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IVD

Agilent CytoDx 2.2

For In Vitro Diagnostic Use
Rx Only

Installation & Set Up Guide

Version A0, July 2024



Intended Use




















For In Vitro Diagnostic Use

Intended Use

GenetiSure Dx Postnatal Assay is a qualitative assay intended for the postnatal detection of copy number variations (CNV) and copy-neutral loss of heterozygosity (cnLOH) in genomic DNA obtained from peripheral whole blood in patients referred for chromosomal testing based on clinical presentation. GenetiSure Dx Postnatal Assay is intended for the detection of CNVs and cnLOH associated with developmental delay, intellectual disability, congenital anomalies, or dysmorphic features. Assay results are intended to be used in conjunction with other clinical and diagnostic findings, consistent with professional standards of practice, including confirmation by alternative methods, parental evaluation, clinical genetic evaluation, and counseling, as appropriate. Interpretation of assay results is intended to be performed only by healthcare professionals, board certified in clinical cytogenetics or molecular genetics. The assay is intended to be used on the SureScan Dx Microarray Scanner System and analyzed by CytoDx Software.

This device is not intended to be used for standalone diagnostic purposes, pre-implantation or prenatal testing or screening, population screening, or for the detection of, or screening for, acquired or somatic genetic aberrations.

Symbol Legend

 Catalog / code number	 In Vitro Diagnostic Medical Device
 Temperature limitation	 Manufacturer
 Consult Instructions for Use	 Use-by date
 Contains sufficient for <N> tests	 Caution
 Authorized representative in the European Community	 Batch code
 Do not reuse	 Humidity limitation
 Unique Device Identifier	 European Conformity
 Corrosive	 Reconstitute with
 Authorized representative in Switzerland	 Importer
 Federal law restricts this device to sale by or on the order of a licensed healthcare provider	

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This chapter shows you how to install Agilent CytoDx 2.2 on computers running a supported Windows operating system.

Installing Agilent CytoDx 2.2

This section includes detailed instructions and important notes for installing the Agilent CytoDx 2.2 software on a system that does not have a previous version of CytoDx installed.

Agilent CytoDx consists of two parts: a PostgreSQL database server and the client software. Once you have installed the database server and client software on one computer, you can install additional copies of the client software on client computers that have network access to the database computer.



The CytoDx software is part of the GenetiSure Dx Postnatal Assay, an in vitro diagnostic medical device.

The CytoDx software is intended for use in an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

The Health Care Organization (HCO) where CytoDx is installed is responsible for maintaining system security on computer systems where the CytoDx software is installed.

The CytoDx software is a clinical laboratory application appropriate for use on computers and networks that meet all relevant security requirements for Electronic Protected Health Information (EPHI). Applicable administrative, physical, and technical safeguards must be in place prior to the installation and use of the CytoDx application.

- Computer systems must be physically and electronically protected
 - HCO policies must be in place allowing only authorized users access to these systems
 - An endpoint security solution must be installed on these systems that includes Virus, Spyware, Proactive, and Network threat protection
 - Systems must be set to automatically secure themselves after periods of inactivity
 - System and application security logs and audit trails must be monitored and evaluated against potential threats
-

Step 1. Prepare for installation

a. Download the Agilent CytoDx installer and release notes

- 1 Go to the Agilent CytoDx website at <https://genetisuredx.agilent.com/user-portal/cytodx-download>.
- 2 Download the Agilent CytoDx 2.2 installer and the Agilent CytoDx 2.2 release notes. Do not start the installation until you have completed the remaining preparation steps.

b. Check system requirements before you start

Check to make sure that your computer systems meet the requirements in [Table 1](#).

Table 1 Minimum Requirements for Agilent CytoDx computers

Operating system	64-bit Windows 10 and Windows 11 Enterprise or Windows Server 2022
Programs	Any program that enables you to open PDF files (for example, Adobe Reader)
Processor	> 2 GHz (> 3 GHz recommended)
Working memory (RAM)	8 GB (12 GB recommended)
Hard disk space	500 GB
Display Resolution	1280 x 768 or higher

c. Set up permissions for Installer and users

- Make sure that the user account used to install the Agilent CytoDx software has administrator permissions on the installation computer.
- Make sure that every user account running the Agilent CytoDx software has read/write permissions on the computer where the client software is installed. In addition, users must have read/write permissions in the installation folder of the computer where the database server is installed.

Contact your network administrator for help in checking or changing user account permissions. If the user account permissions are not set correctly, the software will fail to install or run properly.

1 CytoDx Installation Instructions

Step 2. Install the database server and client on a single computer

d. Adjust user account settings

Change the User Account Control settings from the default setting to “Never Notify.”

- 1 Go to Control Panel.
- 2 Click **User Accounts**.
- 3 Click **Change User Account Control setting**.
- 4 Change the setting to “Never Notify” and click **OK**.
- 5 Restart the machine.

Step 2. Install the database server and client on a single computer

CytoDx is a client-server software application. Only one copy of the server software is installed. The client software can be installed on multiple computers, including on the computer that runs the server software. The client is the program you run when you want to use Agilent CytoDx (the database server software runs silently in the background and manages the shared database for all Agilent CytoDx users). All client computers must have network access to the server computer and users must have read/write permissions.

- 1 Log on to the Windows system where you want to install Agilent CytoDx server. Use an account that has administrator permissions.
- 2 Locate the installation program that you downloaded in Step 1, “[a. Download the Agilent CytoDx installer and release notes](#)” on page 8. Double-click the Agilent CytoDx 2.2 application file to start the installation wizard.

The following message is displayed.

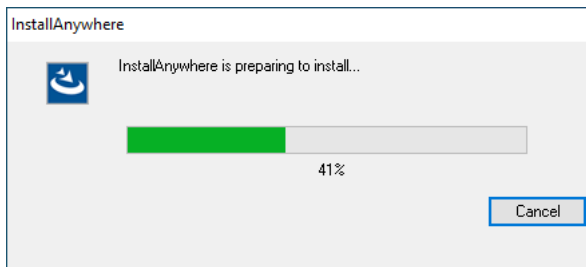


Figure 1 InstallAnywhere dialog box - preparing to install

Step 2. Install the database server and client on a single computer

The installation wizard starts.

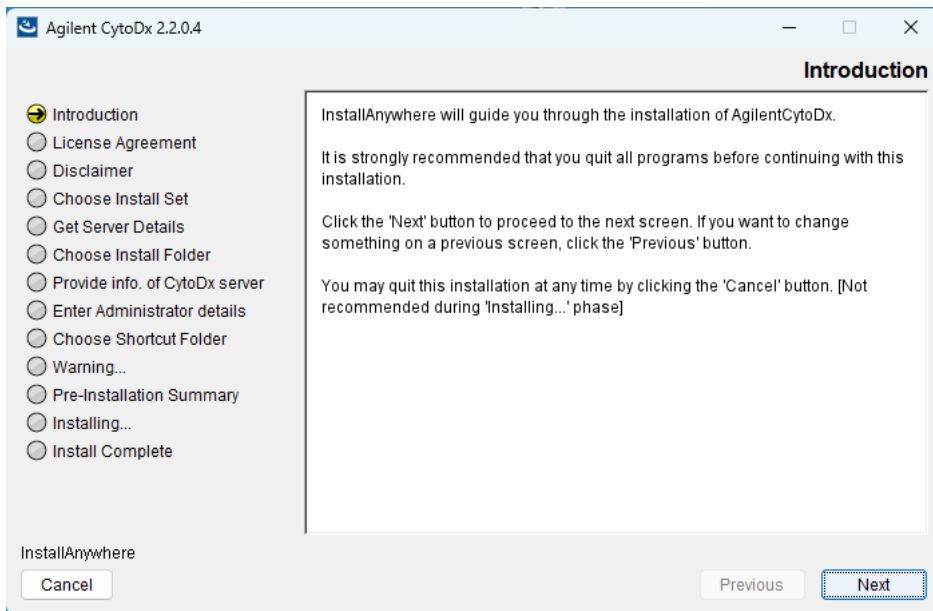


Figure 2 Introduction screen for the installation wizard

3 Read the introductory information.

4 Click **Next**.

The License Agreement screen opens.

1 CytoDx Installation Instructions

Step 2. Install the database server and client on a single computer

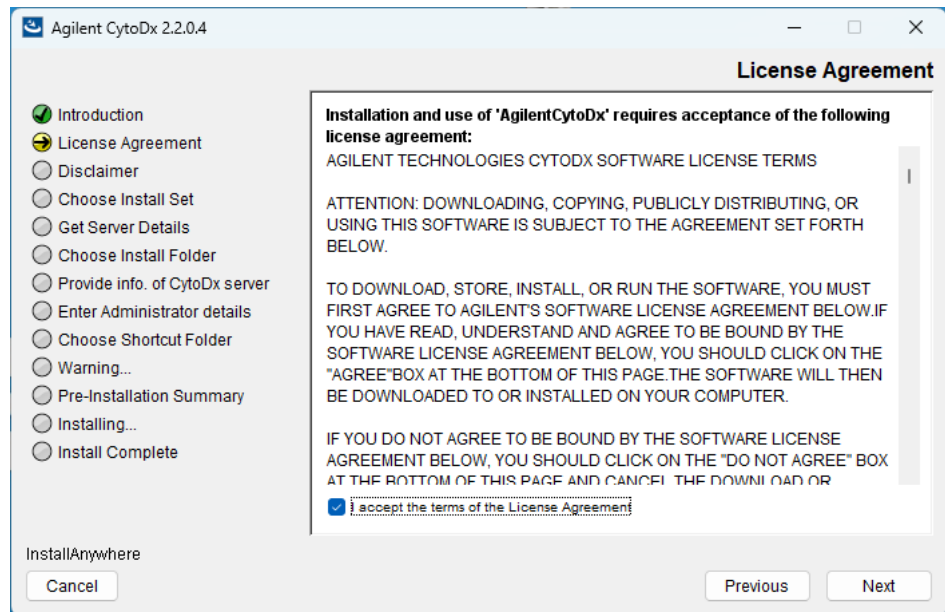


Figure 3 License Agreement screen

- 5 Read the license agreement. Mark **I accept the terms of the License Agreement** and then click **Next**. (Click **Previous** to review information in a previous section.)

The Disclaimer screen opens.

Step 2. Install the database server and client on a single computer

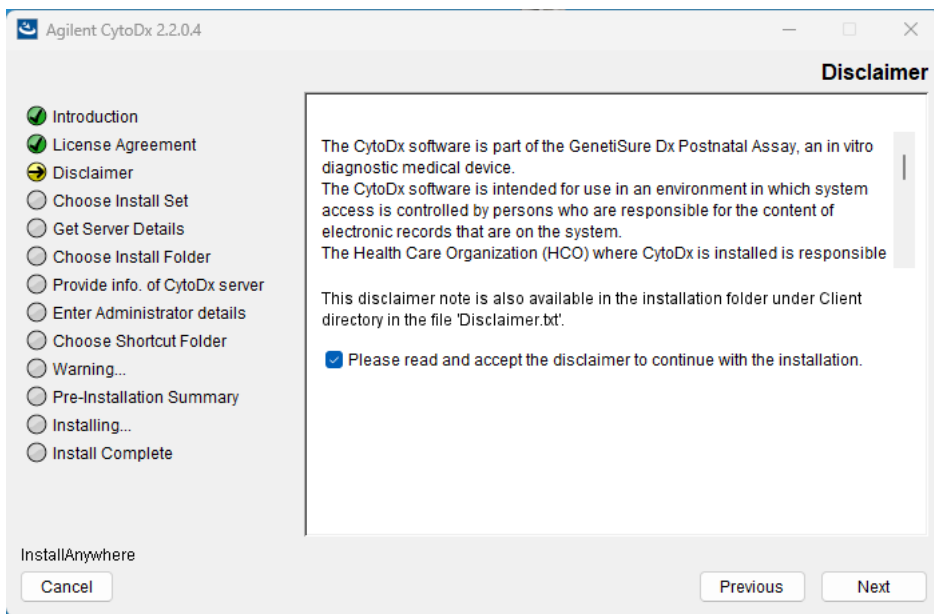


Figure 4 Disclaimer screen

- 6 Read the disclaimer on the screen. To acknowledge and accept the conditions of the disclaimer, mark the check box and click **Next**. The Choose Install Set screen opens.

1 CytoDx Installation Instructions

Step 2. Install the database server and client on a single computer

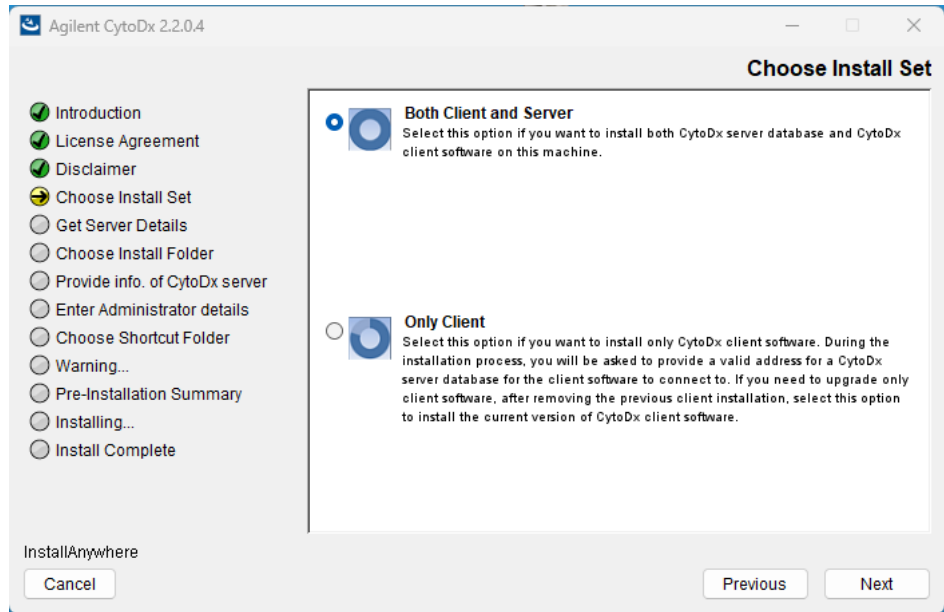


Figure 5 Choose Install Set screen

7 Select **Both Client and Server** to install both the database server and client software on this computer.

8 Click **Next**.

An Information message opens. Click **OK** to continue. The Choose Install Folder screen opens.

