

GeneMapper™ *ID-X* Software v1.6

New features and software verification

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This user bulletin describes new features. For more information on additional issues addressed in v1.6 and on using the software, see “Related documentation” on page 28.

Known installation issue: Full install on Dell™ E5580 laptops with Windows™ 7 operating system

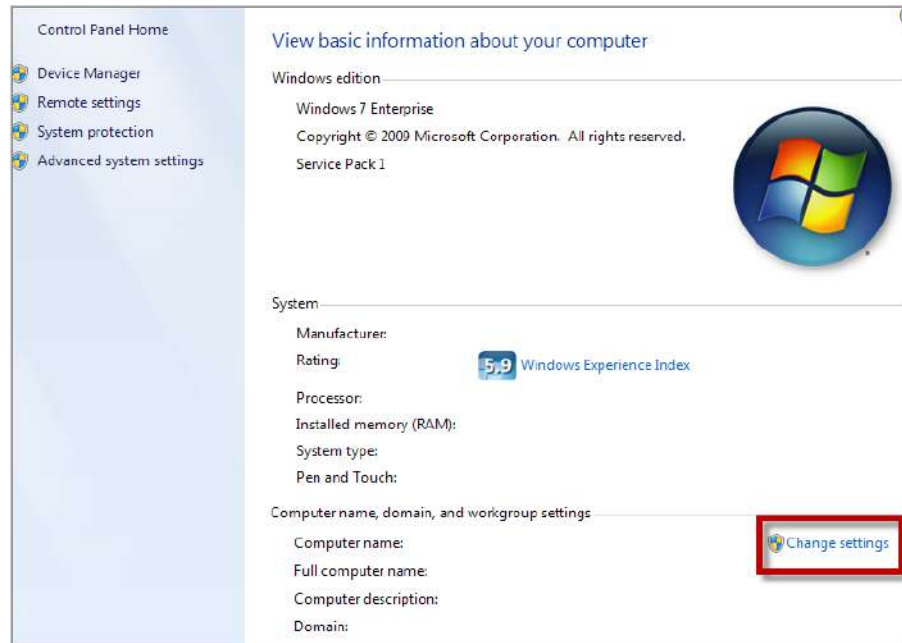
If you are performing a full install on Dell™ E5580 laptops with Windows™ 7 operating system, follow the steps below.

IMPORTANT! If you do not follow the steps below and observe an error message such as "Could not verify Oracle Listener. Setup aborting.", contact Technical Support. The computer must be re-imaged before you can proceed.

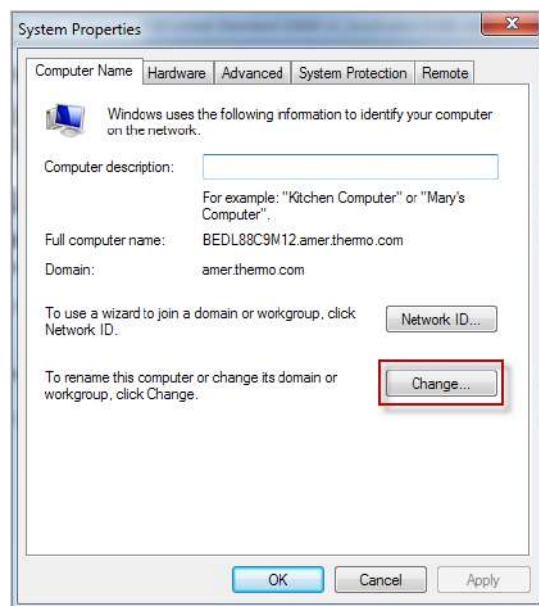
Before installing the software, rename the computer:

1. On the Windows™ desktop, right-click the **Computer** icon.
2. Select **Properties**.

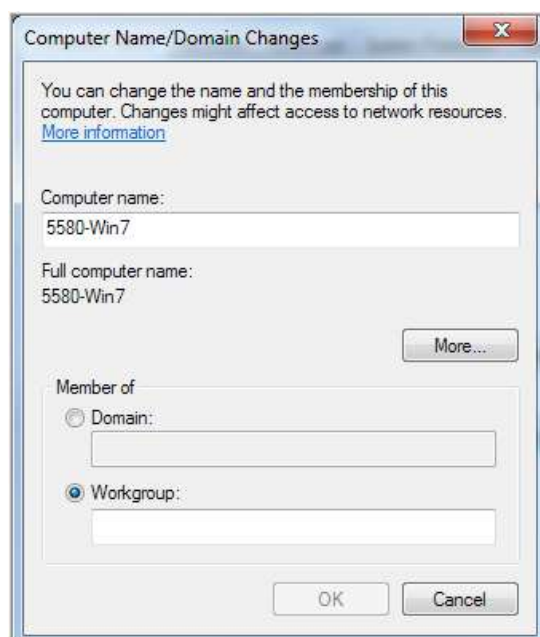
3. In the **Computer Name, Domain, and Workgroup Settings** section, click **Change settings**.



4. In the **System Properties** dialog box, click **Change**.




- Enter **5580-Win7** in the **Computer name** field, select the **Workgroup** button, then click **OK**.



Restart the computer when prompted. Log in to the Windows operating system, then verify that the new computer name is displayed.

Overview of new features

Location	New features	See
Operating system	<ul style="list-style-type: none"> Windows™ 10 Enterprise, 64-bit Windows™ 10 Enterprise 2016 LTSB, 64-bit Windows™ 7 Professional, 64-bit (Service Pack 1) <p>The GeneMapper™ ID-X Software was not tested with antivirus software.</p>	N/A
Recommended computer specifications	Intel™ Core™ i3-3240 CPU, 3.40GHz, 8GB RAM	
General support	<ul style="list-style-type: none"> Data files generated on a SeqStudio™ Genetic Analyzer can be analyzed. Project list is sorted by date with the newest project listed first. 	
	<ul style="list-style-type: none"> Chinese language support. 	"Chinese language support" on page 15

