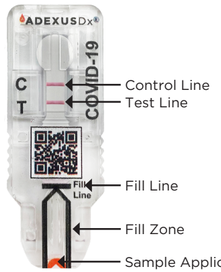
ADEXUSDx® COVID-19 Test
FINGER STICK METHOD

For use under an Emergency Use Authorization only.
For prescription use only.
For *in vitro* diagnostic use only.

IMPORTANT INFORMATION

The ADEXUSDx® COVID-19 Test is an *in vitro* lateral flow immunoassay intended for qualitative detection of total antibodies to SARS-CoV-2 in human fingerstick whole blood. The ADEXUSDx® COVID-19 Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Testing is authorized for use at the Point of Care (POC); i.e. in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.



You will need the following to conduct a test:

1. One (1) sealed aluminum pouch containing one (1) ADEXUSDx® COVID-19 Test
2. One (1) disposable, single-use sterile lancet
3. One (1) alcohol swab
4. One (1) bandage
5. Watch or timer
6. Gloves

PREPARATION

1. Make sure you have a watch or timer ready.
2. If you wear contacts or glasses, make sure that you are wearing them when you read the result.
3. Ensure the patient's hands are clean and warm.
4. Wear gloves.
5. Open a sealed pouch containing one (1) ADEXUSDx® COVID-19 Test and desiccant packet. Remove the test from the pouch and discard the desiccant packet.

   NOTE: Do not use test if pouch was not sealed. Do not use test past the expiration date.
6. Choose either the ring or middle finger of the patient for the puncture site. Wipe the end of the selected finger with an alcohol swab and allow finger to thoroughly air-dry.
7. Massage the palm and the selected finger firmly. Push on the base of the palm and direct the blood flow toward the tip of the selected finger.

DIRECTIONS

❶ Place the patient's palm upward & select where to prick

Place the patient's hand on a flat surface with the palm facing up. Place the lancet against the tip of the disinfected finger in an off-center position toward the side facing the pinky.

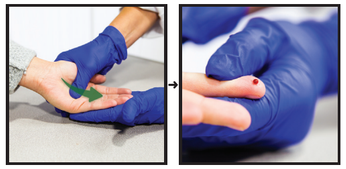
NOTE: Try not to use the center or top of the finger since these are the most sensitive areas of the finger.

❷ Prick the fingertip

Deploy lancet according to manufacturer's instructions.

❸ Get the drop of blood

Massage the finger at the base toward the tip until a drop of blood appears. Do not press directly on the punctured site. Continue massaging until you get a large, full drop of blood.



❹ Apply the drop of blood into the test

Gently touch the drop with the tip of the test (the Sample Application Zone) so that the blood can flow into the test and fill the Fill Zone.

❺ Fill the test

If one drop of blood does not fill the Fill Zone, that's okay. Set the test down and repeat steps 3 and 4 as many times as needed until the Fill Zone is full and the Fill Line is reached.

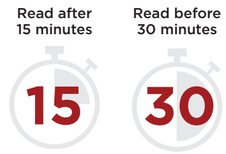
NOTE: Large bubbles within the sample or generated during sample application may cause false results.

❻ Tap the test twice

After the Fill Line is reached, hold the test with the Sample Application Zone facing up and tap the opposite end of the test twice on a hard surface. Then, lay the test on a flat surface.

❼ Set a timer

Set a timer for 15 minutes. If necessary, apply a bandage to the puncture site. Read the result after 15 minutes. Do not read the result after 30 minutes.



INTERPRETATION OF RESULTS

"C" & "T" Lines

Lines may appear at two locations, marked "C" and "T".

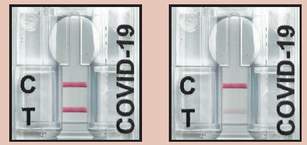
"C" stands for Control Line; it tells you if the test has worked.

"T" stands for Test Line; it tells you if the test is positive or not.

NOTE: Results from antibody testing should not be used to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

Positive Result

A positive result has TWO LINES, one at the "C" and one at the "T". The intensity of the lines may vary, so look carefully as **lines might be faint** as shown in the image on the right.



Positive Result

Positive Result

Negative Result

A line at the "C" and no line at the "T" indicate a negative result.

Negative Result

Invalid Result

If NO line appears at the "C", the test has not worked. You must retest using a new test.

Invalid Result

Invalid Result

EXTERNAL CONTROL TEST

Refer to the Product Insert for complete instructions including appropriate quality control procedures. External positive and negative controls should be tested according to the instructions provided herein.

- Mix each control vigorously for at least 5 seconds.
- Process each control sample according to ADEXUSDx® COVID-19 Test Instructions For Use. One drop from each control sample is equivalent to a volume sufficient for ADEXUSDx® COVID-19 Test performance.
- Apply one drop of control sample to the test Sample Application Zone as many times as needed until the Fill Zone is full and the Fill Line is reached.
- After the Fill Line is reached, hold the test with the Sample Application Zone facing up and tap the opposite end of the test twice on a hard surface. Then, lay the test on a flat surface.
- Set a timer for 15 minutes. Read the result after 15 minutes. Do not read the result after 30 minutes.

EXPECTED EXTERNAL CONTROL RESULTS

Positive Control Result

A positive control result has TWO LINES, one at the "C" and one at the "T".

Negative Control Result

A negative control result has ONE LINE at the "C" and no line at the "T".

Positive Control

Negative Control

- Positive and negative controls should be tested on each new shipment of reagents.
- If the controls do not give expected results, contact NOWDiagnostics via email or phone listed on this document.

ADEXUSDx®
Our lab – at the tip of your finger®

ADEXUSDx® COVID-19 Test
QUICK REFERENCE INSTRUCTIONS

QI-8075-FS
Version 1.0

For questions, please contact us at:

Phone: 1-844-207-3370
Email: cc@nowdx.com
Address: 1200 Stewart Place, Springdale, AR 72764

Do not freeze.

Store tests at 59°F-86°F (15°C-30°C).
Store controls at 35.6°F-46.4°F (2°C-8°C).

Use tests only once.

Rx Only **For EUA Only** **IVD**

A comprehensive Product Insert may be requested at no charge at 1 844-207-3370 and is available on www.c19development.com/resources/.

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for detecting the presence of total antibodies to SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3 (b)(1), unless the declaration is terminated or authorization is revoked sooner.