

TECHNICAL MANUAL

OncoMate™ MSI Dx Interpretive Software Reference Manual

Instructions for Use of Product
MD4140



INSTRUCTIONS FOR
USE OF PRODUCT
MD4140

OncoMate™ MSI Dx Interpretive Software





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 Visit the web site to verify that you are using the most current version of this Technical Manual.
 E-mail Promega Technical Services if you have questions on use of this system: genetic@promega.com

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Symbols Key

Symbol	Explanation	Symbol	Explanation
	In Vitro Diagnostic Medical Device		Catalog number
	Manufacturer		Refer to Instructions for Use

1. About This Manual

This reference manual provides information on specific functions and capabilities of the OncoMate™ MSI Dx Interpretive Software. It is not intended to be a stepwise guide to using the interpretive software. For step-by-step instructions on the import and analysis of fragment data and the interpretation of software results, consult the *OncoMate™ MSI Dx Analysis System Technical Manual #TM543*.

The OncoMate™ MSI Dx Interpretive Software is used in conjunction with the other components of the OncoMate™ MSI Dx Analysis System workflow: DNA isolated from normal and tumor formalin-fixed, paraffin-embedded (FFPE) tissue samples using the Maxwell® CSC Instrument (Cat.# AS6000) and Maxwell® CSC DNA FFPE Kit (Cat.# AS1350); a dye-based DNA quantification system, such as the QuantiFluor® Dx dsDNA System (Cat.# E5900); the OncoMate™ 5C Matrix Standard (Cat.# MD4850); the OncoMate™ MSI Dx Analysis System (Cat.# MD2140) and the Applied Biosystems® 3500 Dx Genetic Analyzer. Consult the *OncoMate™ MSI Dx Analysis System Technical Manual #TM543* for additional information about assay requirements and use.





2. Product Name

OncoMate™ MSI Dx Interpretive Software

Part No. MD4140

Abbreviations

QC, quality control

CE, capillary electrophoresis

CRC, colorectal cancer

DCS, data collection software for the Applied Biosystems® 3500 Dx Genetic Analyzer

FFPE, formalin-fixed, paraffin-embedded

HNPCC, hereditary nonpolyposis colorectal cancer

MMR, mismatch repair

MSI, microsatellite instability

MSI-H, microsatellite instability high

MSS, microsatellite stable

PC, personal computer

PCR, polymerase chain reaction

RFU, relative fluorescence unit

SMTP, simple mail transfer protocol

UDF1, user-defined field 1

IT, Information Technology or computer systems professional

NA, not applicable

3. Intended Use

The OncoMate™ MSI Dx Analysis System is a qualitative multiplex polymerase chain reaction (PCR) test intended to detect the deletion of mononucleotides in five microsatellite loci (BAT-25, BAT-26, NR-21, NR-24 and MONO-27) using matched tumor and normal DNA obtained from formalin fixed, paraffin-embedded (FFPE) colorectal tissue sections. The OncoMate™ MSI Dx Analysis System is for use with the Applied Biosystems® 3500Dx Genetic Analyzer and OncoMate™ MSI Dx Interpretive Software.

The OncoMate™ MSI Dx Analysis System is indicated in patients diagnosed with colorectal cancer (CRC) to detect microsatellite instability (MSI) as an aid in the identification of probable Lynch syndrome to help identify patients that would benefit from additional genetic testing to diagnose Lynch syndrome.

Results from the OncoMate™ MSI Dx Analysis System should be interpreted by healthcare professionals in conjunction with other clinical findings, family history, and other laboratory data.

The clinical performance of this device to guide treatment decision for MSI high patients has not been established.

4. Summary and Explanation

The OncoMate™ MSI Dx Interpretive Software generates automated MSI results by comparing the allelic profiles of normal and CRC tumor samples from the same patient. MSI is indicated by a change in the length of short, repetitive DNA sequences (“microsatellites”) in tumor cell DNA compared to normal cell DNA from the same patient. The software analyzes fragment data (.fsa files) generated by the Applied Biosystems® 3500 Dx Genetic Analyzer during the separation and analysis of OncoMate™ MSI Dx Analysis System (Cat.# MD2140) amplification products.

Five mononucleotide-repeat markers (BAT-25, BAT-26, NR-21, NR-24 and MONO-27) and two pentanucleotide-repeat markers (Penta C and Penta D) are evaluated. Analysis of mononucleotide-repeat markers is used to determine tumor MSI status. A tumor is interpreted as microsatellite-instability high (MSI-H) when two or more of these markers are unstable. A tumor sample is interpreted as microsatellite stable (MSS) when fewer than two mononucleotide markers are interpreted as unstable. The pentanucleotide-repeat markers are analyzed by the software as an identity check between the normal and tumor DNA samples. When all of the alleles detected in the normal sample are also present in the tumor sample, the sample identity check passes. A sample may be interpreted as No Call or Invalid in response to specific QC failures.

Results generated using the OncoMate™ MSI Dx Interpretive Software are intended to help identify patients that would benefit from additional genetic testing to diagnose Lynch Syndrome. CRC patients identified as MSI-H may have Lynch Syndrome and are therefore candidates for DNA sequencing to determine whether they have mutations in DNA mismatch repair genes (1–4).

The main workflow in the OncoMate™ MSI Dx Interpretive Software entails importing samples that define a sample batch, reviewing the results for each sample in the batch as well as the automated interpretation of MSI status for each tumor sample, approving the results for each sample in the batch and creating an export file for each batch (Figure 1).

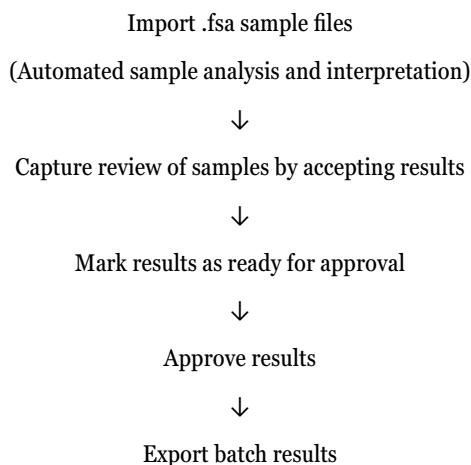


Figure 1. OncoMate™ MSI Dx Interpretive Software workflow.

5. Quality Controls Summary

The OncoMate™ MSI Dx Interpretive Software evaluates the quality of the capillary electrophoresis (CE) data and includes a variety of additional checks to ensure that the data are sufficient for making a valid MSI determination (see Sections 13.1, Minimum Requirements for a Valid Sample Batch, and 13.2, Quality Control Requirements). Patient samples must be identified in the Applied Biosystems® 3500 Dx Genetic Analyzer data collection software (DCS) as ‘Samples’ and imported into the software as matched normal and tumor pairs with the same sample name. Additionally, the ‘user-defined field 1’ (UDF1) field in the DCS must be populated with ‘N’ or ‘T’ to identify patient samples as normal or tumor, respectively (see *OncoMate™ MSI Dx Analysis System Technical Manual #TM543* for instructions on sample labeling during capillary electrophoresis using the UDF1 field). Positive and negative amplification controls must be analyzed in the same plate as corresponding patient samples during the CE separation run, and these controls must be identified as ‘Positive Control’ and ‘Negative Control’ in the Applied Biosystems® 3500 Dx Genetic Analyzer DCS. If amplification controls are not processed with patient samples, the data import and analysis will be invalid. All analyzed samples and controls must contain the Size Standard 500 (added prior to CE), and the size standard peaks analyzed by the software (60, 65, 80, 100, 120, 140, 160, 180, 200, 225, 250, 275, 300 base pairs) must be present between the minimum and maximum relative fluorescence unit (RFU) thresholds prescribed by the software.

6. Principles of the Procedure

During CE, the OncoMate™ MSI Dx Analysis System (Cat. # MD2140) amplification products are separated and analyzed alongside fluorescently labeled DNA fragments of known size, the Size Standard 500. Following CE, the resulting DNA fragment data (.fsa files) are simultaneously imported and analyzed by the OncoMate™ MSI Dx Interpretive Software. During this process, data quality control (QC) checks are performed, and DNA fragments amplified from seven microsatellite regions are sized with reference to the size standard fragments using the Local Southern method (5). For each sample (normal and tumor) or control (positive and negative) analyzed, the software uses an allele-calling routine to distinguish true microsatellite alleles from PCR “stutter” artifacts, which occur due to “slippage” of the DNA polymerase enzyme while copying repetitive DNA sequences (4). Microsatellite instability at a locus is evidenced by a lower molecular weight cluster of peaks (the primary amplicon and stutter products), relative to the cluster of peaks observed with the matched normal sample. For each of the five mononucleotide-repeat markers in both the normal and tumor sample, the peak exhibiting the greatest peak height in each cluster is assigned as the allele of interest for subsequent comparisons.

The OncoMate™ MSI Dx Interpretive Software requires data from paired normal and CRC tumor samples to determine tumor MSI status. The size difference between the alleles of interest in the normal and tumor samples is calculated to determine the stability of each of the five mononucleotide-repeat markers. A marker is interpreted as Unstable when this size difference is at least 3bp (implemented in the software as ≥ 2.75 bp to account for the sizing precision of capillary electrophoresis; Figure 2). A tumor sample is interpreted as MSI-H when two or more markers are Unstable. A tumor sample is interpreted as MSS when zero or one markers are interpreted as Unstable (4). A sample may be interpreted as No Call or Invalid in response to specific QC failures.

Two pentanucleotide-repeat markers are analyzed by the software as an identity check between the normal and tumor DNA samples. When all of the alleles detected in the normal sample are also present in the tumor sample, the sample identity check passes.

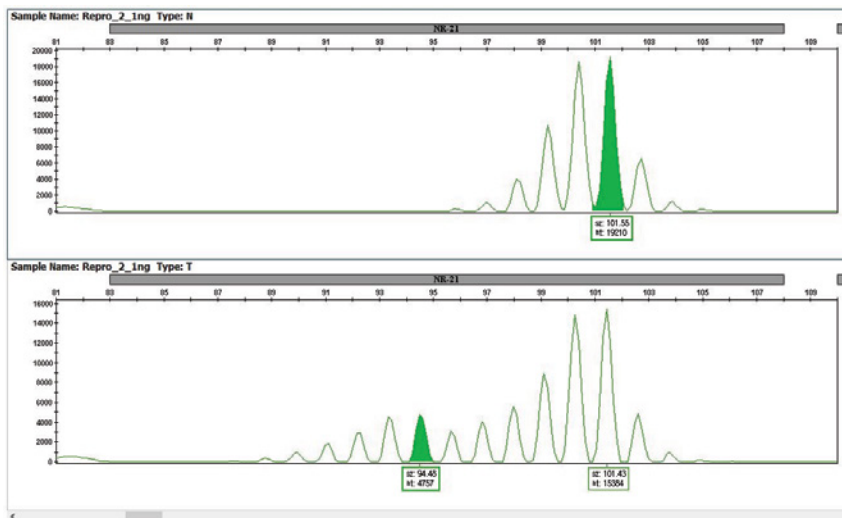


Figure 2. Stability assessment of mononucleotide markers. For a mononucleotide marker, if the allele of interest in the tumor sample has a size difference of at least 2.75bp compared to the allele of interest identified in the normal sample, the marker is interpreted as Unstable. In this example, the allele of interest (NR-21) in the normal sample (top electropherogram) is 101.55bp, while the allele of interest in the tumor sample (bottom electropherogram) is 94.48bp. The size difference between these two alleles is 7.07bp (≥ 2.75 bp); therefore, the NR-21 marker is interpreted as Unstable.

7. Product Components

COMPONENT	SIZE	PART #
OncoMate™ MSI Dx Interpretive Software	1 each	MD4140

The OncoMate™ MSI Dx Interpretive Software is provided with a server license on a USB drive.

8. Software Installation

8.1 System Requirements

The OncoMate™ MSI Dx Interpretive Software has two components: a server and a client. Both components must be installed for the software to function. The system requirements for the OncoMate™ MSI Dx Interpretive Software Server and Client are listed in Table 1.



Table 1. System Requirements for the OncoMate™ MSI Dx Interpretive Software.

Component	OncoMate™ MSI Dx Interpretive Software Server	OncoMate™ MSI Dx Interpretive Software Client
Computer	40GB available disk space 8GB RAM	20GB available disk space 4GB RAM
Operating System	One of the following: Windows® 7, Service Pack 1, 64-bit Windows® 10 Professional, 64-bit Windows® 10 Enterprise, 64-bit	One of the following: Windows® 7, Service Pack 1, 64-bit Windows® 10 Professional, 64-bit Windows® 10 Enterprise, 64-bit
Browser ¹	N/A	Google Chrome™ v.25 or later

¹A browser is required to view the OncoMate™ MSI Dx Interpretive Software Client help topics.

8.2 Installing the OncoMate™ MSI Dx Interpretive Software

Installation of the OncoMate™ MSI Dx Interpretive Software requires a Windows® User Account with administrator privileges. Confirm that the user installing the software has administrative privileges in the Windows® Operating System with read, write and execute permissions as well as permissions for firewall and security configuration.

The OncoMate™ MSI Dx Interpretive Software has two components: a server and a client. Both components must be installed for the software to function. The OncoMate™ MSI Dx Interpretive Software Server can be installed locally (i.e., on the same PC as the client), on a different networked PC or on a server. The instructions below describe the installation of the server on a PC. To install the OncoMate™ MSI Dx Interpretive Software Server on a network server, contact your IT professional for assistance.

Note: It is not necessary for the OncoMate™ MSI Dx Interpretive Software Client and OncoMate™ MSI Dx Interpretive Software Server to be running on the same version of the Windows® Operating System.

During installation of both the server and client, we recommend that you perform the following:

1. Disable antivirus software
2. Disable firewalls
3. Disable network connections

The OncoMate™ MSI Dx Interpretive Software installer is provided on a USB drive.

Notes:

1. Windows® Operating System Administrator permissions are required to install the OncoMate™ MSI Dx Interpretive Software.
2. Do not install the OncoMate™ MSI Dx Interpretive Software on the computer controlling the Applied Biosystems® 3500 Dx Genetic Analyzer. The requirements of the interpretive software are not compatible with the computer controlling the Applied Biosystems® 3500 Dx Genetic Analyzer.

Server Software Installation

Plug the USB drive containing the OncoMate™ MSI Dx Interpretive Software installer into one of the USB ports of the computer on which you wish to install the OncoMate™ MSI Dx Interpretive Software Server, and then follow the instructions below:

1. Using File Browser, open the USB drive.
2. Double-click on the Install file for the OncoMate™ MSI Dx Interpretive Software Server. If a security warning is displayed after starting the installer, select **Run**.
3. An installation wizard for the OncoMate™ MSI Dx Interpretive Software Server will appear (Figure 3). Press **Next >** to proceed with the installation of the OncoMate™ MSI Dx Interpretive Software Server, or press **Cancel** to cancel the installation.

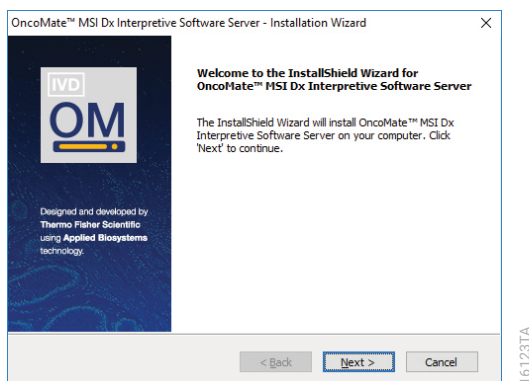
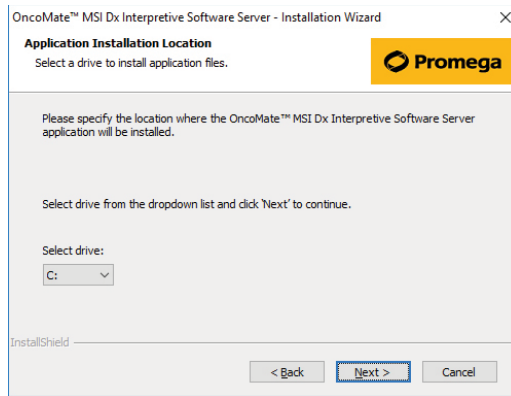


Figure 3. Installation Wizard for the OncoMate™ MSI Dx Interpretive Software Server.

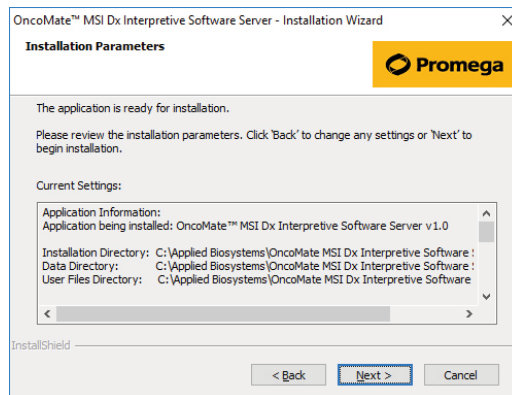
4. On the next three screens (Figure 4) you will be asked to select the drive locations for installation of the Server Application Files (Installation Directory), Application Data Files (Data Directory) and User Files (User Files Directory) folders. Use the drop-down list on these screens to select drive locations for each of these folders. After selecting a drive location, press **Next >** on each screen to proceed through the Installation Wizard. Different drive locations can be specified for each of the different file types.



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Figure 4. Installation drive locations. On this screen you will select a drive for installation of the Server Application Files (Installation Directory). Two other similar screens will ask you to select a drive for installation of the Application Data Files (Data Directory) and User Files (User Files Directory). Select the desired drive for each of these file types from the drop-down menu.

5. A summary of the drive locations specified for the Installation Directory, Data Directory and User Files Directory is displayed (Figure 5). Press **Next >** to proceed with installation using these settings. To change any of the drive location settings, press **< Back**. To cancel installation of the OncoMate™ MSI Dx Interpretive Software Server, press **Cancel**.



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Figure 5. ‘Installation Parameters’ screen with a summary of the directory locations for the Installation Directory, Data Directory and User Files Directory.

6. Installation of the OncoMate™ MSI Dx Interpretive Software Server will proceed at the specified locations. After installation is complete, you will see a screen indicating the successful completion of the OncoMate™ MSI Dx Interpretive Software Server installation (Figure 6). Press the **Finish** button to exit the installation wizard. An icon for the OncoMate™ MSI Dx Interpretive Software Server will appear on the computer desktop.



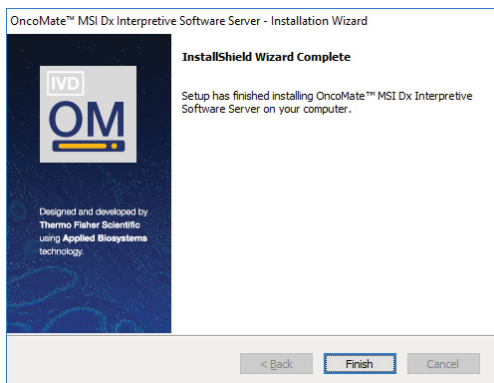


Figure 6. OncoMate™ MSI Dx Interpretive Software Server installation complete. This screen indicates successful completion of the OncoMate™ MSI Dx Interpretive Software Server installation.

7. For users of Windows® 10 Professional and Windows® 10 Enterprise Operating Systems, right-click on the OncoMate™ MSI Dx Server desktop icon. Select **Properties** from the menu. On the 'Properties' screen, select the 'Shortcut' tab, and then press the **Advanced...** button. On the 'Advanced Properties' screen, check the Run as administrator check box. Press **OK** to close the 'Advanced Properties' screen, and then press **OK** to close the 'Properties' screen.
8. After installation of the OncoMate™ MSI Dx Interpretive Software Server, restart any antivirus software, firewalls and network connections that were disabled.

Client Software Installation

Plug the USB drive into one of the USB ports of the computer on which you wish to install the OncoMate™ MSI Dx Interpretive Software Client, and then follow the instructions below:

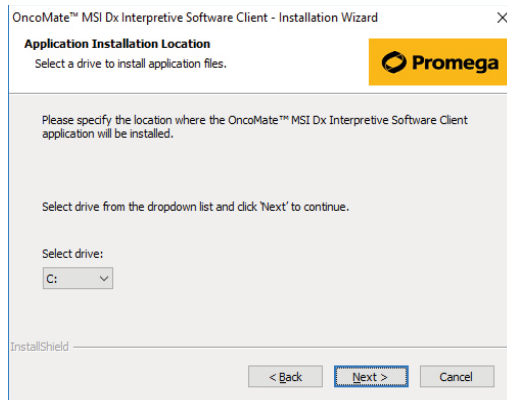
1. Using File Browser, open the USB drive.
2. Double-click on the Install file for the OncoMate™ MSI Dx Interpretive Software Client. If a security warning is displayed after starting the installer, select **Run**.
3. An installation wizard for the OncoMate™ MSI Dx Interpretive Software Client will appear (Figure 7). Press **Next >** to proceed with the installation of the OncoMate™ MSI Dx Interpretive Software Client, or press **Cancel** to cancel the installation.



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Figure 7. Installation Wizard for the OncoMate™ MSI Dx Interpretive Software Client.

- On the next three screens (Figure 8) you will be asked to select the drive locations for installation of the Client Application Files (Installation Directory), Application Data Files (Data Directory) and User Files (User Files Directory) folders. Use the drop-down list on these screens to select drive locations for each of these folders. After selecting a drive location, press **Next >** on each screen to proceed through the Installation Wizard. Different drive locations can be specified for each of the different file types.



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Figure 8. Installation drive locations. On this screen you will select a drive for installation of the Client Application Files (Installation Directory). Two other similar screens will ask you to select a drive for installation of the Application Data Files (Data Directory) and User Files (User Files Directory). Select the desired drive for each of these file types from the drop-down menu.

- A summary of the drive locations specified for the Installation Directory, Data Directory and User Files Directory is displayed (Figure 9). Press **Next >** to proceed with installation using these settings. To change any of the drive location settings, press **< Back**. To cancel installation of the OncoMate™ MSI Dx Interpretive Software Client, press **Cancel**.

