

3500 Series Genetic Analyzers for Human Identification

Key Features

- 8-capillary 3500 System and 24-capillary 3500xL System
- Advanced thermal system design improves temperature control for more consistent data migration and reduced run times
- Reduced signal variation from instrument to instrument, run to run, and capillary to capillary
- Innovative “snap-in-and-go” consumable design with radio frequency identification (RFID) technology that tracks and records key consumables data
- HID-specific workflow preconfigured for AmpF[®]STR kits, simplified run setup and software navigation
- Powerful, integrated data collection and QC analysis software provide real-time assessment of data quality and streamlined STR analyses



Introduction

The 3500 Series Genetic Analyzers are the latest advancements in the Applied Biosystems® industry-leading product line of capillary electrophoresis (CE) systems, recognized for the highest levels of data quality and reliability. The versatile throughput system (48–1200 samples per day) supports a wide variety of applications using its DNA sequencing and fragment-sizing capabilities and, unlike its predecessors, has been designed with a specific feature set and workflow for Human Identification (HID) applications.

The 3500 (8-capillary) and the 3500xL (24-capillary) Genetic Analyzers have improved upon existing CE systems in

virtually every category, including many aspects of the hardware, consumables, and software. Across the entire workflow, from instrument setup to data review, the 3500 Series incorporates innovative design enhancements to help optimize data quality and deliver increased reliability, performance, quality assurance, and ease of use.

Combined with Applied Biosystems® validated HID reagents, consumables, and software, as well as industry-leading support, the 3500 Series provides an integrated HID system solution that significantly enhances productivity and confidence in the HID laboratory.

Improved Thermal Control

The 3500 oven has been redesigned to provide improved temperature control for reproducible sizing precision within an injection and across injections. The newly designed oven is more compact and has an improved door seal and locking mechanism. Combined with a preheat option and a temperature-controlled detection cell heater, these features help maintain temperature consistency across the array and reduce the effects of room temperature fluctuations (Figures 1 and 2). At the cathode end, the array has been redesigned with a shorter needle length, and new array septa help to minimize exposure of the capillaries to ambient air. These thermal subsystem improvements have enabled the development and optimization of AmpF[®]STR[®] kit run modules with shorter run times.

Improved Signal Consistency

The 3500 Series Genetic Analyzers utilize two methods intended to provide greater signal consistency across instruments, injections, and capillaries. The first is a factory-standardized, hardware-based calibration, which improves instrument-to-instrument consistency. The second method is an optional internal standard normalization that uses chemistry and software to enable more consistent results instrument to instrument, injection to injection, and capillary to capillary. This method utilizes the GeneScan[™] 600 LIZ[®] Size Standard v2, which is specifically manufactured to enable the user to obtain consistent lot-to-lot peak heights. The internal standard normalization method allows users to scale sample peak heights relative to the intensity of the coinjected size standard peaks. The average peak height of the internal size standard for each sample is compared to an experimentally defined average size standard peak height (normalization target) to determine the normalization factor. The calculated normalization factor is applied to the sample data and the sample peak heights are adjusted accordingly. Users can elect to run samples with or without the internal standard normalization option, and normalized sample data can be analyzed with and without normalization in GeneMapper[®] ID-X Software v1.2.

