



User's Guide

OncoScan™ Assay Software Module v1.1

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OncoScan™ Assay Software Module v1.1

Introduction

This User's Guide demonstrates how to create a **OncoScan Assay Software Module v1.1 RUO Assay Test Request**.

This software is for use with the GCS3000Dx v.2 system and is also compatible with the following Reagent Kits:

- OncoScan FFPE Reagent Kit

Nomenclature

- The Assay name is **Affymetrix® OncoScan Assay**.
- The Assay display name is **OncoScan v1.1**.
- The term **ASM** refers to **Assay Software Module**.

Major Features of OncoScan v1.1

The major features of OncoScan v1.1 are 4 windows that augment assay record keeping. This user guide will also discuss the use of these windows in setting up the assay. These windows include:

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

OncoScan 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's 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 AMDS Assay protocols, then 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 Diagnostic Software User's Guide (PIN 08-0261)**.



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

- Affymetrix® Molecular Diagnostic Software User's Guide (P/N 08-0261)
- Affymetrix® Molecular Diagnostic Software Quick Reference Card (P/N 08-0262)
- OncoScan™ FFPE Assay Kit User Manual (P/N 703175)

Reagents

Reagents for the OncoScan Array - single array (P/N 520780) comprise the following Reagent Sub-Kits and their associated part numbers:

- OncoScan™ Somatic Mutation Probe Mix 1.0 - (P/N 902272)
- OncoScan™ Copy Number Probe Mix 1.0 & Controls - (P/N 902268)
- OncoScan™ Gap Fill and 1st Stage PCR - (P/N 902269)
- OncoScan™ 2nd Stage PCR and Post PCR Processing - (P/N 902270)
- OncoScan™ Stain Reagents - (P/N 902271)
- Wash Buffer A - (P/N 901680)
- Wash Buffer B - (P/N 901681)

Installing the ASM (Assay Software Module)

To process a OncoScan v1.1 Test Request on the system, you must first:

1. Install a Certificate (only for secure transfers to a Data Transfer Server and not required for CIFS transfers)
2. Install OncoScan v1.1

Installing a Certificate



NOTE: In most cases, the Affymetrix 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 *Installing OncoScan v1.1* [on page 6](#).

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

The Affymetrix 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.

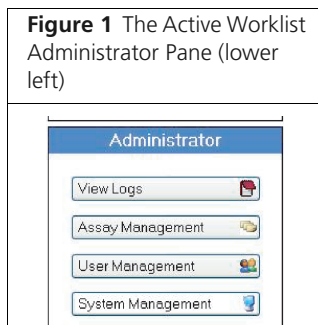
If a proper certificate has not been installed, you can still install the assay and process test requests; however, you will not have permission to access the server, and you cannot transfer test request data to the server.

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



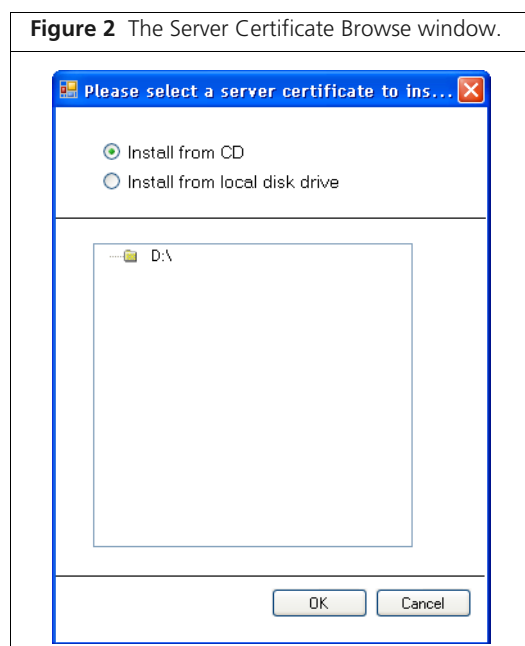
NOTE: You must be logged in with either Laboratory Supervisor or System Maintainer privileges to install a certificate.

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



To install a certificate:

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)



4. Make sure the **Install from CD** radio button is selected, 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 Affymetrix Service Representative for information on obtaining a new certificate.

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

Installing OncoScan v1.1

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

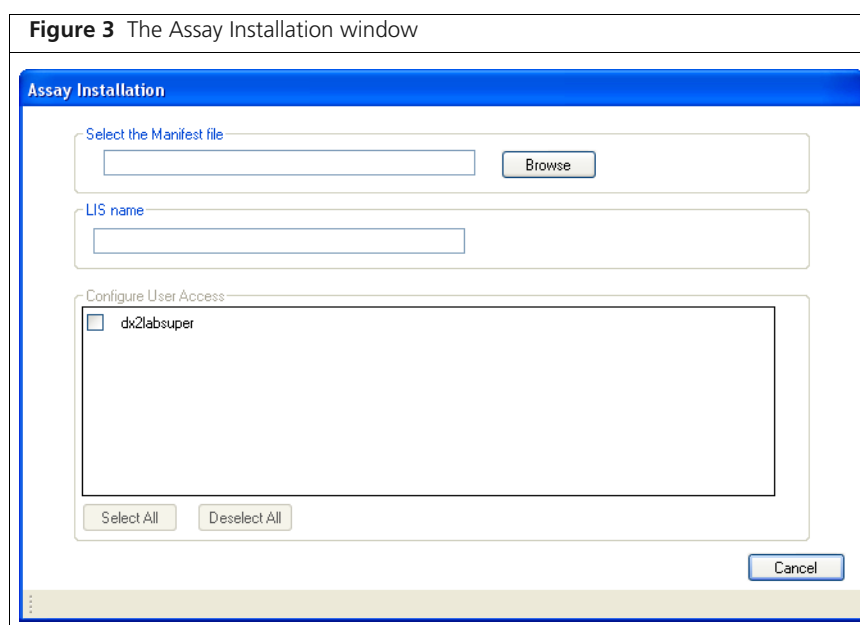


NOTE: You must be logged in with either Laboratory Supervisor or with System Maintainer privileges to install an Assay Software Module.

