CAN KAPTAN	TechnoCath Every Product is a Life **Covid-19 Ag Rapid Test** **(Test Cassette and Swab)**	**Doküman No:**	PR.30.TD.C19Ag
		Yayın Tarihi:	04.01.2021
		Revizyon No:	00
		Revizyon Tarihi:	-

INSTRUCTION FOR USE

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Contents

1- Definition and Features

This kit is used for the in vitro qualitative detection of the SARS-CoV-2 antigen. It is a lateral flow sandwich test designed for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 directly in nasopharyngeal (NP) and nasal (NS) swab specimens. This test is for clinical laboratory use or emergency review only. This test can be done in a laboratory environment, as well as giving individuals the option to take nose samples on their own. It cannot be used as a basis for the diagnosis and exclusion of pneumonia caused by novel coronavirus infection and is not suitable for general population screening. A positive test result needs further confirmation. A negative test result cannot exclude the possibility of infection. Kit and test results are for clinical reference only. It is recommended to combine the patient's clinical signs with other laboratory tests for a comprehensive analysis of the situation. This Kit does not distinguish between SARS-CoV and SARS-CoV-2.

New corona viruses β are acute respiratory infection disease of SARS-COV-2. People are generally sensitive. Currently, patients infected by the new coronavirus are the main source of infection; Asymptomatically infected individuals can also be a source of contagion. According to current epidemiological research, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main symptoms are fever, tiredness, and dry cough. In a few cases, nasal congestion, runny nose, sore throat, myalgia, and diarrhea have been observed.

2- Storage Conditions

Products should be stored in their original boxes in order to avoid damage. Storage temperature should be between 2˚ C - 30˚ C.

3- Indications

The SARS-CoV-2 Rapid Antigen Test is a qualitative membrane-based chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasopharyngeal and nasal swab samples. When samples are processed and added to the test cassette, the SARS-CoV-2 antigens will react with anti-SARS-CoV-2 antibody coated particles, if present in the sample, which were pre-coated on the test strip. Antigen-conjugate complexes travel across the test strip towards the reaction area and are captured by a line of membrane-bound antibodies. Test results are interpreted visually within 15 minutes depending on the presence or absence of visually colored lines. A colored line will always appear in the control line region to act as a procedural control, indicating that the proper volume of sample has been added and membrane wicking has occurred.

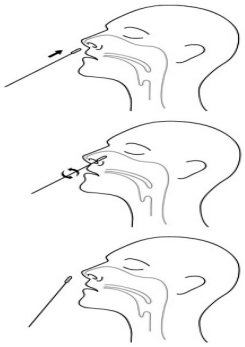
4- Warnings

- For in vitro diagnostic use only.
- The test device should remain in the sealed pouch until use.
- Do not use kit past its expiration date.
- Swabs, tubes, and test devices are for single use only.
- Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.

- Do not interchange or mix components from different kit lots.
- Testing should only be performed using the swabs provided within the kit.
- To obtain accurate results, do not use visually bloody or overly viscous samples.
- Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.
- Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Patient swabs used Test Strips and used extraction buffer vials may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local regulatory requirements.
- Inadequate or inappropriate specimen collection and storage can adversely affect results.
- Humidity and temperature can adversely affect results.
- Dispose of test device and materials as biohazardous waste in accordance with federal, state, and local requirements.

5- Prepation and Use

Sample Requirements



1. Collection of oropharyngeal secretion: Insert the sterile swab from the mouth into the oropharyngeal swelling completely, center the red part of the throat wall, epicondylosis and tonsils, wipe with a swab for 10 times, avoid touching the tongue, after dissolving in VTM, throw the swab into the medical waste box.

2. Collection of nasopharyngeal secretion: Place the sterile swab where the nasopharyngeal secretions are greatest and take the swab from the inner wall of the nasal cavity and remove the swab. After thawing it in VTM, throw the swab into the medical waste bin.

3. Samples should be used as soon as possible after collection (within half an hour).

4. Samples should not be inactivated.

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2. Collection of nasal secretion: Place the sterile swab where the nasopharyngeal secretions are greatest and take the swab from the inner wall of the nasal cavity and remove the swab. After thawing it in VTM, throw the swab into the medical waste bin.

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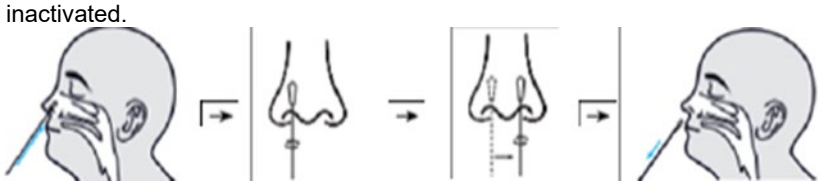


Sample Processing:

1. Remove the swab from the packaging.
2. Tilt the patient's head back slightly so that the nostrils are more accessible.
3. Gently rub across the nasal septum, just above the floor of the nasal airway, into the nasopharynx until resistance is felt.
4. Place the swab in the nostril parallel to the palate. If you find resistance to the passage of the bumper, pull back and try repositioning at a different angle closer to the base of the nasal canal.
5. Swap should reach a depth equal to the distance from the nostrils to the outer opening of the ear.
6. The CDC recommends leaving the swab in place for a few seconds to absorb secretions and then slowly remove the swab while rotating.
7. Rotate the swab several times before removing it.
8. Open the collection tube and place the swab in the tube. Divide the swab in half, place the sample part into the tube and close the mouth.

