

# TDAS CFTR Software User Manual



For *In Vitro* Diagnostic Use.

MLD-024-SUM-001 Rev J  
10/2020



WMDE B.V.  
Bergerweg 18  
6085 AT Horn  
The Netherlands

#### Technical Support

Telephone: 512-381-4397  
North America Toll Free: 1-877-785-2323  
International Toll Free: + 800-2939-4959  
Email: [support@luminexcorp.com](mailto:support@luminexcorp.com)  
[www.luminexcorp.com](http://www.luminexcorp.com)



Luminex Molecular Diagnostics, Inc.  
439 University Ave.  
Toronto, ON, Canada  
M5G 1Y8

# Table of Contents

---

<b>Chapter 1: Software Introduction</b> .....	<b>1</b>
Software Overview.....	1
<b>Chapter 2: Using TDAS CFTR Software</b> .....	<b>3</b>
Start the Software.....	3
Open Data Files.....	4
Target Masking.....	5
Summary View Window.....	13
View the Results.....	15
Print the Results.....	17
Export the Results.....	19
Close Data Files.....	24
<b>Chapter 3: Analyzing Assays with TDAS CFTR Software</b> .....	<b>25</b>
Display Hidden Calls.....	25
Possible Calls.....	25
Summary View Messages.....	29
Detailed View Messages.....	31
<b>Chapter 4: Managing User Access</b> .....	<b>34</b>
User Access.....	34
Luminex Technical Support.....	37

# Chapter 1: Software Introduction

---

## Software Overview

The xTAG<sup>®</sup> Data Analysis Software CFTR (TDAS CFTR) provides genetic calls from data obtained with an xTAG kit that is designed using the Universal Array Tags on the Luminex<sup>®</sup> xMAP<sup>®</sup> system.

The Luminex xMAP system is a bead-based array platform that utilizes Universal Arrays for DNA-based genetic assays. The Luminex xMAP system creates data in the form of a Comma Separated Values (CSV) file, which can be analyzed using TDAS CFTR. By opening the CSV file generated using a Luminex xMAP system, the software will detect the assay file and ensure it is appropriate for that instance of TDAS. It will also analyze the data accordingly and display the summary genetic calls on the screen.

## Main View Window

The Summary View is the main view window and displays the genetic calls of each variation for each sample. It provides links and functions to display, print, and export analysis information. Complete information for each individual sample and each individual variation can be viewed by choosing a sample or a variation and opening a new view. All of the views can be printed individually, or as a complete set of sample views or variation views. Data can be exported into a Comma Separated Values (CSV) file, either with summary data that consists of the genetic calls, or with complete data that includes all data and calls. Data can also be exported to a file in PDF format, with options to include some or all views, some or all samples or variations, and graphical views of the sample or variation data. Alternatively, complete data can be exported in XML format.

Each column header in the summary or complete views may be expanded by double-clicking the right edge of the column header.

## Target Detection Calls

To make genetic calls, the software performs calculations and compares the results to empirically-derived threshold values specific to each genetic assay. The first comparison determines whether the assay result falls within the required ranges for background values for each variation based on the primary negative control sample. All negative control samples must be identified prior to opening the data for analysis. If more than one sample is identified as the negative control sample, then, by default, the last sample identified as a negative control sample will be used as the primary negative control sample. If any of the background signals are higher than the acceptable values, the assay is considered to have failed and a No Call result is made for all samples and all variations. Another negative control can be manually marked as the primary negative control. If the assay shows no background values higher than the acceptable values, then each sample is analyzed individually. Signal values for each variation are analyzed using calculations and thresholds specific to each assay to make the genetic calls. For example, for a bi-allelic single nucleotide polymorphism (SNP), the possible genetic calls may be only wild-type allele detected (WT), only mutant allele detected (Mu D), wild-type and mutant alleles detected (HET), and no call possible, with an explanation displayed in the "Notes and explanations" column (No Call).

## Command-Line Overview

TDAS CFTR provides command-line options which can be run from a DOS prompt, in a Windows® Run dialog box, as part of a DOS batch file, or in another Windows program. To run command-line options from a directory other than the one that TDAS CFTR installed, add the TDAS CFTR installation directory in the PATH environment variable. Contact your system administrator for instructions on setting the PATH environment variable.

The TDAS CFTR features that are currently available as command-line options are:

- launching the TDAS CFTR graphical user interface (GUI)
- exporting analysis results in CSV or XML format

**NOTE:** Some features require passwords as part of the command, when TDAS CFTR is password protected.

# Chapter 2: Using TDAS CFTR Software

---

## Start the Software

There are two Log-on dialog boxes: one asking for a user name only, and one that requires a password. When TDAS CFTR is not password protected, you may still enter a user name for display, print, and export purposes. When TDAS CFTR is password protected, users must log on to TDAS CFTR with a password. The specific password determines the level of access (initially set up at installation) that the user has for that session of TDAS CFTR. Full Access Level users may change passwords during a session.

The Log-on dialog box displays:

- at startup of TDAS CFTR when log-on is enabled
- when TDAS CFTR has timed out
- when switching identity
- when enabling log-on function when TDAS CFTR is not log-on enabled or password protected

1. To start the software, double-click the **TDAS CFTR** icon on your PC desktop.
2. Enter a **User Name**, if desired.

**NOTE:** The user name is used for display, print, and export purposes and may be left blank.

**NOTE:** If the Always show log-on dialog at startup check box is cleared, then the User Name field is disabled.

3. Select or clear the **Always show log-on dialog at startup** check box, if prompted.

**NOTE:** This check box is only available at the startup of TDAS CFTR, and only if the password protection function is NOT enabled.

**NOTE:** If a User Name was entered and the Always show log-on dialog at startup check box is cleared, then the User Name field is cleared and disabled.

4. Enter the **Password**, if prompted.

**NOTE:** The password entered determines the level of access the user has for that session of TDAS CFTR.

5. Click **OK**.

## Start the Software from the Command-Line

**NOTE:** The syntax for each command-line option begins with the executable "TDAS CFTR," followed by a list of parameters. Parameters encased in square brackets are optional. Words in italics should be replaced by the actual values when running the command. Characters in bold must be used as is.

This command-line option launches the TDAS CFTR GUI. The syntax for this command is:

```
"TDAS CFTR" [-q] ["filenames" [-m"Mask_control_filename"]] [-uUser] [-pPassword]
```

**NOTE:** The previous line is a single line command.

The parameters are explained in the following table.

**Table 1. Command-Line Parameters**

Parameters/Filenames	Explanation
-q	This optional flag opens and analyzes the data file specified in the filenames parameter without any user interaction. If TDAS CFTR cannot find an assay module to analyze the data file, TDAS CFTR launches without opening any data file. If the data file is correct but the mask control file is not valid, TDAS CFTR will launch and display the <b>Identify Samples</b> dialog box.
"filenames"	This is the name (and path, if necessary) of the data for analysis. For assays that require more than one data file, the filenames should be separated by a " " character and must be enclosed with a pair of double quotes (for example, "C:\My Batches\OutputA.csv C:\My Batches\OutputB.csv"). If this parameter is not specified in the command-line, or if TDAS CFTR cannot find an assay to analyze the data, TDAS CFTR displays the <b>Open</b> dialog box and explains why the file cannot be opened. If the -q flag is used, the <b>Open</b> dialog box would be suppressed.
-m"Mask_control_filename"	This is the mask control filename (and path, if necessary). This is required only if the data file was not previously analyzed. If the mask control file is valid, masking selections are pre-populated in the masking dialog boxes, unless you use the -q flag. If no filenames are specified in the command-line, this parameter is ignored. If the mask control file is invalid, not specified, or not usable with the data file, TDAS CFTR displays the <b>Identify Negative Control</b> dialog box to allow you to make negative control and masking selections (even when the -q flag is specified).
-uUser	This optional parameter submits the name of the user who runs this command. The name of the user is mainly for log-on information purposes and displays on the TDAS CFTR window. This parameter is ignored if log-on is not enabled.
-pPassword	This parameter submits the password for accessing TDAS CFTR. If TDAS CFTR is not password protected, this parameter is ignored.

