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HG-U133 Plus 2.0 Assay Software Module v2.3

User Guide

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Contents

HG-U133 Plus 2.0 Assay Software Module v2.3

Introduction

This User's Guide demonstrates how to create a **HG-U133 Plus 2.0 Assay Software Module v2.3 RUO Assay Test Request**.

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

- GeneChip™ 3' IVT Express Kit

- GeneChip™ Hybridization Control Kit

- GeneChip™ Hybridization, Wash & Stain Kit

- Gene Profiling Reagent Kit

Nomenclature

- The Assay name is **GeneChip™ Human Genome U133 Plus 2.0 Assay.**

- The Assay display name is **HG-U133 Plus 2.0 ASM v2.3**.

- The term **ASM** refers to **Assay Software Module.**

Major Features of HG-U133 Plus 2.0 ASM v2.3

The major features of HG-U133 Plus 2.0 ASM v2.3 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

HG-U133 Plus 2.0 ASM v2.3 (under the control of the AMDS application), transfers all specimen information to the server.

> **IMPORTANT: It is <u>NOT </u>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 *Molecular Diagnostic Software User's Guide (P/N 08-0261).*

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

- Molecular Diagnostic Software User's Guide (P/N 08-0261)
- Molecular Diagnostic Software Quick Reference Card (P/N 08-0262)
- GeneChip™ 3' IVT Express Kit User Manual (P/N 702646)
- GeneChip™ Expression Analysis Technical Manual (P/N 702232)
- Expression™ Wash, Stain and Scan User Manual for Cartridge Arrays (P/N 702731)

Reagents

Reagents for the GeneChip™ HG-U133 Plus 2.0 Array - single array (P/N 520019) comprise the following Reagent Sub-Kits:

- GeneChip™ 3' IVT Express Kit (10 rxn) - (P/N 901228)
- GeneChip™ 3' IVT Express Kit (30 rxn) - (P/N 901229)
- GeneChip™ Expression 3'-Amplification Reagent Hybridization Controls (30 rxn) (P/N 900454)
- GeneChip™ Hybridization, Wash & Stain Kit (30 rxn) - (P/N 900720)
- RNA Control Kit (IVD Kit 1) - (P/N 901285)
- Transcript Synthesis and Labeling Kit A (IVD Kit 2A) - (P/N 901293)
- Transcript Synthesis and Labeling Kit B (IVD Kit 2B) - (P/N 901298)
- Transcript Detection Kit A (IVD Kit 3A) - (P/N 901307)
- Transcript Detection Kit B (IVD Kit 3B) - (P/N 901310)
- Transcript Detection Kit C (IVD Kit 3C) - (P/N 901312)
- Wash Buffer A - (P/N 900721)
- Wash Buffer B - (P/N 900722)

Installing the ASM (Assay Software Module)

To process a HG-U133 Plus 2.0 ASM v2.3 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 the HG-U133 Plus 2.0 ASM v2.3

Installing a 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 *Installing HG-U133 Plus 2.0 ASM v2.3.*

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 is required for the transfer of HG-U133 Plus 2.0 ASM v2.3 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).

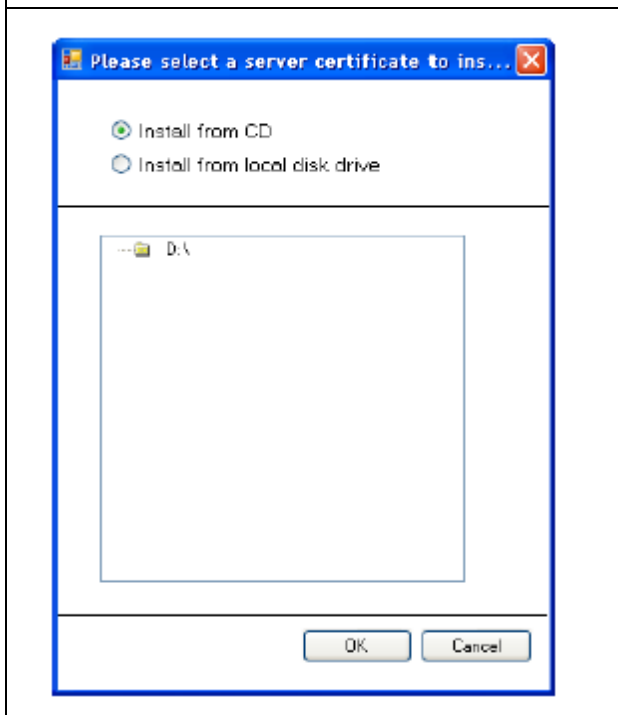| Figure 1 The Active Worklist Administrator Pane (lower left) |
| --- |
| |
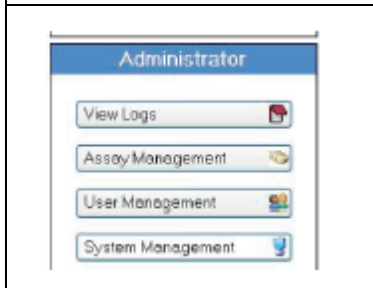
1. Insert the CD into the drive.
2. Click **Assay Management.**

   The Assay Management window appears.

3. Click **Install Certificate.**

   The Server Certificate Browse window appears. (Figure 2)

Figure 2 The Server Certificate Browse window.