Location	New features	See
Peak Height detection enhancement	<p>The Peak Window Size start and end point determination has adjusted the way rounding is performed, to minimize the inclusion of data points from adjacent peaks.</p> <p>In rare circumstances in v1.5 and earlier, data points from a high-level peak could be included in the peak window for a low-level peak, which resulted in an increase in the reported Peak Height for the low-level peak.</p>	N/A
Samples plot peak and marker labeling	<ul style="list-style-type: none"> • Add artifact labels to multiple peaks. • A confirmation dialog box is displayed when you delete an allele label. • The zooming scale is retained on a trace when you display a different trace. • The mouse scroll wheel is enabled to scroll up or down to advance to the next or previous plot. • The down or up arrow keys are enabled to advance to the next or previous sample. • Auditing Reason for Change dialog box—Added Tab-Enter and Alt+O keyboard shortcuts to close the dialog box. 	N/A
	<ul style="list-style-type: none"> • Include QV details with a printed plot. • Specify a PLI (Partial Locus Indicator) for a marker. 	"Samples plot and Samples table new features" on page 6
Samples plot printing	<ul style="list-style-type: none"> • Add custom headers for printed plots. See page 7. • Marker header backgrounds in printed sample plots are unfilled (white) and are outlined in color (green, yellow, or red) to improve readability of the marker names.  <ul style="list-style-type: none"> • Bin color in printed and exported sample plots is adjusted to improve peak visibility. • You can print the Label Edit Viewer table for all plots or individual plots. To print the Label Edit Viewer, select File ▶ Page Setup, then select All Plots Followed by Table or Individual Plot and Table. 	N/A
Samples table	<ul style="list-style-type: none"> • View the SS Norm Factor (Size Standard Normalization Factor) from Data Collection Software. • Analysis method and size standard lists are sorted alphabetically. 	"Samples plot and Samples table new features" on page 6
Genotypes plot	Includes the same PLI (Partial Locus Indicator) and QV details in reports features as the Samples plot.	

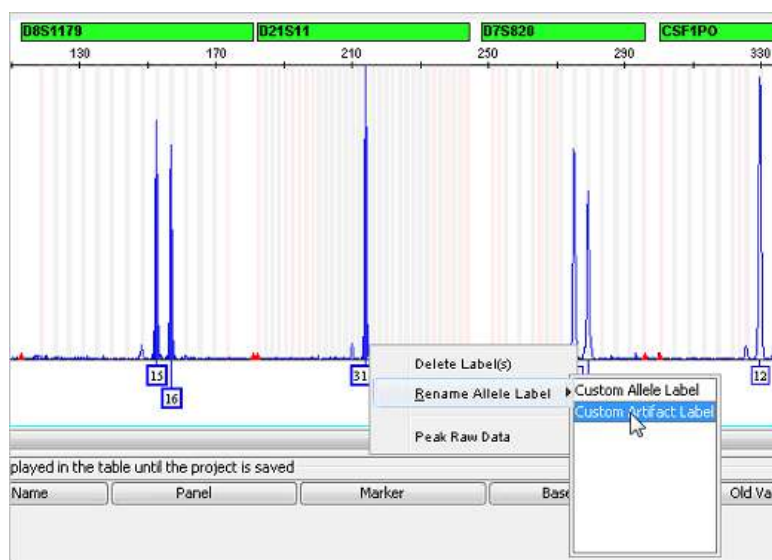
Location	New features	See
Genotypes table	<ul style="list-style-type: none"> Sort by marker name only. Export Genotypes table with stutter. 	"Genotypes plot and Genotypes table new features" on page 9
Report Manager	<ul style="list-style-type: none"> View Table by Marker and export to PDF. View the SS Norm Factor (Size Standard Normalization Factor) from Data Collection Software. 	"Report Manager new features" on page 12
Panel Manager	New items in the Panel Manager : <ul style="list-style-type: none"> Internal QC checkbox to identify the IQCL and IQCS markers from the NGM Detect™ PCR Amplification Kit 	"Panel Manager new feature" on page 13
	<ul style="list-style-type: none"> New AmpFLSTR_Panels_v6x file with newer kits listed first in the file. The stutter range is extended from 8.5 to 12.5. To display the stutter range, open a panel, then double-click the marker of interest. 	N/A
Profile comparison	<ul style="list-style-type: none"> Add sample comments that are included in a Sample Comparison export. Display plots from the Sample Comparison, Lab Reference Comparison, and Control/QC Comparison dialog box. Only selected samples are included in Lab Reference Comparison. 	"Profile Comparison and Profile Manager new features" on page 13
Profile Manager	Import profiles in CMF format.	
CODIS export	Support for CODIS 8: <ul style="list-style-type: none"> Export to CMF 3.3 (CODIS 8.0) format by default. New user-defined fields 7 and 8 in the Samples table for NCIC Number and VICAP Number. User-defined field 4 length for Specimen Comment is increased to 512 characters. New selection for Specimen Type: Forensic Targeted specimen. Support for the Y-markers in the Yfiler™ Plus PCR Amplification Kit. 	"CODIS export new features" on page 14
Command line interface	New commands to: <ul style="list-style-type: none"> Export and import the GeneMapper™ ID-X Software database. Move samples to a new project. Export the information in the sample Info tab. Process multiple commands under the same login. Generate a PDF using the sample file name instead of the default file name, generate in landscape or portrait orientation, and generate with page size of A3, A4, A5, legal, or letter. 	"Command line interface (CLI) new features" on page 15

Location	New features	See
Security, Audit, E-Signature	<ul style="list-style-type: none"> The list of users in the GeneMapper™ ID-X Software log in screen lists up to five of the most recently logged-in users. Inactive and suspended users are no longer included in the list. Delete audit records for a specified date range. 	NA

Samples plot and Samples table new features

Samples plot: Add artifact labels to multiple peaks

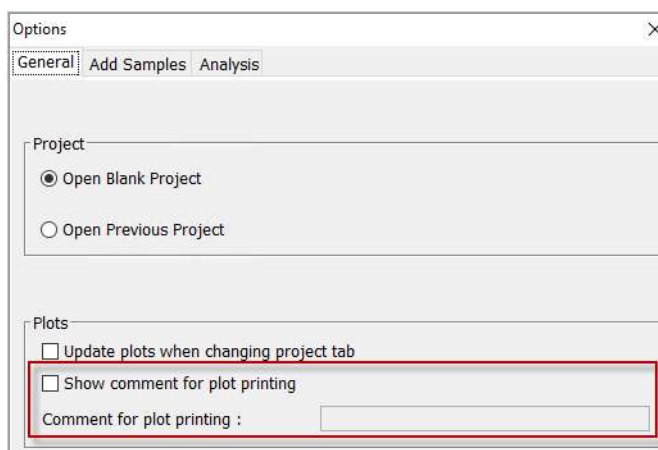
1. Display the Samples plot.
2. **Ctrl+click** to select multiple peaks.
3. Right-click, then select **Custom artifact label**.



Samples plot: Include a custom header for a printed plot

Set **Project Options** to include a header in printed plots.

