appliedbiosystems

TrueMark™ MSI Analysis Software Version 1.0

USER GUIDE

For Microsatellite Instability Research

for use with:
TrueMark™ MSI Assay
3500/3500xL Genetic Analyzer
SeqStudio™ Genetic Analyzer

Publication Number MAN0018874

Revision B00

For Research Use Only. Not for use in diagnostic procedures.

ThermoFisher SCIENTIFIC

Life Technologies Ltd | 7 Kingsland Grange | Woolston, Warrington WA1 4SR | United Kingdom
For descriptions of symbols on product labels or product documents, go to thermofisher.com/symbols-definition.

Revision history: MAN0018874 B00 (English)

Revision	Date	Description
B00	18 April 2024	Document secondary title was updated.
A.0	16 December 2019	New software documentation for version 1.0 of the TrueMark™ MSI Analysis Software.

The information in this guide is subject to change without notice.

Contents

1 About the TrueMark™ MSI Analysis Software

The TrueMark™ MSI Analysis Software for Microsatellite Instability Testing is a secondary analysis software application that interprets TrueMark™ MSI Assay fragment analysis data (FSA files) collected on the 3500/3500xL Genetic Analyzer or SeqStudio™ Genetic Analyzer. The TrueMark™ MSI Analysis Software simultaneously imports and analyzes fragment data, then generates interpretive sample results. Multiple quality checks (QC) are incorporated into the analysis process.

For detailed kit instructions, see the *TrueMark™ MSI Assay User Guide* (Pub. No. MAN0018868).

Features of the software

The TrueMark™ MSI Analysis Software performs data analysis and interpretation for the TrueMark™ MSI Assay by providing:

- Automated microsatellite instability (MSI) interpretive results; you can make manual calls to override the automated results
- Electropherogram plots to visualize peak details
- Specimen- and marker-level quality checks (QC)
- E-signature approval for specimen results
- Audit records to ensure data integrity
- CSV exports and PDF reports to manage test results in laboratory information systems

Kit overview

The Applied Biosystems™ TrueMark™ MSI Assay detects the presence of microsatellite instability in DNA samples through multiplex PCR and fragment analysis. Fragment analysis is performed on the Applied Biosystems™ 3500/3500xL Genetic Analyzer or the Applied Biosystems™ SeqStudio™ Genetic Analyzer. Data is analyzed with the Applied Biosystems™ TrueMark™ MSI Analysis Software for easy reporting of results.

Compatible instruments and Data Collection software

The TrueMark™ MSI Analysis Software is for use with the following instruments and Data Collection software.

Instrument	Data collection software
3500/3500xL Genetic Analyzer	3500 Series Data Collection Software v3.0 or later
SeqStudio™ Genetic Analyzer	SeqStudio™ Data Collection Software v1.1.4 or later

Overview of user roles

- Each user account in the TrueMark™ MSI Analysis Software is assigned a user *role*. The user role determines the permissions that are associated with the user account.
- Three default user roles are included in the TrueMark™ MSI Analysis Software: *Technologist*, *Administrator*, and *Director*.
- The permissions for the default Administrator role cannot be modified. However, your laboratory can assign different permissions to the default Technologist and Director roles, and create new user roles.

Network and password security requirements

Network configuration and security

The network configuration and security settings of your laboratory or facility (such as firewalls, anti-virus software, network passwords) are the sole responsibility of your facility administrator, IT, and security personnel. This product does not provide any network or security configuration files, utilities, or instructions.

If external or network drives are connected to the software, it is the responsibility of your IT personnel to ensure that such drives are configured and secured correctly to prevent data corruption or loss. It is the responsibility of your facility administrator, IT, and security personnel to prevent the use of any unsecured ports (such as USB, Ethernet) and ensure that the system security is maintained.

Password security

Thermo Fisher Scientific strongly recommends that you maintain unique passwords for all accounts in use on this product. All passwords should be reset upon first sign in to the product. Change passwords according to your organization's password policy.

It is the sole responsibility of your IT personnel to develop and enforce secure use of passwords.

Terms you need to know

- **Batch**—All sample files (FSA) that are imported in a single import operation. Typically, each batch is from a single instrument injection of a single plate (one sample file per tested well).
- **Import record**—The **Import Manager** displays an import record for each batch. The import record includes the **Status** (whether or not the import was successful), the **Import ID** (an internal ID used by the software), the **Batch Name**, the **Date of Import**, and other details about the batch.
- **Reportable marker**—By default, all measured markers are included in reports and exports and in the **Overall Call** calculation for the specimen. If you choose to exclude some markers from reporting and/or calculation (either individual specimens or globally for new batches), then only the remaining markers are reportable markers.
- **Sample file (FSA)**—A sample file is an FSA file generated by the Data Collection software during an instrument run. A sample file contains the data collection information for a single well on a 96-well plate.
- **Specimen**—A test event for one individual. A specimen can be any one of the following:
  - A pair of sample files (FSA) from matched Normal (**N**) and Tumor (**T**) tissue samples
  - A single sample file from an unpaired Tumor (**T**) tissue sample
  - A single sample file from a negative control (**NEG**) or no template control (**NTC**)

Workflow

Import samples and manage import records

- **Import samples**
- **Troubleshoot sample file (FSA) imports**
- **Manage import records in the Import Manager**

Review analysis results

- **Review analysis results in the Batch Summary tab**
- **Review analysis results in the Specimen Data tab**
- **Add a comment and/or accept the specimen (Technologist)**

(Optional) Accept and approve specimens

- **Accept the review and move the specimen to Ready for Approval (Director)**
- **Approve a specimen**
- **Export an Approvals Report (PDF file)**

Export reports

Export a Batch Report (PDF file)

Export a Batch Report (CSV file)

Export a Specimen Report (PDF file)

Export a Specimen Report (CSV or VCF file)

2 *(Administrator only)* Install the TrueMark™ MSI Analysis Software

Installation access restrictions

To perform the installation procedures in this chapter, you must have a Windows™ account with privilege to install programs on the computer.

Computer requirements

Component	Requirement
MSI Client	20 GB of available disk space
	4 GB of RAM **Note:** For optimal performance, we recommend 8 GB of RAM.
	Operating system: • Windows™ 10 (Professional), 64-bit • Windows™ 10 (Enterprise), 64-bit
MSI Server	40 GB of available disk space
	8 GB of RAM **Note:** For optimal performance, we recommend 16 GB of RAM.

(continued)

Component	Requirement
MSI Server	Operating system: • Windows™ 10 (Professional), 64-bit • Windows™ 10 (Enterprise), 64-bit

IMPORTANT! We recommend that you routinely perform antivirus and anti-malware scans on your computer, including on all TrueMark™ MSI Analysis Software files and folders. However, we do not recommend performing the scans when the software is running. The scans slow down system performance and may create a file conflict that causes the MSI Server to crash.

About the MSI Server and MSI Client

The TrueMark™ MSI Analysis Software includes the following components.

- **MSI Server**—Consists of server application files, system settings, and imported sample data. The server imports sample files (FSA) from the 3500/3500xL Genetic Analyzer or the SeqStudio™ Genetic Analyzer.
- **MSI Client**—Consists of client application files and user files. Use the client to view batches and perform manual operations (for example, importing FSA files). A client must be connected to a server to perform these operations.

Before you begin

- Decide where to install the MSI Server:
  - On a computer that can be accessed over a local network by multiple users
  - On your own computer
- Download the TrueMark™ MSI Analysis Software from **downloads.thermofisher.com/TrueMark MSI Analysis Software.zip**. Extract the two executable (EXE) files from the ZIP file: **MSI Server.exe** and **MSI Client.exe**.

Install the MSI Server and MSI Client

IMPORTANT! Do not install the TrueMark™ MSI Analysis Software (server or client) on the Data Collection computer.

Note: You can install the MSI Server and MSI Client on the same computer.

1. Install the MSI Server.
   a. Double-click the **MSI Server.exe** file to launch the InstallShield Wizard, then follow the prompts.

      Note: If a security warning is displayed, click **Run**.

   b. When the installation is complete, click **Finish**.

   The MSI Server icon is displayed on the computer desktop, and the installer should have started the server.

2. Install the MSI Client.
   a. Double-click the **MSI Client.exe** file to launch the InstallShield Wizard, then follow the prompts.

      Note: If a security warning is displayed, click **Run**.

   b. When the installation is complete, click **Finish**.

   The MSI Client icon is displayed on the computer desktop.

Sign in to the TrueMark™ MSI Analysis Software (initial sign-in for the default Administrator)

1. On the computer desktop, double-click **(MSI Client)** to start the client.

   IMPORTANT! The MSI Server must already be running on the computer so that the client can connect to the server. The server is configured to automatically start whenever the computer is started.

   If you get a connection error when you start the client, you may need to manually start the server. Try each of the following actions to resolve the connection error; perform the actions in the order listed.
   1. On the computer desktop, double-click **(MSI Server)**.
   2. On the computer desktop, right-click **(MSI Server)**, then select **Run as administrator**.
   3. See “Connect the MSI Client to a different MSI Server” on page 18.

2. Accept the End User License Agreement to continue.

3. In the **Login** dialog box, complete the factory sign-in information for the default Administrator:
   a. In the **User Name** field, enter **Administrator**.
   b. In the **Password** field, enter **Administrator**.
   c. Click **Log In**
4. Change the factory password for the default Administrator. See “Edit a user account” on page 60.
5. Review and update the system security settings. See “Configure system security” on page 64.

   IMPORTANT! The security settings (such as user name and password length) are applied only to new user accounts. The security settings for existing user accounts cannot be modified. If existing user accounts do not meet the new security settings criteria, you may not be able to edit the user account details.
6. Create user accounts and *(if needed)* user roles. See“Configure user accounts” on page 59 and “Configure user roles” on page 61.

Guidelines for uninstalling the software

When you uninstall the TrueMark™ MSI Analysis Software, the installer preserves the following user data and application files at the installation location:

- **MSI Client**—Saved audit records, exported files and reports saved in the default folder, and the client location preference
- **MSI Server**—Imported sample and batch data, imported coefficient files, audit records, security settings, the server location preference, archived batches, and all exports and reports stored in the default folders

If you need to uninstall the TrueMark™ MSI Analysis Software, follow these guidelines:

- **IMPORTANT!** To prevent data loss, do not manually delete these data and application files.

- **IMPORTANT!** Before uninstalling the TrueMark™ MSI Analysis Software, archive all batches that you want to preserve to a single ZIP file. You can use this ZIP file to restore the batches to the same or another computer when the software is reinstalled. For more information, see “Manage batches” on page 57.

3 Get started with the TrueMark™ MSI Analysis Software

Software access restrictions

- The TrueMark™ MSI Analysis Software allows up to five users to be signed in simultaneously. When that limit is reached, no other users are allowed to sign in.
- Your access to functions in the software is based on the permissions associated with your user account. For more information, see “User roles and permissions” on page 61.
- If your system is configured for password expiration, you will be periodically prompted to change your password.
- If your system is configured to monitor failed log in attempts, you will be locked out of the software if you incorrectly enter your user name or password more than the specified number of times.

Sign in to the TrueMark™ MSI Analysis Software (all users)

1. *(First sign-in only)* Obtain your user name and password from your TrueMark™ MSI Analysis Software Administrator.
2. On the computer desktop, double-click **(MSI Client)** to start the client.

   IMPORTANT! The MSI Server must already be running on the computer so that the client can connect to the server. The server is configured to automatically start whenever the computer is started.

   If you get a connection error when you start the client, you may need to manually start the server. Try each of the following actions to resolve the connection error; perform the actions in the order listed.

   1. On the computer desktop, double-click **(MSI Server)**.
   2. On the computer desktop, right-click **(MSI Server)**, then select **Run as administrator**.
   3. See “Connect the MSI Client to a different MSI Server” on page 18.
3. Enter your **User Name** and **Password**, then click **Log in**.
4. *(The first time that you sign in to a new MSI Client)* Accept the End User License Agreement to continue.

The first time that you sign in, the **Home** screen is empty. To begin using the software, you must import sample files (FSA). See “Import samples” on page 25.

Connect the MSI Client to a different MSI Server

Note: The MSI Client can connect to only one MSI Server at a time.

1. On the computer desktop, double-click **(MSI Client)** to start the client.

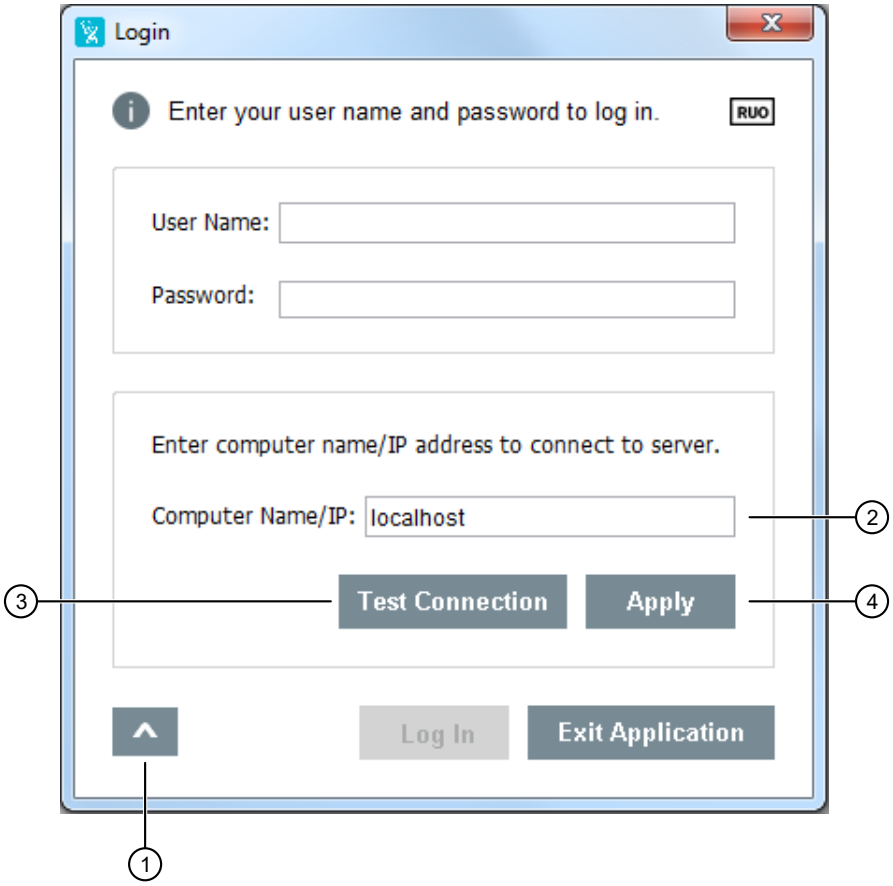
   Alternatively, if you are already signed in to the software: In the top-right corner of any screen, click the ***<user full name>*** dropdown list, select **Log Out**, then click **Yes** to confirm.

   The **Login** dialog box is displayed.
2. Click to expand the dialog box.
3. Enter a computer name or IP address for the MSI Server.
   - If the server and client are installed on the same computer, enter **localhost**.
   - If the server and client are installed on different computers, enter the name or IP address of the server computer.
4. Click **Test Connection**.

   If the connection is not successful, enter another host name or IP address, then click **Test Connection** again.

5. Click **Apply**.

6. When prompted, restart the client.



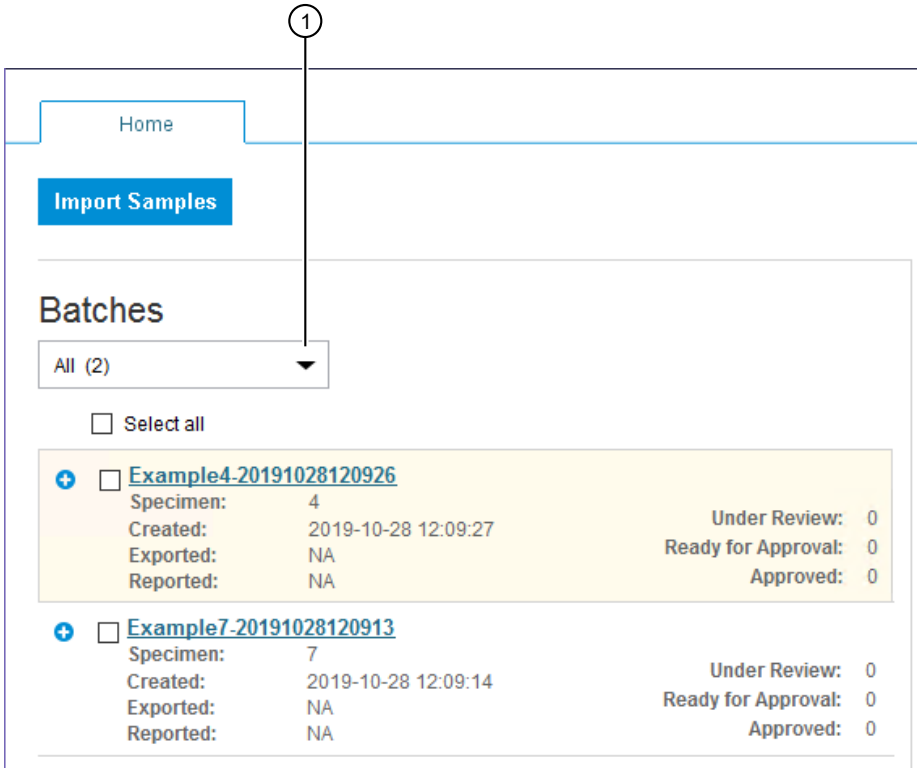
① Expand or collapse the dialog box.
② Enter the host name or IP address of the MSI Server.
③ Test the connection.
④ Apply the changes.