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 Service Representative for information on obtaining a new certificate.

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

Installing HG-U133 Plus 2.0 ASM v2.3

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.
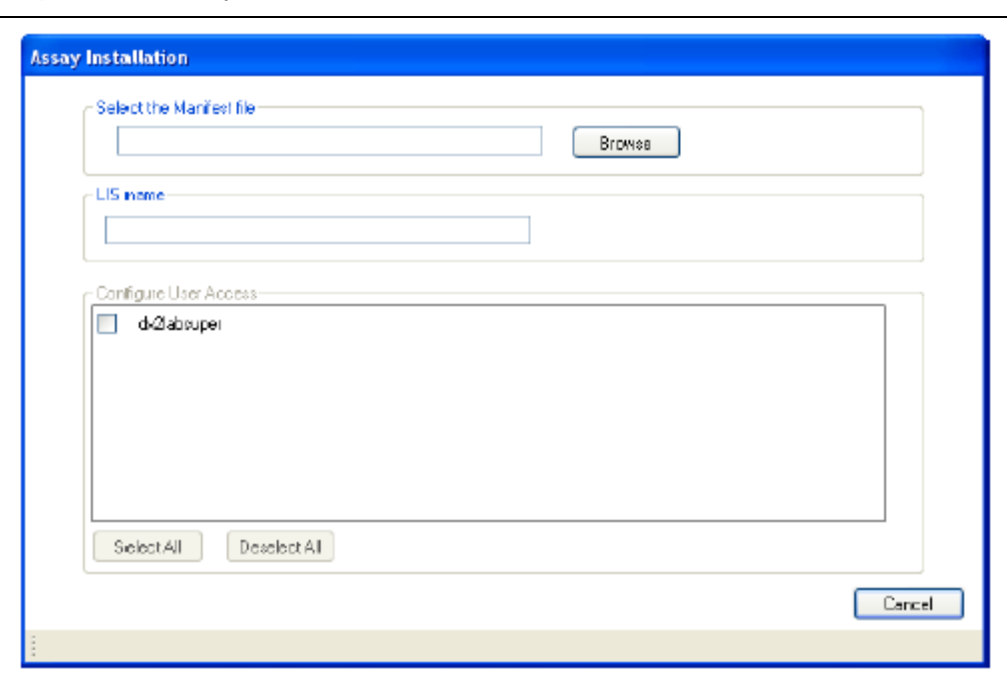
1. Insert the CD into the drive.
2. Click **Assay Management.**

The Assay Management window appears.

3. Click **Install Assay.**

The Assay Installation window appears. (Figure 3)

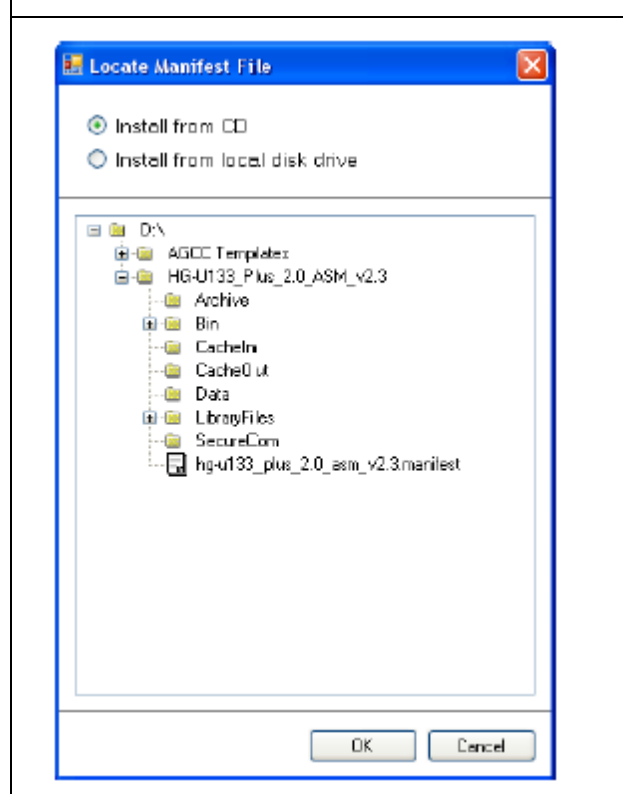**Figure 3** The Assay Installation window

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4. Click **Browse**.