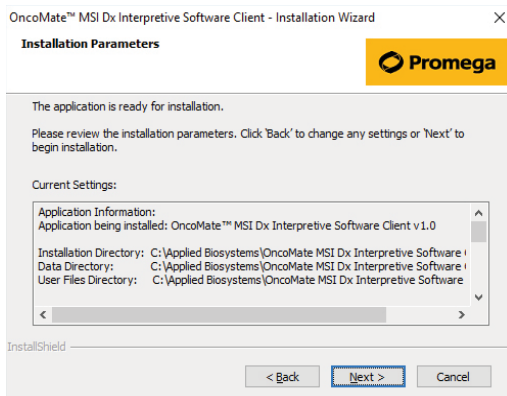


Figure 9. ‘Installation Parameters’ screen with a summary of the directory locations for the Installation Directory, Data Directory and User Files Directory.

6. Installation of the OncoMate™ MSI Dx Interpretive Software Client will proceed at the specified locations. After installation is complete, you will see a screen indicating the successful completion of the OncoMate™ MSI Dx Interpretive Software Client installation (Figure 10). Press **Finish** to exit the installation wizard. An icon for the OncoMate™ MSI Dx Interpretive Software Client will appear on the computer desktop.



Note: Multiple client installations can be performed, all connecting to the same server installation and therefore connecting to the same database. However, only one client can review a batch at a time.

Note: Do not start the software client using the **Run as administrator** option.



Figure 10. OncoMate™ MSI Dx Interpretive Software Client installation complete. This screen indicates successful completion of the OncoMate™ MSI Dx Interpretive Software Client installation.

7. After installation of the OncoMate™ MSI Dx Interpretive Software Client, restart any antivirus software, firewalls and network connections that were disabled.

Notes:

1. We recommend that you routinely perform antivirus and anti-malware scans on your computer, including on all OncoMate™ MSI Dx Interpretive Software files and folders. However, we do not recommend performing the scans when the interpretive software is running. The scans slow down system performance and may create a file conflict that causes the OncoMate™ MSI Dx Interpretive Software server to become unresponsive.
2. The following antivirus and anti-malware applications have been evaluated for compatibility with the OncoMate™ MSI Dx Interpretive Software: Symantec™ Endpoint Protection (versions 12.1.6 and 14.0.3), McAfee Endpoint Security (version 10.5), and Trend Micro™ OfficeScan (version 12.0.5).
3. Be sure to update antivirus and anti-malware software definitions regularly according to the vendor instructions.



8.3 Starting the OncoMate™ MSI Dx Interpretive Software Server

Follow the steps below to start the OncoMate™ MSI Dx Interpretive Software Server.

1. Double-click the OncoMate™ MSI Dx Server icon  to start the OncoMate™ MSI Dx Interpretive Software Server application.

Notes:

1. Registration of the OncoMate™ MSI Dx Interpretive Software is required. Until registration has been completed successfully, a Product Registration screen will be displayed when the OncoMate™ MSI Dx Interpretive Software Server is started. See Section 8.4, Registering the OncoMate™ MSI Dx Interpretive Software, for further information.
 2. While there is no user interface for the OncoMate™ MSI Dx Interpretive Software Server, a command prompt window will open and automatically close during application startup. Even after the command prompt window has closed, it may still take several minutes for the OncoMate™ MSI Dx Interpretive Software Server to be available for use.
 3. Make sure you have followed Step 7 of the Server Software Installation part of Section 8.2, Installing the OncoMate™ MSI Dx Interpretive Software, to check the box to allow the OncoMate™ MSI Dx Interpretive Software Server to run as administrator.
2. To check whether the OncoMate™ MSI Dx Interpretive Software Server is running and available for use, follow the instructions appropriate to your Windows® Operating System below:

Windows® 7 Operating System: In the taskbar, click the up arrow icon  to display hidden icons. If the OncoMate™ MSI Dx Interpretive Software Server is running and available for use, the  icon is displayed in the hidden icons area.

Windows® 10 Professional or Windows® 10 Enterprise Operating Systems: Right-click the **Start** menu, select **Run** and enter “services.msc”. Press **OK** to open the ‘Services’ screen. On the ‘Services’ screen, check to see that the item with the name “OncoMate™ MSI Dx Interpretive Software Server Service” is present and has a status of “Running”.

8.4 Registering the OncoMate™ MSI Dx Interpretive Software

Following installation, product registration is required to use the OncoMate™ MSI Dx Interpretive Software. Until product registration is successfully completed, a Product Registration Screen (Figure 11) is displayed when the OncoMate™ MSI Dx Interpretive Software Server is started. Follow the steps below to register the OncoMate™ MSI Dx Interpretive Software.

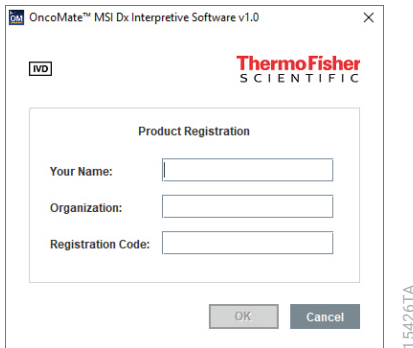
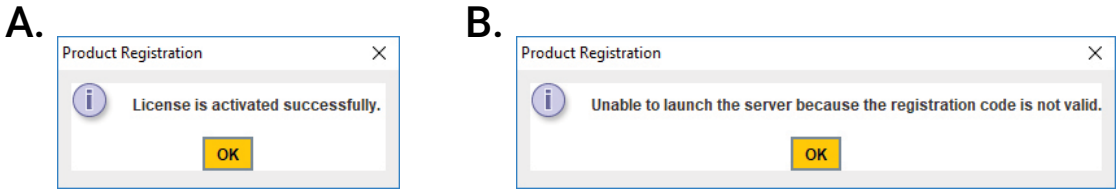


Figure 11. Product Registration screen. Enter the requested information on this screen to complete the product registration process. Information must be entered in all fields. The Registration Code is provided on the USB drive containing the OncoMate™ MSI Dx Interpretive Software.

1. When the product registration screen is displayed, enter information into the ‘Your Name:’ and ‘Organization:’ fields.
2. Enter the license key number provided on the USB drive containing the OncoMate™ MSI Dx Interpretive Software into the ‘Registration Code:’ field. Only after all fields contain information will the **OK** button become active. Click **OK** to confirm the information that was entered, or click **Cancel** to end the product registration process.

If the license key number is valid, you will see a screen indicating that the license is activated successfully, and the product is successfully registered (Figure 12, Panel A). If not, you will see a screen indicating failure to launch the server because the registration code is not valid (Figure 12, Panel B). Double-check the license key number and attempt to register the product again by double-clicking the OncoMate™ MSI Dx Server icon again. If you continue to have problems with registration, please contact Promega Technical Services at: genetic@promega.com for assistance.



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Figure 12. Registration result screens. Panel A. Screen displayed if registration of the OncoMate™ MSI Dx Interpretive Software is successful. **Panel B.** Screen displayed if the registration code entered is not valid and registration was not successful.

8.5 Configuring Server Connection Information

Mutiple instances of the OncoMate™ MSI Dx Interpretive Software Client can be configured to connect to the same OncoMate™ MSI Dx Interpretive Software Server. We have tested up to five instances connected simultaneously. By default, the OncoMate™ MSI Dx Interpretive Software Client is configured to connect to an OncoMate™ MSI Dx Interpretive Software Server running on the same computer. If you wish to connect the Client to a Server running on a different computer, follow these instructions:



1. After confirming that the OncoMate™ MSI Dx Interpretive Software Server is running, double-click the OncoMate™ MSI Dx Client icon on the computer desktop.
WARNING: DO NOT right-click the OncoMate™ MSI Dx Client icon and choose **Run as administrator** to start the Client. Software functionality may be negatively affected.
2. If the ‘Server Connection’ screen (Figure 13, Panel A) is displayed, choose one of the options below:
 - Press **OK** to close the OncoMate™ MSI Dx Interpretive Software Client. Confirm that the OncoMate™ MSI Dx Interpretive Software Server is running and available using the instructions in Section 8.3, Starting the OncoMate™ MSI Dx Interpretive Software Server, and that the network connection is active. Restart the OncoMate™ MSI Dx Interpretive Software Client.
 - Use the **Connect to a Different Server** button to specify a different server name (Figure 13, Panel B). Enter the name “localhost” if the OncoMate™ MSI Dx Interpretive Software Server is installed on the same computer as the OncoMate™ MSI Dx Interpretive Software Client, or enter the name or IP address of the server location of the OncoMate™ MSI Dx Interpretive Software Server. Press **Test Connection** to test whether the OncoMate™ MSI Dx Interpretive Software Client can successfully connect to the OncoMate™ MSI Dx Interpretive Software Server at the specified location. Press **OK** to accept the entered location and start the OncoMate™ MSI Dx Interpretive Software Client or **Cancel** to exit.

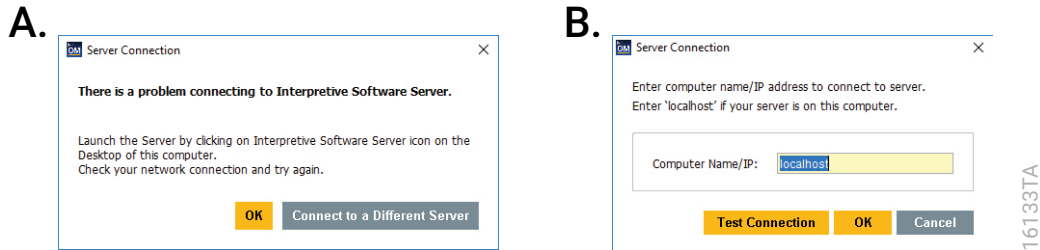


Figure 13. Connecting to the server. Panel A. The ‘Server Connection’ screen indicates that there was an error connecting to the OncoMate™ MSI Dx Interpretive Software Client to the OncoMate™ MSI Dx Interpretive Software Server. **Panel B.** By clicking the **Connect to a Different Server** button, you can specify a different server name or IP address for the connection.

3. In the event that you later need to change the OncoMate™ MSI Dx Interpretive Software Server connection information, on the initial login screen press the **Down Arrow** in the lower left corner (Figure 14).

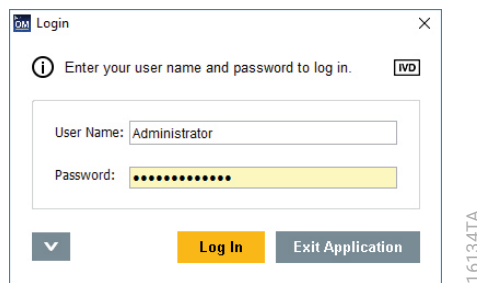


Figure 14. ‘Login’ screen. Press the **Down Arrow** in the lower left corner to access or change server connection information.

In the text box next to the “Computer Name/IP:” field (Figure 15), modify the computer name or IP address of the computer on which the OncoMate™ MSI Dx Interpretive Software Server is installed. If the OncoMate™ MSI Dx Interpretive Software Client and Server are installed on the same computer, enter the computer name “localhost”. Press **Test Connection** to determine whether the OncoMate™ MSI Dx Interpretive Software Client can connect to the Server using the computer name or IP address provided.

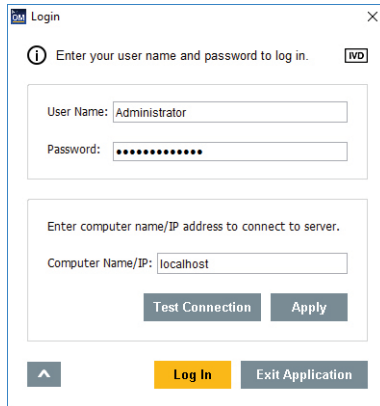


Figure 15. Server connection information. Press the **Up Arrow** to hide server connection information.

If the Client is not able to connect to the Server, a warning will be displayed indicating that the Client is unable to connect to the specified Server. Check the Computer Name/IP address and try again, or contact your IT professional to troubleshoot the issue. Changing the server connection information will display the ‘Server Connection’ screen (Figure 16) and requires a restart of the OncoMate™ MSI Dx Interpretive Software Client to connect to the new Server. Press the **OK** button to close the OncoMate™ MSI Dx Interpretive Software Client.

Note: The OncoMate™ MSI Dx Interpretive Software Client can only connect to the OncoMate™ MSI Dx Interpretive Software Server. The version of the OncoMate™ MSI Dx Interpretive Software Server must match that of the OncoMate™ MSI Dx Interpretive Software Client.

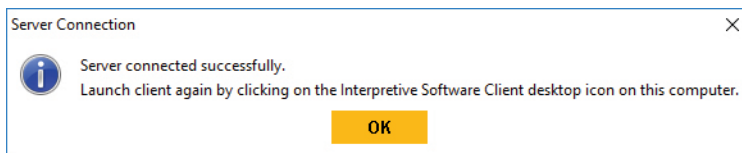


Figure 16. The ‘Server Connection’ screen.

4. If the Client is able to connect to the server, press the **Apply** button to specify the indicated computer name or IP address as the default connection for the Client to the Server.

8.6 End User License Agreement

The first time the OncoMate™ MSI Dx Interpretive Software Client is run, an ‘End User License Agreement’ screen (Figure 17) will appear. Carefully read the license agreement, and use the buttons on this screen to respond.

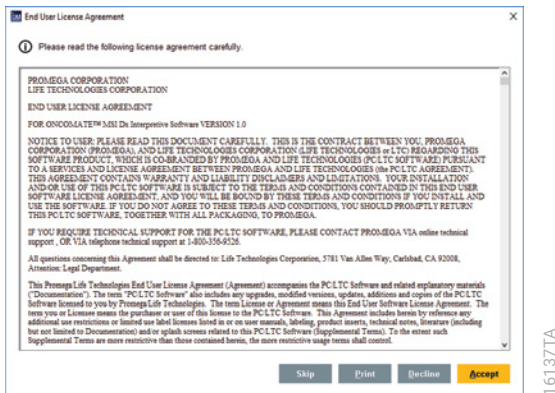


Figure 17. ‘End User License Agreement’ screen. Carefully read and respond to the end user license agreement.

- Press the **Accept** button to agree to the terms of the end user license agreement and start the OncoMate™ MSI Dx Interpretive Software Client.
- Press the **Decline** button to decline the end user license agreement. Declining the end user license agreement will close the OncoMate™ MSI Dx Interpretive Software Client.
- Press the **Skip** button to defer response to the end user license agreement and start the OncoMate™ MSI Dx Interpretive Software Client. It is possible to use the **Skip** button a maximum of three times before **Accept** or **Decline** are the only active options. The ‘End User License Agreement’ screen will continue to appear every time the OncoMate™ MSI Dx Interpretive Software Client is started until the user chooses to accept the agreement.
- Press the **Print** button to print a copy of the end user license agreement using a printer accessible by the computer.

The End User License Agreement is available in the **About** menu. After accepting or skipping the end user license agreement, you will be prompted to log in.

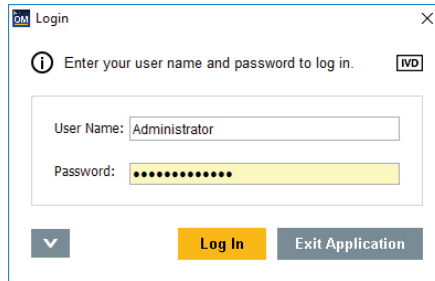
8.7 Standard Client Login Procedure

1. Confirm that the OncoMate™ MSI Dx Interpretive Software Server is running, and double-click the icon for the OncoMate™ MSI Dx Interpretive Software Client on the computer desktop.

WARNING: DO NOT right-click the OncoMate™ MSI Dx Client icon and choose **Run as administrator** to start the Client. Software functionality may be negatively affected.

2. At the ‘Login’ screen (Figure 18), enter your User Name and Password (case sensitive) to activate the **Log In** button. Press **Log In** to enter the OncoMate™ MSI Dx Interpretive Software Client.

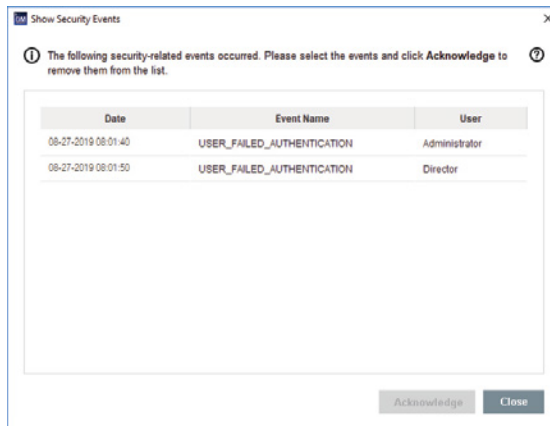
Note: See Section 15.3, Security Settings, for default User Names and Passwords to initialize the software and set up users specific to your system.



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Figure 18. ‘Login’ screen.

3. To exit the application without logging in, press **Exit Application**.
4. Users with an Administrator role will be notified at login of any security-related events that have occurred during operation of the OncoMate™ MSI Dx Interpretive Software Client (Figure 19). Click to select a single item, or Shift-Click or Ctrl-Click to select multiple items in the list. Press **Acknowledge** to clear these items. Press **Close** to close the ‘Show Security Events’ screen and proceed to the ‘Home’ screen.



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Figure 19. The ‘Show Security Events’ screen.

5. After successful login to the OncoMate™ MSI Dx Interpretive Software Client, the ‘Home’ screen of the Client is displayed (Figure 20). See Section 11, Main Workflow, for workflow instructions.

Note: To reactivate a suspended account or reset a user password, see Section 15.3, Security Settings, under the ‘Users’ tab.

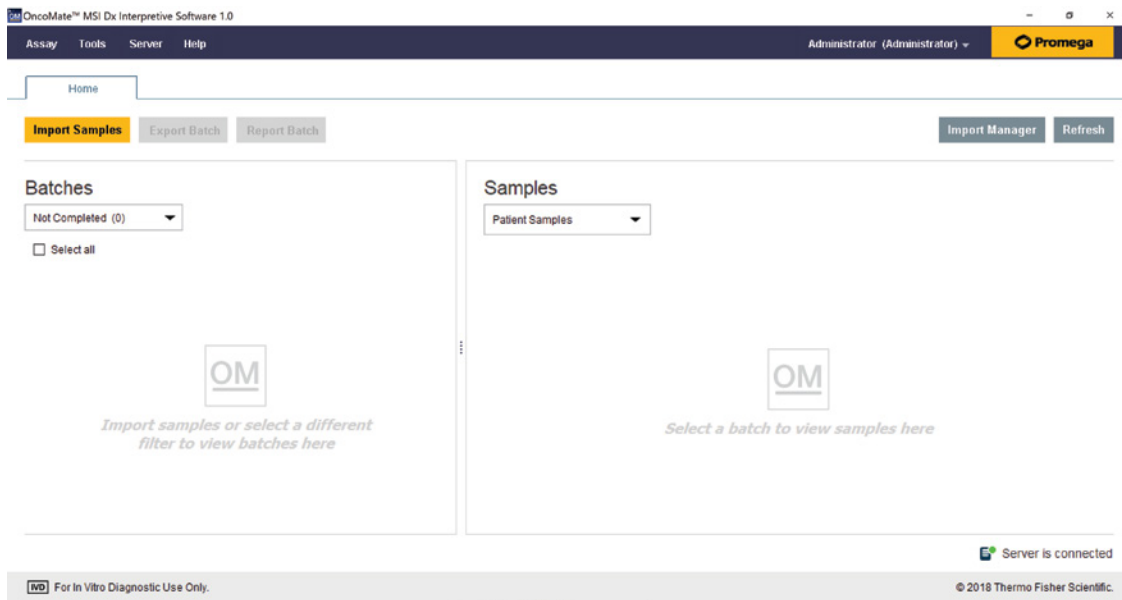


Figure 20. The ‘Home’ screen.

9. ‘Home’ Screen

The sample interpretation workflow is initiated at the ‘Home’ screen of the OncoMate™ MSI Dx Interpretive Software Client (Figure 20). This screen consists of three distinct areas:

- A persistent menu bar at the top of the screen, used to access a variety of functions for software configuration, sample management and managing login status
- A Tab Control area, used to manage workflows and sample interpretation results
- A Notification bar at the bottom right of the screen, used to indicate the connection status to the software server and to notify the user of active processes

9.1 Menu Bar

The menu bar at the top of the ‘Home’ screen displays menus to access a variety of functions within the OncoMate™ MSI Dx Interpretive Software Client. Access to each of these functions is defined by user roles within the software, so not all users will have access to all functions. Table 2 lists the menu items accessible from the menu bar and describes their functions.

Table 2. Functions in the Menu Bar.

Assay Menu	
Function	Description
Report Settings	Configure the images or text appearing in the header of batch reports. See Section 14.1, Report Settings, for detailed information.
Technical Support	Create a Technical Support Export file. After selecting Technical Support , the Export Sample and Peak Details sub-menu item is displayed. Technical Support Exports can only be created from the 'Batch' screen, which is opened by double-clicking a given batch of samples, not from the 'Home' screen. See Section 14.2, Technical Support Export, for detailed information.
Tools Menu	
Function	Description
System Settings	Configure the simple mail transfer protocol (SMTP) server settings necessary to allow e-mail notifications. See Section 15.1, System Settings, for detailed information.
Notification Settings	Configure e-mail notification settings that are applied when a Technical Support Export is created. See Section 15.2, Notification Settings, for detailed information.
Security Settings	Manage users, roles, security settings and audit records for the OncoMate™ MSI Dx Interpretive Software Client. See Section 15.3, Security Settings, for detailed information.
Archive	Create an archive file for one or more sample batches, and indicate whether those batches should be purged from the system after archive. See Section 15.4, Archive, for detailed information.
Restore	Restore an archive file that has previously been created. Samples will be reimported into the software and available in the sample batch list. See Section 15.5, Restore, for detailed information.
Import Manager	View a record of sample batches that were imported into the software, whether the import was successful and the status of the imported samples. See Section 15.6, Import Manager, for detailed information.
Preferences	Specify the default folder locations when importing, exporting, reporting and archiving sample batches. See Section 15.7, Preferences, for detailed information.

Server Menu

Not displayed in Windows® 7 Operating System. See Section 17, Server Menu.