Filter the batches to display

1. Click the **Home** tab to display the **Home** screen (default view).
2. In the **Batches** pane, filter the batches to display.

Select...	To display...
All	All batches that have been imported into the TrueMark™ MSI Analysis Software.
New	Batches that contain only specimens that have not been reviewed. The **Review Status** for all specimens in the batch is **New**.
Under Review	Batches that contain specimens that are currently being reviewed. The **Review Status** for one or more specimens in the batch is **Under Review**.
Approved	Batches that contain only specimens that have been approved. The **Review Status** for all specimens in the batch is **Approved**.
Created Date	A dialog box. In the dialog box, specify start and end dates to view all batches that were imported into the TrueMark™ MSI Analysis Software within the specified date range.

Note: For more information, see Chapter 6, “(Optional) Accept and approve specimens”.



① Select an option to filter the batches that are displayed.

Quick check: View batch information in the Home screen

1. Click the **Home** tab to display the **Home** screen (default view).
2. *(Optional)* In the **Batches** pane, filter the batches to display. See “Filter the batches to display” on page 20.
3. View the following information in the **Batches** pane.

Item	Description
<Batch ID>	The batch name. Click the link to open the **Batch Summary** tab of the **Batch ID** screen.
Specimen	The total number of specimens in the batch.
Created	The date and time that the batch was imported into the TrueMark™ MSI Analysis Software.
Exported	The date and time of the most recent Export Results operation. For more information, see Chapter 7, “Export reports”.
Reported	The date and time of the most recent PDF Report operation. For more information, see Chapter 7, “Export reports”.
Under Review	The total number of specimens in the batch that are currently under review.
Ready for Approval	The total number of specimens in the batch that are ready to be approved.
Approved	The total number of approved specimens in the batch.

Quick check: View specimen information in the Home screen

1. Click the **Home** tab to display the **Home** screen (default view).
2. *(Optional)* In the **Batches** pane, filter the batches to display. See “Filter the batches to display” on page 20.
3. Click inside the row for the batch of interest to view the following information for each specimen in the batch (right pane).

Item	Description
Specimen ID	The unique name/number of a test event for one individual. Click the **Specimen ID** link to view detailed information for this specimen in the **Specimen Data** tab.
Overall Call	The overall MSI result for the specimen that is generated by the TrueMark™ MSI Analysis Software algorithms. • **MSS**—Microsatellite stable. The specimen's proportion of reporting markers calling **Unstable** is below the **MSI-Low Unstable Rate %** threshold. • **MSI-Low**—The specimen's proportion of reporting markers calling **Unstable** is between the **MSI-Low Unstable Rate %** and **MSI-High Unstable Rate %** thresholds. • **MSI-High**—The specimen's proportion of reporting markers calling **Unstable** is at or above the **MSI-High Unstable Rate %** threshold. • **No Call**—The MSI interpretation cannot be made because at least one reportable marker is reporting **No Call**. **Note:** You can change the **Overall Call** by editing individual marker results. See “View marker details and edit as needed” on page 37. The **MSI-Low Unstable Rate %** and **MSI-High Unstable Rate %** thresholds can be configured by any user with the **Analysis Settings** permission. See “Configure analysis settings” on page 54.
Review Flag	• ✔ **(OK)**—There are no reportable markers with a ⚠ **(Warning)** Review Flag. • ⚠ **(Warning)**—There is at least one reportable marker with a ⚠ **(Warning)** Review Flag. We recommend that you review these specimens in detail to confirm the automated interpretation. **Note:** For detailed information on the Review Flags, see “View marker details and edit as needed” on page 37.
Well Pair Status	The status of the sample pair. A sample pair is the Normal (**N**) and Tumor (**T**) tissue samples for the specimen. • **Match**—TH01 and PentaD markers have similar fragment sizes between the Normal and Tumor tissue samples, indicating that the samples likely belong to the same individual. • **Mismatch**—At least one of the two human identification markers is showing fragment sizes that appear inconsistent between the Normal and Tumor tissue samples. • **No Call**—The algorithm cannot determine the **Well Pair Status**. • <no value>—The specimen consists of only one sample; no paired sample comparison is available.
Well	The well location of the sample in the capillary electrophoresis (CE) plate.

(continued)

Item	Description
Review Status	The review status of the specimen through multiple review stages. • **New**—The specimen has not yet been reviewed, or a comment has not yet been added. • **Under Review**—The specimen is under review. When a reviewer adds a comment or clicks the **Accept** button in the **Specimen Data** ► **Review** tab of the **Batch Details** screen, a specimen moves to **Under Review**. • **Ready for Approval**—The specimen is ready to be approved. When a reviewer selects the **Ready for Approval** checkbox in the **Specimen Data** ► **Review** tab of the **Batch Details** screen, a specimen moves to **Ready for Approval**. • **Approved**—The specimen is approved. When the final reviewer clicks the **Approve** button in the **Batch Summary** screen, all **Ready for Approval** specimens move to **Approved**.

Sign out or exit the TrueMark™ MSI Analysis Software

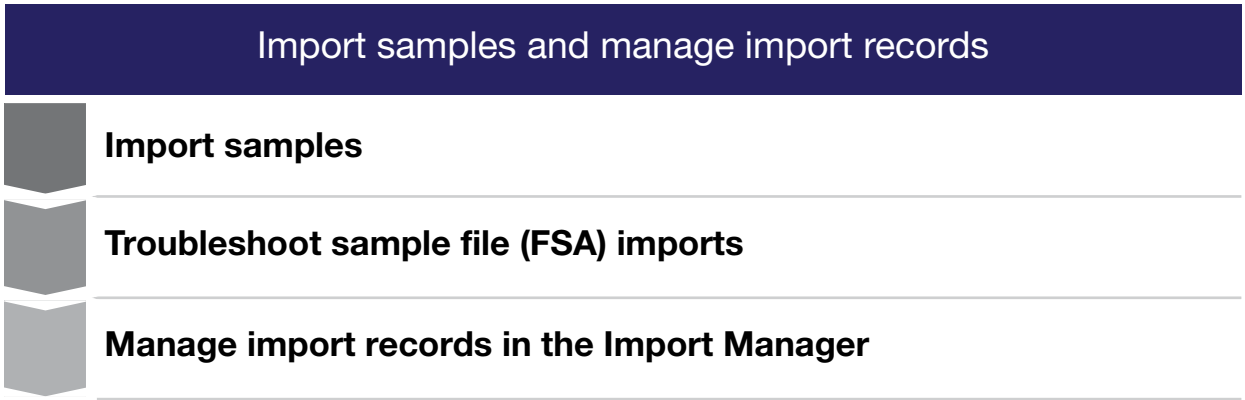
1. In the top-right corner of any screen, click the ***<user full name>*** dropdown list.
2. Sign out or exit, as required.

To...	Do this...
Sign out	Select **Log Out**, then click **Yes** to confirm.
Exit the application	Select **Exit**.

4 Import samples and manage import records

Import workflow

Note: A Technologist typically performs the import tasks, but your laboratory can assign these tasks to different user roles (see “Configure user roles” on page 61).



Import samples

When the instrument run is complete, import the sample files (FSA) into the TrueMark™ MSI Analysis Software.

Confirm that the sample file names are correct

To be successfully imported into the TrueMark™ MSI Analysis Software, the sample file (FSA) names must follow the correct naming conventions.

Confirm that the sample file (FSA) names meet the following conventions.

Sample type	File naming conventions	Guidelines
Specimen	For paired samples, the naming convention is: • `<SpecimenID>`_T _<*>.fsa—Tumor tissue sample • `<SpecimenID>`_N _<*>.fsa—Normal tissue sample from the same individual, adjacent to the Tumor tissue sample where: • `<SpecimenID>` is user-defined, but is identical in the Normal (**N**) and Tumor (**T**) tissue samples • `<*>` is user-defined	• The `<SpecimenID>` prefix identifies the specimen within the TrueMark™ MSI Analysis Software and exported file names. Ensure that the `<SpecimenID>` text does not include an underscore (_). • Within a batch, each `<SpecimenID>` must be unique, unless two files will be analyzed as a Tumor-Normal sample pair. If `<SpecimenID>` duplicates are detected, the software imports only the last file, in alphanumeric sort order. For example, if the files are named "SpecimenIDBlue_aaa.fsa" and "SpecimenIDBlue_zzz.fsa", the software imports only "SpecimenIDBlue_zzz.fsa". • **IMPORTANT!** The TrueMark™ MSI Analysis Software will not import a `<SpecimenID>`_N_<*>.fsa file if there is no matching `<SpecimenID>`_T_<*>.fsa file to import. However, a `<SpecimenID>`_T_<*>.fsa file will be imported even if there is no `<SpecimenID>`_N_<*>.fsa file to import. • **IMPORTANT!** If you are running replicate reactions on the same plate, assign the replicates a unique `<SpecimenID>` before the **_T** or **_N** to ensure that the replicates are processed correctly within the software. For example: – "Spec1.rep1_T" and "Spec1.rep1_N" – "Spec1.rep2_T" and "Spec1.rep2_N"
	For unpaired samples, the naming convention is: `<SpecimenID>`_<*>.fsa where: `<SpecimenID>` and `<*>` are user-defined	

(continued)

Sample type	File naming conventions	Guidelines
Negative control	NEG<*>.fsa where: <*> is user-defined **Note:** The TrueMark™ MSI Assay Amplification Control sample file name must begin with "NEG" to be properly analyzed. For example, "NEGAmp.1_A12_daytimestamp.fsa".	File names that begin with "NEG" are analyzed as negative control samples. The TrueMark™ MSI Analysis Software displays a (Warning) Review Flag if it assigns an **Unstable** call to any reportable marker for a negative control sample.
No template control	NTC<*>.fsa where: <*> is user-defined	File names that begin with "NTC" are no template control samples. The TrueMark™ MSI Analysis Software displays a (Warning) Review Flag if it assigns a call other than **No Call** to any reportable marker for a no template control sample.

Table 1 Examples of files that will or will not import

Files selected for import	Import result
20190917.plate1.tst123_T_A01_datetime.fsa	Tumor/Normal pair of files imported as <SpecimenID> "20190917.plate1.tst123"
20190917.plate1.tst123_N_A02_datetime.fsa	
20190924.plate1.sample1.tumor_T_A02.fsa	Unpaired Tumor file imported as <SpecimenID> "20190924.plate1.sample1.tumor"
20190924.plate1.sample1.normal_N_A01.fsa	Unpaired Normal file is not imported
20190924.plate1.sample1.normal_A01.fsa	Unpaired file imported as <SpecimenID> "20190924.plate1.sample1.normal"
specimen1_injection1.fsa	Both files have the same <SpecimenID>, "specimen1". The software imports only the last file, in alphanumeric sort order. In this example, the software imports only "specimen1_injection2.fsa".
specimen1_injection2.fsa	
specimen2_something.fsa, from the 3500/3500xL Genetic Analyzer	Both files imported as <SpecimenIDs> "specimen2" and "specimen3", because each <SpecimenID> is unique. A single batch can contain specimens from different plates and instrument types.
specimen3_something.fsa, from the SeqStudio™ Genetic Analyzer	
specimen4_T_something.fsa, from the 3500/3500xL Genetic Analyzer	Neither file imported, because Tumor/Normal pair of files from different instrument types is not supported.
specimen4_N_something.fsa, from the SeqStudio™ Genetic Analyzer	
HiDi_something.fsa	Files with HiDi prefix in filename are rejected

Import sample files

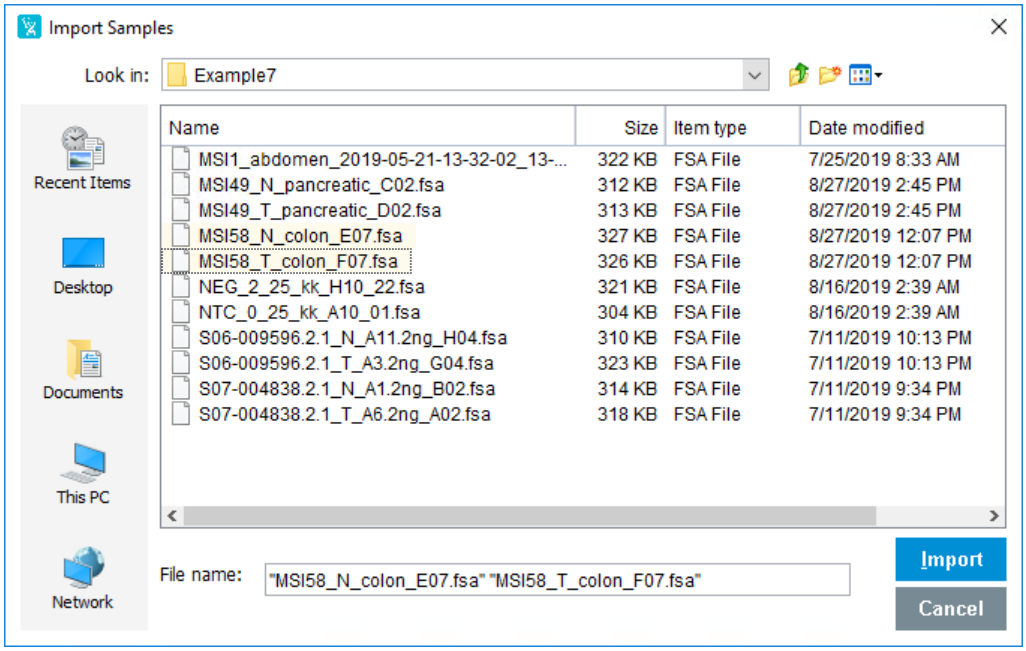
1. In the **Home** screen toolbar, click **Import Samples**.

2. Navigate to and select the sample files (FSA) to import.

   You can select a folder to import all sample files in the folder, or you can select individual sample files. If you select individual sample files, ensure that you select the normal (**N**) and tumor (**T**) sample files for paired samples.

IMPORTANT! We recommend that you group sample files from different injections or plates in separate folders. If you import tumor and normal sample files that have the same `<SampleID>` but are from different injections or plates into the same batch, the software may pair the samples, which increases the risk of a miscall (false positive).

WARNING! Do not import more than 96 sample files in a single import operation. Importing more than 96 sample files may cause some or all specimens in the batch to be miscalled.



The default location is:

`<installation drive>\Applied Biosystems\MSI Client\User Files\Import`

Note: To change the default save location, see “Configure locations for data” on page 53.

3. Click **Import**.

4. In the **Batch Information** dialog box, enter a **Batch Name**, *(optional)* enter the **Instrument ID** and **Operator**, then click **Save**.

Note: It may take several minutes to complete the import process.

The TrueMark™ MSI Analysis Software automatically analyzes the samples at import, using the current analysis settings. The results are displayed in the **Home** screen.

To change the analysis settings, see “Configure analysis settings” on page 54.

IMPORTANT! Changes to the analysis settings apply only to batches that are imported after you save the changes. To reanalyze samples with new analysis settings, import the samples again into a new batch. Changes do not affect existing batches.

Refresh the batch list

In the **Home** screen, the **Batches** pane displays a list of all imported batches. We recommend refreshing the batch list:

- If users from another MSI Client access the same MSI Server while your application is open
- If there is a connectivity error (for example, the connection between the MSI Client and MSI Server is lost)

To refresh:

In the **Home** screen, click **Refresh**.

The software updates the list of batches in the **Batches** pane.

Check for import errors

1. In the **Batches** pane of the **Home** screen, check that the number of imported specimens reflects the number of sample files (FSA) that you selected for import. Each specimen that has paired samples will have two sample files.
2. In the **Home** screen toolbar, check for a warning symbol ⚠ on the **Import Manager** button.
3. If the number of specimens and sample files do not agree, or if ⚠ appears on the **Import Manager** button, see “View details for each import” on page 29.

IMPORTANT! We recommend that you also check the electropherogram plot title to confirm that the expected sample files were selected for each specimen (see “View the electropherogram plots” on page 35). If you import tumor and normal sample files that have the same `<SampleID>` but are from different injections or plates into the same batch, the software may pair the samples, which increases the risk of a miscall (false positive).

View details for each import

1. In the **Home** screen toolbar, click **Import Manager**.

2. *(Optional)* In the **Import Manager**, select an option to filter the batches that are displayed.

Option	Description
Not Completed	Displays all batches that contain one or more sample files (FSA) that were not successfully imported into the TrueMark™ MSI Analysis Software.
Completed	Displays all batches that contain only sample files that were successfully imported into the TrueMark™ MSI Analysis Software.
All	Displays all batches that were imported into the TrueMark™ MSI Analysis Software: **Completed** and **Not Completed**.

3. View details for each batch:

Column	Description
Status	The status of the import: • **Complete**—All the sample files in the batch were imported. • **Incomplete**—Not all the sample files in the batch were imported. • **Acknowledged**—Not all the sample files in the batch were imported, but a user has acknowledged the **Incomplete** import.
Import ID	An internal ID used by the TrueMark™ MSI Analysis Software.
Batch Name	The name of the batch. By default, the batch name is the name of the folder that contains the sample files. However, you can assign a different name when you start the import.
Date of Import	The date and time that the batch was imported into the TrueMark™ MSI Analysis Software.
Total Files	The total number of sample files (FSA) in the batch.
Files Imported	The number of sample files (FSA) in the batch that were successfully imported into the TrueMark™ MSI Analysis Software.
Files Failed	The number of sample files (FSA) in the batch that were not imported into the TrueMark™ MSI Analysis Software.
User Name	The TrueMark™ MSI Analysis Software **User Name** of the person who imported the batch.
Source	How the batch was imported into the TrueMark™ MSI Analysis Software. This will always display **MANUAL**.

