

Read this Product Insert completely before using the control set. Follow the instructions carefully when performing quality control of the test. Failure to follow instructions may result in inaccurate quality control results.

INTENDED USE

The ADEXUSDx® COVID-19 Control Set is a quality control (QC) set designed for monitoring the reliability of the ADEXUSDx® COVID-19 Test. It is recommended that the ADEXUSDx® COVID-19 Control Set is tested to ensure proper performance of the test each time a new lot is used, when a new operator performs the test, when a new shipment of reagents is used, and to investigate the cause of repeated invalid results.

STORAGE:

Store at 2-8°C (35.6-46.4°F)

STORAGE AND STABILITY:

The ADEXUSDx® COVID-19 Control Set should be stored at 2-8°C (35.6-46.4°F).

This product was manufactured in NOWDiagnostics, Inc. facilities based on a quality system compliant with GMP for Medical Devices and ISO 13485.

WARNINGS

- Read the Product Insert completely before using the ADEXUSDx® COVID-19 Control Set.
- 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 is for use with a test 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.

PRODUCT DESCRIPTION

Negative controls were sourced from plasma donors. Positive controls are prepared by diluting pooled plasma, positive for antibodies to SARS-CoV-2, from plasma donors with negative control plasma to achieve a low positive. All plasma samples have been heat-inactivated, defibrinated, and clarified. A low concentration of ProClin™ preservative has been added to the resultant serum controls to extend their shelf life by effectively inhibiting a broad spectrum of microbes. Negative and positive controls are plasma samples, a typical patient sample used for ADEXUSDx® COVID-19 Test performance.

MATERIALS PROVIDED:

- One (1) ADEXUSDx® COVID-19 Negative Control
- One (1) ADEXUSDx® COVID-19 Positive Control
- One (1) Product Insert

MATERIALS REQUIRED BUT NOT PROVIDED:

- ADEXUSDx® COVID-19 Test
- Watch or timer
- Gloves

PRECAUTIONS

SAFETY PRECAUTIONS

- Negative control samples are sourced from human plasma donors who tested negative for HIV, AIDS, Hepatitis B, and Hepatitis C.
- All control samples have been heat-inactivated, defibrinated, and clarified. Heat activation of samples was performed for 30 minutes at 65°C.

HANDLING PRECAUTIONS

- DO NOT USE the controls if the droppers were not sealed.
- DO NOT USE post the expiration date on the label. Expiration is indicated on the labeling as 30 days post shipment. Check the expiration date prior to use.
- Refer to CDC guidelines and local regulations for handling and disposal of positive and negative controls.

INSTRUCTIONS FOR USE

- 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.
- 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 below.

LIMITATIONS OF PROCEDURE

- Quality control materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

INQUIRIES AND GENERAL INFORMATION

Visit website c19development.com.

ORDERING INFORMATION

Laboratories may contact c19development.com/order to place an order.

CATALOG NUMBER

475.002

ITEM

ADEXUSDx® COVID-19 Control Set



ADEXUSDx®

COVID-19 CONTROL SET

For use under an Emergency Use Authorization (EUA) Only
For *in vitro* Diagnostic Use Only
For Prescription Use Only
For Quality Control of the ADEXUSDx® COVID-19 Test

PI-475.002
Version 2.0

MANUFACTURER:

NOWDiagnostics, Inc.
1200 Stewart Place
Springdale, AR 72764

Phone: 1-844-207-3370










Email: techsupport@nowdx.com

Website: www.nowdx.com

AUTHORIZED REPRESENTATIVE:

NOWDiagnostics Europe Srl
Via Campobello, 1 - 00071 Pomezia
Roma (Italy) Phone: +39 06 87678028

SYMBOL LEGEND

	Use by or Expiration Date		Lot Number
	Catalog Number or Product Code		Authorized Representative
	Manufacturer		Caution
	Consult Instructions for Use		Control
	Store between 2-8°C		