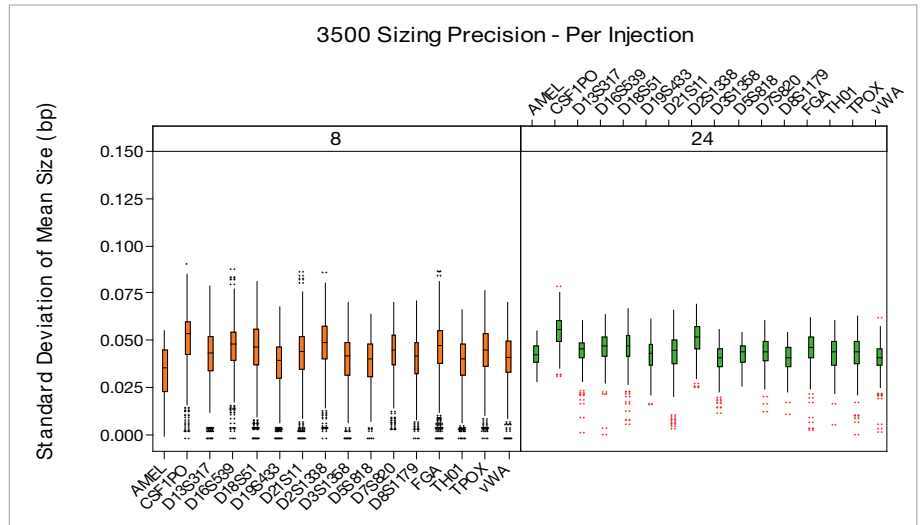


Figure 1. 96 replicates of Identifiler[®] Allelic Ladder with GeneScan[™] 600 LIZ[®] v2 were injected on three 3500 (left) and three 3500xL (right) instruments. The standard deviation of the mean bp size of each allele within an injection was determined and plotted by marker.

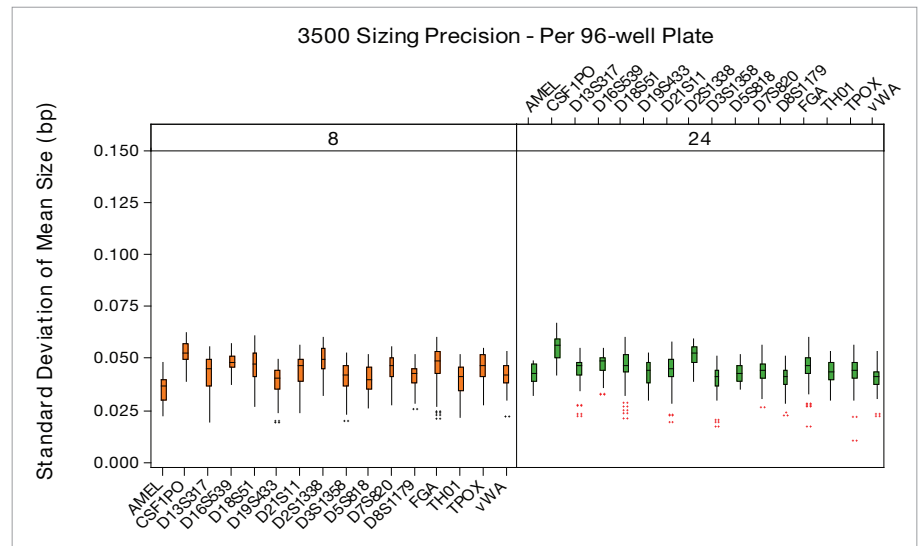
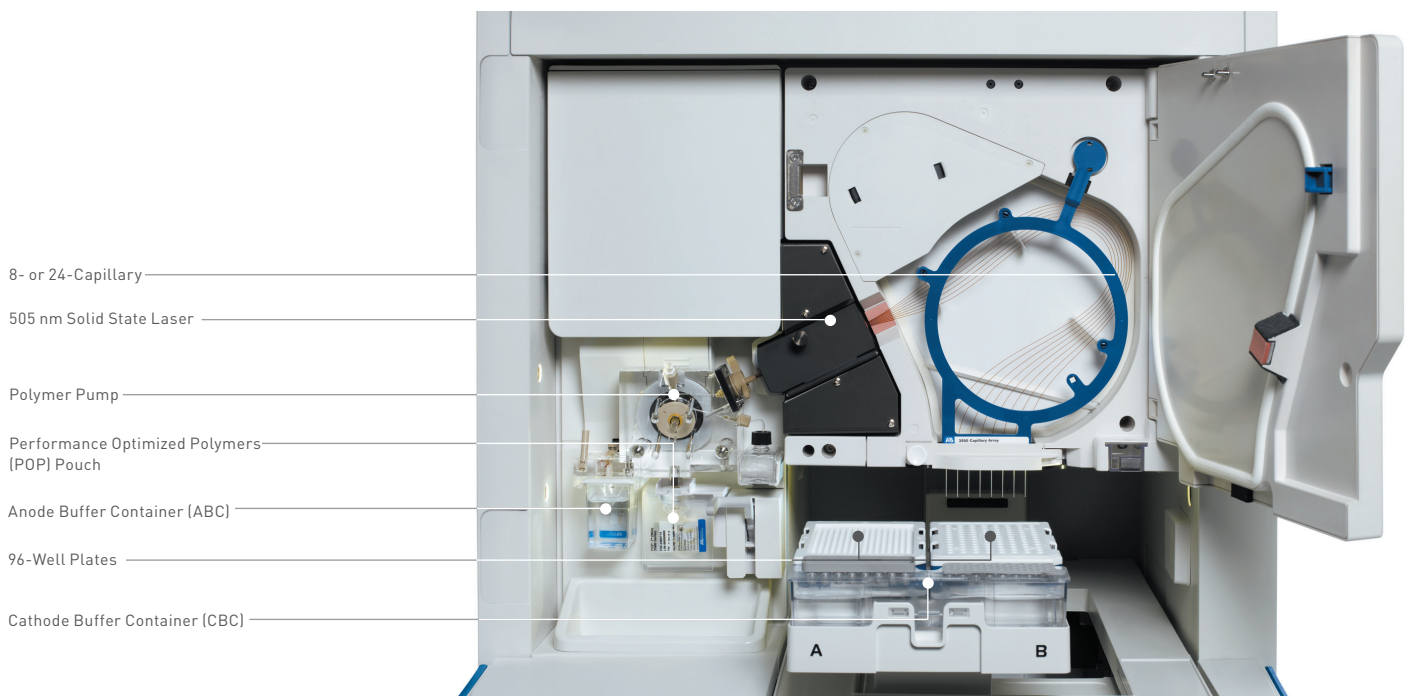


