CytoScan™ Optima Assay Software Module v1.1

USER GUIDE

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CytoScan™ Optima Assay Software Module v1.1

Introduction

This user guide demonstrates how to create a CytoScan™ Optima Assay Software Module v1.1 RUO assay Test Request.

This software is for use with the GeneChip™ System 3000Dx v.2 and is also compatible with the CytoScan™ Optima Array reagent kits.

Nomenclature

- The Assay name is **CytoScan™ Optima Assay**.
- The Assay display name is **CytoScan Optima v1.1**
- The term ASM refers to Assay Software Module.

Features

The CytoScan™ Optima Assay Software Module v1.1 features 4 windows that augment your assay record keeping.

- **Additional Information** window
- **Assay Home** window (or Assay Information window)
- **Batch Edit** window
- **Report** window

CytoScan™ Optima Assay Software Module v1.1 (under the control of the AMDS application) transfers all specimen information to the server.

IMPORTANT! It is *not* the purpose of this abbreviated user guide to instruct you on how to run the assay. This guide instructs only how to create a RUO Test Request and track associated information.

To complete an assay run, you must follow the standard Affymetrix™ Molecular Diagnostics Software (AMDS) and process it through the workflow to register, hybridize, wash/stain, and scan the array (as part of the Array Cartridge). These specifics are discussed in the *Affymetrix™ Molecular Diagnostics Software User Guide*.

IMPORTANT! Before using the information contained in this guide to run the assay, you must thoroughly be familiar with the following documents:

- *Affymetrix™ Molecular Diagnostics Software User Guide* (Pub. No. 703230)
- *Affymetrix™ Molecular Diagnostics Software Quick Reference* (Pub. No. 08-0262)
- *CytoScan™ Optima Reagent Kit Product Information Sheet* (Pub. No. 703253)
- *CytoScan™ Optima Array Product Information Sheet* (Pub. No. 703254)
- *CytoScan™ Optima Assay Manual Workflow User Guide* (Pub. No. 703280)
- *CytoScan™ Optima Assay Manual Workflow Site Preparation Guide* (Pub. No. 703281)
- *CytoScan™ Optima Assay Manual Workflow (8-, 16-, and 24-Samples) Quick Reference* (Pub. No. 703282)

Reagents

Reagents for the CytoScan™ Optima Array - single array (Part. No. 521004) comprise the following reagent subkits:

- CytoScan™ Optima Module 1: Pre-Lab Restriction, Ligation, and Amplification (Part. No. 902527)
- CytoScan™ Optima Module 2: Pre-Lab Negative Control and Water (Part. No. 902528)
- CytoScan™ Optima Module 3: Main Lab Fragmentation, Labeling, and Hybridization (Part. No. 902529)
- CytoScan™ Optima Module 4: Main Lab Stain, Holding Buffer, and Purification Beads (Part. No. 902530)
- CytoScan™ Optima Module 5: Main Lab Elution Buffer, Water, and Wash Buffer (Part. No. 902531)
- Wash Buffer A (Part. No. 902438)
- Wash Buffer B (Part. No. 902439)

Install the ASM

The following steps must be performed before you can process a CytoScan™ Optima v1.1 Test Request on the system.

1. Install a certificate (only for secure transfers to a Data Transfer Server and not required for CIFS transfers).

2. Install the CytoScan™ Optima Assay Software Module v1.1.

Installing the certificate

Note: In most cases, the field service technician installs the certificate and ASM.

Note: The steps in this section apply only if you are using a Data Transfer Server. If you are transferring your data via CIFS, skip to "Install the ASM" on page 7.

As a security measure, AMDS requires that you or the field service technician install a SSL server certificate on your local workstation in order for your workstation to communicate with the server. This step is required for the transfer of CytoScan™ Optima v1.1 Test Request data to the Data Transfer Server.

The service technician should have installed a certificate at the time of the system's installation. If for some reason the service technician did not install a certificate or if the server has changed after the system's initial installation, you must install or reinstall a certificate.

You MUST install the certificate before installing the Assay.

If a proper certificate has not been installed, you can still install the assay and process Test Requests; however, you will not have permission to access the server, and you cannot transfer Test Request data to the server.

If you cannot access the server and have already installed a certificate, contact Technical Support.

Note: You must be logged in with either Laboratory Supervisor or System Maintainer privileges to install a certificate.

The Active Worklist Administrator panel contains the Assay Management button and provides the starting point for installing a certificate (Figure 1).

Figure 1 Active Worklist Administrator panel (lower left)

1. Insert the CD into the drive.

2. Click **Assay Management**.
   The **Assay Management** window appears.

3. Click **Install Certificate**.

   The **Server Certificate Browse** window appears. (Figure 2)

Figure 2   **Server Certificate Browse** window

4. Make sure the **Install from CD** radio button is selected and then navigate to and click the appropriate .cer file.

5. Click **OK**.

   The message "**You have successfully added the server certificate xxxxx.cer to the AMDS trusted certificate store**" appears.