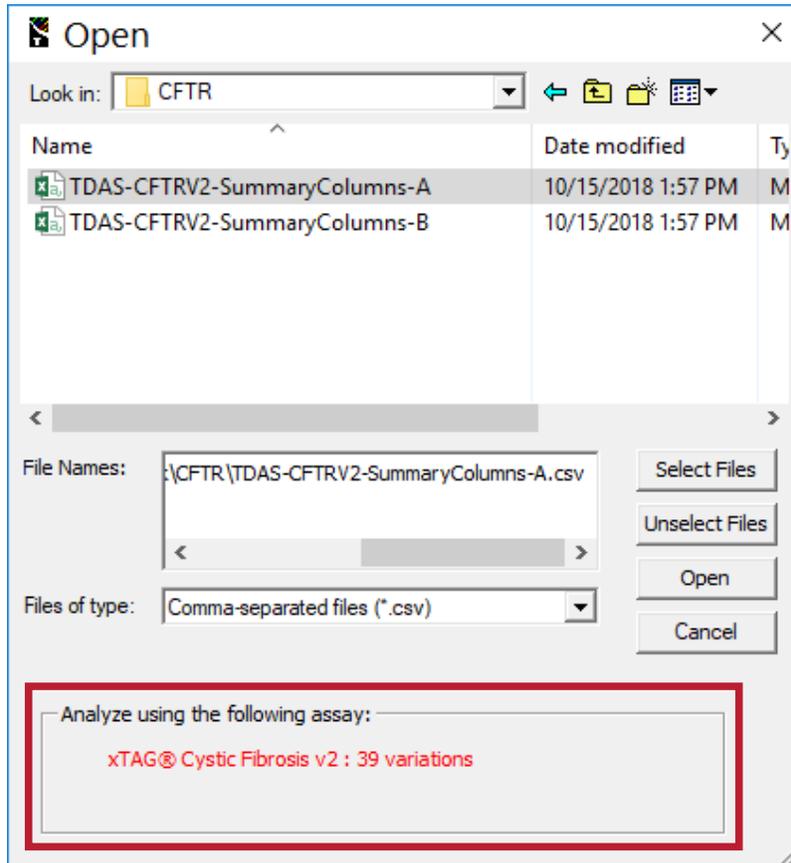
## Open Data Files

1. Navigate to the **File** menu, and choose **Open**.
2. In the **Open** dialog box, choose the **Files of type** from the drop-down menu. Choose to view either "Comma-separated files (\*.csv)" or "All Files (\*.\*)" in the chosen directory.

**NOTE:** Ensure that you choose only files created with the Luminex<sup>®</sup> software, using the assay-specific template described in the package insert. If the chosen data file does not conform to the format required, the software will not analyze the data.

**NOTE:** Depending on the xTAG<sup>®</sup> assay that was run, you may be required to select more than one data file for analysis.

3. Browse to and choose the desired file(s), then click **Select Files**.
4. In the **Analyze using the following assay** panel, ensure the correct assay is displayed and that at least one variation is detected.



5. Click **Open**.

**NOTE:** If the CSV data file that you choose does not conform to the format required, then it is assumed that the data has been corrupted or has not been generated appropriately and TDAS CFTR will not analyze the data. This can occur, for example, if an invalid data acquisition protocol was used to acquire data, or if a sample name contains the double quote character (").

**NOTE:** If this is the first time the data file is opened in TDAS CFTR, then you will need to identify negative controls, as well as make masking selections. If the data file was previously opened, then the Summary View displays.

## Target Masking

You must indicate the amount of genotype information to display for each sample in a run before TDAS CFTR will open data files for analysis. The masking feature in TDAS CFTR allows you to choose all panels or a subset of panels in the assay that should be analyzed and displayed for each sample.

TDAS CFTR does not display genotype information for negative control samples, and will not mask targets that are set as negative control samples. You are required to identify negative control samples prior to applying masking options. If more than one sample is identified as a negative control sample, TDAS CFTR will select the last sample in the list of identified samples as the primary negative control sample. During data analysis, calculations that require background signals will be based on signals in the primary negative control sample.

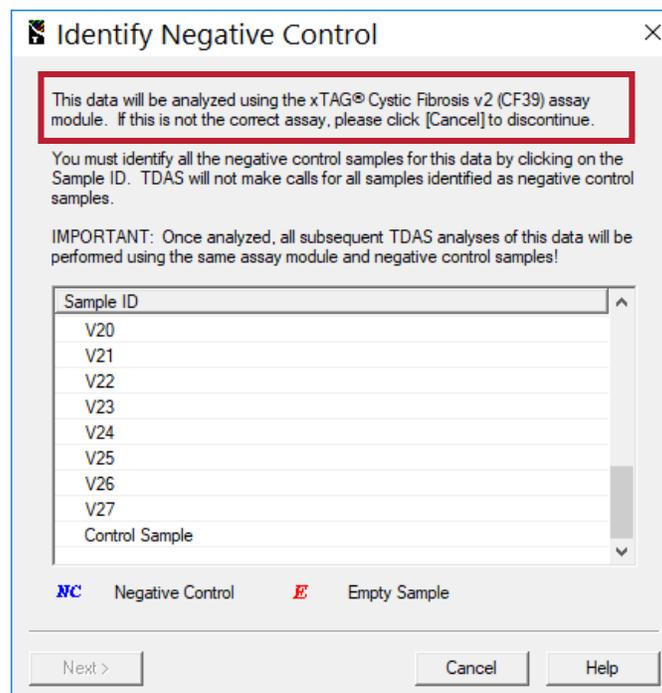
The masking feature is also available as a command-line option. Using a mask control file, you can provide masking options to TDAS CFTR via command-line.

## Identify the Negative Controls and Mask the Targets

After opening the data file for analysis for the first time, identify the negative control samples, prior to making masking selections.

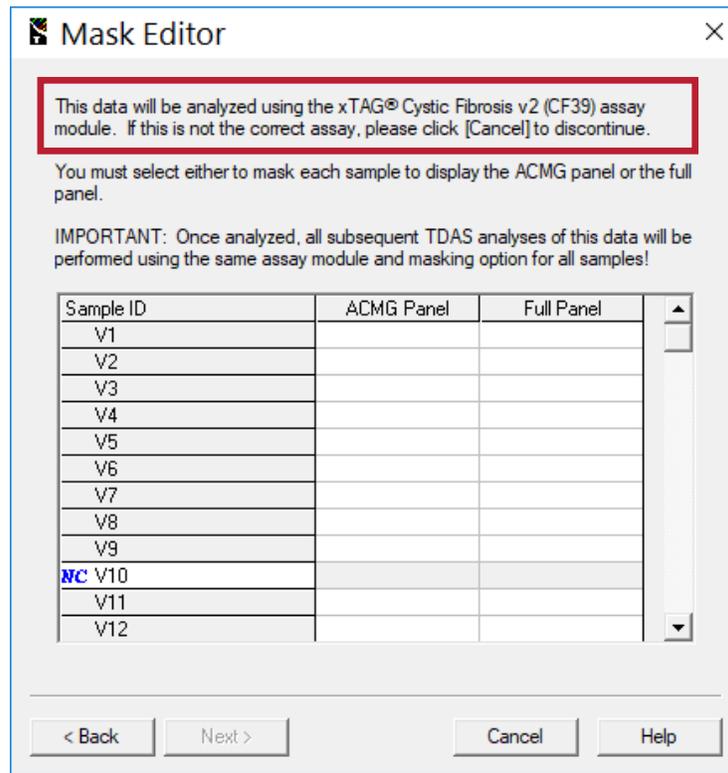
**NOTE:** The Identify Negative Control, Mask Editor, and Mask Confirmation dialog boxes only display when a new data file is opened. A previously opened data file will keep the negative controls and masking selections previously identified.

1. After a new data file has been opened for the first time, in the **Identify Negative Control** dialog box, ensure that the correct assay is identified in the first paragraph of the dialog box. If the assay is incorrect, click **Cancel**, then verify the data file is correct.

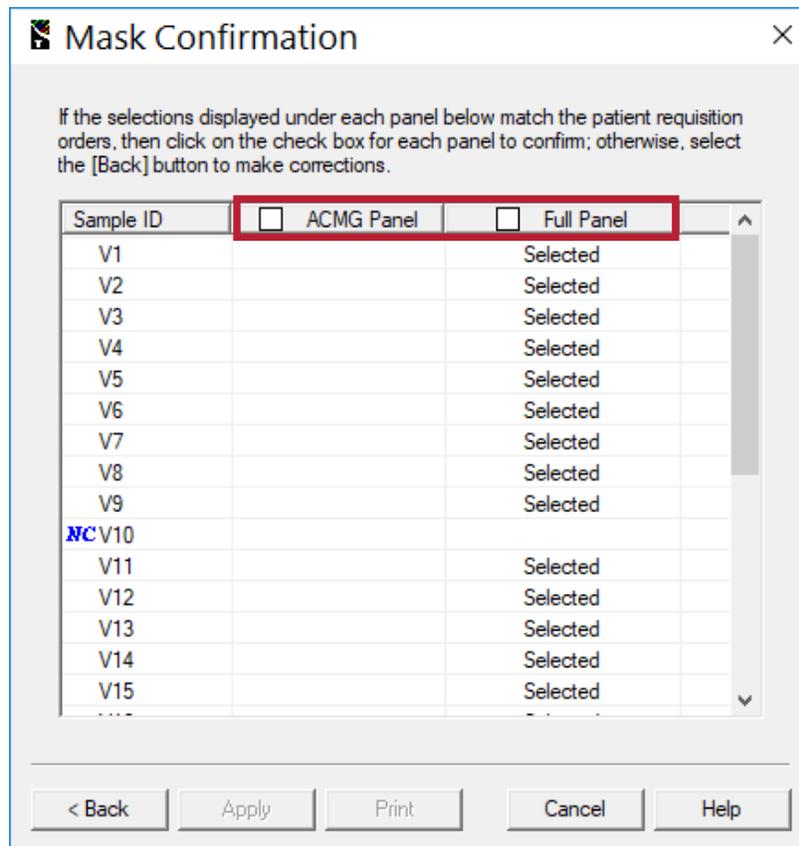


2. Identify the negative controls in the run by choosing the desired **Sample IDs** to mark it with this symbol: **NC**.  
**NOTE:** Samples containing the text "negative control" (case-insensitive) are automatically marked as negative control samples.  
**NOTE:** At least one sample must be marked as a negative control sample in order to continue.
3. If you need to make any necessary corrections, choose the **Sample ID** again to remove the **NC** symbol.  
**NOTE:** Empty samples are automatically identified with **E**.