Function	Description
View OncoMate™ MSI Dx Interpretive Software Server Automation Log	The Server Automation Log provides a high-level overview of automated import activities for the OncoMate™ MSI Dx Interpretive Software Server. The log indicates the time stamp for each activity and whether it was successfully executed or not. These logs are for troubleshooting purposes only.
View OncoMate™ MSI Interpretive Software Server Log	View a record of all activities of the OncoMate™ MSI Dx Interpretive Software Server and any interactions between the OncoMate™ MSI Dx Interpretive Software Client and the OncoMate™ MSI Dx Interpretive Software Server. These logs are for troubleshooting purposes only.

Help Menu

Function	Description
Interpretive Software Help	Use this item to view the Help files specific to the OncoMate™ MSI Dx Interpretive Software Client. Browse or search help topics specific to software features and functions. See Section 16.1, Interpretive Software Help, for detailed information. On selected screens, press the question mark icon to access context-sensitive help topics for that screen. If a screen does not display a question mark icon, press the F1 key to access the context-sensitive help topics for that screen.
About	View information regarding the software version as well as viewing or printing the End User License Agreement. See Section 16.2, About, for detailed information.



Currently Logged In User (User Role)

Function	Description
Log Out	Select the Log Out item to log the current user out of the OncoMate™ MSI Dx Interpretive Software Client. The OncoMate™ MSI Dx Interpretive Software Client remains open and the 'Login' screen is displayed.
Exit	Select Exit to log out and close the OncoMate™ MSI Dx Interpretive Software Client.

9.2 Tab Control

After logging into the software, the ‘Home’ screen is visible (Figure 20). This screen is split into a Batches pane on the left side and a Samples pane on the right side. These panes will be empty until batches of samples are successfully imported. At the top of the ‘Home’ screen is a series of buttons used to manage information related to samples and batches. Additional information about Tab Control functions is described in Section 10, Working with Sample Batches.

Table 3. Buttons Present in the Tab Control Area of the ‘Home’ Screen.

Button	Description
Import Samples	Browse to the location of sample .fsa files to be imported. Import of samples and the requirements for import are covered in Section 11.2, Importing Samples (.fsa Files) for Automated Analysis, and Section 13, Quality Control for Sample Batches, respectively.
Export Batch	Export a summary of the batch information in comma-delimited text format. Export of batch information is discussed in Section 10.2, Creating Sample and Batch Reports and Export Files.
Report Batch	Create a PDF summary report of the batch information. Reporting of batch information is discussed in Section 10.2, Creating Sample and Batch Reports and Export Files.
Import Manager	View a summary list of all sample import events that have occurred. Additional detail can be found in Section 15.6, Import Manager.
Refresh	Refresh the list of batches and samples that were imported. We recommend using Refresh before opening a batch to ensure that the latest information from all instances of the OncoMate™ MSI Dx Interpretive Software is available. Using Refresh will reset the view on the ‘Home’ screen to the default display of batches that have not been completed and clears all search settings.

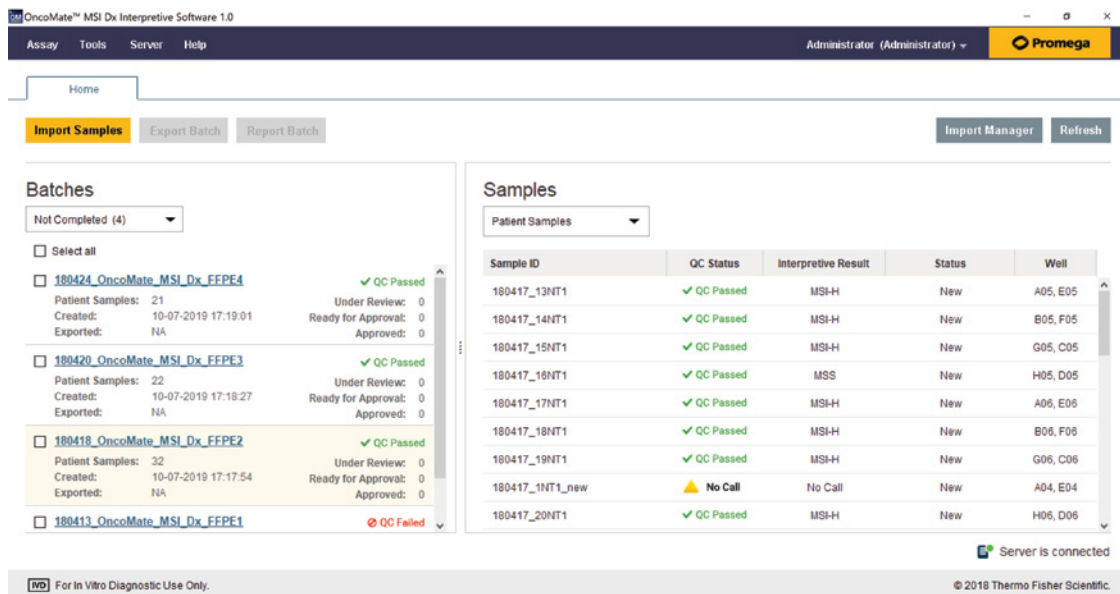
9.3 Notification Bar

At the bottom right of the OncoMate™ MSI Dx Interpretive Software Client user interface is a notification bar that indicates the connection state to the OncoMate™ MSI Dx Interpretive Software Server. If at any time the OncoMate™ MSI Dx Interpretive Software Server becomes unavailable, a warning will be displayed that the connection was lost, and the OncoMate™ MSI Dx Interpretive Software Client will close. Check the status of the OncoMate™ MSI Dx Interpretive Software Server and network connections, if applicable, and restart the OncoMate™ MSI Dx Interpretive Software Client.

Also, the notification bar indicates whether the OncoMate™ MSI Dx Interpretive Software Client is actively performing a function. An Active notification will be displayed while functions like importing, exporting, archiving, reporting, reviewing and approving are being performed. When this notification disappears, the function is complete.

9.4 Display Filters for Sample Batches

After sample batches are imported into the OncoMate™ MSI Dx Interpretive Software, summary information for each batch is displayed on the ‘Home’ screen (Figure 21). You can filter the list of batches using the drop-down menu at the top of the Batches pane.



The screenshot shows the OncoMate™ MSI Dx Interpretive Software 1.0 interface. The top navigation bar includes 'Assay', 'Tools', 'Server', and 'Help'. The user is logged in as 'Administrator (Administrator)'. The main area is titled 'Home' and contains buttons for 'Import Samples', 'Export Batch', 'Report Batch', 'Import Manager', and 'Refresh'. The 'Batches' pane on the left has a filter dropdown set to 'Not Completed (4)' and lists four batches with their respective QC statuses (Passed or Failed). The 'Samples' pane on the right has a filter dropdown set to 'Patient Samples' and displays a table of sample details.

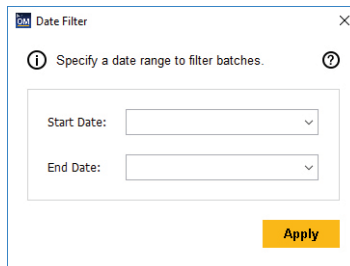
Sample ID	QC Status	Interpretive Result	Status	Well
180417_13NT1	✓ QC Passed	MSI-H	New	A05, E05
180417_14NT1	✓ QC Passed	MSI-H	New	B05, F05
180417_15NT1	✓ QC Passed	MSI-H	New	G05, C05
180417_16NT1	✓ QC Passed	MSS	New	H05, D05
180417_17NT1	✓ QC Passed	MSI-H	New	A06, E06
180417_18NT1	✓ QC Passed	MSI-H	New	B06, F06
180417_19NT1	✓ QC Passed	MSI-H	New	G06, C06
180417_1NT1_new	⚠ No Call	No Call	New	A04, E04
180417_20NT1	✓ QC Passed	MSI-H	New	H06, D06

Figure 21. ‘Home’ screen. Filter the list of sample batches using the drop-down menu at the top of the Batches pane.

Batch display filtering options (Table 4) display batches according to the user's progress along the required review, approval and export workflow (see Section 11, Main Workflow).

Table 4. Batch Display Filtering Options.

Drop-Down Menu Item	Description
All	View all sample batches, regardless of workflow status.
Not Completed	View batches that are not completed (i.e., the review, approval and export workflow has begun but is incomplete).
Completed	View batches that are completed (i.e., the review, approval and export workflow was executed for all samples).
New	View batches for which no samples have started the review, approval and export workflow.
Under Review	View batches for which at least one sample is marked as Under Review or Ready for Approval.
Ready for Export	View batches for which all samples are marked as Approved but are not yet exported.
Created Date	Search for batches created within a specific date range. Selecting Created Date will open a ‘Date Filter’ screen (Figure 22). Press the down arrow on the drop-down menu for the ‘Start Date’ and ‘End Date’ fields to specify a date range. A calendar will open from which you can select the start date and end date of the range. Both a start date and an end date must be selected to filter batches. Press Apply to display only batches with creation dates within the selected range. The selected date range will be displayed at the top right of the Batches pane. Click the blue ‘x’ icon to the right of the date range to turn off the Created Date filter.
Search Sample ID	Search for batches that contain specific text within the Sample ID field. When using the Search Sample ID filter, a text box will appear in the Samples pane on the ‘Home’ screen. Enter the search term and press Enter, or press the Magnifying Glass button to filter the batch and sample lists. Only batches that have samples with Sample IDs that contain the search term will be shown in the Batches pane, and only the samples that contain the search term will be shown in the Samples pane.



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Figure 22. Filter batches by date range. Use the ‘Date Filter’ screen to filter batches by date range.

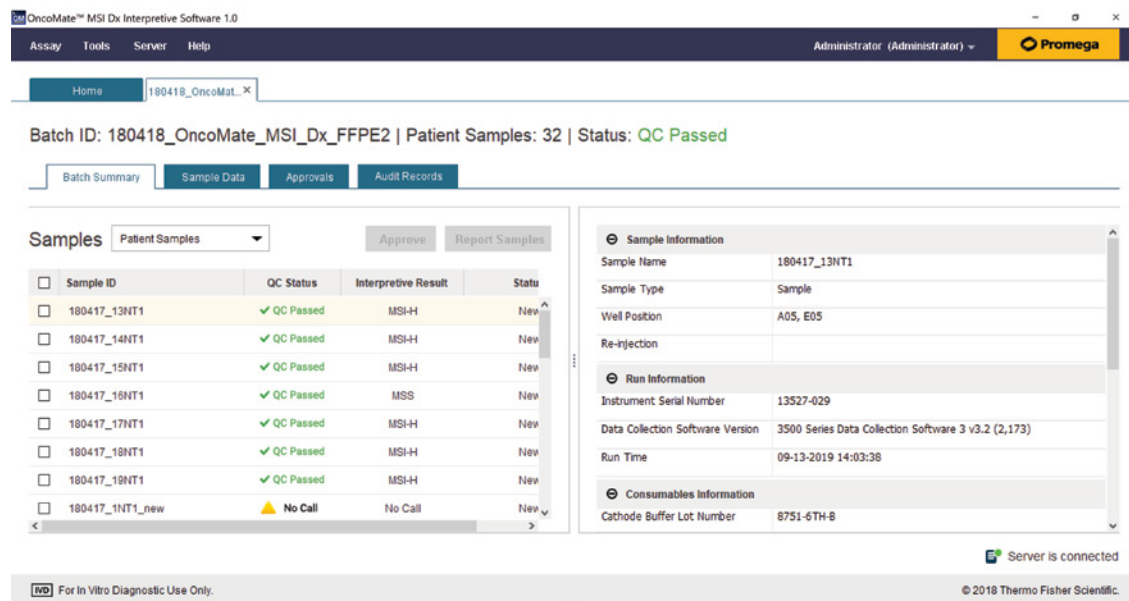
A summary is presented for each batch in the Batches pane on the 'Home' screen (Figure 21). The following attributes are displayed: batch name, number of patient samples, date of creation, most recent batch export date, QC status for the batch (see Section 13.2, Quality Control Requirements), number of samples under review, number of samples ready for approval and number of approved samples. Selecting a batch displays information in the Samples pane of the 'Home' screen. Use the drop-down menu at the top of the Samples pane to view information about Patient Samples or Controls contained within the sample batch. For each sample in the batch, the Sample ID, Sample QC Status, Interpretive Result (i.e., MSI Status), Sample Approval Status and Well Location are displayed. For each Control in the sample batch, the Sample ID, Control QC Status and Well Location are displayed (see Section 13.1, Minimum Requirements for a Valid Sample Batch).

10. Working with Sample Batches

10.1 Viewing Data and Results for an Individual Batch

Once a batch of samples is created in the OncoMate™ MSI Dx Interpretive Software Client, double-click the batch name to open a batch screen (Figure 23) and view batch details, including sample electropherograms, review and approval status, and audit records.

The title bar at the top of the batch screen displays the name of the batch, the number of patient samples in the batch and the QC status of the batch. The batch screen presents four tabs: Batch Summary, Sample Data, Approvals and Audit Records. Each of these tabs is described below.



The screenshot shows the 'Sample Data' tab with the following table:

Sample ID	QC Status	Interpretive Result	Status
180417_13NT1	✓ QC Passed	MSI-H	New
180417_14NT1	✓ QC Passed	MSI-H	New
180417_15NT1	✓ QC Passed	MSI-H	New
180417_16NT1	✓ QC Passed	MSS	New
180417_17NT1	✓ QC Passed	MSI-H	New
180417_18NT1	✓ QC Passed	MSI-H	New
180417_19NT1	✓ QC Passed	MSI-H	New
180417_1NT1_new	▲ No Call	No Call	New

The details pane on the right shows the following information:

- Sample Information:** Sample Name: 180417_13NT1, Sample Type: Sample, Well Position: A05, E05, Re-injection: (empty)
- Run Information:** Instrument Serial Number: 13527-029, Data Collection Software Version: 3500 Series Data Collection Software 3 v3.2 (2,173), Run Time: 09-13-2019 14:03:38
- Consumables Information:** Cathode Buffer Lot Number: 8751-6TH-8

At the bottom of the window, it says 'Server is connected' and '© 2018 Thermo Fisher Scientific.' There is also a small '16142TA' label on the right edge.

Figure 23. A batch screen. The batch screen provides access to information about the samples and controls within a sample batch, including review and approval status, electropherograms and audit records.





'Batch Summary' Tab

The 'Batch Summary' tab presents a summary of the samples and controls within the batch and the associated run parameters for the batch. The Samples pane on the left side of the tab displays a summary of each sample and controls present in the batch. Use the Samples drop-down menu to view summary information for Patient Samples or Control Samples. The summary displays information for each sample or control in the batch, including the Sample ID (Samples and Controls), QC status (Samples and Controls), Interpretive Result (Samples only) and Sample Approval Status (Samples only). Table 5 lists the possible values for Interpretive Result and Sample Approval Status. Click the column headers to sort the sample information in ascending or descending order based on the information in the column. To view the electropherogram for a particular sample or control, select the sample or control from the list, and then click the 'Sample Data' tab.

The right pane on the 'Batch Summary' tab (Figure 23) presents information about the CE run for the selected Patient or Control Sample. Expand the groups on the right by clicking the '+' icons in the black circle to view Sample Information, Run Information and Consumables Information for the selected sample.

Table 5. Sample Summary Information.
Sample Interpretive Result (MSI Status)

The MSI interpretive result assigned to the sample by the OncoMate™ MSI Dx Interpretive Software.

Value	Description
MSI-H	MSI-H (microsatellite instability high) indicates that two or more mononucleotide-repeat markers were identified as unstable.
MSS	MSS (microsatellite stable) indicates that fewer than two mononucleotide-repeat markers were identified as unstable.
No Call 	No Call indicates that no interpretive result could be assigned to the sample due to a data quality issue (see Section 13, Quality Control for Sample Batches). View the QC Details tab for information about failed quality attributes for the sample. See the <i>OncoMate™ MSI Dx Analysis System Technical Manual #TM543</i> for guidance on interpreting No Call results and resolving QC failures that lead to No Call results.
Invalid 	Invalid indicates that the quality of the sample data is unacceptable due to a critical QC failure (see Section 13, Quality Control for Sample Batches). When a batch is marked QC Failed due to an issue with a Control sample, all samples within that batch are marked as Invalid. View the QC Details tab for the sample or the controls for information about failed quality attributes. See the <i>OncoMate™ MSI Dx Analysis System Technical Manual #TM543</i> for guidance on resolving QC failures that lead to Invalid results.

Status

The current status of the sample in review and approval workflow.

Value	Description
New	The sample has not started the review and approval workflow.
Under Review	The sample was reviewed by at least one user.
Ready for Approval	The sample was marked as Ready for Approval.
Approved	The sample was marked as Approved.

'Sample Data' Tab

Electropherograms for samples or controls are displayed on the 'Sample Data' tab. To view electropherograms, select the sample or control on the 'Batch Summary' tab prior to accessing the 'Sample Data' tab. By default for a sample, the electropherogram for the normal sample is shown above the electropherogram for the matched tumor sample, and all dye channels for mononucleotide and pentanucleotide markers are displayed (Figure 24). The horizontal axis indicates fragment size in base pairs, and the vertical axis indicates peak height in relative fluorescent units (RFU).

To the right of the electropherogram is the Details pane with three tabs: Peak Details, QC Details and Review.

The 'Peak Details' tab (Figure 24) displays a table with the marker name, dye channel, allele size for the alleles of interest, and peak height for the alleles of interest in the tumor and normal sample. The interpretive call for each marker is shown in the far-right column. Selecting a marker in the table will identify the allele peaks that were used to determine the marker MSI status by filling those peaks with a solid color in the electropherograms.



Figure 24. Default view for the 'Sample Data' tab.

The 'QC Details' tab (Figure 25) presents details of any failed QC requirements for a sample or control. If a sample or control has a QC Status of QC Failed or No Call, the reason for the QC Status is shown. For samples or controls that have a QC Status of QC Passed, the QC Details tab displays no information. When a batch displays a QC Status of QC Failed in the title bar, all samples within the batch will have an interpretive result of Invalid. When a sample has failed a QC requirement, it will have an interpretive result of Invalid or No Call. See Section 13, Quality Control for Sample Batches, for information on QC requirements and their impact on batch or sample interpretive status.



Figure 25. The ‘QC Details’ tab in the Details pane.

The ‘Review’ tab (Figure 26) displays review comments for individual samples. This tab is not displayed for controls. During the Review and Approval process (see Section 11, Main Workflow) you can add comments for individual samples. Pressing the **Add Comment** button opens an ‘Add Comment’ screen (Figure 27), where comments for the sample can be created. To mark a sample as reviewed, press the **Accept** button at the bottom of the ‘Review’ tab. When accepting a sample, an Accepted comment is automatically recorded in the Comment field recording the review and acceptance of the sample. A user with final review permission (see Section 15.1, System Settings) can check the “Ready for Approval” checkbox to specify that the sample has completed review and is ready for approval.

To hide or expand the ‘Peak Details’, ‘QC Details’ and ‘Review’ tabs, press the small **Arrow** button at the top right of the electropherogram.



OncoMate™ MSI Dx Interpretive Software 1.0

Assay Tools Server Help Director (Director) Promega

Home 180418_OncoMat...

Batch ID: 180418_OncoMate_MSI_Dx_FFPE2 | Patient Samples: 32 | Status: QC Passed

Batch Summary Sample Data Approvals Audit Records

1 5 26 27 28 29 24 C N T

Result: No Call | Status: Under Review 180417_1NT1_new

Sample Name: 180417_1NT1_new Type: N

Sample Name: 180417_1NT1_new Type: T

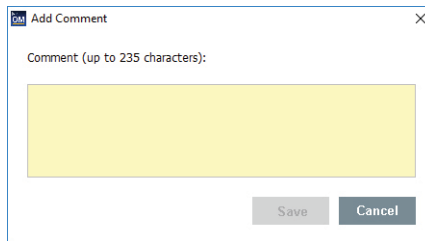
Peak Details	QC Details	Review
User Name	Comment Date	Comment
Director	10-09-2019 08:50:14	Accepted

Add Comment Accept Ready for Approval

Server is connected

For In Vitro Diagnostic Use Only. © 2018 Thermo Fisher Scientific.

Figure 26. The ‘Review’ tab in the Details pane.



Add Comment

Comment (up to 235 characters):






Save Cancel

Figure 27. The ‘Add Comment’ screen.

There are multiple ways to adjust the views of the samples to aid data evaluation. Toggle buttons at the top of the electropherograms allow users to change the view of the electropherogram data.

Table 6 details the functions of these buttons.

Table 6. Electropherogram Display Buttons.

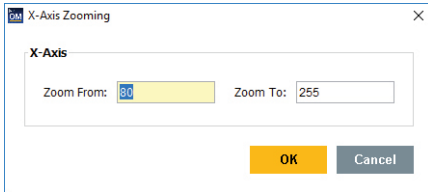
Button(s)	Description
	<p>The Mono (“1”) and Penta (“5”) buttons allow you to include or exclude the size ranges and dye channels associated with mononucleotide and pentanucleotide markers in the display, respectively. Select both buttons to display the size ranges and dye channels for all mononucleotide and pentanucleotide markers, or select an individual button to restrict the size range to the selected markers and dye channels.</p> <p>Note: The wide panel for Penta D typically results in the incidental display of some NR-24 peaks (a mononucleotide marker) when “5” is selected.</p>
	<p>The Dye Channel buttons (Blue Dye, Green Dye, Yellow Dye, Orange Dye) change the display to the specified dye channel on the electropherogram. Selecting the blue dye channel button displays the BAT-26 and Penta D markers. Selecting the green dye channel button displays the NR-21, BAT-25 and MONO-27 markers. Selecting the yellow dye channel button displays the NR-24 and Penta C markers. Selecting the Orange dye channel displays the Size Standard 500.</p> <p>Individual marker buttons in each dye channel (BAT-26, Penta D, NR-21, BAT-25, MONO-27, NR-24, Penta C) are used like the “1” and “5” buttons to change the size range displayed by the electropherogram. Based on the marker or markers selected, the size range for the electropherogram will extend from the minimum size in the smallest displayed marker to the largest size in the largest displayed marker.</p> <p>Notes:</p> <ol style="list-style-type: none"> Individual marker buttons will only restrict the displayed size range when the dye channel buttons are deselected. When only a single dye channel is being viewed, marker bars indicating the size range and marker names are displayed above the electropherogram.
	<p>The All Dyes button toggles the display of all dye channels on or off. When all dye channels are off, the electropherogram area will indicate No Color Data Selected. Pressing the All Dyes button when all dye channels are off will toggle all dye channels on for both normal and tumor samples.</p>
	<p>The Normal and Tumor buttons are used to change the display of only the normal, only the tumor or both sample electropherograms.</p> <p>Note: These buttons are disabled when viewing control electropherograms.</p>
	<p>The Overlay All button toggles between the display of separate electropherograms for normal and tumor samples and an overlaid display of both normal- and tumor-sample electropherograms. When the overlaid electropherograms are displayed, the normal-sample peaks are shown in lighter colors than the tumor-sample peaks.</p>

There are additional ways to change the size range or peak height range of the electropherograms:

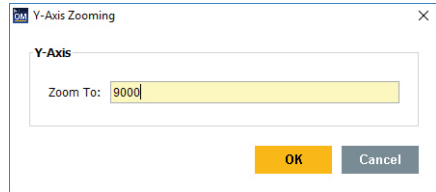
To adjust the size range of the electropherogram, perform one of the following steps:

1. Move the pointer to a point on the size range scale at the top of the electropherogram. The pointer will turn from an arrow to a magnifying glass. Click and drag left or right to create a box around the desired focus area. After releasing the click, the size range of the electropherogram(s) will be adjusted to show only the selected size range.
2. Right-click above the electropherogram to open a pop-up menu.
 - a. Select the **Full View** item to display the full size range across the X axis.
 - b. Select the **Zoom To...** item to open the ‘X-Axis Zooming’ screen (Figure 28, Panel A). Enter the size range to display. Click the **OK** button to adjust the X axis, or click the **Cancel** button to return to the electropherogram without adjusting the size range.