   Note: If the certificate installation fails, an error message appears. You cannot access the server or transfer data without a certificate. Contact your Service Representative for information on obtaining a new certificate.

6. Click **OK** to return to the **Assay Management** window.

Install the ASM

The ASM installation process is relatively simple. It requires the selection of a manifest file and the selection of approved user access.

Note: You must be logged in with either Laboratory Supervisor or with System Maintainer privileges to install an ASM.

1. Insert the CD into the drive.

2. Click **Assay Management**.

   The **Assay Management** window appears.

3. Click **Install Assay**.

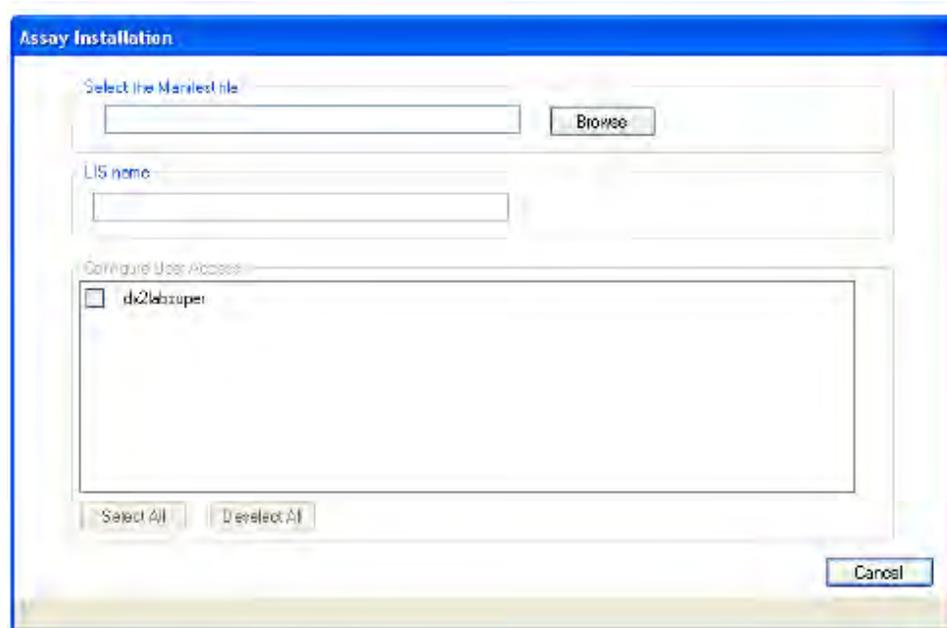   The **Assay Installation** window appears (Figure 3).

Figure 3   **Assay Installation** window

4. Click **Browse**.

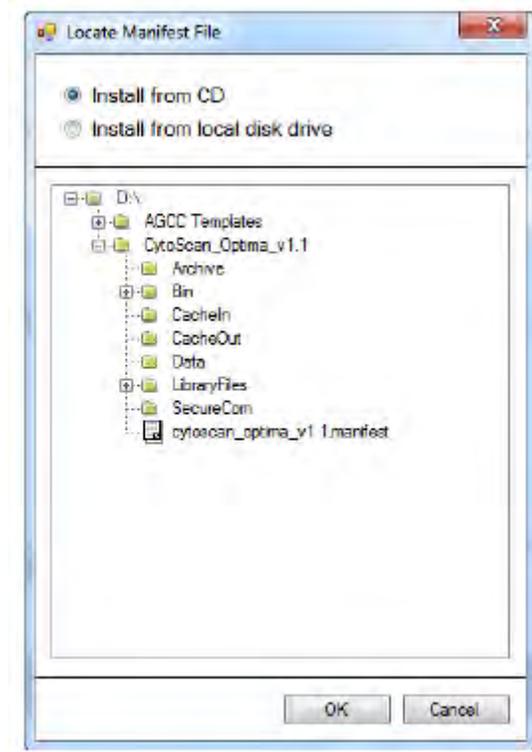The **Locate Manifest File** browse window appears. (Figure 4)

Figure 4   Locate Manifest File browse window

5. Make sure that the Install from CD option is selected, then navigate to and click on **D:\\CytoScan_Optima_v1.1\CytoScan_Optima_v1.1.Manifest**