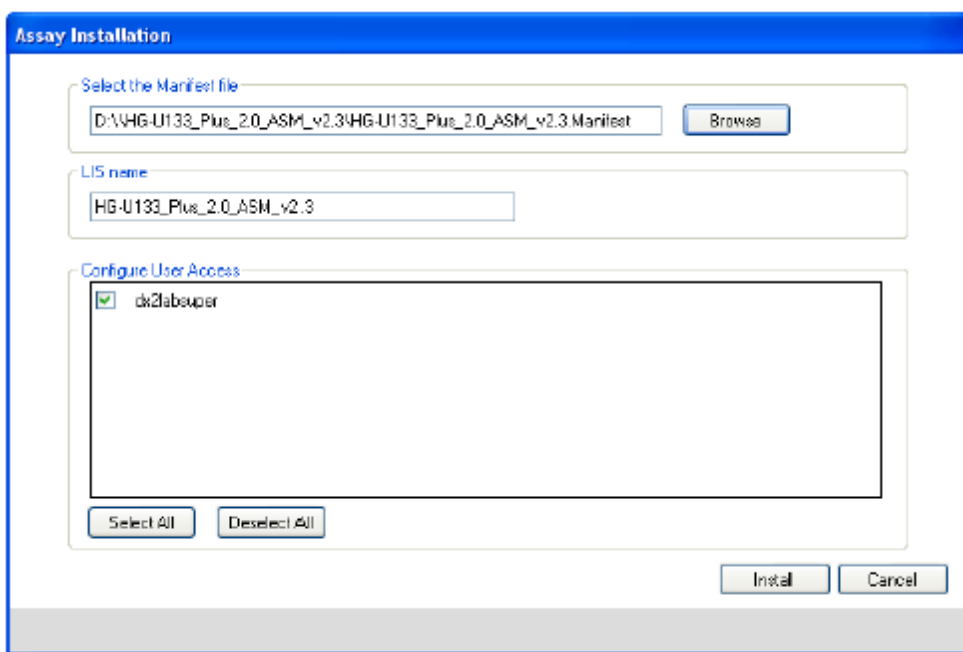The Assay Installation Browse window appears. (Figure 4)

Figure 4 The Assay Installation Browse window

5. Make sure the **Install from CD** radio button is selected, then navigate to and click on **D:\HG-U133_Plus_2.0_ASM_v2.3\hg-u133_plus_2.0_asm_v2.3.manifest**

6. Click **OK**.

The Assay Installation window appears. (Figure 5)

Figure 5 The Assay Installation browse window for the HG-U133 Plus 2.0 ASM v2.3
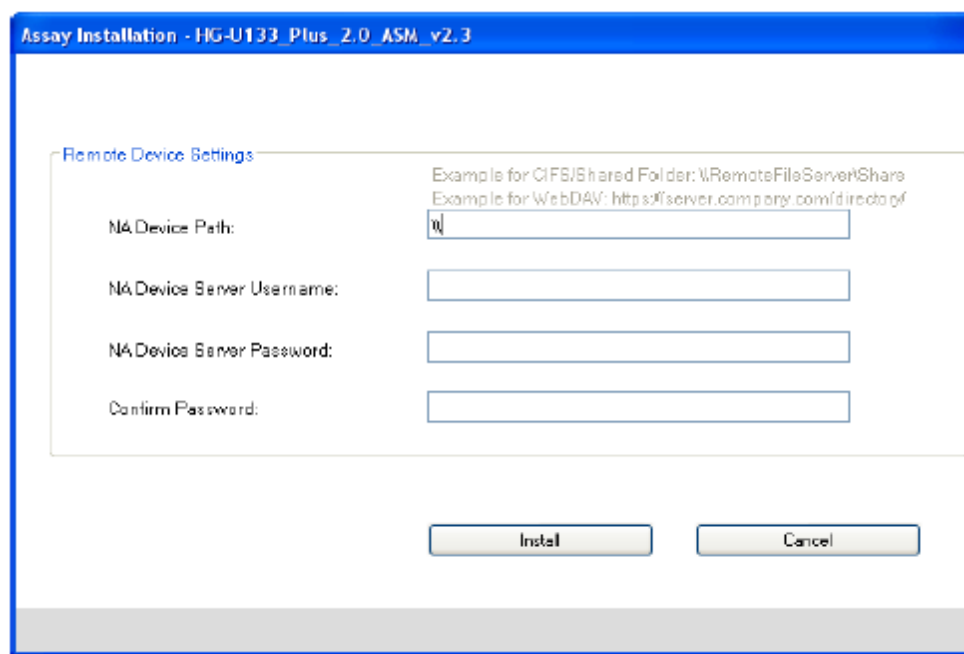

7. Click to choose each authorized Assay User or click **Select All**.
8. Click **Install.**

The Remote Device Settings window appears. (Figure 6)

Figure 6 The Remote Device Settings window

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.

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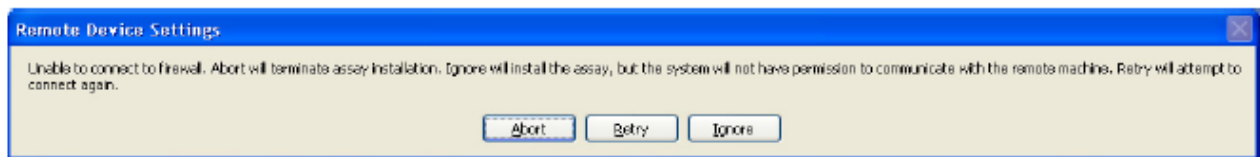
There are 3 buttons to acknowledge the Remote Device Settings Error message.

- **Abort -** Exits the Assay installation.

- **Retry -** Attempts another try.

- **Ignore -** Continues the installation.