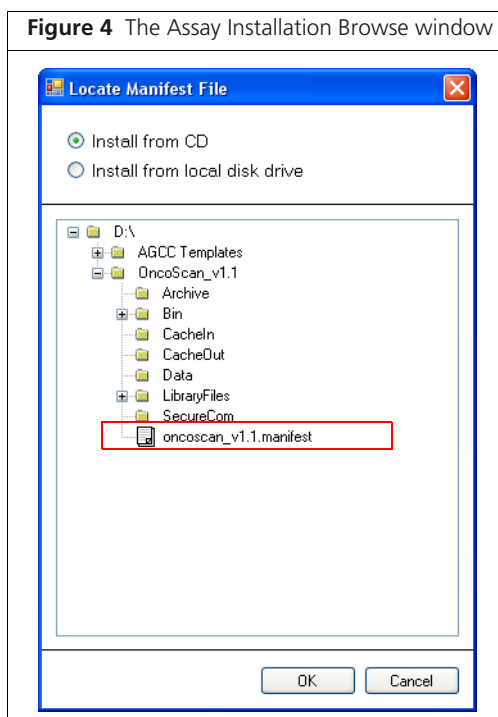
To install OncoScan v1.1:

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)

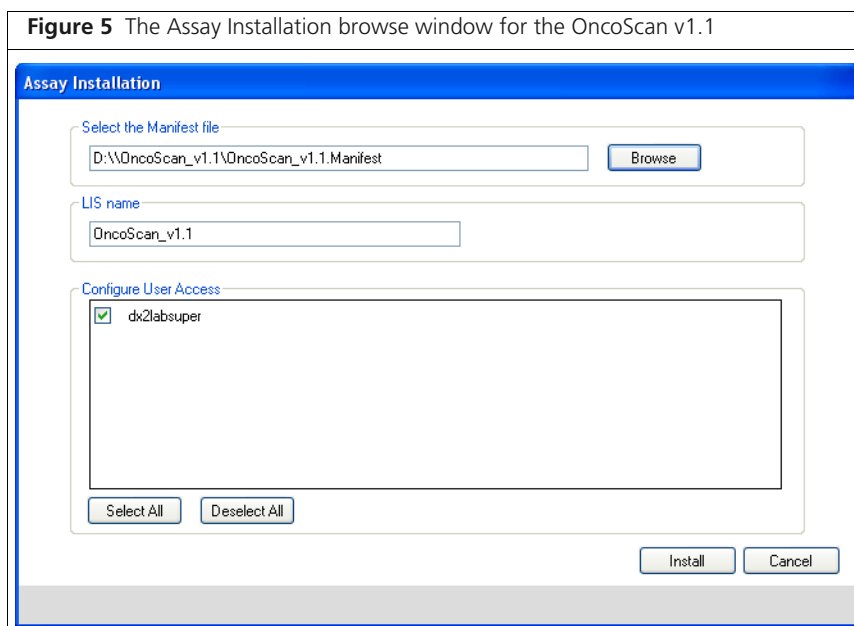


4. Click **Browse**.
The Assay Installation Browse window appears. (Figure 4 on page 7)



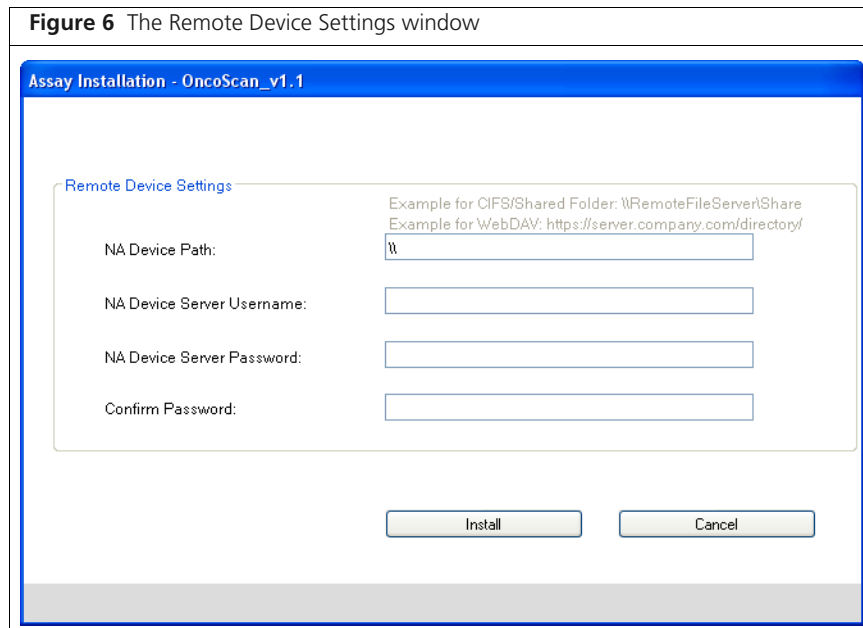
5. Make sure the **Install from CD** radio button is selected, then navigate to and click on D:\OncoScan_v1.1\oncoscan_v1.1.manifest
6. Click **OK**.