6. Click **OK**.

   The **Assay Installation** window appears. (Figure 5)
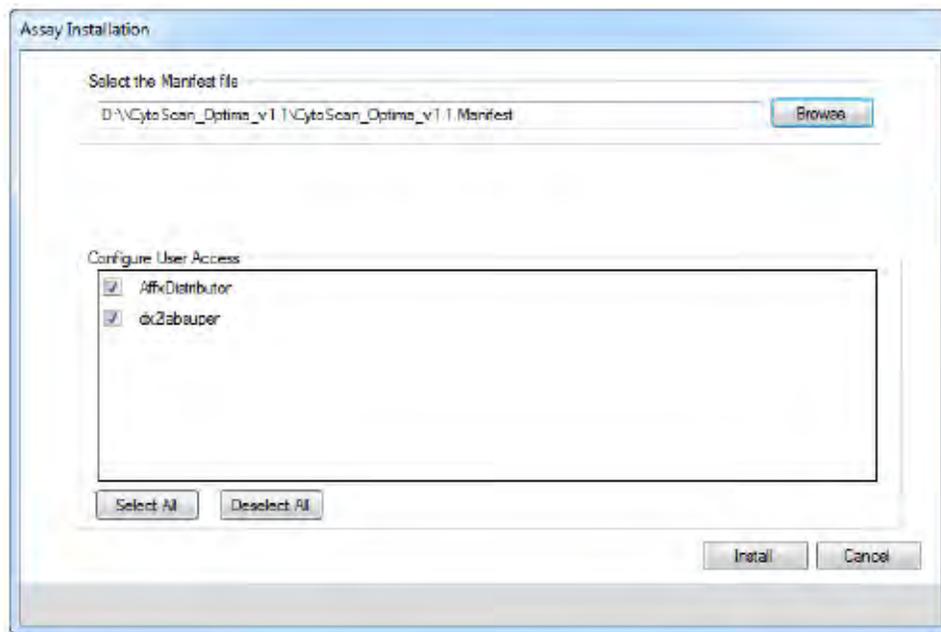

Figure 5 **Assay Installation** browse window

7. Click to choose each authorized Assay User or click **Select All**.

8. Click **Install**.
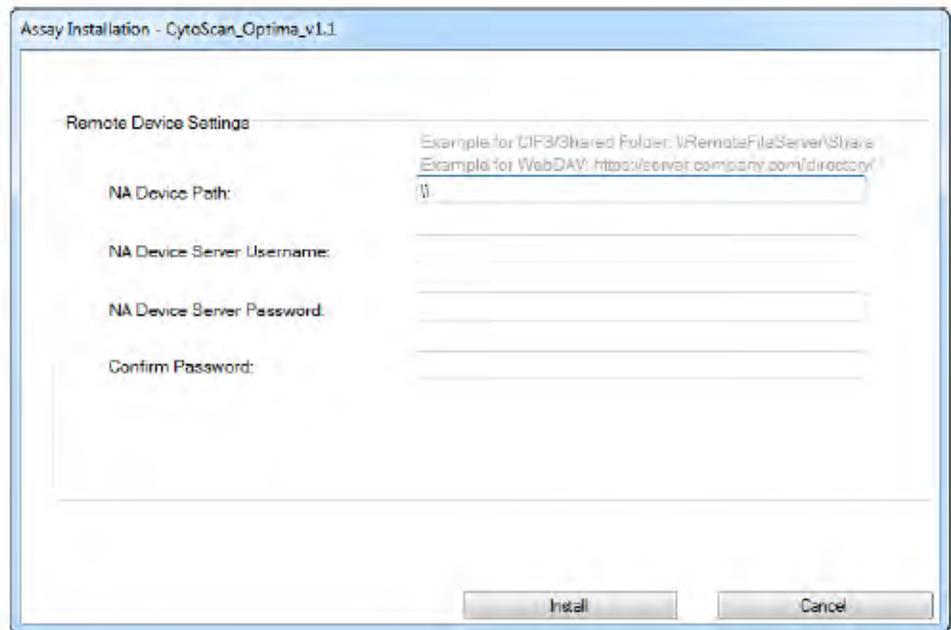
The **Remote Device Settings** window appears (Figure 6).

Figure 6 Remote Device Settings window

Note: In AMDS 1.1.1, users can enter their transfer location either as a WebDav URL (e.g., https://dx2_webdav_server/dx2_ruo) or as a Common Interface File System (CIFS) folder designation (e.g., \\dx2_cifs_folder\dx2_ruo_files). For AMDS releases prior to AMDS 1.1.1, only the WebDav option is available.

9. Locate and enter the **NA Device URL**. This is the location where AMDS sends its completed assay data.

10. Enter the **NA Device Server User Name**. Use the existing server, workstation, or network user name.

11. Enter the **NA Device Server Password**. Use the existing server, workstation, or network password.

12. Confirm the password.

Note: Your **NA Device Server Username** and **Password** are not the user name and password that you used to log into AMDS. You must enter your user name and password that you use to access the server.

13. Confirm that the firewall is **ON** and your workstation is connected to the network.

14. Click **Install**.

Firewall issues

If the software cannot connect through your system's firewall, the following error message appears (Figure 7).
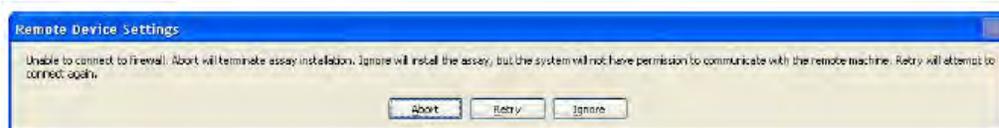

Figure 7 Error message

There are 3 buttons to acknowledge the Remote Device Settings Error message.

- **Abort** - Exits the Assay installation.
- **Retry** - Attempts another try.
- **Ignore** - Continues the installation.

