

A large, vertical, metallic DNA double helix structure that runs along the left side of the page, starting from the bottom and extending towards the top.

## *User's Guide*

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**Affymetrix® Gene Profiling  
Assay - cGMP U133 P2 v1.1  
Assay Software Module**

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# Affymetrix® Gene Profiling Assay - cGMP U133 P2 Software Module, Version 1.1

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## Introduction

This user's guide shows you how to create the Affymetrix® Gene Profiling Assay - cGMP U133 P2 v1.1 RUO assay test request. This module is for the Affymetrix® Gene Profiling Array, cGMP U133 P2, that is run on the GCS3000Dx v.2 system using the Affymetrix® Molecular Diagnostic Software (AMDS).

Affymetrix has designed this assay software to be compatible with the GCS3000Dx v.2 system, Affymetrix® Gene Profiling Reagents Kits, and the GeneChip® 3' IVT Express Kit with GeneChip® Hybridization Wash and Stain Kit.

## Nomenclature

The assay name is “Affymetrix Gene Profiling Assay - cGMP U133 P2 v1.1”

The assay display name is “Gene Profiling cGMP v1.1” and this name will be used to refer to this assay throughout this user's guide.

## Major Features of the Gene Profiling cGMP v1.1 Assay Test Request

The major features of the Gene Profiling cGMP v1.1 Assay are four screens that augment assay record keeping. This user guide will also discuss the use of these screens in setting up the assay. These screens include:

1. an Additional Information screen
2. an Assay Information screen (or Assay Home screen)
3. a Batch screen
4. a Report screen

In addition, the Gene Profiling cGMP v1.1 Assay, under the control of the AMDS application, can transfer all specimen information to an RUO server.

It is not the purpose of this short user's guide to instruct you on how to run the assay. This user's guide will show you how to create the RUO test request. To complete the assay run, you will still need to follow the standard AMDS assay protocols and process it through the workflow to register, hybridize, wash/ stain, and scan the assay (as part of the array cartridge). The details of which are discussed in the *Affymetrix® Molecular Diagnostic Software User's Guide* (P/N 08-0261).

You must be thoroughly familiar with the information contained in the *Affymetrix® Molecular Diagnostic Software User's Guide*, the *Affymetrix® Molecular Diagnostic Software Quick Reference Card* (P/N 08-0262) and the *Affymetrix® Gene Profiling Reagents User Guide* (P/N 702749) before you can use the information contained in this supplement to run the assay.

## Reagents

Reagents for the Affymetrix® Gene Profiling Array, cGMP U133 P2 (array P/N 501009, Box of 8 arrays P/N 901411) comprise the following reagent sub-kits and associated part numbers:

### IVD Reagent Kits

- Affymetrix® Gene Profiling Reagent Kit - RNA Control Kit (IVD Kit 1) - P/N 901285
- Affymetrix® Gene Profiling Reagent Kit - Transcript Synthesis and Labeling Kit (IVD Kit 2) - P/N 901286
  - Kit A - Sub-kit P/N 901293
  - Kit B - Sub-kit P/N 901298
- Affymetrix® Gene Profiling Reagent Kit - Transcript Detection Kit (IVD Kit 3) - P/N 901299
  - Kit A - Sub-kit P/N 901307
  - Kit B - Sub-kit P/N 901310
  - Kit C - Sub-kit P/N 901312

### RUO Reagent Kits

- GeneChip® Sample Cleanup Module kit- 900371
- IVT Labeling Kit - 900449
- GeneChip® Eukaryotic Poly-A RNA Controls Kit - 900433
- GeneChip® Expression Hybridization Controls Kit - 900454
- GeneChip® Hybridization, Wash and Stain Kit - 900720
- IVT cRNA Clean Up Kit - 900547
- GeneChip® 3' IVT Express Kit 10 Reactions - 901228
- GeneChip® 3' IVT Express Kit 30 Reactions - 901229

## Installing the Assay Software Module

To create a Gene Profiling cGMP v1.1 Assay test request, you must first install a certificate, second, install the Gene Profiling cGMP v1.1 Assay, and finally enter the test request.



**NOTE:** In most cases, an Affymetrix field service technician will install the certificate and assay.

## Installing a Certificate

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

You should have the certificate installed before installing the assay.

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 a certificate.

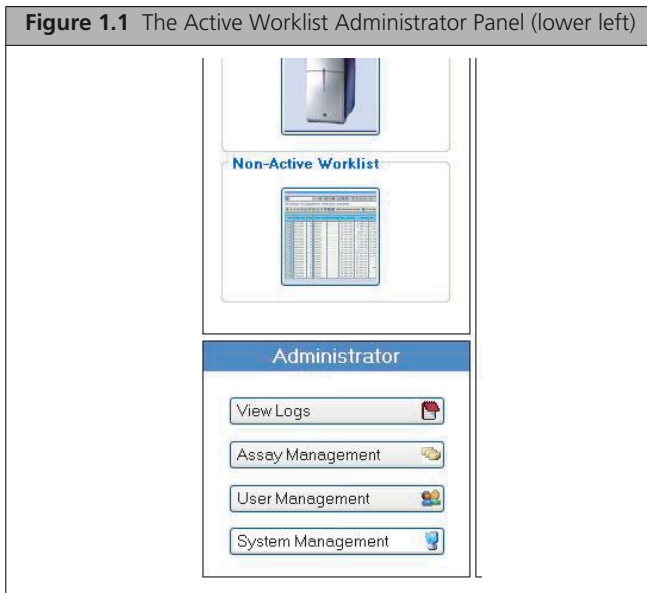
If a proper certificate has not been installed, you can still install the assay and process test requests; however, you will have no permission to access the remote server, and you cannot transfer test request data to the remote server.

If you cannot access the remote server and have already installed a certificate, contact Affymetrix technical support.

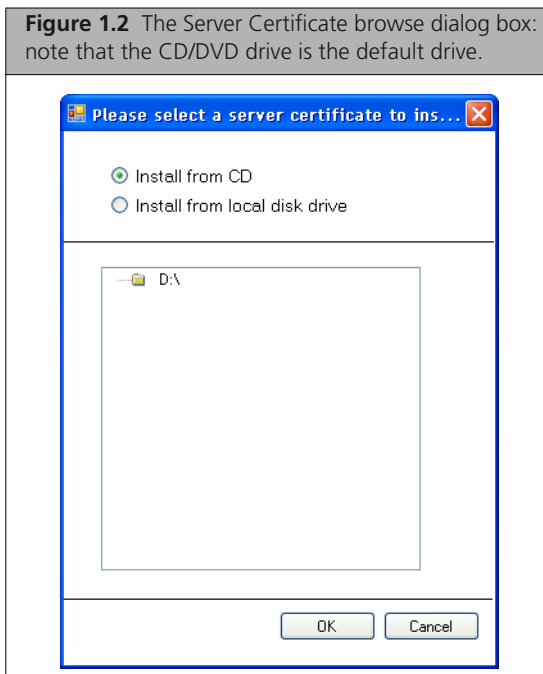
**NOTE:** You must be logged in with either **Laboratory Supervisor** or **System Maintainer** privileges.