The Assay Installation window appears. (Figure 5)



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

The Remote Device Settings window appears. (Figure 6)



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.

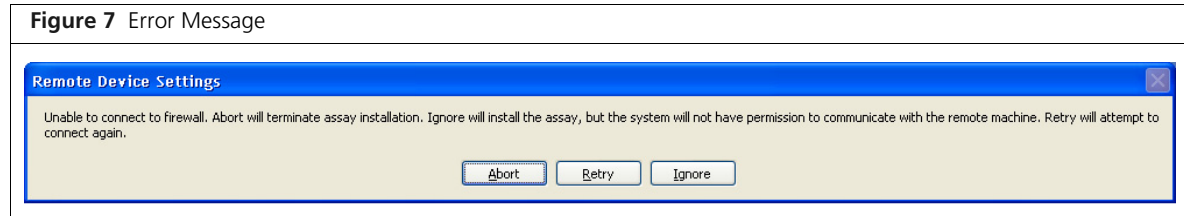


NOTE: Your NA Device Server Username and Password are not the user name and password that you used to log into AMDS. You must enter your user name and password that you use to access the server.

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)



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

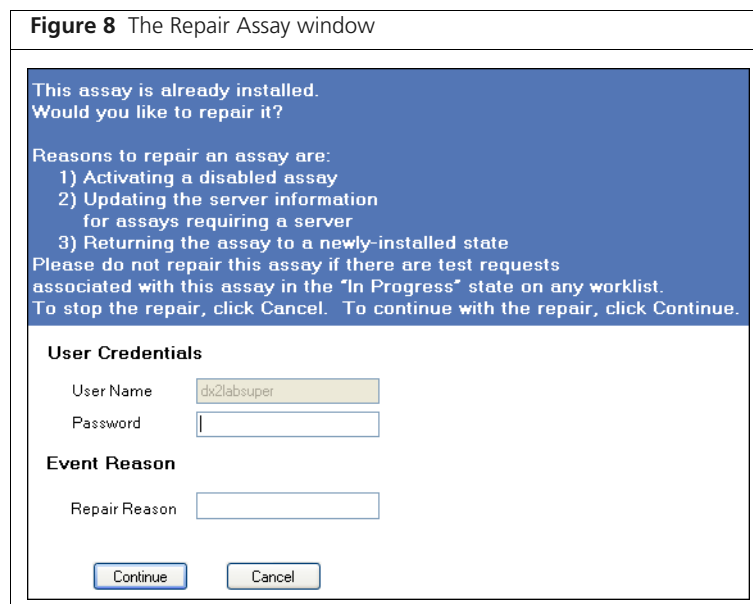
- **Abort** - Exits the Assay installation.
- **Retry** - Attempts another try.
- **Ignore** - Continues the installation.



NOTE: If you select Ignore, AMDS installs the Assay, however you will not be granted permission to communicate with any remote server.

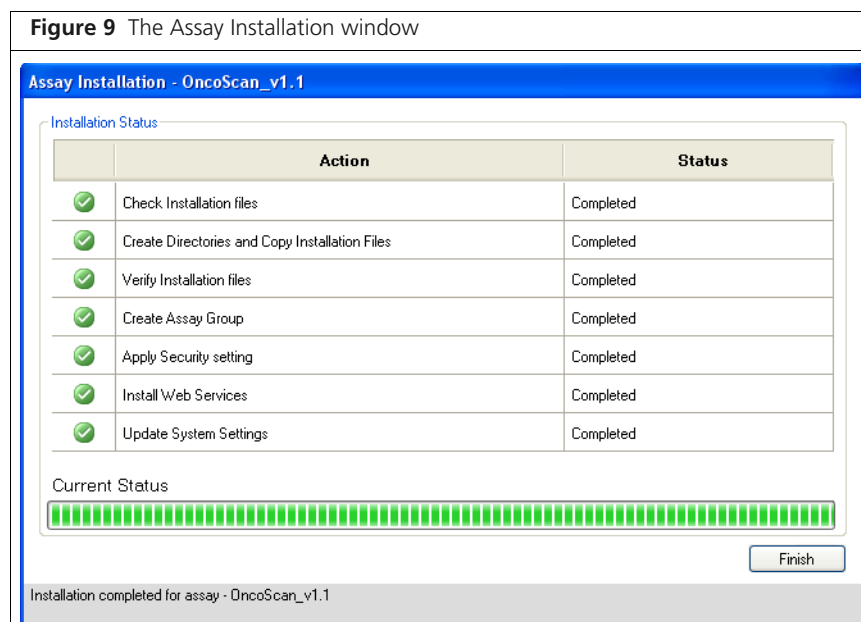
Repairing Currently Installed ASM

If this ASM already exists on the system and it is reinstalled, the following message appears: (Figure 8)



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**.
The ASM Installation status window and progress bar appear. (Figure 9)



2. Click **Finish** to conclude the ASM installation and return to the Assay Management window.
Installation of the ASM is now complete.

