (NAC) is an accreditation body whose headquarters is located in the United States of America, which is a member of Asia Pacific Accreditation Cooperation (APAC).



Technical Universal Verification
Belgelendirme ve Eğitim Hizmetleri Ltd. Şti.
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MANAGEMENT SYSTEM
ISO/IEC 17021:2015
NAC-011-08

FR 32/02.04.2020/REV.01

Zet Medikal Ltd. Şti.

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