### Procedure for Installing a Certificate

The Active Worklist Administrator panel contains the **Assay Management** button and provides the starting point for installing a certificate (Figure 1.1).



1. Click on the **Assay Management** button. The Assay Management window appears.
2. Click the **Install Certificate** button. The server certificate browse dialog box appears (Figure 1.2).



3. Select either the default drive, **Install from CD** (i.e., the internal drive D), or **Install from local disk drive**.
4. Browse for your desired xxxxx.cer file; where xxxxx is the name of the certificate that the installer of the RUO server provided to you.
5. Click the **OK** button or the **Cancel** button.
6. If successful, you will be notified by a message “You have successfully added the server certificate “xxxxx.cer” to the AMDS trusted certificate store.”  
If the certificate installation fails, AMDS will notify you with the particular algorithm error message. The software will prevent you from accessing the server and from transferring data without the proper certificate installed.
7. Click the **OK** button on the message to return to the Assay Management window.

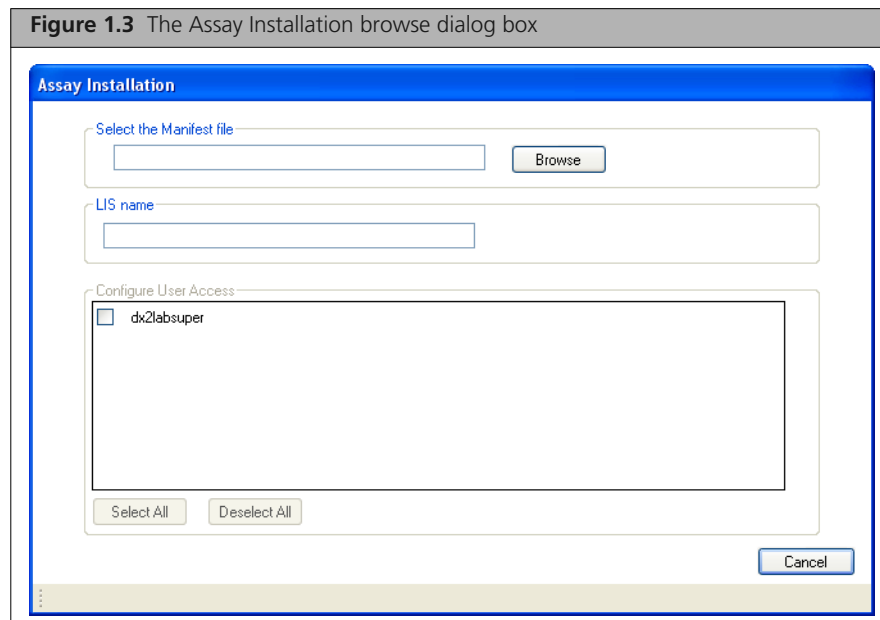
## Installing the Gene Profiling cGMP v1.1 Assay Software Module

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

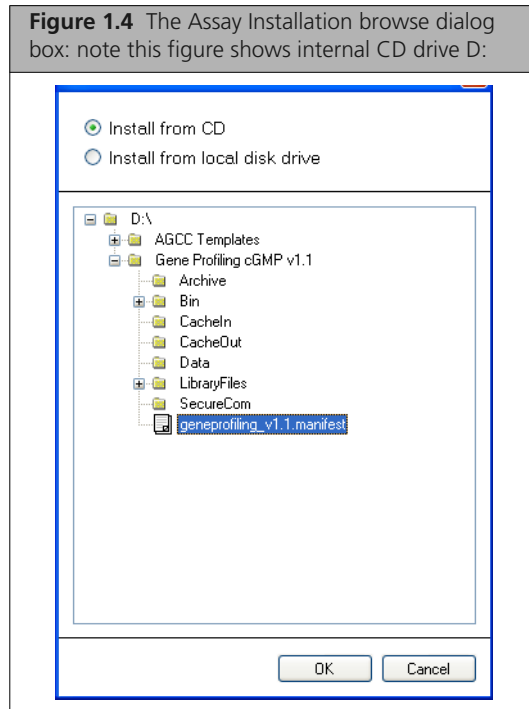


**NOTE:** You must be logged in with either **Laboratory Supervisor** or with **System Maintainer** privileges.

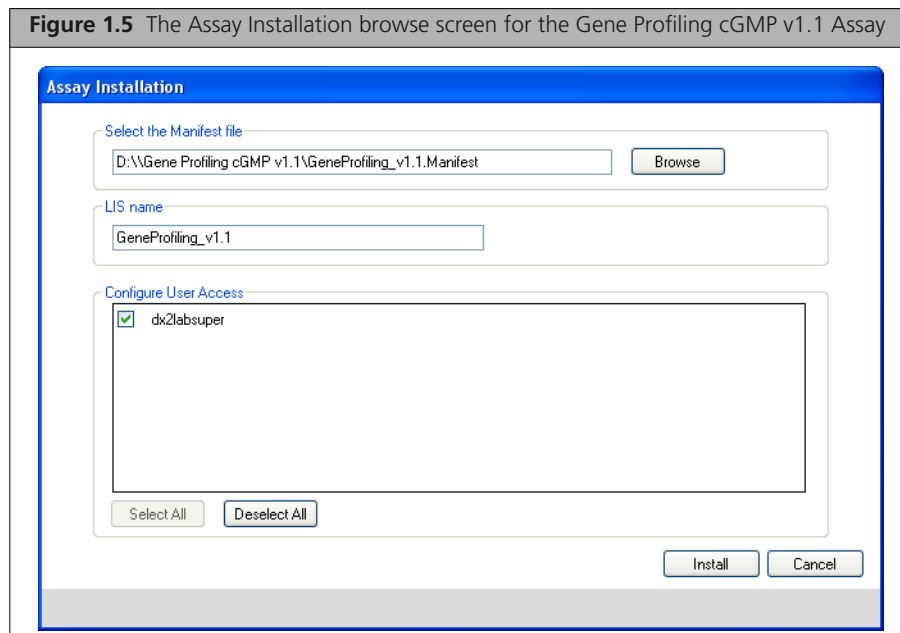
1. Click on the **Assay Management** button. The Assay Management window appears.
2. Click the **Install Assay** button. The Assay Installation browse dialog box appears (Figure 1.3).