Repairing Currently Installed ASM

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

Figure 8 The Repair Assay window

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)

Figure 9 The Assay Installation window
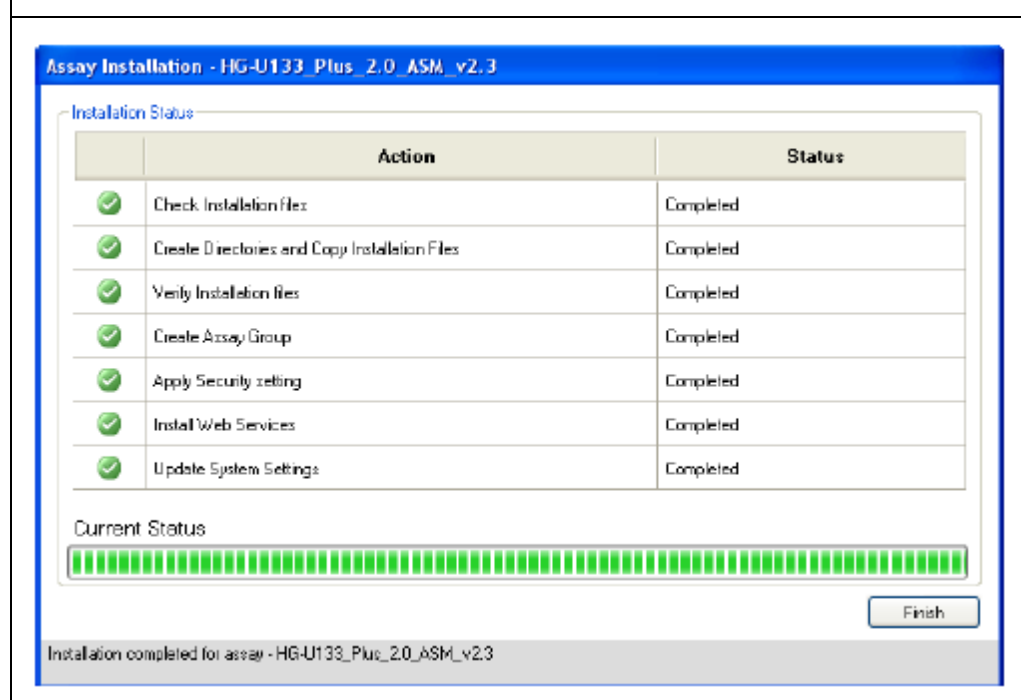
2. Click Finish to conclude the ASM installation and return to the Assay Management window. Installation of the ASM is complete.

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.

Figure 10 The Active Worklist window
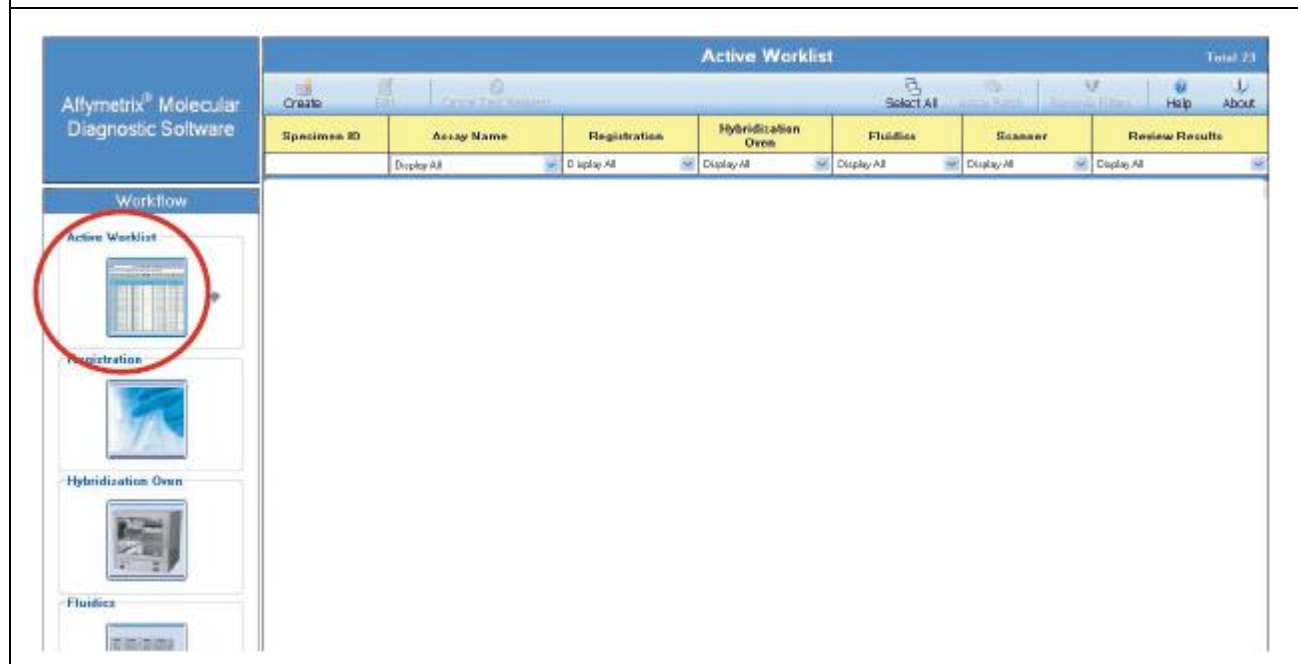
2. From the Active Worklist toolbar, click **Create**.
    The Enter Test Request window appears. (Figure 11)