4. Click **Next**.
5. In the **Mask Editor** dialog box, ensure the correct assay is identified in the first paragraph of the dialog box. If the assay is incorrect, click **Cancel**, then verify the data file is correct.



6. In each **Sample ID** row, choose either **ACMG Panel** or **Full Panel** to indicate which panels should be analyzed.
  - NOTE:** Masking selections cannot be made for samples identified as negative controls.
  - NOTE:** Choosing the column header of a panel marks each sample with a check to indicate it should be analyzed.
7. Once masking selections have been made (except for negative controls), click **Next**.
8. In the **Mask Confirmation** dialog box, confirm that the masking selections are correct, by selecting the check box in each column header. To make changes, click **Back**.



**NOTE:** Ensure that all masking selections are correct. Once the data is analyzed, all subsequent analyses of the same data in TDAS CFTR are performed using the identified software assay and the same masking options. You cannot unhide any masked targets.

- Click **Apply** to generate the analysis results with the confirmed masking selections.

**NOTE:** Apply is enabled only after the check box in each column header has been selected.

## Mask Targets from the Command-Line

In command-line mode, a valid mask control file is required to specify which panel of variations to display. For this assay, you can choose only the ACMG panel or the Full panel. This assay does not support variation masking or gene masking. Refer to the applicable kit package insert for the mutations covered by each supported panel.

The following is an example of a mask control file for the for the xTAG<sup>®</sup> Cystic Fibrosis v2 assay:

```

TDAS CFTR Mask Control File
Date: November 28, 2008
Created by: AB
Batch: xxxxxxxxxxxx

The Listed_Action command field defines the action for the listed variations or genes (if an assay tests for more
than one gene).

Since the xTAG Cystic Fibrosis v2 assay does not support variation masking or gene masking, always use "HIDE"
as the command action.

::Listed_Action=HIDE

The Non_Listed_Sample_Action command field defines what action to take for the samples in the run that are
not listed in this mask control file.

::Non_Listed_Sample_Action=SHOW_FULL

The sample IDs listed below are given specific instructions as to which panel of variations to analyze/display.

%%Sample 1%%, {ACMG}
%%Sample 2%%, {ACMG}
%%Sample 3%%, {ACMG}
%%Sample 4%%, {FULL}
%%Negative Control%%, {FULL}
    
```

This mask control file yields the following results:

- Genotype information for "Sample 1," "Sample 2," and "Sample 3" is displayed for the variations in the ACMG panel only.
- Genotype information for "Sample 4" is displayed for all variations detected by the assay.
- Genotype information for all other samples not listed in this mask control file is displayed for all variations detected by the assay.
- "Negative Control" is not affected by the masking because all samples described as "negative control" are automatically treated as negative control samples. Refer to the applicable kit package insert for the recommended naming convention for sample IDs.

## Create a Mask Control File from the Command-Line

A mask control file is required only when TDAS CFTR is run in the command-line.

A mask control file is a plain text file with contents that conform to the formats defined in the Mask Control File Syntax table. You should save mask control files with an .mcf file extension. Ensure that all mask control files contain plain text only, with no formatting embedded within the text (for example, use Notepad or plain text editor; do not save the file as Rich Text files or Word documents).

**Table 2. Mask Control File Syntax**

Field	Description
TDAS CFTR Mask Control File	A header to indicate that this is a TDAS CFTR mask control file. This must be the first line of the file.

Field	Description
<p><code>::Listed_Action=[SHOW   HIDE]</code></p>	<p>One of the two command fields. (Command fields are prefixed by two consecutive colons, for example, "::")</p> <p><b>NOTE:</b> This field instructs TDAS CFTR to either hide or display the genotype information for the samples and variations that are specified in this control file.</p> <p>TDAS CFTR fails if this field is not included in the mask control file or if some other command keywords are used.</p> <p>The following describes the actions:</p> <p>SHOW:</p> <p>Displays genotype information for the specified variations or genes only.</p> <p>HIDE:</p> <p>Reverse of the "SHOW" action. Hides genotype information for the specified variations or genes.</p>

Field	Description
<p><code>::Non_Listed_Sample_Action=[HIDE_ALL SHOW_ACMG SHOW_FULL]</code></p>	<p>One of the two command fields. (Command fields are prefixed by two consecutive colons, for example, "::")</p> <p><b>NOTE:</b> This field instructs TDAS CFTR to either hide or display the genotype information for those samples that are NOT listed in this control file.</p> <p>TDAS CFTR fails if this field is not included in the mask control file or if other command keywords are used.</p> <p>The following describes the actions:</p> <p>HIDE_ALL:</p> <p>Hides all the genotype information for samples NOT listed in this control file.</p> <p>SHOW_ACMG:</p> <p>Displays all the genotype information for variations in the ACMG panel for samples NOT listed in this control file. Genotype information for the non-ACMG variations for the samples not listed is hidden.</p> <p>SHOW_FULL:</p> <p>Displays all the genotype information for all variations for samples NOT listed in this control file.</p>
<p><i>comment</i></p>	<p>Other than the above action commands, blank lines or any line that does not begin with two consecutive "%%" characters will be ignored and treated as comments.</p> <p>Comment lines can exist anywhere within the file (except the first line) and will be ignored by the software.</p>

Field	Description
<p><code>%%Sample name%%, {ACMG FULL}, [variation/gene], ...</code></p>	<p>Put each masking sample definition on its own line and surround the sample name with two consecutive percentage characters ""%%" (for example, %%ID1234%%).</p> <p>Follow the sample name with a comma and curly brackets enclosing the parameter value: {ACMG} or {FULL}. {ACMG} masks the non-ACMG variations so that the Listed_Action command applies only to the ACMG variations. Using this option, you can hide or show either the ACMG variations or all detected variations for the specified sample.</p> <p>If no variation or gene names are specified for a sample, then Listed_Action has the reverse effect. For example, the selected panel of variations is shown when the HIDE command is used and hidden when the SHOW command is used.</p> <p>Sample names are case-insensitive. TDAS CFTR uses the sample name to look up the corresponding sample in the output file and hide or show the genotype calls for those variations in the selected panel.</p> <p>A sample name cannot start or end with a percent sign, although it can contain them. If the sample name contains two consecutive percent signs, insert a third one. For example:</p> <p>A sample name of 181%%WVT becomes %%181%%WVT%% in the mask control file.</p> <p>All samples with "negative control" in their names are treated as negative control samples, and are not affected by masking, as they are not analyzed to make calls.</p> <p>Double quotes are acceptable around the variation names, and are necessary when there is a comma within the variation name. However, sample names cannot contain double quotes.</p>

## Change the Primary Negative Control Sample

Data analysis is dependent on which sample is set as the primary negative control sample. By default, the last sample read on the plate is used as the primary negative control.

Each run has at least one primary negative control, and the primary negative control sample is highlighted with a distinctive color in the Summary View. Calls are not made for negative controls. In some situations, you may be required to assign a different negative control to be the primary, and TDAS CFTR will re-analyze the data using the new primary negative control once the assignment is made.

To change the primary negative control sample to another sample:

1. In the **Summary View** of an opened data file, right-click the negative control sample and choose **Mark as Primary Negative Control**.
2. If any **Complete data for** windows display, they will be closed automatically. TDAS CFTR will then re-analyze the data and produce new results dependent on the primary negative control sample data.

## Summary View Window

The Summary View is the main window of TDAS CFTR software. When a file is open, it displays a data analysis summary and provides a listing of the genetic calls for each sample. These calls are the key end-point to running xTAG<sup>®</sup> assays. The rows include sample names along with the plate well location to provide unique identification of the samples, which enables the data to be correlated with sample information from other data sources. Each subsequent column corresponds to an individual variation. Depending on the assay, these columns may be preceded with summary columns, providing a list of variations for which certain calls have been made. Finally, the last column contains explanations for No Call, if one or more cells in the row have a No Call or notes relevant to the calls made. The list of possible No Call messages is assay-specific.

1. In the **Summary View**, click the left border of a toolbar and drag it to another location to re-position the toolbar and maximize the data display area.
  - a. Either detach the toolbar from the window and leave it floating, or attach it to any other window side.

**Table 3. Summary View Descriptions**

<b>Menu Bar</b>	Contains the <b>File, View, Sample, Variation, Admin, and Help</b> menus.
<b>Toolbar</b>	Contains icons to open, export, and print files and reports, as well as icons to show or hide the File Information bar, Legend bar, and variation columns. The <b>About</b> icon opens the <b>About TDAS CFTR</b> dialog box.
<b>File Information Bar</b>	Contains information about the current batch.
<b>Data Grid</b>	Displays header rows and multiple sample rows. Double-click on the right edge of a column header to expand the column and display its full contents.
<b>Legend Bar</b>	Lists the name and version of the assay analysis module used to analyze the data file, along with an assay-specific description of the colors used to distinguish the cells within the data grid.
<b>Status Bar</b>	Contains additional assay-specific information to aid in the analysis of the genetic calls.