4. If the status of a batch is **Incomplete**, click ⊕ to view the **File Name**, **Error Message**, and **Corrective Action** for each sample file that was not successfully imported. For more information, see “Troubleshoot sample file (FSA) imports” on page 30.

Troubleshoot sample file (FSA) imports

If an error message is displayed during the import process, perform the appropriate corrective action.

Software message or action	Description	Corrective action
File has been corrupted.	The imported sample file may have been modified or corrupted.	Import the original sample file, which has not been not modified or corrupted.
File rejected due to duplicate specimen name detected.	There are multiple replicate sample files for the same `<SpecimenID>`. The software imports only the last file, in alphanumeric sort order. For example, if the files are named "SpecimenIDBlue_aaa.fsa" and "SpecimenIDBlue_zzz.fsa", the software imports only "SpecimenIDBlue_zzz.fsa".	Import only one Tumor and one Normal sample for a Specimen ID. If there are replicates, rename the replicate pair accordingly.
No matching tumor File.	The `<SpecimenID>`_N _<*>.fsa file is not paired with a `<SpecimenID>`_T _<*>.fsa file.	Import both the normal and tumor sample files. To import an unpaired `<SpecimenID>`_N _<*>.fsa file, remove "_N_" from the file name.
No files in batch were imported because at least one file has low size match quality.	The sample file failed automatic sizing on import. Files are resized upon import. The failure of one file to meet the size quality threshold may prevent any file in the batch from being imported.	Exclude samples with low size quality, then repeat the import. **Note:** If the instrument run time is shorter than specified for the assay, the sample is likely to fail automated sizing on import.
Only .fsa file with 6dye Dye Set are supported.	The sample file does not have 6 dyes.	See the *TrueMark™ MSI Assay User Guide* for information on creating supported sample files.
File is not supported.	The sample file is a HiDi<*>.fsa file.	No action available.
Instrument Model mismatch between Tumor and Normal files.	The matched `<SpecimenID>`_N _<*>.fsa and `<SpecimenID>`_T _<*>.fsa files are not from the same instrument type.	No action available.

Manage import records in the Import Manager

Resubmit or acknowledge Incomplete imports

1. In the **Home** screen toolbar, click **Import Manager**.
2. At the top-left of the **Import Manager**, select **Not Completed** from the dropdown list.
   Only batches that contain one or more sample files (FSA) that were not successfully imported are displayed in the table. (The **Status** column displays *Incomplete*.)
3. Select the batch of interest.
4. Click **+** to display the **File Name**, **Error Message**, and **Corrective Action** columns for each sample file in the batch that failed to import.
5. Perform the appropriate action:

If a sample file failed to import...	Do this...
Because of a connectivity error.	Click **Resubmit**. **Note:** Most of the time, the import automatically resumes as soon as the MSI Server is reconnected.
For any other reason. For example, sample files that are corrupt or not run with the TrueMark™ MSI Assay cannot be imported.	Click **Acknowledge**. **Acknowledge** confirms that you have been notified that a sample file cannot be imported, and that there is no corrective action that can be taken.

Delete import records from the Import Manager

You can delete import records that have a status of **Complete** or **Acknowledged**. You cannot delete import records that have a status of **Incomplete**.

Note: The delete function removes an import record from the **Import Manager**. It does not delete the batch (or any of its sample files) from the TrueMark™ MSI Analysis Software. To delete batches from the TrueMark™ MSI Analysis Software, see “Archive and (optionally) purge batches” on page 57.

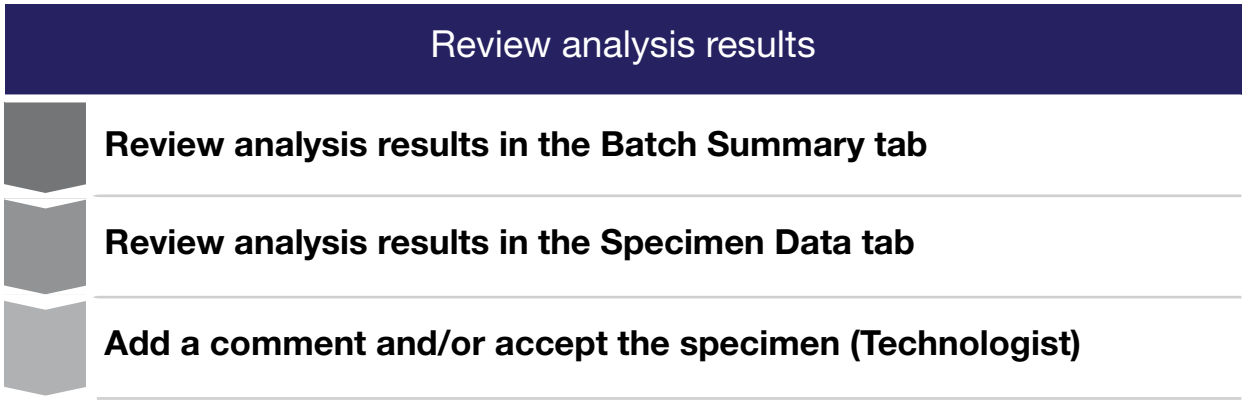
1. In the **Home** screen toolbar, click **Import Manager**.
2. At the top-left of the **Import Manager**, select **Completed** from the dropdown list.
   Only batches that contain only sample files (FSA) that were successfully imported or acknowledged are displayed in the table. (The **Status** column displays **Complete** and/or **Acknowledged**.)
3. Select a **Complete** and/or **Acknowledged** import record to delete.
4. Click **Delete**, then click **OK** to confirm the deletion.

   Note: The **Delete** button is disabled if the status of an import record is **Incomplete**.

5 Review analysis results

Review analysis results workflow

Note: A Technologist or Director typically reviews the analysis results, but your laboratory can assign these tasks to different user roles (see “Configure user roles” on page 61).



Review analysis results in the Batch Summary tab

1. In the **Batches** pane of the **Home** screen, select a batch, then click the <*Batch ID*> link.
   The software displays the **Batch Summary** tab for the selected batch.

2. View analysis results for the batch.

Item	Description
Specimen ID	The unique name/number of a test event for one individual. Click the **Specimen ID** link to view detailed information for this specimen in the **Specimen Data** tab.
Overall Call	The overall MSI result for the specimen that is generated by the TrueMark™ MSI Analysis Software algorithms. • **MSS**—Microsatellite stable. The specimen's proportion of reporting markers calling **Unstable** is below the **MSI-Low Unstable Rate %** threshold. • **MSI-Low**—The specimen's proportion of reporting markers calling **Unstable** is between the **MSI-Low Unstable Rate %** and **MSI-High Unstable Rate %** thresholds. • **MSI-High**—The specimen's proportion of reporting markers calling **Unstable** is at or above the **MSI-High Unstable Rate %** threshold. • **No Call**—The MSI interpretation cannot be made because at least one reportable marker is reporting **No Call**. **Note:** You can change the **Overall Call** by editing individual marker results. See “View marker details and edit as needed” on page 37. The **MSI-Low Unstable Rate %** and **MSI-High Unstable Rate %** thresholds can be configured by any user with the **Analysis Settings** permission. See “Configure analysis settings” on page 54.
Unstable	The number of unstable markers in the specimen. Edited marker calls (**Manual Call**) are included. Markers with **Include value of 'No'** are not included.
Stable	The number of stable markers in the specimen. Edited marker calls (**Manual Call**) are included. Markers with **Include value of 'No'** are not included.
No Call	The number of MSI markers in the specimen that have no call. Edited marker calls (**Manual Call**) are included. Markers with **Include value of 'No'** are not included.
Total	The total number of MSI markers in the specimen. MSI markers with **Include value of 'No'** are not included.
Review Flag	• ✔ **(OK)**—There are no reportable markers with a ⚠ **(Warning)** Review Flag. • ⚠ **(Warning)**—There is at least one reportable marker with a ⚠ **(Warning)** Review Flag. We recommend that you review these specimens in detail to confirm the automated interpretation. **Note:** For detailed information on the Review Flags, see “View marker details and edit as needed” on page 37.

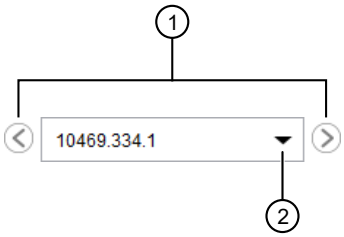
(continued)

Item	Description
Well Pair Status	The status of the sample pair. A sample pair is the Normal (**N**) and Tumor (**T**) tissue samples for the specimen. • **Match**—TH01 and PentaD markers have similar fragment sizes between the Normal and Tumor tissue samples, indicating that the samples likely belong to the same individual. • **Mismatch**—At least one of the two human identification markers is showing fragment sizes that appear inconsistent between the Normal and Tumor tissue samples. • **No Call**—The algorithm cannot determine the **Well Pair Status**. • <no value>—The specimen consists of only one sample; no paired sample comparison is available.
Well	The well location of the sample in the capillary electrophoresis (CE) plate.
Review Status	The review status of the specimen through multiple review stages. • **New**—The specimen has not yet been reviewed, or a comment has not yet been added. • **Under Review**—The specimen is under review. When a reviewer adds a comment or clicks the **Accept** button in the **Specimen Data ► Review** tab of the **Batch Details** screen, a specimen moves to **Under Review**. • **Ready for Approval**—The specimen is ready to be approved. When a reviewer selects the **Ready for Approval** checkbox in the **Specimen Data ► Review** tab of the **Batch Details** screen, a specimen moves to **Ready for Approval**. • **Approved**—The specimen is approved. When the final reviewer clicks the **Approve** button in the **Batch Summary** screen, all **Ready for Approval** specimens move to **Approved**.
Edited?	• **No**—The TrueMark™ MSI Analysis Software automated call has not been edited. • **Yes**—A specimen's **Overall Call** has been edited as follows: – A user specified a **Manual Call** for a marker that is different from the automated call *and/or* – A user changed the **Include** state of a marker
Comment	Use this field to enter and edit comments for the specimen. Comments appear in exports and reports for this specimen.

Review analysis results in the Specimen Data tab

1. In the right pane of the **Home** screen, click a `<Specimen ID>` link.
   The software displays the **Specimen Data** tab for the selected specimen.

2. To select a different specimen, use the arrows or dropdown list at the top-right of the screen.



① Scroll through the specimens
② Select a specific specimen

View the electropherogram plots

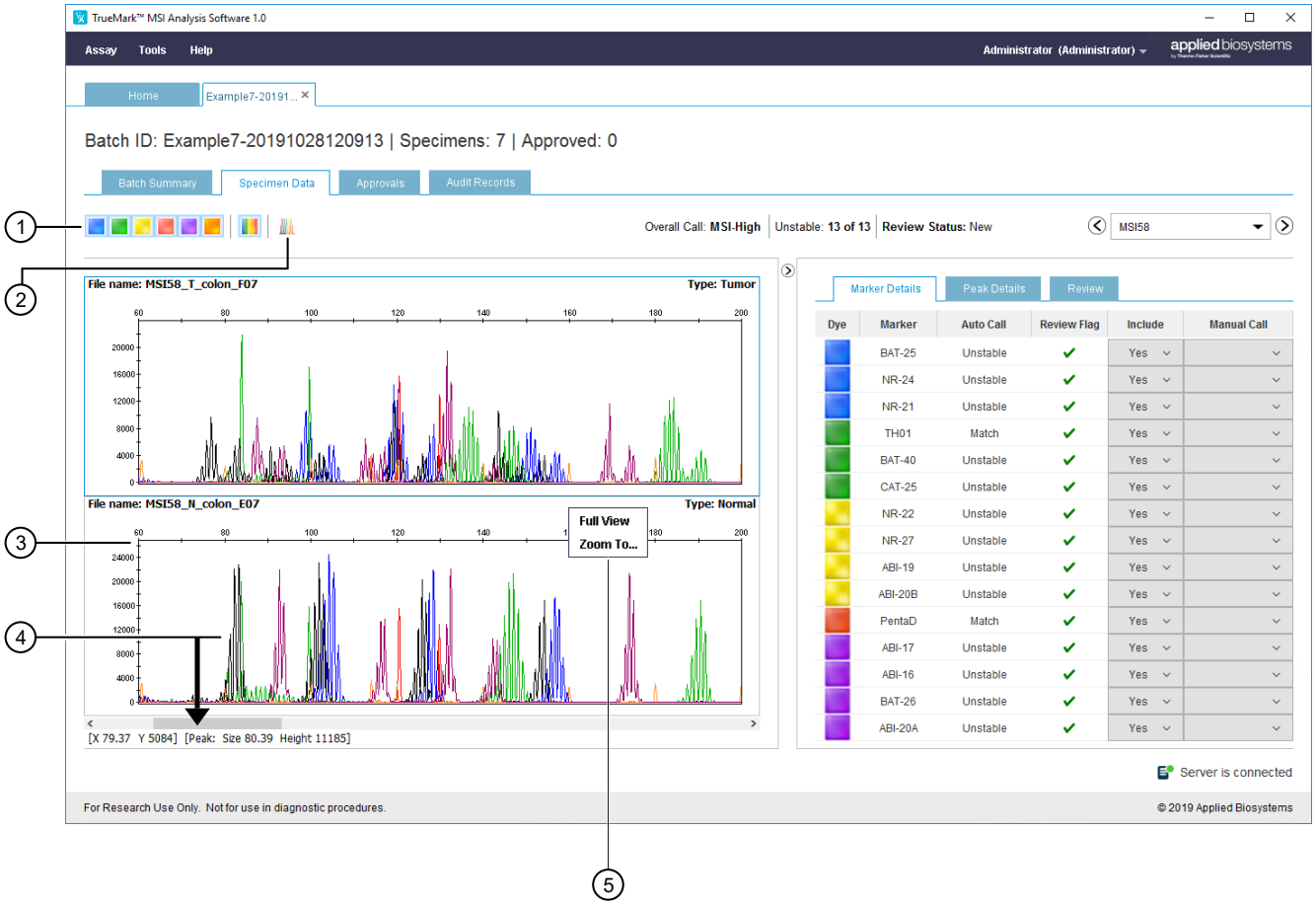
1. In the **Specimen Data** tab, view the electropherogram plot(s) for the selected specimen.
   - Paired samples display two plots (**Tumor** and **Normal**); unpaired samples display one plot.
   - Each plot displays capillary electrophoresis (CE) data for the TrueMark™ MSI Assay, plotted with Relative Fluorescent Units (RFU) on the Y-axis and size (bases) on the X-axis.

2. *(Recommended for paired samples)* Check the electropherogram plot titles to confirm that the expected sample files were selected for each specimen.

Note: If you import tumor and normal sample files that have the same `<SampleID>` but are from different injections or plates into the same batch, the software may pair the samples, which increases the risk of a miscall (false positive)

---

3. Use the buttons at the top of the plot to configure the view.



① Marker toggle buttons:

- **Blue Dye**—Display BAT-25, NR-21, and/or NR-24 markers
- **Green Dye**—Display BAT-40, CAT-25, and/or TH01 markers
- **Yellow Dye**—Display NR-22, NR-27, ABI-19, and/or ABI-20B markers; in the plot, yellow is displayed as black
- **Red Dye**—Display PentaD markers
- **Purple Dye**—Display BAT-26, ABI-16, ABI-17, and/or ABI-20A markers
- **Orange Dye**—Display the size standard (to call peaks)
- **All Dyes**—Display all dyes in the marker panel

② **Overlay All** toggle button—Display the **Normal** and **Tumor** samples together.

③ Hold the pointer over the X- or Y-axis, then drag the magnifying glass to zoom in to a specific range.

④ Hold the pointer over any peak in the plot to view the peak size and height.

⑤ To enter a X-axis range, right-click above a plot, then select **Zoom To**. To enter a maximum Y value, right-click to the left of a plot, then select **Zoom To**.

View marker details and edit as needed

1. In the **Specimen Data** tab, click the **Marker Details** tab (default view).
2. View the marker details for the selected specimen.

