

**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<sup>®</sup> hCG Control Set is an unassayed quality control (QC) set designed for monitoring the reliability of tests for the detection of human chorionic gonadotropin.

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

## STORAGE:

Store unopened controls frozen. Store opened controls at 2-8°C (35.6-46.4°F).

## STORAGE AND STABILITY:

Frozen, unopened controls expire on the date indicated on the label. Opened controls expire 30 days after opening.

## WARNINGS

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

## PRODUCT DESCRIPTION

hCG absent controls are sourced from male plasma donors. hCG present controls are prepared by spiking human chorionic gonadotropin (hCG) standard into pooled plasma from male donors. All plasma samples have been heat-inactivated, defibrinated, and clarified. A low concentration of ProClin™ preservative has been added to the resultant plasma controls to extend their shelf life by effectively inhibiting a broad spectrum of microbes. Both controls are plasma samples, a typical patient sample used for hCG test performance.

## MATERIALS PROVIDED:

- One (1) ADEXUSDx<sup>®</sup> Control: hCG absent
- One (1) ADEXUSDx<sup>®</sup> Control: hCG present
- One (1) Product Insert

## MATERIALS REQUIRED BUT NOT PROVIDED:

- Gloves

## PRECAUTIONS

### SAFETY PRECAUTIONS

- Plasma sourced from human plasma donors who tested negative for HIV, 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 capped.
- DO NOT USE after the expiration date or 30 days after opening, whichever comes first. Expiration date for unopened controls is indicated on the label. After opening controls are good for 30 days.
- 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 hCG test Instructions For Use. One drop from each control sample is equivalent to 50 µL.
- 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 [nowdx.com](http://nowdx.com).

## ORDERING INFORMATION

Laboratories may contact [orders@nowdx.com](mailto:orders@nowdx.com) to place an order.

### CATALOG NUMBER

401.009

### ITEM

ADEXUSDx® hCG Control Set



# ADEXUSDx®

## hCG CONTROL SET

For *in vitro* Diagnostic Use Only

For Prescription Use Only

For Quality Control of Human Chorionic Gonadotropin (hCG) Tests

PI-401.009  
Version 1.0

### MANUFACTURER:

NOWDiagnostics, Inc.  
1200 Stewart Place  
Springdale, AR 72764

**Phone:** 1-844-207-3370









**Email:** [techsupport@nowdx.com](mailto:techsupport@nowdx.com)

**Website:** [www.nowdx.com](http://www.nowdx.com)

### AUTHORIZED REPRESENTATIVE:

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**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		