A.



B.



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Figure 28. Electropherogram axis zooming screens. Panel A. The ‘X-Axis Zooming’ screen. **Panel B.** The ‘Y-Axis Zooming’ screen.

To adjust the peak height range of the electropherogram, perform one of the following steps:

1. Move the pointer to the left of the Y axis of the electropherogram. The pointer will turn from an arrow to a magnifying glass. Click and drag up or down to create a box that spans from 0RFU to the desired top RFU value for the desired focus area. After releasing the click, the peak height range of the electropherogram(s) will be adjusted to show only the specified area.
2. Right-click to the left of the electropherogram to open a pop-up menu.
 - a. Select the **Full View** item to display the full peak height range on the Y axis.
 - b. Select the **Zoom To...** item to open the ‘Y-Axis Zooming’ screen (Figure 28, Panel B). Enter the maximum peak height to display. Click the **OK** button to adjust the Y axis, or click the **Cancel** button to return to the electropherogram without adjusting the signal range.

At the top right of the ‘Sample Data’ tab is the Sample Summary, which displays the interpretive result and the review and approval status for the currently displayed sample or control (Figure 29). The Sample ID for the currently displayed sample or control is also shown. Use the **Left Arrow** and **Right Arrow** buttons to navigate to the previous or next sample or control in the batch. The Sample ID for the currently displayed sample is shown in a drop-down menu box. Use the Samples drop-down menu to display any listed sample or control.

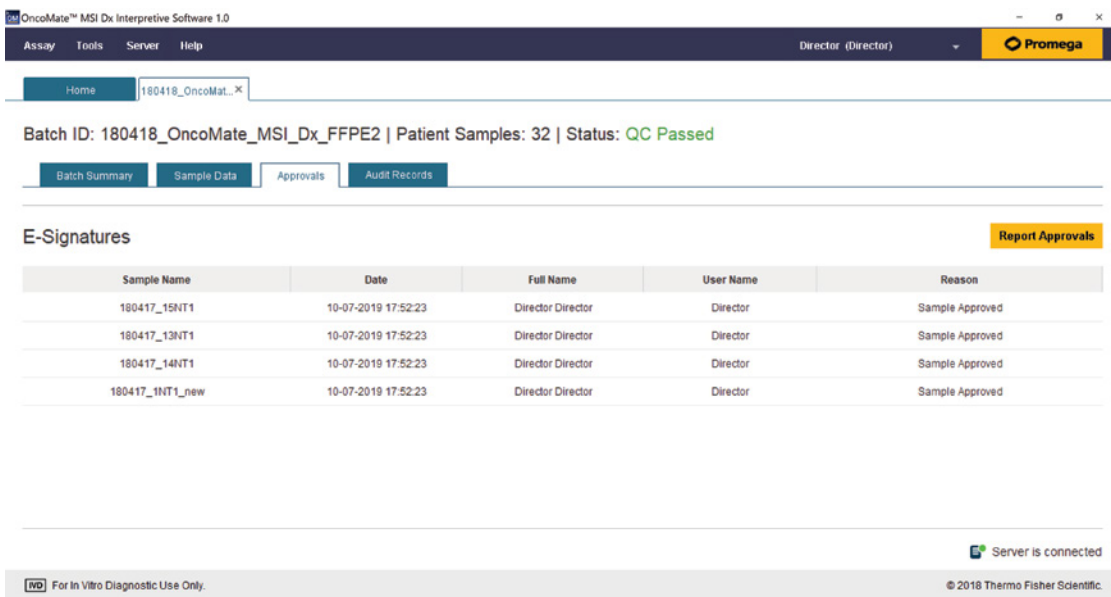
Result: MSI-H | Status: New

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Figure 29. Sample Summary.

‘Approvals’ Tab

E-signatures for all approved samples are displayed on the ‘Approvals’ tab (Figure 30). Approved samples in the batch are listed with the sample name, approval date, full name of the approver, user name of the approver and reason. Press the **Report Approvals** button at the top right of the screen to create a summary PDF report of the approved samples from the open batch.



OncoMate™ MSI Dx Interpretive Software 1.0

Assay Tools Server Help Director (Director) Promega

Home 180418_OncoMat...

Batch ID: 180418_OncoMate_MSI_Dx_FFPE2 | Patient Samples: 32 | Status: QC Passed

Batch Summary Sample Data Approvals Audit Records

E-Signatures Report Approvals

Sample Name	Date	Full Name	User Name	Reason
180417_15NT1	10-07-2019 17:52:23	Director Director	Director	Sample Approved
180417_13NT1	10-07-2019 17:52:23	Director Director	Director	Sample Approved
180417_14NT1	10-07-2019 17:52:23	Director Director	Director	Sample Approved
180417_11NT1_new	10-07-2019 17:52:23	Director Director	Director	Sample Approved

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Figure 30. ‘Approvals’ tab.

‘Audit Records’ Tab

Audit records of activities that were performed on samples in a batch are displayed on the ‘Audit Records’ tab (Figure 31). The Batch Records pane on the left side of the screen presents a summary list of the activities that were performed on the batch. Select an activity to display a detailed view of the actions performed in the Audit Records pane on the right side of the screen. Press the + icon on the left side of an action to expand the item and view more detail. Buttons at the top of the Batch Records pane are used to report, export and refresh the list of audit records. Table 7 describes the actions of each of these buttons.

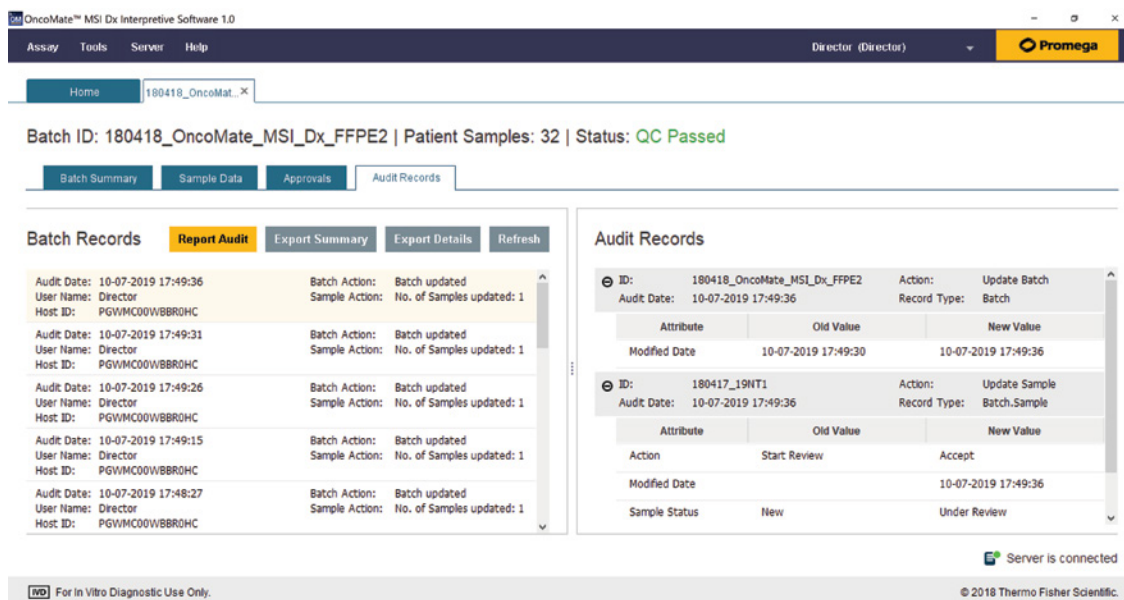


Figure 31. ‘Audit Records’ tab.

Table 7. Functions Present on the ‘Audit Records’ Tab.

Button	Description
Report Audit	Create a detailed PDF report of all activities and actions that were performed on the batch.
Export Summary	Create a comma-delimited (.csv) export file containing summary information for only the activity highlighted in the Batch Records pane.
Export Details	Create a detailed comma-delimited (.csv) export file of the information for all batch activities.
Refresh	Ensure that the lists displayed on the Batch Records and Audit Records panes represent the most current activities performed in the software.

10.2 Creating Sample and Batch Reports and Export Files

There are multiple types of reports and export files that can be generated for individual samples and entire batches of samples within the OncoMate™ MSI Dx Interpretive Software. Reports are created as .pdf files that summarize sample or batch results. Export files are created as .csv files that summarize sample or batch results. This section details the different types of reports and export files that can be generated for samples and batches.

Report Samples

For each sample in a batch, a report (.pdf format) can be created from the ‘Batch Summary’ tab after a batch is opened and the sample is reviewed and approved. See Sections 11.3–11.5 for information on reviewing and approving samples. Sample reports contain a summary of the information and electropherograms for an individual sample. Contained within the sample report are sections detailing:

- **Result Information:** Summary of the results for the sample
- **Marker Stability Information:** Individual marker calls for each mononucleotide marker and a pass/fail indication for pentanucleotide sample identity
- **Run and Analysis Information:** Summary of run and approval information
- **Data Summary:** Electropherogram plots for each marker
- **Peak Details:** Allele sizes and marker calls for each marker
- **Sample QC Details:** Summary of data quality issues identified for a sample (only shown for samples with an interpretive result of No Call or Invalid due to data quality issues)
- **Review Comments:** Comments added to the sample during the review and approval workflow

Follow the steps below to create sample reports.

1. From the ‘Home’ screen, double-click a batch to open a batch.
2. On the ‘Batch Summary’ tab (Figure 32), select one or more approved samples for which a report will be generated by checking the boxes to the left of the sample list.
3. Press **Report Samples** to create a sample report for each selected sample. Sample reports are saved at the Manual Report file location specified in Preferences (see Section 15.7, Preferences). A folder with the batch name is created, and individual sample reports are saved within the folder.

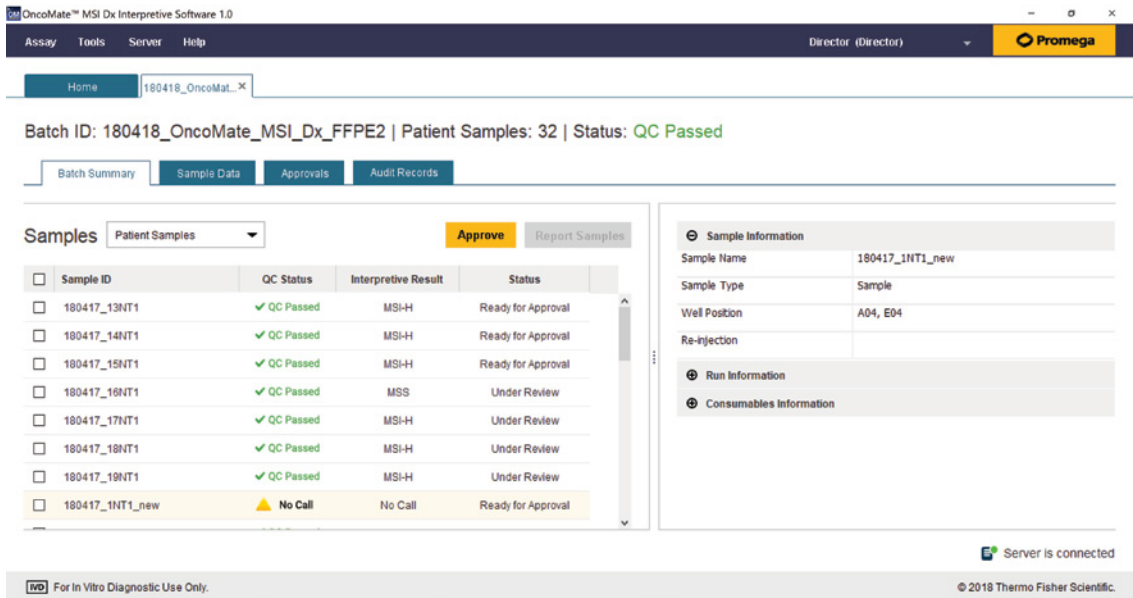


Figure 32. Sample reports are created from the ‘Batch Summary’ tab.

Report Batch

For each batch, a summary report (.pdf format) can be generated from the ‘Home’ screen once all samples within the batch are reviewed and approved. This report provides a high-level summary of controls and samples within a batch. QC Status and Well are reported for both controls and samples. Interpretive Result, Status, and Approval Date and Time are reported for all samples. Follow the steps below to create a batch summary report.

1. From the ‘Home’ screen (Figure 33), select one or more approved batches for which a report will be generated by checking the boxes to the left of the batch list.

Note: Check and then uncheck the **Select all** box at the top of the list of batches before selecting batches to report. This will ensure that all batches are unchecked before making your selection(s).

- Press **Report Batch** to create a batch summary report for each selected batch. Batch summary reports are saved at the Manual Report file location specified in Preferences (see Section 15.7, Preferences).

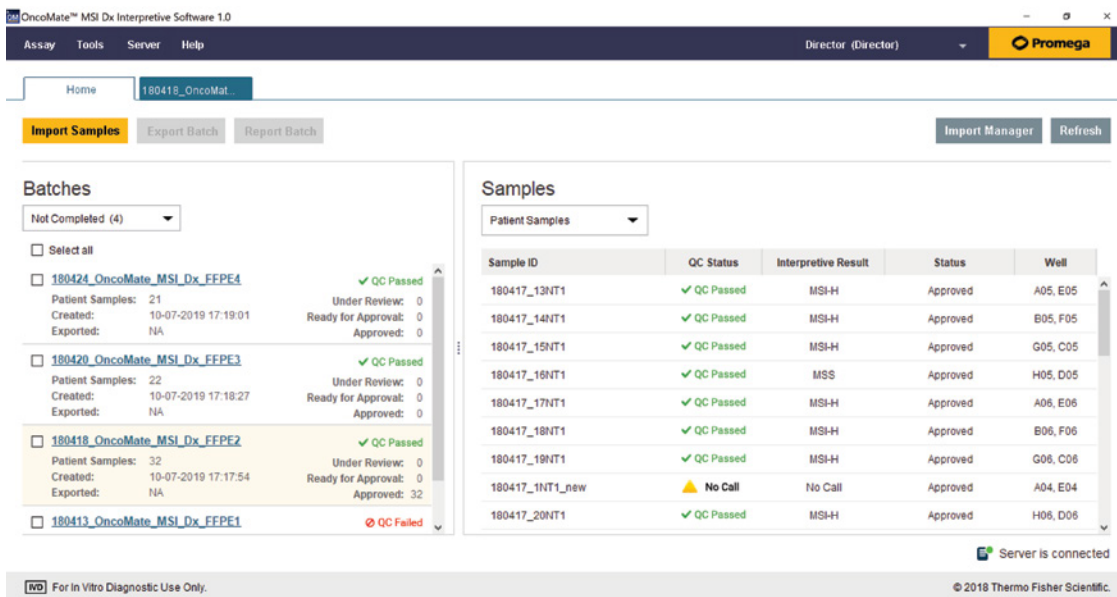


Figure 33. On the ‘Home’ screen, select batches and press **Report Batch** to create a batch summary report.

Export Batch

For each batch, a summary export (.csv format) can be generated from the ‘Home’ screen once all samples within the batch are reviewed and approved. The export file provides a high-level summary of controls and samples within a batch. Included in the export file are: Date and Time, Batch ID(s), Batch QC Status, Sample ID(s), Sample Type, Sample QC Status, Interpretive Results, Status, Approval Date and Time, Well(s), and individual marker stability results. Once an export file is created for a batch, the batch is considered completed. Follow the steps below to create a batch summary export file.

- From the ‘Home’ screen (Figure 33), select one or more approved batches for which an export file will be generated by checking the boxes to the left of the batch list.
Note: Check and then uncheck the **Select all** box at the top of the list of batches before selecting batches to report. This will ensure that all batches are unchecked before making your selection(s).
- Press **Export Batch** to create a batch summary export file for each selected batch. Batch summary export files are saved at the Manual Export file location specified in Preferences (see Section 15.7, Preferences).

11. Main Workflow

The main workflow in the OncoMate™ MSI Dx Interpretive Software Client entails importing samples that define a sample batch, reviewing the results for each sample in the batch, approving the results for each sample in the batch, and creating an export file for each batch (Figure 34).



Figure 34. OncoMate™ MSI Dx Interpretive Software workflow.

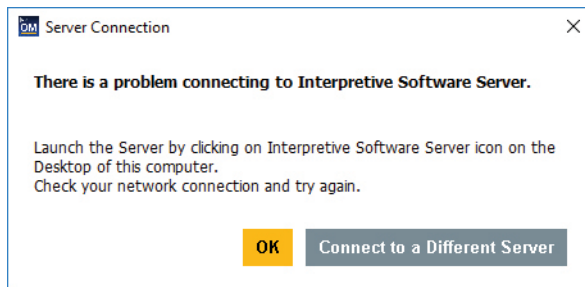
Each of the steps in the interpretive software workflow must be completed for a batch of samples to be considered complete. Depending on the permissions assigned to each user, it may be possible to combine steps (e.g., review and mark as ready for approval) of the workflow. This section describes each of the steps involved in this workflow.

11.1 Client Log-In Procedure

1. Double-click the icon for OncoMate™ MSI Dx Interpretive Software Client on the computer desktop.

WARNING: DO NOT right-click the OncoMate™ MSI Dx Client icon and choose **Run as administrator** to start the client. Software functionality may be negatively affected.

Note: If there is a problem connecting to the OncoMate™ MSI Dx Interpretive Software Server you will see a warning message (Figure 35). Refer to Section 8.3, Starting the OncoMate™ MSI Dx Interpretive Software Server, for information on starting the OncoMate™ MSI Dx Interpretive Software Server. If the Server is running on a different computer than the Client, check that the network connection is active and the Server is running.

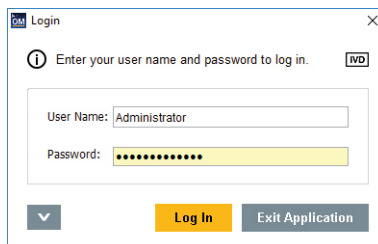


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Figure 35. Server connection problem.

- At the 'Login' screen (Figure 36), enter your User Name and Password (case-sensitive) to activate the **Log In** button. See Section 15.3, Security Settings, for default User Names and Passwords to initialize the software and set up users specific to your system. Press **Log In** to enter the OncoMate™ MSI Dx Interpretive Software Client. To exit the application without logging in, press **Exit Application**.

Note: To reactivate a suspended account or reset a user password, see Section 15.3, Security Settings, under the 'Users' tab.

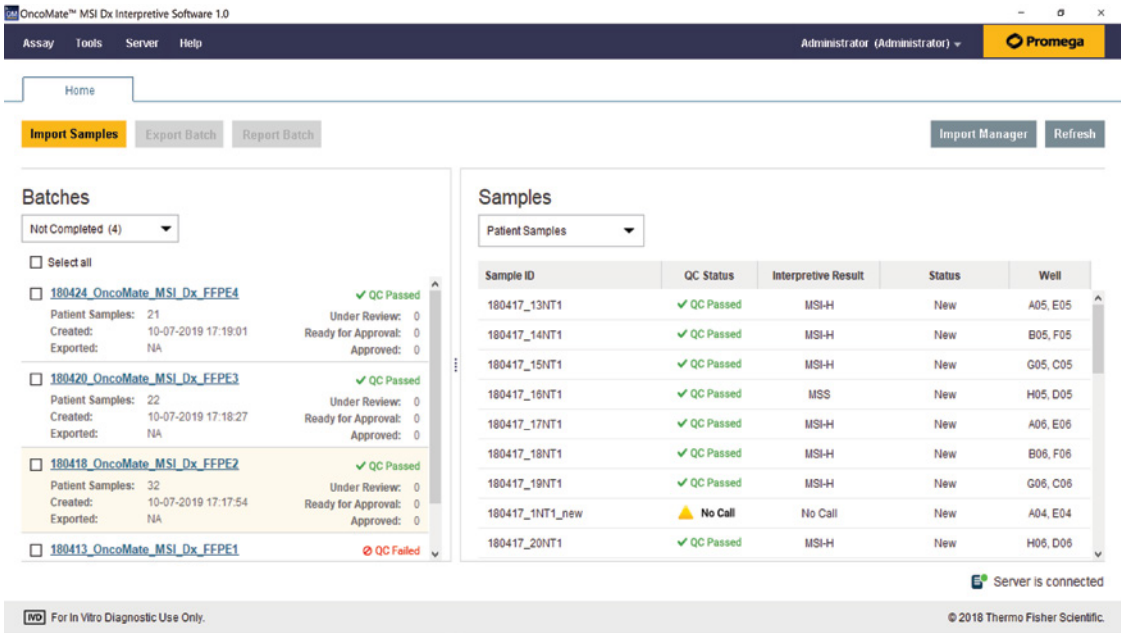


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Figure 36. 'Login' screen.