Column	Description
Dye	The fluorescent channel in which the marker is detected.
Marker	Each microsatellite region tested.
Auto Call	The automated interpretation at each mononucleotide-repeat microsatellite marker using the TrueMark™ MSI Analysis Software algorithm.
	For microsatellite markers: • **Unstable** —The tumor tissue sample has a detected allele that is measurably different from the normal tissue sample. The normal allele peak pattern is obtained from the normal tissue sample for paired analysis, and from the expected peak pattern for unpaired analysis. • **Stable** —The tumor tissue sample does not have detectable alterations at the marker that meet the criteria for instability. • **No Call** —The marker failed a quality check, preventing the automated assignment of an interpretive result.
	For TH01 or PentaD human identification markers: • **Mismatch**—Fragment sizes are not consistent between paired sample files at the marker. • **Match**—Fragment sizes are consistent between paired sample files at the marker. • **No Call** —The marker failed a quality check, preventing the automated assignment of an interpretive result. • Blank—No result is available for unpaired samples.
Review Flag	• ✔ **(OK)**—The call is expected for the specimen type. You may want to review the marker in detail to confirm the automated interpretation. • ⚠ **(Warning)**—The call is not expected for the specimen type. We recommend that you review the marker in detail to confirm the automated interpretation. The ⚠ Review Flag occurs if one or more of the following conditions exist: – There is reduced certainty in the call because of patterns observed in the signals associated with the marker – There is an off-scale indicator (a pink band in the electropherogram) inside the marker's size range – The specimen type is **NEG** and the **Auto Call** is not **Stable** – The specimen type is **NTC** and the **Auto Call** is not **No Call** – The specimen type is not **NTC** and the **Auto Call** is **No Call** – The **Auto Call** for the TH01 or PentaD human identification marker is **Mismatch**

IMPORTANT! The specimen's **Overall Call** is **No Call** if at least one included microsatellite marker's final call is **No Call**. To force an interpretive result for the specimen, each microsatellite marker's **No Call** must be changed by making a manual call (step 5) or by excluding it from reporting (step 4).

3. To display a specific marker in the electropherogram at left, click a marker row.

4. *(As needed)* In the **Include** column, select an option from the dropdown list.

   - **Yes**—Includes the marker when determining the **Overall Call** for the specimen and specimen summary statistics, and includes the marker in exports and reports.
   - **No**—Excludes the marker when determining the **Overall Call** for the specimen and specimen summary statistics, and excludes the marker from exports and reports. The human identification markers cannot be excluded.

Note: To change the markers that are included in the analysis, see "Configure analysis settings" on page 54.

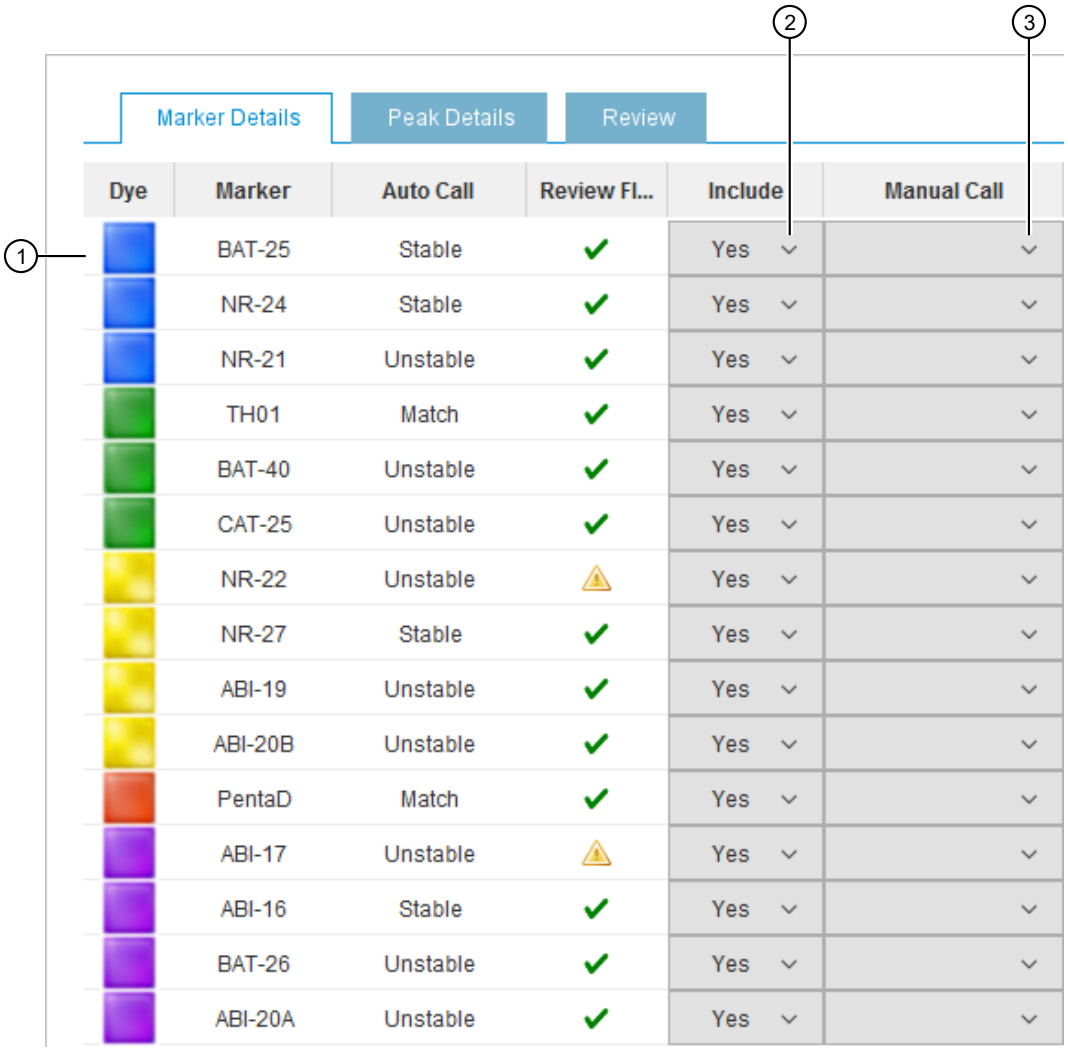
IMPORTANT! Changes to the analysis settings apply only to batches that are imported after you save the changes. To reanalyze samples with new analysis settings, import the samples again into a new batch. Changes do not affect existing batches.

---

5. *(As needed)* In the **Manual Call** column, select an option from the dropdown list to override the **Auto Call**.

   - For microsatellite markers, select **Unstable**, **Stable**, or **No Call**.
   - For TH01 or PentaD human identification markers, select **Mismatch**, **Match**, or **No Call**.

   To revert back to the **Auto Call**, select **Clear Manual Call**.



① Click a marker row to display the marker in the electropherogram.
② Select an option from the dropdown list to include or exclude the marker.
③ Select an option from the dropdown list to override the **Auto Call**.

IMPORTANT! If the connection to the MSI Server is slow, it may take time to update manual call or include/exclude changes. Look for the **Active** spinner in the bottom-right of the screen; avoid making multiple changes while the **Active** spinner is displayed because there is a risk that some changes will not be saved to the MSI Server.

IMPORTANT! If multiple users edit the same batch at the same time, there may be unexpected behavior in some views. If this happens, close the batch until the other user has completed their edits.

View peak details

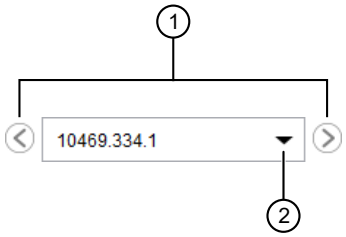
1. In the **Specimen Data** tab, click the **Peak Details** tab.
2. View the peak details for the selected specimen.

Column	Description
Dye	The fluorescent channel in which the marker is detected.
Marker	Each microsatellite region tested.
Size	The size (in bases) of the strongest peaks within the marker region.
Height	The signal intensity (in Relative Fluorescent Units, RFU) of the strongest peak within the marker region.
Sample Filename	The name of the file.

Add a comment and/or accept the specimen

You must have **Initial Review** permission in the TrueMark™ MSI Analysis Software.

1. In the right pane of the **Home** screen, click a `<Specimen ID>` link.
   The software displays the **Specimen Data** tab for the selected specimen.
2. To select a different specimen, use the arrows or dropdown list at the top-right of the screen.



① Scroll through the specimens
② Select a specific specimen

3. Click the **Review** tab.
4. To add a comment: Click **Add Comment**, enter comments, then click **Save**.
   Your comment is displayed in the **Review** tab, and the **Review Status** changes to **Under Review**.
5. To accept a review: Click **Accept** to acknowledge that you have reviewed the specimen.
   The comment **Accepted** is displayed, and the **Review Status** changes to **Under Review**.

6 *(Optional)* Accept and approve specimens

Accept and approve workflow

Note: A Director typically accepts and approves the specimens. However, your laboratory can assign these tasks to different user roles (see "Configure user roles" on page 61).

(Optional) Accept and approve specimens

Accept the review and move the specimen to Ready for Approval (Director)

Approve a specimen

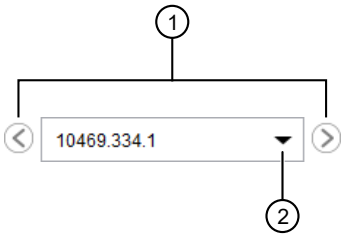
Export an Approvals Report (PDF file)

Accept the review and move the specimen to Ready for Approval

You must have **Initial Review** and **Final Review** permissions in the TrueMark™ MSI Analysis Software.

1. In the right pane of the **Home** screen, click a `<Specimen ID>` link.
   The software displays the **Specimen Data** tab for the selected specimen.

2. To select a different specimen, use the arrows or dropdown list at the top-right of the screen.



① Scroll through the specimens
② Select a specific specimen

3. Click the **Review** tab.

4. *(Optional)* Click **Add Comment**, enter comments, then click **Save**.
   Your comment is displayed in the **Review** tab, and the **Review Status** changes to **Under Review**.

5. Click **Accept** to acknowledge that you have reviewed the specimen.
   The comment **Accepted** is displayed, and the **Review Status** changes to **Under Review**.

6. Select the **Ready for Approval** checkbox.
   The **Review Status** changes to **Ready for Approval**.

Approve a specimen

You must have **Approve Sample** permission in the TrueMark™ MSI Analysis Software.

1. In the **Batches** pane of the **Home** screen, select a batch, then click the *<Batch ID>* link.
   The software displays the **Batch Summary** tab for the selected batch.

2. Click **Approve**.

Note: You can approve only specimens with a **Review Status** of **Ready for Approval**. If no specimens are **Ready for Approval**, the **Approve** button is inactive.

---

3. Enter your username and password, *(optional)* enter a comment, then click **Approve**.

Note: Your comments are displayed in the **Batch Summary** tab and in the **Review** tab of the **Specimen Data** tab.

---

4. Click **OK** to close the confirmation message.
   The status for all **Ready for Approval** specimens in the batch changes to **Approved**.

   IMPORTANT! Users cannot edit an approved specimen.

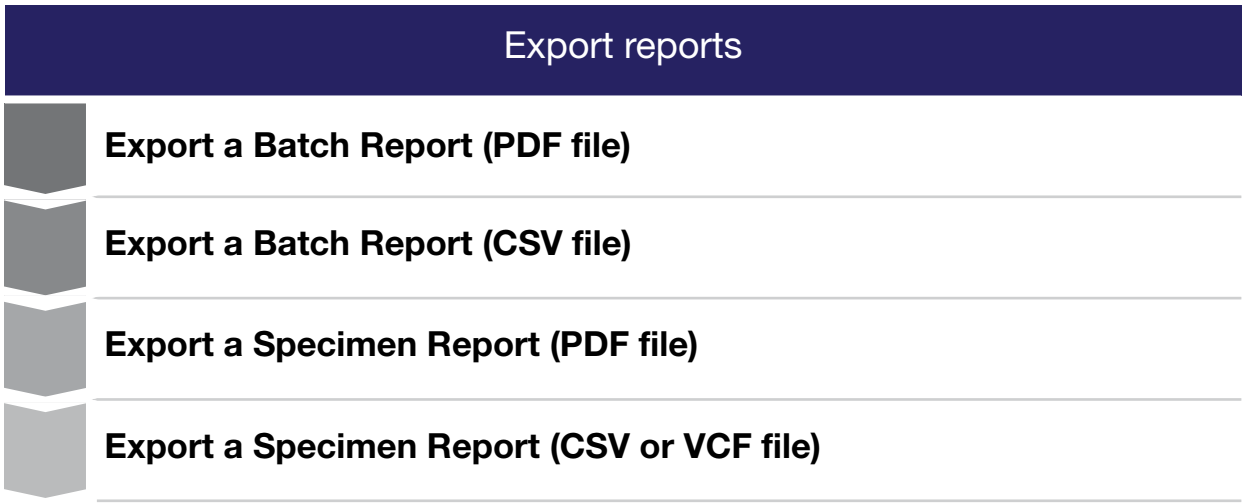
Export an Approvals Report (PDF file)

1. In the **Batches** pane of the **Home** screen, select a batch, then click the <*Batch ID*> link.
   The software displays the **Batch Summary** tab for the selected batch.
2. Click the **Approvals** tab to view all approved specimens in the selected batch.
3. Click **Report Approvals**.
4. Click **Open folder location** to view the Approvals Report (PDF file). The software exports one Approvals Report for all approved specimens in the batch.
   The default location is:
   `<installation drive>\Applied Biosystems\MSI Client\User Files\SecurityExport`

   Note: To change the default save location, see “Configure locations for data” on page 53.
5. Click **OK** to close the dialog box.

7 Export reports

Export reports workflow



Export a Batch Report (PDF file)

1. In the **Batches** pane of the **Home** screen, select a batch, then click the <*Batch ID*> link.
   The software displays the **Batch Summary** tab for the selected batch.
2. Click **PDF Report**, then select **Batch Summary**.
3. Click **Open folder location** to view the files.
   The default location is:
   `<installation drive>\Applied Biosystems\MSI Client\User Files\Report`

   Note: To change the default save location, see “Configure locations for data” on page 53.
4. Click **OK** to close the dialog box.

Export a Batch Report (CSV file)

1. In the **Batches** pane of the **Home** screen, select a batch, then click the <*Batch ID*> link.
   The software displays the **Batch Summary** tab for the selected batch.
2. Click **Export Results**, then select **Batch Summary (.csv)**.
3. Click **Open folder location** to view the files.
   The default location is:
   `<installation drive>\Applied Biosystems\MSI Client\User Files\Export`

   Note: To change the default save location, see “Configure locations for data” on page 53.
4. Click **OK** to close the dialog box.

Export a Specimen Report (PDF file)

1. In the **Batches** pane of the **Home** screen, select a batch, then click the <*Batch ID*> link.
   The software displays the **Batch Summary** tab for the selected batch.
2. Select the checkbox for each specimen to export a report for.

   Note: If you select multiple specimens, the TrueMark™ MSI Analysis Software generates a separate Specimen Report (PDF file) for each specimen.
3. Click **PDF Report**, then select **Specimen**.
4. Click **Open folder location** to view the files.
   The default location is:
   `<installation drive>\Applied Biosystems\MSI Client\User Files\Report`

Note: To change the default save location, see “Configure locations for data” on page 53.

5. Click **OK** to close the dialog box.

Export a Specimen Report (CSV or VCF file)

1. In the **Batches** pane of the **Home** screen, select a batch, then click the <*Batch ID*> link.
   The software displays the **Batch Summary** tab for the selected batch.
2. Select the checkbox for each specimen to export a report for.

   Note: If you select multiple specimens, the TrueMark™ MSI Analysis Software generates a separate Sample Report (PDF file) for each specimen.
3. Click **Export Results**, then select **Batch Summary (.csv)** or select **Batch Summary (.vcf)**.
4. Click **Open folder location** to view the files.
   The default location is:
   `<installation drive>\Applied Biosystems\MSI Client\User Files\Export`

   Note: To change the default save location, see “Configure locations for data” on page 53.
5. Click **OK** to close the dialog box.

8 Manage auditing

Batch and specimen auditing

Items audited

For batch and specimen auditing, the software automatically audits:

- Creation of a new batch
- Creation of a new specimens within an existing batch
- Changes in specimen review or approval status
- Addition of comments

Refresh the Audit Records tab

The **Audit Records** tab displays audit records for each batch imported into the TrueMark™ MSI Analysis Software.

To refresh:

1. In the **Batches** pane of the **Home** screen, select a batch, then click the <*Batch ID*> link.
   The software displays the **Batch Summary** tab for the selected batch.
2. Select the **Audit Records** tab.

3. In the **Audit Records** tab, click **Refresh**.
   The software updates the **Batch Records** list and the associated the **Audit Records** list.

4. To view more information for each audit record, click ⊕.

Table 2 Batch Records pane (left)

Item	Description
Audit Date	The date and time that the audited action occurred.
User Name	The name of the user who performed the action.
Host ID	The computer name of the MSI Server.
Batch Action	The action performed for the batch (for example, **Batch created**) .
Batch Action	The action performed for the specimen (for example, **No. of Specimens created**) .

Table 3 Audit Records pane (right)

Item	Description
ID	An internally generated audit record number.
Audit Date	The date and time that the audited action occurred.
Action	The action performed for the batch or specimen (for example, **Create Batch** or **Create Specimen**) .
Record Type	The type of record that the audit pertains to (for example, **Batch** or **Batch.Specimen**).
Attribute	Various values specific to the selected audit record (for example, **Created Date**).
Old Value	The old value of the attribute (if any).
New Value	The current value of the attribute.

Export audit records

1. In the **Batches** pane of the **Home** screen, select a batch, then click the <*Batch ID*> link.
   The software displays the **Batch Summary** tab for the selected batch.

2. Select the **Audit Records** tab.

3. In the **Batch Records** pane (left), select an event row.

   Note: You cannot select multiple events.

4. Export information for the selected event:
   - Click **Report Audit** to export audit information for all specimens in the selected batch.
   - Click **Export Summary** to export the summary information displayed in the **Batch Records** pane.
   - Click **Export Details** to export the summary information displayed in the **Batch Records** pane, plus the associated information displayed in the **Audit Records** pane (right).