Figure 1: Summary View

The screenshot shows the TDAS CFTR software interface. At the top is a menu bar (1) with options: File, View, Sample, Variation, Admin, Help. Below it is a toolbar (2) with icons for file operations. The File Information Bar (3) displays file and batch names, and creation/analysis dates. The central Data Grid (4) shows a table of genetic calls for various samples (A1-V8) across different loci (G85E, 394delTT, R117H, Y122X, 621+1G>T, 711+1G>T, 1078delT, R334W). The Legend Bar (5) defines call colors: orange for mutant alleles, yellow for wild-type and mutant alleles, pink for samples with at least one mutant allele, and red for missing calls. The Status Bar (6) at the bottom shows 'Ready' and a 'NUM' field. A caution message is displayed in the lower part of the interface.

Lo...	Sample	Mu D Calls	HET Calls	Variant Ca...	G85E	394delTT	R117H	Y122X	621+1G>T	711+1G>T	1078delT	R334W
A1	V1				No Call	No Call	WT	WT	WT	WT	WT	WT
B1	V2	G85E			Mu D	WT	WT	WT	WT	WT	WT	WT
C1	V3	394delTT			WT	Mu D	WT	WT	WT	WT	WT	WT
D1	V4	R117H, Y1...		5T	WT	WT	Mu D	Mu D	WT	WT	WT	WT
E1	V5	621+1G>T...			WT	WT	WT	WT	Mu D	Mu D	WT	WT
F1	V6				WT	WT	WT	WT	WT	WT	WT	WT
G1	V7	1078delT, ...			WT	WT	WT	WT	WT	WT	Mu D	Mu D
H1	V8	R347P, R3...			WT	WT	WT	WT	WT	WT	WT	WT

- |              |               |                         |
|--------------|---------------|-------------------------|
| 1. Menu Bar  | 2. Toolbar    | 3. File Information Bar |
| 4. Data Grid | 5. Legend Bar | 6. Status Bar           |

## Menu Bar

The menu bar contains the following menus:

**Table 4. Menu Bar Options**

<b>File</b>	Open or close a data file, export results, view file properties, print results, or exit the program.
<b>View</b>	<p>Change the viewing options to show or hide the <b>Toolbar</b>, <b>Status Bar</b>, <b>File Information Bar</b>, and <b>Legend Bar</b>. Toggling these user interface elements off will maximize the data display area. Choose <b>Variation Columns</b> to display all or none of the variation columns in the <b>Summary View</b>.</p> <p><b>NOTE:</b> The Variation Columns option is only available when the opened assay supports this feature. This display option has corresponding effects on the printing of the results summary and the exporting of the results to PDF.</p> <p>Choose <b>Preferences</b> to change user-defined preferences in the <b>View Preferences</b> dialog box.</p>
<b>Sample</b>	For the selected sample(s), choose <b>Mark as Primary Negative Control</b> , <b>Show Complete Data</b> , or <b>Print Complete Data</b> .
<b>Variation</b>	Show or print the complete data for the chosen variation(s).
<b>Admin</b>	Disable or enable log-on and password functionality, switch identity, change passwords, or change options.
<b>Help</b>	Show the complete help manual, or open the <b>About TDAS CFTR</b> dialog box to display the TDAS CFTR version, copyright information, and a list of all installed assays with their version numbers.

## View the Results

TDAS CFTR displays the summary results of open data files. You can launch two types of complete views from the Summary View:

- A complete view of the sample data provides a listing of the complete data for all variations for the chosen sample.
- A complete view of the variation data provides the complete data for all samples for a chosen variation.

**NOTE:** By selecting more than one sample or variation, TDAS CFTR opens multiple windows that provide complete views of the samples or variations, respectively.

## View the Complete Sample Results

**NOTE:** When TDAS CFTR is password protected, this feature is only available to Full Access Level users.

Data displayed in the complete sample view provides information used to determine the genetic calls for that sample. Sample data for each variation is listed on independent rows. Variations based on more than two analytes are displayed on multiple rows.

To view the complete sample data for any sample(s):

1. Choose the sample(s) in the **Summary View** by clicking on the respective entries. To choose more than one sample, hold down the **Ctrl** key. To choose a continuous group of samples, hold down the **Shift** key.
2. Right-click any chosen sample and choose **Show Complete Sample Data**.

Location	Sample	Mu D Calls	HET Calls	Variant C...	G85E
A1	V1				No Call
B1	V2	G85E			Mu D
C1	V3				WT
D1	V4				WT
E1	V5				WT
F1	V6				WT
G1	V7	1078delT, R334W			WT

The image shows a screenshot of a table with a context menu open over the 'Show Complete Sample Data...' option. The table has columns for Location, Sample, Mu D Calls, HET Calls, Variant C..., and G85E. The rows are labeled A1 through G1. The context menu options are: Mark as Primary Negative Control, Show Complete Sample Data... (highlighted with a red box), and Print Complete Sample Data...

**NOTE:** You can also navigate to the Sample menu, and choose Show Complete Data, or double-click the Location or Sample column of a specific sample to view the complete data for the sample.

**NOTE:** TDAS CFTR displays complete sample data for each of the chosen samples in a separate window. If you chose multiple samples, multiple windows open.

3. If you open more than five samples, a **Warning** dialog box displays. Click **Yes** to continue.
  - Click and drag the **Complete data for sample** dialog box borders to resize the dialog box.
  - Double-click on the right edge of a column header to display the full contents of the column.

## View the Complete Target Results

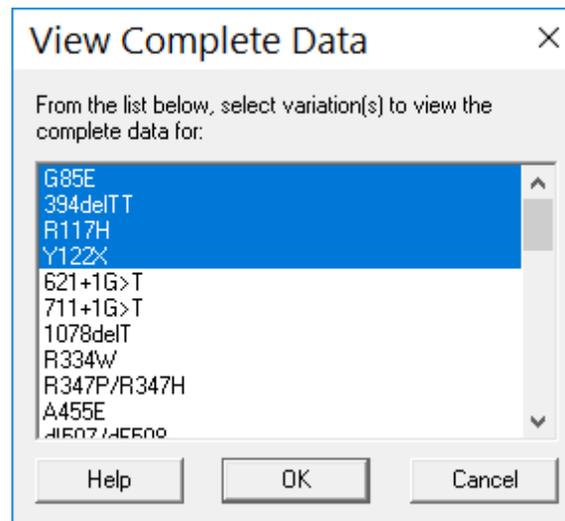
**NOTE:** When TDAS CFTR is password protected, this feature is only available to Full Access Level users.

Data displayed in the complete variation view provides information used to determine the genetic calls for all samples, for that particular variation. Each row contains data for one sample.

To view the complete data for any variation:

1. Navigate to the **Variation** menu, and choose **Show Complete Data**.

- In the **View Complete Data** dialog box, choose the desired variation(s). To choose multiple variations, use the **Ctrl** or **Shift** keys.



**NOTE:** You can also right-click the variation in the Summary View, or double-click on the column heading of a specific variation to view the complete data.

- Click **OK**.

**NOTE:** TDAS CFTR displays complete variation data for each of the chosen variations in a separate window. If you chose multiple variations, multiple windows open.

- If you open more than five variations, a **Warning** dialog box displays. Click **Yes** to continue
  - Click and drag the **Complete data for variation** dialog box borders to resize the dialog box.
  - Double-click on the right edge of a column header to display the full contents of the column.

---

## Print the Results

### Print the Results Summary

You can print results summary data of an open data file. These printouts are ideal for creating hard copy reports of the variation detection calls. They contain the same information displayed in the software window.

To print the results summary of an open data file:

- Navigate to the **File** menu, and choose **Print**.
- In the **Print** dialog box, specify the desired options in the **Printer**, **Margins (inches)**, and **Copies** panels.
- Clear the **Scale printout to fit in page width** check box in the **Printing Options** panel, to print in the default size. This disables TDAS CFTR from scaling the view to fit horizontally on one page, and may print on several pages.

**NOTE:** Due to size and readability issues, a printout may not fit on one page.

- To preview the summary printout before printing, navigate to the **File** menu, and choose **Print Preview**.

4. Clear the **Send color data to the printer** check box in the **Printing Options** panel, to print in black and white without using gray-scale to replace colors. The resulting printout contains alternate row shading, and does not use color to distinguish the genetic calls.

**NOTE:** If you print in color, the colors used to distinguish the calls are the same as in the Summary View legend, and alternate rows are shaded to differentiate subsequent rows.

5. Click **OK**.

## Print the Complete Sample Results

**NOTE:** When TDAS CFTR is password protected, this feature is only available to Full Access Level users.

Choose one of the following methods to either print all complete sample data or a set of complete data for one or more samples:

1. The Summary View displays the complete results for the samples. To print, navigate to the **File** menu, and choose **Print**. This method has the advantage of showing you exactly what will be printed, since you have the results on display.
2. Navigate to the **File** menu, and choose **Print All**.
  - a. In the **Print Items** dialog box, ensure that the **Include the following Samples** check box is selected, and click **OK**. This method is most useful for quickly generating hard copy reports of all samples, all variations, or data from all views.

**NOTE:** If you do not want to include all samples, choose a specific sample. Hold down the Ctrl key to choose more than one sample, or use the Shift key to choose a continuous group of samples. Click Select All Samples to include all of the samples.