Note: We recommend using pipettes when transferring samples to decrease the deviations.

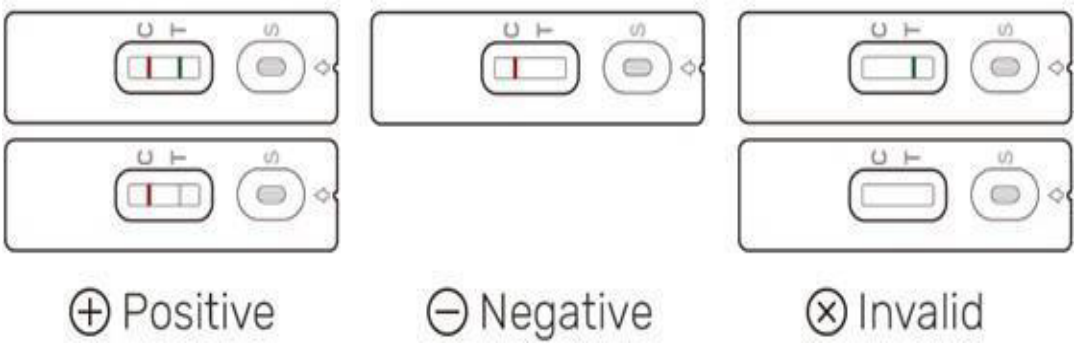
Procedure:
Please read the user manual before testing.
1. The clinical sample antigen in the tube is added to the well in the test cassette.
2. Lateral flow will move the sample through the test.
3. Next, the sample / conjugate complex moves to the nitrocellulose membrane. Here, it comes into contact with two test lines: antibody and control.
4. An antibody line containing an immobilized capture antibody recognizing the SARS-CoV-2 nucleocapsid protein will bind here. However, only antibody / COVID-19 antigen / gold nanoparticle complexes will produce a visible colored line.

5. The control line is the last line the sample will encounter. The control line contains an immobilized antibody that recognizes the control antibody, rabbit IgG. To serve as a procedural control, a red line should always appear in the control line region indicating that the appropriate volume of sample has been added and membrane wicking has occurred**.**

6- Interpretation of Test Results

This product can only perform qualitative analysis on the detection object.

Positive Result:
If the C and T lines appear within 15 minutes, the test result is positive and valid.
Note: Samples containing very low levels of target antibodies can form two colored lines within 15 minutes.
Negatif Result:
If the T line in the Test area does not have color and the control area has formed a colored line, the result is negative and valid..
Invalid Result:
If a line C is not formed as a result of the test, the test result is considered invalid. The sample should be applied again to another test.



7- Product Life

Product life is TWO (2) year when stored under appropriate storage conditions.

8- Signs and Symbols

The signs and symbols on the label of the medical device and on the user manual are specified in accordance with EN TS EN ISO 15223-1: 2016 standard.

IVD	: In Vitro Diagnostic Medical Device	LOT	Medical Device Lot number
	Medical Device is for single use only.	REF	Medical Device Reference number
	Medical Device Date of manufacture		Use with caution.
	Medical Device Expiration date		Do not use damaged packaged product.
	Consult instruction for use.		: Upper and lower temperature limits (2˚C - 30˚C)

9- Supplementary Information and Warnings

1. The result of the product should not be taken as a confirmed diagnosis for clinical reference only. The decision should be made in conjunction with RT-PCR results, clinical symptoms, epidemiological information and other clinical data.
2. The contents of this kit will be used for the qualitative detection of SARS-CoV-2 antigens from oropharyngeal and nasopharyngeal and nasal swabs.
3. This test detects both living and non-living, SARS-CoV and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not be associated with viral culture results performed on the same sample.
4. Sample buffer and test card must be equilibrated to room temperature (18 ~ 26 ℃) before use, otherwise results may be inaccurate.

5. A negative test result may occur if the antigen level in a sample is below the detection limit of the test or if the sample was improperly collected or handled.
6. Failure to follow the Test Procedure may adversely affect test performance and / or invalidate the test result.
7. Waiting for less than 7.10 minutes may lead to false negative results; Reacting for more than 15 minutes may result in a false positive result.
8. Positive test results do not exclude the possibility of co-infection with other pathogens.
9. Positive test results do not distinguish between SARS-CoV and SARS-CoV-2.
10. Negative test results are not intended to be valid for other non-SARS viral or bacterial infections.
11. Negative results should be considered hypothetical and confirmed by a molecular test.
12. Users should test samples as quickly as possible after sample collection.

Precautions:

1. For in vitro diagnostic use.
2. Do not use the contents of the kit after the expiry date printed on the outside of the box.
3. Take appropriate precautions during collection, handling, storage and disposal of patient samples and used kit contents.
4. The use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.
5. Do not reuse used Test Card, Reagent Tubes or Swabs.
6. The user should not remove the Test Card from its foil pouch until ready for use immediately.
7. Discard and do not use the damaged or dropped Test Card or material.
8. If the reagent solution comes in contact with the skin or eyes, rinse with copious amounts of water.
9. Inadequate or improper specimen collection, storage, and transport may cause false test results.
10. Specimen collection and handling procedures require special training and guidance.
11. Do not use visually bloody or highly viscous samples to obtain accurate results.
12. To obtain accurate results, an opened and exposed Test Card should not be used inside the laminar flow hood or in a highly ventilated area.
13. Testing should be done in an area with adequate ventilation.
14. Wear appropriate protective clothing, gloves, and eye / face protection when handling the antigen test kit.
15. Wash hands thoroughly after use.

Contact

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