11.2 Importing Samples (.fsa Files) for Automated Analysis

- From the 'Home' screen of the OncoMate™ MSI Dx Interpretive Software Client (Figure 37), press **Import Samples** to open the 'Import Samples' file browser.



OncoMate™ MSI Dx Interpretive Software 1.0

Assay Tools Server Help Administrator (Administrator) Promega

Home

Import Samples Export Batch Report Batch Import Manager Refresh

Batches

Not Completed (4)

Select all

- 180424_OncoMate_MSI_Dx_FFPE4 ✓ QC Passed
Patient Samples: 21 Under Review: 0
Created: 10-07-2019 17:19:01 Ready for Approval: 0
Exported: NA Approved: 0
- 180420_OncoMate_MSI_Dx_FFPE3 ✓ QC Passed
Patient Samples: 22 Under Review: 0
Created: 10-07-2019 17:18:27 Ready for Approval: 0
Exported: NA Approved: 0
- 180418_OncoMate_MSI_Dx_FFPE2 ✓ QC Passed
Patient Samples: 32 Under Review: 0
Created: 10-07-2019 17:17:54 Ready for Approval: 0
Exported: NA Approved: 0
- 180413_OncoMate_MSI_Dx_FFPE1 ✗ QC Failed

Samples

Patient Samples

Sample ID	QC Status	Interpretive Result	Status	Well
180417_13NT1	✓ QC Passed	MSI-H	New	A05, E05
180417_14NT1	✓ QC Passed	MSI-H	New	B05, F05
180417_15NT1	✓ QC Passed	MSI-H	New	G05, C05
180417_16NT1	✓ QC Passed	MSS	New	H05, D05
180417_17NT1	✓ QC Passed	MSI-H	New	A06, E06
180417_18NT1	✓ QC Passed	MSI-H	New	B06, F06
180417_19NT1	✓ QC Passed	MSI-H	New	G06, C06
180417_1NT1_new	⚠ No Call	No Call	New	A04, E04
180417_20NT1	✓ QC Passed	MSI-H	New	H06, D06

Server is connected

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Figure 37. The ‘Home’ screen.

- Browse to the folder containing all of the sample files (or injection folders containing sample files) that you wish to import. All .fsa files in the selected folder and within all subfolders of the selected folder will be imported.

Notes:

- Import selection is through a folder browser; individual .fsa files will not be displayed. It is not possible to select individual .fsa files for import.
- Only a single folder at a time can be selected for import. Ensure that the base folder selected contains all .fsa files and subfolders containing .fsa files that you wish to import.
- Additional requirements are necessary to define a set of samples and amplification controls as a complete and valid sample batch. See Section 13.1, Minimum Requirements for a Valid Sample Batch, and Section 13.2, Quality Control Requirements, for information about these requirements.
- Flash drives and other portable media may be sources of computer viruses and malware. If portable storage devices are necessary in your workflow for file transfer, we recommend restricting their use with other computers and scanning these devices with up-to-date antivirus and anti-malware software prior to each use.

3. Press **Import** to initiate the import process, or press **Cancel** to cancel the import. If presented with the 'Confirmation' screen, press **Continue** to import files from the selected folder, or press **Cancel** to cancel import.

Notes:

1. While samples are importing, an Active notification and rotating status icon are displayed in the Notification Bar at the bottom right of the screen.
2. The OncoMate™ MSI Dx Interpretive Software Client will import the samples that were selected and assign them to a sample batch. Successful batch creation requires at a minimum a positive control, a negative control and one sample consisting of a matched pair of normal and tumor .fsa data files. The sample must share the same Sample ID, and UDF1 in the .fsa files must identify the samples as N for normal or T for tumor (see Section 5 of this reference manual for information on sample labeling using UDF1). Import will fail for sample files that do not conform to these requirements. See *OncoMate™ MSI Dx Analysis System Technical Manual #TM543* for instructions on sample labeling using UDF1.



3. You can access a record of all sample file import events using the Import Manager (see Section 15.6, Import Manager).
4. As sample files are imported into the OncoMate™ MSI Dx Interpretive Software Client, they are assigned to a sample batch based on the capillary electrophoresis plate name assigned by the user and stored in the .fsa file. After successful import of sample files, batches of samples are listed in the Batches pane of the 'Home' screen.
5. Sample analysis occurs automatically upon import.
4. When the import process is finished, confirm that all samples intended for analysis were imported and are displayed in the Samples pane on the 'Home' screen.

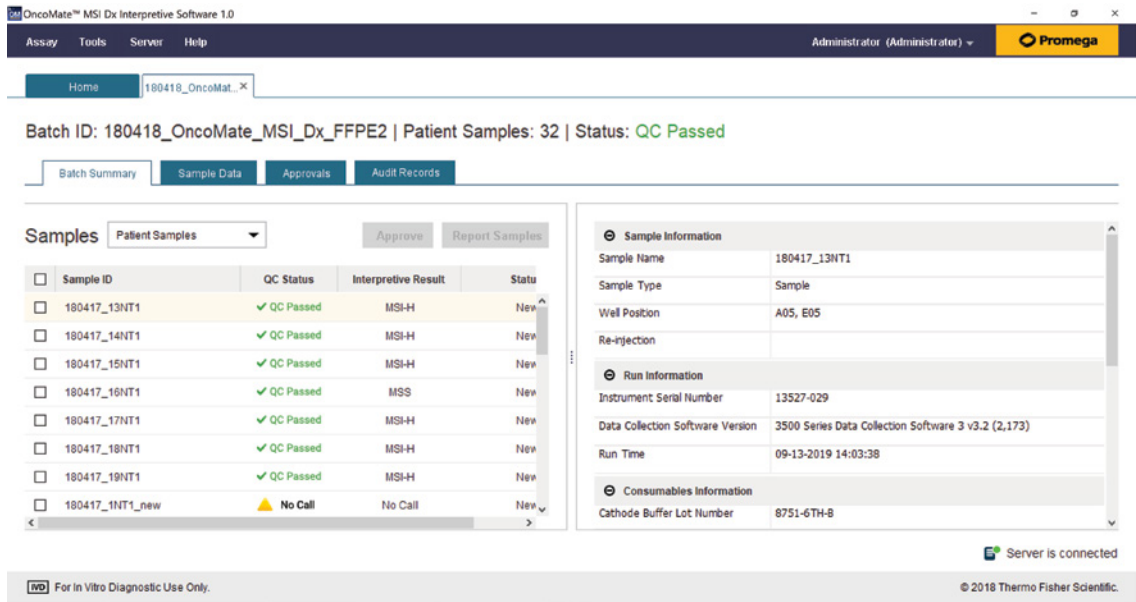
11.3 Reviewing Sample Results

After sample import, it is the responsibility of the initial reviewer to mark samples as Reviewed. A user who has a role with Review permission will complete the following steps.

1. Once a batch of samples is created in the OncoMate™ MSI Dx Interpretive Software Client, double-click the batch name in the Batches pane to open a batch screen (Figure 38) and view the associated data including sample electropherograms, approvals and audit records.

Notes:

1. The title bar at the top of the batch screen displays the name of the batch, the number of patient samples in the batch and the QC status of the batch.
2. Batches that have a status of QC Failed are considered invalid and are not subject to the standard review and approval process. For a QC Failed batch it is only necessary to approve the batch; no review is possible. Proceed to Section 11.5, Approving Results, for steps to approve a QC Failed batch.



OncoMate™ MSI Dx Interpretive Software 1.0

Assay Tools Server Help Administrator (Administrator) Promega

Home 180418_OncoMat... X

Batch ID: 180418_OncoMate_MSI_Dx_FFPE2 | Patient Samples: 32 | Status: QC Passed

Batch Summary Sample Data Approvals Audit Records

Samples Patient Samples Approve Report Samples

Sample ID	QC Status	Interpretive Result	Status
<input type="checkbox"/> 180417_13NT1	✓ QC Passed	MSI-H	New
<input type="checkbox"/> 180417_14NT1	✓ QC Passed	MSI-H	New
<input type="checkbox"/> 180417_15NT1	✓ QC Passed	MSI-H	New
<input type="checkbox"/> 180417_16NT1	✓ QC Passed	MSS	New
<input type="checkbox"/> 180417_17NT1	✓ QC Passed	MSI-H	New
<input type="checkbox"/> 180417_18NT1	✓ QC Passed	MSI-H	New
<input type="checkbox"/> 180417_19NT1	✓ QC Passed	MSI-H	New
<input type="checkbox"/> 180417_1NT1_new	▲ No Call	No Call	New

Sample Information

Sample Name: 180417_13NT1

Sample Type: Sample

Well Position: A05, E05

Re-injection:

Run Information

Instrument Serial Number: 13527-029

Data Collection Software Version: 3500 Series Data Collection Software 3 v3.2 (2,173)

Run Time: 09-13-2019 14:03:38

Consumables Information

Cathode Buffer Lot Number: 8751-6TH-8

Server is connected

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Figure 38. The batch screen. The batch screen provides access to information about the samples included in a sample batch including electropherograms, approvals and audit records.

- Select the 'Sample Data' tab (Figure 39) to display results for the sample selected in the Samples pane. The MSI interpretive result for the sample is displayed at the upper right of the 'Sample Data' tab.

Note: See Section 10.1, Viewing Data and Results for an Individual Batch, for information about how to adjust the electropherogram view and present the information for each sample.



Figure 39. View electropherograms in the ‘Sample Data’ tab.

- Review the sample data. If the MSI interpretive result is Invalid or No Call, select the ‘QC Details’ tab (Figure 40) to view any quality control flags that apply to the electropherograms for the sample.



Figure 40. The ‘QC Details’ tab.

4. Select the ‘Review’ tab (Figure 41) to the right of the electropherograms. To add comments to the review for the displayed sample, press **Add Comment**. Refer to Section 6 of the *OncoMate™ MSI Dx Analysis System Technical Manual #TM543* for information on notable MSI results that may warrant additional review (e.g., MSS with a single unstable locus).
5. Record the initial review of the sample by pressing **Accept**. Once a sample is accepted, the sample Status is updated to Under Review on the ‘Batch Summary’ tab.



The screenshot displays the OncoMate MSI Dx Interpretive Software 1.0 interface. At the top, the title bar reads "OncoMate™ MSI Dx Interpretive Software 1.0". Below it is a navigation bar with "Assay", "Tools", "Server", and "Help" menus, and a "Director (Director)" dropdown. A "Home" button and a text input field containing "180418_OncoMat..." are visible. The main header shows "Batch ID: 180418_OncoMate_MSI_Dx_FFPE2 | Patient Samples: 32 | Status: QC Passed". Below this are tabs for "Batch Summary", "Sample Data", "Approvals", and "Audit Records". A toolbar contains various icons for navigation and analysis. The "Sample Data" tab is active, showing two chromatograms for "Sample Name: 180417_1NT1_new". The top chromatogram is for "Type: N" and the bottom for "Type: T". To the right, the "Review" tab is selected, showing a table with columns "User Name", "Comment Date", and "Comment". The table contains one entry: "Director", "10-09-2019 08:50:14", and "Accepted". Below the table are buttons for "Add Comment", "Accept", and a checkbox for "Ready for Approval". At the bottom right, it says "Server is connected" and "© 2018 Thermo Fisher Scientific".

Figure 41. The ‘Review’ tab in the Details pane.

- Use the drop-down menu, **Left Arrow** or **Right Arrow** buttons at the upper right of the ‘Sample Data’ tab to access the remaining samples in the batch. For each sample, repeat Section 11.3, Steps 3–6, to continue the sample review process.

11.4 Marking Results as Ready for Approval

After initial review of one or more samples is completed, it is the responsibility of the final reviewer to mark samples as Ready For Approval. A user who has permission as a Final Reviewer will complete the following steps:

1. Starting from the 'Home' screen of the software, double-click the desired sample batch to review. This will open a batch screen in the software (Figure 38). The Samples pane of the 'Batch Summary' tab summarizes the QC Status, MSI interpretive result, and the review and approval Status for each sample in the batch.

Notes:

1. When logging out of the OncoMate™ MSI Dx Interpretive Software, all open batches will be closed, and the software will return to the 'Home' screen.
2. If the batch status is QC Failed, all samples in the batch will have an MSI interpretive result of Invalid. In this case, the 'QC Details' tab will not display any quality control flags for the individual sample electropherograms. Quality control flags for controls are accessed by returning to the 'Batch Summary' tab, selecting Control Samples from the Samples drop-down menu, and then returning to the 'Sample Data' tab to view the control sample electropherograms and 'QC Details' tab.
2. Select the 'Sample Data' tab (Figure 39) to display results for the sample highlighted in the Samples pane. The MSI interpretive result for the sample is displayed at the upper right of the 'Sample Data' tab.
Note: See Section 10.1, Viewing Data and Results for an Individual Batch, for information about how to adjust the electropherogram view and present the information for each sample.
3. Review the sample data. If the MSI interpretive result is Invalid or No Call, select the 'QC Details' tab (Figure 40) to view any quality control flags that apply to the electropherograms for the sample.
4. Select the 'Review' tab (Figure 41) to the right of the electropherograms.
5. **Complete this step only if different users perform the reviews described in Sections 11.3 and 11.4:** Press **Accept** to record the final review of the selected sample. Press **Add Comment** to record any applicable notes.
6. Check the **Ready for Approval** checkbox to complete the review process for the sample. The sample Status is updated to Ready For Approval on the 'Batch Summary' tab.
7. Use the drop-down menu, **Left Arrow** or **Right Arrow** buttons at the upper right of the 'Sample Data' tab to access the remaining samples in the batch. For each sample, repeat Section 11.4, Steps 3–7, to complete the sample review process.

11.5 Approving Results

After review of samples, it is the responsibility of a user with permission to approve samples to approve the MSI interpretive call for each reviewed sample. This user will perform the following steps:

1. Starting from the 'Home' screen, double-click the name of sample batch requiring approval. This will open a batch screen in the software (Figure 38). Within the batch screen, the 'Batch Summary' tab indicates which samples have completed the review process and have a status of Ready For Approval.
Note: When logging out of the OncoMate™ MSI Dx Interpretive Software, all open batches will be closed, and the software will return to the 'Home' screen.
2. If the batch has a Status of QC Passed, press **Approve** at the top right of the Samples pane to open the 'Approve' screen (Figure 42, Panel A).
3. On the 'Approve' screen, enter the user name and password and any notes for this approval, and then press **OK**. All samples marked as Ready for Approval will be approved.
4. If the batch has a Status of QC Failed, all samples are marked as Invalid and an individual sample review is not required before approval. After opening the batch, press **Approve** to open the 'Approve' screen for failed batches (Figure 42, Panel B). Press **Add Comment** to add any comments to the batch approval. Press **Accept** to mark all samples in the batch with an action of Accepted. Next, enter a user name and password, and then press **Approve** to approve the entire batch of samples.

Notes:

1. To view the individual sample electropherograms, select the sample on the 'Batch Summary' tab and then select the 'Sample Data' tab (Figure 39). The MSI interpretive result for the sample is displayed at the upper right of the 'Sample Data' tab.
2. See Section 10.1, Viewing Data and Results for an Individual Batch, for information about how to adjust the electropherogram view and present the information for each sample.
3. If the MSI interpretive result is Invalid or No Call, select the 'QC Details' tab (Figure 40) to view any quality control flags that apply to the electropherograms for the sample.
4. If the batch status is QC Failed, all samples in the batch will have an MSI interpretive result of Invalid. In this case, the 'QC Details' tab will not display any quality control flags for the individual sample electropherograms. Quality control flags for controls are accessed by returning to the 'Batch Summary' tab, selecting Control Samples from the Samples drop-down menu, and then returning to the 'Sample Data' tab to view the control sample electropherograms and 'QC Details' tab.
5. Batches that have a status of QC Failed are considered invalid and are not subject to the standard review and approval process. For a QC Failed batch it is only necessary to approve the batch; no review is possible.

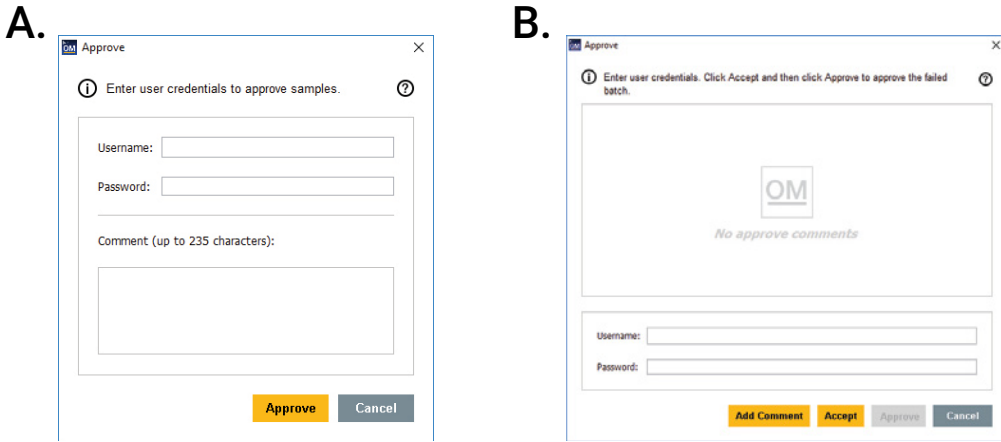


Figure 42. ‘Approve’ screen. Panel A. ‘Approve’ screen shown for samples marked as Ready for Approval. **Panel B.** ‘Approve’ screen shown for batches marked as QC Failed.

11.6 Exporting Results



Instructions for creating Sample Reports and Batch Reports are provided in *OncoMate™ MSI Dx Analysis System Technical Manual #TM543*.

1. To create a batch export file, from the ‘Home’ screen, check the box(es) to the left of batch(es) for which an export file will be generated and press **Export Batch**.

Notes:

1. Check and then uncheck the **Select all** box at the top of the list of batches before selecting batches to export. This will ensure that all batches are unchecked before making your selection(s).
2. The batch export file is a comma-delimited text file (.csv) that is saved with the following information:
 - Date and time of export file creation
 - Batch ID(s)
 - Batch QC Status
 - Sample ID(s)
 - Sample Type
 - Sample QC status
 - MSI interpretive result for each control and patient sample in the batch
 - Status
 - Approval Date and Time
 - Well(s)
 - Individual marker stability results

After the batch export file is generated, the sample batch is considered completed.

12. Results

The OncoMate™ MSI Dx Interpretive Software analyzes microsatellite allele data from normal and tumor samples to determine the stability of five mononucleotide-repeat markers and an overall sample MSI status. Pentanucleotide-repeat markers are analyzed to assess identity between the normal and tumor samples. The following sections describe this process in greater detail and review the marker- and sample-level results that are possible for patient samples.

 For information related to the OncoMate™ MSI Dx Interpretive Software results, including guidance on user interpretation of No Call samples, consult the *OncoMate™ MSI Dx Analysis System Technical Manual #TM543*.

12.1 How the OncoMate™ MSI Dx Interpretive Software Determines MSI Results

The OncoMate™ MSI Dx Interpretive Software analyzes microsatellite fragment data (.fsa files) that are generated by the Applied Biosystems® 3500 Dx Genetic Analyzer during the separation and analysis of OncoMate™ MSI Dx Analysis System amplification products. DNA fragments from five mononucleotide-repeat markers (BAT-25, BAT-26, NR-21, NR-24 and MONO-27) and two pentanucleotide-repeat markers (Penta C and Penta D) are sized, and alleles are assigned at each marker for patient samples. These allele calls are analyzed to determine the stability of each mononucleotide-repeat marker and the MSI status of the sample.

Analysis of mononucleotide-repeat markers is used to determine tumor MSI status. Mononucleotide-repeat markers produce distributions of stutter peaks during amplification, and multiple stutter peak distributions can exist for each marker. Within any individual stutter peak distribution, the peak with the greatest peak height is identified as the allele for that stutter peak distribution. For each marker, the OncoMate™ MSI Dx Interpretive Software determines size difference between the shortest alleles identified in the normal and tumor samples of the pair to determine marker stability. A marker is interpreted as Unstable when this size difference is at least 3bp (implemented in the software as ≥ 2.75 bp to account for the sizing precision of capillary electrophoresis). If the size difference is less than 2.75bp, then the marker is interpreted as Stable. A tumor is interpreted as microsatellite-instability high (MSI-H) when two or more markers are unstable. A tumor sample is interpreted as microsatellite stable (MSS) when fewer than two mononucleotide markers are interpreted as Unstable.

Two pentanucleotide-repeat markers are analyzed by the software as an identity check between the normal and tumor DNA samples. Pentanucleotide markers exhibit one or more allele peaks. When all of the pentanucleotide alleles detected in the normal sample are also present in the tumor sample, the sample identity check passes. A sample may be interpreted as 'No Call' or 'Invalid' in response to specific QC failures (see Section 13.2, Quality Control Requirements, for additional information).

12.2 Marker Stability Calls and Sample Interpretive Results

Tables 8 and 9 summarize the marker stability calls and sample interpretive results, respectively, returned by the interpretive software. Refer to Section 13.2, Quality Control Requirements, for information on QC checks that may affect marker stability calls and sample interpretive results.

Table 8. Marker-Level Stability Calls Provided by the OncoMate™ MSI Dx Interpretive Software.





Value	Description
Stable	Microsatellite instability was not detected for the marker. The difference in allele size of the mononucleotide-repeat region analyzed was less than 2.75bp for the normal and tumor sample.
Unstable	Microsatellite instability was detected for the marker. The difference in allele size of the mononucleotide-repeat region analyzed was at least 2.75bp for the normal and tumor sample.
No Call 	No Call indicates that the marker stability could not be determined due to a data quality issue (see Section 13, Quality Control for Sample Batches). View the 'QC Details' tab for information about failed quality attributes for the sample. See the <i>OncoMate™ MSI Dx Analysis System Technical Manual #TM543</i> for guidance on interpreting No Call results and resolving QC failures that lead to No Call results.
Invalid 	Invalid indicates that the quality of the sample data is unacceptable due to a critical QC failure (see Section 13, Quality Control for Sample Batches). View the 'QC Details' tab for the sample or the controls for information about failed quality attributes. See the <i>OncoMate™ MSI Dx Analysis System Technical Manual #TM543</i> for guidance on resolving QC failures that lead to Invalid results.
NA	For pentanucleotide markers, stability is not assessed, and not applicable (NA) is reported.