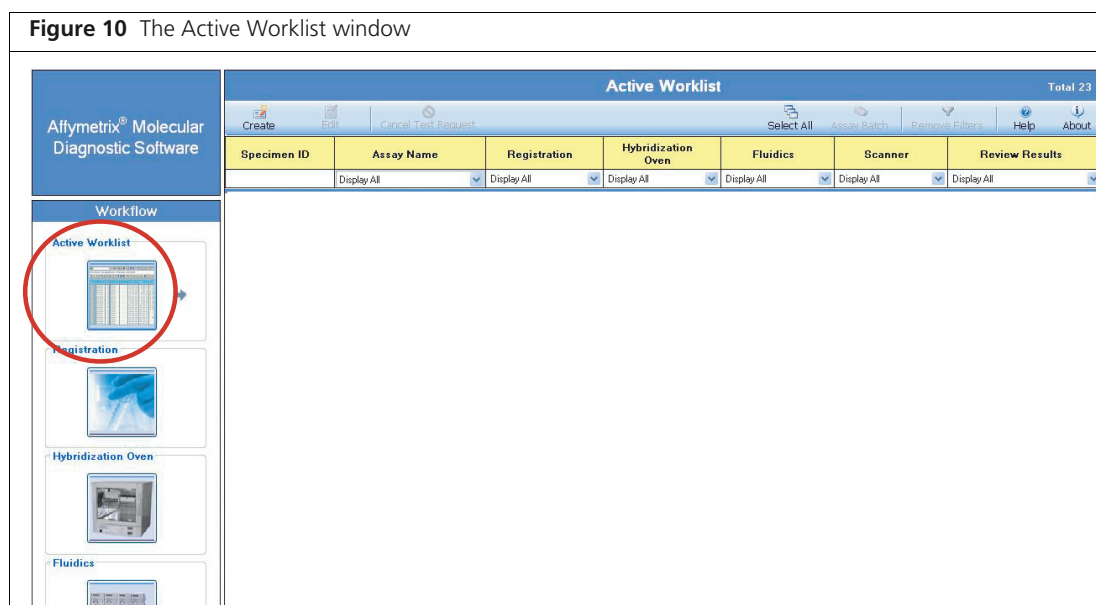
Creating a Test Request



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

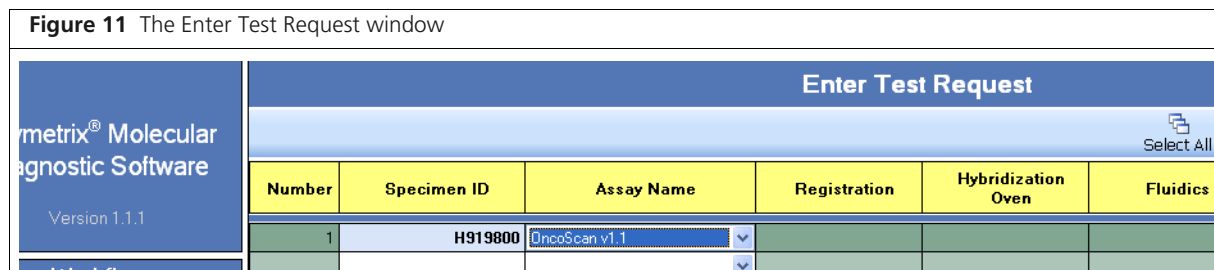
1. If you are not already in the Active Worklist window, click the **Active Worklist** button. (Figure 10)

The Active Worklist panel appears.



2. From the Active Worklist toolbar, click **Create**.

The Enter Test Request window appears. (Figure 11)



3. Use the handheld barcode scanner to enter one or more **Specimen IDs**. You may also enter the Specimen IDs manually.
4. Select the **Assay Name** from the drop-down menu - for EACH Specimen ID.



NOTE: The current Assay Name for the OncoScan Assay Software Module v1.1 is: *OncoScan v1.1*

5. Once you have made your entries, click **Submit**.

The Enter Test Request window closes. The software displays the Active Worklist window with the newly created test request(s) 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 Diagnostic Software User's Guide* (P/N 08-0261). 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 on page 13](#))

Figure 12 The Specimen ID Additional Information window

Additional Information: OncoScan v1.1

Affymetrix® OncoScan Assay For Research Use Only. Not for use in diagnostic procedures.

Specimen ID: H919800

Red Field Names indicate required fields for data transfer. **Bolded Value** indicates new value to be saved. Enter Date as YYYY-MM-DD, Time as HH:MM:SS am/pm.

Field Name	Field Values
<i>Channel</i>	AT
Individual Record Number	P-0051
Individual Family Name	Archer
Individual Given Name	Wendy
Sex	Female
Date of Birth	2002-12-18
Specimen Type	Other
Collection Date	
Collection Time	
Requestor Family Name	
Requestor Given Name	
Requesting Institution	
Request Date	
Additional info 1	
Additional info 2	
Additional info 3	
Additional info 4	
Additional info 5	

2. Add the following information:

- **Channel** - Select: AT - GC - Blank Field. This field requires a value in order to process a test request through the workflow.
- **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
- **Date of Birth** - Enter manually using a defined format. The format must be entered in an ISO 8601 format: 4-digit year first, then month, then day. (Example: 2012-11-09 for November 9, 2012) **No other date format is allowed.**
- **Specimen Type** - Select: FFPE - Other - Blank Field
- **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**, one of the following occurs:
 - If no edits were made, the window closes.
 - If you made edits, a **Would you like to save changes?** message appears.
If the **Would you like to save changes?** message appears, do one of the following:
 - 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 Specimen ID additional information window (with edits displayed).