Figure 2. 96 replicates of Identifiler[®] Allelic Ladder with GeneScan[™] 600 LIZ[®] v2 were injected on three 3500 (left) and three 3500xL (right) instruments. The standard deviation of the mean bp size of each allele across all injections was determined and plotted by marker.



Effortless Consumable Installation

Newly designed consumable packaging was developed with extensive testing to define on-instrument reagent stability and establish expiration dating parameters. The POP-4™ polymer and prediluted (1X) anode and cathode buffers are provided in ready-to-use, recyclable containers that are easy to install. These innovative “snap-in-and-go” consumables help eliminate the potential introduction of foreign contaminants and minimize maintenance and troubleshooting. The capillary array has been designed to include an array holder to simplify the array installation process and allow for easy array storage off the instrument.

Consumable Tracking with RFID Technology

The prepacked polymer pouches (Figure 3), buffer containers, and easy-to-install capillary arrays are labeled with radio frequency identification (RFID) tags that enable viewing, tracking, and reporting of critical information by the 3500 Series Data Collection Software. The recorded information allows users to monitor consumables usage, lot numbers, part numbers, expiry dates, and on-instrument lifetimes. This feature enables the operator to easily evaluate consumable levels and viability, helps maximize reagent use, minimize instrument downtime, and maintain quality control records.



Figure 3. Efficient, ready-to-use polymer pouch with radio frequency identification (RFID) tag.