**NOTE:** The Print Items dialog box also allows you to include the summary and complete variation results.

3. Choose the desired **Location** or **Sample** cell(s) in the **Summary View**. Use the **Ctrl** or **Shift** keys to choose multiple samples.
  - a. Right-click any of the chosen samples and choose **Print Complete Sample Data**. This method will print multiple samples at one time, without requiring you to open each sample individually to print. This is a faster printing method, but it requires you to only choose the samples you want printed.

Location	Sample	Mu D Calls	HET Calls	Variant C...	G85E
A1	V1				No Call
B1	V2				Mu D
C1	V3				WT
D1	V4				WT
E1	V5				WT
F1	V6				WT
G1	V7				WT

The image shows a screenshot of a table with a context menu open over the 'Print Complete Sample Data...' option. The table has columns for Location, Sample, Mu D Calls, HET Calls, Variant C..., and G85E. The rows are labeled A1 through G1. The context menu is open over the row for sample V6 (F1), and the 'Print Complete Sample Data...' option is highlighted with a red box.

4. Choose the desired **Location** or **Sample** cell(s) in the **Summary View**. Use the **Ctrl** or **Shift** keys to choose multiple samples.
  - a. Navigate to the **Sample** menu, and choose **Print Complete Data**. This method is convenient for printing specific sample data, and you do not need to preview the data prior to printing.

## Print the Complete Target Results

**NOTE:** When TDAS CFTR is password protected, this feature is only available to Full Access Level users.

Choose one of the following methods to either print all complete variation results or a set of complete results for one or more variations:

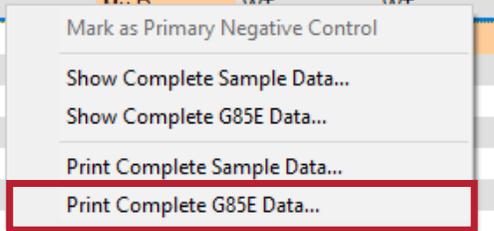
1. The Summary View displays the complete results for the variations. To print, navigate to the **File** menu, and choose **Print**. This method has the advantage of showing you exactly what will be printed, since you have the results on display.
2. Navigate to the **File** menu, and choose **Print All**.
  - a. In the **Print Items** dialog box, ensure that the **Include the following Variations** check box is selected and click **OK**. This method is the most useful for quickly generating hard copy reports of all variations (and all samples, or data from all views).

**NOTE:** If you do not want to include all variations, choose a specific variation. Use the Ctrl or Shift keys to choose multiple variations. Click Select All Variations to include all of the variations.

**NOTE:** The Print Items dialog box also allows you to include the summary and complete sample results.

3. Choose the desired variation cell(s) you want to print in the **Summary View**. Hold down the **Ctrl** key to choose more than one variation, or use the **Shift** key to choose a continuous group of variations.
  - a. Right-click any of the chosen variations, and choose **Print Complete "variation" Data**, where "variation" is the name of the variation you have chosen. This method will print the specific variation(s) you chose without opening the complete view display.

Location	Sample	Mu D Calls	HET Calls	Variant C...	G85E	394delTT	R117H	Y122X
A1	V1				No Call	No Call	WT	WT
B1	V2	G85E			Mu D	WT	WT	WT
C1	V3	394delTT			WT			
D1	V4	R117H, Y122X		5T	WT			
E1	V5	621+1G>T, 711+1G>T			WT			
F1	V6				WT			
G1	V7	1078delT, R334W			WT			
H1	V8	R347P, R347H			WT			
A2	V9	A455E			WT			
B2	V10							



4. Navigate to the **Variation** menu, and choose **Print Complete Data**.
  - a. Choose the variation(s) you want to print the complete data for and click **OK**. This method allows you to choose specific variation(s) to print, without opening the complete view display.

## Export the Results

To preserve the integrity of the data file, the data file cannot be edited. Therefore, there is no Save option.

However, there is an option to export the results to a spreadsheet, but the exported file CANNOT be opened in TDAS CFTR. TDAS CFTR only opens the original data file. You can also export results to a PDF file.

## Export the Results Summary

You can export summary data of an open data file to a CSV file. You can then import the CSV file to any common spreadsheet program for further analysis or presentation. The exported summary data contains all the data displayed in the Summary View.

To export summary results:

1. Navigate to the **File** menu, and choose **Export Summary As**.
2. In the **Export Summary** dialog box, specify the location and file name for the exported data.
3. Click **Save**.

## Export the Results Summary from the Command-Line

**NOTE:** When TDAS CFTR is password protected, this feature is available to users of all access levels.

**NOTE:** The syntax for each command-line option begins with the executable "TDAS CFTR," followed by a list of parameters. Parameters encased in square brackets are optional. Words in italics should be replaced by the actual values when running the command. Characters in bold must be used as is.

The syntax for exporting the results summary to a CSV file is:

```
"TDAS CFTR" -export "filenames" -o"Export_filename" [-uUser] [-pPassword] [-m"Mask_control_filename"] [-q]
```

**NOTE:** The previous line is a single line command.

The parameters and filenames are outlined in the following table:

**Table 5. Command-Line Parameters**

Parameters/Filenames	Explanation
<i>"filenames"</i>	This is the name (and path, if necessary) of the data file for analysis. For assays that require more than one data file, the filenames must be separated by a " " character and must be enclosed within a pair of double quotes (for example, "C:\My Batches\OutputA.csv C:\My Batches\OutputB.csv"). If this parameter is not specified in the command-line or TDAS CFTR cannot find an assay to analyze the data file, the export process fails.
-o <i>Export_filename</i>	This is the name (including the path, if necessary) of the exported file that is the output of this command. This parameter must be provided. Otherwise, the export process fails.
-u <b>User</b>	This optional parameter submits the name of the user who runs this command. The name of the user is mainly for log-on information purposes and displays in the export file. This parameter is ignored if log-on is not enabled.
-p <b>Password</b>	This parameter submits the password for accessing TDAS CFTR. If TDAS CFTR is not password protected, this parameter is ignored.  <b>NOTE:</b> When TDAS CFTR is password protected, the -exportall feature is only available to Full Access Level users.

Parameters/FileNames	Explanation
<b>-m</b> " <i>Mask_control_filename</i> "	This is the mask control filename (and path, if necessary). This is required only if the data file was not previously analyzed by TDAS CFTR. Otherwise, this parameter is optional, as TDAS CFTR can remember the previous masking selections. If the specified mask control file is invalid or cannot be applied to the data file, the export process fails.
<b>-q</b>	This optional flag tells TDAS CFTR to export the analyzed data without logging any messages to the log file.

## Export the Complete Results

**NOTE:** When TDAS CFTR is password protected, this feature is only available to Full Access Level users.

You can export complete data from an open data file to a CSV file. The raw and background signals displayed in the complete views, as well as calls for all samples and all variations are exported to one CSV file. You can then import the CSV file into any common spreadsheet program for further analysis or presentation, but it cannot be used by TDAS CFTR to re-analyze the data.

To export the complete sample data:

1. Navigate to the **File** menu, and choose **Export Full Data As**.
2. In the **Export Complete Data** dialog box, specify the location and file name for the exported data.
3. Click **Save**.

## Export the Complete Results from the Command-Line

**NOTE:** When TDAS CFTR is password protected, this feature is only available to Full Access Level users.

**NOTE:** The syntax for each command-line option begins with the executable "TDAS CFTR," followed by a list of parameters. Parameters encased in square brackets are optional. Words in italics should be replaced by the actual values when running the command. Characters in bold must be used as is.

The syntax for exporting the complete results to a CSV file is:

**"TDAS CFTR" -exportall "*filenames*" -o"*Export\_filename*" [-u*User*] [-p*Password*] [-m"*Mask\_control\_filename*"] [-q]**

**NOTE:** The previous line is a single line command.

The parameters and filenames are outlined in the following table:

**Table 6. Command-Line Parameters**

Parameters/FileNames	Explanation
<i>"filenames"</i>	This is the name (and path, if necessary) of the data file for analysis. For assays that require more than one data file, the filenames must be separated by a " " character and must be enclosed within a pair of double quotes (for example, "C:\My Batches\OutputA.csv C:\My Batches\OutputB.csv"). If this parameter is not specified in the command-line or TDAS CFTR cannot find an assay to analyze the data file, the export process fails.

Parameters/FileNames	Explanation
<code>-oExport_filename</code>	This is the name (including the path, if necessary) of the exported file that is the output of this command. This parameter must be provided. Otherwise, the export process fails.
<code>-uUser</code>	This optional parameter submits the name of the user who runs this command. The name of the user is mainly for log-on information purposes and displays in the export file. This parameter is ignored if log-on is not enabled.
<code>-pPassword</code>	This parameter submits the password for accessing TDAS CFTR. If TDAS CFTR is not password protected, this parameter is ignored.  <b>NOTE:</b> When TDAS CFTR is password protected, the <code>-exportall</code> feature is only available to Full Access Level users.
<code>-m"Mask_control_filename"</code>	This is the mask control filename (and path, if necessary). This is required only if the data file was not previously analyzed by TDAS CFTR. Otherwise, this parameter is optional, as TDAS CFTR can remember the previous masking selections. If the specified mask control file is invalid or cannot be applied to the data file, the export process fails.
<code>-q</code>	This optional flag tells TDAS CFTR to export the analyzed data without logging any messages to the log file.