Step 2. Install the database server and client on a single computer

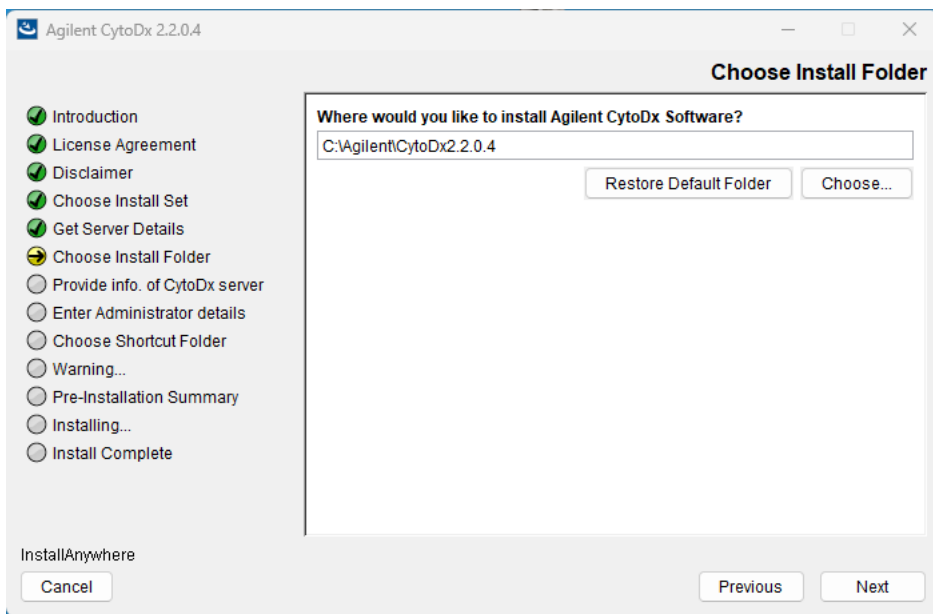


Figure 6 Choose Install Folder screen

- 9** By default, the program is installed in: C:\Agilent\CytoDx2.2.X.X (where X.X is the revision number). Leave this folder as-is, or type the location and name of the folder where you want to install Agilent CytoDx. Alternatively, click **Choose**, browse to a location where you want to install the program, and then click **Save**.

Make sure to install CytoDx on a drive with at least 500 GB of hard drive space available.

Within the installation folder, a subfolder is created for the server software and another subfolder is created for the client software.

- 10** Click **Next**.

The Enter Administrator details screen opens.

1 CytoDx Installation Instructions

Step 2. Install the database server and client on a single computer

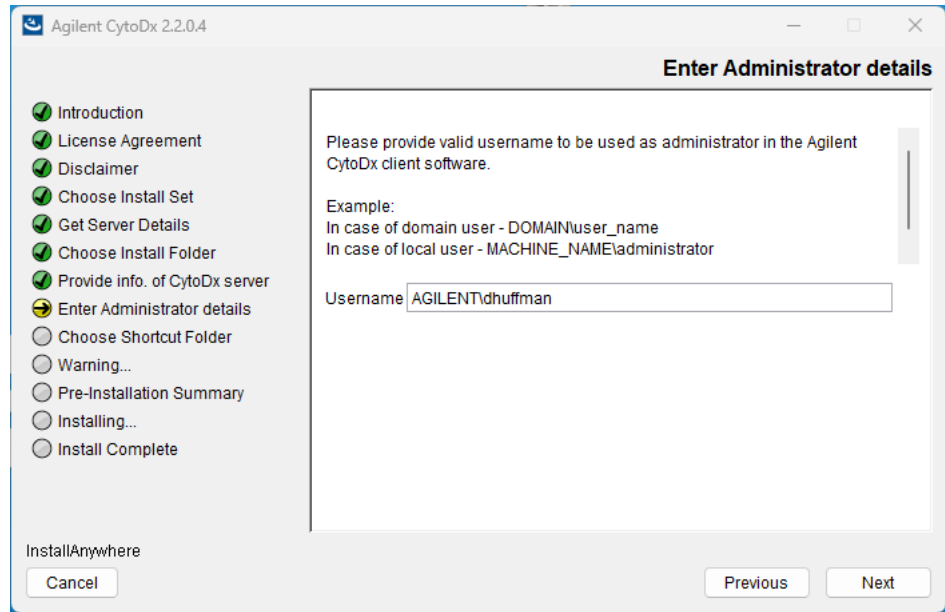


Figure 7 Enter Administrator details screen

11 The domain and user name of the person currently logged on to the computer appear in Username. If this Username is not the System Admin for the Agilent CytoDx software, type the correct user, using the format example shown.

For domain user: DOMAIN\username

For local machine: MACHINENAME\username

12 Click **Next**.

The Choose Shortcut Folder screen opens.

Step 2. Install the database server and client on a single computer

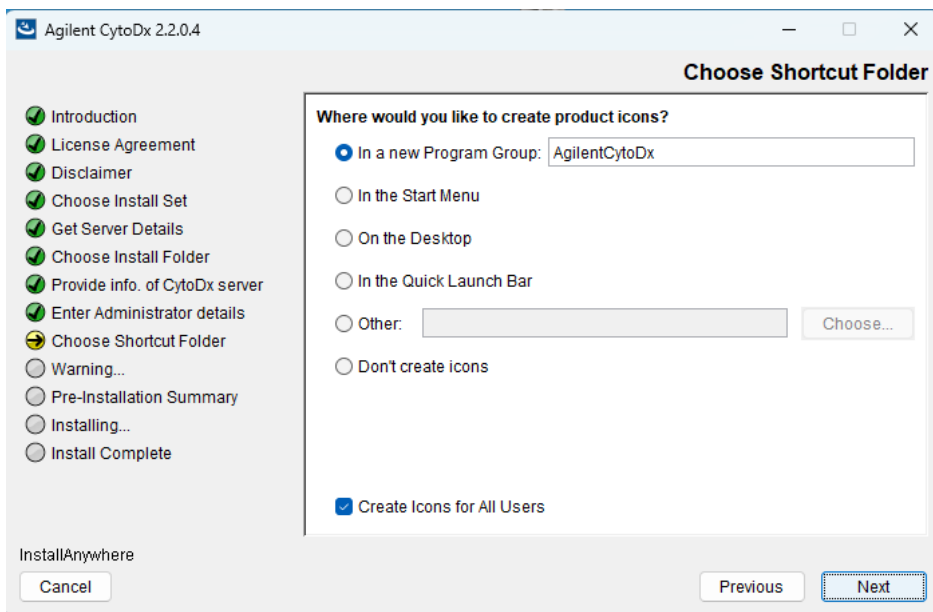


Figure 8 Choose Shortcut Folder screen

13 By default, program icons are installed in the Agilent CytoDx 2.2.X.X program group on your computer (where X.X is the revision number). To select another location for the program icons, select the desired location (on the desktop, for example) and then click **Next**.

NOTE

If more than one user plans to use Agilent CytoDx on this computer, select **Create Icons for All Users**. Otherwise, other users do not see the program icons.

The Warning screen opens.

1 CytoDx Installation Instructions

Step 2. Install the database server and client on a single computer

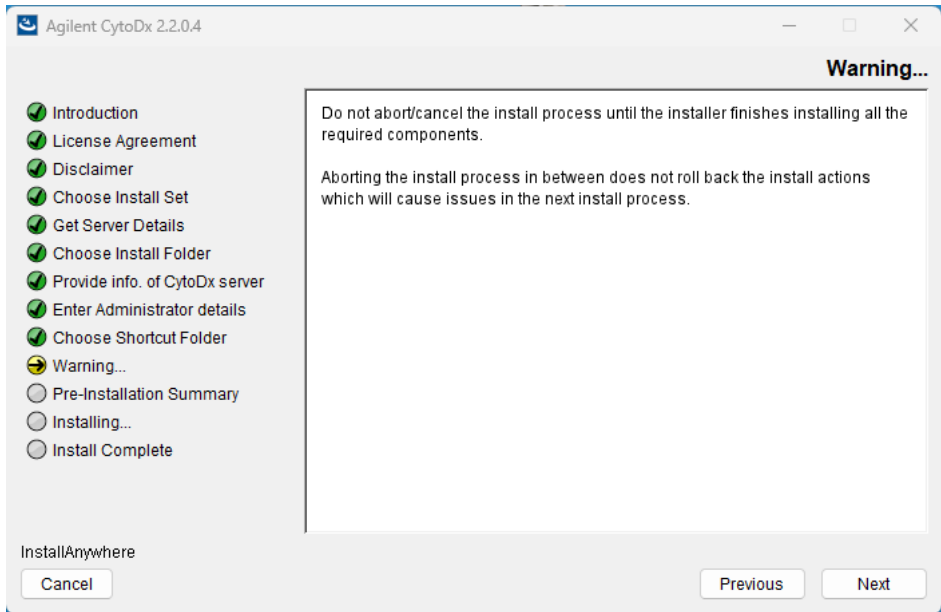


Figure 9 Warning screen

14 Read the message that cautions you not to stop the installation once it has started, and then click **Next**.

The Pre-Installation Summary screen opens.

Step 2. Install the database server and client on a single computer

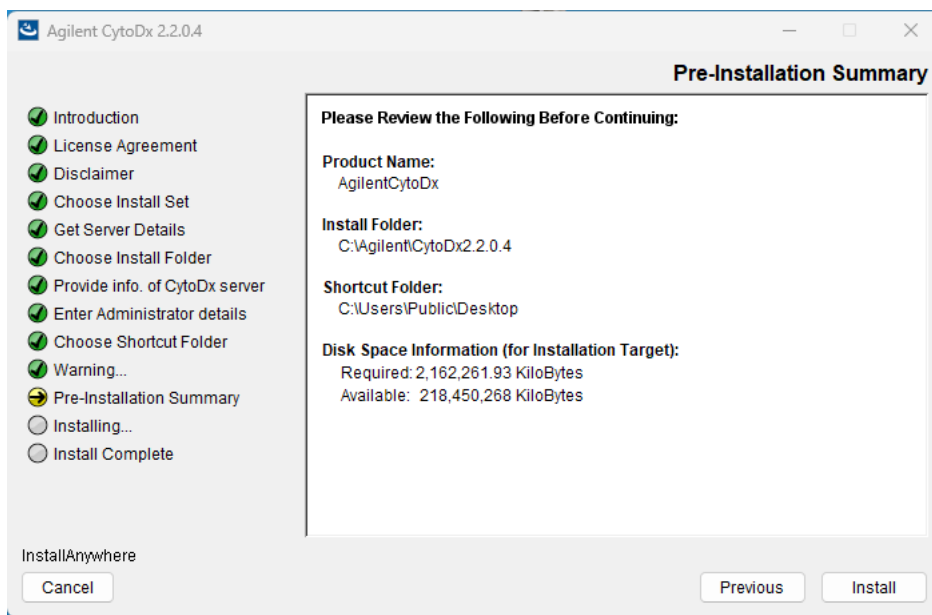


Figure 10 Pre-Installation Summary screen

15 Review the installation setup information. If you want to change any of the settings, click **Previous** and go back and change the settings. To start the installation, click **Install**.

The Installing Agilent CytoDx screen opens and is displayed until the installation is complete.

1 CytoDx Installation Instructions

Step 3. Install the client software on additional Windows computers

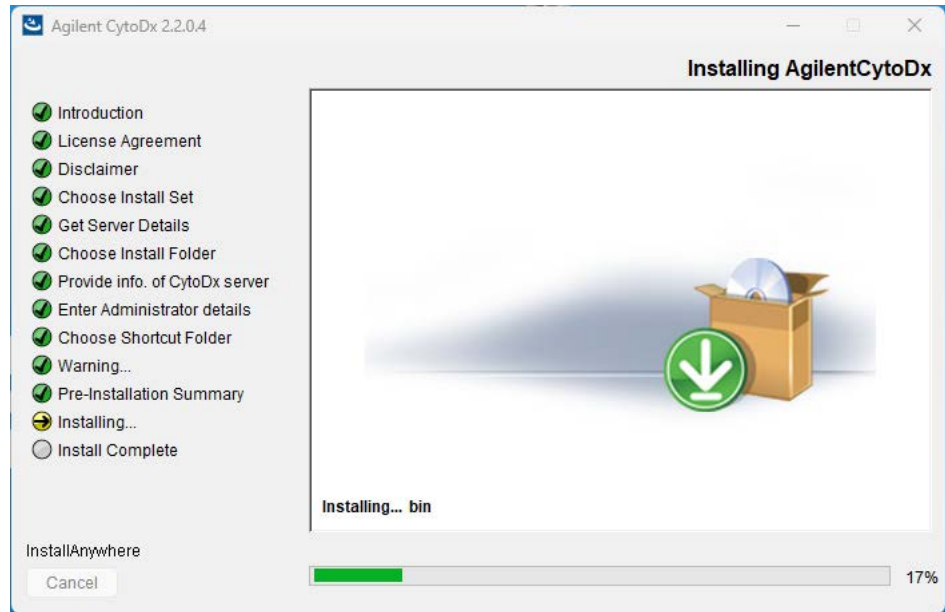


Figure 11 Installing Agilent CytoDx screen

When the installation is complete, the Installation Complete screen opens.

16 Click Done.

17 Make sure the folder where you installed the software is shared with read/write permission for all client computers and for all users who run Agilent CytoDx.

