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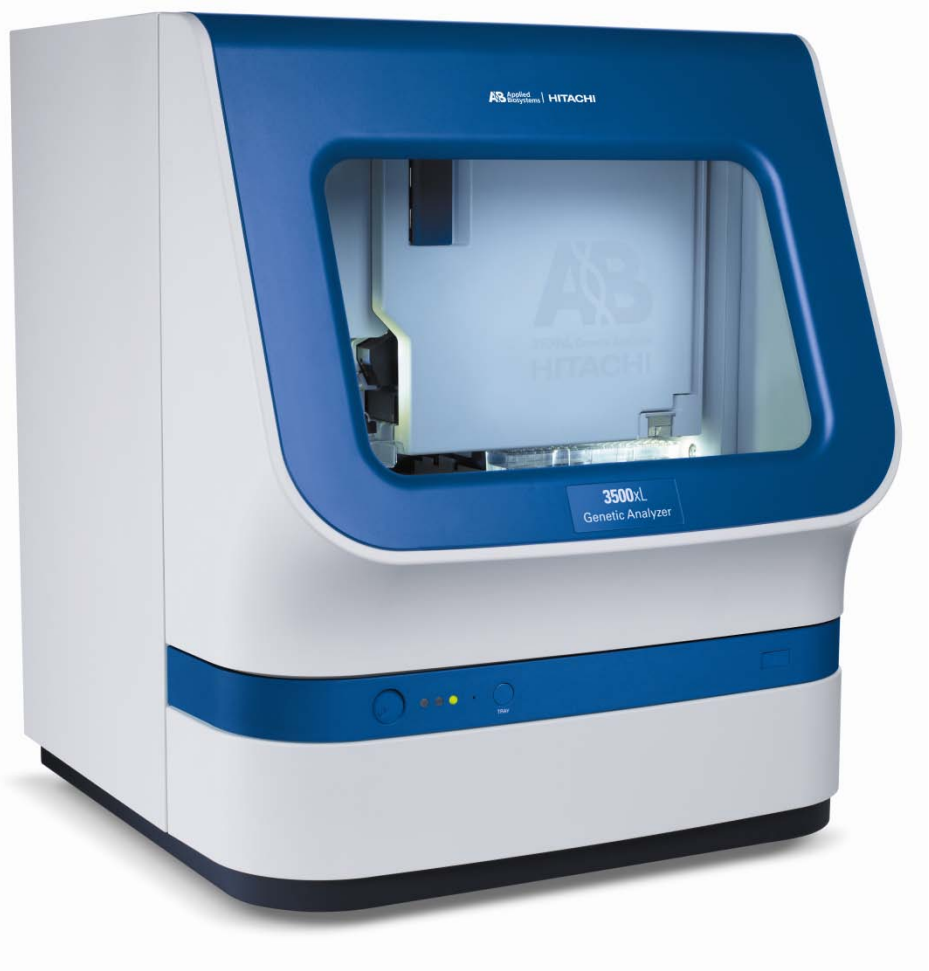
Next Generation Capillary Electrophoresis System: *The 3500 Series Genetic Analyzers*

Topics

- Development Goals
- Hardware Overview
- Consumables
- Software Overview
- Product Availability



3500 System Development Goals

Customer Requirements	Feature and Benefit
Improved Data Quality	
Instrument to Instrument Consistency	Hardware and software-based internal lane normalization provide more comparable results instrument to instrument and injection to injection
Better First Pass Success Rate	Redesigned consumables and hardware for improved instrument reliability and performance.
Improved Temperature Control	Improved oven design and oven door seal provides more consistent data migration
Ease of Use	
Instrument Setup and Maintenance	Pre-packaged and quality controlled consumables with RFID technology simplifies instrument setup and provides real-time reagent status information
HID Workflow Support	Newly designed HID workflow driven software and AmpfISTR® kit plate templates with pre-configured with validated protocols
Faster Time to Result	
Higher Throughput	Available in 8 or 24 capillary configurations and decreased run times lead to higher throughput

System and Components

3500

3500xL

The 3500 System is available in two configurations: a 8 capillary array (3500) or a 24 capillary array (3500xL). An option to upgrade the 3500 to a 3500xL will be available in the future.

