

# ADEXUSDx<sup>®</sup> 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<sup>®</sup> COVID-19 Test

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.

## STORAGE:

Store at 2-8°C (35.6-46.4°F)

## INTENDED USE:

The ADEXUSDx<sup>®</sup> COVID-19 Control Set is a quality control (QC) set designed for monitoring the reliability of the ADEXUSDx<sup>®</sup> COVID-19 Test. It is recommended that the ADEXUSDx<sup>®</sup> 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.

## 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<sup>™</sup> 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<sup>®</sup> COVID-19 Test performance.

## MATERIALS PROVIDED:

- One (1) ADEXUSDx<sup>®</sup> COVID-19 Negative Control
- One (1) ADEXUSDx<sup>®</sup> COVID-19 Positive Control
- One (1) Product Insert

## MATERIALS REQUIRED BUT NOT PROVIDED:

- ADEXUSDx<sup>®</sup> COVID-19 Test
- Watch or timer
- Gloves

## WARNINGS:

- Read the Product Insert completely before using the ADEXUSDx<sup>®</sup> 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.

## 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.

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

## STORAGE AND STABILITY:

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

## 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.
- 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/](http://c19development.com/)

### ORDERING INFORMATION:

Laboratories may contact [c19development.com/order/](http://c19development.com/order/) to place an order.

| Catalog number | Item                                       |
|----------------|--|
| 475.002        | ADEXUSDx <sup>®</sup> COVID-19 Control Set |

### MANUFACTURER:

NOWDiagnostics, Inc.

1200 Stewart Place

Springdale, AR 72764

Phone: 1-844-207-3370

E-mail Address: [techsupport@nowdx.com](mailto:techsupport@nowdx.com) or [cc@nowdx.com](mailto:cc@nowdx.com)

Website: [www.nowdx.com](http://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      |
|  | Catalog Number or Product Code |
|  | Manufacturer                   |
|  | Consult Instructions for Use   |
|  | Store between 2-8°C            |
|  | Lot Number                     |
|  | Authorized Representative      |
|  | Caution                        |
|  | Control                        |

PI-475.002 V1.0