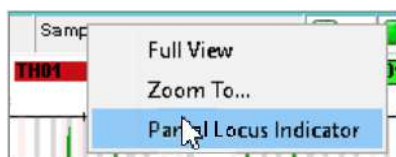
1. In the **Project** window, select **File ► Project Options**.
2. Select **Show comment for plot printing**, then enter a comment to display next to the project name on all pages of the printed or PDF plot.



Samples plot and Genotypes plot: Add Partial Locus Indicator

PLI (Partial Locus Indicator) can be used to flag allele dropout.

1. In the **Genotypes plot**, click a marker header.
2. Right-click, then select **Partial Locus Indicator**.



The marker header is flagged with ** and the PLI column in the Genotypes table is flagged with ✓.



To remove a Partial Locus Indicator, select, then right-click a marker header. Deselect **Partial Locus Indicator**.

The PLI marker information is included when you export in CODIS CMF 3.3 format. See “Export to CMF 3.3 (CODIS 8.0) format” on page 14.

Samples table: View size standard normalization factor

In the Samples table, view the **SS Normalization Factor** field (the **Normalization Factor** from the Data Collection Software).

Status	Sample Name	Sample Type	SS Normalization Factor
1	RD14-0003-15d2l	Sample	1.043
2	RD14-0003-17d2l	Sample	1.076
3	RD14-0003-15d3l	Sample	1.054
4	RD14-0003-17d3l	Sample	1.047
5	RD14-0003-16d3l	Sample	0.963
6	RD14-0003-18d1l	Sample	1.196
7	BJ_ladder2	Allelic Ladder	N/A

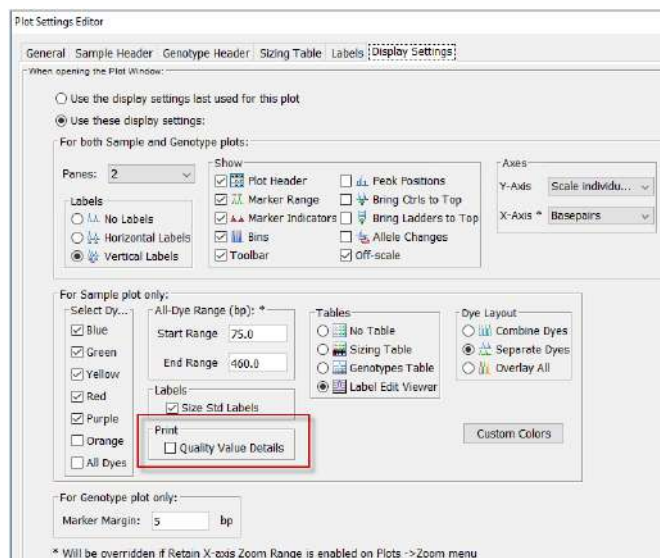
If the sample file was not collected with a normalization size standard in the Data Collection Software, the **SS Normalization Factor** field displays N/A.

To hide the **SS Normalization Factor** column, create a table setting that does not include the field.

Genotypes plot and Genotypes table new features

Genotypes plot: Include QV details in printed plots


1. In the Samples plot window, select **Tools ▶ Plot Settings**, then select the **Display Settings** tab.
2. In the **For Sample Plot only** section, select **Quality Value Details**.

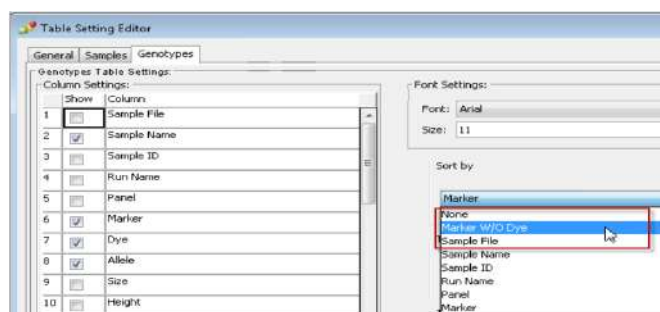


Genotypes table: Sort by marker name

When you sort the **Marker** column, it sorts by marker dye, then by marker size within the dye.

To sort by marker name only, create a table setting that specifies **Marker W/O Dye** sorting criteria.

1. With the **Genotypes table** displayed, click  (Table Settings).
2. Select **Marker W/O Dye**, then click OK.



Genotypes table: Export with stutter alleles

By default, filtered stutter alleles are not exported, are not labeled in the plots, and are not listed as alleles in the **Genotypes table**.

To include stutter alleles when you export the **Genotypes table**, use the **Export Table with Stutter** option.

Note: Exporting with stutter alleles does not affect the peaks that are labeled in the **Genotypes plot** or the peaks that are listed in the **Genotypes table**.

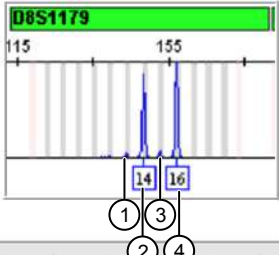
Note the following when you export **Genotypes table** with stutter.

- Stutter alleles are not exported for Allelic Ladder sample type.
- Only the columns that are displayed in the **Genotypes table** at the time of export are included in the export file.
- PQVs in the exported file are based on the original analysis, not on all exported/unfiltered alleles.
- Peaks with artifact or custom artifact labels are not exported.
- Peaks with custom allele labels are exported with the custom allele label name.

1. Open a project.
If you import a project from v1.5 or earlier software, analyze the project.
2. With the **Genotypes table** displayed, select **File ► Export Table with Stutter**.
3. Specify the export location and file name.

Examples of exported files are shown below.

Example 1: Export without stutter and with stutter



Without stutter

	A	B	C	D	E	F
1	Sample N	Marker	Allele 1	Allele 2	Allele 3	Allele 4
2	Sample 01	D8S1179	② 14	④ 16		

With stutter

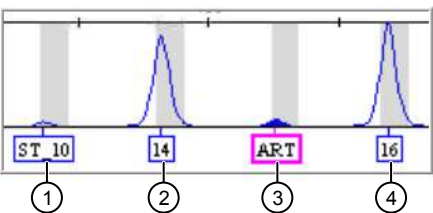
	A	B	C	D	E	F
1	Sample N	Marker	Allele 1	Allele 2	Allele 3	Allele 4
2	Sample 01	D8S1179	① 13	② 14	③ 15	④ 16

- ① Stutter peak
- ② Labeled allele peak
- ③ Stutter peak
- ④ Labeled allele peak

When you export without stutter, labeled allele peaks are identified as Allele 1 and Allele 2.