Table 9. Sample-Level Interpretive Results Provided by the OncoMate™ MSI Dx Interpretive Software.

Value	Description
MSI-H	MSI-H (MSI high) indicates that two or more mononucleotide-repeat markers were identified as unstable.
MSS	MSS (MSI stable) indicates that fewer than two mononucleotide-repeat markers were identified as unstable.
No Call 	No Call indicates that no interpretive result could be assigned to the sample due to a data quality issue (See Section 13, Quality Control for Sample Batches). View the ‘QC Details’ tab for information about failed quality attributes for the sample. See the <i>OncoMate™ MSI Dx Analysis System Technical Manual #TM543</i> for guidance on interpreting No Call results and resolving QC failures that lead to No Call results.
Invalid 	Invalid indicates that the quality of the sample data is unacceptable due to a critical QC failure (see Section 13, Quality Control for Sample Batches). When a batch is marked QC Failed due to an issue with a Control sample, all samples within that batch are marked as Invalid. View the ‘QC Details’ tab for the sample or for the controls for information about failed quality attributes. See the <i>OncoMate™ MSI Dx Analysis System Technical Manual #TM543</i> for guidance on resolving QC failures that lead to invalid results.

13. Quality Control for Sample Batches

The OncoMate™ MSI Dx Interpretive Software analyzes controls and interprets normal and tumor samples in the context of the capillary electrophoresis separation plate on which they were processed. Samples and controls are assigned to a sample batch based on the capillary electrophoresis plate name contained in the .fsa files. Each sample within a batch consists of a normal and tumor sample that both have the same Sample ID and for which UDF1 in the .fsa files identifies a sample as N or n for normal and T or t for tumor. Additional requirements are necessary to define a set of samples and amplification controls as a complete and valid sample batch. See Sections 13.1, Minimum Requirements for a Valid Sample Batch, and 13.2, Quality Control Requirements, for information about these requirements.



See *OncoMate™ MSI Dx Analysis System Technical Manual #TM543* for instructions on sample labeling during capillary electrophoresis setup.

13.1 Minimum Requirements for a Valid Sample Batch

Sample batches must contain a minimum set of information to be considered valid for interpretation. The minimum requirements for a sample batch are detailed below:

- The batch must have both a Positive Control and a Negative Control, and these controls must be identified accordingly in the corresponding .fsa files. These designations are added to the amplification controls during capillary electrophoresis run setup in the Applied Biosystems® 3500 Dx Genetic Analyzer data collection software, Sample Type field. It is acceptable to have more than one of each control type; however, each control in a batch must conform to the Quality Control requirements listed in Section 13.2, Quality Control Requirements. If even one control does not meet Quality Control requirements, the batch QC will fail and all samples will be considered invalid.
- The samples in the batch must be identified in the .fsa file as Samples. Additionally, each sample must have the designation of N or T in the UDF1 field to indicate whether the sample is a normal or a tumor sample. The N or T designation is case-insensitive. Samples without the N or T designation in UDF1 will not be imported. These designations are added to the patient samples during capillary electrophoresis run setup in the Applied Biosystems® 3500 Dx Genetic Analyzer data collection software, Sample Type and UDF1 fields (see the *OncoMate™ MSI Dx Analysis System Technical Manual #TM543* for instructions on sample identification and labeling using the UDF1 field).
- Samples must contain both normal and tumor samples with the same Sample ID. If there are no matched normal and tumor samples with the same Sample ID, .fsa files will not be imported. If more than one normal or one tumor sample exists for a Sample ID, only the first file encountered will be imported, and any additional files will not be imported.
- All controls and samples must be analyzed during the same capillary electrophoresis separation with a single plate Name and Run Date.



13.2 Quality Control Requirements

The OncoMate™ MSI Dx Interpretive Software evaluates several quality attributes associated with control and patient samples to determine whether the batch and samples are of sufficient quality for MSI interpretation. These quality attributes are summarized in the next paragraph and detailed in Table 10.

For amplification controls, any QC failure will result in a batch QC failure, and all patient samples within the batch will have an interpretive result of Invalid. For patient samples, a QC failure can have two possible outcomes. QC failures associated with critical quality attributes (Sizing Quality, Off Scale, Spectral Pull-Up, Broad Peak) are considered severe; in these cases, an interpretive result of Invalid will be returned for that sample. The other class of QC failures involves data warnings or deficiencies that affect automated sample interpretation but are not necessarily considered critical (Marker Dropout, Maximum Allele, Authentication, Signal Sensitivity); in these cases, an interpretive result of No Call will be returned for that sample. A No Call result indicates that the OncoMate™ MSI Dx Interpretive Software cannot interpret the MSI status of the sample and further evaluation is required. When a sample or control fails one or more QC requirements, the failure reason is displayed in the ‘QC Details’ tab, which is accessed by selecting the ‘Sample Data’ tab after opening a batch (see Section 10.1, Viewing Data and Results for an Individual Batch).



See the *OncoMate™ MSI Dx Analysis System Technical Manual #TM543* for guidance on interpreting No Call results and resolving QC failures that lead to No Call results.

Note: Data analysis using the OncoMate™ MSI Dx Interpretive Software is more sophisticated than the basic analysis performed within the Applied Biosystems® 3500 Dx Genetic Analyzer data collection software. Quality warnings displayed in the DCS may be triggered by broad peaks, signal spikes, etc., that are ignored by the OncoMate™ software or that occur outside of the analysis range relevant for MSI status determination. Therefore, analyze all samples using the OncoMate™ MSI Dx Interpretive Software as the final assessment of data quality.

Table 10. QC Details Messages Displayed by the OncoMate™ MSI Dx Interpretive Software in Response to Quality Issues Affecting Control or Patient Samples. When a quality issue affects the positive or negative control, a batch status of QC Failed is displayed and Invalid results are returned for all patient samples in the batch. When no quality issues are observed for control samples, Invalid or No Call MSI results are returned for patient samples exhibiting a quality issue.

QC Details Message	Description of QC Test	Samples Evaluated ¹	MSI Result from QC Failure	
			Control Sample Fails QC ²	Patient Sample Fails QC ³
Poor sizing quality	The observed pattern of Size Standard 500 peaks must match the expected pattern.	+, -, N, T	All samples Invalid	Invalid
Spectral issues detected	Peaks that are aligned by length in separate dye channels are evaluated for spectral pull-up (i.e., signal bleedthrough between dye channels). When a peak in one dye channel has a signal intensity greater than 10% of an aligned peak in a separate dye channel, the lower-intensity peak is flagged as spectral pull-up.	+, N, T	All samples Invalid	Invalid
Marker peak height too high to evaluate	The intensity (RFU) of peaks in a given sample must not exceed the maximum detectable range of the Applied Biosystems® 3500 Dx Genetic Analyzer.	+, N, T	All samples Invalid	Invalid
Broad peak shape detected	The width of peaks must not exceed the value assigned for MSI analysis.	+, N, T	All samples Invalid	Invalid
No allele detected	At least one allele above 175RFU must be present within each marker.	+, N, T	All samples Invalid	No Call
Unexpected allele count detected	For each pentanucleotide marker, there can be no more than two alleles present in the normal sample.	+, N	All samples Invalid	No Call
Unexpected peaks detected	For the positive amplification control, the alleles present in the pentanucleotide markers must match the expected alleles for the 2800M Control DNA within 1.5 base pairs. For negative amplification controls, there must be no peaks detected above the calling threshold (175RFU).	+, -	All samples Invalid	No Call

		MSI Result from QC Failure (continued)		
QC Details Message	Description of QC Test	Samples Evaluated¹	Control Sample Fails QC²	Patient Sample Fails QC³
Normal allele not detected in tumor sample	For each pentanucleotide marker, the alleles identified in the normal sample must be present in the tumor sample (within 1.5 base pairs).	T	Controls not evaluated	No Call
Low allele peak height detected	For mononucleotide markers that have been interpreted as Stable, allele peak height(s) in the tumor sample must be greater than 700RFU to ensure assay sensitivity.	T	Controls not evaluated	No Call

¹N, normal sample; T, tumor sample; +, positive control; –, negative control

²The MSI interpretive result is Invalid for all patient samples in the batch when a control sample exhibits a QC issue and the batch status is QC Failed.

³The MSI interpretive results are Invalid or No Call for an individual patient sample exhibiting a QC issue when the batch status is QC Passed.

13.3 Summary of Known Amplification Artifacts and Capillary Electrophoresis Anomalies

A known amplification artifact at the NR-21 marker can result in a single broad peak in the size range of 83 to 87.7 base pairs. The OncoMate™ MSI Dx Interpretive Software will not call this peak as an allele or consider this peak when determining the stability of the NR-21 marker. Although the peak may appear on the electropherogram, it will not affect MSI interpretation using the OncoMate™ MSI Dx Interpretive Software.

Note: During execution of the Applied Biosystems® 3500 Dx Genetic Analyzer **Change Polymer Type and Wash Pump and Channels** wizard, complete the optional bubble purge steps and the Fill Array step when installing or re-installing polymer. When the bubble purge and fill array steps are not completed, the artifact in NR-21 may be observed at sizes above 87.7bp, and the OncoMate™ MSI Dx Interpretive Software will no longer ignore this peak.

The second known amplification artifact occurs when too much DNA is used as input to the OncoMate™ MSI Dx Analysis System. The baseline signal in the BAT-26 marker may become elevated and jagged. Except for extreme DNA input amounts (≥ 4 ng 2800M Control DNA), the OncoMate™ MSI Dx Interpretive Software will not call these peaks as alleles or consider them when determining the stability of the BAT-26 marker.

The OncoMate™ MSI Dx Interpretive Software minimizes the impact of known, but random, anomalies that may be observed during capillary electrophoresis. Three such rare anomalies predominate: failed injections, broad peaks and signal spikes.

1. When an injection fails, little or no sample DNA is injected into the capillary array. In these cases, a Sizing Quality QC failure will be observed due to the lack (or poor quality) of Size Standard 500 peaks, and the sample interpretive result will be Invalid.
2. A peak may be detected during capillary electrophoresis that exhibits a broad (i.e., not sharp) morphology. A broad peak may originate from polymer crystals or other aberrant material migrating through the capillary array. When the interpretive software detects a broad peak, the sample interpretive result will be Invalid.
3. A signal “spike” may be observed during capillary electrophoresis in the form of a near-zero width peak that spans most or all color channels. Such spikes are detected and ignored by the interpretive software and will not interfere with data analysis using the OncoMate™ MSI Dx Interpretive Software.

14. Assay Menu

The **Assay** menu resides on the left side of the menu bar and contains functions for defining the headers and footers for batch reports as well as creating a Technical Support export file for troubleshooting purposes. This section contains information regarding the functions present in this menu.

14.1 Report Settings

The report header can be customized to include images and text based on the needs of the laboratory. To customize the header for reports, follow the instructions below.

1. From the **Assay** menu, choose **Report Settings** to open the ‘Report Settings’ screen (Figure 43).

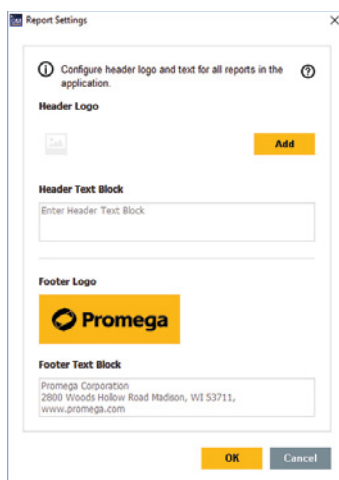


Figure 43. ‘Report Settings’ screen.

2. Use the **Add** button to add an image to the report header. In the file browser, navigate to the location of the desired image file. Images must be in the .jpg format and must be exactly 185 pixels wide × 60 pixels high. When an image is assigned to the header, the **Add** button changes to a **Remove** button. Use the **Remove** button to remove an image from the report header.
3. Use the “Header Text Block” text field to add up to three lines of text to the report header.
4. Press **OK** to accept and save the report settings and return to the previous screen, or press **Cancel** to discard changes and return to the previous screen.



14.2 Technical Support Export

During sample batch analyses, you may need to troubleshoot issues with Promega Technical Services (genetic@promega.com) and create a Technical Support Export file. The Technical Support Export file contains information regarding peak heights, called alleles, quality control information and MSI interpretive results for a sample batch. The Technical Support Export file is an encrypted file that can be decrypted by Promega Technical Services. Follow the instructions below to create a Technical Support Export.

1. From the 'Home' screen, double-click the desired sample batch to open the corresponding 'Batch' screen.
2. From the **Assay** menu, choose **Technical Support**, and then choose the subheading **Export Sample and Peak Details** to open an 'Export' screen.
3. On the 'Export' screen, enter or browse to the desired file location, and enter a file name for the Technical Support Export file as well as the file type (.csv, .txt, .xls, .xlsx).
4. Press **OK** to create the Technical Support Export file, or press **Cancel** to close the 'Export' screen without exporting a file.

15. Tools Menu

Multiple functions for managing SMTP server settings, e-mail notifications, security settings, archiving batch data, restoring batch data and managing sample data import are present in the **Tools** menu on the left side of the menu bar. Descriptions of the functions and settings that can be accessed from the **Tools** menu are present in this section.

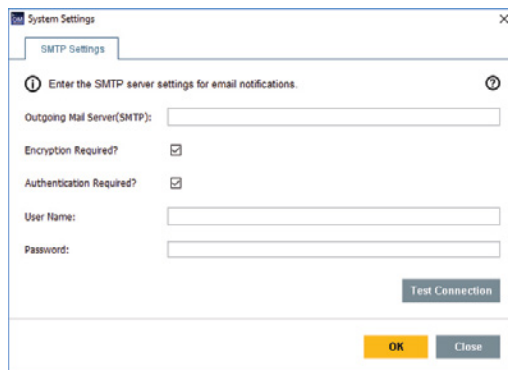
15.1 System Settings

The 'System Settings' screen is used to enter SMTP settings and configure e-mail server information. To use e-mail notifications, you must provide the details of the e-mail server to be used. Defining e-mail notification settings for system security activities is covered in Section 15.3, Security Settings, and the notification settings to create Technical Support Exports is covered in Section 15.2, Notification Settings.

Request the SMTP settings necessary to define the e-mail server from your IT professional. Follow the instructions below to enter e-mail server setting information.

Note: Only user accounts with permission to modify SMTP settings can access the 'System Settings' screen.

1. From the **Tools** menu, select **System Settings** to open the 'System Settings' screen (Figure 44). This screen will automatically open to the 'SMTP Settings' tab.



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Figure 44. The ‘SMTP Settings’ tab on the ‘System Settings’ screen.

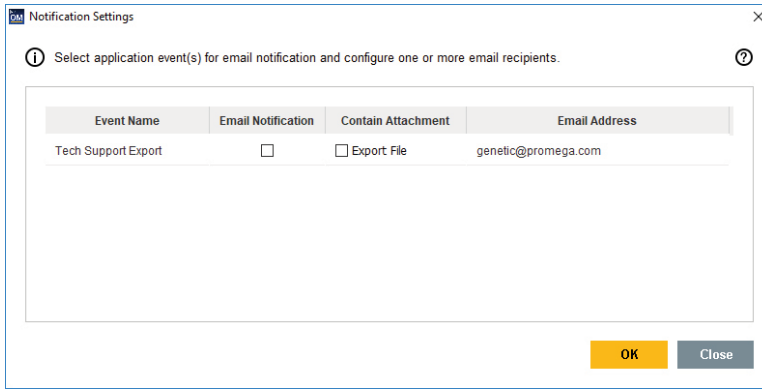
2. Enter the SMTP server information requested on the ‘System Settings’ screen. The “User Name:” and “Password:” fields on this screen correspond to the e-mail account from which notifications will be sent.
3. Press **Test Connection** to check whether the OncoMate™ MSI Dx Interpretive Software Client can communicate with the SMTP server using the supplied credentials. If connection is unsuccessful, contact your IT professional for troubleshooting advice.
4. Once a successful connection to the SMTP server is achieved, press **OK** to accept and save these settings or press **Close** to exit the ‘System Settings’ screen without saving.

15.2 Notification Settings

E-mail notifications can be sent to a distribution list of e-mail accounts every time a Technical Support Export is created from the OncoMate™ MSI Dx Interpretive Software Client. Follow the instructions below to enable e-mail notifications.

Note: Only user accounts with permission to Configure Email Notifications can access the ‘Notification Settings’ screen.

1. From the **Tools** menu, select **Notification Settings** to open the ‘Notification Settings’ screen (Figure 45).



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Figure 45. ‘Notification Settings’ screen.

2. Check the checkbox in the “Email Notification” column to send an e-mail notification whenever a Technical Support Export is created.
3. Check the box in the “Contain Attachment” column to include the exported file as an attachment on the e-mail notification.
4. Enter a single e-mail address or a list of e-mail addresses, separated by commas with no spaces, in the “Email Address” column to define the distribution list for the e-mail notification.
5. Press **OK** to accept and save the settings on the ‘Notification Settings’ screen, or press **Cancel** to discard any changes and return to the ‘Home’ screen.

15.3 Security Settings

The OncoMate™ MSI Dx Interpretive Software Client provides a variety of security settings to create or edit users; create, edit or delete roles; and customize the software to the security needs of the laboratory. Only users with permissions to modify Security Settings are allowed to access these settings. All batches must be closed to access Security Settings.

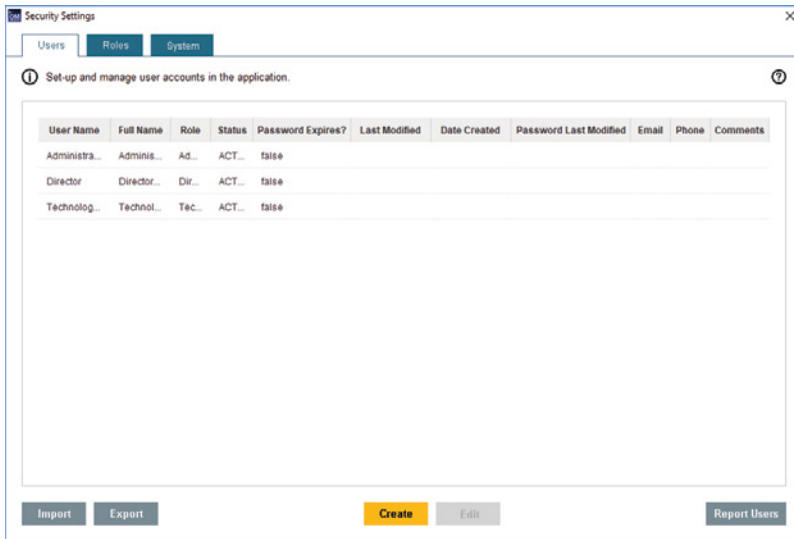
Functions of the ‘Security Settings’ Screen

The ‘Security Settings’ screen displays two buttons that are present on all tabs.

1. Press the **Import** button to import Security Settings that were exported from another OncoMate™ MSI Dx Interpretive Software Client and apply them to this instance of the Client. User accounts, permission roles and system settings will be imported from the export file.
2. Press **Export** to open the ‘Export’ screen. On the ‘Export’ screen, choose whether to export all users, roles and system security settings, or create a custom export of either users and roles or system security settings and roles. Press **OK** to export Security Settings from this instance of the OncoMate™ MSI Dx Interpretive Software Client or **Cancel** to return to the ‘Security Settings’ screen without exporting settings. Exported Security Settings can be imported into other instances of the OncoMate™ MSI Dx Interpretive Software Client to create common user accounts, permission roles and system settings across multiple PCs running this software.

Follow the instructions below to access Security Settings in the OncoMate™ MSI Dx Interpretive Software Client.

1. Log in to the OncoMate™ MSI Dx Interpretive Software Client.
2. Select **Security Settings** from the **Tools** menu to open the ‘Security Settings’ screen (Figure 46).
3. The ‘Security Settings’ screen will display the ‘Users’ tab by default. Select the tab appropriate to the settings that will be modified, and follow the instructions in the appropriate section below.



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Figure 46. ‘Security Settings’ screen.

‘Users’ Tab

The ‘Users’ tab displays a summary table of the user accounts created in this instance of the OncoMate™ MSI Dx Interpretive Software Client.

By default the OncoMate™ MSI Dx Interpretive Software Client is installed with three user accounts that have unique permission levels in the software. Users can log in with the following User Name and Password combinations:

1. User Name: Administrator, Password: Administrator
2. User Name: Director, Password: Director
3. User Name: Technologist, Password: Technologist

To create a new user account, press the **Create** button to display the ‘Create User Account’ screen (Figure 47). To edit an existing user account, click on a user name and press the **Edit** button. Press **Report Users** to create a pdf report of all user accounts in the software. When creating or editing user accounts, the same options will be available, but when editing user accounts, the existing information for the user account is prepopulated in the appropriate fields.

If a user has been locked out of the OncoMate™ MSI Dx Interpretive Software Client or forgotten their password, access can be restored or a password reset in the ‘Users’ tab. To reactivate a user account or reset their password, follow the instructions below:

1. Select the user on the ‘Users’ tab and press the **Edit** button.
2. On the ‘Edit User Account’ screen, change the Status to ACTIVE to reactivate an account.
3. Enter a new password (case sensitive) into the Password text box and confirm the new password using the Re-Enter Password text box.
4. To have the user change their password when they log in, confirm that the checkbox for Password Expires at First Login is checked.
5. After making changes to a user account, press the **Save** button to accept changes or press the **Cancel** button to discard changes.

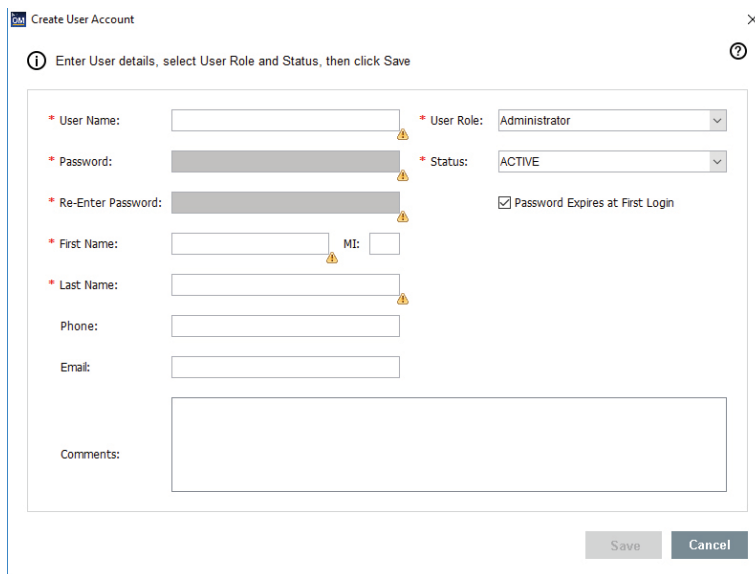


Figure 47. Creating and editing user accounts.