Step 3. Install the client software on additional Windows computers

To use other computers to run Agilent CytoDx client software (with a shared database), install the client software on each of the computers.

- 1** On each computer you want to run the Agilent CytoDx program, run the installation wizard, as described in “[Step 2. Install the database server and client on a single computer](#)” on page 9.
- 2** When the Choose Install Set screen opens, select **Only Client**.

Step 3. Install the client software on additional Windows computers

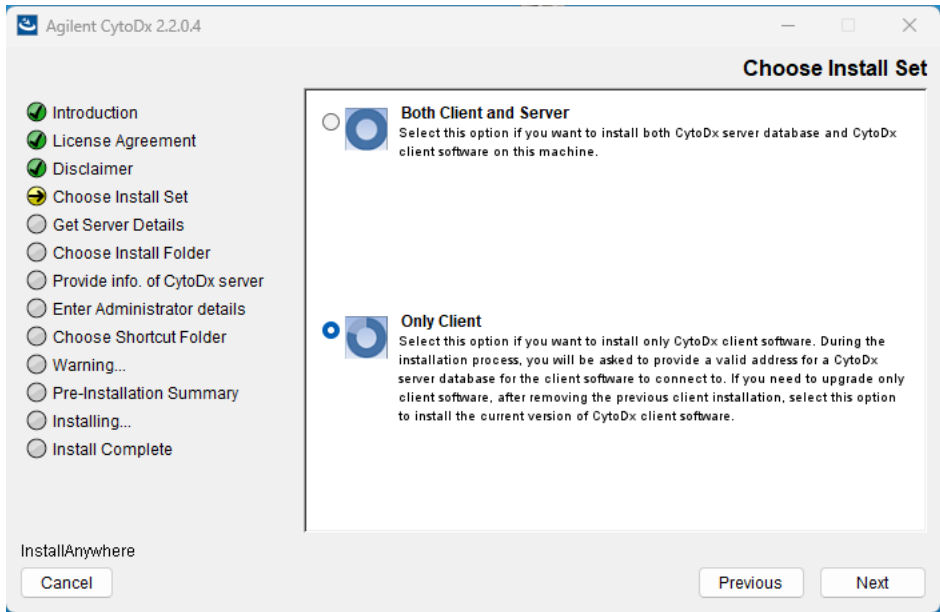


Figure 12 Choose Install Set screen – select **Only Client**

3 Click **Next**.

The following dialog box opens to inform you that you have selected to only install the CytoDx client.



Figure 13 Dialog box – Agilent CytoDx software installation

4 Click **OK** in the dialog box to continue.

The Choose Install Folder screen opens.

1 CytoDx Installation Instructions

Step 3. Install the client software on additional Windows computers

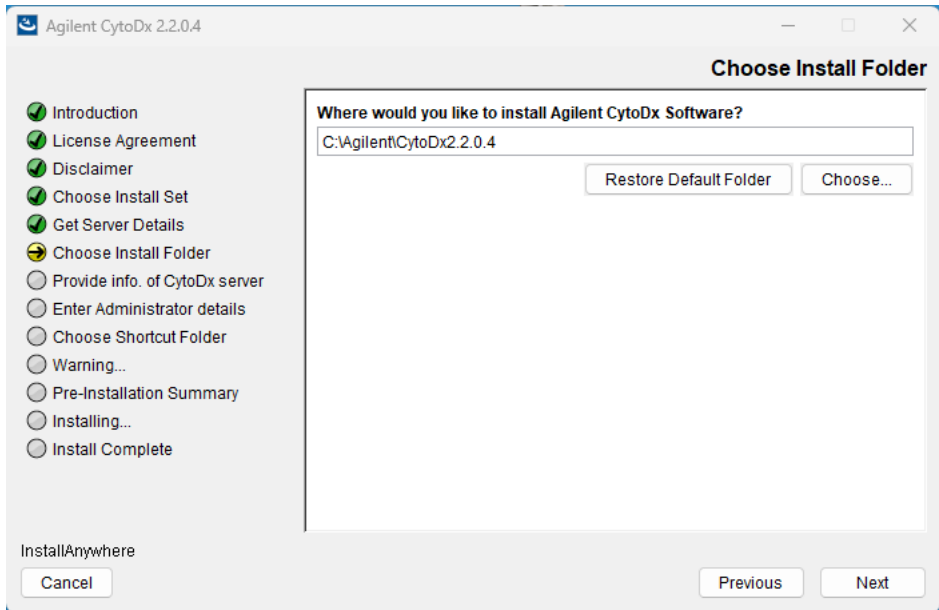


Figure 14 Choose Install Folder screen

- 5 By default, the program is installed in C:\Agilent\CytoDx2.2.X.X (where X.X is the revision number). Leave this folder as-is, or type the location and name of the folder where you want to install Agilent CytoDx.

OR

Click **Choose** and browse to a location where you want to install the program, and then click **Save**.

- 6 Click **Next**.

The Provide Info. of CytoDx server screen opens.

Step 3. Install the client software on additional Windows computers

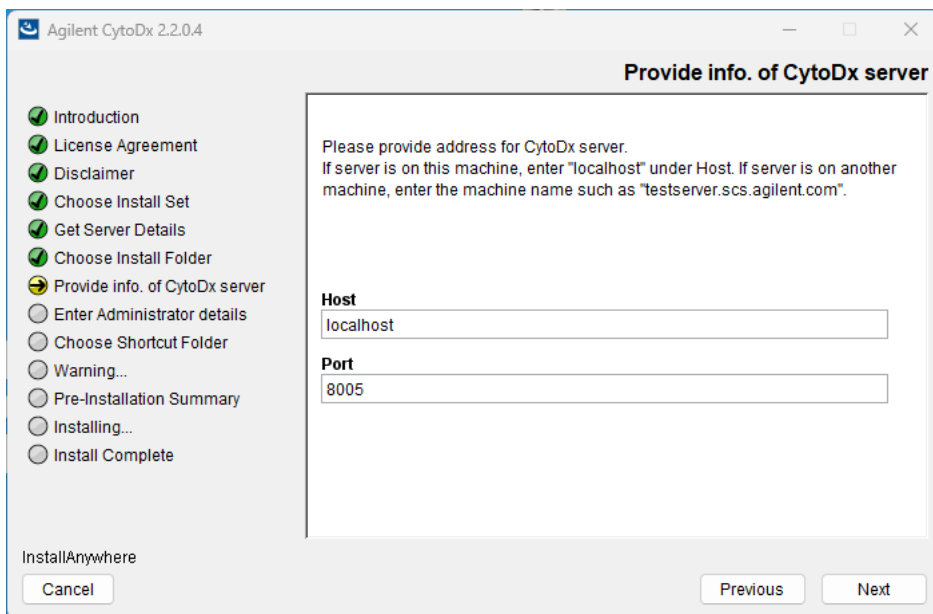


Figure 15 Provide Info. of CytoDx Server screen

- 7 Under **Host**, type the assigned computer name or IP address of the computer (from [step 2](#)) where you installed the Agilent CytoDx database server.

To find the name of your current computer, click **Start > Control Panel > System and Security > System** (Windows 10 and Windows Server 2022) or **Start > Control Panel > System** (Windows 11).

The name of the database service is `CYTODX_SERVICE`.

- 8 Accept the default **Port**, unless your system administrator tells you otherwise. The default port is 8005.
- 9 Click **Next**.

Installer immediately tests the connection to the specified database. If incorrect database parameters are provided, or the PostgreSQL database service is not running, a message is displayed.

You can choose to complete the installation and change database connection parameters when launching the client software. However, Agilent recommends that you provide the correct database information during installation.

1 CytoDx Installation Instructions

Step 4. Start the Agilent CytoDx client software

Continue the installation wizard. The next screen is the Choose Shortcut Folder screen. Follow the instructions for the installation wizard to choose a shortcut location and start the installation. For information, see [step 13 \(page 16\)](#) through [step 17 \(page 19\)](#) in the section “[Step 2. Install the database server and client on a single computer](#)”.

Step 4. Start the Agilent CytoDx client software

After you install the Agilent CytoDx database server and client programs, start the program.

- Double-click the Agilent CytoDx icon, or select Agilent CytoDx from the Windows Start menu.

NOTE

How you start the program depends on the choice you made for Shortcut Folder during installation of the Agilent CytoDx client.

Step 5. Log in to Agilent CytoDx

After you start the program, the Login screen opens. The name and domain for the System Admin set during installation appears in the dialog box.

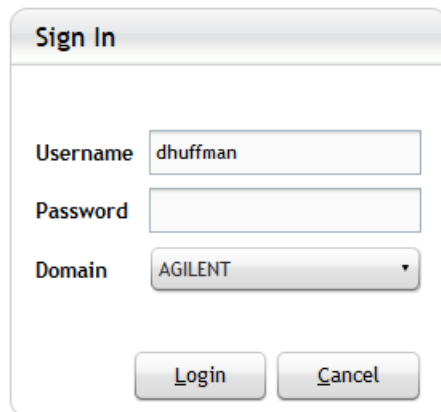
A screenshot of a 'Sign In' dialog box. The dialog has a title bar with the text 'Sign In'. Below the title bar, there are three input fields: 'Username' with the text 'dhuffman', 'Password' which is empty, and 'Domain' with a dropdown menu showing 'AGILENT'. At the bottom of the dialog, there are two buttons: 'Login' and 'Cancel'.

Figure 16 Sign In panel of the Login screen

Step 6. Add your software license and launch the software

- 1 Log in with your user name and password. After the software is started, a System Admin can add additional users and assign their roles.
- 2 Next to **Password** type your password.
- 3 To change the domain, click the arrow next to **Domain** and select the correct domain. Otherwise, leave it as-is.
- 4 Click **Ok**.

NOTE

If you are using a local machine that is not part of a domain, you see a message that the software cannot find the domain. Click **OK** to ignore this message.

Step 6. Add your software license and launch the software

When you log in for the first time, the Enter License dialog box opens (Figure 17).

- 1 If you do not already have the license file saved to your computer, click **Request for license** to open the Agilent website to the CytoDx license request page. Enter the username and password for your GenetiSure Dx account, which was created by Agilent upon purchase of the GenetiSure Dx Postnatal Assay. You will then be directed to a license request form. Complete the form on the page, making sure to select the appropriate version of the CytoDx software. When the form is complete, submit your request for a license.

Agilent will send you the license file, at no charge, within 24 hours. The license is contained in a text file. Each computer on which you install CytoDx needs its own license file. The license is specific to the version of CytoDx that you selected in the request form.

1 CytoDx Installation Instructions

Step 6. Add your software license and launch the software

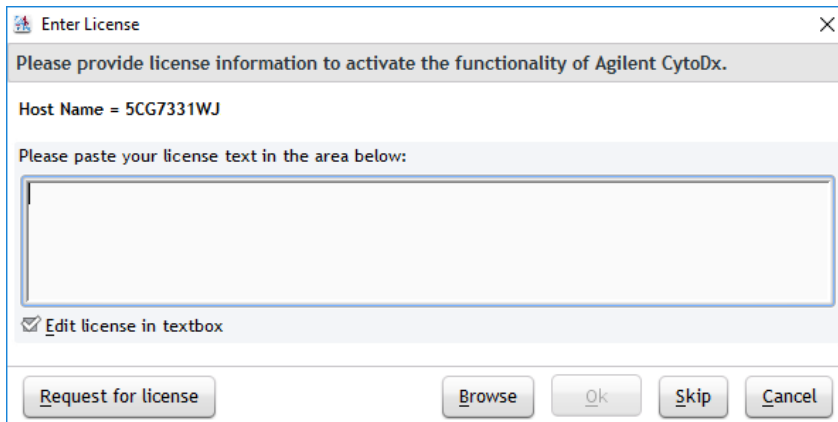


Figure 17 Enter License dialog box

- 2 At the bottom of the Enter License dialog box, click **Browse**.
The Open dialog box opens.
- 3 Browse to the saved license text file. Select the file and click **Open**.
The program loads the contents of the file into the text box on the Enter License dialog box.
- 4 Click **OK**.
The Agilent CytoDx program opens to the Home screen ([Figure 18](#)).