Note: If you select **Ignore**, AMDS installs the assay; however, you will not be granted permission to communicate with any remote server.

Repair a currently installed ASM

If this ASM already exists on the system and it is reinstalled, the Repair Assay message appears (Figure 8).

Figure 8 Repair Assay message

Any AMDS user with valid AMDS credentials and appropriate permissions can repair the previously installed ASM.

1. Enter your User Name and Password, then click **Continue**.

    An Assay Installation window showing installation status and a progress bar appears (Figure 9).
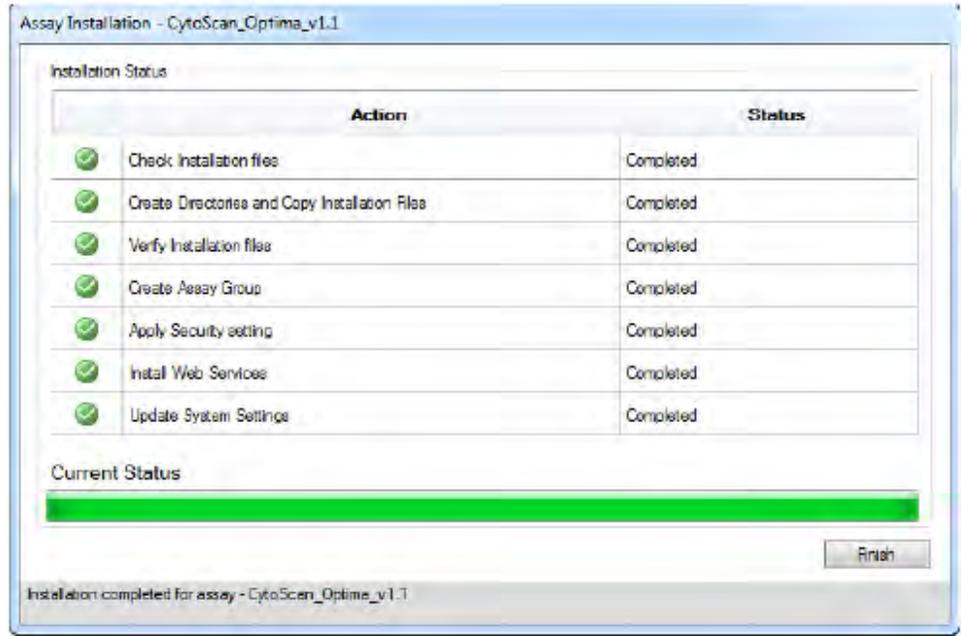

Figure 9   Assay Installation window.

2. Click **Finish** to conclude the ASM installation and return to the Assay Management window.

    Installation of the ASM is complete.

Create a Test Request

Note: You must be a Laboratory Supervisor, Technician, or Technologist to create a Test Request.

1. Click the **Active Worklist** button (Figure 10) if you are not already in the Active Worklist window.

   The **Active Worklist** panel appears.

Figure 10   **Active Worklist** window

2. Click **Create** from the Active Worklist toolbar.

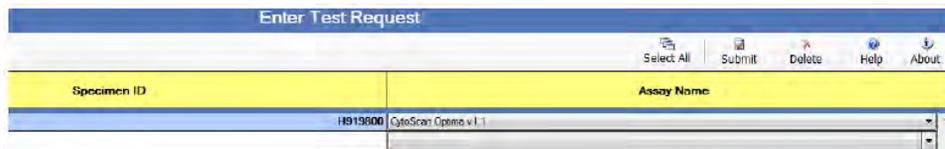   The **Enter Test Request** window appears (Figure 11).

Figure 11   **Enter Test Request** window

3. Use the handheld barcode scanner to enter one or more **Specimen ID**. You may also enter the ***Specimen ID*** manually.

4. Select the **Assay Name** from the drop-down menu for *each* **Specimen ID**.

   Note: The current **Assay Name** for the CytoScan™ Optima Assay Software Module v1.1 is CytoScan Optima v1.1.

5. Click **Submit** when you have made your entries.

   The **Enter Test Request** window closes. The software displays the **Active Worklist** window with the newly created Test Requests on the window.

   Note: After you have submitted the Test Request, the procedures for registration, hybridization, fluidics station processing and scanning are the same as those steps outlined in the *Affymetrix™ Molecular Diagnostics Software User Guide* (Pub. No. 703230). Refer to that document for further instructions.

Adding specimen information

After you create a Test Request and return to the Active Worklist, you can add certain types of pertinent information about the specimen. You can also add this information later here, or in other worklists. This information is not necessary in order to run the assay.

IMPORTANT! You cannot associate any additional information with Test Requests after scanning has started. You will not be able to save your edits. If you attempt to save, the software displays an error message.

Editing specimen information requires an e-signature upon saving, however an e-signature is *not* required for initial data entry.

1. Click the desired **Specimen ID** field.

   The **Additional Information** window appears (Figure 12).