5. Click the link to go to the save location and open the file or click **OK** to close the message.

   The default location is: `<installation drive>\Applied Biosystems\MSI Client\User Files\SecurityExport`

Note: To change the default save location, see “Configure locations for data” on page 53.

System auditing

System auditing restrictions

To access system auditing, you must have **Security and Auditing** permission in the TrueMark™ MSI Analysis Software.

Items audited

For system auditing, the software automatically audits:

- Changes to system configurations, for example:
  - User name and password settings (length, characters allowed, etc.)
  - Security policies (password expiration limits, allowed login attempts, etc.)
  - User account changes (create, edit, or delete functions)
  - User role changes (create, edit, or delete functions)
- System events, for example:
  - User logins and logouts
  - Session timeouts
  - Account suspensions
  - Sample file (FSA) imports

View and export system configuration history records

1. In the **Home** screen menu bar, select **Tools ▸ Security Settings**.
2. Select the **System** tab, then click **View System Audit**.
3. Select the **System Configuration History** tab.
4. Select the system configuration history records to export:

To export...	Do this...
All system-level auditing records (see “System auditing” on page 50)	Click **Report System Configuration History**.
Summary information for specific records **Note:** The summary information is displayed in the left table.	Select the records to export, then click **Export Summary**.
Summary information and associated details for specific records **Note:** The summary information is displayed in the left table. The associated details are displayed in the **Details** pane at right.	Select the records to export, then click **Export Details**.

5. Click the link to go to the save location and open the file or click **OK** to close the message.
   The default location is:

```
<installation drive>\Applied Biosystems\MSI Client\User
Files\SecurityExport
```

Note: To change the default save location, see “Configure locations for data” on page 53.

View and export system events

1. In the **Home** screen menu bar, select **Tools** ▸ **Security Settings**.
2. Select the **System** tab, then click **View System Audit**.
3. Select the **System Event** tab.
4. Select the system event records to export:

To export...	Do this...
All system event records	Click **Report System Events**.
Specific system event records	Select the records to export, then click **Export** .

5. Click the link to go to the save location and open the file or click **OK** to close the message.

   The default location is:

   ```
   <installation drive>\Applied Biosystems\MSI Client\User
   Files\SecurityExport
   ```

Note: To change the default save location, see “Configure locations for data” on page 53.

Archive system configuration history records or system events

The archive function saves a copy (.par file) of the system configuration history records or system events.

1. In the **Home** screen menu bar, select **Tools** ▸ **Security Settings**.
2. Select the **System** tab, then click **View System Audit**.
3. Select the tab of interest:
   - **System Configuration History** tab—Displays changes to system configurations (for example, user name and password settings).
   - **System Event** tab—Displays system events (for example, user logins and logouts).
4. Select the records to archive, then click **Archive**.
5. In the **Archive** dialog box, enter or select the save options, then click **Archive**.
6. In the **Purge archived records** dialog box, select the purge option:
   - **Yes**—Deletes the records from the **System Audit** screen after archiving them. Records that are archived before purging can be restored.
   - **No**—Archives the records without deleting them.

The default location is:
`<installation drive>\Applied Biosystems\MSI Client\User Files\SecurityExport`

Note: To change the default save location, see “Configure locations for data” on page 53.

7. Click **OK** to close the confirmation message.

Restore system configuration history records or system events

The restore function adds system configuration history records or system events that have been archived back into the **System Audit** screen.

1. In the **Home** screen menu bar, select **Tools** ▸ **Security Settings**.
2. Select the **System** tab, then click **View System Audit**.
3. Select the tab of interest:
   - **System Configuration History** tab—Displays changes to system configurations (for example, user name and password settings).
   - **System Event** tab—Displays system events (for example, user logins and logouts).
4. Click **Restore**.
5. In the **Restore** dialog box, browse to the .par file to restore, then click **Restore**. If any of the records in the file already exist in the system, you are prompted to overwrite or skip them.
6. Click **OK** to close the confirmation message.

Purge system records or events

IMPORTANT! The purge function permanently deletes the selected system configuration history records or system event. The purged records and events cannot be restored, unless they were previously archived (see “Archive system configuration history records or system events” on page 51).

1. In the **Home** screen menu bar, select **Tools** ▸ **Security Settings**.
2. Select the **System** tab, then click **View System Audit**.
3. Select the tab of interest:
   - **System Configuration History** tab—Displays changes to system configurations (for example, user name and password settings).
   - **System Event** tab—Displays system events (for example, user logins and logouts).
4. Select the records to purge.
5. Click **Purge**, then click **OK** to confirm the purge.
6. Click **OK** to close the confirmation message.

9 Set up and maintain the TrueMark™ MSI Analysis Software

Configure locations for data

Configure locations restrictions

To configure locations for data, you must have **Modify Preferences** permission in the TrueMark™ MSI Analysis Software.

Configure locations for MSI Client data

Configure the locations for the following data:

- **Manual Import**—Location for samples (FSA files) to import
- **Manual Report**—Location for generated Batch Reports
- **Manual Export**—Location for exported Batch Results
- **Security Export**—Location for exported security settings (user accounts, user roles, and system security); location for exported audit records, system configuration history records, and system events; location for archived system configuration history records and system events

1. In the menu bar, select **Tools** ▸ **Preferences**.
2. Select the **Client Locations** tab.
3. Select a save location:

To save data to the...	Do this...
Last folder used	Select **Use Last File Location**.
Folder displayed in the field	a. Select **Use Default Location**. b. *(If needed)* Click **Browse** to select a different location.

The default location is:

```
<installation drive>\Applied Biosystems\MSI Client\User Files
```

Note: To change the default save location, see “Configure locations for data” on page 53.

4. Click **Apply**, then click **OK** to close the confirmation message.
5. Click **OK** to close the dialog box.

To restore the software default settings, click **Restore Defaults**.

Configure locations for MSI Server data

You can configure locations for the MSI Server data only when the MSI Client and MSI Server are installed on the same computer. Otherwise, the options in the **Server Locations** tab are disabled.

Configure the location for **Archive** data, which is the location for archived batches.

1. In the menu bar, select **Tools** ▸ **Preferences**.
2. Select the **Server Locations** tab.
3. Select the location for archived batches (**Archive**): In the **Default Location** field, accept the default, or click **Browse** to select a different location.

   The default location is:

   `<installation drive>\Applied Biosystems\MSI Server\User Files`

Note: To change the default save location, see “Configure locations for data” on page 53.

4. Click **Apply**, then click **OK** to close the confirmation message.
5. Click **OK** to close the dialog box.

To restore the software default settings, click **Restore Defaults**.

Configure analysis settings

You must have **Analysis Settings** permission in the TrueMark™ MSI Analysis Software.

IMPORTANT! Changes to the analysis settings apply only to batches that are imported after you save the changes. To reanalyze samples with new analysis settings, import the samples again into a new batch. Changes do not affect existing batches.

1. Close any open `<Batch ID>` tabs.
2. In the menu bar, select **Assay** ▸ **Analysis Settings**.

   The **Analysis Settings** dialog box is displayed.

3. To change the markers that are included in the analysis, select or deselect the **Include** checkbox next to each marker.

   Included markers are used to calculate the **Overall Call** and summary statistics for a specimen. Included markers appear in reports and exports.

   Note: The human identification markers cannot be excluded.

4. To adjust the **MSI-Low Unstable Rate (%)** and **MSI-High Unstable Rate (%)**, move the pointers along the scale or enter a value in each field.

   The rates are the fraction of microsatellite markers that must be called **Unstable** in order to assign the **Overall Call** for a specimen. The software makes the following calls:

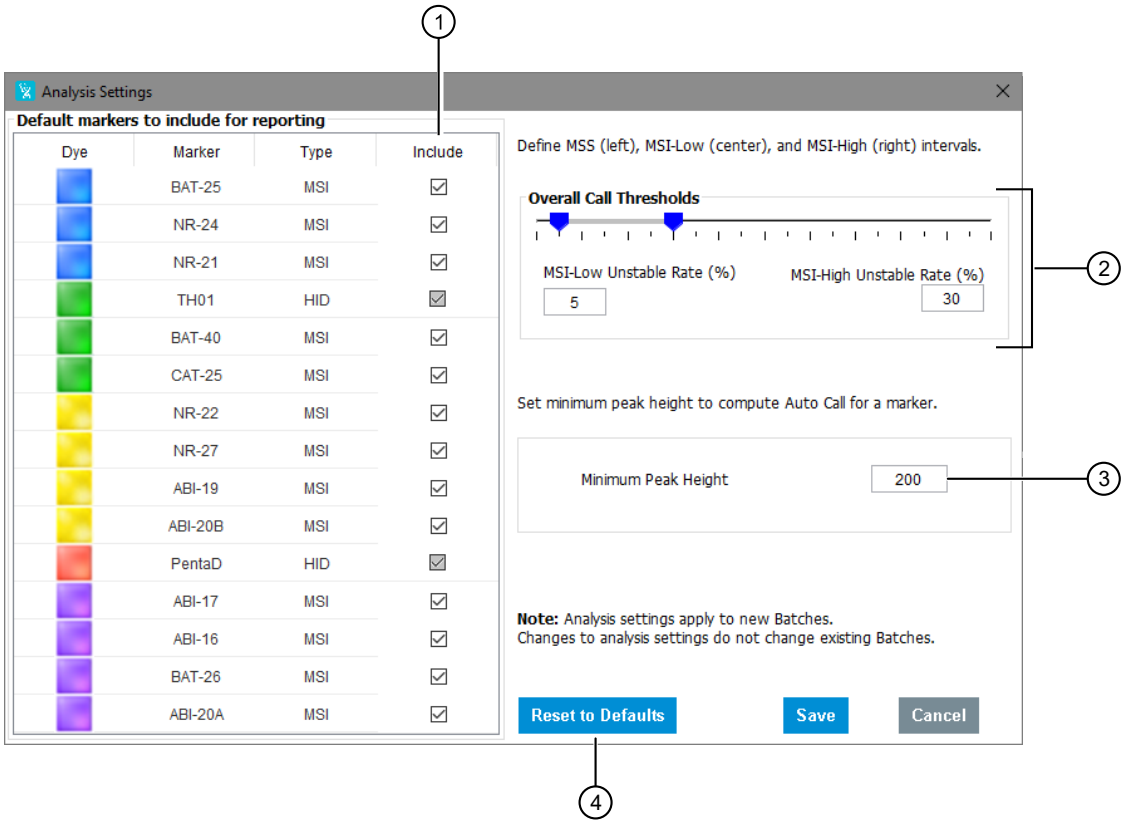
   - **MSS**, if the percentage of included MSI markers reporting **Unstable** is below the **MSI-Low Unstable Rate (%)**
   - **MSI-Low**, if the percentage of included MSI markers reporting **Unstable** is greater than or equal to the **MSI-Low Unstable Rate (%)** and less than the **MSI-High Unstable Rate (%)**
   - **MSI-High**, if the percentage of included MSI markers reporting **Unstable** is greater than or equal to the **MSI-High Unstable Rate (%)**

5. To set the minimum peak height for the highest peak in a marker region, enter a value in the **Minimum Peak Height** field.

   The minimum peak height setting is used to calculate the **Auto Call** for a marker.

   Note: The minimum peak height setting does not affect the set of peaks reported in the **Peak Details** table of the **Specimen Data** tab.

6. Click **Save** to save the changes and close the dialog box.



① Select the checkbox to include a marker in the analysis; deselect the checkbox exclude a marker from the analysis.
② Move the pointers or enter values to adjust the **MSI-Low Unstable Rate (%)** and **MSI-High Unstable Rate (%)**.
③ Enter a value to set the minimum peak height for the highest peak in a marker region.
④ Click to return to the factory default analysis settings.

To return to the factory default analysis settings, click **Reset to Defaults**. The default settings are listed in the following table.

Setting	Default
MSI-Low Unstable Rate (%)	5
MSI-High Unstable Rate (%)	30
Minimum Peak Height	200

Manage batches

Archive and *(optionally)* purge batches

- To archive batches, you must have **Archive/Restore** permission in the TrueMark™ MSI Analysis Software.
- To purge batches after archiving them, you must use the *default* Administrator role in the TrueMark™ MSI Analysis Software. The purge permission cannot be assigned to other user roles.

IMPORTANT! The software can store up to 500 batches at a time; be sure to archive, then purge, batches before exceeding the maximum storage capacity. We strongly recommend that the archive save location is a drive or directory that is regularly backed up by your IT department. For more information, see "Configure locations for MSI Server data" on page 54.

1. In the **Home** screen ▶ **Batches** pane, select the checkbox for each batch to archive.

   Note: If needed, you can filter the batches that are displayed. See "Filter the batches to display" on page 20.

2. From the menu bar, select **Tools** ▸ **Archive**.

3. In the dialog box, enter a name for the archive file.

4. *(Optional)* Select the **Purge batches after archiving** checkbox.

   Note: Purge removes the selected batches from the software immediately after the batches are archived. Purge does not delete the batches from the archive save location.

5. Click **OK**.

   The default location is:

   `<installation drive>\Applied Biosystems\MSI Server\User Files\Archive`

   Note: To change the default save location, see "Configure locations for data" on page 53.

   The software archives the selected batches and saves the archive file (ZIP) to the default save location. The archive may take several minutes to complete.

6. Click **OK** to close the confirmation message.

Restore batches

To restore batches:

- You must have **Archive/Restore** permission in the TrueMark™ MSI Analysis Software.
- The archive folder must contain the archive file (ZIP) and its associated checksum file (ZIP.TXT).

1. From the menu bar, select **Tools ▸ Restore**.
2. In the dialog box, select an archive file (ZIP) to restore, then click **OK**.
   The software restores all batches within the selected archive file. The restore may take several minutes to complete.
3. Click **OK** to close the confirmation message.

10 Manage software security

Security access restrictions

To access the **Security Settings** screen and perform the procedures in this chapter, the following restrictions apply.

- You must have **Security and Auditing** permission in the TrueMark™ MSI Analysis Software.
- You must close all open batches.

Configure user accounts

Create a user account

1. In the **Home** screen menu bar, select **Tools** ▸ **Security Settings**.
2. Select the **Users** tab, then click **Create**.
3. Enter a user name, password, first name, *(optional)* middle initial, and last name.

   IMPORTANT! You cannot change the user name after you save the user account.
4. Select a **User Role**: **Administrator**, **Director**, **Technologist**, or other user-defined role.
5. Select or deselect the **Password Expires at First Login** checkbox.
   If selected, the user must specify a new password at first sign in.
6. For **Status**, select **ACTIVE**.
7. *(Optional)* Enter a phone number, email address, and/or comments.

8. Click **Save**.

Note: A disabled **Save** button indicates an invalid entry in a field. Place the cursor over the yellow alert symbol to display the limits for the field, then enter a valid entry.
Field limits are specified in the **System** tab. To change field limits, see "Configure system security" on page 64.

Edit a user account

1. In the **Home** screen menu bar, select **Tools ▸ Security Settings**.
2. Select the **Users** tab, select the user account to edit, then click **Edit**.
3. In the dialog box, edit the settings if needed.

Note: Some fields may be disabled, depending on the user role. For example, only the password can be edited for the Administrator user role.

4. Click **Save** to save the changes and close the **Edit User Account** dialog box.

Note: A disabled **Save** button indicates an invalid entry in a field. Place the cursor over the yellow alert symbol to display the limits for the field, then enter a valid entry.
Field limits are specified in the **System** tab. To change field limits, see "Configure system security" on page 64.

Activate, inactivate, or suspend a user account

Note: You cannot delete a user account. Instead, set the account status to **INACTIVE**.

1. In the **Home** screen menu bar, select **Tools ▸ Security Settings**.
2. Select the **Users** tab, select a user account, then click **Edit**.
3. In the dialog box, select a **Status**:
   - **ACTIVE**—The user can access the software, according to his/her permissions.

     Note: Choose **ACTIVE** to activate new user accounts and to reactivate suspended or inactive accounts.
   - **INACTIVE**—The user cannot access the software.
   - **SUSPENDED**—The user made too many unsuccessful sign in attempts, and is temporarily locked out of the software.

     Note: To set time limits, see "Set security policies" on page 64.
4. Click **Save** to save the changes and close the **Edit User Account** dialog box.

Note: A disabled **Save** button indicates an invalid entry in a field. Place the cursor over the yellow alert symbol to display the limits for the field, then enter a valid entry.

Field limits are specified in the **System** tab. To change field limits, see “Configure system security” on page 64.

Save a Users Report

The Users Report contains account information for all system users (for example, the user name, full name, and user role).

1. In the **Home** screen menu bar, select **Tools** ▸ **Security Settings**.
2. Select the **Users** tab.
3. Click **Report Users**.
4. Click the link to go to the save location and open the file or click **OK** to close the message.
   The default location is:
   `<installation drive>\Applied Biosystems\MSI Client\User Files\SecurityExport`

Note: To change the default save location, see “Configure locations for data” on page 53.

Configure user roles

User roles and permissions

- Each user account in the TrueMark™ MSI Analysis Software is assigned a user *role*. The user role determines the permissions that are associated with the user account.
- Three default user roles are included in the TrueMark™ MSI Analysis Software: *Technologist*, *Administrator*, and *Director*. Table 4 describes the permissions that are assigned to each default user role.
- The permissions for the default Administrator role cannot be modified. However, your laboratory can assign different permissions to the default Technologist and Director roles, and create new user roles.