Step 6. Add your software license and launch the software

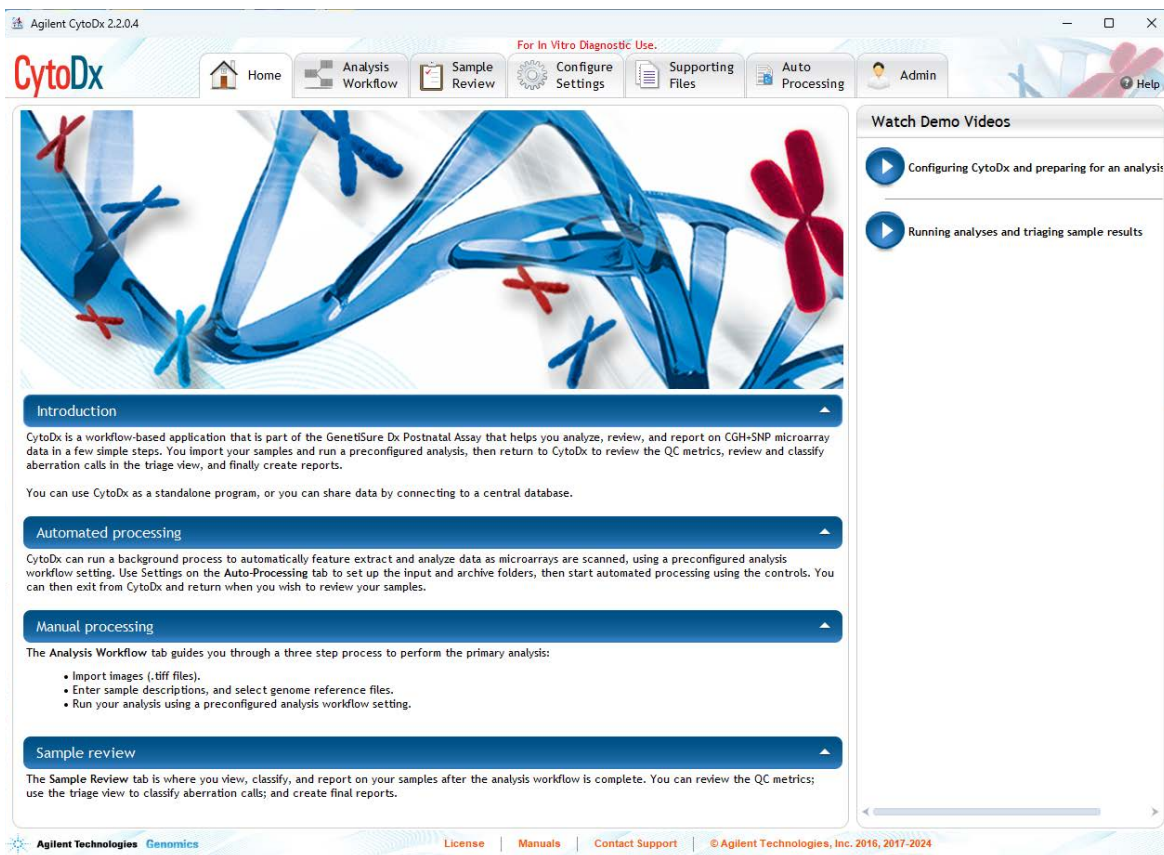


Figure 18 Agilent CytoDx program Home screen

1 CytoDx Installation Instructions

Step 1. Upgrade to CytoDx 2.2 on the server computer

Upgrading from CytoDx 2.0 or 2.1 to CytoDx 2.2

NOTE

When upgrading from CytoDx 2.0/2.1 to CytoDx 2.2, you need to uninstall the existing CytoDx client application, then install the CytoDx 2.2 client and server. You do not need to migrate data from the previous version to the new version.

These instructions are for users of CytoDx 2.0 or 2.1 who want to upgrade to CytoDx 2.2 while retaining all records currently in their database.

For instructions on upgrading to CytoDx 2.2 from a version prior to 2.0, see [“Upgrading from an Older Version of CytoDx and Migrating Data”](#) on page 40.

If you want to upgrade from a previous version of CytoDx to CytoDx 2.2, but do not want to retain the records in your current database, first completely uninstall your existing version of CytoDx (see [“Uninstalling Agilent CytoDx server and client software”](#) on page 50), then follow the instructions in [“Installing Agilent CytoDx 2.2”](#) on page 7.

Step 1. Upgrade to CytoDx 2.2 on the server computer

- 1 Download CytoDx 2.2 from Agilent Technologies and check the system requirements.

See [“a. Download the Agilent CytoDx installer and release notes”](#) on page 8 for detailed instructions on this step.

- 2 Double-click the CytoDx 2.2.X.X application file that you downloaded from Agilent.
- 3 On the Introduction screen, read the introductory information and then click **Next**.

The License Agreement screen opens.

- 4 Read the license agreement. Click **I accept the terms of the License Agreement** and then click **Next**.

The Disclaimer screen opens.

Step 1. Upgrade to CytoDx 2.2 on the server computer

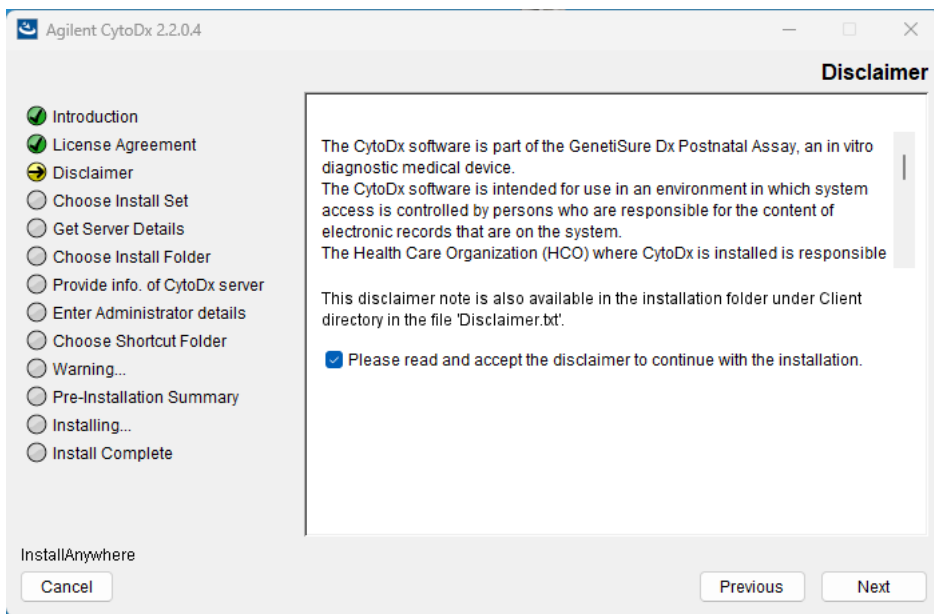


Figure 19 Disclaimer screen

- 5 Read the disclaimer on the screen. To acknowledge and accept the conditions of the disclaimer, mark the check box and click **Next**.
The Choose Install Set screen opens.

1 CytoDx Installation Instructions

Step 1. Upgrade to CytoDx 2.2 on the server computer

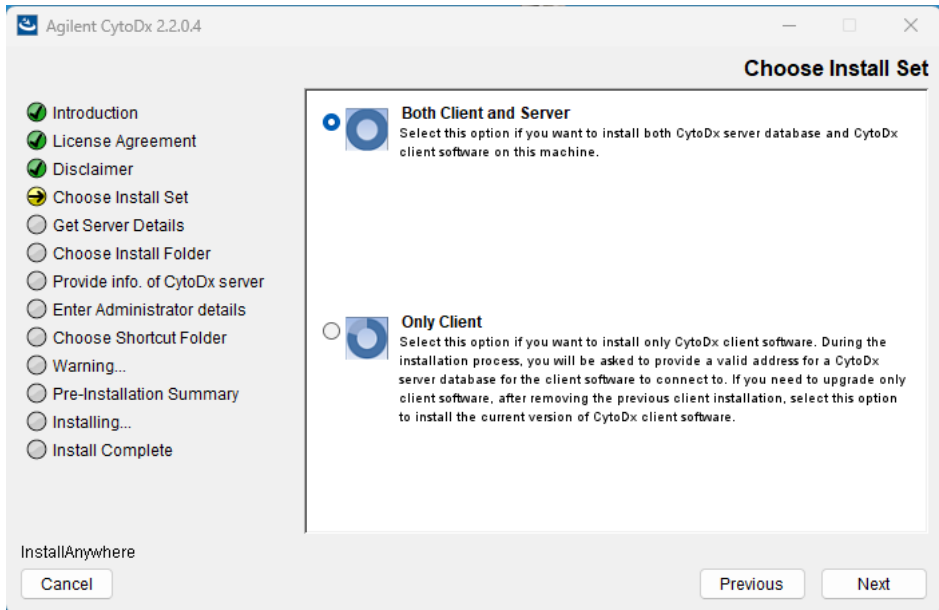


Figure 20 Choose Install Set screen - select **Both Client and Server**

6 On the Choose Install Set screen, select **Both Client and Server**.

7 Click **Next**.

The Information dialog box shown in [Figure 21](#) opens, notifying you that the CytoDx client application is already installed and must be uninstalled before proceeding with the upgrade.

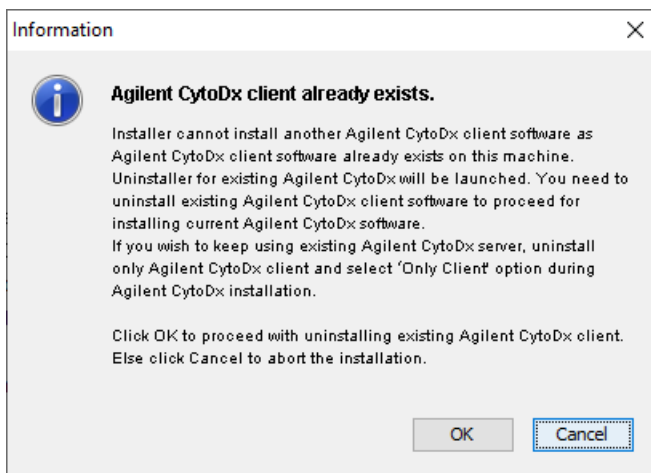


Figure 21 Dialog box – Agilent CytoDx client already exists

- 8** Click **OK** in the Information dialog box to launch the CytoDx Uninstaller.
The Uninstaller program starts.
- 9** Read the introductory information on the Uninstaller screen, and then click **Next**.
- 10** Read the warning information. You are cautioned not to stop the Uninstaller once it has started to remove the programs. Click **Next**.
The Uninstall Options screen opens.

1 CytoDx Installation Instructions

Step 1. Upgrade to CytoDx 2.2 on the server computer

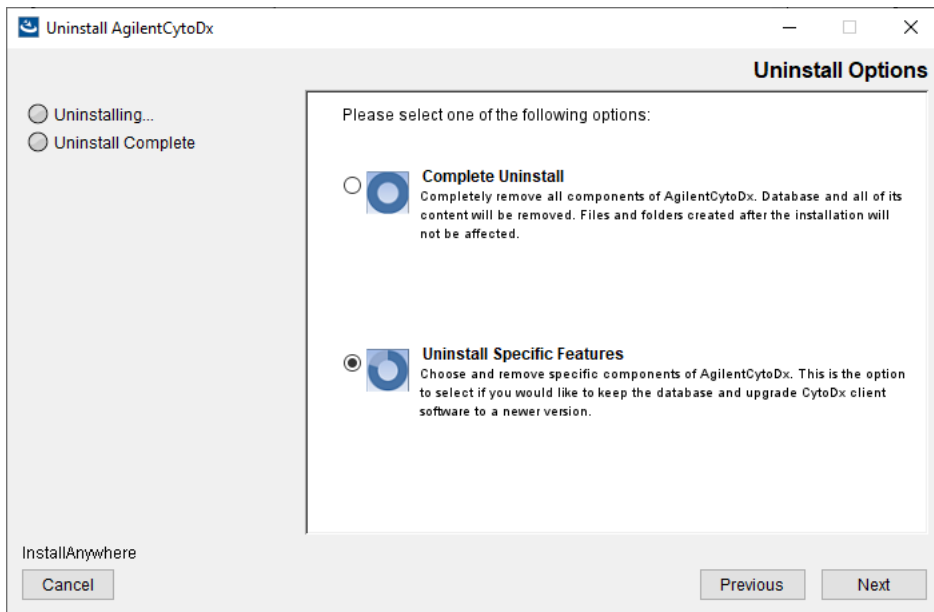


Figure 22 Uninstall Options screen – select **Uninstall Specific Features**

11 Select **Uninstall Specific Features**.

12 Click **Next**.

The Choose Product Features screen opens.

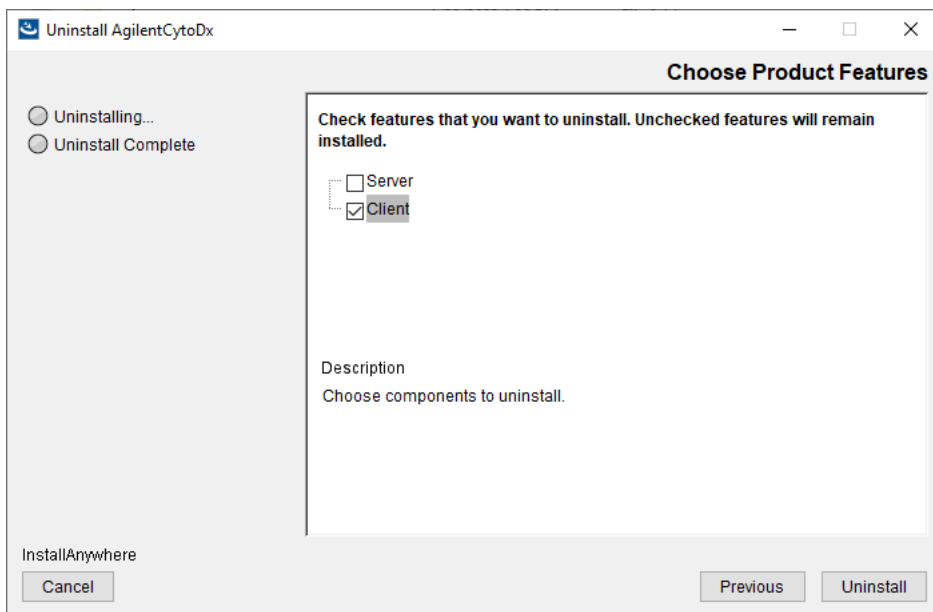


Figure 23 Choose Product Features screen – mark **Client**

13 Mark the check box labeled **Client**.

14 Click **Uninstall**.

A message box opens asking you to confirm that you want to uninstall the CytoDx client software.

15 Click **Yes** in the message box to continue.

The Uninstalling Agilent CytoDx screen opens and is displayed until the uninstallation is complete.

When the uninstallation is complete, the Uninstall Complete screen opens.

16 Click **Done** to close the Uninstaller.

The Agilent CytoDx client program was removed from your computer. You are returned to the installer for CytoDx 2.2 at the Choose Install Set screen with the **Both Client and Server** option selected.

17 Click **Next** on the [Choose Install Set](#) screen.

A message box opens notifying you that CytoDx server is already installed and will be upgraded to the latest version.

1 CytoDx Installation Instructions

Step 2. Upgrade to CytoDx 2.2 on the client computers

18 Click **OK** in the message box to continue.

The Choose Install Folder screen opens.

