

# User Bulletin

## GeneMapper® ID Software v3.2.1 Patch

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01/2007

### **SUBJECT: GeneMapper® ID Software v3.2.1 Patch**

#### **In This User Bulletin**

This user bulletin provides information about four minor changes provided in the GeneMapper® ID Software v3.2.1 patch:

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#### **Obtaining and Installing the GeneMapper® ID Software v3.2.1 Patch**

The GeneMapper® ID Software v3.2.1 Patch and Read Me file are available for download from the Applied Biosystems website:  
<http://www.appliedbiosystems.com/support/software/genemapperid/updaters.cfm>

For CD containing GeneMapper® ID Software v3.2.1 patch, order Part Number 4377230.

Follow the instructions in the Read Me file to install the patch.

## New AmpFLSTR\_Panels\_v2.txt and AmpFLSTR\_Bins\_v2.txt Files

New AmpFLSTR\_Panels\_v2.txt and AmpFLSTR\_Bins\_v2.txt files are provided with the GeneMapper® ID Software v3.2.1 software.

The new bin file contains an updated allele-size designation for the 18 allele in the D2S1338 marker from the Identifiler kit (see below).

| v1 Bin Designations<br>Marker D2S1338 |               |     |     | v2 Modified Bin Designations<br>Marker D2S1338 |               |     |     |
|---------------------------------------|---------------|-----|-----|--|---------------|-----|-----|
| 14                                    | 305.31        | 0.5 | 0.5 | 14   | 305.31        | 0.5 | 0.5 |
| 15                                    | 309.31        | 0.5 | 0.5 | 15   | 309.31        | 0.5 | 0.5 |
| 16                                    | 313.31        | 0.5 | 0.5 | 16   | 313.31        | 0.5 | 0.5 |
| 17                                    | 317.31        | 0.5 | 0.5 | 17   | 317.31        | 0.5 | 0.5 |
| <b>18</b>                             | <b>319.31</b> | 0.5 | 0.5 | <b>18</b>                                      | <b>321.31</b> | 0.5 | 0.5 |
| 19                                    | 325.31        | 0.5 | 0.5 | 19   | 325.31        | 0.5 | 0.5 |

**Note:** Due to bin offsetting, Applied Biosystems has verified through testing that the original v1 bin designation for the 18 alleles gave accurate genotyping results.

### If You Are Analyzing Identifiler® Kit Data

**Note:** If you are not using Identifiler® reagents, you can skip this step and continue to use the original AmpFLSTR\_Panels\_v1 and AmpFLSTR\_Bins\_v1 files.

When you install the GeneMapper® ID Software v3.2.1 patch, the AmpFLSTR\_Panels\_v2 and AmpFLSTR\_Bins\_v2 are added to the Panel folder (X:/AppliedBiosystems/GeneMapper/Panels). Existing v1 panel and bin files are retained in the Panels folder. You must import the v2 files into the Panel Manager in order to use them.

After installing the software:

1. Import the v2 panel and bin files from the Panels folder (X:/AppliedBiosystems/GeneMapper/Panels) into the Panel Manager.

**IMPORTANT!** If you used an existing v1 panel and binset to analyze a project, do not delete the v1 panels and bins from the Panel Manager.

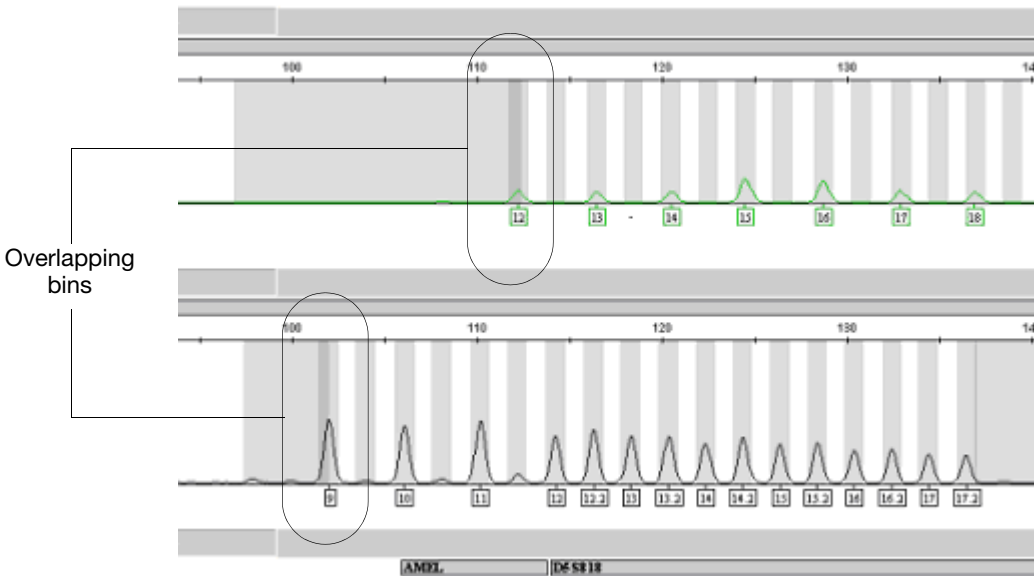
2. Create a new analysis method and select the new AmpFLSTR\_Bins\_v2 in the Allele tab of the Analysis Method Editor.