Table 4 Permissions

Category	Permission	Default user role		
		Administrator[1]	Director	Technologist
Review	Initial Review	No	Yes	Yes
	Final Review	No	Yes	No
Approve	Approve Sample	No	Yes	No
Preferences	Modify Preferences	Yes	No	No
	Analysis Settings	Yes	Yes	No

Table 4 Permissions *(continued)*

Category	Permission	Default user role		
		Administrator[1]	Director	Technologist
Security	**Security and Auditing**	Yes	No	No
Repository	**Archive/Restore** **Note:** Only the *default* Administrator role can purge batches after archiving them. The purge permission cannot be assigned to other user roles.	Yes	No	No

[1] The permissions for the default Administrator role cannot be modified.

Create a user role

1. In the **Home** screen menu bar, select **Tools ▸ Security Settings**.
2. Select the **Roles** tab, then click **Create**.
3. In the dialog box, enter a new role name and *(optional)* description.
4. Select permissions:

To assign...	Do this...
All permission categories	Select the **Select All Permissions** checkbox. **Note:** Only the *default* Administrator role can purge batches after archiving them. The purge permission cannot be assigned to other user roles.
All permissions in a category	Select the checkbox for each category to assign. For example, select the **Preferences** checkbox.
Specific permissions in a category	a. Click **+** to expand the category. b. Select the checkbox for each permission to assign. For example, click **+** next to the **Preferences** checkbox, then select the **Modify Preferences** checkbox.

5. Click **Save** to save the changes and close the **Create Role** dialog box.

Edit a user role

1. In the **Home** screen menu bar, select **Tools ▸ Security Settings**.
2. Select the **Roles** tab, select the user role to edit, then click **Edit**.

   Note: You cannot edit the Administrator user role.

3. In the dialog box, edit the role name and *(optional)* description.

4. Edit permissions:

To assign...	Do this...
All permission categories	Select the **Select All Permissions** checkbox.
All permissions in a category	Select the checkbox for each category to assign. For example, select the **Preferences** checkbox.
Specific permissions in a category	a. Click **+** to expand the category. b. Select the checkbox for each permission to assign. For example, click **+** next to the **Preferences** checkbox, then select the **Modify Preferences** checkbox.

5. Click **Save** to save the changes and close the **Edit Role** dialog box.

Delete a user role

You can delete only user roles that have no associated users. You cannot delete the default Administrator user role.

1. In the **Home** screen menu bar, select **Tools** ▸ **Security Settings**.
2. Select the **Roles** tab.
3. Select the user role to delete, then click **Delete**.
4. Click **Yes** to confirm the deletion, then click **OK** to close the confirmation message.

Save a User Roles Report

The User Roles Report contains role information for all system users (for example, the last time the role was modified and the number of users that have each role).

1. In the **Home** screen menu bar, select **Tools** ▸ **Security Settings**.
2. Select the **Roles** tab.
3. Click **Report Roles**.
4. Click the link to go to the save location and open the file or click **OK** to close the message.

   The default location is:

   `<installation drive>\Applied Biosystems\MSI Client\User Files\SecurityExport`

Note: To change the default save location, see “Configure locations for data” on page 53.

Configure system security

System security controls user access to the software.

Set user account limits

1. In the **Home** screen menu bar, select **Tools** ▸ **Security Settings**.
2. Select the **System** tab.
3. In the **User Names** pane, specify:
   - Length limits
   - Allowed spaces

   Note: If you allow spaces in user names, be aware of the following issues:
   - Leading spaces, trailing spaces, and the number of consecutive spaces in a user name are difficult to detect on the screen and in printed reports.
   - Spaces in user names may cause confusion when searching for an audit record associated with a user name. To find a record associated with a user name, you must specify the user name exactly, including leading, consecutive, and trailing spaces.
4. In the **User Passwords** pane, specify:
   - Length limits
   - Allowed spaces
   - Reuse limits
   - Allowed characters
5. Click **Apply Settings** to save the changes, then click **OK** to close the confirmation message.

Set security policies

The security policies include time limits for passwords, accounts, and sessions, and an option to open non-secure data.

1. In the **Home** screen menu bar, select **Tools** ▸ **Security Settings**.
2. Select the **System** tab.

3. Set the security policies, as required:

To set...	Do this...
Password Expiration	Specify password expiration, including when to notify a user before a password expires.
Account Suspension	Specify account suspension. A user account is suspended if the number of times a user attempts and fails to log in exceeds the limit.
Session Timeout	Specify session timeout. A session times out if the timeout period is exceeded and there is no user activity.

4. Click **Apply Settings** to save the changes, then click **OK** to close the confirmation message.

Import security settings

If you export the security settings from one installation of the TrueMark™ MSI Analysis Software, you can import those security settings into a second installation for fast setup.

1. In the **Home** screen menu bar, select **Tools** ▸ **Security Settings**.
2. Click **Import**.

   Note: You can click **Import** from any tab: **Users**, **Roles**, or **System**.

3. In the dialog box, browse to the .dat file to import, then click **Import**.
4. In the **Import** dialog box, select the settings to import:

To...	Do this...
Import all settings for user accounts, user roles, and system security (such as password limits, account suspension rules, and session timeouts)	Select **All**.
Limit the imported settings	a. Select **Custom**. b. Select the custom options: • Select the **Users & Roles** checkbox to import user and user role settings. *and/or* • Select the **System & Roles** checkbox to import user role and system security settings.

5. Click **OK**.

   If any settings exist in the system, you are prompted to overwrite or skip them.

6. Click **OK** to close the confirmation message.

Export security settings

We recommend exporting security settings for backup purposes. The exported files are encrypted.

1. In the **Home** screen menu bar, select **Tools** ▸ **Security Settings**.
2. Click **Export**.

   Note: You can click **Export** from any tab: **Users**, **Roles**, or **System**.

3. Select the settings to export:

To...	Do this...
Export all settings for user accounts, user roles, and system security (such as password limits, account suspension rules, and session timeouts)	Select **All**.
Limit the exported settings	a. Select **Custom**. b. Select the custom options: • Select the **Users & Roles** checkbox to export user and user role settings. *and/or* • Select the **System & Roles** checkbox to export user role and system security settings.

4. Click **OK** to open the **Export Security Settings** dialog box.
5. Enter or select the save options, then click **Export** to export the DAT file.

   Note: If the file exists in the save location, you are prompted to overwrite or cancel the export.

   The default location is:

   ```
   <installation drive>\Applied Biosystems\MSI Client\User
   Files\SecurityExport
   ```

   Note: To change the default save location, see “Configure locations for data” on page 53.

6. Click **OK** to close the confirmation message.

Acknowledge or ignore security-related system events

Security-related system events

The TrueMark™ MSI Analysis Software records the following system events related to security.

- **User did not enter correct password**—A user attempted to sign in with an incorrect password.
- **User account suspended**—A user exceeded the maximum number of sign-in attempts with an incorrect password, resulting in a suspended account.
- **User session timed out**—No activity occurred in a user account for the specified period of inactivity.

When a user with the Administrator role signs in, the software displays a list of the security-related system events in the **Show Security Events** dialog box.

Acknowledge or ignore security-related system events

To view the **Show Security Events** dialog box, you must have the Administrator role in the TrueMark™ MSI Analysis Software.

1. Start the TrueMark™ MSI Analysis Software.
   The software displays the **Show Security Events** dialog box.

2. Acknowledge or ignore the events:

To...	Do this...
Acknowledge events	Select the events to acknowledge, then click **Acknowledge** to remove the selected events from the list and close the dialog box.
Ignore events	Click **Close** to close the dialog box without acknowledging the events. Events continue to appear in the **Show Security Events** dialog box until they are acknowledged.

To view previous security-related system events, see “View and export system events” on page 51.

A Troubleshooting

Shut down the MSI Server

The MSI Server is configured to automatically start whenever you start your computer. You may need to shut down the server to troubleshoot connection issues.

1. In Windows™ 10, press **Ctrl+Shift+Esc** to open the **Task Manager**.
2. Click the **Services** tab.
3. Right-click **MSIServerSoftwareService**, then select **Stop**.

B Representative data

Examples of microsatellite instability in colon tumor tissue samples

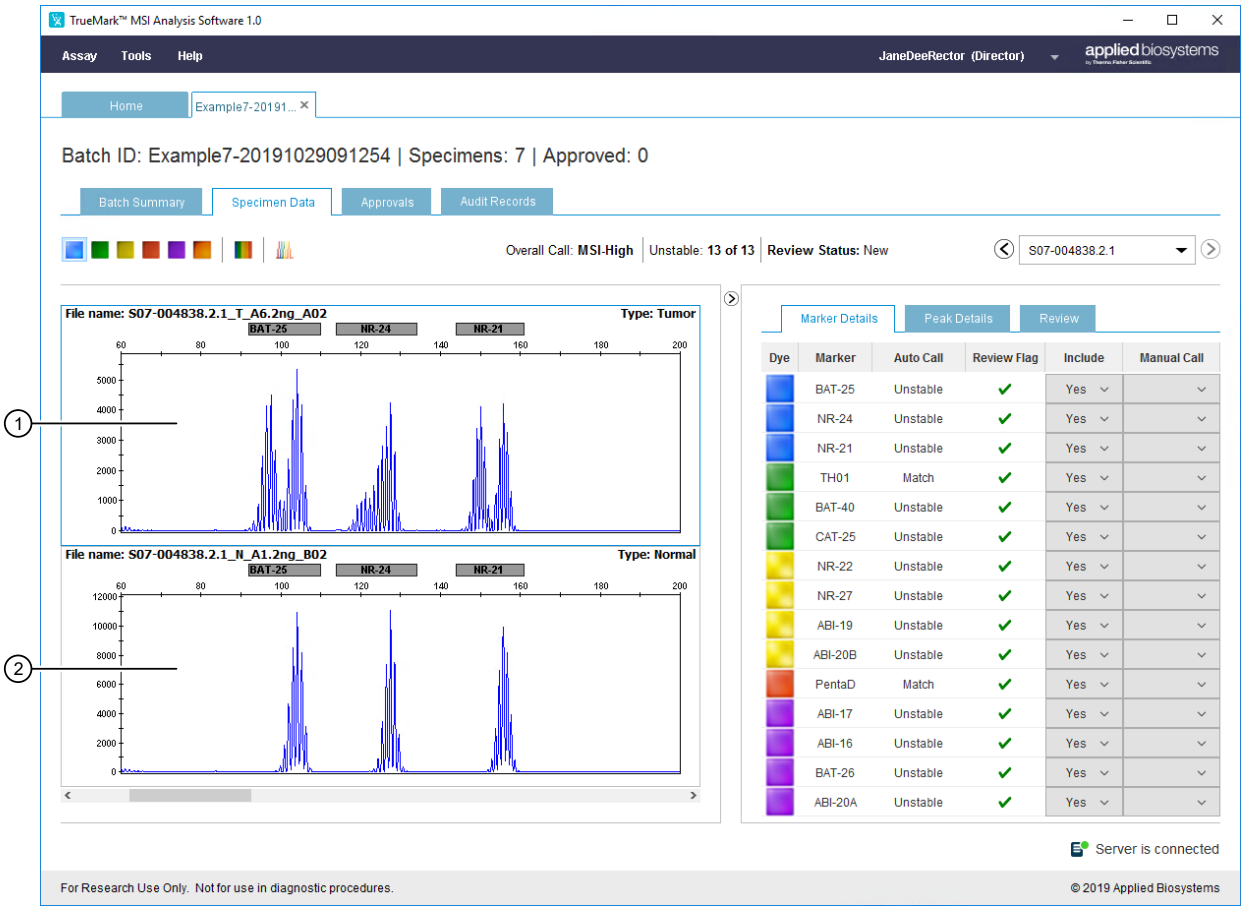


Figure 1 Example electropherogram of a FFPE colon tumor tissue sample.

① Tumor trace—Displays extra peaks that are not present in the normal trace.

② Normal trace—Displays standard peaks for the marker.

The colon tumor tissue sample was amplified with the TrueMark™ MSI Assay, run on a SeqStudio™ Genetic Analyzer, and analyzed with TrueMark™ MSI Analysis Software (Y-axis scale 0–12,000 RFU). The extra peaks in the tumor trace have a smaller fragment size than the main peak for each marker, indicating microsatellite instability in the tumor sample.

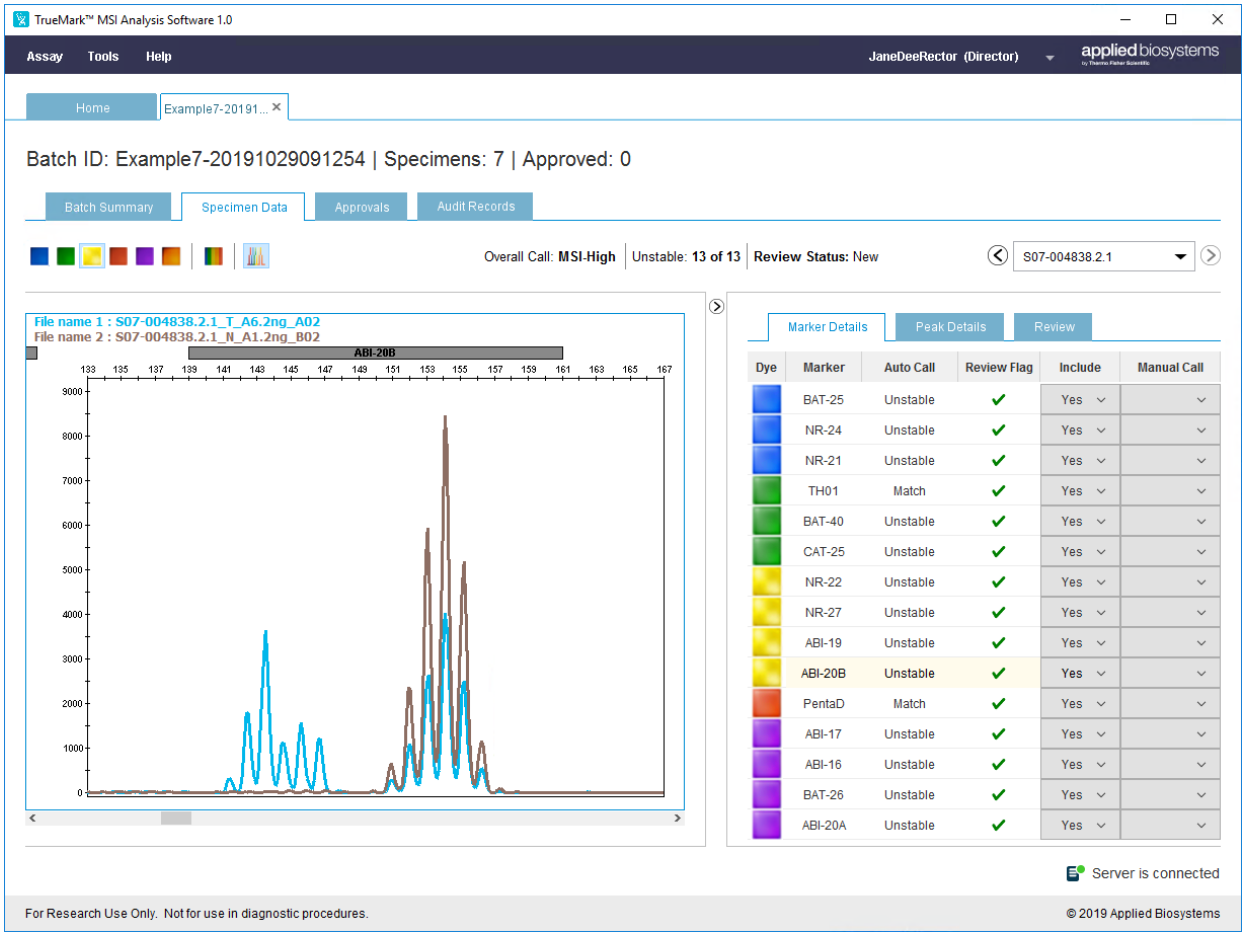


Figure 2 Alternative view: tumor and normal traces are overlaid to more easily evaluate smaller differences in fragment size distribution.

Automatic calling of low frequency small deletions in synthetic constructs

Instability in colon tumor tissue microsatellites are readily identified by large base pair deletions. However, extra-colonic tumors can feature small deletions that are more difficult to distinguish. To accurately report microsatellite instability in colon and other tumor tissue types, it is important to identify these small deletions.

We designed synthetic constructs with varying lengths of small deletions for microsatellite markers in the TrueMark™ MSI Assay, then evaluated them at several allele frequencies. Examples of these small deletions are shown in Figure 3 and Figure 4.

IMPORTANT! Run the tumor and normal samples on the same plate. The software can give inaccurate results if you use tumor and normal sample files from different runs. Additionally, the signal strength of tumor and normal samples should match as closely as possible in order to detect small deletions or low allele frequencies.