19 At the Choose Install Folder screen, the default folder for installation of the program is C:\Agilent\AgilentCytoDx2.2.X.X (where X.X is the revision number). Leave this folder as-is, or click **Choose** and browse to a location where you want to install the program, and then click **Save**.

NOTE

The client software is installed to the folder indicated in the Choose Install Folder screen. The server software remains in the program folder for the previous version of CytoDx.

20 Click **Next**.

The Choose Shortcut Folder screen opens.

21 Continue the installation wizard.

See [step 13](#) through [step 17](#) in the section “[Step 2. Install the database server and client on a single computer](#)” on page 9.

Step 2. Upgrade to CytoDx 2.2 on the client computers

1 Download CytoDx 2.2 from Agilent Technologies and check the system requirements.

See “[a. Download the Agilent CytoDx installer and release notes](#)” on page 8 for detailed instructions on this step.

2 Double-click the CytoDx 2.2.X.X application file that you downloaded from Agilent.

3 On the Introduction screen, read the introductory information and then click **Next**.

The License Agreement screen opens.

4 Read the license agreement. Click **I accept the terms of the License Agreement** and then click **Next**.

The Disclaimer screen opens.

Step 2. Upgrade to CytoDx 2.2 on the client computers

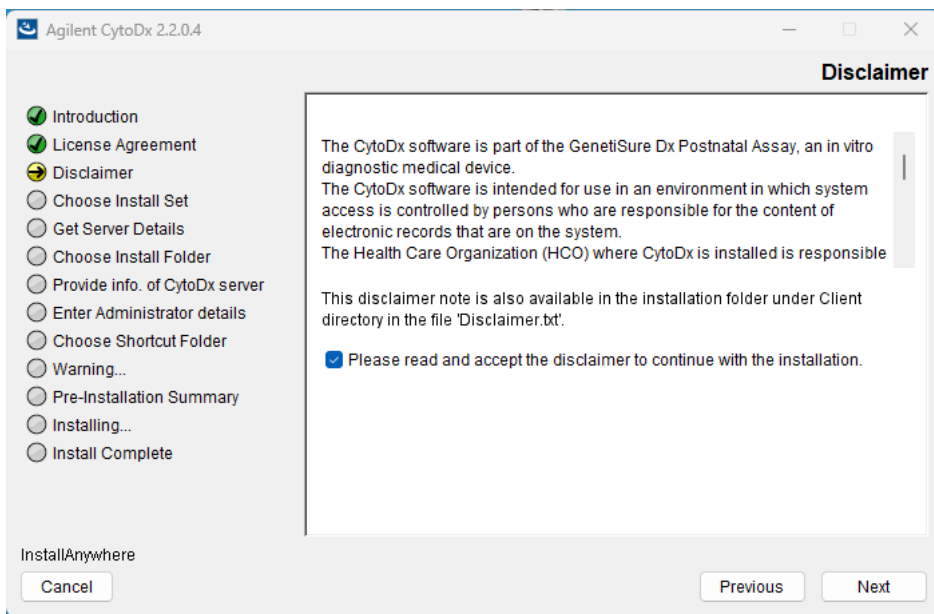


Figure 24 Disclaimer screen

- 5 Read the disclaimer on the screen. To acknowledge and accept the conditions of the disclaimer, mark the check box and click **Next**.
The Choose Install Set screen opens.

1 CytoDx Installation Instructions

Step 2. Upgrade to CytoDx 2.2 on the client computers

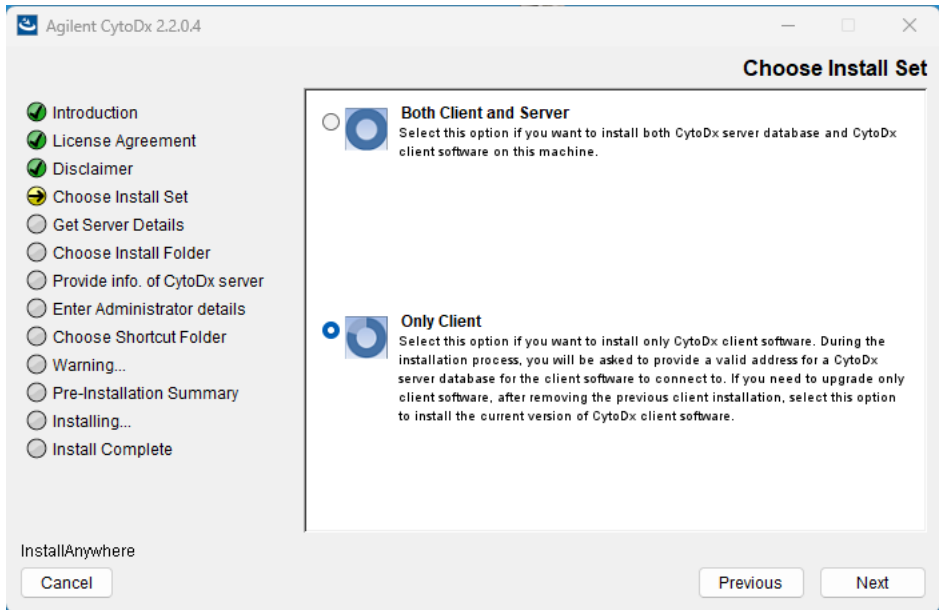


Figure 25 Choose Install Set screen - select **Only Client**

6 On the Choose Install Set screen, select **Only Client**.

7 Click **Next**.

The Information dialog box shown in [Figure 21](#) opens, notifying you that the CytoDx client application is already installed and must be uninstalled before proceeding with the upgrade.

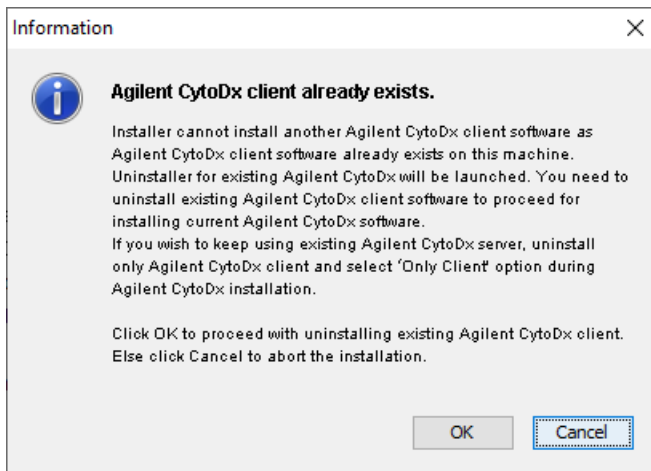


Figure 26 Dialog box – Agilent CytoDx client already exists

- 8** Click **OK** in the Information dialog box to launch the CytoDx Uninstaller.
The Uninstaller program starts.
- 9** Read the introductory information on the Uninstaller screen, and then click **Next**.
- 10** Read the warning information. You are cautioned not to stop the Uninstaller once it has started to remove the programs. Click **Next**.
The Uninstall Options screen opens.

1 CytoDx Installation Instructions

Step 2. Upgrade to CytoDx 2.2 on the client computers

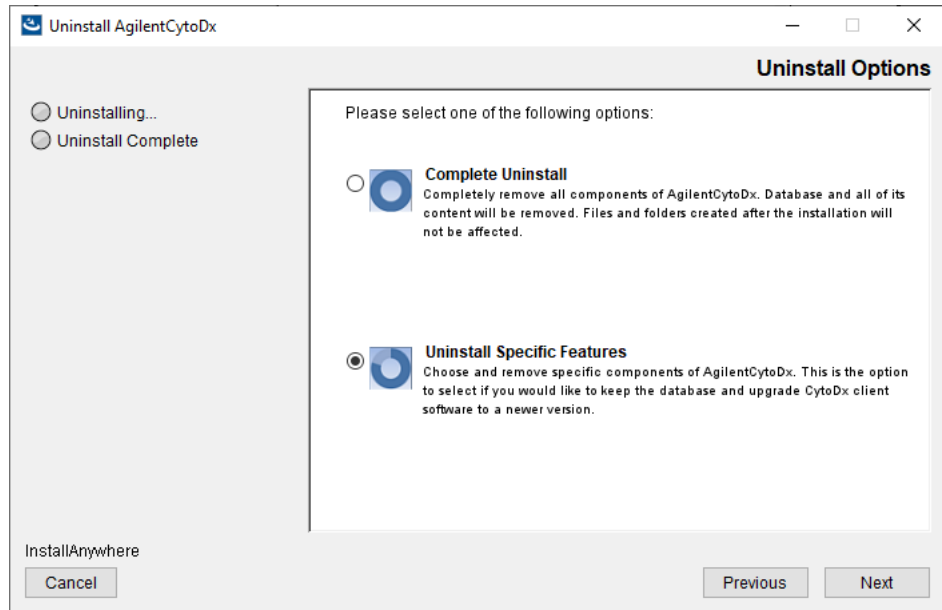


Figure 27 Uninstall Options screen – select **Uninstall Specific Features**

11 Select **Uninstall Specific Features**.

12 Click **Next**.

The Choose Product Features screen opens.

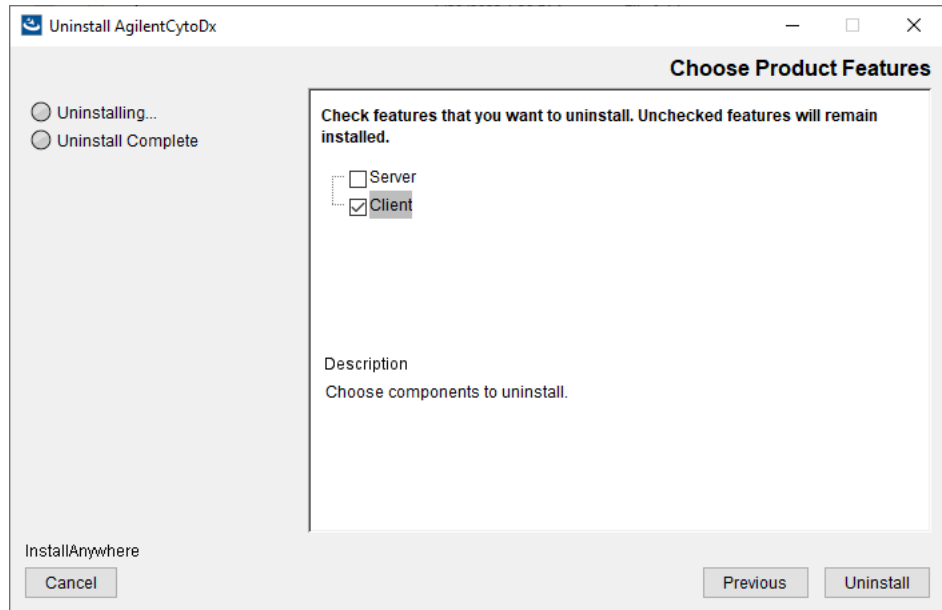


Figure 28 Choose Product Features screen – mark **Client**

13 Mark the check box labeled **Client**.

14 Click **Uninstall**.

A message box opens asking you to confirm that you want to uninstall the CytoDx client software.

15 Click **Yes** in the message box to continue.

The Uninstalling Agilent CytoDx screen opens and is displayed until the uninstallation is complete.

When the uninstallation is complete, the Uninstall Complete screen opens.

16 Click **Done** to close the Uninstaller.

The Agilent CytoDx client program was removed from your computer. You are returned to the installer for CytoDx 2.2 at the Choose Install Set screen with the **Only Client** option selected.

17 Click **Next** on the Choose Install Set screen.

The following dialog box opens to inform you that you have selected to only install the CytoDx client.

1 CytoDx Installation Instructions

Step 3. Start the Agilent CytoDx client software, log in, and add new software license



Figure 29 Dialog box – Agilent CytoDx software installation

18 Click **OK** in the dialog box to continue.

The Choose Install Folder screen opens.

19 Continue the installation wizard.

See [step 5](#) through [step 9](#) in the section “[Step 3. Install the client software on additional Windows computers](#)” on page 19.

Step 3. Start the Agilent CytoDx client software, log in, and add new software license

1 On the server and client computers, start the Agilent CytoDx program.

See “[Step 4. Start the Agilent CytoDx client software](#)” on page 23.

2 Log in.

See “[Step 5. Log in to Agilent CytoDx](#)” on page 23.

3 Enter your updated license information.

See “[Step 6. Add your software license and launch the software](#)” on page 24.

Upgrading from an Older Version of CytoDx and Migrating Data

These instructions are for users of CytoDx 1.1 or 1.2 who want to upgrade to CytoDx 2.2 and migrate all sample records from the previous database to the new CytoDx 2.2 database.

To upgrade from CytoDx 2.0 or 2.1 to CytoDx 2.2, see [“Upgrading from CytoDx 2.0 or 2.1 to CytoDx 2.2”](#) on page 27.

NOTE

CytoDx 2.2 is compatible with and can co-exist on the same machine as CytoDx 1.1 or 1.2. It is not necessary to uninstall the previous version of CytoDx in order to install version 2.2.

Step 1. Install CytoDx 2.2 on the server computer

Follow these steps to install Agilent CytoDx 2.2 on the computer where the CytoDx server software is installed.

- 1 Download Agilent CytoDx 2.2.X.X from Agilent Technologies and check the system requirements.

See [“a. Download the Agilent CytoDx installer and release notes”](#) on page 8 for detailed instructions on this step.

- 2 Double-click the Agilent CytoDx 2.2 application file that you downloaded from Agilent to start the installation wizard.

The following message is displayed.

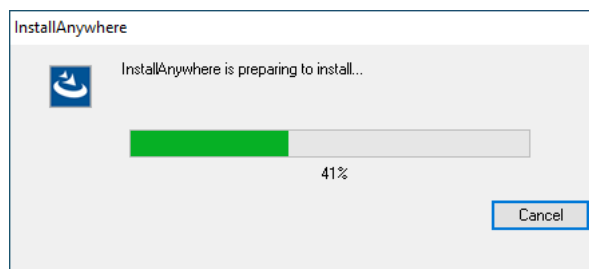


Figure 30 InstallAnywhere dialog box - preparing to install

The installation wizard starts.