When you export with stutter, stutter peaks and labeled allele peaks are labeled sequentially.

Example 2: Export with stutter with custom-labeled and artifact-labeled peaks




	A	B	C	D	E
1	Sample N	Marker	Allele 1	Allele 2	Allele 3
2	Sample 01	D8S1179	ST_10 ①	② 14	④ 16

- ① Custom-labeled peak
- ② Labeled allele peak
- ③ Artifact-labeled peak
- ④ Labeled allele peak

When you export with stutter, custom-labeled peaks are exported, artifact-labeled peaks are not exported.

Report Manager new features

Report Manager: View table by marker and export to PDF

1. In the **Project window**, select **View ▶ Samples**.
2. Select the rows in the **Samples table** to report.
3. Click  (**Report Manager**).
4. Select **Edit ▶ View Table by Marker**.




	Sample 01	Sample 02[...	Sample 02[...
D8S1179	14,16	14,16	15,16
D21S11	29,31	29,31	31,2
D7S820		test	11,12
C5F1PO	11,12	test,test	11,12
D3S1358	14,17	14,17	16
TH01	6,9	6,9	OL,9,3
D13S317	8,11	8,11	8,12
D16S539	9,12	9,12	12
D2S1338	20,25	20,25	19,25
D19S433	14	14	14
vWA	OL,14,15	14,15	16,18
TPOX	8,10	8,10	8
D18S51	17	17	14,15
AMEL	X,Y	X,Y	X,Y
D5S818	10,11	10,11	10,11,13
FGA	23,24	23,24	22
D8S1179_12345			

5. Select **File ▶ Export**. PDF format is specified at the top right of the dialog box.
6. Click **Export**.

Report Manager: View size standard normalization factor

Note: Before viewing the size standard normalization factor in a report, create a report setting and include the the **SS Normalization Factor** field.

1. In the **Project window**, click  (**Report Manager**).
2. Select a table setting that includes the **SS Normalization Factor** field (the **Normalization Factor** from the Data Collection Software).

Report Manager - *Untitled			
File Edit View Tools Help			
Report Setting:   			
	Status	Sample N...	SS Normalization Factor
1	true	RD14-000...	1.043
2	true	RD14-000...	1.043
3	true	RD14-000...	1.043
4	true	RD14-000...	1.043

If the sample file was not collected with a normalization size standard in the Data Collection Software, the **SS Normalization Factor** field displays N/A.


Panel Manager new feature

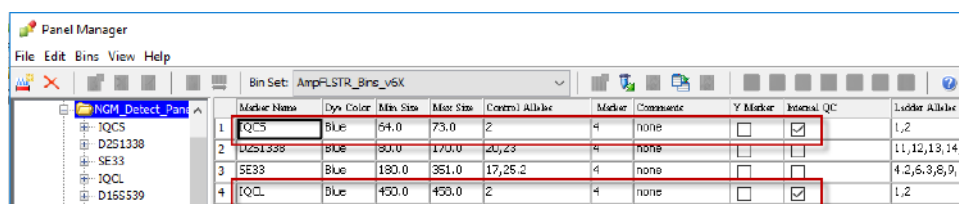
Panel Manager: Mark alleles for Internal QC

Data generated with the NGM Detect™ PCR Amplification Kit includes two markers that are used to determine the quality of the data (IQCL and IQCS markers). The presence of the IQCL and IQCS markers in negative control samples triggers the CC (Control Concordance) PQV.

To prevent the 🟡 CC PQV in negative control samples, a new **Internal QC** column for the markers is added to the **Panel Manager**.

The new NGM_Detect_Panel file provided has the **Internal QC** checkbox selected for these markers.

1. To view the panel: In the Project window, click  (**Panel Manager**).
2. Select the panel for the NGM Detect™ PCR Amplification Kit.

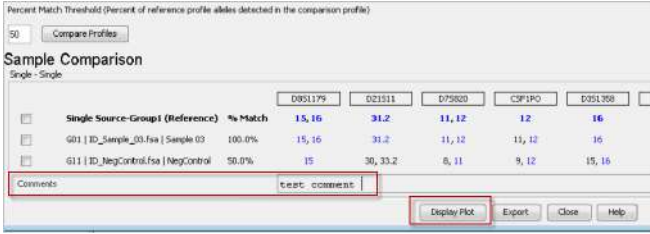


Marker Name	Dyn Color	Min Size	Max Size	Control Allele	Marker	Comments	Y Marker	Internal QC	Ladder Allele
1 IQCS	Blue	54.0	73.0	2	4	none	<input type="checkbox"/>	<input checked="" type="checkbox"/>	1,2
2 D2S1338	Blue	90.0	170.0	20,23	4	none	<input type="checkbox"/>	<input type="checkbox"/>	11,12,13,14,1
3 SE33	Blue	180.0	381.0	17,25,2	4	none	<input type="checkbox"/>	<input type="checkbox"/>	4,2,5,3,5,9,1
4 IQCL	Blue	450.0	450.0	2	4	none	<input type="checkbox"/>	<input checked="" type="checkbox"/>	1,2

Profile Comparison and Profile Manager new features

Profile Comparison: Display plots, add Sample Comparison comment, and select samples for Lab Reference Comparison

1. Select samples in the **Samples** table, then select **Tools ▶ Profile Comparison**.
2. As needed:

Click this tab	Then
Sample Comparison	<ul style="list-style-type: none"> Click Display Plot to view the electropherogram for the selected profiles. Enter a comment to associate with the comparison. This comment is included if you export and is not saved.  <p>Note: The comment is discarded if you close the screen.</p>
Lab Reference Comparison or Control/QC Comparison	Click Display Plot to view the electropherogram for the selected profiles.
Lab Reference Comparison	Select the profiles to include in the comparison before you run profile comparison.

Profile Manager: Import profiles in CMF format

1. In the **Project window**, select **Tools ▶ Profile Manager**.
2. Click **Import**, then navigate to the XML (CMF format) file to import.
The profile is imported. **Specimen ID** is assigned as **Profile ID** and **Profile Type** is set to **Lab Reference**.

CODIS export new features

Export to CMF 3.3 (CODIS 8.0) format

1. In the **Project window**, select the **CODIS Export** table setting, then make entries in the **Samples table** as needed to automatically populate CODIS fields when you export.

These new features are available:

- Two new fields are included in the **Samples table** for CMF 3.3:
 - **User-Defined 7** is NCIC Number (10 characters required)
 - **User-Defined 8** is VICAP Number (12 characters required)
- **User-Defined 4 Specimen Comment** length is increased to 512 characters.
- A new selection for **Specimen Category** is available: **Forensic Targeted**.