Figure 12   **Additional Information** window showing the Specimen ID

2. Add the following information into the Field Values column:
   - **Sample_ID**—Enter manually or from a barcode.
   - **Family_ID**—Enter manually or from a barcode.
   - **Individual_ID**—Enter manually or from a barcode.
   - **Father_ID**—Enter manually or from a barcode.
   - **Mother_ID**—Enter manually or from a barcode.
   - **Individual Record Number**—Enter manually or from a barcode.
   - **Individual Family Name**—Enter manually.
   - **Individual Given Name**—Enter manually.
   - **Sex**—Select: Male - Female - Unknown - Blank Field
   - **Affection Status**—Select: Unknown - Unaffected - Affected - Blank Field
   - **Date of Birth**—Enter manually using a defined format. The format <u>must be</u> entered in an ISO 8601 format: 4-digit year first, then month, then day. (Example: 2012-11-09 for November 9, 2012) <u>No other date format is allowed.</u>
   - **Sample_Type**—Select: Amniotic Fluid - CVS Sample - POC - Blood - Solid Tissue - Soft Tissue - Saliva - Buccal Swab - Plasma - Blank
   - **Sample Size Unit**—Select: mL - µL - oz - mg - g - inch - cm - mm - Blank Field
   - **Sample Size Value**—Enter manually using a floating-point numeric value.
   - **Method of Collection**—Enter manually.
   - **Collection Date**—Enter manually using an ISO 8601 approved date format.
   - **Collection Time**—Enter manually using either a 12 or 24-hour time format. Twenty-four hour entries are automatically converted to 12-hour. (Example: 13:15 -> 1:15 pm)
   - **Requestor Family Name**—Enter manually.
   - **Requestor Given Name**—Enter manually.
   - **Requesting Institution**—Enter manually.
   - **Request Date**—Enter manually using an ISO 8601 approved date format.
   - **Additional Info 1-5**—Manually enter up to 5 fields.

3. Click **Save and Close** or **Close** (to exit without saving). After clicking **Close**, the following may occur:
   - If no edits were made, the window closes.
   - If you made edits, a message appears and asks if you would like to save changes.

   - Click **Yes** to collect an e-signature, save edits, and close window.
   - Click **No** to discard edits and close window.
   - Click **Cancel** to display the Additional Information window that shows the Specimen ID (with edits displayed).

Assay Home window

The **Assay Home** (or Assay Information) window provides a summary of all specimen information, Test Request logs, and pertinent reagent information for each assay type.

The Assay Home window has the following tabs.

- **Reagent Information** tab
- **Specimen Report** tab
- *Test Request Log* tab

Add reagent information

1. Navigate to the Assay Name field from any worklist window and click **Assay Name**.

   The Assay Home (or Assay Information) window appears.

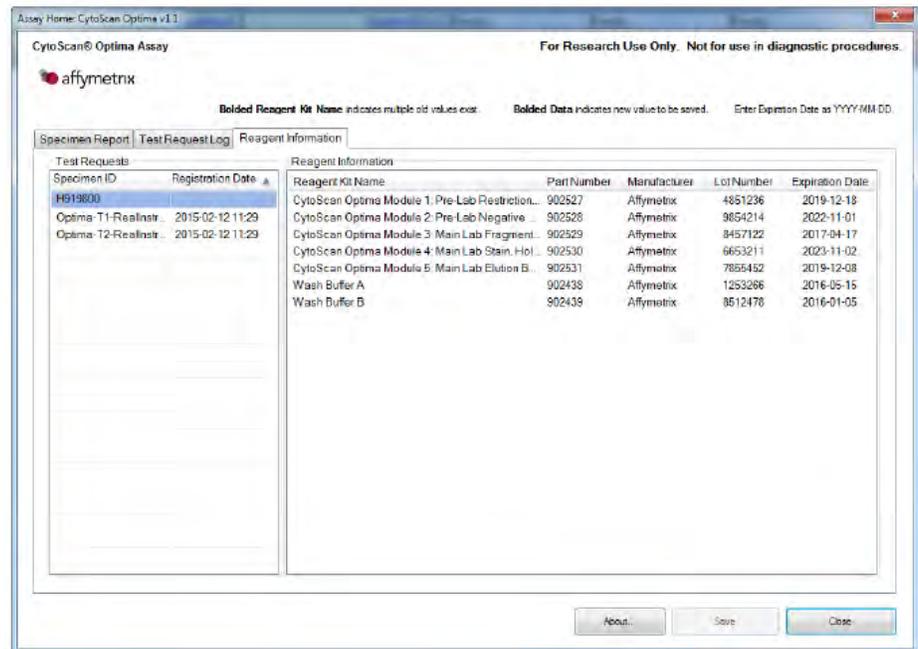2. Click the **Reagent Information** tab (Figure 13) to view current reagent information.

Figure 13 Reagent Information tab

3. Click to select each appropriate Specimen ID from the list (left pane).

4. Use the hand-held barcode scanner to scan each reagent kit barcode.

   Note: You can also enter the reagent kit information manually by selecting Test Requests in the left side of the window, placing the cursor in to the lot number and expiration date fields for the appropriate kits and typing in the correct

information. This method should be used for all reagents manufactured by companies other than Thermo Fisher Scientific.