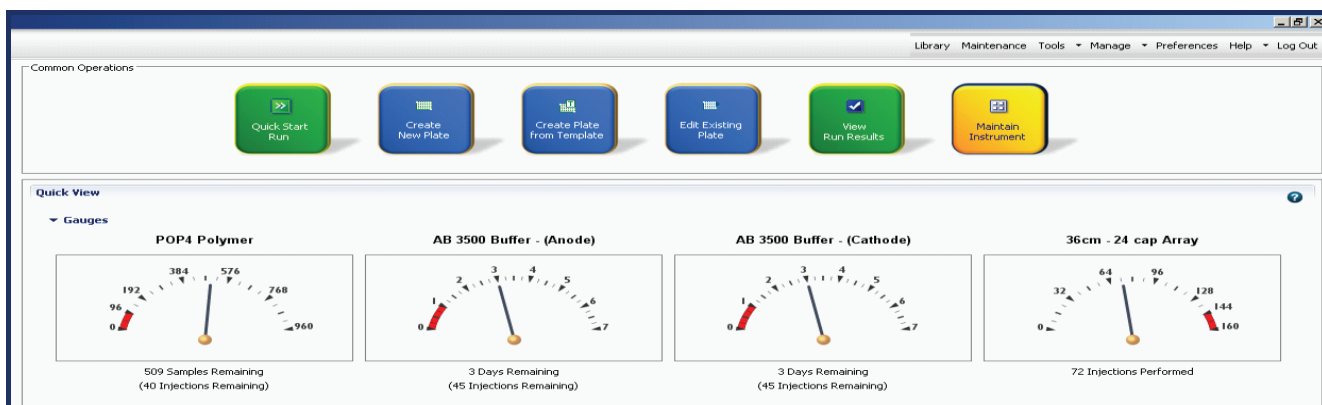


Figure 4. The 3500 Data Collection Software’s intuitive dashboard design features highly visible buttons for common operations and easy-to-read graphical displays to monitor the state of the installed consumables.

Intuitive, HID-Specific Software Workflow

The first of its kind, the 3500 Data Collection Software was developed specifically with the HID workflow in mind. The software breaks new ground in user-friendly navigation with an intuitive dashboard design, highly visible buttons for common operations, easy-to-read graphical displays to monitor the state of consumables, and handy maintenance scheduling calendar functionality (Figure 4). Using a workflow-driven user interface, the software walks the user step-by-step through setting up a run, real-time data quality assessment, and sample re-injection. These features help to significantly reduce the learning curve for implementation and streamline the execution of everyday tasks.

The 3500 Data Collection Software comes preconfigured with validated protocols for AmpF[®]STR kits. To start a run, the user simply selects an HID-specific template, manually enters or imports sample information, and assigns the assay to the sample(s) from the preconfigured assay list (Figure 5).

All sample information is captured in a .HID sample file. This new file format contains information on the specific analysis parameters and electrophoresis run conditions used in the analysis of the sample. In addition, the file contains consumable-related information such as lot number, expiration date, and time on the instrument as well as the sample normalization factor and re-injection information.

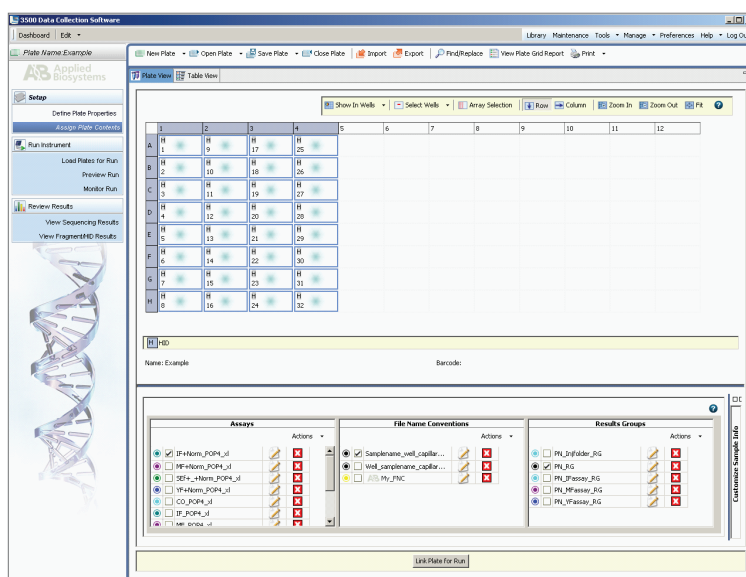


Figure 5. HID Plate template shown in a plate view format preconfigured with validated AmpF[®]STR assays.