2. Select **File ▶ Export Table for CODIS**.

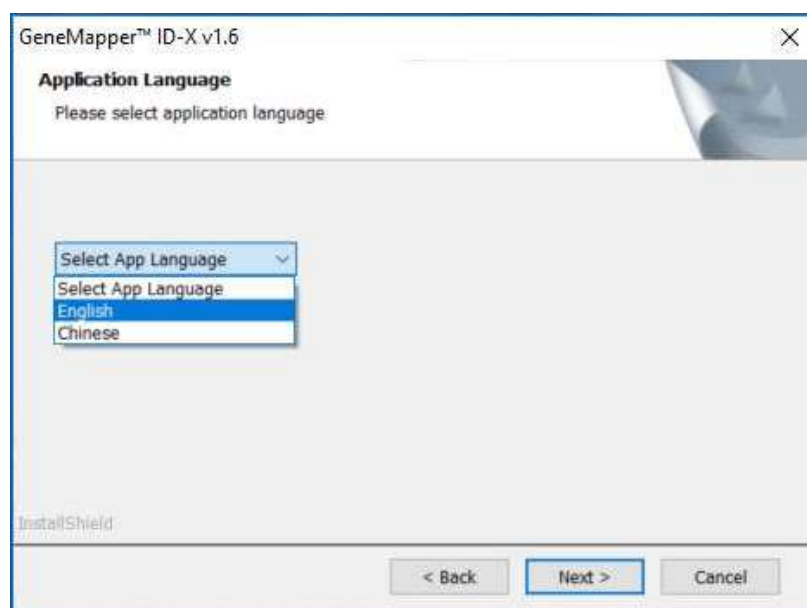
The exported CODIS file lists the **NCIC Number** and **VICAP Number** in the locations highlighted below. It also includes the **Partial Locus Indicator** status (described in “Samples plot and Genotypes plot: Add Partial Locus Indicator” on page 7).

```
<?xml version="1.0" encoding="UTF-8"?>
- <CODISImportFile xmlns="urn:CODISImportFile-schema">
  <HEADERVERSION>3.3</HEADERVERSION>
  <MESSAGE TYPE>Import</MESSAGE TYPE>
  <DESTINATIONORI>destlab</DESTINATIONORI>
  <SOURCELAB>src1ab</SOURCELAB>
  <SUBMITBYUSERID>gmidx</SUBMITBYUSERID>
  <SUBMITDATETIME>2018-05-03T13:45:05.457+05:30</SUBMITDATETIME>
  <SPECIMEN VICAP="123456789123" NCIC="1234567891">
    <SPECIMENID>test</SPECIMENID>
    <SPECIMENCATEGORY>Alleged Father</SPECIMENCATEGORY>
  - <LOCUS KIT="Identifiler Plus" PARTIALLOCUS="true">
    <LOCUSNAME>D7S820</LOCUSNAME>
    <READINGBY>gmidx</READINGBY>
    <READINGDATETIME>2018-05-02T14:10:52.000+05:30</READINGDATETIME>
  - <ALLELE>
```

Chinese language support

When you install the GeneMapper™ ID-X Software, you can select the language for the software.

You cannot change the language after the software is installed.



To change the language, uninstall, then reinstall the software. Select the language on the screen shown above.

Command line interface (CLI) new features

This section describes new commands:

- Export and import the GeneMapper™ ID-X Software database
- Move samples to a new project
- Export the information in the sample Info tab
- Process multiple commands under the same login
- Generate a PDF using the sample file name instead of the default file name, generate in landscape or portrait orientation, and generate with page size of A3, A4, A5, legal, or letter.

For details on using the Command line interface, see *GeneMapper™ ID-X Software v1.5 Command Line Interface User Bulletin* (Pub. No. 100031709).

A command line uses the following syntax.

```
GeneMapper.exe -commandline -option h -username "user" -password "password"
```

where:

- *GeneMapper.exe* is the name and directory path for the GeneMapper™ ID-X Software executable (enclosed in double quotes).
- *-commandline* instructs the *GeneMapper.exe* to run the command line.
- (Optional) *-option h* instructs the command line to run without displaying the graphic user interface. If you want to display the graphic user interface, do not enter the *-option h* argument.
- *-username* and *-password* instruct the command line to log in to the software with "user" and "password" (enclosed in double quotes). The user account must have the privileges required to perform the desired functions.

Move samples to new project (merge)

Command	Description	Example ^[1]
<code>-newproject -merge -mergeproject</code>	<p>Create a new project, move specified sample files from an existing project into the new project.</p> <p>If the project name already exists in the database, no action is performed.</p> <p>Audit records are not created for these actions.</p> <p>Note: After this command is executed, the files are no longer accessible in the original project.</p>	<pre>-newproject "NewProjectName" -merge -mergeproject "FirstProjectNameToMerge" "FileName1.fsa" "FileName2.fsa" -mergeproject "SecondProjectNameToMerge" "FileName3.fsa" "FileName4.fsa"</pre>

^[1] Requires `genemapper.exe-commandline -option h -username "gmidx" -password "1234"` at the start of the command.

Sample info export

Command	Description	Example ^[1]
<code>-exportsampleinfo</code>	<p>Export Info tab content (run conditions, reagent information, and analysis settings) for all samples in a project.</p> <p>To export specific samples in a project, add the <code>-samplelist</code> command and the file names to export.</p>	<pre>-project "ProjectName" -exportsampleinfo "C:\NameOfSCVFile.csv" -samplelist "FileName1.fsa" "FileName2.fsa"</pre>

^[1] Requires `genemapper.exe-commandline -option h -username "gmidx" -password "1234"` at the start of the command.

Execute multiple CLI commands in a TXT file

This function requires TXT file that contains all commands you want executed (see Figure 1). It allows you to run multiple commands in one login session.

Note: The `-pageorientation "landscape"` command is ignored if it is included in a TXT file with multiple commands.

```

① -importanalysismethod "g:\AnalysisMethods\myMethod.xml" CR LF
② -importsizestandard "g:\SizeStandards\mySS.xml" CR LF
③ -exportall "C:\Archive\Project01" -deleteproject "Project01" CR LF
④ -project "ProjectName" -exportsampleplot "C:\Location" -splitfile "true" -samplelist Sample01.fsa
   Sample02.fsa Sample03.fsa -outputfilename "samplefilename" CR LF
  
```

Figure 1 Example TXT file with multiple CLI commands

- ① Import analysis method
- ② Import size standard
- ③ Export all samples from project, then delete the project
- ④ Export plots for two samples and use sample file name for PDF

Command	Description	Example ^[1]
<code>-commandsfile</code>	Executes multiple commands with one TXT file under the same login.	<code>-commandsfile "C:\Location\FileContainingMultipleCom mands.txt"</code>

^[1] Requires `genemapper.exe-commandline-option h-username "gmidx" -password "1234"` at the start of the command.

