Teucer Healthcare

Ningbo Beautiful Life Medical Biotechnology Development Co., Ltd.

One Step Saliva SARS-Cov-2 Antigen Combined Test kit instructions

INTENDED USE:

SARS-CoV-2 is a Corona Virus that causes Covid-19, a disease that systemically affects the body. Individuals currently infected by SARS-CoV-2, whether having symptoms or not, are the main source of infection. This test is intended to reduce avoidable spread of Covid-19.

The main symptoms of COVID-19 include fever, body aches, dry cough, shortness of breath as well as loss of taste and smell. Many infected people do not experience these symptoms. These individuals are carriers and are the cause of much of the silent spread of Covid-19.

Saliva SARS-Co-V-2 (COVID-19) Antigen Combined Test is a lateral flow, one-step immunoassay for the qualitative detection of N/S antigen in a saliva sample. This product is used to obtain a visual, qualitative results and is intended for professional use.

This Saliva Self-Test is a Lateral Flow Test for detection of The Nucleocapsid (N) and Spike (S) Antigens that are present on the surface of viable SARS CoV-2 virus particles. It is intended as a preliminary test. A more specific test (usually PCR) should be used to confirm all Positive results.

Saliva One Step COVID-19 Antigen Test is a rapid chromatographic immunoassay based on the principle of sandwich antibody and antigen binding. During testing the COVID-19 N/ S antigen, if the virus antigens are present in the saliva specimen, will bind to the antibody conjugates to form a complex. That complex will migrate upward by capillary movement, then will be captured by the immobilized antibody coated at the Test line region on the NC membrane. A visible black line will show up in the test line region. The black line will not form in the test line region if there is no virus antigen in the sample.

A virus antigen-positive saliva specimen will generate a line in the test line region because of antigen binding, while a virus antigen-negative saliva specimen or a specimen containing a very low concentration will not generate a line in the test line region. To serve as a procedural control, a line will always appear at the control line region (C line), indicating that proper volume of specimen has been added and membrane wicking has occurred.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

STORAGE AND STABILITY

- For in vitro diagnostic use only. For professional use only.
- Do not use after the expiration date.
- The test Cassette should remain in the sealed pouch and until use.
- Saliva specimen may be potentially infectious. Proper handling and disposal methods should be established.
- The used test Cassette should be discarded according to local regulations.

MATERIALS

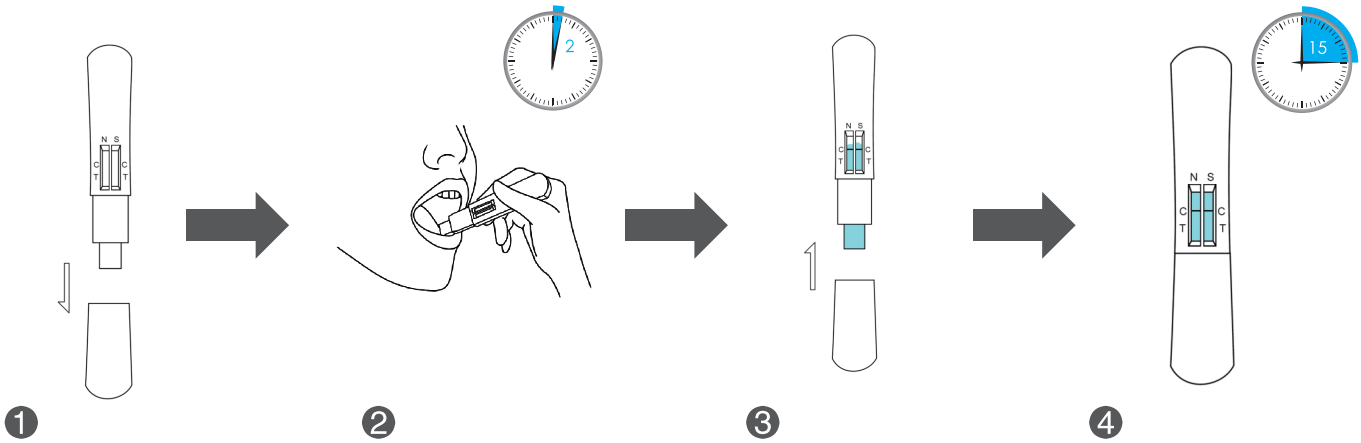
- Individually wrapped test cassette devices
- Package Insert
- Desiccants

SPECIMIEN COLLECTION AND PREPARATION

For optimal results, the sample should be produced at room temperature. Cassettes showing a positive result should be treated as infectious clinical waste.

