TOYO®

INSTRUCTION FOR USE
2019-nCoV Ag Test
For 2019-nCoV antigen
Detection in human nasal swab, throat swabs and deep sputum

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: TCV02

2019-nCoV AgTest detects 2019-nCoV antigen in human nasal swab, throat swabs and deep sputum samples

BACKGROUND INFORMATION

The 2019-Novel Coronavirus is a new type of coronavirus belonging to the genus β. It has a capsule, and its particles are round or oval, often polymorphous, with a diameter of 60-140nm. Its genetic characteristics are significantly different from SARSr-CoV and MERSr-CoV. Current research shows that it has more than 85% homology with bat SARS-like coronavirus (bat-SL-CoVZC45). In vitro isolation and culture, 2019-nCoV can be found in human respiratory epithelial cells in about 96 hours, while it takes about 6 days to isolate and culture in Vero E6 and Huh-7 cell lines.
2019-nCoV Ag Test is for in vitro emergency use only during the pneumonia epidemic of the 2019-nCoV infection since December 2019.

INTENDED USE

The 2019-nCoV Ag Test is a colloidal gold enhanced double antibody sandwich immunoassay for the qualitative determination of 2019-nCoV antigen in human nasal swabs, throat swabs and deep sputum samples.

REAGENTS

This test included 2019-nCoV antibody, goat anti-chicken IgY polyclonal antibody, chicken IgY colloidal gold conjugate, 2019-nCoV antibody colloidal gold conjugate.

METHOD

2019-nCoV Ag Test is a rapid, qualitative, immunochromatographic assay for the detection of 2019-nCoV antigen in human nasal swab, throat swabs and deep sputum samples from patients with suspected 2019-nCoV infection, patients with suspected clustering cases, and others who need to diagnose or differentially diagnose 2019-Novel Coronavirus. 2019-nCoV antibody are immobilized in the test region on nitrocellulose membrane. If the specimen contains 2019-nCoV antigen at detectable level, during the assay specimen is allowed to react with the colored conjugate; the mixture then migrates chromatographically on the membrane by the capillary action. This complex, is captured by the specific antibody antigen colored conjugate, produces a colored line in test line region, indicates positive test result. If the specimen does not contain 2019-nCoV antigen at detectable level, no colored line will appear in the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Read this insert completely and carefully prior to use of the test. Test must be performed in strict accordance with these instructions to obtain accurate results.
3. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
4. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
5. Wear disposable gloves while performing the test.
6. The test device and swabs should be discarded in a proper biohazard container after testing.
7. This test kit should be handled only by adequately qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
8. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
9. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
10. This test will indicate only the selectively total 2019-nCoV antigens in the sample, and should not be used as the only basis for the diagnosis of coronavirus.
As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.
11. In the early stage of infection, the test result may be negative because the 2019-nCoV antigen or low antigen level has not yet appeared in the sample.
12. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of coronavirus.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used maximum one hour after the foil is opened.
Kit components : Test cassettes, swab, sample extraction solution, extraction tube holder, extraction tube tips, sample collection tube and instructions for use.
Additional materials required but not provided : Timer.
Additional materials recommended but not provided : Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

SAMPLE COLLECTION AND PREPARATION

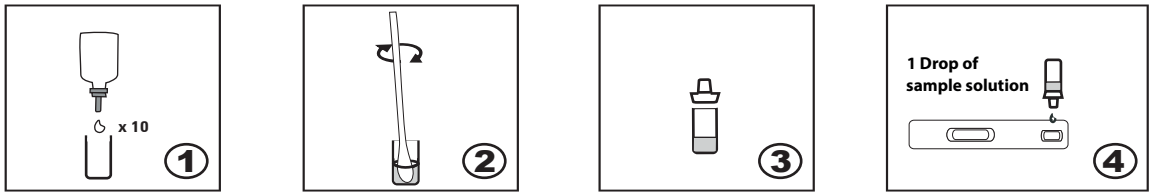
The test can be performed using human nasal swabs, throat swabs and deep sputum. The samples should be used as soon as possible after they are collected, otherwise they should be stored in a closed container and placed in a refrigerator at 2-8°C, but not longer than 24 hours, and can be stored at -70°C for a long time. Avoid repeated freezing and thawing.