PDF file commands

These commands allow you to override the default settings for PDF files created by the command line interface.

Command	Description	Example ^[1]
-outputfilename	Use sample file name for PDF instead of the default name <i>ProjectName_RunName_SampleFileName</i> that is used with the -exportsampleplot and -splitfile commands.	-project " <i>ProjectName</i> " -exportsampleplot " <i>C:\Location</i> " -splitfile "true" -samplelist <i>Sample01.fsa Sample02.fsa Sample03.fsa</i> -outputfilename "samplefilename" Note: Create the location folder before executing the command.
-pageorientation "landscape" Note: This command is ignored if it used with multiple commands (see "Execute multiple CLI commands in a TXT file" on page 17).	Print PDF in landscape or portrait orientation from command line. To print with page orientation of portrait, do not specify a page orientation.	-project " <i>ProjectName</i> " -exportsampleplot " <i>C:\Location</i> " -splitfile "true" -samplelist <i>Sample01.fsa Sample02.fsa Sample03.fsa</i> -outputfilename "samplefilename" -pageorientation "landscape"
-papersize "A3" -papersize "A4" -papersize "legal"	Print PDF with page size of A4 (8.3 × 11.7 inch), A5 (5.8 × 8.3 inch), or legal (8.5 × 14 inch). To print with page size of letter (8.5 × 11 inch), do not specify a page size.	-project " <i>ProjectName</i> " -exportsampleplot " <i>C:\Location</i> " -splitfile "true" -samplelist <i>Sample01.fsa Sample02.fsa Sample03.fsa</i> -outputfilename "samplefilename" -pageorientation "landscape" -pagesize "A4"

^[1] Requires genemapper.exe-commandline -option h -username "gmidx" -password "1234" at the start of the command.

Database backup

This command uses a different syntax than previous commands.

```
DatabaseDashboard.exe -commandline -option h
```

where:

- *DatabaseDashboard.exe* is the name and directory path for the DatabaseDashboard executable (enclosed in double quotes).
- *-commandline* instructs the *DatabaseDashboard.exe* to run the command line.
- (Optional) *-option h* instructs the command line to run without displaying the graphic user interface. If you want to display the graphic user interface, do not enter the *-option h* argument.

Command	Description	Example
-export -filepath -import -filepath	<p>Export or import the GeneMapper™ ID-X Software database without using the Database Dashboard software.</p> <p>Export creates a .dmp file, Dashboard.log, and export.log.</p> <p>Import creates a .bat file in C:\AppliedBiosystems\Database Dashboard dashboardImport_<i>DateAndTimeStamp</i></p> <p>IMPORTANT! Log off all users before running this command.</p>	<pre>-export -filepath "C: Location FileName.dmp"[1] -import -filepath "C: Location FileName.dmp"</pre>

[1] If the Database Dashboard is set to require a password, you are prompted to enter the password when the export command is executed.

GeneMapper™ ID-X Software v1.6 verification

The verification was performed according to the guidelines from the Scientific Working Group on DNA Analysis Methods (SWGDM, December 2016).

Computers

Make/model	Operating system (OS)/Service pack (SP)	GeneMapper™ ID-X Software
Dell Latitude E5570	Windows™ 10, 64-bit Windows™ 10 Enterprise, 64-bit Windows™ 7 Enterprise, 64-bit	v1.6 (full and client installations)
Dell Latitude E5580	Windows™ 10 Enterprise, 64-bit Windows™ 7 Enterprise, 64-bit	v1.6 (full and client installations)
Dell Latitude E6540	Windows™ 7 Enterprise, 64-bit	v1.6 (client installation)
Dell Latitude E6420	Windows™ 7, SP1, 64-bit	v1.5 (full installation)
Dell Precision 5510	Windows™ 7, SP1, 64-bit	v1.5 (full installation)
Dell Latitude 7480	Windows™ 7, SP1, 64-bit	v1.5 (full installation)

Samples used for concordance testing A total of 2,214 sample files (.fsa and .hid) were used in the sizing and genotyping concordance test. These samples were analyzed using both versions 1.6 and 1.5. The Combined table was exported to determine whether any differences in data output resulted. The peak heights, peak areas, data points, sizes, allele names, and all the PQV scores were compared between the two software versions.

Table 1 Number of samples used in concordance testing

Instrument	Kit	Single source	Sensitivity	Mixture	Low quality	LOR	OMR	Spike	Ladder	Low-quality ladder	Positive	Negative	Total
3100 v1.1/2.0	COfiler™	6	3	6	12	—	—	—	3	—	1	1	32
	Profiler Plus™	6	3	6	12	—	—	—	3	—	1	1	32
	Identifiler™	6	6	6	12	—	—	—	3	—	1	1	35
	SEfiler™	6	6	6	12	—	—	—	1	2	1	1	35
3100-Avant v2.0	COfiler™	6	6	6	12	—	—	—	3	—	1	1	35
	Profiler Plus™	6	6	6	12	—	—	—	3	—	1	1	35
	Identifiler™	6	6	6	12	—	—	—	2	1	1	1	35
3130x/v3.0	Profiler Plus™				—	—	—	—	23	1	—	—	24
	Identifiler™	48	24	12	—	12	10	9	35	54	2	2	208
	SGM Plus™		—	—	—	—	—	—	18	6	—	—	24
	SEfiler™		—	—	—	—	—	—	15	1	—	—	16
	Yfiler™	10	—	2	—	—	—	15	32	1	1	1	62
	MiniFiler™	10	—	2	—	—	—	—	32		1	0	45
	NGM SElect™ Express	48	—	—	—	—	—	—	12	—	—	—	60
3130x/v3.1.1	Yfiler™	—	—	—	—	—	—	—	24	—	24	—	48
	NGM SElect™	—	—	—	—	—	—	—	24	—	24	—	48
<i>(continued on next page)</i>													