## Export the Results to a PDF

You can export data to a PDF file once a data file has been successfully opened and TDAS CFTR displays the summary results. You specify the contents of the PDF report through a dialog box. The PDF report can contain all or some of the following sets of data in tabular format:

- Summary View data
- Complete sample data
- Complete variation data

You can also export complete sample and variation data in graphical format. The PDF export contains bookmarks to each individual sample and each individual variation present in the report, as well as other analysis information as presented by TDAS CFTR views.

**NOTE:** If password protection is enabled, only Full Access Level users can export complete sample and variation data. All users can export Summary View data.

1. Navigate to the **File** menu, and choose **Export to PDF**.

**NOTE:** If the Export to PDF command is grayed out, you will need to reinstall TDAS CFTR, allowing printer installation privileges. See your IT administrator if you do not have the appropriate privileges.

2. In the **Export to PDF** dialog box, choose your desired settings in the **Summary**, **Samples**, and **Variations** panels.
3. In the **PDF file** panel, click **Browse**.
4. In the **Export to PDF File** dialog box, specify the location and name of the exported file.

**NOTE:** The default file extension of the exported file is `.pdf`.

5. Click **Save**.
6. In the **Export to PDF** dialog box, click **OK**.
7. In the **PDF Page Setup** dialog box, choose your desired settings. Then click **OK**.
8. If a **Summary warning** dialog box displays, click **OK** to print the data or click **Cancel** to adjust the print settings.

## Export the PDF to a Condensed Format

**NOTE:** When using Windows® 10, TDAS CFTR must be run as an administrator to access the administrative functions.

To export the complete sample and variation data in a condensed format:

1. Navigate to the **Admin** menu, and choose **Options**.
2. In the **PDF Report Setting** panel, select the **Condensed report format** check box.
3. Click **OK**.

## Export the Results to an XML File

When a file is open and displays the summary results, you can export data to an XML file.

**NOTE:** If TDAS CFTR is not password protected, all data and results are exported to the XML file. When TDAS CFTR is password protected, only Full Access Level users can export complete sample and variation results. Restricted Access Level users can export only calls, sample messages, and variation messages.

1. Navigate to the **File** menu, and choose **Export to XML**.
2. In the **Export to XML** dialog box, specify the location and name of the exported file.

**NOTE:** The default file extension of the exported file is .xml.

3. Click **Save**.

## Export the Results to an XML File from the Command-Line

**NOTE:** If TDAS CFTR is not password protected, all data and results are exported to the XML file. When TDAS CFTR is password protected, only Full Access Level users can export complete sample and variation results. Restricted Access Level users can only export calls, sample messages, and variation messages.

**NOTE:** The syntax for each command-line option begins with the executable "TDAS CFTR," followed by a list of parameters. Parameters encased in square brackets are optional. Words in italics should be replaced by the actual values when running the command. Characters in bold must be used as is.

The syntax for exporting the results to an XML file is:

```
"TDAS CFTR" -exportxml "filenames" -o"Export_filename" [-uUser] [-pPassword] [-m"Mask_control_filename"] [-q]
```

**NOTE:** The previous line is a single line command.

The parameters and filenames are outlined in the following table:

**Table 7. Command-Line Parameters**

Parameters/Filenames	Explanation
<i>"filenames"</i>	This is the name (and path, if necessary) of the data file for analysis. For assays that require more than one data file, the filenames must be separated by a " " character and must be enclosed within a pair of double quotes (for example, "C:\My Batches\OutputA.csv C:\My Batches\OutputB.csv"). If this parameter is not specified in the command-line or TDAS CFTR cannot find an assay to analyze the data file, the export process fails.
<b>-o</b> <i>Export_filename</i>	This is the name (including the path, if necessary) of the exported file that is the output of this command. This parameter must be provided. Otherwise, the export process fails.
<b>-u</b> <i>User</i>	This optional parameter submits the name of the user who runs this command. The name of the user is mainly for log-on information purposes and displays in the export file. This parameter is ignored if log-on is not enabled.
<b>-p</b> <i>Password</i>	This parameter submits the password for accessing TDAS CFTR. If TDAS CFTR is not password protected, this parameter is ignored.  <b>NOTE:</b> When TDAS CFTR is password protected, the -exportall feature is only available to Full Access Level users.
<b>-m</b> <i>"Mask_control_filename"</i>	This is the mask control filename (and path, if necessary). This is required only if the data file was not previously analyzed by TDAS CFTR. Otherwise, this parameter is optional, as TDAS CFTR can remember the previous masking selections. If the specified mask control file is invalid or cannot be applied to the data file, the export process fails.
<b>-q</b>	This optional flag tells TDAS CFTR to export the analyzed data without logging any messages to the log file.

---

## Close Data Files

Navigate to the **File** menu, and choose **Close**.

# Chapter 3: Analyzing Assays with TDAS CFTR Software

The xTAG<sup>®</sup> Cystic Fibrosis v2 assay consists of bi-allelic and tri-allelic loci, and two special polymorphisms. Each bi-allelic locus has the same potential genetic calls based on signals from two hybridization probes. Each tri-allelic locus has the same potential genetic calls based on signals from three hybridization probes, when the full panel is displayed. For the tri-allelic loci, R347P/R347H and 2183/2184, when you display only the ACMG panel of variations for a sample, the R347H allele and the 2183AA>G allele are masked because these mutations are not part of the ACMG Panel. When only the ACMG panel of variations is displayed, the R347P allele and the 2184delA allele are analyzed along with their respective wild-type alleles as bi-allelic loci.

There are two special polymorphisms in the assay: 5T/7T/9T and I506V,I507V,F508C. The 5T/7T/9T variants are analyzed similar to a tri-allelic locus, except none of the three alleles is considered to be the wild-type allele, and the display of the call is dependent on the R117H call. The I506V,I507V,F508C variants have three associated probes but each probe is analyzed independently and each probe detects the presence of its respective mutation (e.g., the I506V probe detects the I506V mutation). The display of the call for I506V,I507V,F508C depends on the dI507 and dF508 calls.

The call for the special polymorphisms may be CH, which indicates that the call is hidden (Call Hidden). Whether a call is hidden or displayed is determined by the reference locus (for example, R117H for the 5T/7T/9T variants, and dI507 and dF508 for the I506V,I507V,F508C variants).

---

## Display Hidden Calls

**NOTE:** The toggle feature for displaying hidden calls is only available to customers outside of the U.S.

Outside of the U.S., you may be able to display hidden calls for the special polymorphisms by performing one of the following options:

- Right-click on any cell of the sample in the **Summary View**, and choose the **Hide call for 5T/7T/9T** or **Hide call for I506V,I507V,F508C** menu item from the dialog box.
- Choose the appropriate sample in the **Summary View**. To choose more than one sample, hold down the **Ctrl** key, or use the **Shift** key to choose a continuous group of samples. Navigate to the **Sample** menu, and choose **Hide call for 5T/7T/9T** or **Hide call for I506V,I507V,F508C**.

---

## Possible Calls

Calls and data display in different views of TDAS CFTR, and have the following assay-specific components:

**Table 8. Bi-allelic Loci**

Bi-allelic Loci	Description
WT	Only the wild-type allele was detected.
HET	Both the wild-type and the mutant alleles were detected.
Mu D	The mutant allele was detected.
No Call	A call could not be made.
NS	No signal due to a possible homozygous deletion for the corresponding amplicon.
-	The call was masked by the user.

**Table 9. Tri-allelic Loci**

Tri-allelic Loci	Description
WT	Only the wild-type allele was detected.
Wt D	The corresponding wild-type allele was detected.
HET	Both the wild-type and the mutant alleles were detected.
Mu D	The mutant allele was detected.
No Call	A call could not be made.
NS	No signal due to a possible homozygous deletion for the corresponding amplicon.
-	The call was masked by the user.

**Table 10. 5T/7T/9T Variants**

5T/7T/9T Variants	Description
5T D	The 5T allele was detected.
7T D	The 7T allele was detected.
9T D	The 9T allele was detected.
5T/7T D	The 5T and 7T alleles were detected.

5T/7T/9T Variants	Description
5T/9T D	The 5T and 9T alleles were detected.
7T/9T	The 7T and 9T alleles were detected.
CH	Call hidden as the call for R117H is not HET or Mu D.
No Call	A call could not be made.
Uncalled	<p>A call could not be made. (The criteria used to make this call are the same as for No Call. However, Uncalled is used for displaying calls that are initially displayed as CH, but are subsequently manually toggled to display the hidden call.)</p> <p><b>NOTE:</b> The toggle feature for displaying hidden calls is only available to customers outside of the U.S.</p>
I506V D	The I506V variant was detected.
I507V D	The I507V variant was detected.
F508C D	The F508C variant was detected.
I506V,I507V D	The I506V and I507V variants were detected.
I506V,F508C D	The I506V and F508C variants were detected.
I506V,I507V,F508C D	The I506V, I507V, and F508C variants were detected.
ND	The I506V, I507V, and F508C variants were not detected.
CH	Call hidden as the calls for dI507 and dF508 are not Mu D.
No Call	A call could not be made.