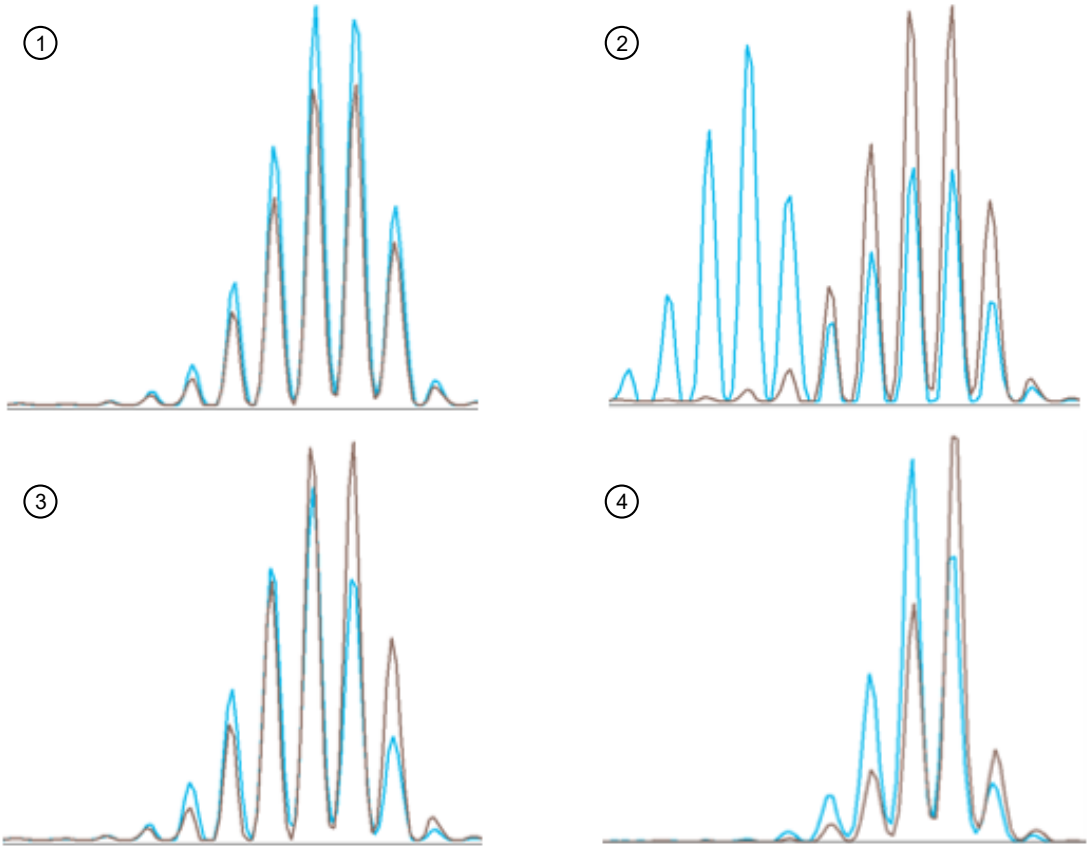


Figure 3 Examples of microsatellite stability and instability in synthetic constructs. The synthetic construct containing the wild-type allele is displayed in brown. The synthetic construct containing the mutant allele is displayed in blue.

① Marker BAT-25—Stable microsatellite with no deletions
② Marker BAT-25—Large unstable microsatellite with a 5 bp deletion at 50% allele frequency
③ Marker BAT-25—Unstable microsatellite with a 1 bp deletion at 50% allele frequency
④ Marker ABI-20A—Unstable microsatellite with a 1 bp deletion at 50% allele frequency

It is possible to detect small deletions (2–5 bp) at lower allele frequencies by visual inspection. However, single base pair deletions at 20% allele frequency are difficult to discern (Figure 4 and Figure 5).

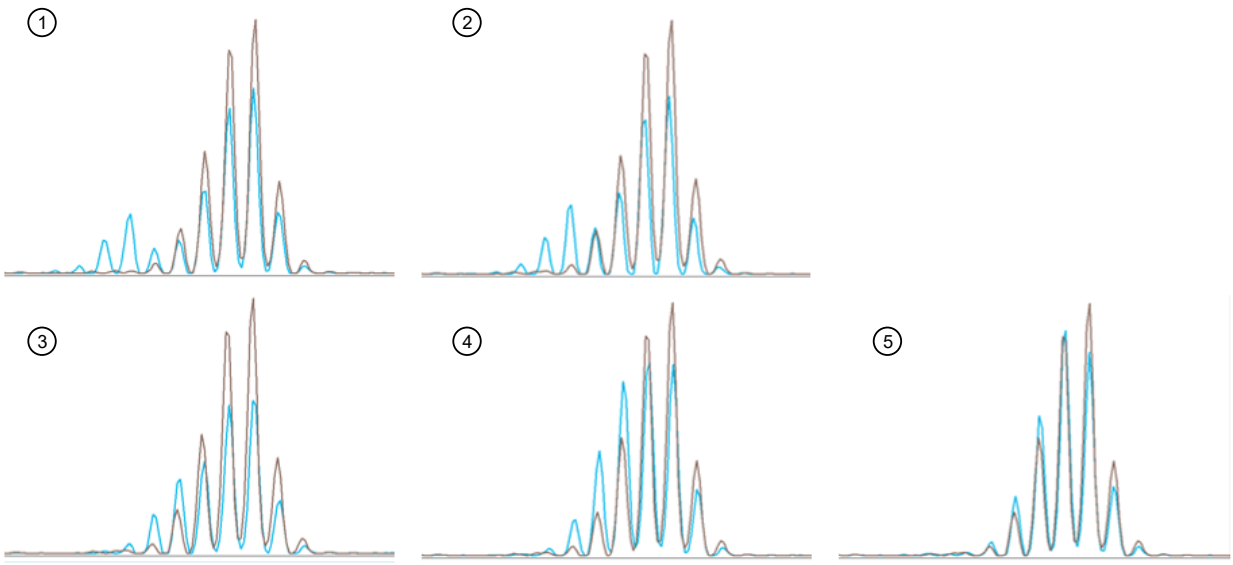


Figure 4 Examples of small low frequency deletions in synthetic constructs. The synthetic construct containing the wild-type NR-24 allele is displayed in brown. The synthetic construct containing the mutant NR-24 allele is displayed in blue.

① Unstable microsatellite with a 5 bp deletion at 20% allele frequency
② Unstable microsatellite with a 4 bp deletion at 20% allele frequency
③ Unstable microsatellite with a 3 bp deletion at 20% allele frequency
④ Unstable microsatellite with a 2 bp deletion at 20% allele frequency
⑤ Unstable microsatellite with a 1 bp deletion at 20% allele frequency

Automatic calling of low frequency small deletions in an endometrial tumor tissue sample

As an example of how the TrueMark™ MSI Analysis Software interprets low frequency small deletions, results from an endometrial tumor tissue sample with a relatively low fraction of tumor content (~25%) is shown in Figure 5.

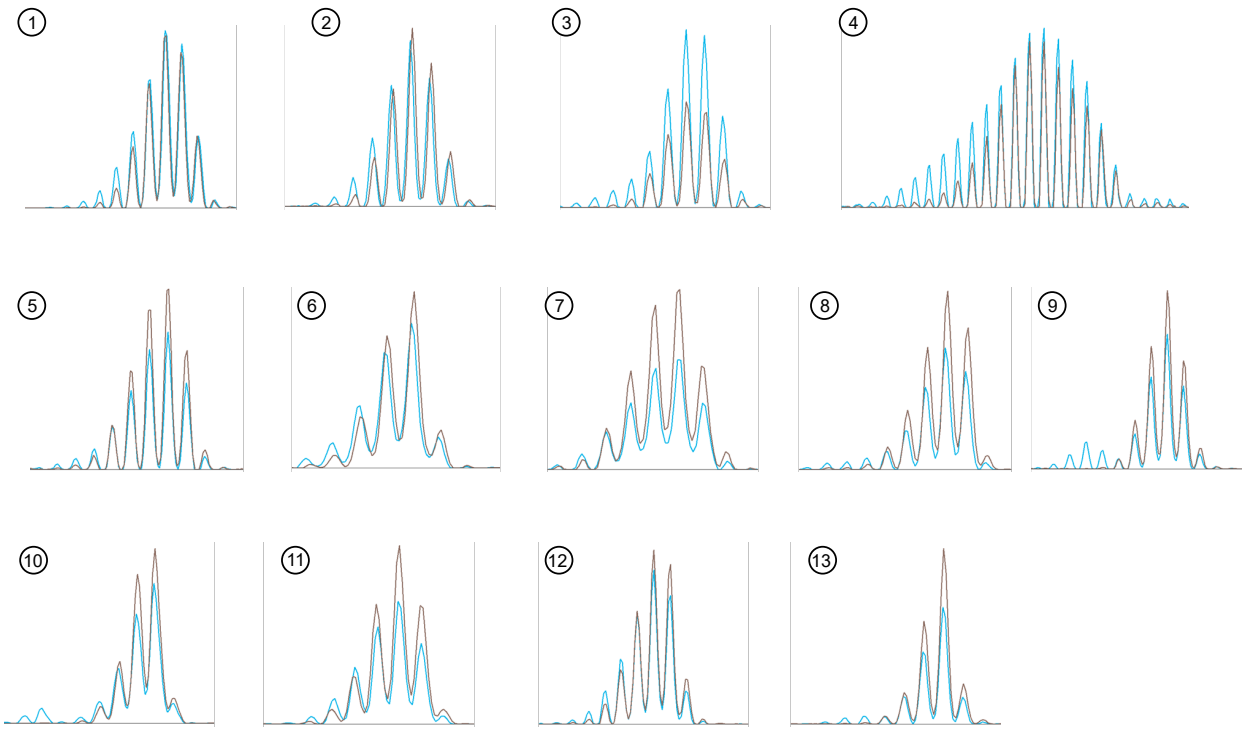
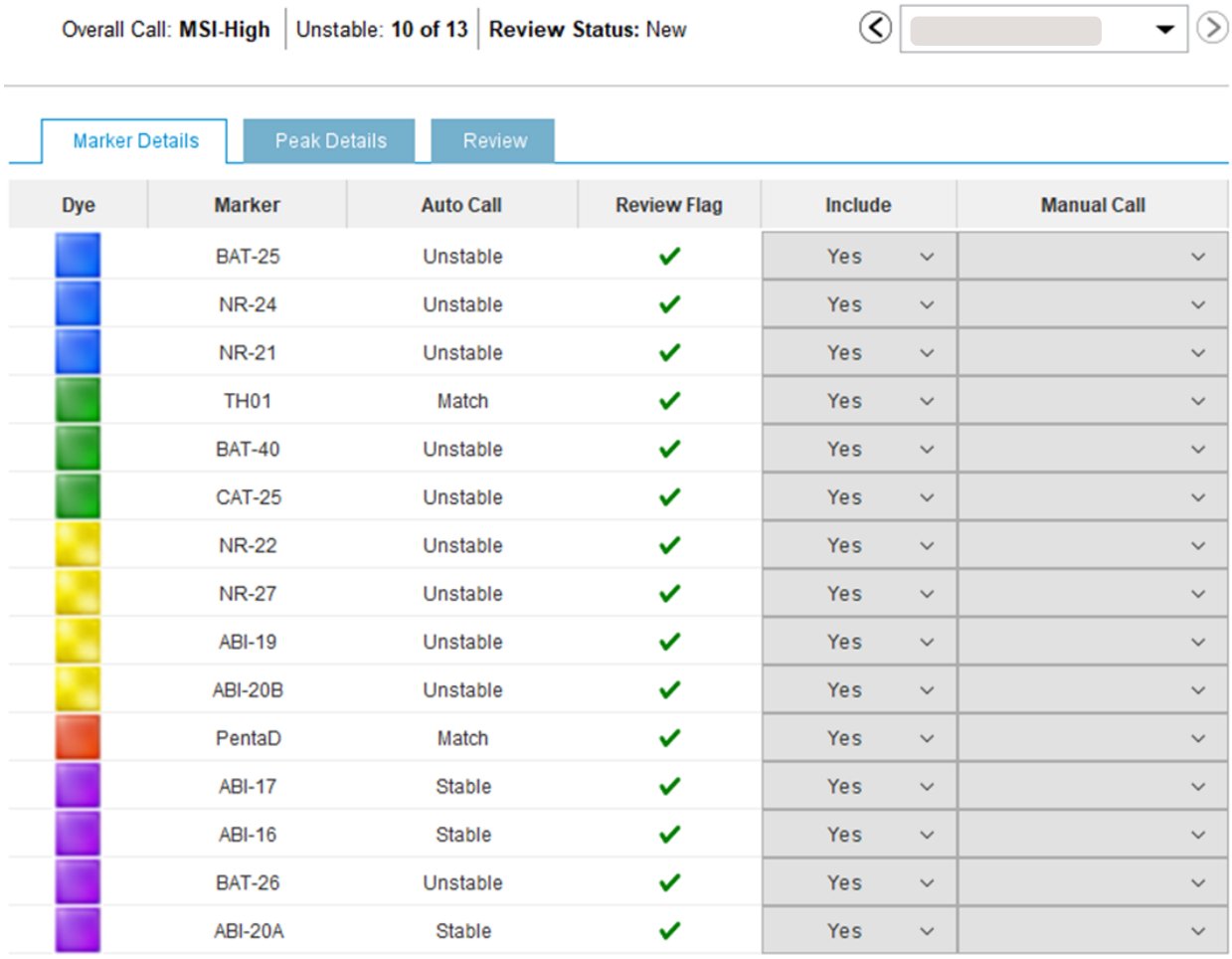


Figure 5 Example of small low frequency deletions in a mismatch repair (MSH2 and MSH6) deficient endometrial tumor tissue sample. The normal sample is displayed in brown. The tumor sample is displayed in blue. The tumor content of this specimen was 25%.

1. BAT-25
2. NR-24
3. NR-21
4. BAT-40
5. CAT-25
6. NR-22
7. NR-27
8. ABI-19
9. ABI-20B
10. ABI-17
11. ABI-16
12. BAT-26
13. ABI-20A

The TrueMark™ MSI Analysis Software called 10 of 13 markers in the endometrial tumor tissue sample as unstable, with an overall call of **MSI-High** (Figure 6).



Dye	Marker	Auto Call	Review Flag	Include	Manual Call
	BAT-25	Unstable	✔	Yes	
	NR-24	Unstable	✔	Yes	
	NR-21	Unstable	✔	Yes	
	TH01	Match	✔	Yes	
	BAT-40	Unstable	✔	Yes	
	CAT-25	Unstable	✔	Yes	
	NR-22	Unstable	✔	Yes	
	NR-27	Unstable	✔	Yes	
	ABI-19	Unstable	✔	Yes	
	ABI-20B	Unstable	✔	Yes	
	PentaD	Match	✔	Yes	
	ABI-17	Stable	✔	Yes	
	ABI-16	Stable	✔	Yes	
	BAT-26	Unstable	✔	Yes	
	ABI-20A	Stable	✔	Yes	

Figure 6 Marker calls in the TrueMark™ MSI Analysis Software

C Navigating within the software

Menu bar

Menu	Option	Select to...
Assay	**Analysis Settings**	"Configure analysis settings" on page 54
Tools	**Security Settings**	• "Configure user accounts" on page 59 • "Configure user roles" on page 61 • "Configure system security" on page 64
	Archive	"Archive and (optionally) purge batches" on page 57
	Restore	"Restore batches" on page 57
	Import Manager	"Manage import records in the Import Manager" on page 31
	Preferences	"Configure locations for data" on page 53
Help	**MSI User Guide**	Download the *TrueMark™ MSI Analysis Software User Guide*. **Note:** Additionally, in some of the software screens, you can click ? to download the user guide.
	About	View TrueMark™ MSI Analysis Software version and licensing information
<user full name>	**Log Out**	"Sign out or exit the TrueMark™ MSI Analysis Software" on page 23
	Exit	

Toolbar

The toolbar is a row of buttons that appears at the top of a screen; the buttons that are available depend on the context of the current screen.

Screen	Button	Click to...
Home screen	**Import Samples**	"Import sample files" on page 27
	Import Manager	"Manage import records in the Import Manager" on page 31
	Refresh	"Refresh the batch list" on page 28
<Batch ID> screen		
Batch Summary tab	**Approve**	"Approve a specimen" on page 42
	PDF Report	Chapter 7, "Export reports"
	Export Results	
Audit Records tab	**Report Audit**	"Export audit records" on page 48
	Export Summary	
	Export Details	
	Refresh	"Refresh the Audit Records tab" on page 47

Status bar

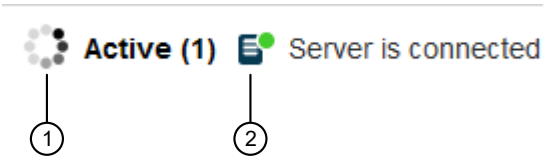


Table 5 Status bar descriptions

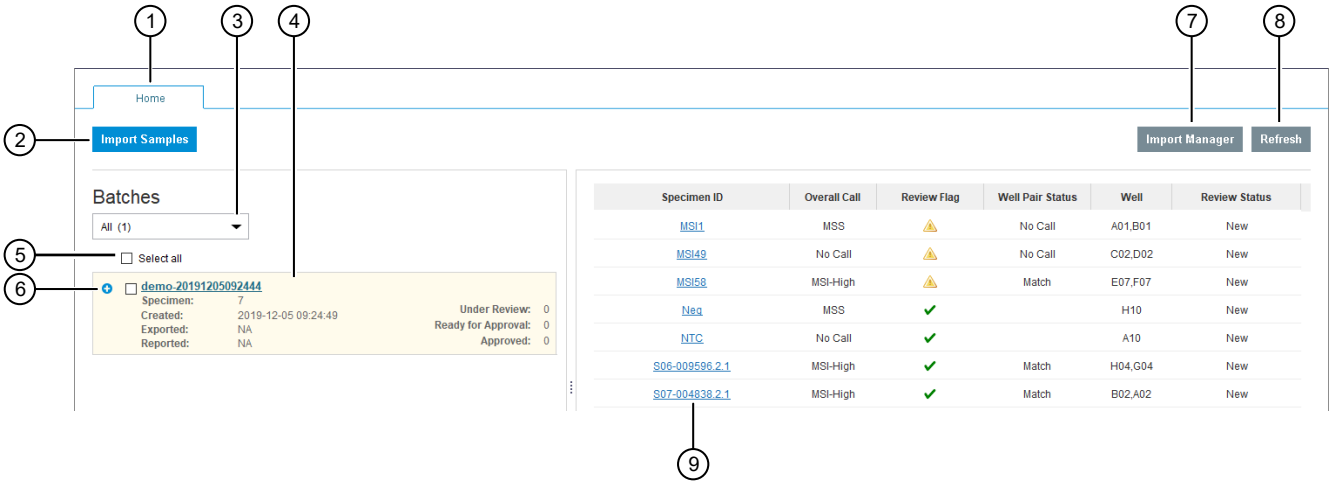
Item		Description
1	Progress wheel	Indicates that an import operation is in progress. The number in parentheses indicates the number of MSI Server operations in progress.
2	Connection status	Displays the connection status of the MSI Server. • Server is connected • Server is disconnected

D Screen descriptions

Home screen

The **Home** screen displays the batches that are currently in the TrueMark™ MSI Analysis Software.