Instrument	Kit	Single source	Sensitivity	Mixture	Low quality	LOR	OMR	Spike	Ladder	Low-quality ladder	Positive	Negative	Total
3730 v3.0	Identifiler™	48	42	—	—	—	—	—	22	2	1	1	116
3730 v3.1.1	Identifiler™	—	—	—	—	—	—	—	24	—	24	—	48
3500xL v1.0	Identifiler™ Plus	82	—	—	—	—	—	—	12	—	1	1	96
	Identifiler™ Direct	48	—	—	—	—	—	—	12	—	—	—	60
	NGM SElect™ Express	52	—	—	—	—	—	—	6	—	—	—	58
	GlobalFiler™ Express		—	—	—	—	—	—	6	—	1	1	8
3130xL v4.0	SGM Plus™	48	—	—	—	—	—	—	12	—	12	12	84
	Identifiler™ Plus	48	—	—	—	—	—	—	12	—	12	12	84
	Yfiler™	48	—	—	—	—	—	—	12	—	12	12	84
	NGM SElect™	48	—	—	—	—	—	—	11	1	12	12	84
	GlobalFiler™ Express	48	—	—	—	—	—	—	48	—	5	4	105
3730 v4.0	Identifiler™	41	—	—	—	—	—	—	8	—	12	9	70
	GlobalFiler™ Express	48	—	—	—	—	—	—	37	11	3	3	102
<i>(continued on next page)</i>													

Instrument	Kit	Single source	Sensitivity	Mixture	Low quality	LOR	OMR	Spike	Ladder	Low-quality ladder	Positive	Negative	Total
3500xL v2.0	Yfiler™	48	—	—	—	—	—	—	13	—	12	12	85
	NGM SElect™	48	—	—	—	—	—	—	12	—	12	12	84
	GlobalFiler™ Express	48	—	—	—	—	—	—	48	—	4	4	104
	GlobalFiler™	20	—	10	—	—	—	—	2	—	—	—	32
3500xL v3.0	GlobalFiler™	—	60	—	—	—	—	—	6	—	10	10	86
	Yfiler™ Plus	10	—	10	—	—	—	—	10	—	10	10	50
Total		891	162	78	84	12	10	24	546	80	202	125	2,214

Samples used for mixture analysis

A historical mixture sample data set was used to verify the concordance of the mixture analysis results between GeneMapper™ ID-X Software versions 1.6 and 1.5. The samples include eight pairs of 2-contributor mixtures from different genders and populations. They were selected to have 1, 2, 3, or 4 allele peaks in various numbers of loci. Each of the 2-contributor mixture samples was diluted to 11 mixture ratios: 1:0, 1:1, 1:2, 1:3, 1:5, 1:9, 9:1, 5:1, 3:1, 2:1, and 0:1. The 1:0 and 0:1 mixtures are single contributor samples and are used as the known references. The data set also includes a 3-contributor sample with a mixture ratio of 1:1:2 and a sample with a tri-allelic pattern at the D7 locus. All mixture samples were previously amplified with Identifiler™ kit using 1 ng and 250 pg total input. Additionally, all mixture samples were amplified with the Profiler Plus™ and COfiler™ kits using 1ng DNA input. Five pairs were also amplified with the GlobalFiler™ kit using 1 ng DNA input. The samples were collected from either a 3130xl Genetic Analyzer or 3500xL Genetic Analyzer.

The following mixture analysis features and number of sample files were tested:

- Genotype concordance: 209 samples
- Mixture Interpretation Threshold (MIT) pruning and sample segregation: 209 samples
- Pattern extraction comparison: 209 samples
- Statistics: 7 samples
- Known matching: 30 samples
- Multiple kit merging: 20 samples

Mixture analysis log files and result export files were generated from both software versions with the same sample file sets. These file were compared for concordance.

Tests cases performed

Table 2 GeneMapper™ ID-X Software v1.6 concordance testing with GeneMapper™ ID-X Software v1.5. All v1.6 testing used the AmpfLSTR_v6x version of panel, bin, and stutter files.

Test	Test description
Sizing and genotyping	<ul style="list-style-type: none"> • Export Combined Table and compare peak heights, areas, data points, sizes, allele names, and PQV scores. • <i>(Chinese language version only)</i> Compare the matrix results using a 310 data set.
Profile comparison	Compare Sample and Lab Reference results.
Mixture analysis	Compare mixture analysis calculations and flags using the same analysis methods and thresholds.
AmpfLSTR_v6x version of panel, bin, and stutter files	<ul style="list-style-type: none"> • Compare to AmpfLSTR_v5x, GlobalFiler v1.0.1, and GlobalFiler Express v1.3.1 versions of panel, bin, and stutter files. • Ensure the NGM Detect™ PCR Amplification Kit and VeriFiler™ Express PCR Amplification Kit panel, bin, and stutter files in AmpfLSTR_v6x are accurate. • Confirm the new Internal QC column in the Panel Manager was checked for appropriate NGM Detect™ PCR Amplification Kit markers only.

Table 3 GeneMapper™ ID-X Software v1.6 new feature testing

Test	Feature
Data Analysis and Review	<ul style="list-style-type: none"> • Label multiple artifact peaks • Confirmation on deleting single allele label. • Retained zoom • Mouse and arrow scrolling • Keyboard shortcut to close Reason for Change • PLI functionality • Sorting of project list and analysis method and size standard lists • View the SS Norm Factor in samples table • Sorting of genotypes table by marker name only • Export genotypes table with stutter • Extended stutter range
Printing	<ul style="list-style-type: none"> • QV details and Label Edit Viewer table printed from samples plot • Custom headers for printed plots • Unfilled marker header backgrounds and bin color adjustment • Report manager print table by marker to pdf
Profile Comparison tool	<ul style="list-style-type: none"> • Sample comments • Display plots • Select samples for Lab Reference comparison • Import a profile in .cmf format
CODIS	<ul style="list-style-type: none"> • Export CMF 3.3 (.xml) format • PLI functionality
CLI	<ul style="list-style-type: none"> • <code>-newproject -merge -mergeproject</code> • <code>-exportsampleinfo</code> • <code>-commandsfile</code> • <code>-outputfilename</code> • <code>-pageorientation "landscape"</code> • <code>-papersize "A3", "A4", or "legal"</code> • <code>-export -filepath</code> • <code>-import -filepath</code>
Security, Audit, E-Signature	<ul style="list-style-type: none"> • Log-in drop down • Delete audit records for specified period of time
New software and chemistry	<ul style="list-style-type: none"> • Analyze data files generated from 3500 Series Data Collection Software 4. • Functionality of internal quality check for NGM Detect™ PCR Amplification Kit • Functionality of CODIS export for more than 32 y-markers for the Yfiler™ Platinum PCR Amplification Kit

Results

Table 4 GeneMapper™ ID-X Software v1.6 concordance testing with GeneMapper™ ID-X Software v1.5.