The Assay Information/Home Window

Adding Reagent Information

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

The Assay Information/Home window has the following tabs/sub-windows:

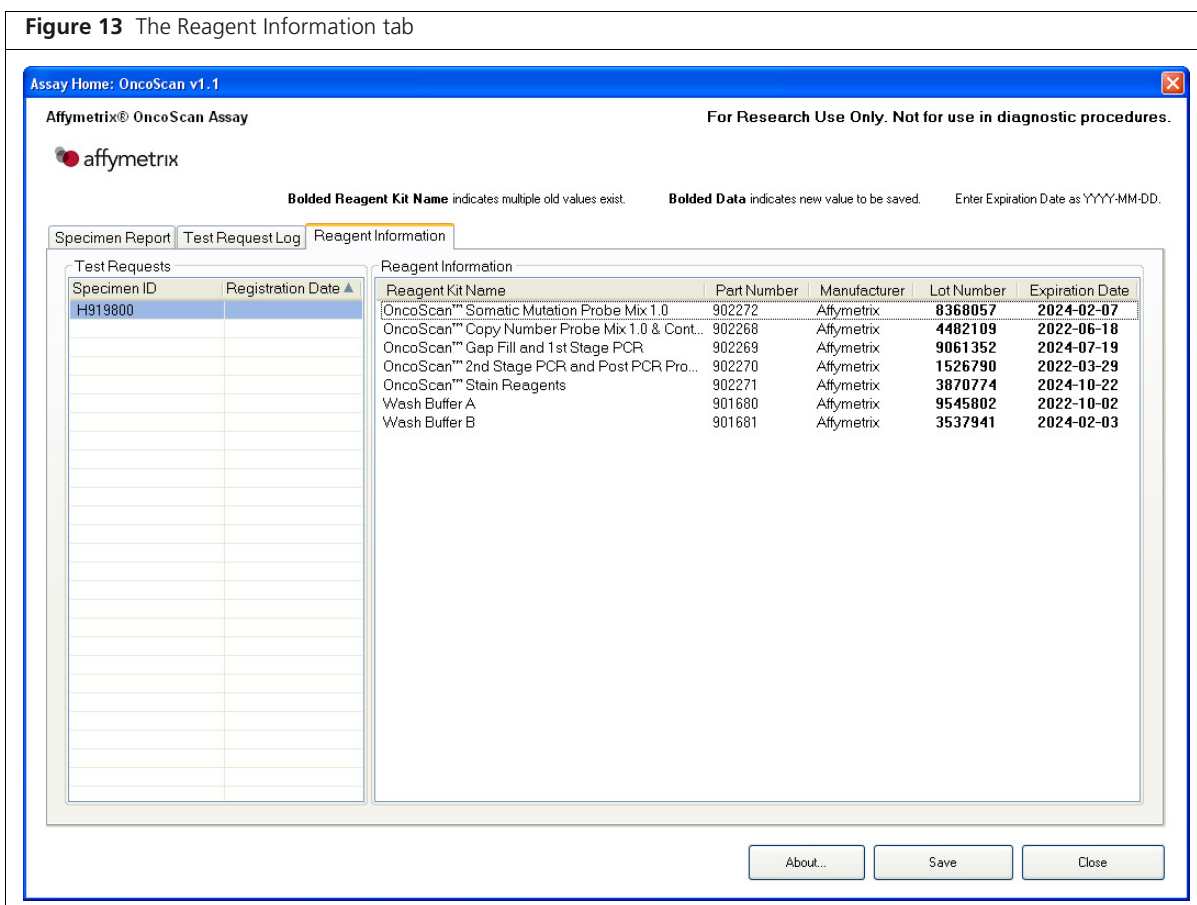
- Reagent Information
- Specimen Report
- Test Request Log

1. From any worklist window, go to the Assay Name field and click **Assay Name**.

The Assay Information/Home window appears.

2. Click the **Reagent Information** tab [Figure 13 on page 15](#) to view current Reagent information

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



- Use the handheld 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, then 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 Affymetrix, Inc.

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.

- Click **Save**.

Reagent Kit Information

The OncoScan v1.1 Assay Information/Home window contains the following Reagent Kit information:

- Reagent Kit Name
 - OncoScan™ Somatic Mutation Probe Mix 1.0 - (P/N 902272)
 - OncoScan™ Copy Number Probe Mix 1.0 & Controls - (P/N 902268)
 - OncoScan™ Gap Fill and 1st Stage PCR - (P/N 902269)
 - OncoScan™ 2nd Stage PCR and Post PCR Processing - (P/N 902270)
 - OncoScan™ Stain Reagents - (P/N 902271)
 - Wash Buffer A - (P/N 901680)
 - Wash Buffer B - (P/N 901681)
- 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 No. and Expiration Date to the server, along with other test request information.

Reagents marked with **Affymetrix** 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 GCS3000Dx v.2 scanner.

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

- If no edits were performed, the window closes.
- If edits were made, the message **Would you like to save changes?** (with 3 buttons) appears. Do one of the following:
 - 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 OncoScan v1.1 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. Click **Save** to 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.