IMPORTANT! When you start the TrueMark™ MSI Analysis Software for the first time, the **Home** screen is empty. You must import sample files (FSA) before you can use all the features in the **Home** screen.



① Select the **Home** tab (default view).
② Click to import samples.
③ Filter the batches to display.
④ Select a batch, then click the **<Batch ID>** link to open the **Batch Summary** tab.
⑤ Select the checkbox for batch to archive or restore. Select the top checkbox to select all batches.
⑥ Click to expand the information displayed for the batch.
⑦ Click to open the **Import Manager**.
⑧ Click to update the list of batches displayed in the **Batches** pane.
⑨ Click a link to open the **Specimen Data** tab.

How to ...

"Import samples" on page 25

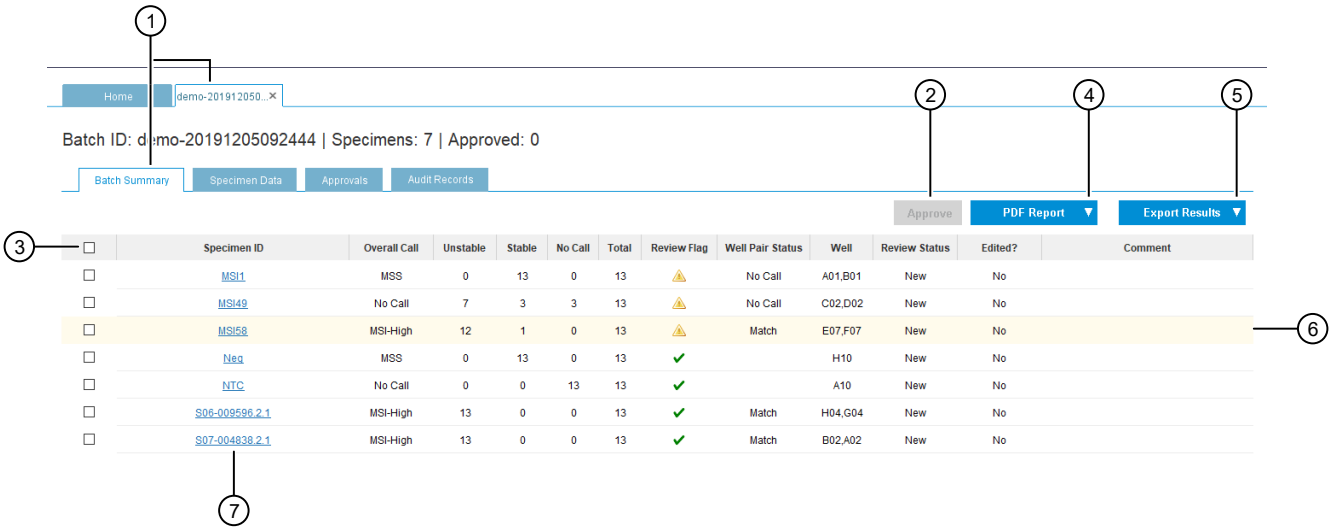
"Quick check: View batch information in the Home screen" on page 21

"Quick check: View specimen information in the Home screen" on page 22

Batch Summary tab

The **Batch Summary** tab displays detailed information for a selected batch. In the **Batch Summary** tab, you can approve results and export reports.

To access the **Batch Summary** tab: In the **Batches** pane of the **Home** screen, select a batch, then click the <*Batch ID*> link.



1. In the **<Batch ID>** screen for the batch of interest, select the **Batch Summary** tab.
2. Select the **<Batch ID>** tabs.
   Click to Approve specimens.

   Note: You can approve only specimens with a **Review Status** of **Ready for Approval**. If no specimens are **Ready for Approval**, the **Approve** button is inactive.
3. Select the checkbox for each specimen to export a report for. Select the top checkbox to select all specimens.
4. Export a Batch Report (PDF file) or Specimen Report (PDF file).
5. Export a Batch Report (CSV file) or Specimen Report (CSV or VCF file).
6. Enter comments for a specimen.
7. Click a link to open the **Specimen Data** tab.

How to ...

Chapter 5, “Review analysis results”

“Approve a specimen” on page 42

Chapter 7, “Export reports”

Specimen Data tab

The **Specimen Data** tab displays detailed information for a selected specimen. In the **Specimen Data** tab, you can edit the marker calls, add review comments, and accept specimens.

To access the **Specimen Data** tab: In the right pane of the **Home** screen, click a `<Specimen ID>` link.

1. In the **`<Batch ID>`** screen for the batch of interest, select the **Specimen Data** tab.
2. Use the buttons at the top of the plot to configure the view.
3. Hold the pointer over the X- or Y-axis, then drag the magnifying glass to zoom in to a specific range.
4. Select the **Marker Details** tab (default view). To display a specific marker in the electropherogram at left, click a marker row.
5. Select the **Peak Details** tab.
6. Select the **Review** tab.
7. Scroll through or select specific specimens.

How to ...

"View the electropherogram plots" on page 35

"View marker details and edit as needed" on page 37

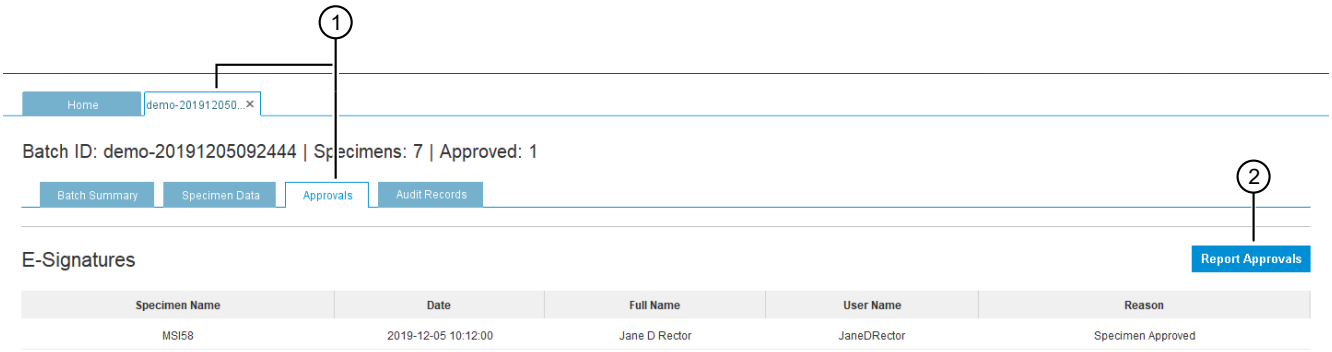
"View peak details" on page 40

"Add a comment and/or accept the specimen (Technologist)" on page 40

Approvals tab

The **Approvals** tab displays all approved specimens in the selected batch and allows you to export an Approvals Report.

To access the **Approvals** tab: In the right pane of the **Home** screen, click a `<Specimen ID>` link. The **Specimen Data** tab is displayed; click the **Approvals** tab.



① In the **<Batch ID>** screen for the batch of interest, select the **Approvals** tab.
② Click to export an Approvals Report (PDF file) for all approved specimens in the batch.

How to ...

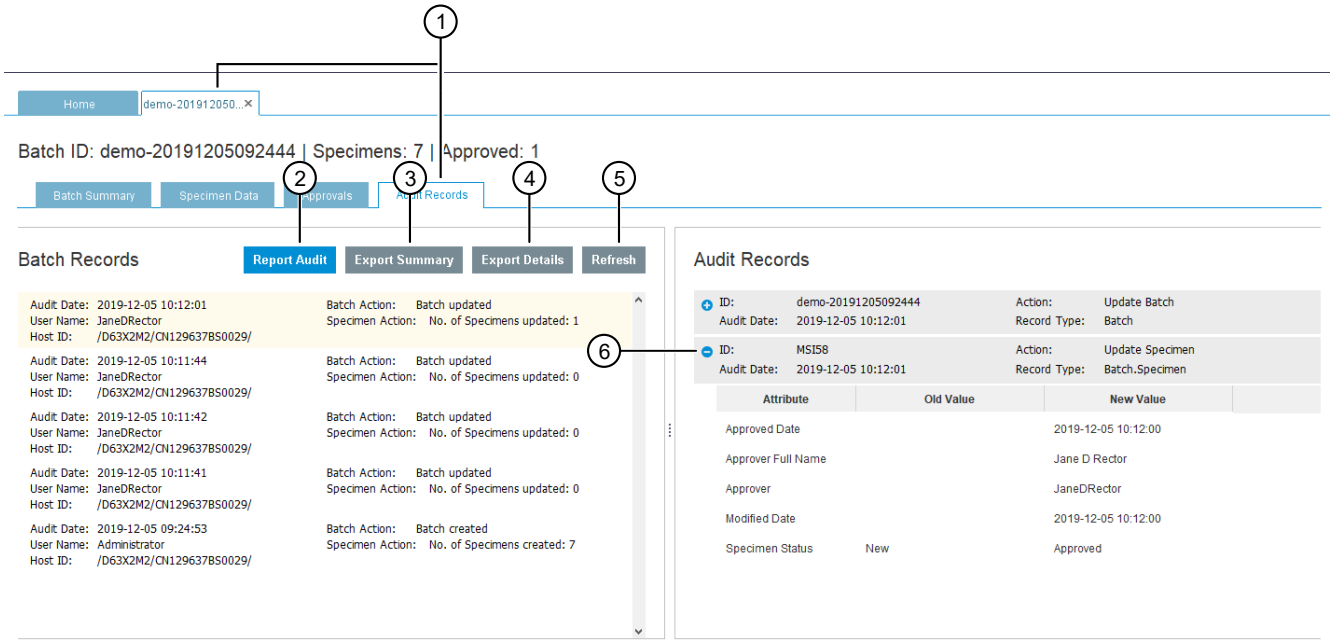
"Approve a specimen" on page 42

"Export an Approvals Report (PDF file)" on page 43

Audit Records tab

The **Audit Records** tab displays detailed information for batch, specimen, and system auditing.

To access the **Audit Records** tab: In the right pane of the **Home** screen, click a `<Specimen ID>` link. The **Specimen Data** tab is displayed; click the **Audit Records** tab.



① In the **<Batch ID>** screen for the batch of interest, select the **Audit Records** tab.

② Click to export audit information for all specimens in the selected batch.

③ Click to export the summary information displayed in the **Batch Records** pane.

④ Click to export the summary information displayed in the **Batch Records** pane, plus the associated information displayed in the **Audit Records** pane (right).

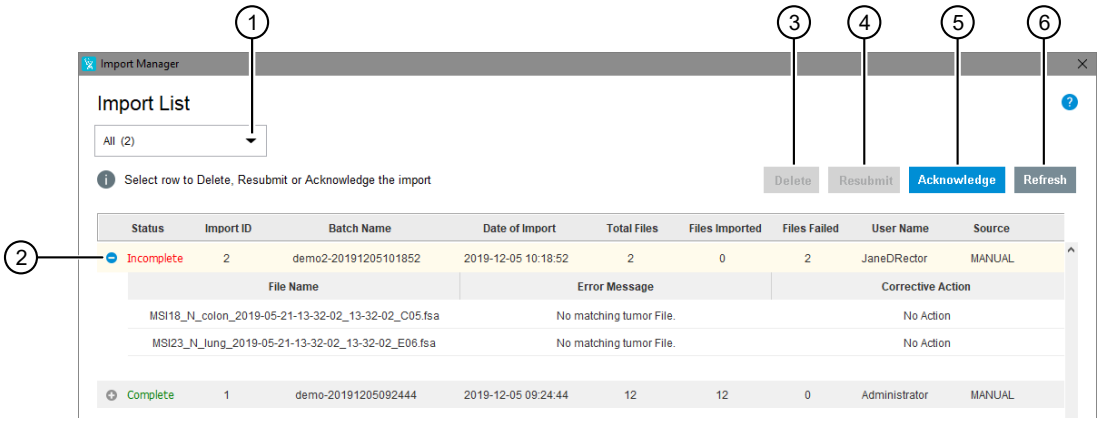
⑤ Click to expand the information displayed for the audit record.

How to ...	Learn more about ...
"Export audit records" on page 48	"Batch and specimen auditing" on page 47 "System auditing" on page 50

Import Manager

The **Import Manager** displays an import record for each batch. The import record includes the **Status** (whether or not the import was successful), the **Import ID** (an internal ID used by the software), the **Batch Name**, the **Date of Import**, and other details about the batch.

To access the **Import Manager**, click **Import Manager** in the **Home** screen toolbar.



1. Filter the import records to display.
2. Click to expand the information displayed for the import record.
3. Click to delete the selected import record.
4. Click to resubmit the selected import record.
5. Click to acknowledge the selected import record.
6. Click to update the list of import records displayed in the **Import Manager**.

How to ...

"Import samples" on page 25

"Troubleshoot sample file (FSA) imports" on page 30

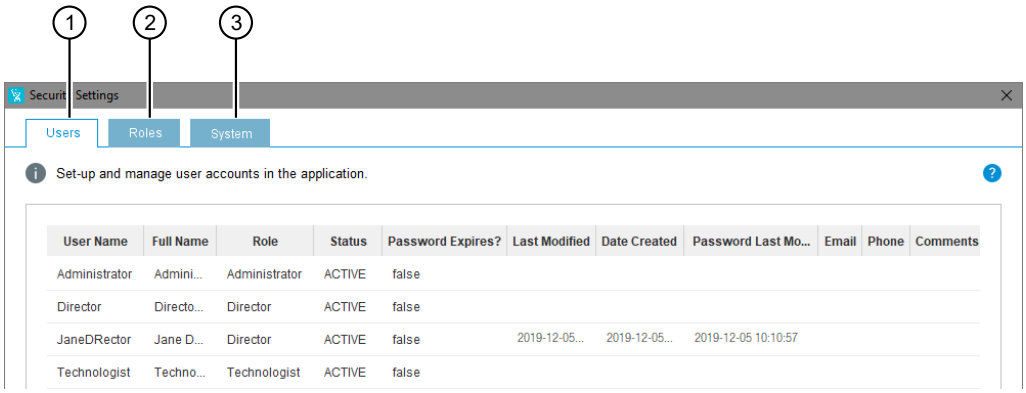
"Manage import records in the Import Manager" on page 31 (delete, resubmit, or acknowledge)

Security Settings screen

The **Security Settings** screen allows you to configure user accounts, user roles, and the system-level audit events that are tracked by the software.

To access the **Security Settings** screen: In the **Home** screen menu bar, select **Tools ▸ Security Settings**. The following restrictions apply.

- You must have **Security and Auditing** permission in the TrueMark™ MSI Analysis Software.
- You must close all open batches.



① Click to configure user accounts.
② Click to configure user roles.
③ Click to configure system security.

How to ...	Learn more about ...
"Configure user accounts" on page 59	"User roles and permissions" on page 61
"Configure user roles" on page 61	
"Configure system security" on page 64	

Documentation and support

Related documentation

Document	Publication number
TrueMark™ MSI Assay Quick Reference Guide	MAN0018869
TrueMark™ MSI Assay User Guide	MAN0018868
3500/3500xL Genetic Analyzer with 3500 Series Data Collection Software v 3.1 User Guide	100031809
3500/3500xL Genetic Analyzer with 3500 Series Data Collection Software v3.3 User Guide	100079380
SeqStudio™ Genetic Analyzer Instrument and Software User Guide	MAN0016138
SeqStudio™ Genetic Analyzer Instrument and Software User Guide	MAN0018646
GeneMapper™ Software v4.1 Quick Reference Guide	4403615

Customer and technical support

Visit **thermofisher.com/support** for the latest service and support information.

- Worldwide contact telephone numbers
- Product support information
  - Product FAQs
  - Software, patches, and updates
  - Training for many applications and instruments
- Order and web support

- Product documentation
  - User guides, manuals, and protocols
  - Certificates of Analysis
  - Safety Data Sheets (SDSs; also known as MSDSs)

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

Limited product warranty

Life Technologies Corporation and its affiliates warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale at **www.thermofisher.com/us/en/home/global/terms-and-conditions.html**. If you have questions, contact Life Technologies at **www.thermofisher.com/support**.