1 CytoDx Installation Instructions

Step 1. Install CytoDx 2.2 on the server computer

- 3 On the Introduction screen, read the introductory information and then click **Next**.

The License Agreement screen opens.

- 4 Read the license agreement. Click **I accept the terms of the License Agreement** and then click **Next**.

The Disclaimer screen opens.

- 5 Read the disclaimer on the screen. To acknowledge and accept the conditions of the disclaimer, mark the check box and click **Next**.

The Choose Install Set screen opens.

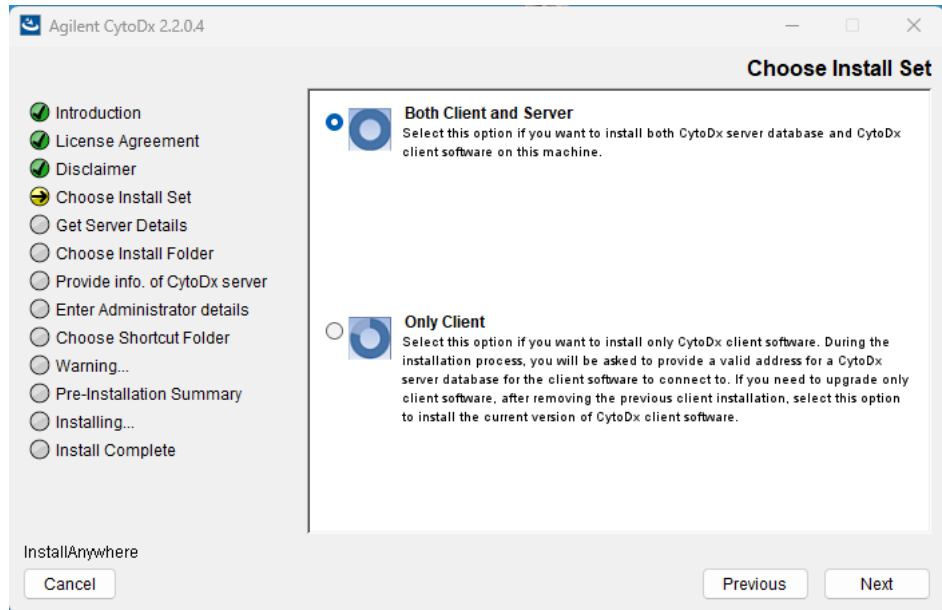


Figure 31 Choose Install Set screen – select **Both Client and Server**

- 6 On the Choose Install Set screen, select **Both Client and Server**. Click **Next**.

The following dialog box opens to inform you that you have selected to install the CytoDx server and client.



Figure 32 Dialog box – Agilent CytoDx software installation

- 7 Click **OK** in the dialog box to continue.
- 8 Continue the installation wizard. The next screen is the Choose Install Folder screen. Follow the instructions for the installation wizard to enter the client data folder location, choose a shortcut location, and start the installation. For information, see [step 9 \(page 14\)](#) through [step 17 \(page 19\)](#) in the section “[Step 2. Install the database server and client on a single computer](#)”.

At the completion of installation, the Launch Migration Utility dialog box opens asking if you want to launch Agilent’s migration utility tool designed to transfer data from a previous version of CytoDx server to the CytoDx 2.2 server.

- 9 Depending on your needs, click either **Launch Migration Utility** or **Skip**.
 - Click **Launch Migration Utility** if you have data saved to the previous version of CytoDx server (e.g., sample results, track files, and other supporting files) and you want to transfer that data to the CytoDx 2.2 server. The migration utility tool launches on your PC. Proceed to “[Step 2. Migrate data to CytoDx 2.2 server](#)” on page 43.
 - Click **Skip** if you do not want to transfer any data (e.g., sample results, track files, and other supporting files) from the previous version of CytoDx server to the CytoDx 2.2 server at this time. The dialog box will close and that data will remain on the previous version of the server. Proceed to “[Step 3. Upgrade to CytoDx 2.2 on the client computers](#)” on page 48.

1 CytoDx Installation Instructions

Step 2. Migrate data to CytoDx 2.2 server

NOTE

To protect against loss of data and ensure migration of all analyzed samples, Agilent strongly recommends migrating data immediately upon completion of the CytoDx 2.2 installation.

If you click **Skip** with the intention of migrating your data at a later time, be aware that if CytoDx 2.2 already contains data at the time of migration, the Migration Utility application will delete that data and overwrite it with data from the previous version of CytoDx.

Step 2. Migrate data to CytoDx 2.2 server

If you selected to launch the migration utility tool, follow these step to use the tool to transfer data from a previous version of CytoDx server to CytoDx server 2.2. If you do not want to transfer data, bypass this step and proceed to “[Step 3. Upgrade to CytoDx 2.2 on the client computers](#)” on page 48.

- 1 On the Sign In screen of the migration utility application ([Figure 33](#)), review the list of migration prerequisites and make sure they are all met before you continue.

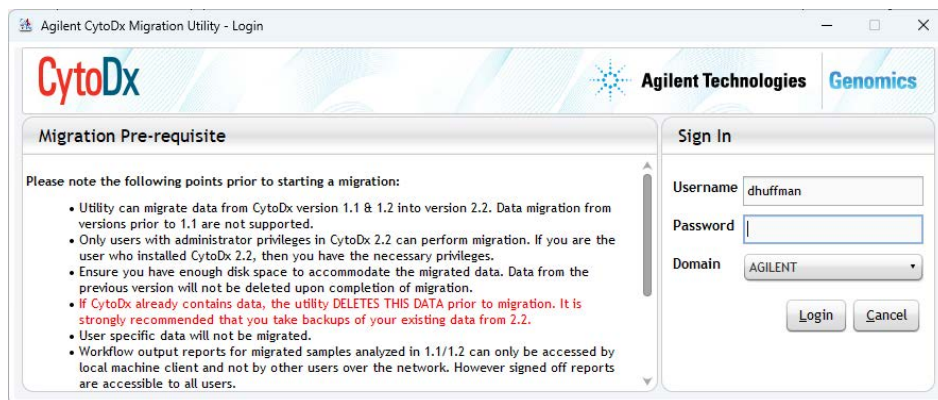


Figure 33 CytoDx Migration Utility application login screen

- 2 Log in with your username and password. The username and domain for the administrator set during installation appears in the Sign In area of the screen. (Only accounts with administrator privileges can migrate data.)

The CytoDx Migration Utility application opens.

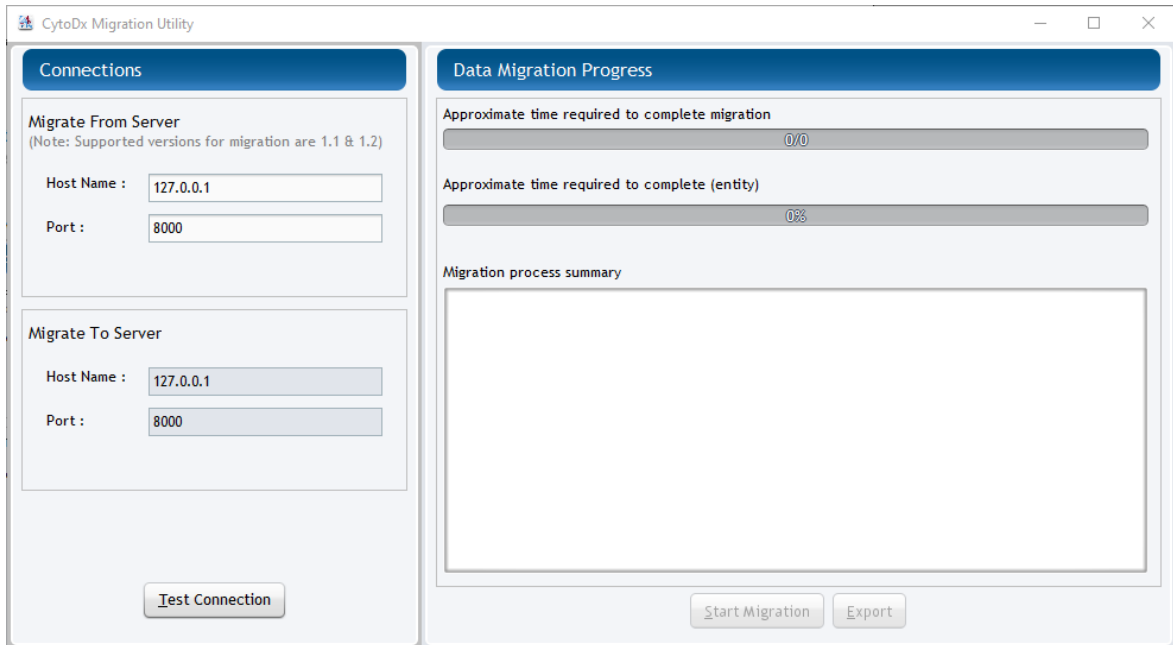


Figure 34 CytoDx Migration Utility application

- 3** Under **Migrate From Server**, enter the host name (i.e., IP address) and port number where the previous version of CytoDx server is installed.
- 4** Under **Migrate To Server**, enter the host name (i.e., IP address) and port number where the CytoDx 2.2 server is installed.

NOTE

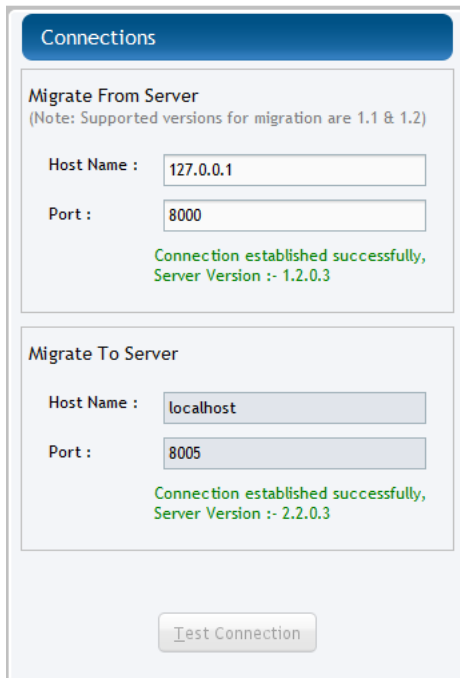
If CytoDx 2.2 server is installed on the same PC as the previous version of CytoDx server, then the host names of the two servers are the same.

- 5** Click **Test Connection**.

The screen displays the results of connection test with each server.

1 CytoDx Installation Instructions

Step 2. Migrate data to CytoDx 2.2 server



The screenshot displays the 'Connections' window of the CytoDx Migration Utility. It is divided into two sections: 'Migrate From Server' and 'Migrate To Server'. The 'Migrate From Server' section shows a host name of '127.0.0.1' and a port of '8000', with a green message indicating a successful connection to server version 1.2.0.3. The 'Migrate To Server' section shows a host name of 'localhost' and a port of '8005', also with a green message indicating a successful connection to server version 2.2.0.3. A 'Test Connection' button is located at the bottom of the window.

Figure 35 CytoDx Migration Utility application – Connections established

NOTE

If the application was unable to successfully establish a connection to one or both servers, verify that the correct host name and port number are entered and test the connection again. You cannot proceed to data migration until the application connects to the servers.

- 6 Once the application has successfully connected to the servers, click **Start Migration**.

The Warning message box opens.

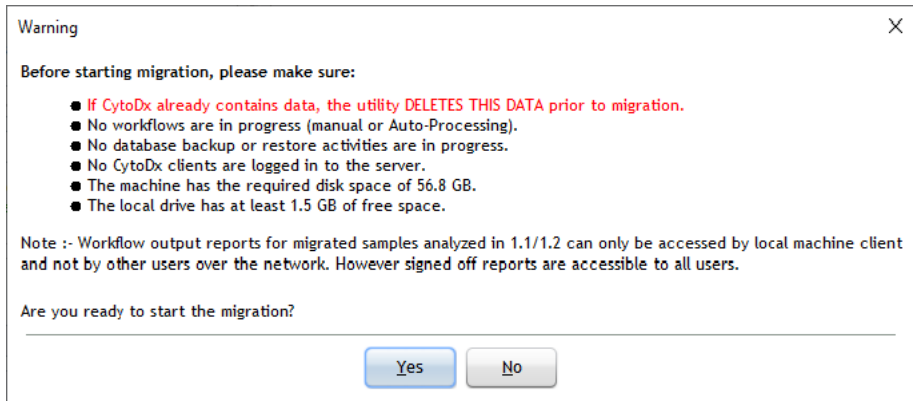


Figure 36 Warning message box

- 7 As instructed in the Warning message box, make sure that CytoDx is not actively running any workflows or performing any database backup or restore activities and that all clients are logged out. If your CytoDx 2.2 database already contains data, make sure that data has been backed up. Then, click **Yes** to continue with the migration.

The right side of the screen (under **Data Migration Process**) displays the progress of the migration and the migration process summary.