The fields available for creating or editing a user account are displayed on the screen. When creating a new user account, required fields are indicated by a red asterisk, and a yellow triangle with an exclamation point indicates a required field or a warning. Hover over the yellow triangle with an exclamation point to view the warning associated with this field. Table 11 details the fields available for a user account.



Table 11. User Account Fields.

Field Title	Field Information	Required
User Name:	When logging in to the Client, this is the login name for the user account.	Yes
Password:	The initial password for the user account.	Yes
Re-Enter Password:	Confirm the initial password by re-entering it in this field.	Yes
First Name:	The first name of the user assigned to this user account.	Yes
MI:	The middle initial of the user assigned to this user account.	No
Last Name:	The last name of the user assigned to this user account.	Yes
Phone:	The phone number of the user assigned to this user account.	No
Email:	The e-mail address of the user assigned to this user account.	No
Comments:	Any comments the administrator associates with this user account.	No
User Role:	A drop-down list of user roles defined in the Client. The user role determines the permissions associated with this user account in the OncoMate™ MSI Dx Interpretive Software Client. (For more information, see the “Roles Tab” description below.)	Yes
Status:	A drop-down list of user account status. “ACTIVE” accounts are able to log in and use the software, “SUSPENDED” accounts have exceeded the maximum number of failed log-in attempts and “INACTIVE” accounts are unable to log in and use the software.	Yes
Password Expires at First Login	Checking this box requires users to change the initial password the first time they log into the Client.	No

'Roles' Tab

Permissions to access functions and configurations are controlled by user roles assigned within the OncoMate™ MSI Dx Interpretive Software Client. After the software is installed, three user roles are defined by default. Additional roles with customized permissions may be created within the OncoMate™ MSI Dx Interpretive software to meet the needs of the laboratory.

Administrator:

1. Modify software preferences
2. Edit report and e-mail settings
3. Configure security and auditing settings
4. Archive and restore sample batches from the repository
5. Create Technical Support Exports for troubleshooting purposes

Director:

1. Start, resume or complete review of sample data sets
2. Mark sample data sets as Ready for Approval
3. Approve the MSI interpretive results for the data sets and create sample reports
4. Create Technical Support Exports for troubleshooting purposes

Technologist:

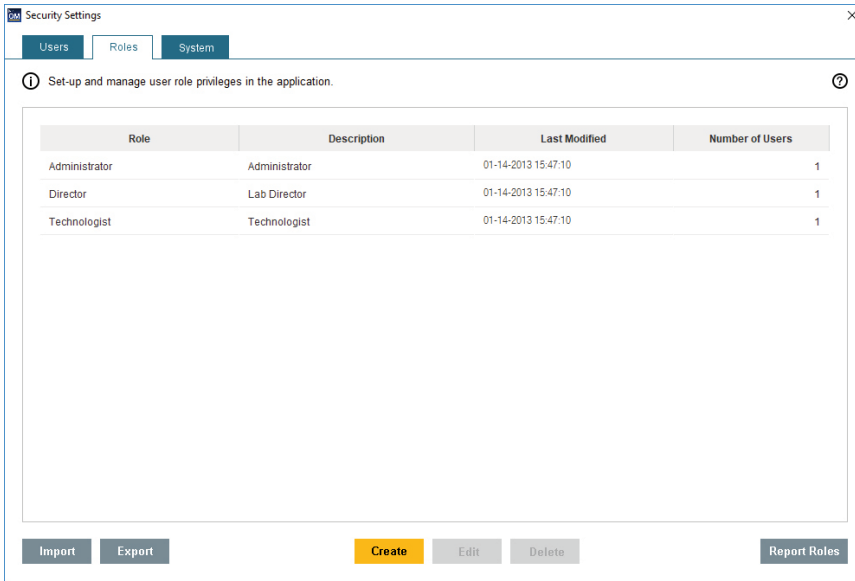
1. Start, resume or complete review of sample data sets
2. Create Technical Support Exports for troubleshooting purposes

Permissions to perform a variety of actions in the OncoMate™ MSI Dx Interpretive Software Client are assigned to Users through role definitions created on the 'Roles' tab. Users with permission to edit the software security configuration can create new roles, edit existing roles or delete roles.

Note: It is not possible to delete or edit the Administrator role.

To moderate user roles in the software, follow the steps outlined below.

1. From the **Tools** menu, select **Security Settings** to open the 'Security Settings' screen.
2. Choose the 'Roles' tab to view the roles currently assigned in the software (Figure 48).



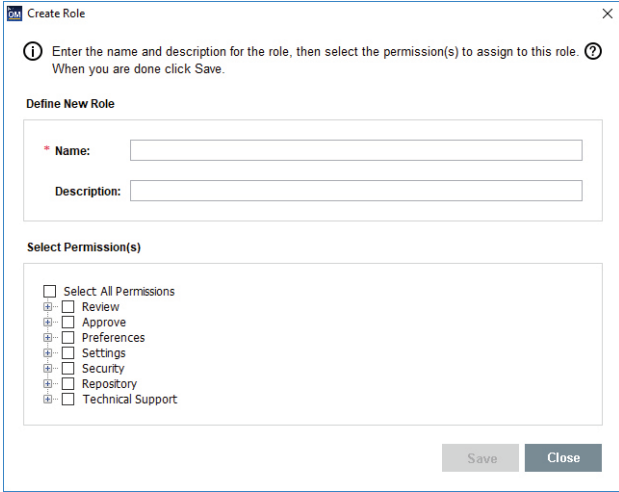
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Figure 48. The ‘Roles’ tab. Use the ‘Roles’ tab on the ‘Security Settings’ screen to create, edit, delete, import or export user roles.

3. On the ‘Roles’ tab:

- To create a new user role, press **Create** to open the ‘Create Role’ screen (Figure 49).
- To edit an existing user role, select an existing user role and then press **Edit** to open the ‘Edit Role’ screen.
- To delete an existing user role, select the user role and then press the **Delete** button. You will be asked to confirm the deletion.
- To create a pdf report of all user accounts in the software, press **Report Roles**.

Whether you are editing or creating user roles, the same options will be available (Figure 49). When editing user roles, the existing information for the user role is prepopulated in the appropriate fields.



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Figure 49. Creating and editing roles. Whether you are creating or editing roles, the same options are available. Enter a name (required) and description for the role, and then select the permissions to be assigned to this role.

- On the 'Create Role' or 'Edit Role' screen, enter a name (required) and description for the user role. Check the checkbox next to Select All Permissions to apply all permissions to the user role, or select individual permissions for this user role by checking the checkbox by individual permissions (Table 12).

Table 12. Account Role Options.

Permission Title	Description of Permission
Review	<p>Initial Review: Provides permission to review samples</p> <p>Final Review: Provides permission to mark samples as Ready for Approval</p> <p>Note: When assigning the Final Review permission, you must also assign the Initial Review permission to the role.</p>
Approve	Approve samples that were reviewed
Preferences	Modify default folder location preferences for imports, exports, reports and archives
Settings	<p>Configure report and e-mail settings. Use the group checkbox to provide permission for all sub-options or expand this group to specifically assign configuration permission for:</p> <p>Report: Edit the header picture and text for reports</p> <p>Email Notifications: Specify e-mail notifications for Technical Support Exports</p> <p>SMTP: Edit e-mail server settings</p> <p>Instrument: Not Used</p>
Security	Create and edit users and roles, modify software security and audit settings
Repository	Archive or restore sample batches
Technical Support	Create a Technical Support Export for troubleshooting purposes

5. Press **Save** to create the role, or press **Close** to discard changes and return to the 'Security Settings' screen.

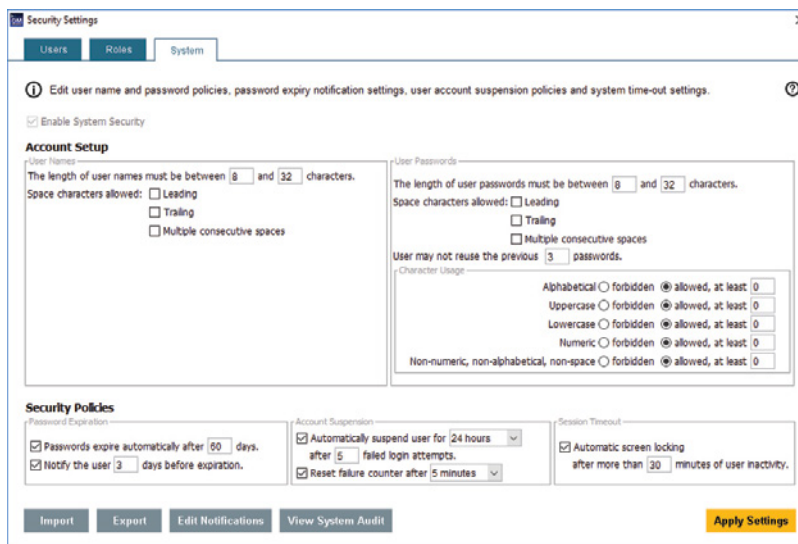
'System' Tab

The 'System' tab (Figure 50) is where rules for user names, passwords, security policies and messaging notifications are specified and where audit records can be reviewed and organized. After defining the settings that are applicable to the laboratory, press **Apply Settings** to save these settings. The 'System' tab is organized into groups of settings described below:

Account Setup Pane

User Names: Specify the rules surrounding user names in this group. Indicate the allowed size range and whether space characters are allowed as leading, trailing or multiple consecutive characters within user names. The minimum possible user name size is 8 characters, and the maximum possible size is 256 characters. Check the checkboxes to specify rules surrounding the use of space characters in user names.

User Passwords: Specify the rules surrounding user passwords in this group. Indicate the allowed size range, whether space characters are allowed as leading, trailing or multiple consecutive characters, rules surrounding password reuse and the character usage requirements for user passwords. For user passwords, the minimum possible size is 8 characters, and the maximum possible size is 256 characters. Check the checkboxes to specify rules surrounding the use of space characters in user passwords. Restrict reuse of user passwords to prevent users from using between 0 and 10 of their previous user passwords. Within the character usage area, check the checkboxes to enforce rules surrounding the use of characters within user passwords. Each character type listed can be prohibited or required for use in user passwords. When making the use of a specific character type a requirement, it is also possible to specify a minimum number of this character type that must be incorporated in the user password using the text boxes at the right of the specified character type.



The screenshot shows the 'Security Settings' window with the 'System' tab selected. The window title is 'Security Settings' and it has three tabs: 'Users', 'Roles', and 'System'. The main content area is titled 'Edit user name and password policies, password expiry notification settings, user account suspension policies and system time-out settings.' and includes a checkbox for 'Enable System Security' which is checked.

Account Setup

User Names
The length of user names must be between and characters.
Space characters allowed: Leading, Trailing, Multiple consecutive spaces

User Passwords
The length of user passwords must be between and characters.
Space characters allowed: Leading, Trailing, Multiple consecutive spaces
User may not reuse the previous passwords.

Character Usage

Alphabetical	<input type="radio"/> forbidden	<input checked="" type="radio"/> allowed, at least: <input type="text" value="0"/>
Uppercase	<input type="radio"/> forbidden	<input checked="" type="radio"/> allowed, at least: <input type="text" value="0"/>
Lowercase	<input type="radio"/> forbidden	<input checked="" type="radio"/> allowed, at least: <input type="text" value="0"/>
Numeric	<input type="radio"/> forbidden	<input checked="" type="radio"/> allowed, at least: <input type="text" value="0"/>
Non-numeric, non-alphabetical, non-space	<input type="radio"/> forbidden	<input checked="" type="radio"/> allowed, at least: <input type="text" value="0"/>

Security Policies

Password Expiration <input checked="" type="checkbox"/> Passwords expire automatically after <input type="text" value="60"/> days. <input checked="" type="checkbox"/> Notify the user <input type="text" value="3"/> days before expiration.	Account Suspension <input checked="" type="checkbox"/> Automatically suspend user for <input type="text" value="24"/> hours after <input type="text" value="5"/> failed login attempts. <input checked="" type="checkbox"/> Reset failure counter after <input type="text" value="5"/> minutes	Session Timeout <input checked="" type="checkbox"/> Automatic screen locking after more than <input type="text" value="30"/> minutes of user inactivity.
--	---	--

Buttons at the bottom: Import, Export, Edit Notifications, View System Audit, and Apply Settings.

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Figure 50. Security settings on the 'System' tab.

Security Policies Pane

Password Expiration: Specify the times and notifications surrounding the expiration of user passwords. To require that user passwords expire after a specified number of days, check the checkbox next to “Passwords expire automatically after” and enter a number of days after which a user will need to create a new password. To have the software notify users a specified number of days prior to password expiration, check the checkbox next to “Notify the user” and enter a number of days before password expiration that the software will notify the user. Uncheck the boxes to prevent automatic password expiration or user notification prior to password expiration.

Account Suspension: Specify whether user accounts are suspended based on failed login attempts. Check the checkbox next to “Automatically suspend user for” to automatically suspend user accounts for a specified timeframe after a specified number of failed login attempts. Use the drop-down menu to specify the timeframe over which the user will be suspended, and enter the number of failed login attempts that will result in user account suspension. If a timeframe of “Indefinitely” is chosen, a user account with Security Setting permissions must manually reactivate suspended user accounts. Check the box next to “Reset failure counter after”, and specify a timeframe after which the counter of failed login attempts will be automatically reset. Uncheck the boxes to prevent user account suspension due to failed login attempts or automatic reset of the failure counter.

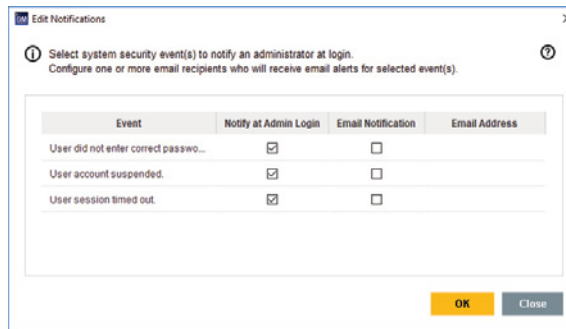
Note: Reactivating suspended accounts is detailed in Section 15.3, Security Settings, under ‘Users’ Tab.

Session Timeout: Specify how long the OncoMate™ MSI Dx Interpretive Software Client can remain inactive before requiring a new login. Check the checkbox next to “Automatic screen locking after more than”, and enter a number of minutes of inactivity after which the OncoMate™ MSI Dx Interpretive Software Client will require a new login. Uncheck the checkbox to prevent the software from locking due to inactivity.

Messaging Notifications

Press **Edit Notifications** to open the ‘Edit Notification Settings’ screen (Figure 51). Indicate the conditions and ways in which user accounts with Security Settings permission will be notified of the indicated software states. Notifications can be configured for incorrect password entry, suspension of user accounts and locking of the software due to inactivity. Check the checkboxes in the “Notify at Admin Login” column to display a notification window of each software state at the next login of a user account with the Administrator role. Check the checkboxes in the “Email Notification” column to automatically send an e-mail to the specified e-mail address(es) for the indicated software states. For each checkbox in the “Email Notification” column, select the “Email Address” column for that row to enter an e-mail address to which notifications are sent for the specified software state. To enter multiple e-mail addresses, separate each address with a comma and no spaces.

Note: To use e-mail notifications, the e-mail server information must be configured from the **System Settings** item in the **Tools** menu (see Section 15.1, System Settings).



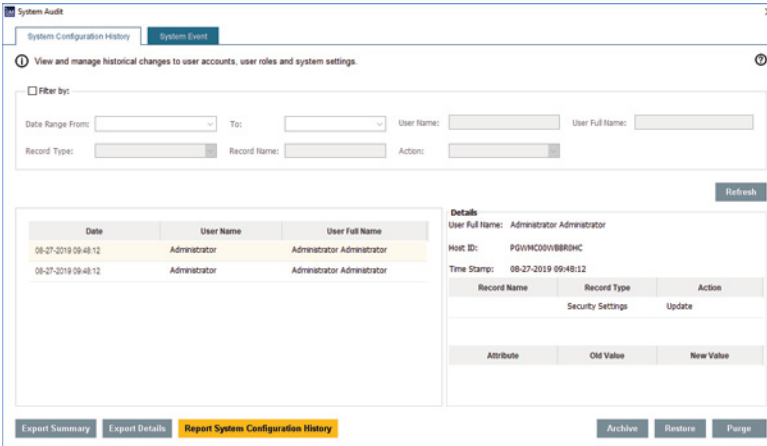
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Figure 51. ‘Edit Notifications’ screen.

System Audit

Press **View System Audit** to open the ‘System Audit’ screen (Figure 52). An audit trail of the system configuration history is presented on the ‘System Configuration History’ tab (Figure 52, Panel A), and an audit trail of all system events is presented on the ‘System Event’ tab (Figure 52, Panel B). On either tab, check the “Filter by:” checkbox to specify filter conditions to display only certain records. After specifying a set of filters, press **Apply** to filter the audit record list. To display the entire list of audit records, uncheck the “Filter by:” checkbox and then press **Refresh**. On the ‘System Configuration History’ tab, select an item from the audit record summary table to view the detail for that item in the Details table. Once an item is selected, select the record name in the Details table to view the Attribute(s), Old Value(s) and New Value(s) associated with this record.

A.



System Audit

System Configuration History | System Event

View and manage historical changes to user accounts, user roles and system settings.

Filter by:

Date Range From: [] To: [] User Name: [] User Full Name: []

Record Type: [] Record Name: [] Action: []

Date	User Name	User Full Name
08-27-2019 09:48:12	Administrator	Administrator Administrator
08-27-2019 09:48:12	Administrator	Administrator Administrator

Details

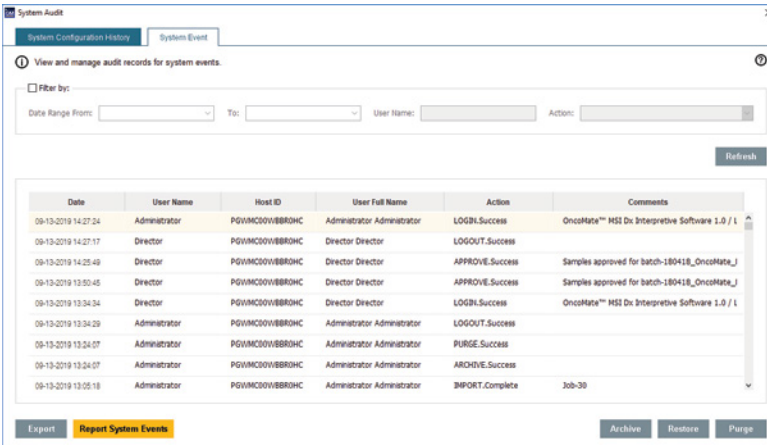
User Full Name: Administrator Administrator
Host ID: PGVMCO0VBBR0HC
Time Stamp: 08-27-2019 09:48:12

Record Name	Record Type	Action
	Security Settings	Update

Attribute	Old Value	New Value
-----------	-----------	-----------

Export Summary | Export Details | **Report System Configuration History** | Archive | Restore | Purge

B.



System Audit

System Configuration History | System Event

View and manage audit records for system events.

Filter by:

Date Range From: [] To: [] User Name: [] Action: []

Date	User Name	Host ID	User Full Name	Action	Comments
09-13-2019 14:27:24	Administrator	PGVMCO0VBBR0HC	Administrator Administrator	LOGIN.Success	OncoRate™ MSI Dx Interpretive Software 1.0 / L
09-13-2019 14:27:17	Director	PGVMCO0VBBR0HC	Director Director	LOGOUT.Success	
09-13-2019 14:25:49	Director	PGVMCO0VBBR0HC	Director Director	APPROVE.Success	Samples approved for batch-180418_OncoRate_L
09-13-2019 13:50:45	Director	PGVMCO0VBBR0HC	Director Director	APPROVE.Success	Samples approved for batch-180418_OncoRate_L
09-13-2019 13:34:34	Director	PGVMCO0VBBR0HC	Director Director	LOGIN.Success	OncoRate™ MSI Dx Interpretive Software 1.0 / L
09-13-2019 13:34:29	Administrator	PGVMCO0VBBR0HC	Administrator Administrator	LOGOUT.Success	
09-13-2019 13:24:07	Administrator	PGVMCO0VBBR0HC	Administrator Administrator	PURGE.Success	
09-13-2019 13:24:07	Administrator	PGVMCO0VBBR0HC	Administrator Administrator	ARCHIVE.Success	
09-13-2019 13:05:18	Administrator	PGVMCO0VBBR0HC	Administrator Administrator	IMPORT.Complete	Job-30

Export | **Report System Events** | Archive | Restore | Purge

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Figure 52. ‘System Audit’ screen. Panel A. ‘System Configuration History’ tab. Panel B. ‘System Event’ tab.

Buttons at the bottom of the ‘System Audit’ screen are used to export, report and curate the list of audit records. The function of each of these buttons is detailed in Table 13.

Table 13. ‘System Audit’ Screen Buttons.

Button	Tab Name	Description
Export Summary	“System Configuration History”	Select one or more audit records, and press this button to export a comma-delimited text file (.csv) of the information contained in the summary table for the records. Select a file location to save the export summary. ¹
Export Details	“System Configuration History”	Select one or more audit records, and press this button to export a comma-delimited text file (.csv) of the information contained in the details table for the records. Select a file location to save the export summary. ¹
Report System Configuration History	“System Configuration History”	Press this button to create a PDF report of all audit trail records in the system configuration history.
Export	“System Event”	Select one or more audit records, and press this button to export a comma-delimited text file (.csv) of the information contained in the table for the records. Select a file location to save the export summary. ¹
Report System Events	“System Event”	Press this button to create a PDF report of all audit trail records in the system event history.
Archive	Both	Press this button to create an archive file of one or more selected audit records. Select a file location to save the archive file. ¹
Restore	Both	Press this button to restore audit records that were previously archived. Select the file location of the archive file to restore.
Purge	Both	Press this button to delete one or more selected audit records from the system configuration or system event history. ¹

¹To select multiple audit records, use one of the following methods: click and drag across multiple records; select a record and Shift-click the last record to select; or Ctrl-click multiple records.