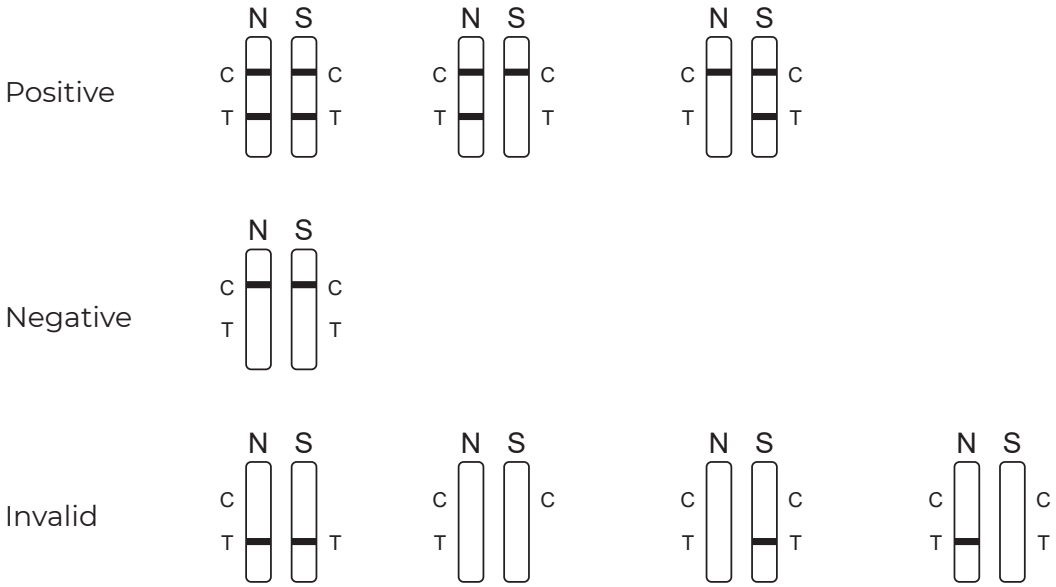
SAMPLE COLLECTING METHOD:

1. Do not eat, drink, smoke or vape for 30 minutes before testing.
2. Open the pouch, remove the cassette from its packaging and place it on a clean and level surface.
3. Remove the cap and the wick can be placed directly under the tongue for two minutes to saturate with saliva. The wick must remain immersed in saliva for two (2) minutes or until liquid appears in the observation window of the cassette.
4. After two minutes, remove the test from the sample or under the tongue, replace cap and place on a flat surface.
5. Start the timer.
6. Read the result after 15 minutes.



TEST RESULTS:

There are two tests being carried out, one to look for the Spike (S) Antigen and one for the Nucleocapsid (N) Antigen. Either one being positive should be treated as a positive test. There are two positions for lines to appear. The C position is for "Control". This must show in both windows for the test to be valid. The T position is for "Test". If a line shows at either T position it is a Positive even if it is a faint line.



***Positive:** Two lines will appear in one or both windows on the cassette. One line will appear alongside 'C', whilst the second line appears alongside 'T' in one or both windows.
A positive reading indicates SARS Co-V-2 virus Antigens are present in the saliva specimen. COVID-19 infection or carrier status is indicated.

***Negative:** Only one line appears next to 'C', with no line appearing in the 'T' region in either window. There is no evidence of virus being present in sufficient quantity to be detected.

Invalid: If the control line 'C' fails to appear in either window, the test is deemed to be invalid. In this instance, a new test should be acquired, and the process is to be repeated. If the problem persists, discontinue testing and contact your distributor.

*The **Saliva SARS-Cov-2 Antigen Combined Test** is limited to providing only an analytical result. A secondary analytical method should be completed to confirm the result. It is possible that technical or procedural errors, including other interfering substances in the saliva specimen may cause adverse effect towards the results.

ACTION TO BE TAKEN AFTER TESTING:

Negative Test Result – Go about your activities as normal taking recommended precautions to prevent infection (Hands, Face, Space). Always remember that the virus may still have been passed to you in the last few days and not yet have developed to a level where it can be detected.

Positive Test Result – Immediately start your Self-Isolation. This applies to others in your household of Bubble. Request a PCR Test through normal NHS Channels:

https://www.gov.uk/get-coronavirus-test

Inform any close contacts (family and work / school).

Await formal testing by PCR via a laboratory.

More detailed information is on the leaflet enclosed.