3. Click the **Browse** button. The Assay Installation browse dialog box appears (Figure 1.4).

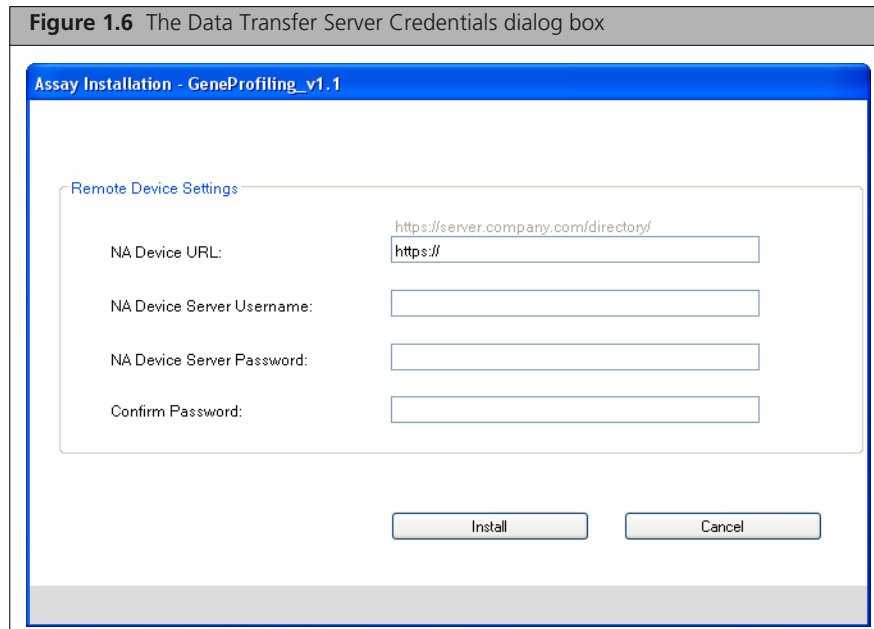


4. Select either the default drive, **Install from CD** (i.e., an internal CD drive D), or **Install from local disk drive** (i.e., the C: drive).
5. Browse for your desired xxxxx.Manifest file. In the present case, it is the geneprofiling\_v1.1.manifest file. For most applications, the D drive will contain the file. It should be in the folder similar to D:\\Gene Profiling cGMP v1.1. Browse for it and select it.
6. Click the **OK** button. The Assay Installation browse screen appears (Figure 1.5).



7. Choose those users who will have access to this assay either by selecting individual users, or by clicking the **Select All** button, or if you desire to start the selection over, click the **Deselect All** button.
8. Click the **Install** button or the **Cancel** button.

9. If you clicked the Install button, the Data Transfer Server credentials dialog box window appears (Figure 1.6).

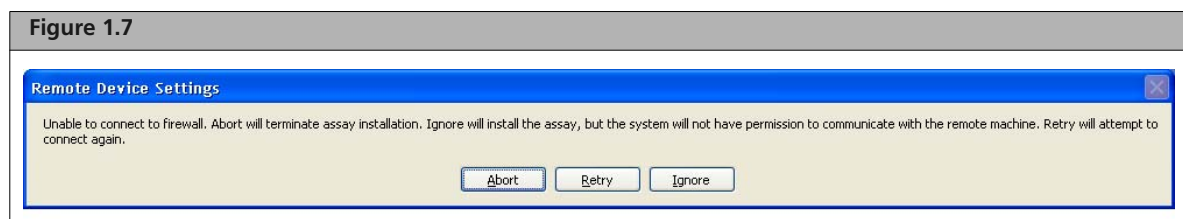


10. Locate and enter the **NA Device URL**, i.e., the secure URL server where AMDS will send the completed assay data (as an example: `https://dx2webdavserver/RUO`).
11. Enter the **NA Device Server Username**. This is your user name for the DTS, usually your workstation user name or network user credentials.
12. Enter the **NA Device Server Password**. This is your password for the DTS, usually your workstation user password or network user credentials.
13. Confirm your 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 remote server.

14. Confirm that the firewall is on and that your workstation is connected to the network.
15. Click the **Finish** button or the **Cancel** button.
- If you clicked Finish and if AMDS accepts your user ID and password, the system will check for the appropriate firewall parameters. The system also checks the proper server credentials, and will display an error message if it detects the wrong credentials. If the system detects the proper firewall setup, it will accept the assay installation and return to the Assay Management window. Setup is done. You can now begin to use the assay software module.
16. If the system does not pass your system's firewall settings, you will get the following error message (Figure 1.7).



17. Click the **Abort** button to exit the assay installation procedure.
  - or click the **Retry** button to attempt another try.
  - or click the **Ignore** button to continue.

**!** **IMPORTANT:** If you select **Ignore**, the AMDS will still install the assay, but you will not have permission to communicate with any remote server.

18. If the same assay already exists in the system, a message will appear asking if you would like to repair the assay (Figure 1.8).

**Figure 1.8** The Repair Assay dialog box

- Any AMDS user with valid AMDS credentials and with the right permissions can repair, or reinstall, the assay. You can include a reason, but this is optional.

19. Click the **Continue** button or the **Cancel** button. If you clicked Continue, an Assay Installation status window will appear and display the progress of the assay installation (Figure 1.9).

**Figure 1.9** The Assay Installation status window

	Action	Status
✓	Check Installation files	Completed
✓	Create Directories and Copy Installation Files	Completed
✓	Verify Installation files	Completed
✓	Create Assay Group	Completed
✓	Apply Security setting	Completed
✓	Install Web Services	Completed
✓	Update System Settings	Completed