Special Note About Changing Expiration Dates

If you change the expiration date for a previously entered lot number, then click OK, the following message appears:

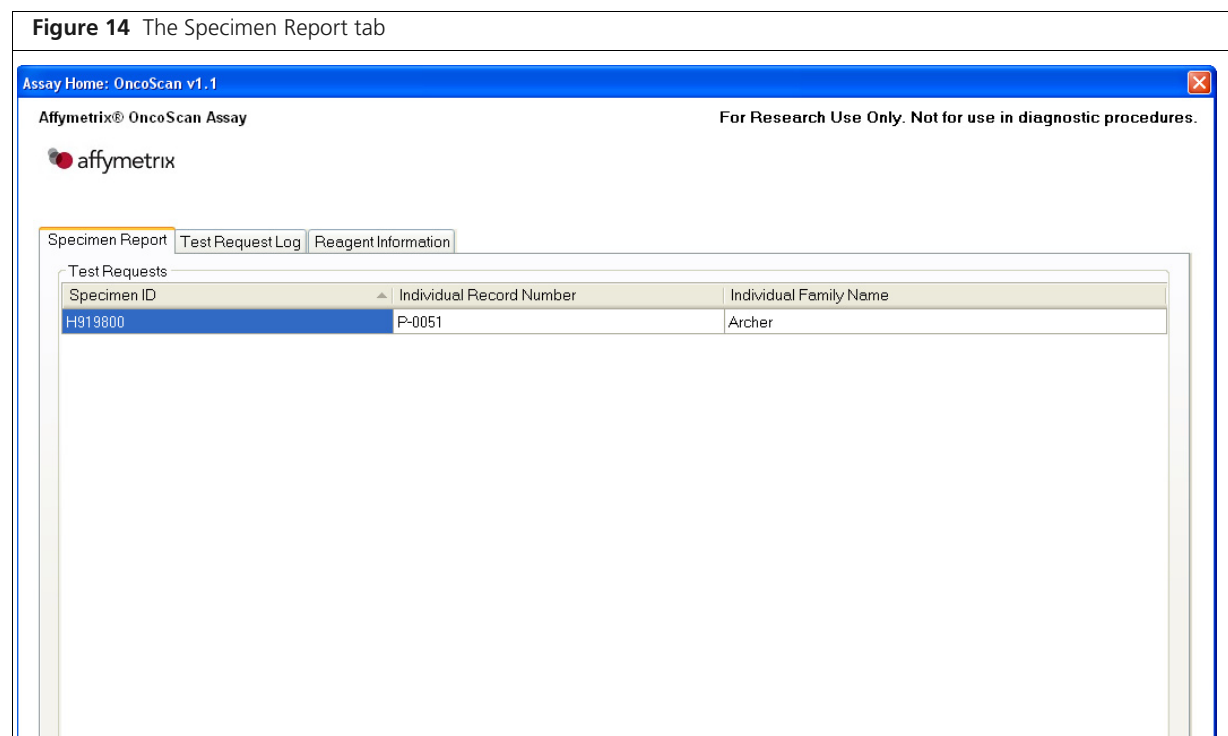
You have changed the expiration date for <reagent kit name> Lot <lot number> from <old date> to <new date>.

This affects <count> Test Requests.

After saving (clicking OK), the new Expiration Date(s) are retained. ALL pre-scanned Test Request(s) and Lot Number(s) now include their new Expiration Date(s).

Specimen Report Tab

Click the **Specimen Report** tab (Figure 14) to view all the Specimen IDs associated with that Assay type (in this case the OncoScan v1.1).