3500 System Workflow and Feature Highlights

Data Collection

Optional Signal Normalization

Shorter Run Times

Run Set-Up

Predefined Protocols and HID Templates

Intuitive Run Set-Up and System Monitoring

QC Analysis

Data Analysis QC Tools and Flags

Simplified Reinjection Scheme

Instrument

Simplified Consumables with Tracking

Redesigned Laser and Oven

GMID-X v1.2

ID-X 1.1.1 Upgrade Supports Windows XP and Vista

Analyzes .fsa & New .hid File Format

Instrument → Run Set-Up → Data Collection → QC Analysis → GMID-X v1.2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3500 Series Hardware

Instrument Interior

Array +
Array holder

Array head lock
mechanism

Pump Delivery System

Anode Buffer
Container

Oven
condensation
reservoir

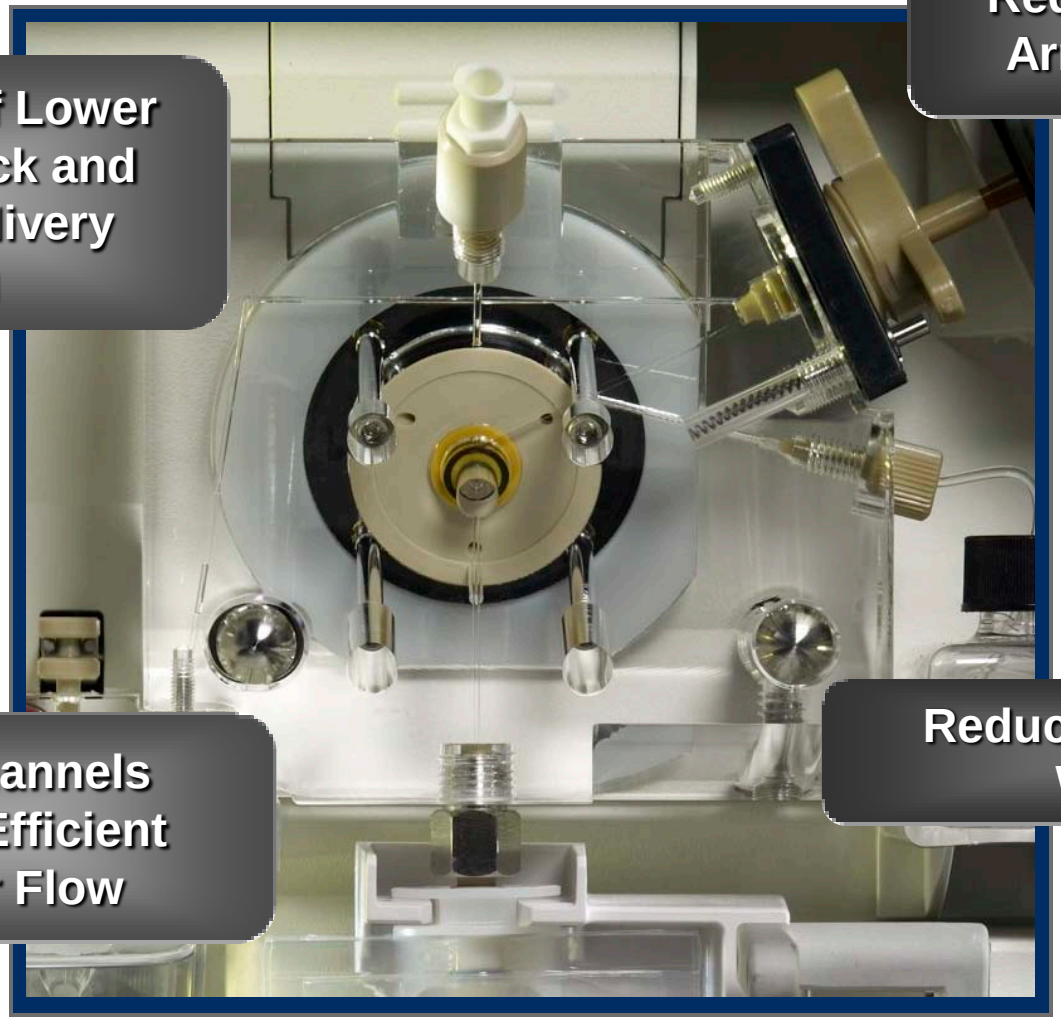
Cathode Buffer
Container

Polymer pouch

Pump water
overflow
reservoir

Autosampler

Redesigned Polymer Pump



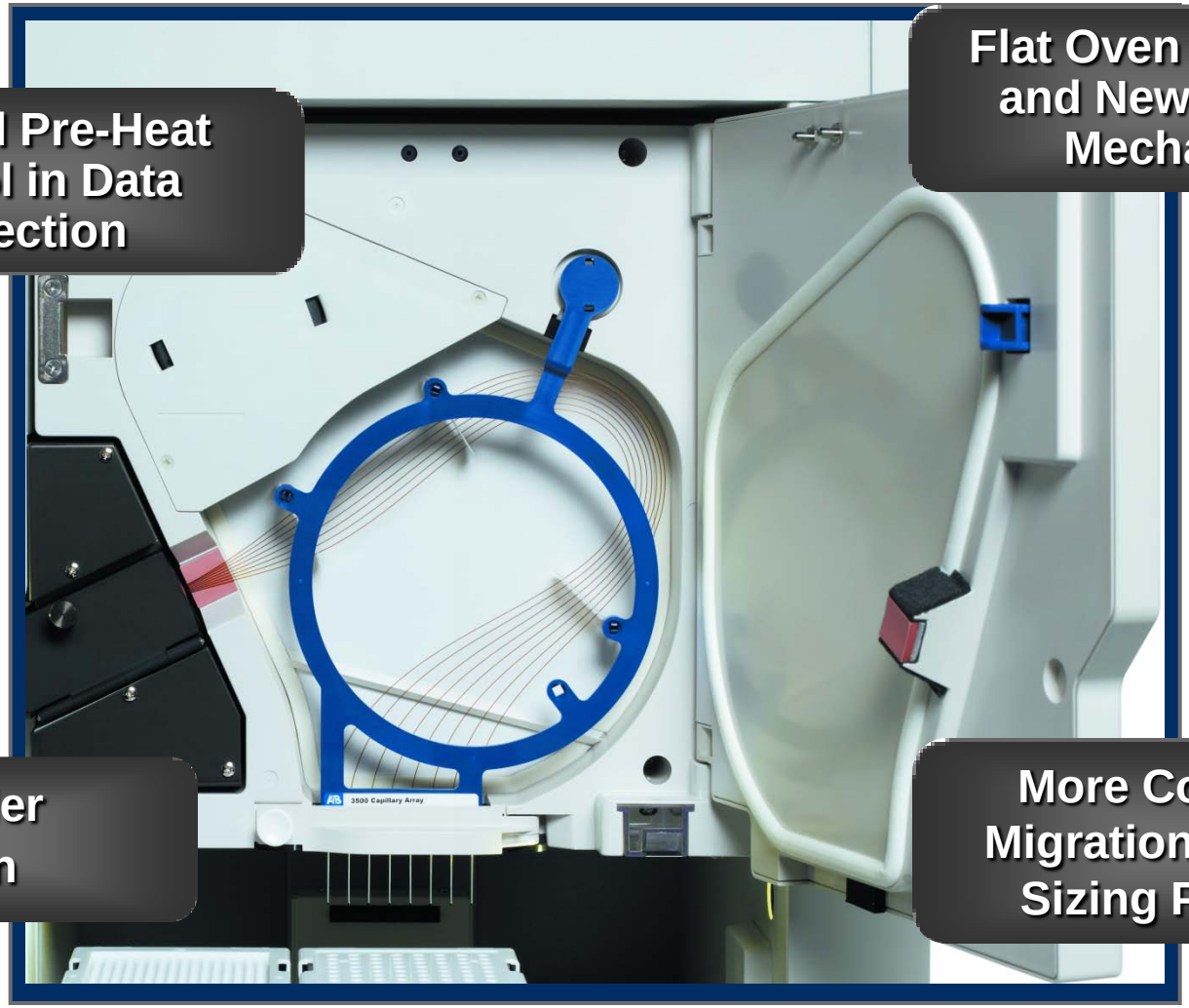
Redesigned Array Port

Elimination of Lower Polymer Block and Polymer Delivery Tubing

Direct Channels Promote Efficient Polymer Flow