Current Status

Installation completed for assay - GeneProfiling\_v1.1

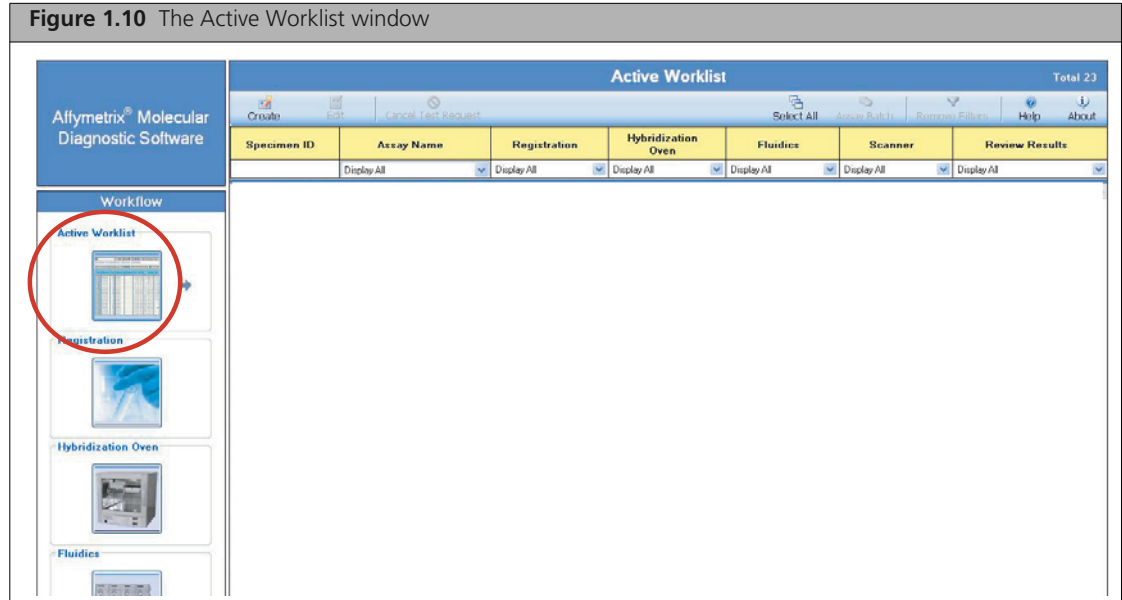
- If AMDS detects no errors, it will enable the **Finish** button.

20. Click the **Finish** button to conclude the assay installation procedure and return to the Assay Management window.

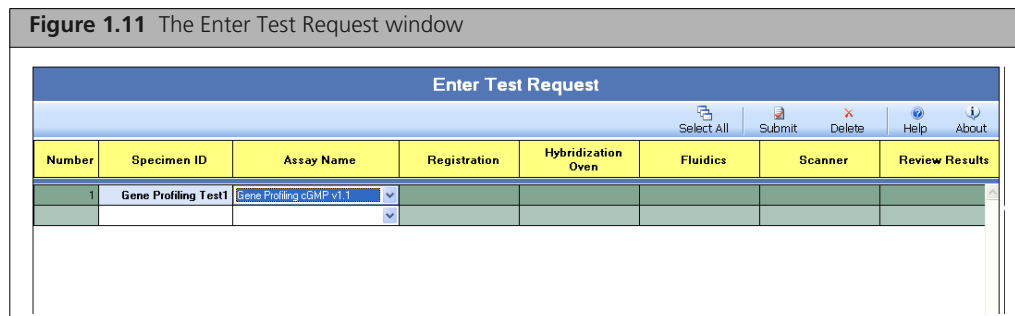
## Creating the Test Request

You must be either a Laboratory Supervisor, Technician or a Technologist in order to create a test request.

1. If you are not already in the Active Worklist window, select **Active Worklist** from the Workflow panel on the left (Figure 1.10). The Active Worklist panel opens.



2. Click the **Create** button on the toolbar of the Active Worklist. The Enter Test Request Screen will appear (Figure 1.11).



3. Enter one or more **Specimen ID** and **Assay Name** combinations. The current assay name for the Affymetrix Gene Profiling Assay - cGMP U133 P2 is Gene Profiling cGMP v1.1.
4. Once you have made the entries, click the **Submit** button and the Enter Test Request screen closes. The software will display the Active Worklist window with the newly created test request(s) on the screen.



**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 Additional Information to the Specimen

After you add a specimen, and return to the Active Worklist window, you can add certain types of pertinent information about the specimen. You can also add this information at a later date in other worklist windows. 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, and, if you attempt to save, the software will display an error message.

Saving and editing specimen information requires an e-signature upon saving.

1. Click on the desired **Specimen ID** field. The Additional Information dialog box opens (Figure 1.12).

**Figure 1.12** The Specimen ID Additional Information dialog box

Field Name	Field Values
Patient ID	<b>G55507193</b>
Patient Last Name	<b>Wilson</b>
Patient First Name	<b>Lynn</b>
Sex	<b>Male</b>
Date of Birth	<b>2011-03-15</b>
Specimen Type	<b>Blood</b>
Specimen Size Unit	<b>oz</b>
Specimen Size Value	<b>1</b>
Method of Collection	<b>venipuncture</b>
Collection Date	<b>2011-05-11</b>
Collection Time	<b>4:47:00 PM</b>
Requestor Last Name	<b>Clark</b>
Requestor First Name	<b>Sydney</b>
Request Date	<b>2011-05-11</b>
Additional info 1	
Additional info 2	
Additional info 3	
Additional info 4	
Additional info 5	

2. Add the following information. This information includes:
  - Patient ID—manually entered as freeform text
  - Patient Last Name—manually entered as freeform text
  - Patient First Name—manually entered as freeform text
  - Sex—chosen from a drop down menu. The menu includes the following choices:
    - Male
    - Female
    - Unknown
    - blank field
  - Date of Birth—manually entered with defined format. The format must be entered in an ISO 8601 format: that is with 4-digit year first, then month, then day. (e.g., 2001-11-09 for November 9, 2001) No other format is allowed.

- Specimen Type—manually entered or from a drop down menu
    - Blood
    - Solid Tissue
    - Soft Tissue
    - Saliva
    - Buccal Swab
    - Plasma
    - blank field
  - Specimen Size Unit—manually entered or from a drop down menu
    - mL
    - µL
    - oz
    - mg
    - g
    - inch
    - mm
    - cm
    - blank field
  - Specimen Size Value—manually entered floating-point numeric value.
  - Method of Collection—manually entered as freeform text
  - Collection Date—manually entered as an ISO 8601 format date
  - Collection Time—manually entered using either a 12- or 24-hour time scale. (e.g. 1:15 pm or 13:15). The software will display the time using 12-hour time scale (e.g. 1:15 pm).
  - Requestor Last Name—manually entered as freeform text
  - Requestor First Name—manually entered as freeform text
  - Request Date—manually entered with defined format manually entered as an ISO 8601 format date
  - Additional Info 1-5 (Five Additional fields—manually entered as freeform text)
3. When you have completed adding the information, click **Save and Close** or just **Close** to exit without saving.
- When you click **Close** only, the following events may occur.
    - If you made no edits, the screen will close.
    - If you made edits, a pop-up **Would you like to save changes?** (with Yes, No, and Cancel) will appear
      - Click **Yes** in the dialog box and the software saves and closes the screen.
      - Click **No** and the software discards and closes the screen.
      - Click **Cancel** and the software will return to the Specimen ID additional information screen with edits preserved.

## The Assay Information Screen—Adding Reagent Information

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

The Assay Home screen has the following tabs/sub-screens:

- Reagent Information
- Specimen Report
- Test Request Log

In a worklist window, in the Assay Name field, click on the Assay Name.