15.4 Archive

Archiving data is a way to manage the list of batches displayed within the OncoMate™ MSI Dx Interpretive Software Client, reduce the overall active data set present in the OncoMate™ MSI Dx Interpretive Software Client or store data that does not need to be immediately accessed. Archived data will retain the individual sample and control data associated with a batch and the review and approval status of the batch. All archived data can be restored at a later date using the **Restore** function in the **Tools** menu (see Section 15.5, Restore). Follow the instructions below to create archive files of sample batches.

1. From the list of sample batches present on the ‘Home’ screen, check the checkboxes next to the batches to be archived
Note: Check and then uncheck **Select all** the box at the top of the list of batches before selecting batches to archive. This will ensure that all batches are unchecked before making your selection(s).
2. For users with Repository permission, select the **Archive** function from the **Tools** menu to open the ‘Archive’ screen (Figure 53).

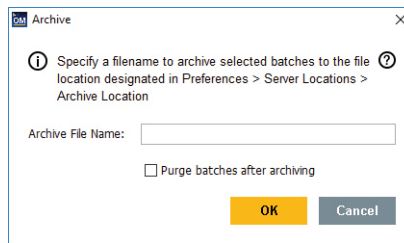


Figure 53. Creating an archive file.

3. Enter a name for the archive file.
4. To remove the selected batches from the batch list in the OncoMate™ MSI Dx Interpretive Software Client, check the checkbox titled “Purge batches after archiving”.
5. Press **OK** to create an archive file of the selected batches, or press **Cancel** to close the ‘Archive’ screen without creating an archive. If the “Purge batches after archiving” box was checked, a warning is displayed that the selected data will be removed from the OncoMate™ MSI Dx Interpretive Software Client. Archive files will be saved at the default folder location for archive files (see Section 15.7, Preferences). An archive exists as a zip file containing the batch information and a separate text file. The zip file contains individual folders named for the batches contained in the archive.

15.5 Restore

Batch data that was previously archived can be restored to the batch sample lists in the OncoMate™ MSI Dx Interpretive Software Client using the **Restore** function in the **Tools** menu. Follow the instructions below to restore archived batch data.

1. For users with Repository permission, select **Restore** from the **Tools** menu to open the ‘Restore’ screen (Figure 54).
2. The ‘Restore’ screen displays a list of archive files that are present in the default folder location for archives (see Section 15.7, Preferences). Select an archive file from the list of available archives.
Note: An archive exists as a zip file containing the batch information and a separate text file. Both files must be present to restore a batch to the OncoMate™ MSI Dx Interpretive Software Client.
3. Press **OK** to restore the information in the selected archive to the OncoMate™ MSI Dx Interpretive Software Client, or press **Cancel** to close the ‘Restore’ screen. A notification will be displayed indicating that the selected batch(es) were restored.

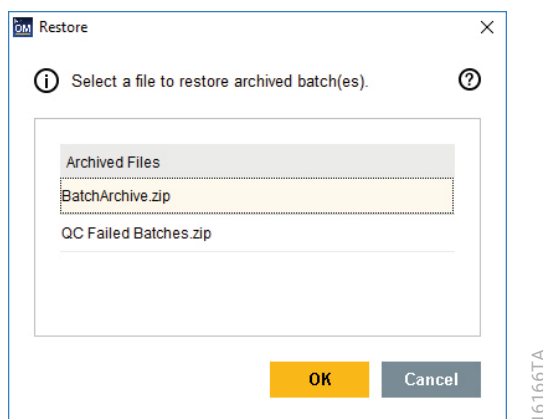
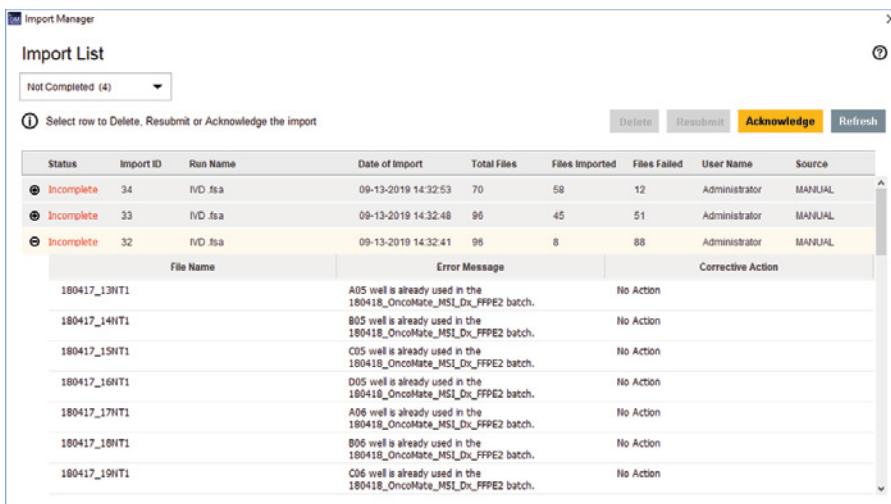


Figure 54. Restoring archived batches.

15.6 Import Manager

The Import Manager provides a summary list of all import activities that have occurred in the OncoMate™ MSI Dx Interpretive Software Client. Incomplete import of samples will result in the display of a red triangle with an exclamation point in the **Import Manager** button on the ‘Home’ screen; for more information, see Section 18, Troubleshooting. All users have permission to access the Import Manager where they can review, acknowledge and delete items from the list of imported samples. Two mechanisms exist for accessing the import manager: select **Import Manager** from the **Tools** menu, or press the **Import Manager** button on the right top of the ‘Home’ screen. Either mechanism will open the ‘Import Manager’ screen (Figure 55).



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Figure 55. The ‘Import Manager’ screen.

At the top left of the ‘Import Manager’ screen is a drop-down list used to filter the list entries. Selecting **All** will display all list entries of imported samples. Selecting **Completed** will show only list entries where import of samples was complete. Selecting **Not Completed** will show only list entries where import of samples was incomplete. The ‘Import Manager’ screen will show the list filtered to Not Completed entries by default.

Notes:

1. If sample import was incomplete, the **Import Manager** button on the ‘Home’ screen of the OncoMate™ MSI Dx Interpretive Software Client will display a red triangle with an exclamation point until the incomplete entry is acknowledged.
2. Items marked as Incomplete can be expanded to view the identified import error states by pressing the ‘+’ icon at the left side of the list entry.

The main portion of the ‘Import Manager’ screen displays a list of the import activities that have occurred in the OncoMate™ MSI Dx Interpretive Software Client. For each item on the list, Table 14 describes the available information.

Table 14. Import Manager Activity Information.

Item	Description
Status	The status of the import operation for the selected samples. Status will be displayed as Complete for samples that were successfully imported and Incomplete for samples that were not successfully imported. Samples must be imported as matched pairs of normal and tumor samples with the same SampleID and the UDF1 field indicating N for normal and T for tumor. Samples that do not conform to these designations will not import into the OncoMate™ MSI Dx Interpretive Software Client.
Import ID	A sequential numbering of each import presenting a unique identifier for the import activity.
Run Name	The plate Name indicated in the sample .fsa files that were imported.
Date of Import	The date when the import activity occurred.
Total Files	The total number of files for which import was attempted. There must be a minimum of two files, a normal and a tumor file, for import to occur for each sample.
Files Imported	The total number of files in the import attempt that were successfully imported into the OncoMate™ MSI Dx Interpretive Software Client.
Files Failed	The number of files in the import attempt that failed to be imported successfully into the OncoMate™ MSI Dx Interpretive Software Client.
User Name	The name of the user who was logged in to the OncoMate™ MSI Dx Interpretive Software Client and initiated the import activity.
Source	Indication that the import was performed as a manual process.

You can review the results of each import activity. To ensure that the list of import activities accurately reflects all activities that have occurred, press **Refresh**. After the list is refreshed, the filter drop-down menu will automatically return to the Not Completed view. To acknowledge entries marked as Incomplete, select the item and press **Acknowledge**. Acknowledging all incomplete import activities in the list will remove the red triangle containing an exclamation point from the **Import Manager** button on the 'Home' screen. To remove entries from the list, select the entry to be removed and press **Delete**. Entries marked as incomplete must be acknowledged before they can be deleted from the list. After deleting an entry, the filter drop-down menu will automatically return to the Not Completed view. To close the 'Import Manager' screen, click the **X** at the upper right of the screen.

15.7 Preferences

Multiple functions within the OncoMate™ MSI Dx Interpretive Software Client access folder locations to save and retrieve files. Define the default folder locations for these functions, including: importing sample batches, reporting on sample batches, exporting sample batches, creating security exports and archiving sample batches. The default folder location determines the initial location for file browsers for the indicated functions. Setting folder locations requires permission to modify Preferences. To define the default locations for these functions, follow the instructions below.

1. For users with Preferences permission, select **Preferences** from the **Tools** menu to open the ‘Preferences’ screen (Figure 56).

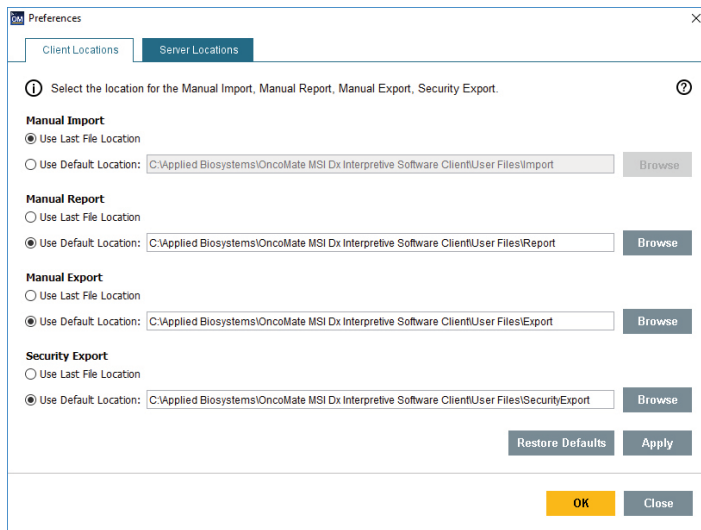


Figure 56. Setting default folder locations.

2. For any of the indicated functions (manual import, manual report, manual export, security export), use the radio buttons to **Use Last File Location** or **Use Default Location** as the initial location to which file browsers will open. If the radio button is set to **Use Last File Location**, the file browser will always start at the last file location that was accessed by a user. If the radio button is set to **Use Default Location**, either enter a file path or use the **Browse** button to open a file browser and navigate to a default location to be used.
3. After making changes, press **Apply** to save the indicated settings. To return all settings to the default values specified when the OncoMate™ MSI Dx Interpretive Software Client was installed, press **Restore Defaults**.
4. To change the location where archive files will be saved, select the ‘Server Locations’ tab (Figure 57).

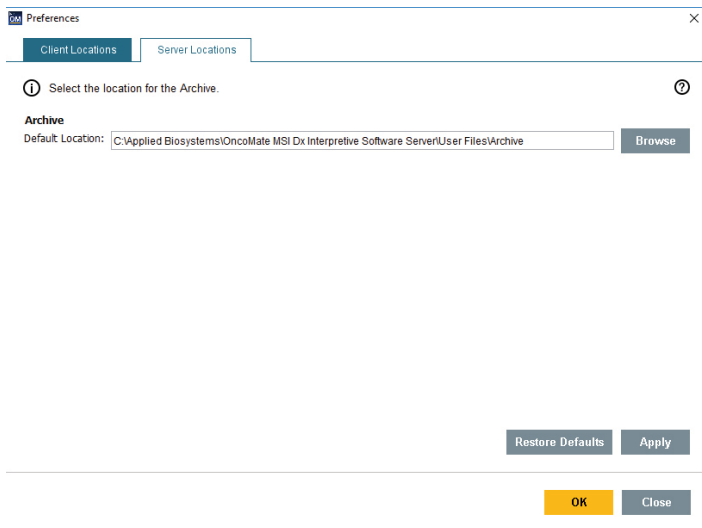


Figure 57. Setting default location of archive files.

5. Press **OK** to accept all changes and close the ‘Folder Locations’ screen, or press **Close** to close the ‘Folder Locations’ screen without saving changes.

16. Help Menu

The **Help** menu provides access to the help files for the OncoMate™ MSI Dx Interpretive Software Client, software version information, and the ability to view and print the end user license agreement.

Note: It is necessary to have the Google Chrome™ browser version 25 or later installed on the computer to view help files.

16.1 Interpretive Software Help

From the **Help** menu, choose **Interpretive Software Help** to view the help files specific to the OncoMate™ MSI Dx Interpretive Software Client. Within the help files it is possible to search for topics or refer to sections specific to functions available within the software. Context-sensitive help is available on all screens within the OncoMate™ MSI Dx Interpretive Software Client. Press the question mark icon if displayed on a screen, or press the F1 key to access context-sensitive help topics for that screen.

Note: It is necessary to have the Google Chrome™ browser version 25 or later installed on the computer to view help files.

16.2 About

From the **Help** menu, choose **About** to open the ‘About’ screen and view information about the software version and release date as well as view and print the end user license agreement (Figure 58). Press **View License Agreement** to open the ‘End User License Agreement’ screen and view the end user license agreement. From this screen, press **Print** to print a copy of the end user license agreement using a printer installed on this computer. Press **OK** to close the ‘End User License Agreement’ screen and return to the ‘About’ screen. On the ‘About’ screen, press **OK** to return to the ‘Home’ screen.



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Figure 58. The ‘About’ screen.

17. Server Menu

The **Server** menu is only displayed when the OncoMate™ MSI Dx Interpretive Software Client is installed in the Windows® 10 Professional or Windows® 10 Enterprise Operating System. This menu provides access to view logs of OncoMate™ MSI Dx Interpretive Software Server activities. Table 15 indicates the functions present in the **Server** menu.

Notes:



1. In the Windows® 7 Operating System the functions found in the **Server** menu can be accessed from the taskbar of the computer on which the Server is installed. Select the up arrow  icon to display hidden icons, and then right-click the OncoMate™ MSI Dx Server  icon.
2. Two other functions are available when accessing the server icon from the taskbar: **Stop OncoMate™ MSI Dx Interpretive Software Server** and **About**.
 - a. Press **Stop OncoMate™ MSI Dx Interpretive Software Server** to shut down the Server.
 - b. Press **About** to view information about the OncoMate™ MSI Dx Interpretive Software version and release date.

Table 15. Functions in the Server Menu.

View OncoMate™ MSI Dx Interpretive Software Server Automation Log	The Server Automation Log provides a high-level overview of automated server activities. These activities are not supported within the OncoMate™ MSI Dx Interpretive Software.
View OncoMate™ MSI Dx Interpretive Software Server Log	The Server Log provides a record of all activities of the OncoMate™ MSI Dx Interpretive Software Server and any interactions between the OncoMate™ MSI Dx Interpretive Software Client and the OncoMate™ MSI Dx Interpretive Software Server. These logs are used for troubleshooting purposes only.

18. Troubleshooting

For questions not addressed here, please contact your local Promega Branch Office or Distributor. Contact information available at: www.promega.com. E-mail: genetic@promega.com

Symptom

On startup, OncoMate™ MSI Dx Interpretive Software Client displays an error that “There is a problem connecting to Interpretive Software Server”.

Causes and Comments

Confirm that the OncoMate™ MSI Dx Interpretive Software Server was started. See Section 8.3, Starting the OncoMate™ MSI Dx Interpretive Software Server, for instructions on determining whether the OncoMate™ MSI Dx Interpretive Software Server is started and for instructions on starting the OncoMate™ MSI Dx Interpretive Software Server.

Confirm that the OncoMate™ MSI Dx Interpretive Software Server is installed. If not, refer to Section 8.2, Installing the OncoMate™ MSI Dx Interpretive Software.

If the OncoMate™ MSI Dx Interpretive Software Server is installed on a server or a different network computer, contact your IT professional to check that the connection to the server or computer is active.

Use the **Connect to a Different Server** button to open a ‘Server Connection’ screen and check whether the computer name or IP address connection information for the OncoMate™ MSI Dx Interpretive Software Server is correct. See Section 8.3, Starting the OncoMate™ MSI Dx Interpretive Software Server, for instructions on changing and testing the connection information.

Symptoms

After selecting a button or menu item, the desired function does not occur.

Causes and Comments

Not all functions are available at all times within the OncoMate™ MSI Dx Interpretive Software Client. Consult the section in this reference manual that describes the function to see whether there are restrictions on how, when or where it can be used.

Many functions are restricted based on user account permissions. Consult the section in this reference manual that describes the function to see whether there are permission requirements for the function. Consult with the site administrator to determine whether the user account was granted permission to perform the desired function.

Sample .fsa files will not import.

Sample files must conform to a series of attributes to be imported into the OncoMate™ MSI Dx Interpretive Software Client. See Section 11.2, Importing Samples (.fsa Files) for Automated Analysis, for instructions on importing .fsa files and the attributes to which they must conform. Sample files with errors in the Sample Name or UDF1 field(s) can be opened, edited and saved using the Applied Biosystems® 3500 Dx Genetic Analyzer data collection software. See the *Applied Biosystems® 3500 Dx Genetic Analyzer and 3500xL Dx Genetic Analyzer IVD User Guide* for additional information.

The Import Manager maintains a record of import activities and a description of any error states that may have occurred during import of sample files. See Section 15.6, Import Manager, for information about using the import manager.

Not all sample .fsa files were imported.

The Import Manager maintains a record of import activities and a description of any error that may have occurred during import of sample files. See Section 15.6, Import Manager, for information about using the import manager.

Importing additional samples into an existing batch may be unsuccessful. It may be necessary to archive and purge a partial batch and then reimport the entire batch. See Section 15.4, Archive, for information about archiving and purging batches.

The **Reinject** option was used in the Applied Biosystems® 3500 Dx data collection software and reinjected samples were not imported. Samples that are reinjected during an active CE run using the **Reinject** option in the DCS will have the same sample names as those analyzed during the initial injection. Open the .fsa files for the reinjected samples in the DCS, and rename the matched Normal and Tumor samples (e.g., add a “_RI” suffix to the sample name). Repeat the import operation in the OncoMate™ MSI Dx Interpretive Software.

Symptoms

Causes and Comments

A batch cannot be reviewed or approved.

Check the QC status of the batch on the “Home” or batch screen to see whether the QC has failed. Batches of samples must pass QC requirements to be eligible for review and approval. Batches that do not pass QC requirements are considered invalid. See Section 13.1, Minimum Requirements for a Valid Sample Batch, and Section 13.2, Quality Control Requirements, for information about the QC requirements for a sample batch.

A user account must be granted permission to review or approve batches. Consult with the site administrator to determine whether the user account was granted permission to perform the desired function.

A sample cannot be reviewed or approved.

Check the QC status of the batch on the ‘Home’ or batch screen to see whether a QC failure has resulted in the entire batch being marked as QC Failed. For batches that are marked as QC Failed, review and approval of individual samples is not allowed. Rather, the entire batch can be approved at one time (see Section 11, Main Workflow). See Section 13.2, Quality Control Requirements, for information about the QC requirements that result in a batch being marked as QC Failed.

User account cannot log in to the OncoMate™ MSI Dx Interpretive Software Client.

The user account may be suspended because the maximum number of failed login attempts allowed in the OncoMate™ MSI Dx Interpretive Software Client was exceeded. Consult with the site administrator to amend the status of the user account. Reactivating suspended accounts is detailed in Section 15.3, Security Settings, under ‘Users’ tab.

The software was opened by a different user and is now locked due to inactivity. When this happens, the same user who was logged in before the software locked must log in to unlock the software. The name of the user who was logged in before the software locked can be viewed on the right side of the menu bar of the ‘Home’ screen. To log in as a different user, choose to exit the software and then restart the OncoMate™ MSI Dx Interpretive Software Client.

The user account was inactivated by the site administrator. Consult with the site administrator to amend the status of the user account. Reactivating suspended accounts is detailed in Section 15.3, Security Settings, under ‘Users’ tab.

Symptoms

A sample batch was fully reviewed and approved but is not considered Completed.

A sample batch was fully reviewed and approved, but the sample status displayed in software exports and reports for one or more samples is “Ready For Approval”.

When defining a new password for a user account, the new password is not accepted.

The list of sample batches is excessive.

When trying to restore an archive, an error indicates the archive is invalid or corrupt.

Network drive locations are not viewable when importing samples.

A Technical Support Export cannot be created.

When opened, the Technical Support Export file does not contain understandable information.

Causes and Comments

For a sample batch to be considered completed, it must be exported. See Section 10.2, Creating Sample and Batch Reports and Export Files, for information on exporting.

An unreproducible anomaly occurred while updating the Status to Approved for the sample(s). Archive and purge the batch from the software, recreate the batch by re-importing the same .fsa files into the software, and repeat the review and approve workflow for the batch.

Passwords must have a minimum of eight characters and must conform to the additional requirements set by the site administrator. When creating a new password, hover the mouse over the yellow rectangle with an exclamation point at the right side of the New Password text box to see the failed requirements for the password. Adjust the password to conform to the requirements.

The administrator may have specified rules surrounding the re-use of previous passwords. If this is the case, ensure that the new password is not the same as a previous password and meets the requirements specified by the administrator.

Sample batches can be archived and purged from the OncoMate™ MSI Dx Interpretive Software Client. See Section 15.4, Archive, for information.

Archives exist as two files: a compressed folder (.zip) and a separate text file (.zip.txt), both with the same file name. Both files must be present in the archive directory to restore the archive. If the contents of the compressed folder were modified, the archive is considered invalid.

The client was started by right-clicking the desktop icon and selecting **Run as administrator**. Do not use the **Run as administrator** option in the Windows® operating system to start the client software. See your network administrator to address other root causes for limited network access.

Technical Support Exports can only be created from the batch screen for a sample batch. See Section 14.2, Technical Support Export, for information about creating a Technical Support Export.

The Technical Support Export is created as an encrypted file that cannot be read by the user. The file can be interpreted only by a Promega Technical Services representative.

19. References

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