1 CytoDx Installation Instructions

Step 2. Migrate data to CytoDx 2.2 server

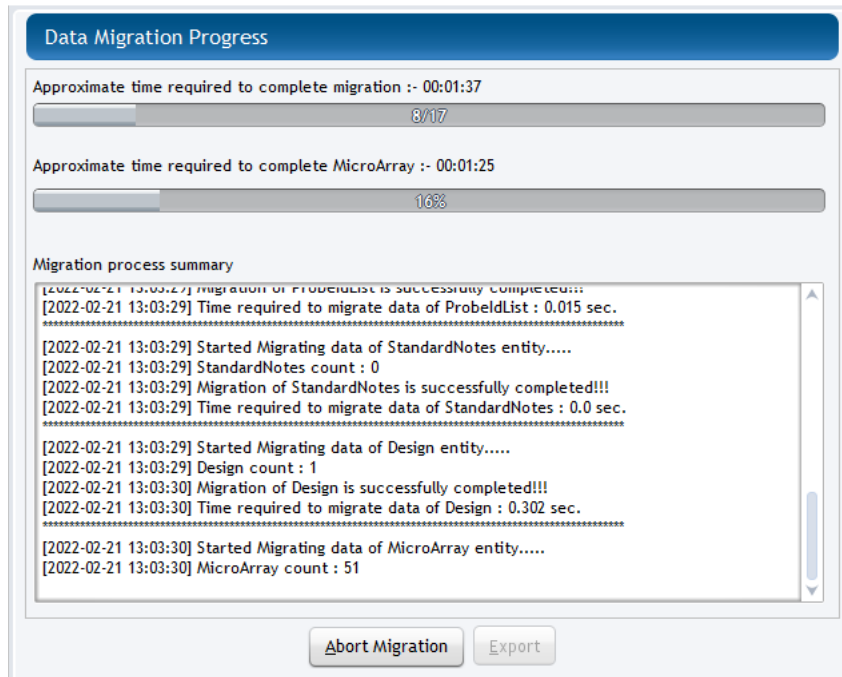


Figure 37 CytoDx Migration Utility application – Migration in progress

Upon completion of the migration process, the following message box opens.

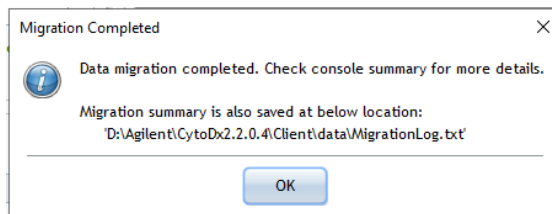


Figure 38 CytoDx Migration Utility application – Data migration complete

- 8 Click **OK** to close the message box.
- 9 If desired, click **Export** to export a summary of the migration job.
- 10 Click the X in the top right corner of the Migration Utility application window to close the application.

Step 3. Upgrade to CytoDx 2.2 on the client computers

Follow these steps to install Agilent CytoDx 2.2 on each client computer.

- 1 Double-click the Agilent CytoDx 2.2.X.X application file that you downloaded from Agilent.
- 2 On the Introduction screen, read the introductory information then click **Next**.

The License Agreement screen opens.

- 3 Read the license agreement. Click **I accept the terms of the License Agreement** and then click **Next**.

The Disclaimer screen opens.

- 4 Read the disclaimer on the screen. To acknowledge and accept the conditions of the disclaimer, mark the check box and click **Next**.

The Choose Install Set screen opens.

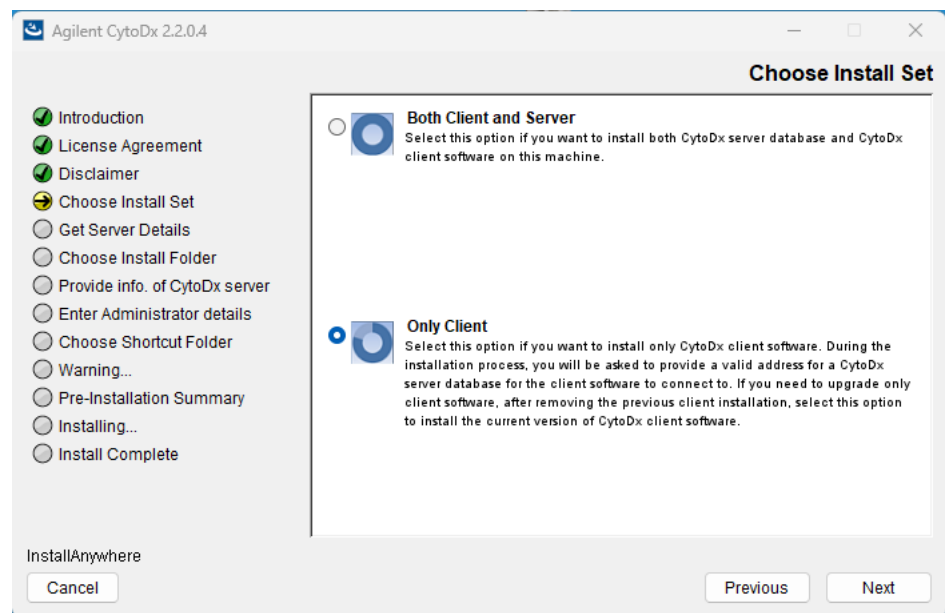


Figure 39 Choose Install Set screen – select **Only Client**

- 5 On the Choose Install Set screen, select **Only Client**. Click **Next**.

1 CytoDx Installation Instructions

Step 4. Start the Agilent CytoDx client software, log in, and add new software license

The following dialog box opens to inform you that you have selected to only install the CytoDx client.



Figure 40 Dialog box – Agilent CytoDx software installation

- 6 Click **OK** in the dialog box to continue.
The Choose Install Folder screen opens.
- 7 At the Choose Install Folder screen, the default folder for installation of the program is C:\Agilent\CytoDx2.2.X.X (where X.X is the revision number). Leave this folder as-is, or click **Choose**, and browse to a location where you want to install the program, and then click **Save**.
- 8 Click **Next**.
- 9 Continue the installation wizard. Follow the instructions to provide server information, choose a shortcut location, and start the installation. See [step 7 \(page 22\)](#) through [step 9 \(page 22\)](#) in the section “[Step 3. Install the client software on additional Windows computers](#)”.

Step 4. Start the Agilent CytoDx client software, log in, and add new software license

- 1 On the server and client computers, start the Agilent CytoDx program.
See “[Step 4. Start the Agilent CytoDx client software](#)” on page 23.
- 2 Log in.
See “[Step 5. Log in to Agilent CytoDx](#)” on page 23.
- 3 Enter your updated license information.
See “[Step 6. Add your software license and launch the software](#)” on page 24.

Uninstalling Agilent CytoDx server and client software

If you need to uninstall the entire CytoDx program, the Uninstall application for Agilent CytoDx provides an easy way to remove the client, server, and PostgreSQL programs from your computer.

CAUTION

When you completely uninstall Agilent CytoDx server and client software, the database and the data contained in it are completely removed. Do not uninstall the server unless you have backed up your database or no longer wish to use it.

- 1 Start the Uninstall executable file for the version of CytoDx that you want to uninstall.
 - For CytoDx 1.0, 1.1 and 1.2, the executable file is called **Uninstall Agilent CytoDx 1.X.X.X.exe** (where X.X.X is the version number of the software) and is located in the *Uninstall_Agilent CytoDx 1.X.X.X* folder of your program folder.
 - For CytoDx 2.X, the executable file is called **Uninstall AgilentCytoDx.exe** and is located in the *Uninstall_AgilentCytoDx* folder of your program folder.

The Uninstaller program starts.

- 2 Read the introductory information, and then click **Next**.
- 3 Read the warning information. You are cautioned not to stop the Uninstaller once it has started to remove the programs. Click **Next**.
The Uninstall Options screen opens.

1 CytoDx Installation Instructions

Step 4. Start the Agilent CytoDx client software, log in, and add new software license

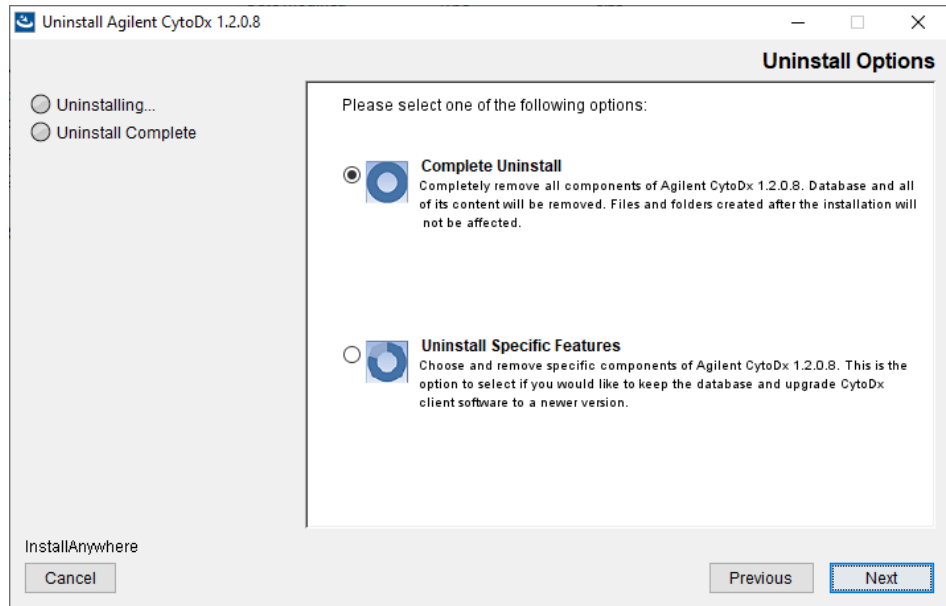


Figure 41 Uninstall Options screen – select **Complete Uninstall**

4 Select **Complete Uninstall**.

5 Click **Next**.

6 When the uninstallation is complete, a message appears. Click **Done**.

The Agilent CytoDx client program, server program and database, and PostgreSQL program were removed from your computer. Program folders and data folders (such as data output folders) created after installation were not removed.

Administering user accounts

Before other users can log in to Agilent CytoDx, the System Admin must add the users and assign user roles. The user role determines what capabilities the user has within the program. Each user can have more than one role assigned.

NOTE

Perform these tasks from the computer that has both the CytoDx server and client software installed. You cannot add or edit accounts on a computer that only has the CytoDx client software.

Add users

In order to access the tools for adding new CytoDx users, you must open CytoDx in Administrator mode. To open in Administrator mode, launch CytoDx by right-clicking on the application executable file and clicking the **Run as administrator** menu option.

- 1 At the top of the CytoDx program window, click **Admin** to open the Admin screen.
- 2 In the command navigator on the left side of the screen, click **Manage Users & Roles**.

- 3 Click **Add New User**.

A list of all the users in the domain or on the local machine appears.

- 4 Next to **Add New User**, type the user name, and then click **Find**.

If you are adding a user for a local machine, next to **User**, type the computer name and user in the format **machinename\username**.

- 5 At the bottom of the Add User dialog box, click **Add User**.

The Add User message box opens asking you to confirm addition of the user.

If you added a user for a local machine, a warning dialog box opens stating that there was a problem fetching user details from the LDAP server. You can ignore this warning and click **OK** to close it.

- 6 As instructed in the Add User message box, confirm that none of the clients on the database are running Auto-Processing workflows and that none of the clients are in the processing of signing off a sample. Once confirmed, click **Yes** in the message box.

1 CytoDx Installation Instructions

Change a user's role

Clicking **Yes** while an Auto-Processing workflow is running or while a user is signing off a sample may cause the workflow or sign-off process to fail.

- 7 In the Authentication dialog box, type your username and password, and then click **Ok**.

A message box opens confirming that the user was successfully added.

- 8 Click **OK** in the message box to close it.
- 9 Repeat [step 4](#) through [step 8](#) for additional users you want to add.
- 10 When you are finished adding users, click **Close** to close the Add User dialog box.

Change a user's role

- 1 At the top of the CytoDx program window, click **Admin** to open the Admin screen.
- 2 In the command navigator on the left side of the screen, click **Manage Users & Roles**.
- 3 In the row for the user whose role you intend to change, click **View/Edit**.

The Edit User Roles dialog box opens ([Figure 42](#)). The roles listed in the right panel are those that are currently assigned to the user.

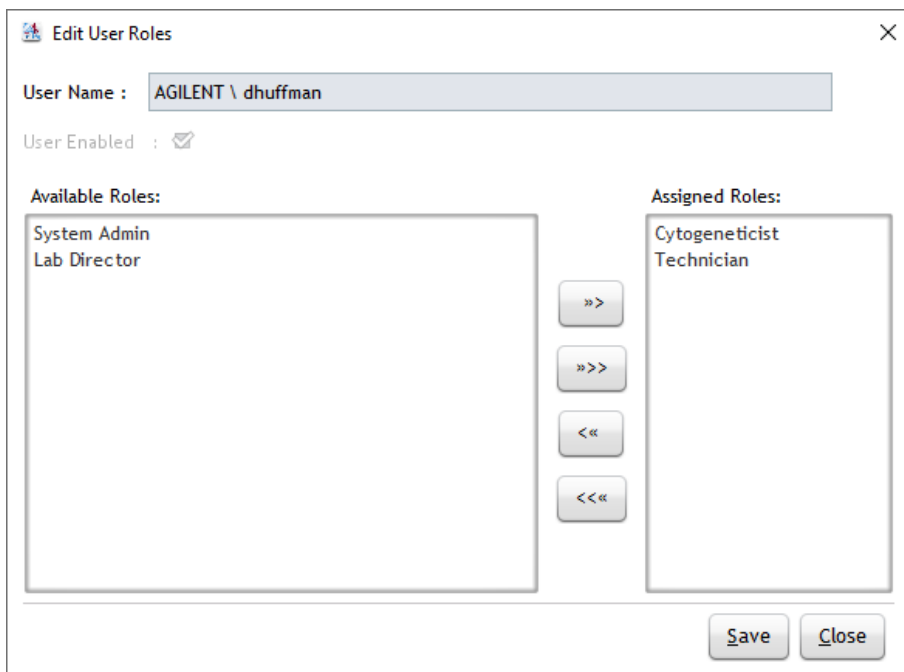


Figure 42 Edit User Roles dialog box

- 4** To remove a role that is assigned to the user, select the role in the right panel, and then click the left arrow (<) to move the role to the left panel.
- 5** To assign a new role to the user, select the role in the left panel, and then click the right arrow (>) to move the role to the right panel.
- 6** Click **Save**.
- 7** In the Authentication dialog box, type your username and password, and then click **Ok**.
A message box opens confirming that the user roles have been updated.
- 8** Click **OK** to close the message box.
- 9** Click **Close** to close the Edit User Roles dialog box.