- The Assay Home (aka Assay Information) window appears (Figure 1.13). Reagent Information screen is the default tab.

### Reagent Information Tab

Click the **Reagent Information** tab (Figure 1.13) to view current reagent information.



**NOTE:** If you scan the reagent kit barcode, the software will parse the reagent information and will enter the lot number and expiration date into the correct fields for all selected test requests without manual intervention.

**Figure 1.13** The Reagent Information tab

Assay Home: Gene Profiling cGMP v1.1

Affymetrix® Gene Profiling Assay- cGMP U133 P2 v1.1

For Research Use Only

Bolded Reagent Kit Name indicates multiple old values exist. Bolded Data indicates new value to be saved. Enter Expiration Date as YYYY-MM-DD.

Specimen Report | Test Request Log | **Reagent Information**

Specimen ID	Registration Date	Reagent Kit Name	Part Number	Manufacturer	Lot Number	Expiration Date
H919808		RNA Control Kit 1	901285	Affymetrix	<b>8327810</b>	<b>2011-02-07</b>
H919809		Transcript Synthesis and Labeling Kit 2A	901293	Affymetrix	<b>8497579</b>	<b>2012-06-18</b>
H919814		Transcript Synthesis and Labeling Kit 2B	901298	Affymetrix	<b>3739880</b>	<b>2011-07-19</b>
H919896		Transcript Detection Kit 3A	901307	Affymetrix	<b>532680</b>	<b>2012-03-29</b>
H919900		Transcript Detection Kit 3B	901310	Affymetrix	<b>8832379</b>	<b>2011-10-22</b>
H919901		<b>Transcript Detection Kit 3C</b>	<b>901312</b>	<b>Affymetrix</b>	<b>7949853</b>	<b>2012-10-02</b>
H919912		GeneChip® Sample Cleanup Module	900371	Affymetrix		
		IVT Labeling Kit	900449	Affymetrix		
		GeneChip® Eukaryotic Poly-A RNA Controls	900433	Affymetrix		
		GeneChip® Expression Hybridization Controls	900454	Affymetrix		
		GeneChip® Hybridization Wash and Stain Kit	900720	Affymetrix		
		IVT cRNA Clean Up Kit	900547	Affymetrix		
		GeneChip® 3' IVT Express Kit 10 Reactions	901228	Affymetrix		
		GeneChip® 3' IVT Express Kit 30 Reactions	901229	Affymetrix		

About... Save Close



**NOTE:** Select one or more test requests on the Test Requests list on the left pane. You can enter data only for those test requests that you have selected.

You can view the:

- Reagent kit name—in the Gene Profiling cGMP v1.1 Assay (array P/N 501009), this includes the following reagent kit information:

#### IVD Reagent Kits

- Affymetrix® Gene Profiling Reagent Kit - RNA Control Kit (IVD Kit 1)- 901285
- Affymetrix® Gene Profiling Reagent Kit - Transcript Synthesis and Labeling Kit (IVD Kit 2) 901286
  - Kit A - Sub-kit P/N 901293
  - Kit B - Sub-kit P/N 901298
- Affymetrix Gene Profiling Reagent Kit - Transcript Detection Kit (IVD Kit 3)- 901299
  - Kit A - Sub-kit P/N 901307
  - Kit B - Sub-kit P/N 901310
  - Kit C - Sub-kit P/N 901312

#### RUO Reagent Kits

- GeneChip® Sample Cleanup Module kit- 900371
- IVT Labeling Kit - 900449
- GeneChip® Eukaryotic Poly-A RNA Controls Kit - 900433
- GeneChip® Expression Hybridization Controls Kit - 900454
- GeneChip® Hybridization, Wash and Stain Kit - 900720
- IVT cRNA Clean Up Kit - 900547
- GeneChip® 3' IVT Express Kit 10 Reactions - 901228
- GeneChip® 3' IVT Express Kit 30 Reactions - 901229
- Reagent kit part number information
- Reagent kit manufacturer information
- Reagent lot number
- Reagent expiration date

The Reagent Kit Name, Manufacturer, Part Number, Lot No. and Expiration Date are not required to run the assay.

AMDS provides the ability to transfer to the RUO server the Reagent Kit Name, Manufacturer, Part Number, Lot No. and Expiration Date.

1. In the Reagent Information tab, select the test requests in the test request list on the left side of the screen. Scan the barcodes from the reagents you used.  
The software will enter the corresponding lot number and expiration date into the appropriate fields. Remember you cannot make any edits after scanning has begun to that particular test request.
2. Click the **Save** button.
3. When you click **Close** only, the following events may occur.
  - If you made no edits, the screen will close.
  - If you made edits, a pop-up **Would you like to save changes?** A Yes, No, and Cancel window appears.
    - Click **Yes** in the dialog box and the software saves and closes the screen.
    - Click **No** and the software discards and closes the screen.
    - Click **Cancel** and the software will return to the Reagent Information screen with edits preserved.



**NOTE:** You can also enter the reagent kit information manually by selecting test requests in the left side of the screen, then placing the cursor in to the lot number and expiration date fields for the appropriate kits and typing in the correct information.

The Gene Profiling cGMP v1.1 Assay Software Module remembers the association between a reagent kit and expiration date. Scenarios are as follows:

1. Enter a lot number and expiration date for the first time, click **Save**.
  - AMDS saves the data.
2. Enter a lot number already associated with another test request. AMDS auto-populates the expiration date that you had previously used.
  - Click **Save** and the data is saved for all associated test requests.
3. Enter a lot number already associated with another test request. AMDS auto-populates the expiration date that you had previously used. Modify expiration date and click **Save**.
  - The software will display a pop-up with the following message (or words to this effect): “Do you want to save this expiration date for all other test requests with this lot number?”
  - Click **Yes**, **No** or **Cancel**.
    - Yes saves this information for all test requests,
    - No discards all changes.
    - Cancel returns to the screen with edits preserved.