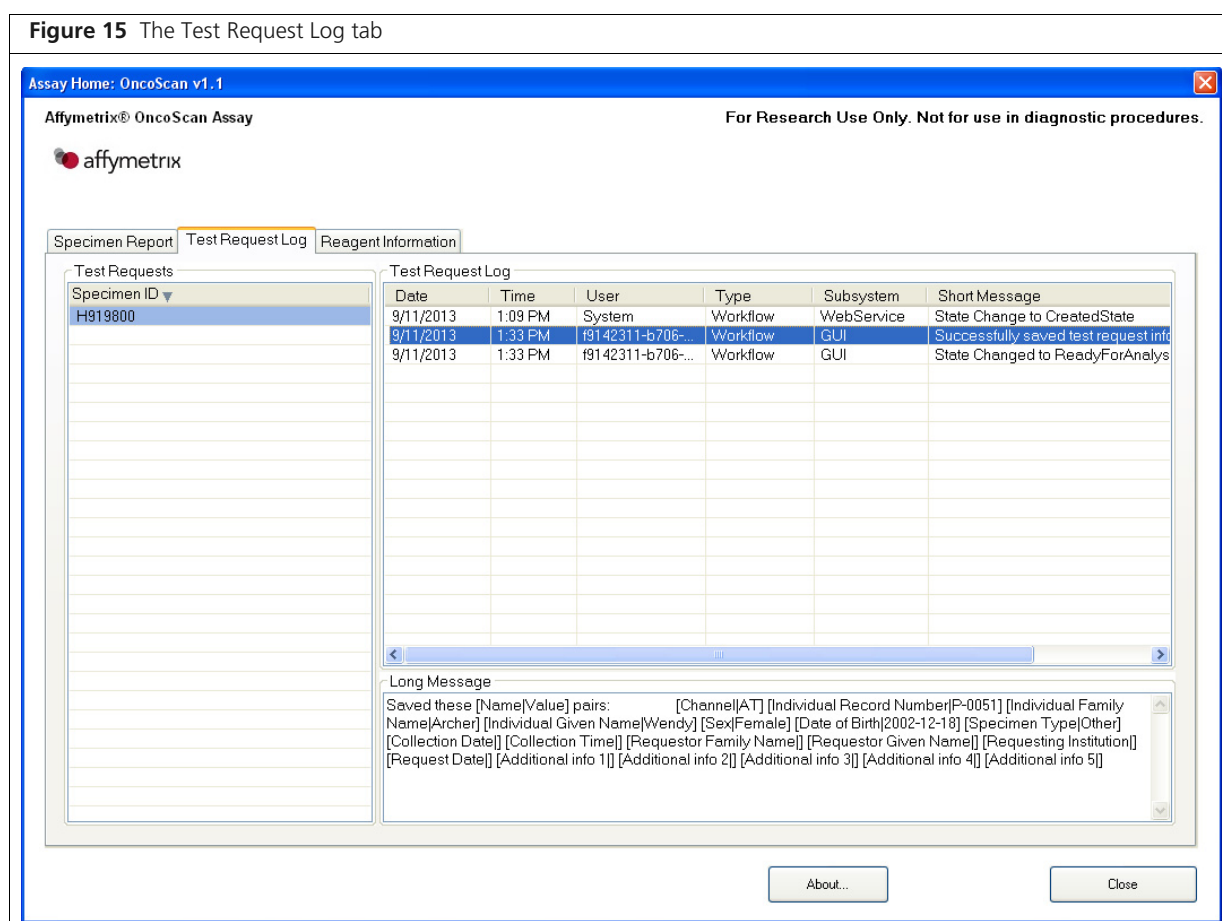
Click the **Specimen Report** tab to view ALL Specimen IDs associated with an Assay type. This window includes the following fields:

- Specimen ID
- Individual Record Number
- Individual Family Name
- Individual Given Name
- 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. Each Test Request includes the following **Log Entry** information:

- Date (of the log entry)
- Time (of the log entry)
- User (who logged in when the log entry was created)
- Type (of log entry)
- Subsystem (associated with log entry)
- Short Message (associated with the log entry)
- Long Message (related to the selected short message)



Gridding Manually

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 Affymetrix GeneChip® System 3000Dx v.2 User Guide (P/N 08-0261), the Affymetrix® GeneChip® Command Console™ 1.0 User's Guide (P/N 702569), the GeneChip® System 3000Dx (for EU) User's Guide (P/N 08-0136), or other applicable Affymetrix documentation. The AMDS manual's gridding procedure is based on the gridding procedure outlined in these manuals.

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

Do the following to address this manual grid alignment alert:

1. Click the Alert (Alerts window - right side).
2. View the Alert, 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 **DatImageViewer**.

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 - .DAT - .LOG - .MD5 - .JPG**

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, **OncoScan_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.

Reviewing the Test Report

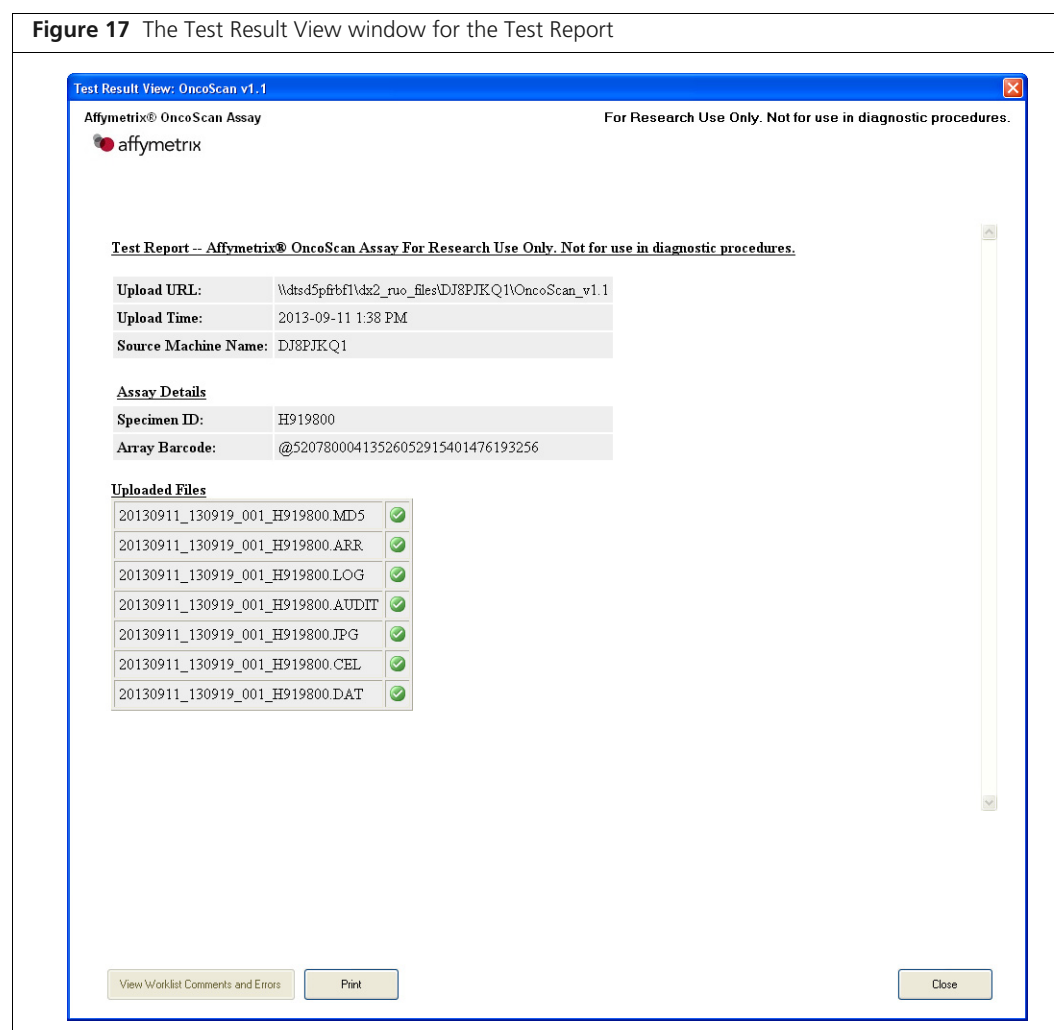
After completing all Assay steps (Registration, Hybridization, Wash/Stain, Scanning, etc.), the Test Request moves to a Non-Active Worklist. ASM generates a Date/Time stamp hyperlink.