Reduced Polymer Waste

Improved Temperature Control System



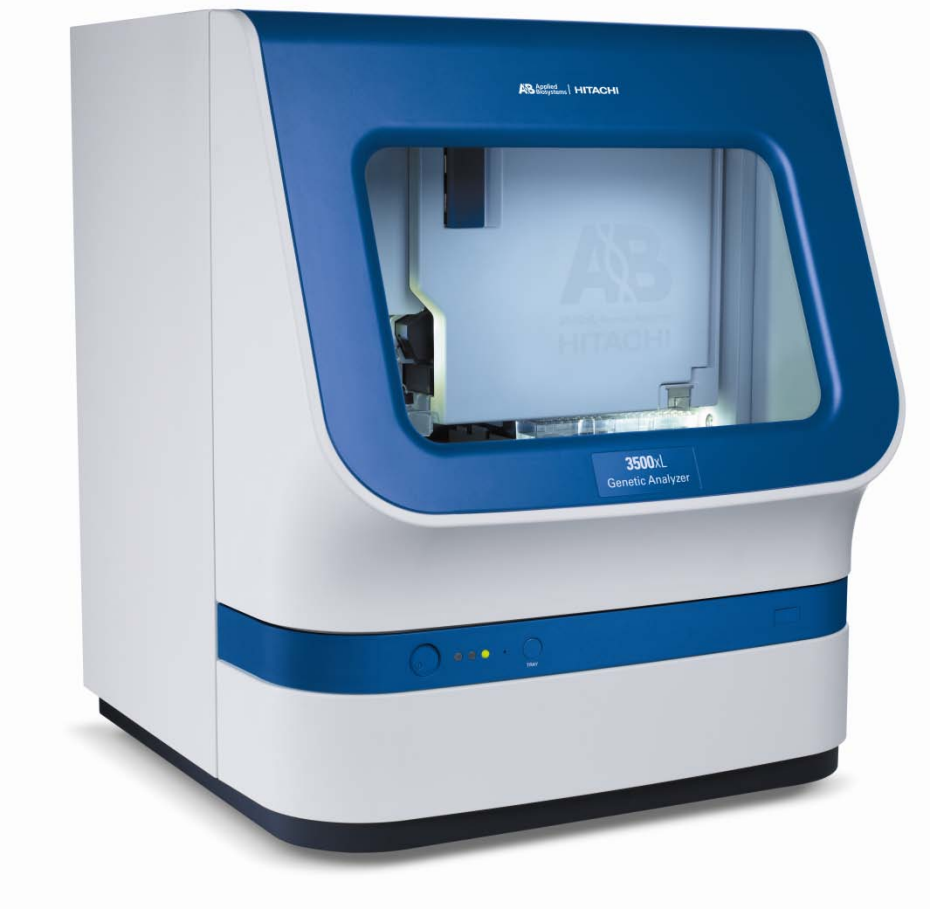
Optional Pre-Heat Control in Data Collection

Flat Oven Door Seal and New Locking Mechanism

Smaller Oven

More Consistent Migration for Better Sizing Precision

3500 Laser Design



Smaller, Single Excitation Line Solid State Laser

Minimal Heat Output

Standard Voltage Plug

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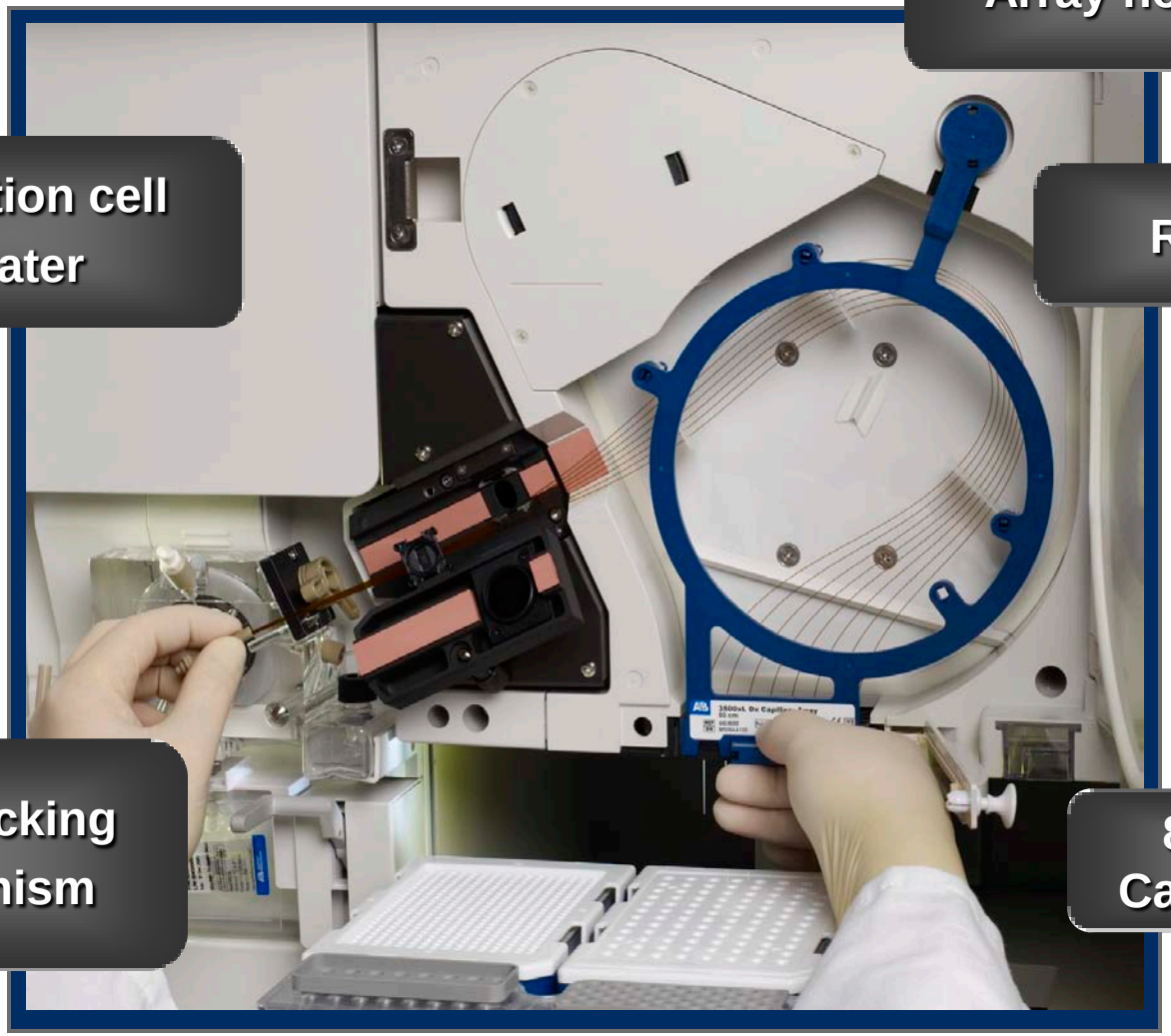
RFID Technology and New Consumable Design

