

NOVODIAX CoNab™ SARS-COV-2 NAb Lateral Flow Test Kit For Research Use Only



PRODUCT DESCRIPTION

CoNab™ Lateral Flow Test Kit is to detect an individual's neutralizing antibodies (NAb) to the COVID-19 virus.

INTENDED USE

The CoNab Test Kit is a lateral flow test intended for qualitative detection of neutralizing antibodies (NAb) to SARS-CoV-2 in human blood, plasma or serum. The CoNab Test Kit is intended for use as an aid in determining whether an individual, either a recipient of a COVID-19 vaccine or a patient recovered from COVID-19 disease, has developed NAb to SARS-CoV-2 or not. The CoNab Test Kit should not be used to diagnose acute SARS-CoV-2 infection. This test is limited for Research Use Only before being authorized by FDA or CE Mark for diagnostic use.

PRINCIPLE

CoNab Test Kit utilizes the principle of lateral flow or immuno- and protein-chromatography. SARS-CoV-2 spike protein S1 subunit and a tag protein are conjugated to gold nanoparticles (GNP) and embedded in conjugate pad of the device. Recombinant ACE2 and anti-tag antibody are immobilized on the nitrocellulose membrane to form Test (T) line and Control (C) line, respectively.

The S1 protein and tag protein on GNP can be captured at T line and C line when moving across nitrocellulose membrane. When NABs exist in the test sample, they will bind onto S1 protein on GNP, blocking or neutralizing the interaction between S1 and ACE-2, leading to signal at T line diminished or disappeared dependent on the level of NAB in test sample. In contrast, nothing in test sample should interfere the interaction between the tag protein and the anti-tag antibody. The C line will be always showing a colored band, serving as a built-in system positive control. The test fails if C line doesn't show up.

PACKAGE

CoNab Test is packed 18 tests per box. All kit components are listed below.

K55101-018: CoNab SARS-COV-2 NAb Lateral Flow Test Kit

Component	Quantity
CoNab SARS-COV-2 NAb Test Kit L55101-001 (foil bag)	18
Lancet	19
Transfer Pipette (20µl)	19
Alcohol pad	19
Sample Buffer	19
Instruction for Use	1
Result Analysis Reference (on the back of the box lid)	1

L55101-001: The foil bag contains one CoNab SARS-COV-2 NAb Test Strip and one desiccant bag (1g).

MATERIALS REQUIRED BUT NOT SUPPLIED

Clock or timer, biohazard waste container, disposable gloves, Band-Aid.

STORAGE AND EXPIRATION

1. Store the test kit at 4-30°C. Do Not Freeze.
2. Correctly stored kits are valid for 6 months (See the expiration date indicated on the packaging).
3. The test device should remain in its original sealed pouch until ready for use. After opening, the test device should be used immediately.
4. Do not reuse the device.
5. For long-term storage, refrigeration is recommended.

SPECIMEN COLLECTION AND PREPARATION

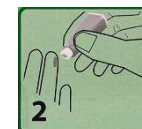
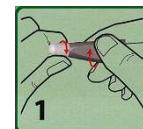
1. This test is suitable for human serum, plasma, or finger prick blood.
2. Whole blood samples must be tested immediately.
3. The test works best on fresh samples. If testing cannot be performed immediately, serum and plasma may be stored at 2-8°C up to 3 days in case of delay in testing. Avoid repeated freezing/thawing cycles.

QUALITY CONTROL

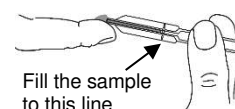
A system of quality control is included in the test. It will appear as a red line in the C line if the test has been performed correctly and the reagents are reactive.

PROCEDURE

1. Read the instructions carefully before use.
2. Bring the kit components to room temperature before testing.
3. Open the foil bag and remove all items on a flat surface. Once opened, the test strip must be used immediately.
4. If using fingertip sample, clean the collection area with alcohol pad provided. Middle finger or ring finger are recommended.



5. Puncture fingertip using the spring-loaded lancet. To use the lancet, twist its cap 360° to open it, then push gently against test site until you hear a click, hold lancet for one second before removing it from the site. Gently squeeze the finger to help bleeding for sample collection.



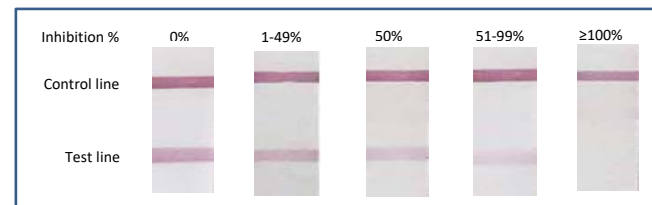
Fill the sample to this line



6. Hold the transfer pipette **horizontally without squeezing the pipette**, touch the blood with its tip, wait till blood reach the 20µl scale line, then transfer the blood to the sample hole of cassette by squeezing the bulb. (If sample won't expel, it probably means the sample does not fill to the line, please touch the tip to the blood sample again and allow it to fill completely).
7. Wait for about 20 seconds to allow the blood to settle into sample hole, then open the sample buffer dispenser and gently squeeze to add **five** drops of sample buffer into sample hole.
8. Read result within 15-30 minutes after adding test sample. Do not read result after 30 minutes.
9. If testing serum or plasma in a laboratory, make sure it is prewarmed to room temperature. Use **10µl** of sample for the test.

INTERPRETATION OF RESULTS

First of all, if the Control (C) line doesn't show up, the result is invalid. C line must be positive in any situation. The Test (T) line may show one of the following 5 results:



A product lot-specific Result Analysis Reference showing 0% and 50% inhibition is provided in each box and attached at back of the box lid as indicated. If the test line shows a color intensity equal to or less than 50%, you have developed neutralizing antibodies against SARS-CoV-2. If the T line intensity is stronger than 50%, most likely you have not developed neutralizing antibodies against SARS-CoV-2 that can be detected by this product, and we recommend you to confirm your NAb situation with a more sophisticated NAb laboratory test (ELISA or PRNT) or consult with your medical doctor.