The scanner parses the reagent information, then enters its lot number and expiration date into the correct fields (for all selected test requests). Using the barcode scanner eliminates manual entry errors.

5. Click **Save**.

Reagent kit information

The **Assay Home** (or **Assay Information**) window contains the following reagent kit information:

- Reagent kit name
  - CytoScan™ Optima Module 1: Pre-Lab Restriction, Ligation, and Amplification (Part. No. 902527)
  - CytoScan™ Optima Module 2: Pre-Lab Negative Control and Water (Part. No. 902528)
  - CytoScan™ Optima Module 3: Main Lab Fragmentation, Labeling, and Hybridization (Part. No. 902529)
  - CytoScan™ Optima Module 4: Main Lab Stain, Holding Buffer, and Purification Beads (Part. No. 902530)
  - CytoScan™ Optima Module 5: Main Lab Elution Buffer, Water, and Wash Buffer (Part. No. 902531)
  - Wash Buffer A (Part. No. 902438)
  - Wash Buffer B (Part. No. 902439)
- Reagent kit manufacturer information
- Reagent lot number
- Reagent expiration date

Note: The reagent kit lot number, and expiration date are *not* required to run the assay.

Reagent entry information

AMDS provides the ability to transfer the reagent kit name, manufacturer, part number, lot number and expiration date to the server, along with other Test Request information.

Reagents marked with Thermo Fisher Scientific as the manufacturer can be entered using a barcode scanner. The corresponding lot number and expiration date (for ALL selected Test Requests) are automatically entered into their appropriate field.

Reagent information manufactured by other companies must be entered manually.

Note:
You cannot make any edits to a Test Request after the array associated with that particular Test Request has started scanning on the GeneChip™ Scanner 3000Dx v.2.

If you click **Close** only, the following occurs:

- If no edits were performed, the window closes.
- If edits were made, a message appears that asks if you would like to save changes.
    - Click **Yes** to save edits and close the window.
    - Click **No** to discard ALL edits and return to the **Reagent Information** window.
    - Click **Cancel** to return to the **Reagent Information** window (with edits saved).

Reagent kit lot numbers and expiration dates

The CytoScan™ Optima Assay Software Module retains the association between a reagent kit lot number and its expiration date.

Expiration date scenarios

If you enter a lot number already associated with another test request, AMDS auto-populates the Expiration Date field. Clicking **Save** will save all associated Test Requests.

To modify an AMDS auto-populated Expiration Date field, enter the date change, then click **Save**. The message: Do you want to save this expiration date for all other test requests with this lot number? appears. Do the following:

- Click **OK** to save this Expiration Date for ALL Test Requests.
- Click **Cancel** to return to the window without modifying the original expiration date.

Clicking **OK**, generates the following message: You have changed the expiration date for <reagent kit name> Lot <lot number> from <old date> to <new date>.

This operation affects <count> Test Requests.

After saving, the new expiration dates are retained. ALL prescanned Test Requests and lot numbers now include their new expiration dates.

Specimen Report tab

Click the **Specimen Report** tab (Figure 14) to view all of the specimen IDs associated with that assay type (in this case the CytoScan™ Optima Assay Software Module v1.1).
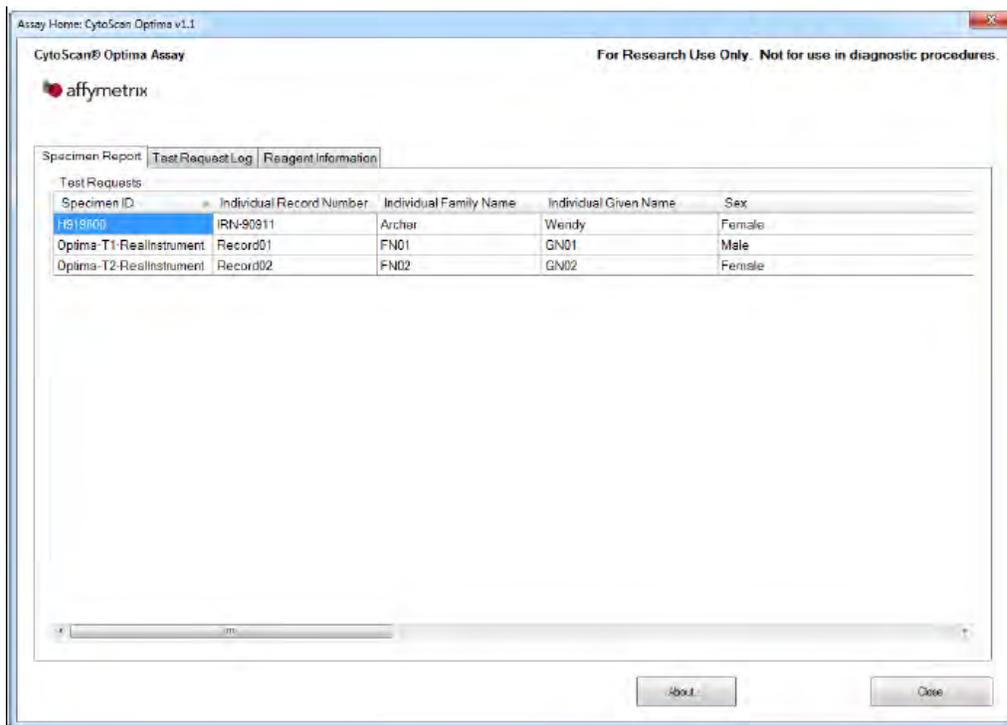