#### **Special Note Regarding the Changing of Expiration Dates**

If you change the expiration date for a previously entered lot number (see [step 3](#) above), and choose to save this change for all the test requests with this lot number, the application will display the following message:

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

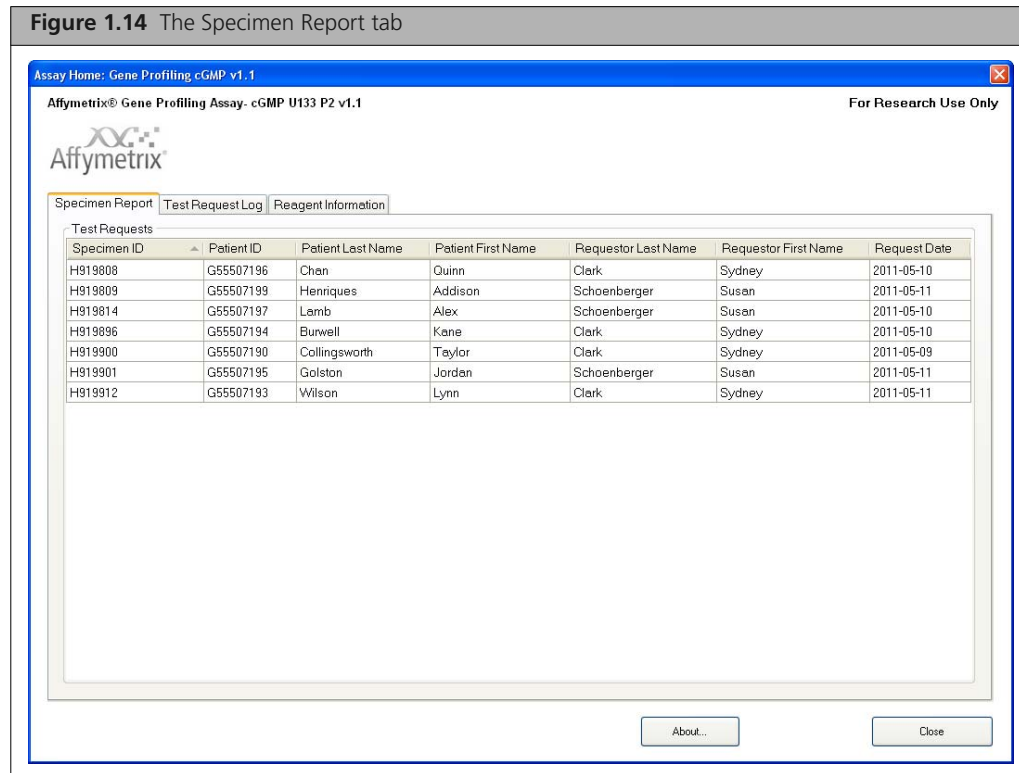
“This affects <count> Test Requests.”

The the application will remember the new expiration date and will update all the test requests with those lot number(s), which have not yet started scanning, with the correct expiration date(s).

If you click **Cancel**, the software will return to the Reagent Information Screen with all edits preserved.

## Specimen Report Tab

Click on the **Specimen Report** tab (Figure 1.14) to view all the specimen IDs associated with that assay type.



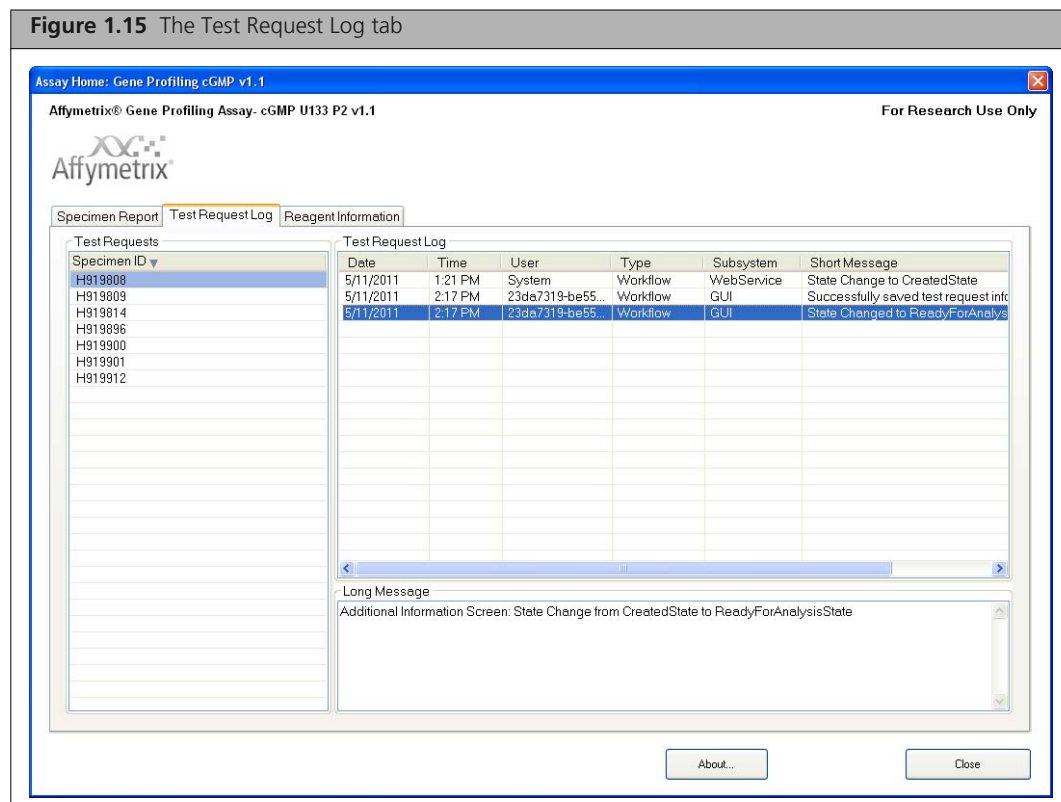
Click the **Specimen Report** tab to view all the specimen IDs associated with that assay type (in this case the Affymetrix Gene Profiling Assay - cGMP U133 P2 v1.1). You can view the:

- Specimen ID
- Patient ID
- Patient Last Name
- Patient First Name
- Requestor Last Name
- Requestor First Name
- Request Date

## Test Request Log Tab

Click the **Test Request Log** tab (Figure 1.15) to view all the test requests associated with that assay type. Each test request will include information regarding the following:

- Specimen ID
- Date (of the log entry)
- Time (of the log entry)
- User (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)



## Batching Additional Test Request Information

If you want to enter or edit the same information for multiple test requests at the same time, you can use the Batch Edit feature.