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

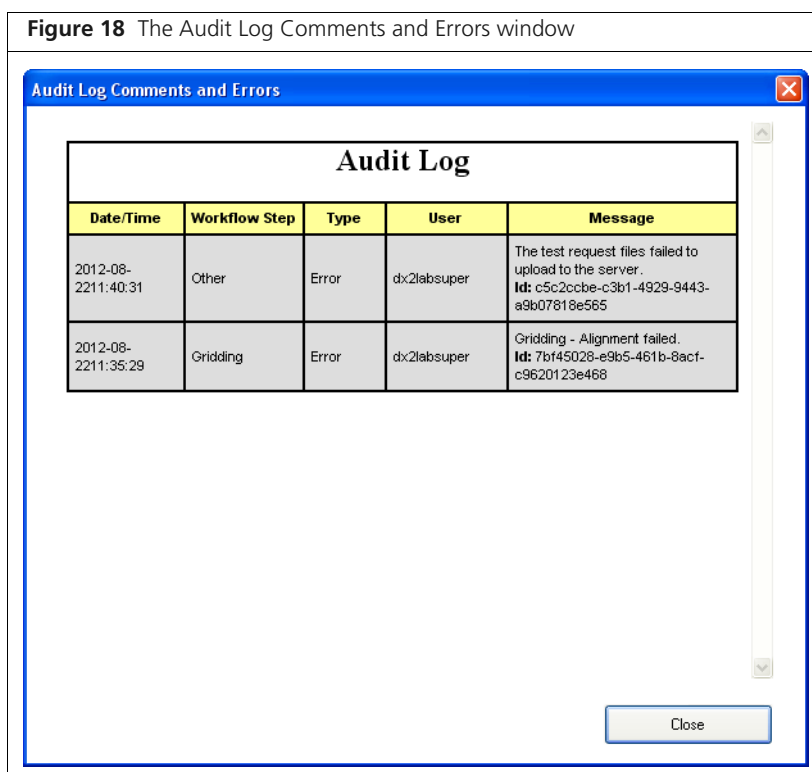
1. From the Review Results column (far right), Locate the Test Request Record you want to review, then click its Date/Time hyperlink. The Test Results/Test Report window appears. (Figure 17)

Figure 17 The Test Result View window for the Test Report



The **Test Report** (Figure 17 on page 22) 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
 - .AUDIT
 - .CEL
 - .DAT
 - .JPG
 - .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.



Ordering Information

The table below lists the **OncoScan v1.1** Reagents, Arrays and associated part numbers.

Name	P/N	Supplier
OncoScan™ FFPE Assay Kit - Array and Reagent Kit Bundle	902293	Affymetrix
OncoScan™ Training Kit - Array and Reagent Kit Bundle	902305	Affymetrix

Technical Support

Affymetrix, Inc.
 3420 Central Expressway
 Santa Clara, CA 95051
 USA
www.affymetrix.com

Email: support@affymetrix.com
 Tel: 1-888-362-2447 (1-888-DNA-CHIP)
 Fax: 1-408-731-5441

Affymetrix UK Ltd
 Voyager, Mercury Park,
 Wycombe Lane, Wooburn Green
 High Wycombe HP10 0HH
 United Kingdom
www.affymetrix.com

Email: supporteurope@affymetrix.com
 UK: 0800 328 0056
 France: 08-00-91-95-05
 Germany: 01803-001334
 Italy: 800-91-59-74
 Other: +44-1628-552550
 Fax: +44-(0)1628-552598

Affymetrix Japan, K. K.
 ORIX Hamamatsucho Bldg, 7F
 1-24-8 Hamamatsucho, Minato-ku
 Tokyo 105-0013 Japan

Email: supportjapan@affymetrix.com
 Tel: +81-3-6430-4030

For complete contact information and specific regional support contact information, please go to www.affymetrix.com/browse/contactUs.jsp