Figure 14   Specimen Report tab

This window includes the following fields:

- Specimen ID
- Individual Record Number
- Individual Family Name
- Individual Given Name
- Sex
- Affection Status
- Sample_ID
- Sample_Type
- Requestor Family Name
- Requestor Given Name
- Requesting Institution
- Request Date

Test Request Log tab

Click the **Test Request Log** tab (Figure 15) to view all the Test Requests associated with an assay type.
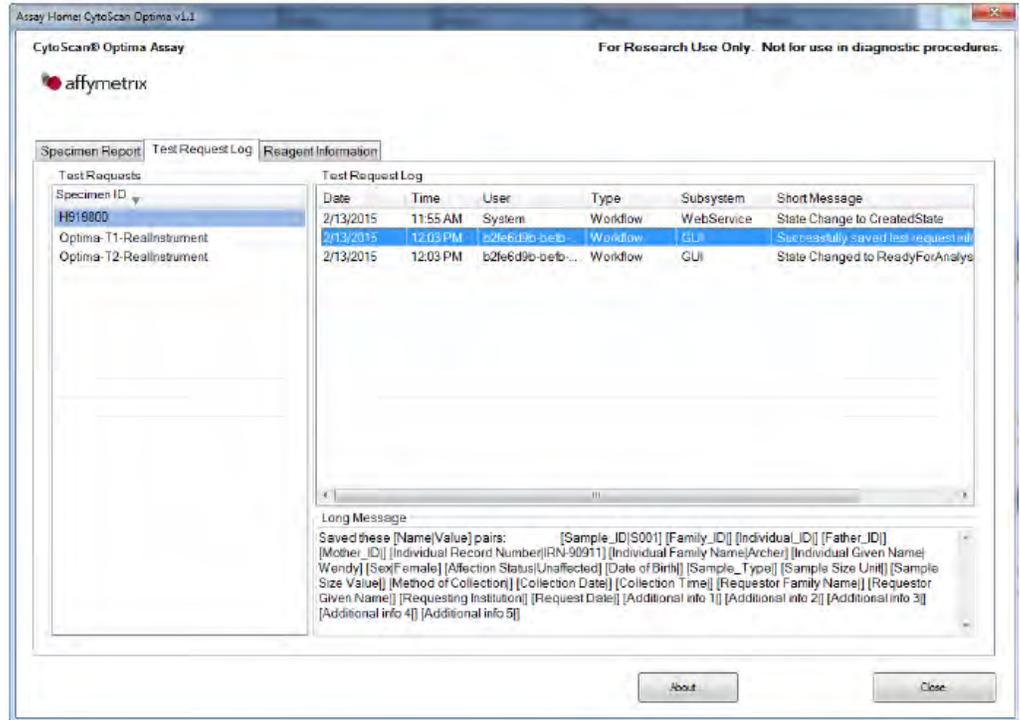

Figure 15   Test Request Log tab

Each Test Request includes the following log entry information:

- Date
- Time
- User
- Type
- Subsystem
- Short Message
- Long Message

Batching additional Test Request information

Use the Batch Edit feature to enter or edit the identical information over multiple Test Requests.

IMPORTANT! To ensure data accuracy, changes must be saved before scanning. You cannot add or edit information after scanning is complete.

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1. Select your Test Requests from the Active Worklist or any of the worklist window.

2. Click the **Batch Edit** button. The Assay Batch Information window appears (Figure 16) listing Specimen IDs (left pane).

Figure 16 Assay Batch Information window

3. Navigate to the Field Value column (right column of right pane), and enter or change the following:
   - Sex
   - Affection Status
   - Sample_Type
   - Method of Collection
   - Collection Date
   - Collection Time
   - Requestor Family Name
   - Requestor Given Name
   - Requesting Institution
   - Request Date
   - Additional Info 1-5 (five user-defined fields)

4. Click **Save and Close** to save your changes. Otherwise, click **Close** to exit the Batch Edit window and then click to select the appropriate button.

    - Click **Yes** to save edits.
    - Click **No** to discard ALL edits.
    - Click **Cancel** to return to the Batch Edit window (with edits saved).

Perform a manual grid alignment

If an alert (error) occurs during the automatic gridding process you can perform a manual grid alignment.

IMPORTANT! Before gridding manually, you must be familiar with the gridding function referenced in the *GeneChip™ System 3000Dx v.2 User Guide* (Pub. No. 703227), *GeneChip™ Command Console™ (GCC) 4.0 User Guide* (Pub. No. 702569), or other applicable documentation. The gridding procedure in the AMDS User Guide is based on the gridding procedure outlined in these documents.