**Note:** If you change existing analysis methods to specify the new v2 binset, the analysis status changes for samples previously analyzed with the v1 binset analysis method.

3. Use the Identifiler\_v2 panel and new analysis method that specifies the v2 binset to analyze new projects.

## Bin Sorting Update

GeneMapper® ID Software v3.2.1 corrects a bin-sorting error that occurred in rare instances in the GeneMapper® ID Software v3.2 software. This error could result in mislabeling of the allelic ladder peaks and/or a pattern resembling two or more bins overlapping one another. The figure below illustrates overlapping bins that may be observed in GeneMapper® ID Software v3.2 before upgrading to GeneMapper® ID Software v3.2.1.



## Export Combined Table Internal Error Update

GeneMapper® ID Software v3.2.1 software corrects a rare “Internal Error has Occurred” message observed when exporting a combined table.

## Marker-Specific Stutter Ratio Update

GeneMapper® ID Software v3.2.1 software now displays values up to four digits after the decimal point in the Marker Specific Stutter Ratio column in the Panel Manager. Previously, only two digits after the decimal point were displayed, even though four digits after the decimal point were used for analysis.

For example, in the GeneMapper® ID Software v3.2 software, the marker-specific stutter ratio value displayed for D8S1179 is 0.08. In the GeneMapper® ID Software v3.2.1 software, the marker-specific stutter ratio value displayed for D8S1179 is 0.082.

# Applied Biosystems Verification Testing

The four software modifications implemented in the GeneMapper® *ID* Software v3.2.1 patch DO NOT affect the analysis algorithms (peak detection, size-standard matching, sizing, allele calling, bin offsetting, and filtering).

Because no changes were made to the analysis algorithms, the primary goals of the Applied Biosystems software verification tests were to:

- Confirm the patch successfully addresses the items of intent
- Confirm the modifications do not affect the existing functionality within software, and
- Demonstrate genotype concordance between GeneMapper® *ID* Software v3.2 and GeneMapper® *ID* Software v3.2.1

The results of Applied Biosystems internal testing show that the four reported items have been addressed by the modifications included in the GeneMapper® *ID* Software v3.2.1 patch. Furthermore, we have also determined that these minor software modifications do not affect any existing functionality, and that no new issues were observed.

To demonstrate concordance, a set of 56 samples amplified with Identifiler® reagents were analyzed in both GeneMapper® *ID* Software v3.2 and GeneMapper® *ID* Software v3.2.1 using the same peak detection and filtering parameters. Peak detection values and genotypes were then compared. The results are displayed below.

| Value     | Percent Concordance |
|-----------|---------------------|
| Size      | 100%                |
| Height    | 100%                |
| Peak Area | 100%                |
| Genotype  | 100%                |

To further test the updated binset, over 500 injections of the Identifiler allelic ladder from four different instrument platforms were analyzed with the v1 and v2 binset files. The results are displayed below.

| <b>Instrument</b> | <b>Number of Ladder Injections</b> | <b>Percent Concordance</b> |
|-------------------|------------------------------------|----------------------------|
| 3100              | 138                                | 100%                       |
| 3130x/            | 276                                | 100%                       |
| 3130              | 62                                 | 100%                       |
| 310               | 30                                 | 100%                       |

In addition, results are shown below for various types of samples:

- Amplified with Identifiler reagents and
- Run on multiple instruments and
- genotyped using the v1 and v2 binset files

| Instrument                      | Sample Type and Number of Samples per Type |        |         |           |          |           |           |        |
|---------------------------------|--|--------|---------|-----------|----------|-----------|-----------|--------|
|                                 | Male                                       | Female | Mixture | Inhibited | Degraded | Low Input | Off scale | Ladder |
| 3100                            | 8  | 8      | 6       | 6         | 6        | 3         | 3         | 3      |
| 3100- <i>Avant</i> <sup>™</sup> | 8  | 8      | 6       | 6         | 6        | 3         | 3         | 3      |
| 310 Windows                     | 8  | 9      | 6       | 9         | 6        | 3         | 3         | 3      |
| 310Mac                          | 8  | 7      | 6       | 6         | 5        | 3         | 3         | 4      |
| 377NT                           | 16   | 16     | 9       | 9         | 9        | 5         | 5         | 7      |
| Concordance                     | 100%                                       | 100%   | 100%    | 100%      | 100%     | 100%      | 100%      | 100%   |

## Internal Verification

Based on the nature of the modifications addressed in this software patch and the testing performed at Applied Biosystems, it is recommended that laboratories conduct a performance verification to demonstrate concordance. Laboratories should determine the appropriate level of testing required based on their internal software validation guidelines and those of the appropriate governing agencies.

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**Headquarters**

850 Lincoln Centre Drive  
Foster City, CA 94404 USA  
Phone: +1 650.638.5800  
Toll Free (In North America): +1 800.345.5224  
Fax: +1 650.638.5884

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