Simplified Instrument Setup and Consumable Tracking

Consumables

- Pre-Filled, Quality-Controlled Reagents
- Information Recorded via RFID
  - **Lot numbers**
  - **Part Numbers**
  - **Serial numbers**
  - **Dates (expiration and installation)**
  - **Capacity/Usage**
- Per Sample Running Cost Comparable to 31xx

Redesigned Capillary Array



New Capillary Array Locking Mechanism

- No ferrule for the array head
- Simple array installation and removal (¼ turn)
- Easier bubble flush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3500 Data Collection Software

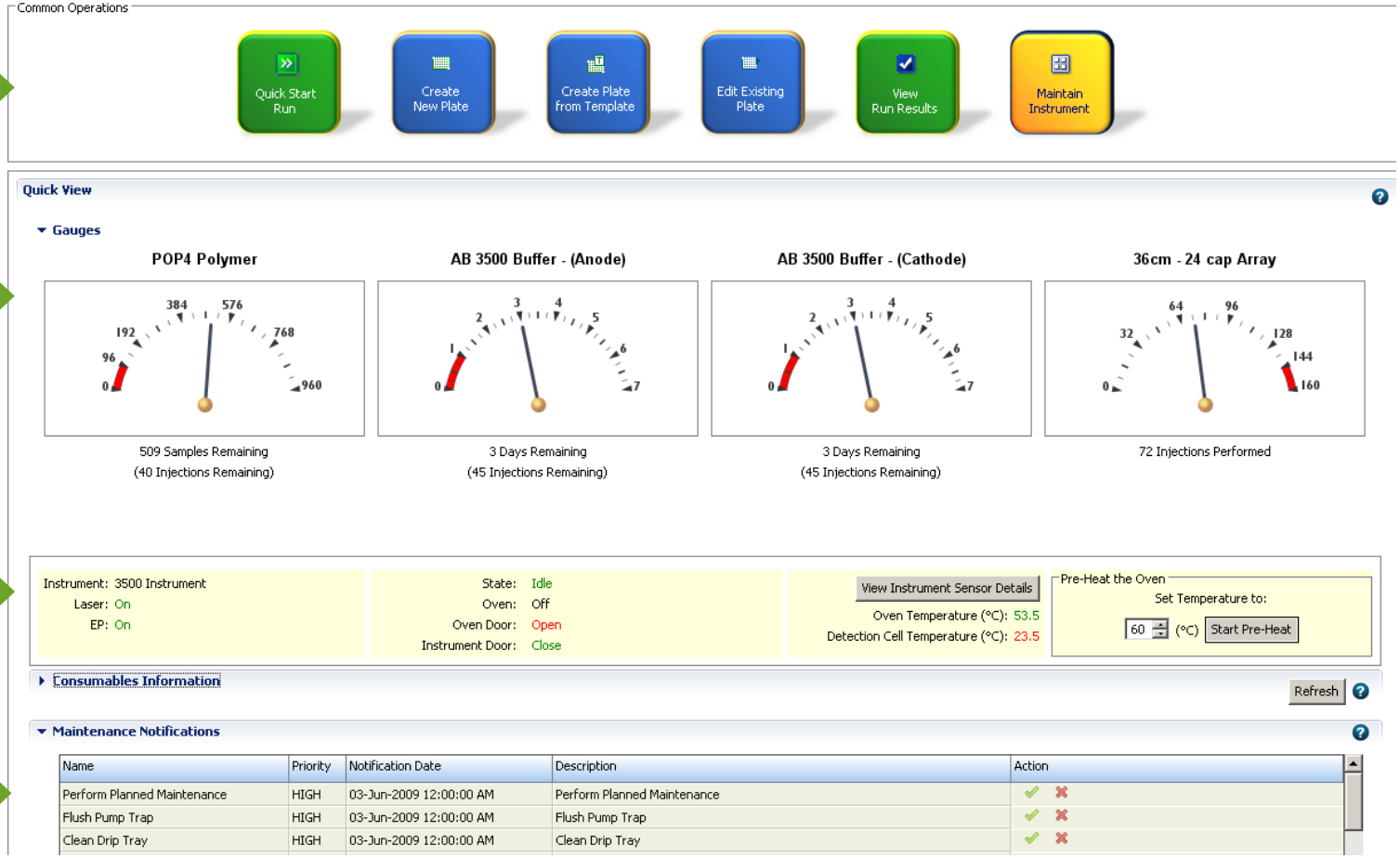
Dashboard