Figure 11 The Enter Test Request window
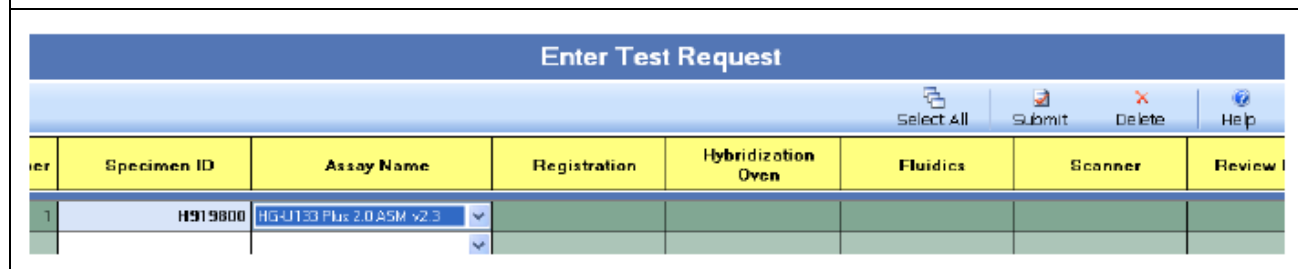
3. Use the handheld barcode scanner to enter one or more **Specimen IDs.** You may also enter the Specimen IDs manually.

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

NOTE: The current Assay Name for the HG-U133 Plus 2.0 ASM v2.3 is HG-U133 Plus 2.0 ASM v2.3.

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 *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)

Figure 12 The Specimen ID Additional Information window

2. Add the following information:

- **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 <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>**.

- **Specimen Type** - Select: Blood - Solid Tissue - Soft Tissue - Saliva - Buccal Swab - Plasma - Blank Field

- **Specimen Size Unit** - Select: mL - µL - oz - mg - g - inch - cm - mm - Blank Field

- **Specimen 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 **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) to view current Reagent information
3. Click to select each appropriate Specimen ID from the list (left pane).

Figure 13 The Reagent Information tab

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4. 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 Thermo Fisher, Inc.**

The scanner parses the Reagent information, and 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 HG-U133 Plus 2.0 ASM v2.3 Assay Information/Home window contains the following Reagent Kit information:

- Reagent Kit Name

    - GeneChip™ 3' IVT Express Kit (10 rxn) - (P/N 901228)

    - GeneChip™ 3' IVT Express Kit (30 rxn) - (P/N 901229)

    - GeneChip™ Expression 3'- Amplification Reagent Hybridization Controls (30 rxn) (P/N 900454)

    - GeneChip™ Hybridization, Wash & Stain Kit (30 rxn) - (P/N 900720)

    - RNA Control Kit (IVD Kit 1) - (P/N 901285)

    - Transcript Synthesis and Labeling Kit A (IVD Kit 2A) - (P/N 901293)

    - Transcript Synthesis and Labeling Kit B (IVD Kit 2B) - (P/N 901298)

    - Transcript Detection Kit A (IVD Kit 3A) - (P/N 901307)

    - Transcript Detection Kit B (IVD Kit 3B) - (P/N 901310)

    - Transcript Detection Kit C (IVD Kit 3C) - (P/N 901312)

    - Wash Buffer A - (P/N 900721)

    - Wash Buffer B - (P/N 900722)

- 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 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 HG-U133 Plus 2.0 ASM v2.3 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.

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>.
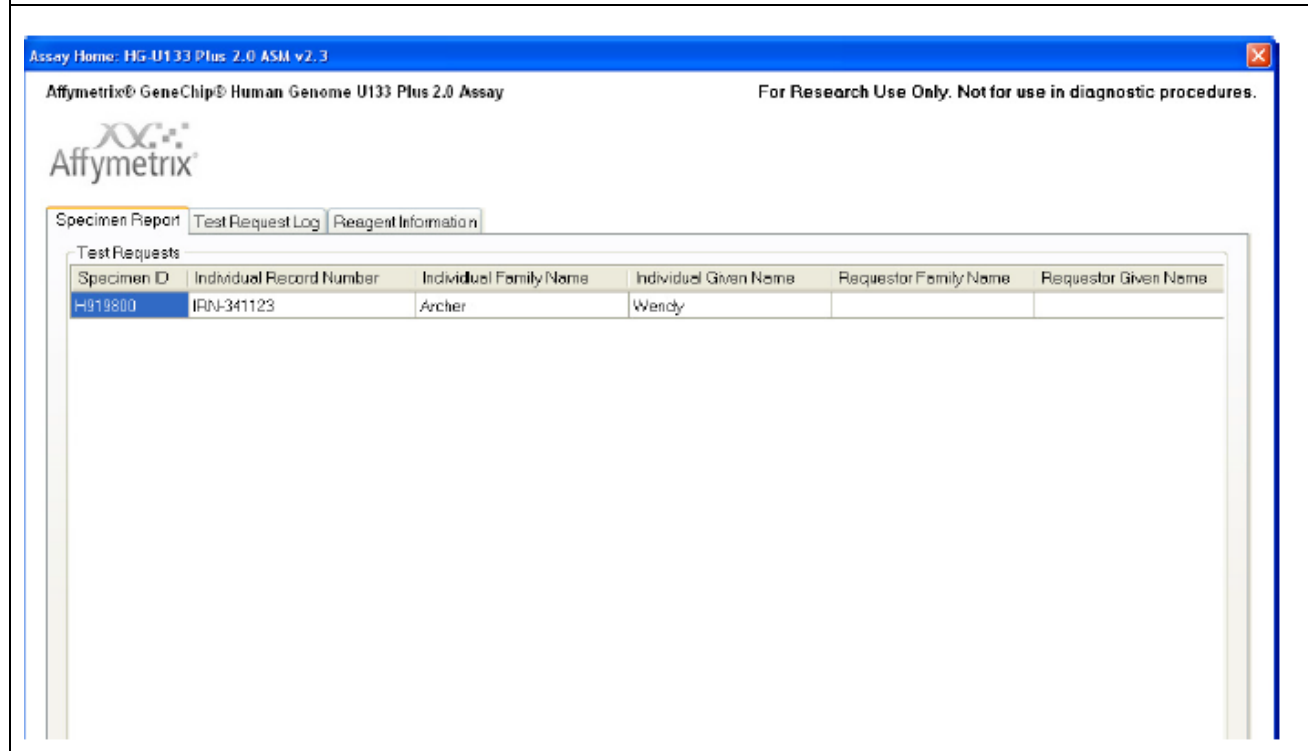
This affects <count> Test Requests.

