

## Development and Validation of the 3500 Series Genetic Analyzer

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This presentation will focus on the research and development and validation studies conducted on the 3500 Series Genetic Analyzer. The gold standard for STR fragment analysis continues to be capillary electrophoresis (CE) genetic analysis platforms. From instrument set-up to data review, the next generation 3500 (8-capillary) and the 3500xL (24-capillary) genetic analysis systems have improved upon the industry standard for CE with enhancements to the software, consumables and hardware that help enable greater throughput, ease-of use and instrument performance improvements. An overview of the system advancements will be discussed including: an improved polymer delivery pump design, ready-to-use consumables and containers, Radio Frequency Identification (RFID) consumable tracking, quality control software features for rapid identification and re-injection of failed samples, increased throughput, new laser technology, reduced power requirements, peak height normalization, intuitive user software, and integrated primary analysis software, improved peak height uniformity across capillaries, runs and instruments. In addition, instrument protocols have been optimized and validated for the analysis of all AmpF $\ell$ STR<sup>®</sup> kit products.

Validation studies were conducted on six different instruments on single source and mixed DNA samples amplified with each AmpF $\ell$ STR<sup>®</sup> Kit. Data was examined to evaluate the performance of the 3500series instruments including: sizing precision, accuracy, sensitivity, color balance and peak height uniformity between instruments, injections and capillaries.

A new version of GeneMapper<sup>®</sup> *ID-X* Software (v1.2) was developed adding the support of the new 3500 file format, Windows Vista operating system, peak height normalization feature, and RFID consumable tracking capability to the existing GeneMapper<sup>®</sup> *ID-X* Software v1.1.1. GeneMapper<sup>®</sup> *ID-X* v1.2 Software is compatible with all currently supported CE system data. Validation studies were conducted to confirm the ability of GeneMapper<sup>®</sup> *ID-X* Software v1.2 to accurately genotype and process 310, 31xx, 3730 and 3500 series data.

The next generation 3500-series Genetic Analyzers were designed to support a specific feature set and workflow for Human Identification applications. The developmental validation data support its use on all HID STR kits and demonstrate enhancements in many areas over previous instruments, including faster run times, more consistent peak heights and improvements in data quality.