5T/7T/9T Variants	Description
Uncalled	<p>A call could not be made. (The criteria used to make this call are the same as for No Call. However, Uncalled is used for displaying calls that are initially displayed as CH, but are subsequently manually toggled to display the hidden call.)</p> <p><b>NOTE:</b> The toggle feature for displaying hidden calls is only available to customers outside of the U.S.</p> <p><b>NOTE:</b> As with any hybridization-based assay, underlying polymorphisms in primer-binding regions can affect the alleles being detected and subsequently the calls made. In particular, in the case of a Mu D call, it is possible that the wild-type allele is also present but remains undetected because of interference by another polymorphism nearby.</p>

The Legend Bar at the bottom of the display page lists the name of the assay analysis module used, along with an assay-specific description of the colors used to distinguish the cells within the data display grid. For the xTAG<sup>®</sup> Cystic Fibrosis v2 assay, there are six legend items showing the colors used. For example, the colors used in an assay containing only bi-allelic variations would visually differentiate the call cells as WT, Mu D, HET, and No Call, as well as the Sample and Location cells. These colors would indicate the presence of mutant allele(s) in one or more variants or the presence of a No Call call, and to flag the Notes and explanations cells if a No Call explanation or other note warrants it.

**Table 11. Legend Bar Descriptions**

<b>Mutant allele(s) detected</b>	Distinguishes cells to indicate that at least one mutant allele was detected for the corresponding variation in this sample.
<b>Wild-type and mutant alleles detected</b>	Distinguishes data cells to indicate that both the wild-type allele and one mutant allele were detected for the corresponding variation in this sample.
<b>Sample has at least one mutant allele detected</b>	Distinguishes the <b>Location</b> and <b>Sample</b> cells, if a mutant allele was detected for at least one variation for this sample.
<b>Call(s) not made</b>	Distinguishes the data cells for which a call could not be made, and distinguishes the <b>Location</b> , <b>Sample</b> , and <b>Notes and explanations</b> cells, to indicate that at least one data cell has a No Call for this sample.
<b>Signal significant</b>	Used only in the complete view (not in the Summary View) to highlight net signal cells, for which the corresponding raw signal is significant.
<b>Primary negative control sample</b>	Distinguishes primary negative control sample cells in the Summary View and complete variation views (the data cells and the <b>Location</b> , <b>Sample</b> , and <b>Notes and explanation</b> cells).

**Figure 2: Legend Bar**



## Summary View Messages

The following messages may display in the Notes and explanations column of the Summary View:

**Table 12. Summary View Messages**

Message	Explanation
This well was not read by the Luminex machine	No data is available to process because the Luminex <sup>®</sup> analyzer did not read any values in this well.
This well has been identified as a negative control sample	This sample is a negative control sample, but it is not the primary negative control sample.
Assay failed: '<instrument message>'. Check the Luminex instrument for details	The Luminex <sup>®</sup> analyzer gave an error message '<instrument message>' in the Warnings/Errors section in the output file for the primary negative control sample. Check the logs of the Luminex instrument for more information.
Assay failed: 'Sample Empty' message from the Luminex machine for the primary negative control sample	The Luminex <sup>®</sup> analyzer found the primary negative control sample well to be empty and could not take any reliable readings for the well.
Assay failed: 'User cancel' message from the Luminex machine for the primary negative control sample	The Luminex <sup>®</sup> analyzer was interrupted by the user when reading the primary negative control sample well and could not take any reliable readings for the well.
Assay failed: low bead count(s) for the primary negative control sample	The bead count for at least one of the bead populations used by the kit is too low for the primary negative control sample. This may indicate that the readings for this well are not reliable.
Assay failed: unexpected value(s) encountered for the primary negative control sample	An unexpected value was encountered for at least one variation in the primary negative control sample, which indicates that the data values for this run of the assay may be in question.
Assay failed: a primary negative control signal exceeds acceptable value	At least one of the primary negative control values exceeds the accepted threshold value, which indicates that the data values for this run of the assay may be in question.
Sample failed: '<instrument message>'. Check the Luminex instrument for details	The Luminex <sup>®</sup> analyzer gave an error message '<instrument message>' in the Warnings/Errors section in the output file for this sample. Check the logs of the Luminex instrument for more information.
Sample failed: 'Sample Empty' message from the Luminex machine for this well	The sample fails because the Luminex <sup>®</sup> analyzer found the sample well to be empty and could not take any reliable readings.
Sample failed: 'User cancel' message from the Luminex machine for this well	The Luminex <sup>®</sup> analyzer was interrupted by the user when reading this sample well and could not take any reliable readings.

Message	Explanation
Sample failed: low bead counts, unexpected values, or inadequate signals for all variations	All variations in this sample have low bead counts, encountered an unexpected value, or have low signals, indicating that the readings for this sample are not reliable.
Variation(s) failed: low bead count(s)	The bead count of one or more variations is too low, indicating that the readings for this well are not reliable.
Variation(s) failed: unexpected value(s) encountered	An unexpected value was encountered for one or more variations in this sample, indicating that the readings for this well are not reliable.
Variation(s) failed: signal(s) inconsistent with local deletion	The signal for at least one variation in Exon 3 is inconsistent with the call of the deletion variation (del e2e3). This prevents genetic calls to be made for del e2e3 and any of the variations in Exon 3.
Variation(s) failed: signal(s) inadequate	Signal(s) for at least one variation in this sample do not meet the signal threshold requirement and the signal-to-noise threshold requirement, indicating that the readings for that well are not reliable.
Variation failed: raw signal(s) not within predefined ranges	The Intron 1 and Intron 3 signals for del e2e3 are inconsistent with each other.
Variation(s) failed: allelic ratio(s) not within predefined ranges	The allelic ratio for one or more variations does not fall within the predetermined ranges that would allow a call to be made.
Warning: presence of benign variant(s) affected interpretation of the dI507/dF508 result. Refer to Kit Package Insert for details	At least one of the benign variants (I506V, I507V, F508C) is detected when dI507 or dF508 has a Mu D call.
Warning: '<instrument message>'. Check the Luminex instrument for details	The sample analysis is performed as for a normal well, but the message warns the user that something unusual may have happened during the data reading process, which may affect the results. Check the logs of the Luminex <sup>®</sup> instrument for more information.

## Detailed View Messages

The following messages may display in the Notes and explanations column of the Detailed Views:

**Table 13. Detailed View Messages**

Message	Explanation
This well was not read by the Luminex machine	No data is available to process because the Luminex <sup>®</sup> analyzer did not read any values in this well.
This well has been identified as a negative control sample	This sample is a negative control sample, but it is not the primary negative control sample.
Assay failed: '<instrument message>'. Check the Luminex instrument for details	The Luminex <sup>®</sup> analyzer gave an error message '<instrument message>' in the Warnings/Errors section in the output file for the primary negative control sample. Check the logs of the Luminex <sup>®</sup> instrument for more information.
Assay failed: 'Sample Empty' message from the Luminex machine for the primary negative control sample	The Luminex <sup>®</sup> analyzer found the primary negative control sample well to be empty and could not take any reliable readings for the well.
Assay failed: 'User cancel' message from the Luminex machine for the primary negative control sample	The Luminex <sup>®</sup> analyzer was interrupted by the user when reading the primary negative control sample well and could not take any reliable readings for the well.
Assay failed: low bead count(s) for the primary negative control sample	The bead count for at least one of the bead populations used by the kit is too low for the primary negative control sample, which indicates that the data values for this run of the assay may be in question.
Assay failed: unexpected value(s) encountered for the primary negative control sample	An unexpected value was encountered for at least one variation in the primary negative control sample, which indicates that the data values for this run of the assay may be in question.
Assay failed: a primary negative control signal exceeds acceptable value	At least one of the primary negative control values exceeds the accepted threshold value, which indicates that the data values for this run of the assay may be in question.
Sample failed: '<instrument message>'. Check the Luminex instrument for details	The Luminex <sup>®</sup> analyzer gave an error message '<instrument message>' in the Warnings/Errors section in the output file for this sample. Check the logs of the Luminex instrument for more information.
Sample failed: 'Sample Empty' message from the Luminex machine for this well	The sample fails because the Luminex <sup>®</sup> analyzer found the sample well to be empty and could not take any reliable readings.
Sample failed: 'User cancel' message from the Luminex machine for this well	The Luminex <sup>®</sup> analyzer was interrupted by the user when reading this sample well and could not take any reliable readings.