1 CytoDx Installation Instructions

Change a user's role

Table 2 Privileges by user role

Privilege	System Admin	Technician	Cytogeneticist	Lab Director
Install CytoDx	Yes	No	No	No
Administer user functions (add users, set user roles, etc.)	Yes	No	No	Yes
Configure software database	Yes	No	No	No
Configure software proxies and paths	Yes	No	No	Yes
Set up connections to partner software programs	No	No	No	Yes
Configure settings (samples attributes, classifications, standard notes, tracks, etc.)	Global Settings, Local Settings, and Viewing Preferences	No	No	Yes
Import/export supporting files	No	No	No	Yes
Set up Auto-Processing parameters	Yes	No	No	Yes
Start and stop Auto-Processing	No	Yes	Yes	Yes
Run analysis workflows manually	No	Yes	Yes	Yes
Check out sample results in Triage View (which permits editing and annotating of calls)	No	No	Yes	Yes
Sign off sample results	No	No	No	Yes
Generate reports	Yes	Yes	Yes	Yes
View job logs	Yes	Yes	Yes	Yes
View audit trails	Yes	No	Yes	Yes



2 CytoDx Set Up Instructions

- Creating classifications 57
- Importing tracks 58
- Creating sample attributes 59
- Designing report templates 61
- Configuring Auto-Processing settings 63

This chapter shows you how to set up classifications for aberrations, import track files, create sample attributes, design report templates, and configure Auto-Processing settings.

NOTE

CytoDx users are responsible for protecting data, including input tiff images and database files, from loss. Periodically back up the CytoDx database from the Admin screen of the software, and back up the drives where your sample files and output files are stored.

Creating classifications

Classifications are user-defined annotations (up to 70 characters) that can be used to classify the CNVs and LOH intervals identified in a sample. Cytogeneticists and Lab Directors can assign classifications while reviewing sample results in Triage View, but first the classifications must be created from the Configure Settings screen. Only Lab Directors can perform this task.

Create classifications that are in accordance with the existing practices in your laboratory. Commonly used classifications are listed in [Table 3](#).

Table 3 Common classifications

Pathogenic
Likely pathogenic
VOUS (or, variant of unknown significance)
Likely benign
Benign

Use the instructions below to add classifications.

- 1 At the top of the CytoDx program window, click **Configure Settings**.
- 2 In the command navigator on the left side of the screen, click **Classification**.
The Classification screen displays a table of all existing classifications (if any).
- 3 At the bottom of the screen, click Create Classification.
The Create Classification dialog box opens.
- 4 In the Name field, type the name of the custom classification (e.g., Pathogenic).
- 5 Click **OK**.
The classification is added to the table, and a message opens confirming that the classification was added successfully.
- 6 Repeat [step 3](#) through [step 5](#) for the remaining classifications to be added.

Importing tracks

Tracks are BED files (*.bed), which are tab-delimited text files that define specific genomic intervals. CytoDx comes preloaded with several tracks, and Lab Directors can create new tracks by importing BED files.

Use the instructions below to import a BED file as a track.

- 1** At the top of the CytoDx program window, click **Configure Settings**.
- 2** In the command navigator on the left side of the screen, click **Tracks**.
The Tracks screen displays a table of all tracks in CytoDx.
- 3** At the bottom of the screen, click **Import Track from BED File**.
The Import Track dialog box opens.
- 4** In the Build Name drop-down list, select the specific genome build to which the track applies.
- 5** (Optional) Change the color used to display the track in Triage View.
 - a** Under **Color**, click **Change**. The Choose Track Color dialog box opens.
 - b** In the Swatches tab of the dialog box, select a color for the track.
 - c** Click **OK** to close the Choose Track Color dialog box and return to the Import Track dialog box.
- 6** In the Track Name field, type a name for the track. This name identifies the track within CytoDx.
- 7** Next to the Track File field, click **Browse**.
The Open dialog box opens.
- 8** Browse to the BED file. Select the file and click **Open**.
- 9** Click **OK** in the Import Track dialog box.
The track now appears in the table on the Configure Settings > Tracks screen.

Creating sample attributes

In CytoDx, a sample attribute is a characteristic or property assigned to a sample. You can assign attributes to a sample during the workflow, either manually or using a sample attribute file. The required sample attributes are described in [Table 4](#).

Table 4 Required sample attributes

Sample attribute	Description
Array ID	The Array ID is the barcode number of the microarray slide followed by the number 1 and the number of the microarray on the 4x slide. An example of an Array ID would be 254457710741_1_4, where 254457710741 is the barcode number and 4 is the number of the microarray.
Global Display Name	The Global Display Name can be identical to the Array ID, or it can be a custom name, such as a sample or patient identifier. If you use a custom name, make sure it is unique to that microarray. This Global Display Name is displayed throughout CytoDx for the microarray (e.g., in reports) and cannot be repeated for another microarray, even if that microarray was hybridized to the same sample.
Green Sample	This attribute designates the genotype reference file to be used in the analysis. If you used the female reference DNA, type Agilent Female Reference. If you used the male reference DNA, type Agilent Male Reference.
Red Sample	This attribute is the identifier for the patient sample.
Polarity	For the Polarity, enter 1. A polarity of 1 confirms to the software that the Green Sample is the reference sample.

In addition to the sample attributes that come preloaded with CytoDx, you can add custom sample attributes to the program. Creating a custom sample attribute makes it available for assignment, either through a sample attribute file or while manually setting up an analysis workflow. Custom sample attributes are always optional. That is, you can assign them for a sample or leave them blank.

Use the instructions below to create a custom sample attribute.

- 1** At the top of the CytoDx program window, click **Configure Settings**.
- 2** In the command navigator on the left side of the screen, click **Sample Attributes**.
- 3** Above the task area of the screen, click the Sample Attributes tab (if not already selected).

The screen displays the existing custom sample attributes, if any.

- 4** At the bottom of the screen, click **Create Sample Attribute**.

The Create Attribute message box opens.

- 5** In the field under **Enter Attribute Name**, type the name of the new custom sample attribute.

- 6** Click **Ok**.

The message box closes and the new attribute appears in the table on the screen.

2 CytoDx Set Up Instructions

Create a new Cyto report template from scratch

Designing report templates

Cyto reports are generated when a Lab Director signs off on the sample results in the Triage View window. The Cyto report provides loss, gain, and LOH results in tabular and graphical formats according to a specified report template. You can select to use a default Cyto report template, or you can select a custom report template.

Lab Directors can design custom report template from the Configure Settings > Reports screen.

You can create a Cyto report template from a blank template (using the Create Cyto Report Template wizard), or you can edit an existing template and save it under a new name (using the Edit Cyto Report Template wizard). Except for the report contents when you start the wizard, the Create Cyto Report Template wizard and the Edit Cyto Report Template wizard are identical.

Create a new Cyto report template from scratch

- 1 At the top of the CytoDx program window, click **Configure Settings**.
- 2 In the command navigator on the left side of the screen, click **Reports**.
- 3 Above the task area of the screen, click the PDF Report Templates tab (if not already selected).
This tab displays a list of the existing Cyto report templates.
- 4 Near the bottom of the screen, click **Create Template**.
- 5 In the message box, type a name for the new template and click **OK**.
The Create Cyto Report Template wizard opens.
- 6 Complete the steps of the wizard. See the CytoDx help system for information on the tools available in the Create Cyto Report Template wizard.
- 7 When you are finished designing the report temple, click **Save** from the last step of the wizard.
The wizard closes and the new template is now listed on the PDF Report Templates tab.

Create a Cyto report template from an existing template

- 1 At the top of the CytoDx program window, click **Configure Settings**.
- 2 In the command navigator on the left side of the screen, click **Reports**.
- 3 Above the task area of the screen, click the PDF Report Templates tab (if not already selected).

This tab displays a list of the existing Cyto report templates.

- 4 Click **View** or **View/Edit** for the template that you want to edit.
The Edit Cyto Report Template wizard opens.
- 5 Complete the steps of the wizard. See the CytoDx help system for information on the tools available in the Edit Cyto Report Template wizard.
- 6 When you are finished designing the report temple, click **Save As** from the last step of the wizard.
- 7 In the Input dialog box, type the new name for the template and click **OK**.

The new template is now listed on the PDF Report Templates tab.

Configuring Auto-Processing settings

CytoDx offers two different methods for running workflows: the manual method and the Auto-Processing method. When you run a workflow manually, you select the input files, describe the samples that you are analyzing, and then start the workflow. When you run a workflow using Auto-Processing, the program automatically picks up and uses image files as they are placed in a designated folder (or one of multiple designated folders) by a scanner and runs the workflow according to the Auto-Processing configuration settings. These settings determine the folder locations that the program uses for importing and archiving tiff images and SAF files.

- 1** At the top of the CytoDx program window, click **Auto Processing**.
The screen displays the settings for Auto-Processing workflows, including the default folder locations. You can use the default folder locations, or continue to step 2 to set new folder locations.
- 2** Set up the Tiff Image Input Folder. This folder is where the program picks up microarray tiff image files (in format **.tif*) for Auto-Processing. Typically, this folder is where your scanner deposits the scanned tiff files.
 - a** Next to the Tiff Image Input Folder text box, click **Add Folders**. The Tiff Image Input Folder dialog box opens.
 - b** Select the desired folder and click **Open**. The dialog box closes and the file path of the selected folder appears in the Tiff Image Input Folder text box.
 - c** (Optional) To remove the default folder location, select it in the Tiff Image Input Folder text box and click **Remove Folders**.
- 3** Set up the SAF File Input Folder. This folder is where the program picks up the sample attribute files that are needed for Auto-Processing and imports them into the CytoDx database.
 - a** Next to the SAF File Input Folder text box, click **Add Folders**. The SAF File Input Folder dialog box opens.
 - b** Select the desired folder and click **Open**. The dialog box closes and the file path of the selected folder appears in the SAF File Input Folder text box.
 - c** (Optional) To remove the default folder location, select it in the SAF File Input Folder text box and click **Remove Folders**.

- 4 Set up the SAF Archive Folder. This folder is where the program saves sample attribute files after they are imported to the database during Auto-Processing.
 - a Next to **SAF Archive Folder**, click **Browse**. The Open dialog box opens.
 - b Select the desired folder and click **Open**. The Open dialog box closes and the file path of the selected folder appears in the SAF Archive Folder field.
- 5 Set up the Tiff Image Archive Folder. This folder is where the program saves reports and files generated during analysis workflows run in Auto-Processing mode.
 - a Under **Tiff Image Archive Folder**, select the desired archiving option. The options are:
 - Do Not Archive Tiff Image Files - The program leaves the files in the input folder after importing into the database.
 - Archive Tiff to Sample Output Folder - The program moves the files to the Auto-Processing output folder after importing into the database.
 - Archive Tiff to Different Location - The program moves the files to the folder indicated in the adjacent field. Click **Browse** to browse to and select the desired folder.
- 6 Click **Apply Settings** at the bottom of the screen.

NOTE

The Auto-Processing settings also allow you to:

- Set the number of attempts that CytoDx tries to process a tiff file before setting the status of the analysis workflow to “Failed.”
- Change the time-out setting which determines the length of the idle time required before CytoDx turns off Auto-Processing.
- View the audit trail of changes to the Auto-Processing settings.

You can find instructions for performing these tasks in the CytoDx help system.

2 CytoDx Set Up Instructions

Create a Cyto report template from an existing template



3 Cybersecurity Guidance

Cybersecurity Guidance 67

This chapter contains guidelines on maintaining security and privacy for the HealthCare Organizations that use CytoDx.

Cybersecurity Guidance

CytoDx uses Microsoft Windows Commercial Off-The-Shelf Operating System (COTS OS) for user account management which allows for creating, changing, safeguarding, and terminating accounts. The HealthCare Organization shall create corresponding internal procedures to address the following items:

- 1 All the network equipment, computer hardware, software, databases etc. must be protected by user authentication (ID and password).
- 2 System should be accessible though domain as well as local user.
- 3 System should use Windows and/or Hospital Information (IT) infrastructure password policy.
- 4 System should support role management access. Access to files and drives should be given for appropriate role.
- 5 System should allow appropriate users to
 - Create new users
 - Add/remove privileges to user
 - Terminate/disable user
 - Create groups with defined privileges
 - Add/remove users to/from group.
- 6 System should be locked after predefined time of inactivity.
- 7 All systems should have anti-virus and anti-spyware software installed.
- 8 The anti-virus and anti-spyware software should be updated regularly.
- 9 Important data should be secured using Cryptography or encryption-decryption equipment.
- 10 Data transmitted to and from devices must be encrypted.
- 11 Unauthorized devices trying to connect to the network must be blocked.
- 12 Unused ports should be blocked to minimize risk of tampering.
- 13 Firewall should be set to prevent unauthorized access from internet/intranet.
- 14 The use of mobile devices must follow mobile device management policy.
- 15 Documented procedures for addressing security breaches must be available.

- 16** Authorized user accounts must be regularly audited.
- 17** Database backup must be performed on a regular basis and must be performed before installing any software upgrades.
- 18** Employees must be educated on privacy and security policies through a strict training process.
- 19** The number of remote computers, portable devices and ports used to connect to IVD systems should be kept to a minimum.
- 20** Software must be kept up-to-date and any available patches promptly installed.
- 21** A documented security plan for disposal of unwanted data must be available.
- 22** Policies and processes for data security must be regularly reviewed and updated.

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United States: clinical.support@agilent.com

Europe: genomics_dx_tech_europe@agilent.com

Japan: email_japan@agilent.com

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.

A Summary of Safety and Performance (SSP) is located on the Agilent product website at <https://genetisuredx.agilent.com> and at <https://ec.europa.eu/tools/eudamed>, after launch of the European Database on Medical Devices (Eudamed), where it is linked to the Basic UDI-DI (570057R0403P3011C040700PB).

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