After saving, 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 HG-U133 Plus 2.0 ASM v2.3).

Figure 14 The Specimen Report tab

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

- Time

- User

- Type

- Subsystem

- Short Message

- Long Message

Figure 15 The Test Request Log tab
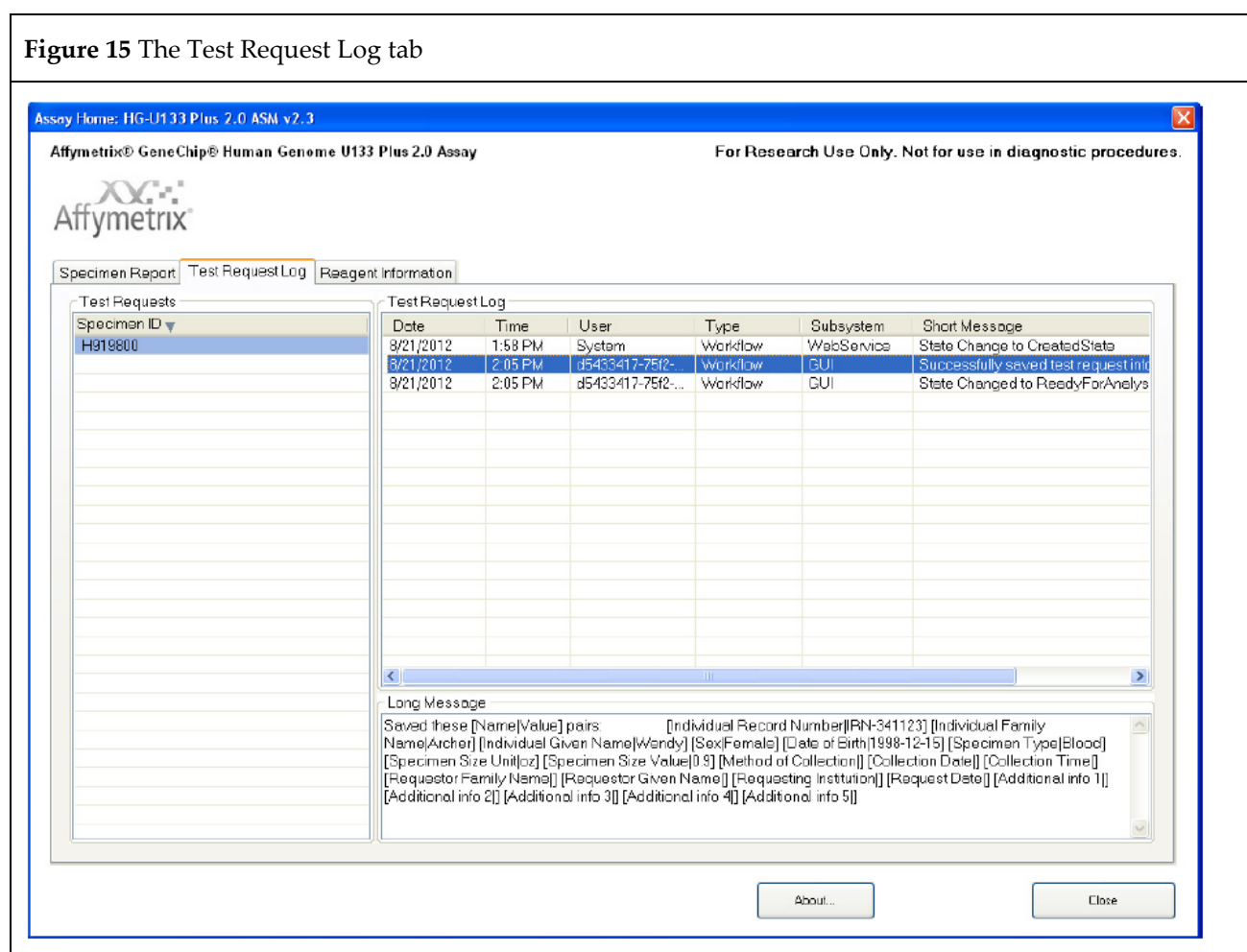
Batching Additional Test Request Information

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

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

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 window appears (Figure 16) listing Specimen IDs (left column).
3. Use the right column to enter or change the following:

   - Sex

   - Specimen Type

   - 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 changes. To exit the Batch Edit window click **Close**, then click the appropriate button.