Key Operations

Consumable Gauges

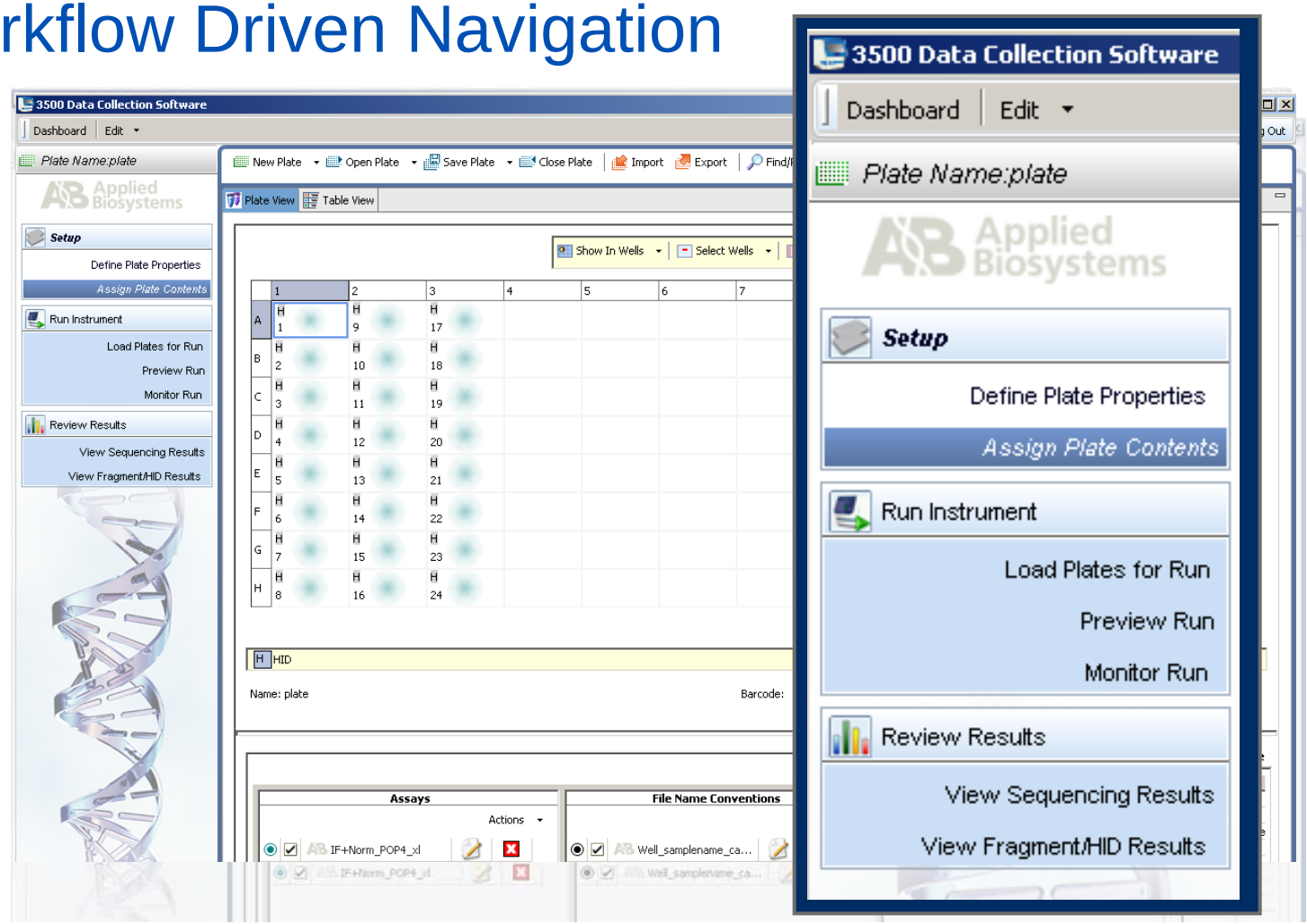
Instrument Status

Maintenance Alerts



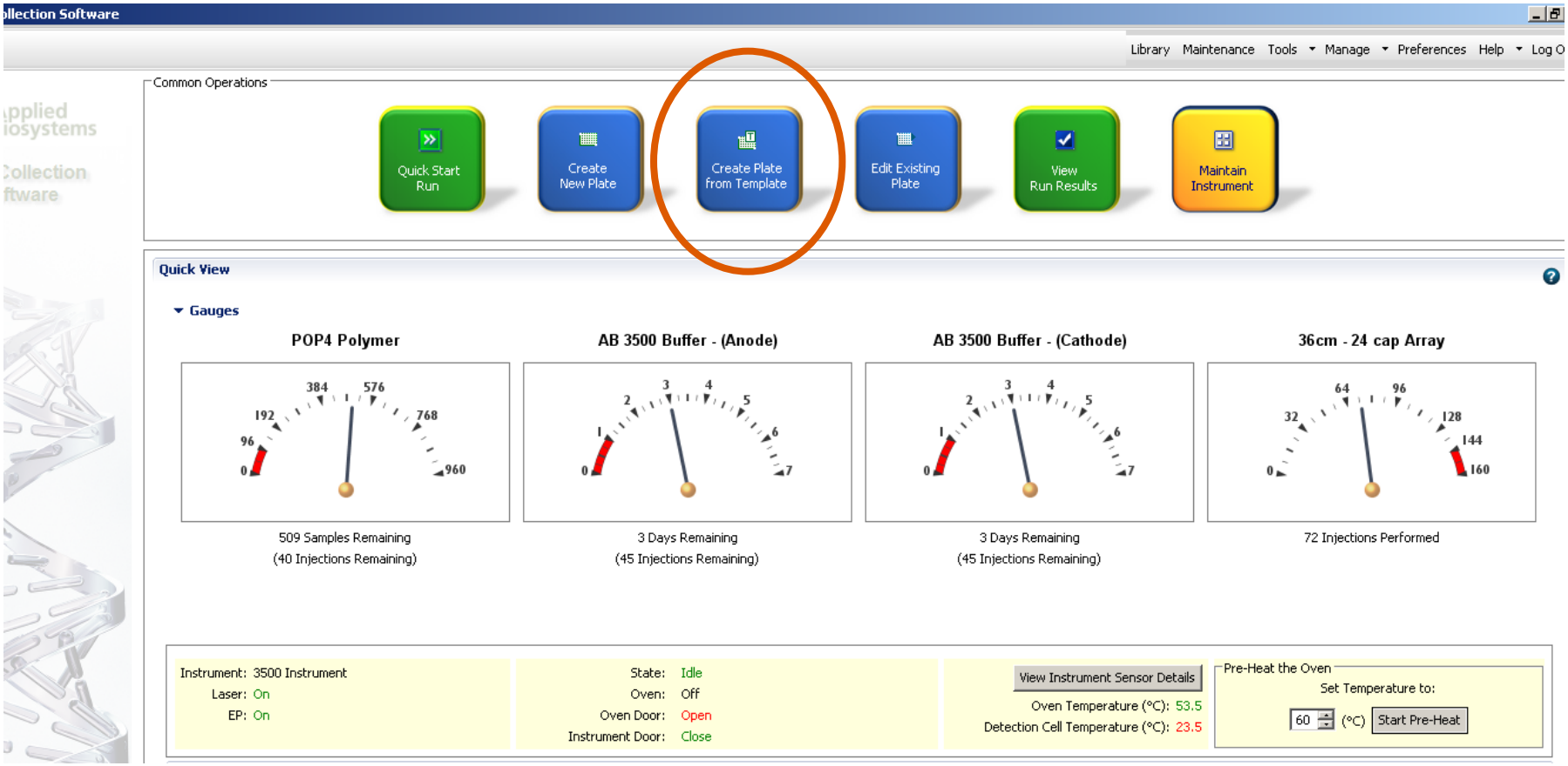
The Dashboard screen provides current instrument and consumable information and direct access to key functionality to quickly perform common tasks