Message	Explanation
<b>Sample failed: low bead counts, unexpected values, or inadequate signals for all variations</b>	All the variations in this sample have low bead counts, encountered an unexpected value, or have low signals, indicating that the readings for this sample are not reliable.
<b>Variation failed: low bead count(s)</b>	The bead count of this variation is too low, indicating that the readings are not reliable.
<b>Variation failed: unexpected value(s) encountered</b>	An unexpected value was encountered for this variation, indicating that the readings are not reliable.
<b>Variation failed: signal(s) inconsistent with local deletion</b>	The signal for at least one variation in Exon 3 is inconsistent with the call of the deletion variation (del e2e3). This prevents genetic calls to be made for del e2e3 and any of the variations in Exon 3.
<b>Note: variation signals not detected, sample probably a local deletion</b>	This Exon 3 variation does not have significant signals because the call for del e2e3 is Mu D.
<b>Variation failed: signal(s) inadequate</b>	Signal(s) for this variation do not meet the signal threshold requirement and the signal-to-noise threshold requirement, indicating that the readings for that well are not reliable.
<b>Variation failed: raw signal(s) not within predefined ranges</b>	The Intron 1 and Intron 3 signals for del e2e3 are inconsistent with each other.
<b>Variation failed: allelic ratio(s) not within pre-defined ranges</b>	The allelic ratio for this variation does not fall within the pre-determined ranges that would allow a call to be made.
<b>Warning: presence of benign variant(s) affected interpretation of the dI507/dF508 result. Refer to Kit Package Insert for details</b>	The signals of this variation may be affected by the del e2e3 variation.
<b>Note: signals may be affected by local deletion</b>	The sample analysis is performed as for a normal well, but the message warns the user that something unusual may have happened during the data reading process, which may affect the results. Check the logs of the Luminex instrument for more information.
<b>Warning: '&lt;instrument message&gt;'. Check the Luminex instrument for details</b>	The sample analysis is performed as for a normal well, but the message warns the user that something unusual may have happened during the data reading process, which may affect the results. Check the logs of the Luminex <sup>®</sup> instrument for more information.

# Chapter 4: Managing User Access

---

## User Access

Log-on, password, and timeout functions provide controlled access to TDAS CFTR. The log-on function allows you to enter a user name for display, print, and export purposes. The password function distinguishes between a Restricted Access Level user and a Full Access Level user through the use of two distinct passwords. The timeout option requires you to log-on if TDAS CFTR is idle for a set period of time.

When TDAS CFTR is log-on enabled, you are prompted to enter a user name when the software is started, if the software log-on has timed out, or when switching user names. The user name is used for display, print, and export purposes, and may be left blank. The user name entered to log on to TDAS CFTR displays on the information bar beside the Analyzed by label in the Summary View. It is incorporated in all printouts and export files.

You can disable the log-on function. If TDAS CFTR is password protected, disabling the log-on function also disables password protection and the timeout functions. When TDAS CFTR is password protected, you are prompted to enter a user name and a password when the software is started, if the software log-on has timed out, and when switching user names. Although the user name may be left blank, you must enter a valid password.

The password determines the level of access you have within the software. A Full Access Level user has access to summary results, complete views, full data export, and administrative privileges. A Restricted Access Level user has access to summary results only. Passwords for the two access levels are set up at the time of installation or by enabling the function after the software is installed. A Full Access Level user may change the passwords at any time or disable the function completely.

The timeout function is available only when TDAS CFTR is log-on enabled. You must log on to access TDAS CFTR, if idle for over a pre-set time. The default timeout is 10 minutes. You can change the timeout period during an active session of TDAS CFTR. When TDAS CFTR is log-on and password enabled, only Full Access Level users can change the timeout period.

## Enable Password Controlled Access

**NOTE:** When using Windows<sup>®</sup> 10, TDAS CFTR must be run as an administrator to access the administrative functions.

Enabling password protection automatically enables the log-on function. Password protection may be set up at the time of installation.

To enable password protection after installation:

1. Navigate to the **Admin** menu, and choose **Enable Password**.
2. In the **Setup Passwords** dialog box, enter the **Full Access Level** and/or **Restricted Access Level** passwords.
  - a. If you choose to set only a **Full Access Level** password, enter and re-enter the password in the appropriate text boxes under **Full Access Level**, leaving the **Restricted Access Level** password blank.

**NOTE:** You must set up a Full Access Level password before you can set up a Restricted Access Level password. If you want to give full access to all users, you should disable password protection rather than leaving both passwords blank.

**NOTE:** Passwords must be 30 alphanumeric characters or less.

- b. If you choose to set a **Restricted Access Level** password, enter and re-enter the password in the appropriate text boxes under **Restricted Access Level**.
3. Click **OK**.
4. Once setup of password protection is complete, you are prompted to log on with a password before proceeding with TDAS CFTR. Enter the **User Name** and **Password** and click **OK**.

**NOTE:** To reset passwords if the Full Access Level password is lost or forgotten, you must re-install TDAS CFTR.

## Change Passwords

**NOTE:** When using Windows® 10, TDAS CFTR must be run as an administrator to access the administrative functions.

You must have Full Access Level to change passwords.

**NOTE:** Passwords must be 30 alphanumeric characters or less.

1. Navigate to the **Admin** menu, and choose **Change Passwords**.
2. In the **Change Passwords** dialog box, enter the current **Full Access Level** password.

**NOTE:** You will need to enter the current Full Access Level password to change the Full Access Level password or the Restricted Access Level password.

3. If you want to update the Full Access Level password, select the **Update Full Access Level Password** check box, and enter and confirm the new password information.
4. If you want to update the Restricted Access Level password, select the **Update Restricted Access Level Password** check box, and enter and confirm the new password information.
5. Click **OK**.

## Disable Password Controlled Access

**NOTE:** When using Windows® 10, TDAS CFTR must be run as an administrator to access the administrative functions.

**NOTE:** Only Full Access Level users can disable the password controlled access.

**NOTE:** Disabling password protection does not disable the log-on function.

1. Navigate to the **Admin** menu, and choose **Disable Password**.
2. In the **Disable Password** dialog box, enter the current **Full Access Level** password.

**NOTE:** The Disable Password dialog box allows you to enter the Full Access Level password in order to turn off password protection. Disabling password protection does NOT automatically disable the log-on functionality.

3. Click **OK**.

## Enable Log-on Function

**NOTE:** When using Windows® 10, TDAS CFTR must be run as an administrator to access the administrative functions.

The log-on function is automatically enabled if TDAS CFTR is password protected.

To enable log-on when TDAS CFTR is not password protected:

1. Navigate to the **Admin** menu, and choose **Enable Log-on**.
2. In the **Log-on** dialog box, enter a **User Name**. The user name is used for display, print, and export purposes and may be left blank.
3. Click **OK**.

## Switch Identity

**NOTE:** When using Windows® 10, TDAS CFTR must be run as an administrator to access the administrative functions.

To change identity when TDAS CFTR is log-on enabled:

1. Navigate to the **Admin** menu, and choose **Switch Identity**.
2. In the **Log-on TDAS CFTR** dialog box, enter a new **User Name** and **Password**, if a password is required.
3. Click **OK**.

## Disable Log-On Function

**NOTE:** When using Windows® 10, TDAS CFTR must be run as an administrator to access the administrative functions.

If access to TDAS CFTR is password protected, disabling the log-on function also disables password protection.

To turn off log-on and password protection:

1. Navigate to the **Admin** menu, and choose **Disable Log-on**.
2. In the **Disable Password** dialog box, enter the current **Full Access Level** password.
3. Click **OK**.

## Reactivate TDAS CFTR After a Timeout

When the log-on function is enabled, TDAS CFTR can be set to time out after it has idled for longer than a pre-determined period of time.

To reactivate a session:

1. Click anywhere in the TDAS CFTR window.
2. In the **Log-on** dialog box, enter a **User Name** and **Password**, if a password is required.
3. Click **OK**.

## Change or Disable Timeout Period

**NOTE:** When using Windows® 10, TDAS CFTR must be run as an administrator to access the administrative functions.

If TDAS CFTR is log-on and password enabled, only Full Access Level Users can change the timeout period.

To change or disable the timeout function:

1. Navigate to the **Admin** menu, and choose **Options**.
2. In the **Log-on Session** panel of the **Options** dialog box, enter the desired timeout period in minutes or change the timeout period to zero minutes to disable the timeout function.

**NOTE:** The default timeout period is 10 minutes.

3. Click **OK**.

---

## Luminex Technical Support

Contact Luminex Technical Support by telephone in the U.S. and Canada by calling: 1-877-785-2323

Contact outside the U.S. and Canada by calling: +1 512-381-4397

International: + 800-2939-4959

Fax: 512-219-5114

Email: [support@luminexcorp.com](mailto:support@luminexcorp.com)

Additional information is available on the Luminex website. Search on the desired topic, navigate through menus. Also, review the website's FAQ section. Enter <http://www.luminexcorp.com> in your browser's address field.

This manual can be updated periodically. To ensure that you have a current version, contact Technical Support.

© 2015 - 2020 Luminex Corporation. All rights reserved. No part of this publication may be reproduced, transmitted, transcribed, or translated into any language or computer language, in any form or by any means without prior express, written consent of Luminex Corporation.

Luminex Molecular Diagnostic, Inc. is an affiliate of Luminex Corporation. Luminex Corporation and its affiliates (collectively, "Luminex") reserves the right to modify its products and services at any time. Notifications will be sent to end users regarding changes that impact the use, performance and /or safety and effectiveness of the device. Any modifications to the device will be made in accordance with applicable regulatory requirements. Luminex assumes no liability for any damages resulting from the off-label application or misuse of this information.

Luminex, xMAP, and xTAG are trademarks of Luminex Corporation, registered in the U.S. and other countries.

All other trademarks, including Microsoft and Windows, are trademarks of their respective companies.

This product, or use thereof, is covered, in whole or in part, or made by processes covered by one or more patents: [www.luminexcorp.com/patents](http://www.luminexcorp.com/patents).