   - **Yes** - Saves changes.

   - **No** - Discards changes.

   - **Cancel** - Returns to **Batch Edit** window with previous changes saved.

Figure 16 The Assay Batch Information window

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 GeneChip^{TM} System 3000Dx v.2 User Guide (P/N 08-0261), the GeneChip^{TM} Command Console™ 1.0 User's Guide (P/N 702569), the GeneChip^{TM} System 3000Dx (for EU) User's Guide (P/N 08-0136), or other applicable 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:

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**

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, **HG-U133_Plus_2.0_ASM_v2.3.**

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
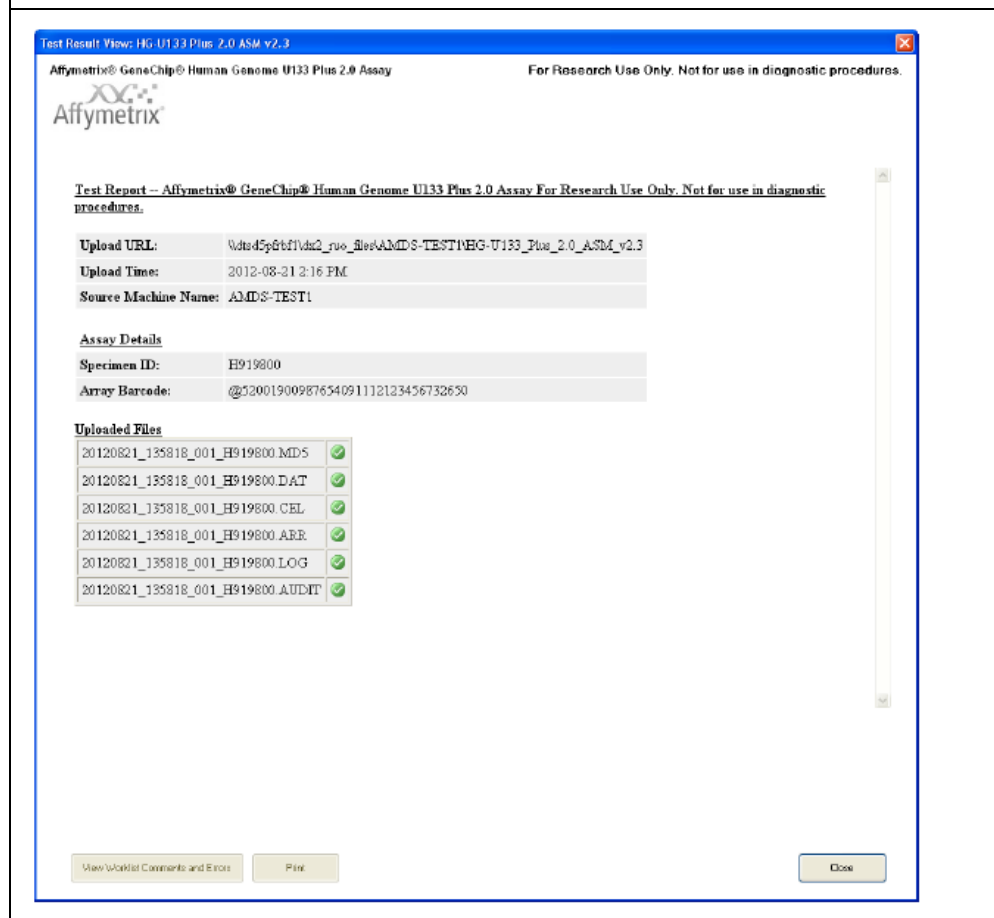

The **Test Report** (Figure 17) displays the following information:

*   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
    - .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 The Audit Log Comments and Errors window
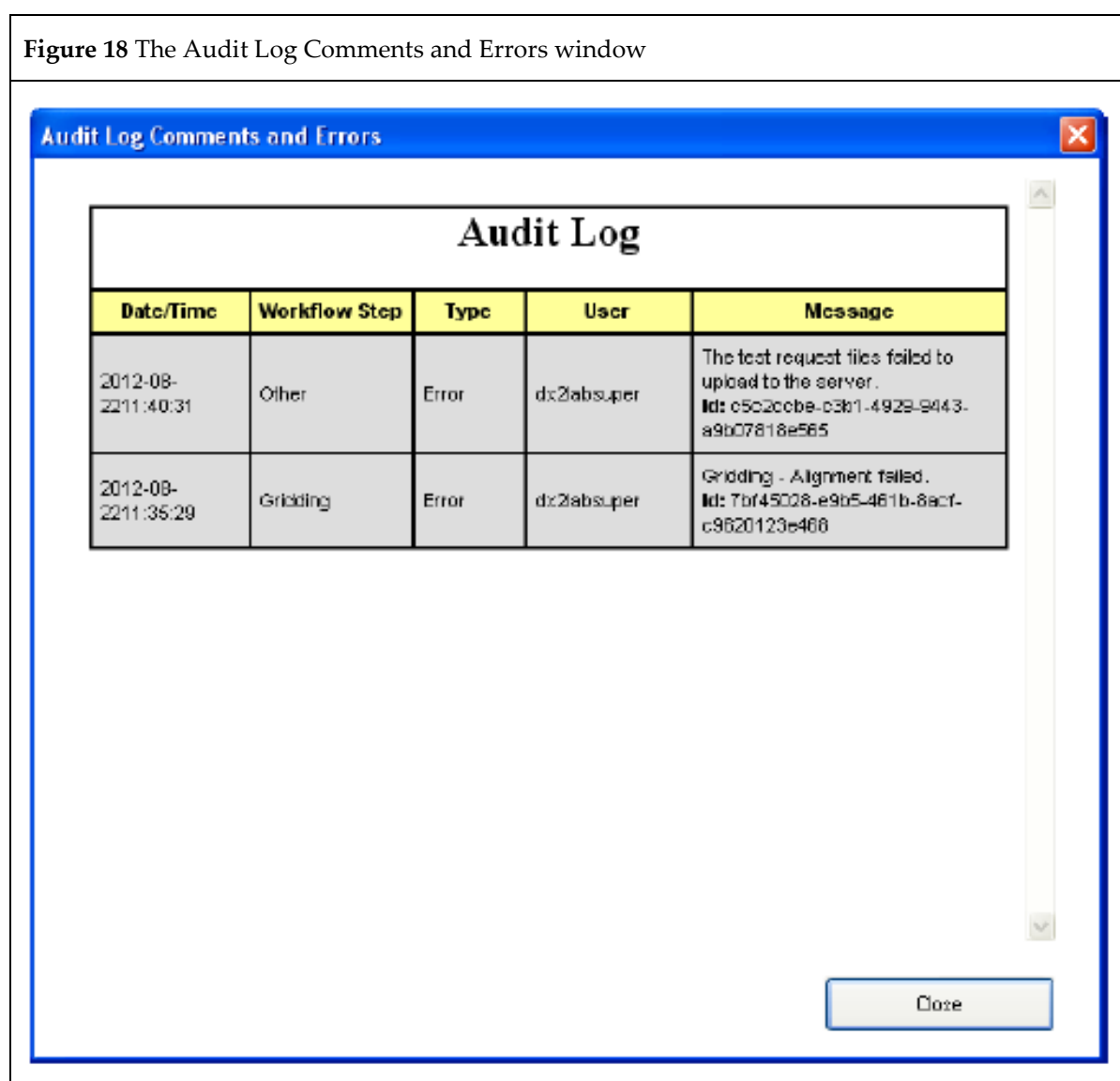
Ordering Information

The table below lists the HG-U133 Plus 2.0 ASM v2.3 Reagents, Arrays and associated part numbers.

Name	P/N	Supplier
GeneChip™ 3' IVT Express Kit (10 rxn)	901228	Thermo Fisher
GeneChip™ 3' IVT Express Kit (30 rxn)	901229	Thermo Fisher
GeneChip™ Expression 3'-Amplification Reagent Hybridization Controls (30 rxn)	900454	Thermo Fisher
GeneChip™ Hybridization, Wash & Stain Kit (30 rxn)	900720	Thermo Fisher
RNA Control Kit (IVD Kit 1)	901285	Thermo Fisher
Transcript Synthesis and Labeling Kit A (IVD Kit 2A)	901293	Thermo Fisher
Transcript Synthesis and Labeling Kit B (IVD Kit 2B)	901298	Thermo Fisher
Transcript Detection Kit A (IVD Kit 3A)	901307	Thermo Fisher
Transcript Detection Kit B (IVD Kit 3B)	901310	Thermo Fisher
Transcript Detection Kit C (IVD Kit 3C)	901312	Thermo Fisher
Wash Buffer A	900721	Thermo Fisher
Wash Buffer B	900722	Thermo Fisher
GeneChip Human Genome U133 Plus 2.0 Array and 3' IVT Express Kit Bundle (10 rxn)	901226	Thermo Fisher
GeneChip Human Genome U133 Plus 2.0 Array and 3' IVT Express Kit Bundle (30 rxn)	901227	Thermo Fisher
GeneChip Human Genome U133 Plus 2.0 Array (2 arrays)	900470	Thermo Fisher
GeneChip Human Genome U133 Plus 2.0 Array (6 arrays)	900466	Thermo Fisher
GeneChip Human Genome U133 Plus 2.0 Array (30 arrays)	900467	Thermo Fisher

Documentation and support

Obtaining support

Technical support
    For the latest services and support information for all locations, visit **www.thermofisher.com**.

At the website, you can:

- Access worldwide telephone and fax numbers to contact Technical Support and Sales facilities

- Search through frequently asked questions (FAQs)

- Submit a question directly to Technical Support (**thermofisher.com/support)**

- Search for user documents, SDSs, vector maps and sequences, application notes, formulations, handbooks, certificates of analysis, citations, and other product support documents

- Obtain information about customer training

- Download software updates and patches

Safety Data Sheets (SDS)
    Safety Data Sheets (SDSs) are available at **thermofisher.com/support**.

Limited product warranty
    Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale found on Life Technologies' website at **www.thermofisher.com/us/en/home/global/terms-and-conditions.html**. If you have any questions, please contact Life Technologies at **www.thermofisher.com/support**.

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