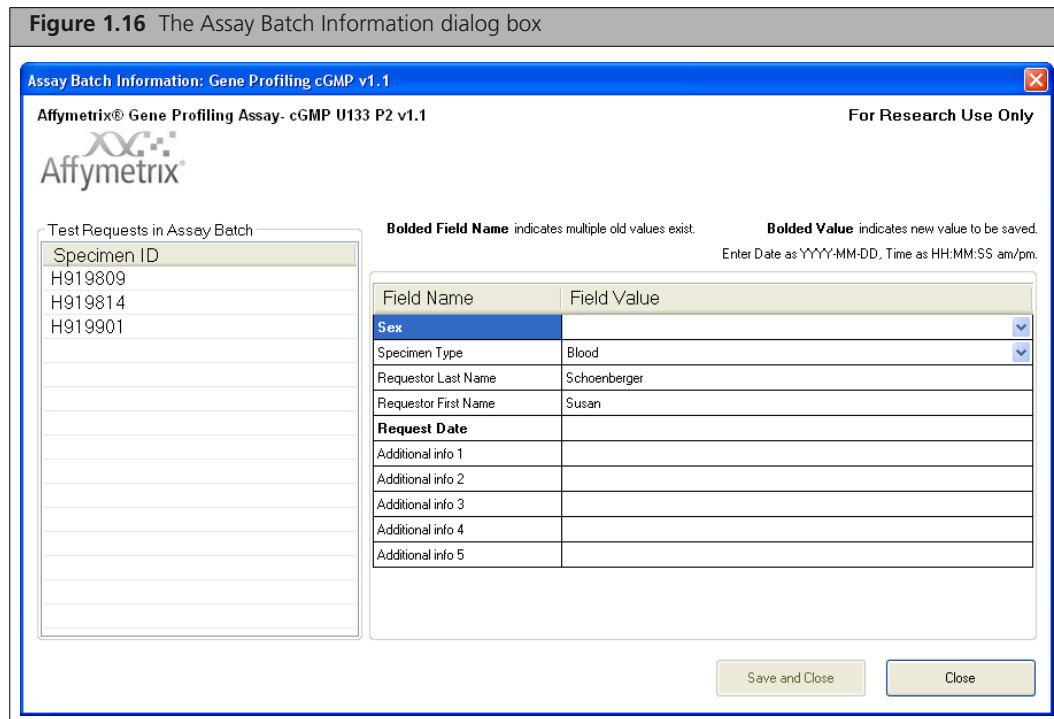


**NOTE:** You cannot associate any additional information with test requests after scanning has started. You will not be able to save your edits, and, if you attempt to save, the software will display an error message.

1. In the Active Worklist or any of the worklist windows, select your test requests.
2. Click the **Batch Edit** button.
  - The Assay Batch Information dialog box appears (Figure 1.16)  
The left column lists the selected Specimen IDs
3. Enter or change in the right dialog box:
  - Sex (of the test request subject)
  - Specimen Type
  - Requestor Last Name
  - Requestor First Name
  - Request Date
  - Additional Info 1-5 (five user-defined fields)
4. Click the **Save and Close** button to save your changes and close the window.
5. Click the **Close** button. If you did not make any edits, the Assay Batch screen will close. If you made any edits, a Yes, No, Cancel window will appear.
  - Click **Yes**, **No** or **Cancel**.
    - Yes saves this information.
    - No discards all changes.
    - Cancel returns you to the Assay Batch screen with edits preserved.



**NOTE:** You must save this information before you begin the scanning step. This is to ensure the safety of the data. Do not attempt to add or edit this information after scanning.



If the selection contains one or more test requests that have either started or completed scanning, when you click the **Batch Edit** button, the application will display the Assay Batch Information screen with the statement **Test Requests have passed scanning step. Data cannot be changed.**

## Gridding Manually

You can manually grid your results if an error arises in the automatic gridding function.

Before you attempt to grid manually, you must be familiar with the gridding function referenced in the *GeneChip® Operating Software User's Guide* (P/N 701439), the *Affymetrix® GeneChip® Command Console™ 1.0 User's Guide* (P/N 702569), or the *GeneChip® System 3000Dx (for EU) User's Guide* (P/N 08-0136) or other Affymetrix documentation. The AMDS manual gridding procedure is based on the gridding procedure outlined in these manuals.

A .dat grid failure for a test request will trigger a manual grid alignment alert. To remedy this gridding failure:

1. In the Active Worklist, or in another main worklist window, click on the alert that is visible on the right side of the page in the Alerts panel.
2. View the alert, then click the **Resolve** button.
3. Enter your user ID and password. Click **OK**. The DatImageViewer window will appear.
4. Manually adjust the grid.
5. Click the **Save** button.
6. Close the 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 file
  - .AUDIT
  - .CEL file
  - .DAT file
  - .log file
  - .MD5 file

The .MD5 file is a checksum file. You can use a utility such as FastSum (Windows®) or md5sum (Linux) to confirm that AMDS has transferred all the files correctly.

- All Specimen Information descriptor labels and their corresponding data fields which may be filled in or not
- All tracked Reagent Information descriptor labels and their corresponding data fields which may be filled in or not

The AMDS confirms that the data has completed transfer successfully by the following two criteria:

- the assay module detects no exceptions upon transferring
- the assay module confirms that every file listed as transferred indeed exists on the server

Once AMDS transfers the files to the remote server, AMDS will place all the associated files in a folder named Affymetrix Gene Profiling Assay - cGMP U133 P2 v1.1\_RUO2.0. This folder will reside on the server. All data files are intermingled. Upon transfer, the software will assign file names: specimenID+"\_" +barcode+original extension (.DAT, .CEL, etc.). This will make it easy to determine which files are associated with a particular test request.



**IMPORTANT:** if you use any of the characters \ / : \* ? " < > | in your specimen ID, those characters will get converted to the underscore character ('\_') in the file name on the server. The reason is because Microsoft Windows does not allow any of those characters in the names of any files or folders.



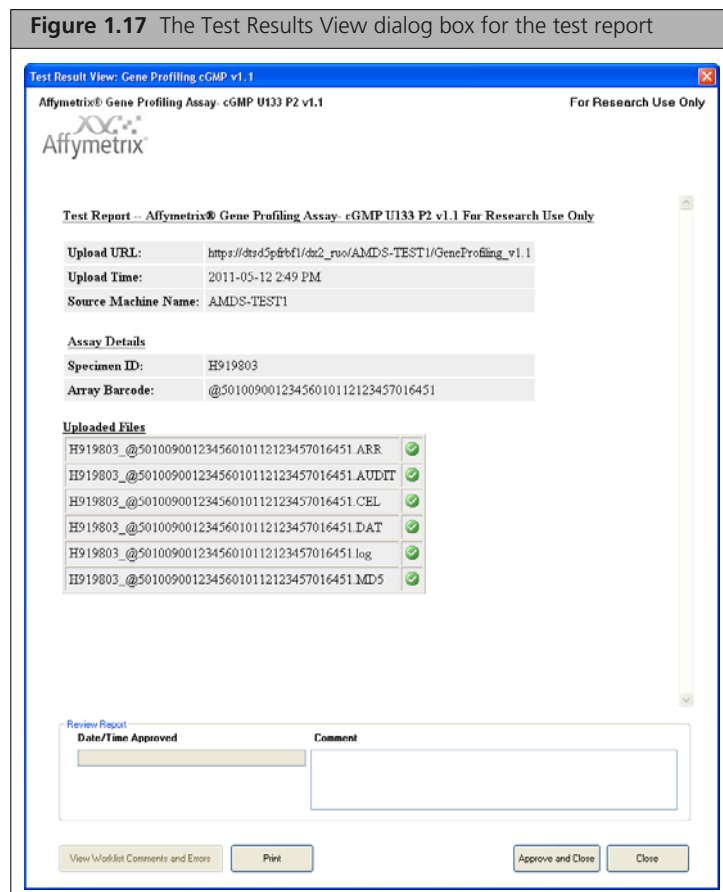
**NOTE:** Upon successful data transfer, AMDS will delete, from the local AMDS hard drive, the .dat and .cel files for the transferred test requests.