Test	Expected outcome	Result
Sizing and genotyping	100% concordance of allele calls.	PASS
	100% concordance of peak height, peak area, and data points.	Peak area and artifact peak height: PASS with exception ^[1]
	100% concordance of all PQV scores, including SQ.	PQV scores: PASS with exception ^[1,2, 3]
	100% concordance of 310 matrix results.	PASS
Profile comparison	100% concordance of Sample/Lab Reference results.	<ul style="list-style-type: none"> Sample concordance: PASS Sample comparison and Lab Reference: PASS with Exception^[4]
Mixture analysis	100% concordance of MIT pruning, sample segregation, pattern extraction, UI flag, known matching, RMP, CPI, LR, and multi-kit merging process.	PASS with exception ^[5]
AmpflSTR_v6x version of panel, bin, and stutter files	<ul style="list-style-type: none"> AmpflSTR_v6x and AmpflSTR_v5x version of panel, bin, and stutter files are identical, except for updated version numbers for individual kits; new panel, bin, and stutter files; the addition of the Internal QC column. Updated GlobalFiler and GlobalFiler Express panel, bin, and stutter files are 100% accurate. The new NGM Detect and VeriFiler Express panel, bin, and stutter files in v6x are 100% accurate. The NGM Detect panel includes IQC markers checked for Internal QC. 	PASS

^[1] See the *Peak Height Detection Update to GeneMapper ID-X v1.6 Technical Note* [Revision A 17 October 2018] for detailed information on the discordance related to the peak height detection enhancement described in "Overview of new features" on page 3 of this user bulletin.

^[2] See the *Issues Addressed* section in the *GeneMapper™ ID-X Software v1.6 Release Notes* [Pub. No. 100077835] for information on the update to the y-marker and AN functionality. This update led to expected PQV discordance between the two software versions.

^[3] There was one SQ value rounding difference observed. For one sample the SQ value was 0.0050 in v1.5 and 0.005 in v1.6.

^[4] Percent match and matching allele data was 100% concordant. The order of the listed matches was observed to be different in the sample comparison and lab reference tabs.

^[5] The order of sister alleles in the genotypes column was observed to be different in a few cases; re-import or re-analysis was found to resolve the ordering discordance. Some rounding differences were observed for both PHR and Mx calculations at the third decimal place. For statistical calculations, some rounding differences were observed at the seventh or eighth decimal place. All other results were concordant.

Table 5 GeneMapper™ ID-X Software v1.6 new feature testing results

Test	Result
Data Analysis and Review	All new features functioned as expected with one exception. The CLI – pageorientation "landscape" command is not recognized when executing multiple CLI commands via text file (described on page "Execute multiple CLI commands in a TXT file" on page 17). To print in landscape orientation using the CLI, execute the command individually. See the <i>3500 Series Data Collection Software 4 User Bulletin: New Features and Developmental Validation</i> (Pub. No. 100075298 Rev. B) for validation of off-scale data recovery and pull-up reduction features in GeneMapper™ ID-X Software v1.6.
Printing	
Profile Comparison tool	
CODIS	
CLI	
Security, Audit, E-Signature	
New software and chemistry	

Conclusions

- GeneMapper™ ID-X Software v1.6 can be used to process sample files generated on all HID CE instruments and with existing PCR Amplification kits.
- The same results for sizing, genotyping, profile comparison, and mixture analysis were obtained using GeneMapper™ ID-X Software versions 1.6 and 1.5 with noted exceptions related to the peak height detection update, y-marker/ AN functionality, rounding, and sorting. None of these exceptions affected the overall results or correct genotyping.
- All updates to GeneMapper™ ID-X Software v1.6 were successfully and correctly implemented without deleterious effects on other software functionality.

Based on the nature of the modifications addressed in this update, and the testing that we performed, it is recommended that users evaluate this software as it pertains to their laboratory workflow to demonstrate concordance to previously validated GeneMapper™ ID-X Software versions. Laboratories should determine the appropriate level of testing required based on their internal software validation guidelines and those of the appropriate governing agencies.

Documentation and support

Related documentation

For more information on features, updates, and known issues for GeneMapper™ ID-X Software v1.6, see the following:

- *GeneMapper™ ID-X Software v1.6 Release Notes* located in <drive>:\AppliedBiosystems\GeneMapperID-X\Docs, where <drive> is the drive on which you installed the GeneMapper™ ID-X Software.
- *GeneMapper™ ID-X Software Help*—Start the GeneMapper™ ID-X Software, then press **F1** or select **HelpContents and Index**. To access context-sensitive help in the software application, click ? or **Help**.

Document	Publication number
<i>GeneMapper™ ID-X Software v1.6 Release Notes</i>	100077835
<i>3500 Series Data Collection Software 4 User Bulletin: New Features</i>	100075298
<i>GeneMapper™ ID-X Software v1.5 Administrator Guide</i>	100031703
<i>GeneMapper™ ID-X Software v1.5 Getting Started Guide— Basic Features</i>	100031701
<i>GeneMapper™ ID-X Software v1.5 Quick Reference— Basic Features</i>	100031702
<i>GeneMapper™ ID-X Software v1.5 Getting Started Guide— Mixture Analysis Tool</i>	100031705
<i>GeneMapper™ ID-X Software v1.5 Installation Guide</i>	100031706
<i>GeneMapper™ ID-X Software v1.5 Reference Guide</i>	100031707
<i>GeneMapper™ ID-X Software v1.5 Conversion Utility User Bulletin</i>	100031710
<i>GeneMapper™ ID-X Software v1.5 Command Line Interface User Bulletin</i>	100031709

Customer and technical support

For support:

- **In North America**—Send an email to HIDTechSupport@thermofisher.com, or call 888-821-4443 option 1.
- **Outside North America**—Contact your local support office.

For the latest services and support information for all locations, go to **thermofisher.com/support** to obtain the following information.

- Worldwide contact telephone numbers
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- Safety Data Sheets (SDSs; also known as MSDSs)

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For descriptions of symbols on product labels or product documents, go to thermofisher.com/symbols-definition.

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Revision history: Pub. No. 100073905

Revision	Date	Description
B	21 February 2019	Add: Known installation issue, minor additions to new features, and software verification section for GeneMapper™ /ID-X Software v1.6.
A	15 August 2018	New document.

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