A gridding failure on a Test Request triggers a manual grid alignment alert. Do the following to remedy this alert:

1. Click the Alert (Alerts window - right pane).

2. View the Alert and then click **Resolve**.

3. Enter your User ID and Password.

4. Click **OK**.
    The DatImageViewer window appears.

5. Manually adjust the grid.

6. Click **Save**.

7. Close the DatImageViewer window.

Transferring data

AMDS automatically transfers the completed assay data to the URL that you set up when you originally installed your assay. The descriptor labels and data that AMDS transfers to the non-AMDS system include the following file types: .ARR - .AUDIT - .CEL - .JPG - .DAT - .LOG - .MD5

The .MD5 file is a CHECKSUM file. Use the utility FastSum (Windows™) or md5sum (Linux™) to confirm the AMDS has correctly transferred all the files.

Note: Specimen and tracked reagent information labels (and their corresponding data fields) can either be completed or left blank.

The AMDS confirms the data has completed its transfer successfully, by the following criteria:

- The assay module detects no exceptions upon transferring.
- The assay module confirms that every file listed has successfully transferred to the server.

After AMDS transfers files to the server, it places all associated files in a folder named, CytoScan_Optima_v1.1

The AMDS renames the transferred files using the following convention:

Test Request Date and Time + "_" + 3 digits + "_" + specimenID + original file extension. Example: 20120821_153910_001_H919800.DAT

Note: After a successful data transfer, AMDS auto-deletes the .DAT and .CEL files from its local hard drive.

Review the Test Report

After completing all assay steps (registration, hybridization, wash/stain, scanning, etc.), the Test Request moves to a Non-Active Worklist. ASM generates a Date/Time stamp hyperlink.

IMPORTANT! To view the Test Result report, you must be in the Non-Active Worklist window.

Locate the Test Request record that you want to review from the Review Results column (far right). Then, click its Date/Time hyperlink.

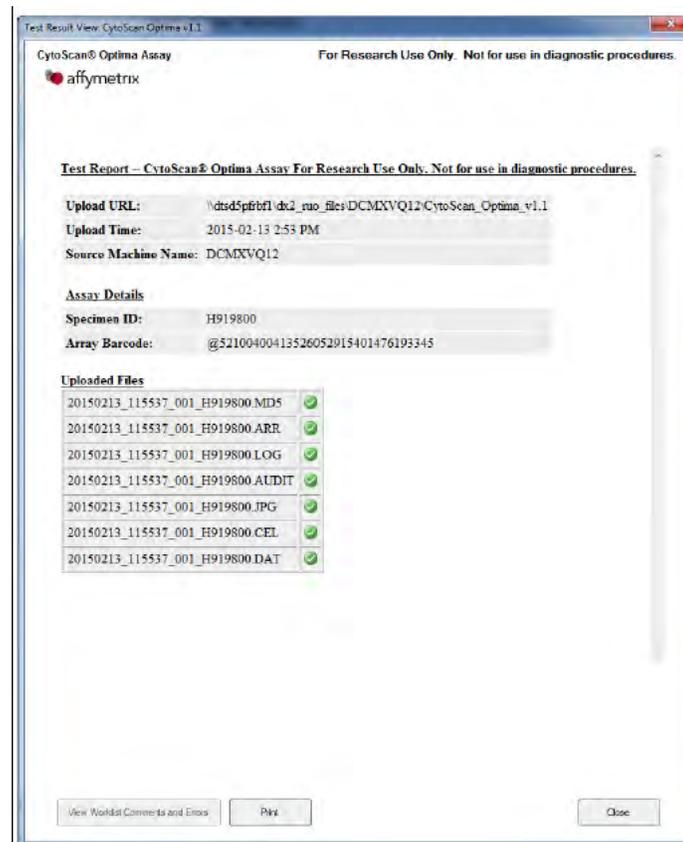The Test Review window appears (Figure 17).

Figure 17   Test Result View window for the Test Report

The Test Report displays the following information:

- Upload details
  - Upload URL (Save location of files)
  - Upload Time
  - Source Machine Name
- Assay Details
  - Specimen ID
  - Array barcode

- Uploaded Files (Transferred files)
  - .ARR
  - .JPG
  - .AUDIT
  - .CEL
  - .DAT
  - .LOG
  - .MD5
- **Close** - Closes the Results window.
- **Print** - Prints the results to a pre-configured default printer.
- View Worklist Comments and Errors - The Audit Log Comments and Errors window appears (Figure 18). Any comments or errors associated with the Test Request are listed here.

Figure 18 Audit Log Comments and Errors window

Ordering information

Product	Source
CytoScan™ Optima Kit	902533
CytoScan™ Optima Training Kit	902534

A Documentation and support

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  - Safety Data Sheets (SDSs; also known as MSDSs)

    Note: For SDSs for reagents and chemicals from other manufacturers, contact the manufacturer.

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