## Reviewing the Test Report

When you have completed all the remaining assay steps (Registration, Hybridization, Wash/Stain, Scanning, etc.), the Active Worklist will display the test report as a hyperlink called Awaiting Review in the Review Results field of the Test Request record.

To view the test result report, you must be in the Active Worklist window.

1. Click on the hyperlink, **Awaiting Review**, in the desired test request record. The Test Results dialog box will appear (Figure 1.17).

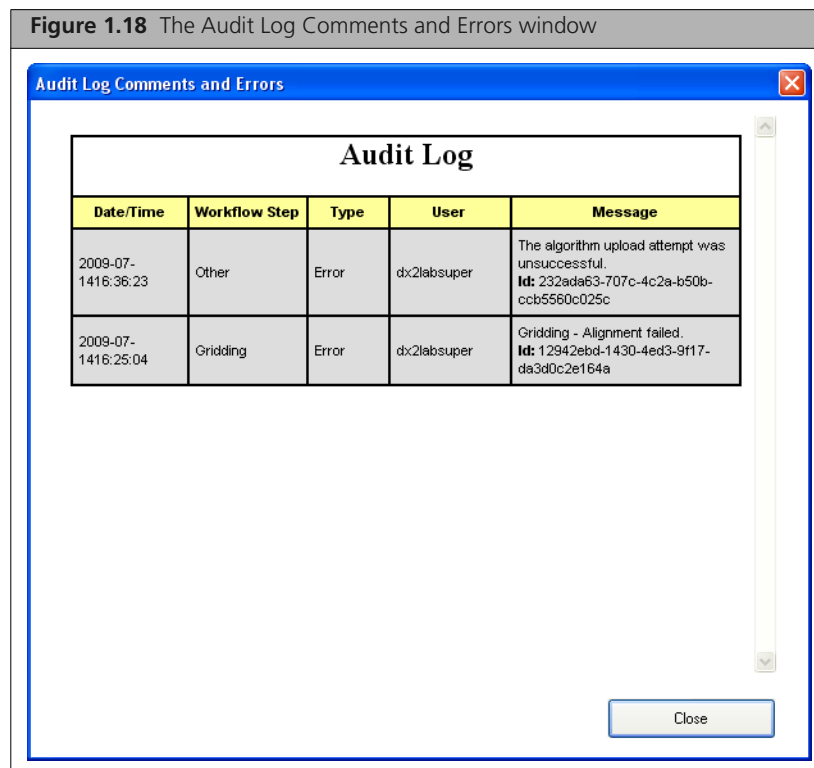


The reports displays:

- Upload details
  - Upload URL (where the files went)
  - Upload Time
  - Source Machine Name
- Assay Details
  - Specimen ID
  - Array Barcode
- Uploaded files (the list of the files that were transferred)
  - .ARR file
  - .AUDIT
  - .CEL file
  - .DAT file
  - .log file
  - .MD5 file

- You can also add comments (in the Comment field).
- Click the **Approve and Close** button to accept the results and move the test request to the Non-Active Worklist.
- Click the **Close** button to close the results screen without doing anything. The Awaiting Review hyperlink remains active.
- Click the **Print** button to print the results to the default printer.
- Click the **View Worklist Comments and Errors** button.
  - The Audit Log Comments and Errors window opens (Figure 1.18). This window displays any comments or errors that the user or AMDS application associated with that test request.

If you clicked the **Approve and Close** button, the completed test report will appear.



## Ordering Information

Table 1.1 lists the Gene Profiling cGMP v1.1 Assay reagents and associated part number.

**Table 1.1**

Name	P/N	Supplier
Gene Profiling Array cGMP U133 P2	901411	Affymetrix
<b>IVD Reagent Kits</b>		
Affymetrix® Gene Profiling Reagent Kit - RNA Control Kit (IVD Kit 1)	901285	
Affymetrix® Gene Profiling Reagent Kit - Transcript Synthesis and Labeling Kit (IVD Kit 2), consists of: <ul style="list-style-type: none"> <li>□ Kit A - Sub-kit P/N 901293</li> <li>□ Kit B - Sub-kit P/N 901298</li> </ul>	901286	
Affymetrix® Gene Profiling Reagent Kit - Transcript Detection Kit (IVD Kit 3) <ul style="list-style-type: none"> <li>□ Kit A - Sub-kit P/N 901307</li> <li>□ Kit B - Sub-kit P/N 901310</li> <li>□ Kit C - Sub-kit P/N 901312</li> </ul>	901299	
<b>RUO Reagent Kits</b>		
Sample Clean Up Module Kit	900371	Affymetrix
IVT Labeling Kit	900449	Affymetrix
GeneChip® Eukaryotic Poly-A RNA Controls Kit	900433	Affymetrix
GeneChip® Expression Hybridization Controls Kit	900454	Affymetrix
GeneChip® Hybridization, Wash and Stain Kit	900270	Affymetrix
IVT cRNA Clean Up Kit	900547	Affymetrix
GeneChip® 3' IVT Express Kit (10 rxn)	901228	Affymetrix
GeneChip® 3' IVT Express Kit (30 rxn)	901229	Affymetrix

## Technical Support

### **Affymetrix, Inc.**

3420 Central Expressway  
Santa Clara, CA 95051  
USA  
[www.affymetrix.com](http://www.affymetrix.com)

Email: [support@affymetrix.com](mailto: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

Tel: +44 (0) 1628 552550  
Fax: +44 (0) 1628 552585  
France Tel. +33 800919505  
Germany Tel. +49 1803001334  
Email: [supporteurope@affymetrix.com](mailto:supporteurope@affymetrix.com)

### **Affymetrix Japan, K. K.**

ORIX Hamamatsucho Bldg, 7F  
1-24-8 Hamamatsucho, Minato-ku  
Tokyo 105-0013 Japan  
Email: [supportjapan@affymetrix.com](mailto:supportjapan@affymetrix.com)

Tel: +81-3-6430-4020  
Fax: +81-3-6430-4021