For nasal secretion: Insert the sterile swab into the place where the nasal secretions are the most, and rotate the swab close to the inner wall of the nasal cavity 3 times, remove the swab.
For throat secretion: Insert the sterile swab from mouth completely into the throat swelling, centering on the red part of the throat wall, epicondylosis, and tonsils, wipe and rotate 3 times with moderate force to avoid touching the tongue and remove the swab.
For deep sputum: Patients are instructed to have a deep cough while wearing a mask, and the sputum is collected and kept in a special clean container.

Samples stored at low temperature should be equilibrate to room temperature before use. If the clinical samples need to be frozen at -20°C or below, it is recommended that the frozen samples should not be frozen for more than three months and repeatedly frozen and thawed not more than three times.

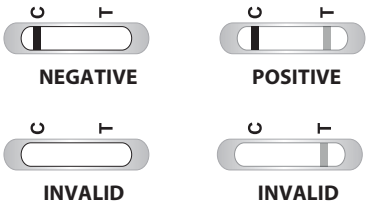
TEST PROCEDURE

1. Bring the tests, reagents and samples to room temperature.
2. Add 500 µL (about 10 drops) of Sample Extraction Buffer to the tube before putting in the specimen swab to prevent contaminating the Extraction Buffer vial (Figure 1).
3. Put the specimen swab into the tube with 500µL of sample extraction solution. Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least 10 times (while submerged) or squeeze the tube 5 times by hand. Best results are obtained when the specimen is vigorously mixed in the buffer (Figure 2).
4. Squeeze out as much liquid as possible from the swab by pinching the side of the flexible test tube as the swab is removed. Discard the swab in a suitable biohazards waste container. Cover the dripper and mix the liquid thoroughly (Figure 3).
5. Remove the test device from the foil pouch and place on a clean dry surface.
6. Dispense 80µL (1 drop) of the specimen into the circular sample well on the cassette. Add 1 drop more if the sample does not migrate (Figure 4).
7. Results should be read at 15 minutes as shown below. Results forming after 20 minutes should be regarded as invalid.



INTERPRETATION OF RESULTS

Negative : Only one colored line is visible in "C" area.
Positive: One colored line should be in "C" area and a colored line appears in "T" area.
NOTE: Low concentration of the virus antigens in the sample may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
Invalid : No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.



QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

2019-nCoV Ag Test has been evaluated using clinical samples. PCR methods are used to compare 2019-nCoV Ag Test and following results are obtained.

Sensitivity:

Sample	Turklab 2019-nCoV Ag Test		
	Turklab Positive	PCR Positive	Sensitivity
Swab	131	145	90.34%
Deep sputum	11	12	91.67%
Total	142	157	90.44%

Specificity:

Sample	Turklab 2019-nCoV Ag Test		
	Turklab Negative	PCR Negative	Specificity
Swab	149	150	99.33%
Deep sputum	13	13	100%
Total	162	163	99.38%

According to the above data, the total accuracy is 94.91%.

Intra Assay
The test was repeated 10 times with 1 enterprise replicate reference product, and the results should all be positive, and the reaction results should be consistent, and the color rendering should be uniform.

Inter Assay
Take three different batches of kits and test with 1 enterprise replicate reference product. The results should all be positive, and the reaction results should be consistent. There is no difference and in chromaticity and even.

Interferences:

Through the test kit to the reference product testing analysis, when the samples containing hemoglobin (≤6 mg/mL), bilirubin (≤12 mg/dL), triglycerides (≤15 mg/mL), cholesterol (10 mg/mL) or rheumatoid factor (≤80 IU/mL)in different concentrations, decision does not affect the test result, test results are no interference.

Cross Reactivity:

This product does not cross-react with samples of influenza A virus, influenza B virus, adenovirus type 3, adenovirus type 7, human parainfluenza virus and respiratory syncytial virus.

REFERENCES

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CE

Manufacturer
Consult instruction for use
Attention, see instruction for use
IVD *In vitro* diagnostic medical device
For single use only
Number of test
REF Catalog number
Storage temperature
LOT Lot number
Expiry date