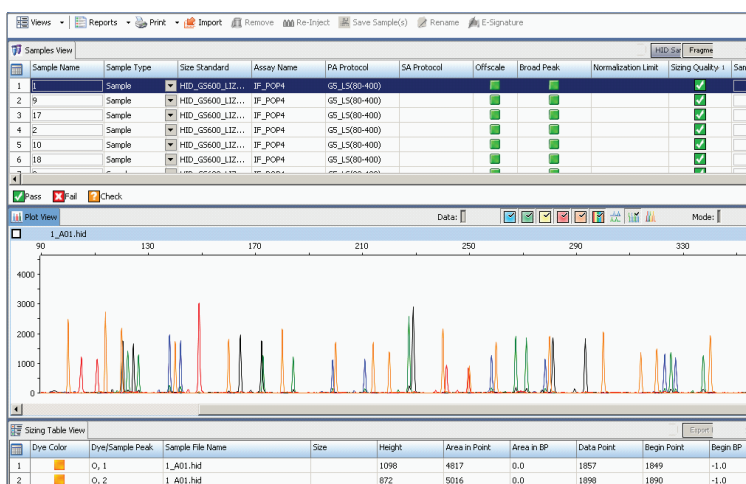


Figure 6. Review Results window for QC analysis and sample re-injections.

The new GeneMapper® *ID-X* Software v1.2 builds upon the functionality of the GeneMapper® *ID-X* Software v1.1.1 with expanded features to analyze the 3500 Series .HID files and report the additional information described above in the sample info tab. Additionally, GeneMapper® *ID-X* Software v1.2 has the capability to analyze all legacy capillary electrophoresis instrument data in .fsa format.

Real-Time Data Quality Assessment

Multiple tools have been introduced that enable the user to evaluate data in real time at the decision point for re-injections. Featured in the Review Results window of the 3500 Data Collection Software (Figure 6) are sized data, quality flags, and various plot options for preliminary

data analysis to quickly identify samples that may require additional processing and schedule them for re-injection. Once data collection is complete, .HID sample files are generated for import into the GeneMapper® *ID-X* Software v1.2.

Enhanced Performance and Convenience

With innovative hardware design, a whole new approach to consumables, and intuitive, application-specific software, the 3500 Series enables new levels of performance and convenience for the work that HID professionals do every day. Additional features include:

- **Enhanced Throughput**

Faster data generation with 8 or 24 capillary arrays and shorter run times

- **Improved Polymer Pump Design**

Compact design helps reduce instrument setup time, consumable waste, and the potential for bubble formation

- **Simplified Instrument Installation and Operation**

New single-line 505 nm, solid-state long-life laser utilizes a standard power supply and requires no heat-removal ducting

- **Streamlined Instrument Maintenance**

HID-specific performance check and maintenance scheduling tools

- **Data Chain of Custody**

Controlled access and tracking through Security, Audit, and eSignature features

MATERIALS PROVIDED WITH THE 3500 SERIES INSTRUMENTS FOR HUMAN IDENTIFICATION

3500 Series Instrument
Dell Computer System
HID-Specific Installation Consumables

ORDERING INFORMATION

Description	Part Number
3500 Genetic Analyzer for Human Identification	4406017
3500xL Genetic Analyzer for Human Identification	4406016
GeneMapper® <i>ID-X</i> v1.2 Full	4443261
GeneMapper® <i>ID-X</i> v1.2 Client	4443260
3500 Capillary Array (36 cm)	4404683
3500xL Capillary Array (36 cm)	4404687
3500 POP-4™ Polymer (960 samples)	4393710
3500 POP-4™ Polymer (384 samples)	4393715
Polymer Pouch Cap	4412619
Anode Buffer Container (ABC) 3500 Series	4393927
Cathode Buffer Container (CBC) 3500 Series	4408256
Septa Cathode Buffer Container 3500 Series	4410715
Conditioning Reagent 3500 Series	4393718
Hi-Di™ Formamide (5 ml)	4440753
Matrix Standard Set DS-33 3500 Series (6-FAM™, VIC®, NED™, PET®, LIZ® dyes)	4345833
GeneScan™ 600 LIZ® v2.0 Size Standard 3500 Series	4408399
Validation Support and Training for 3500 Series Genetic Analyzer Implementation	Contact Sales Representative

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