Workflow Driven Navigation



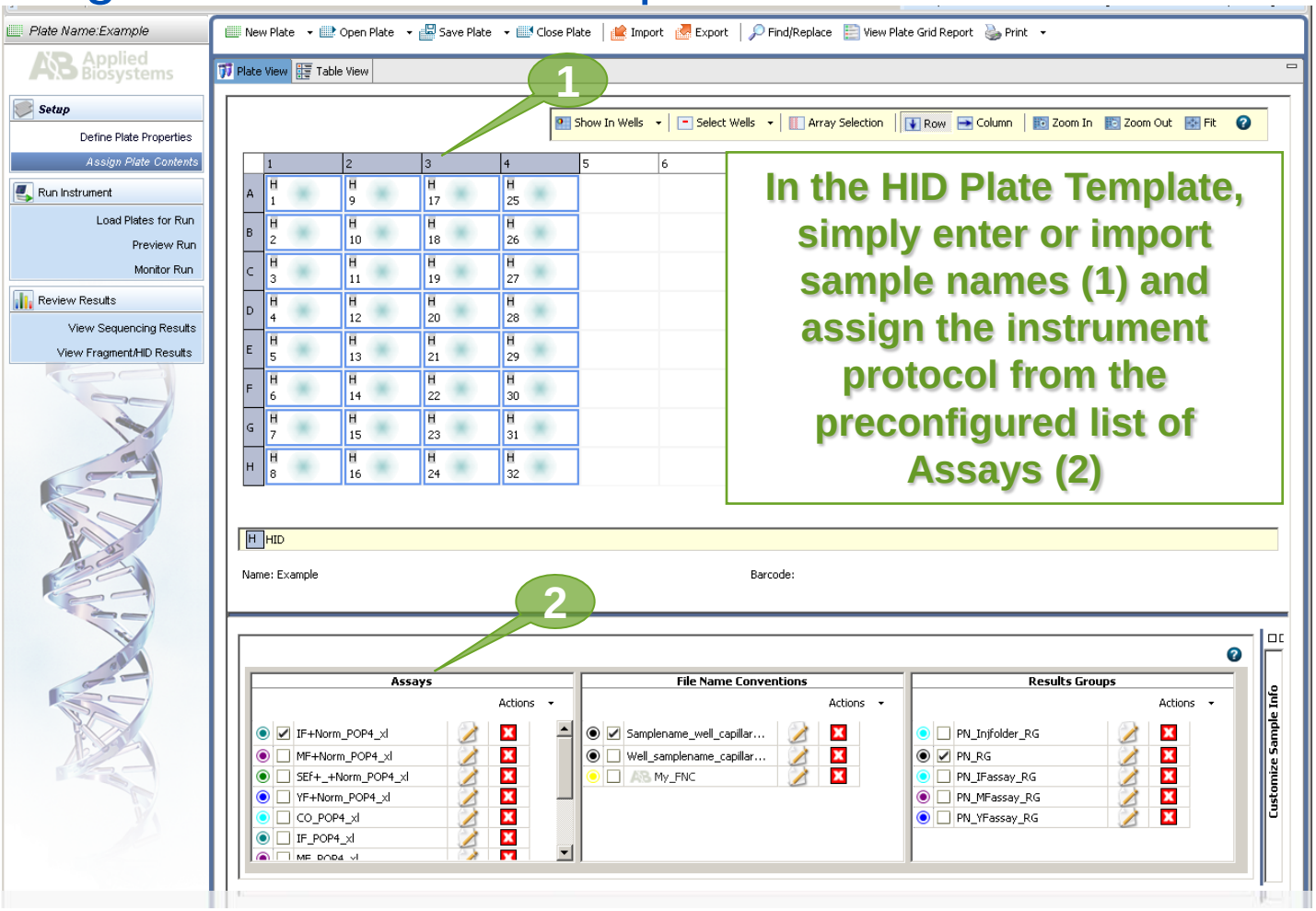
Most screens contain a left hand navigation pane which lists every step in the order in which it should be performed. This workflow navigation makes the software easy to learn and use.

Simplified Run Set Up:
Preconfigured HID Plate Templates

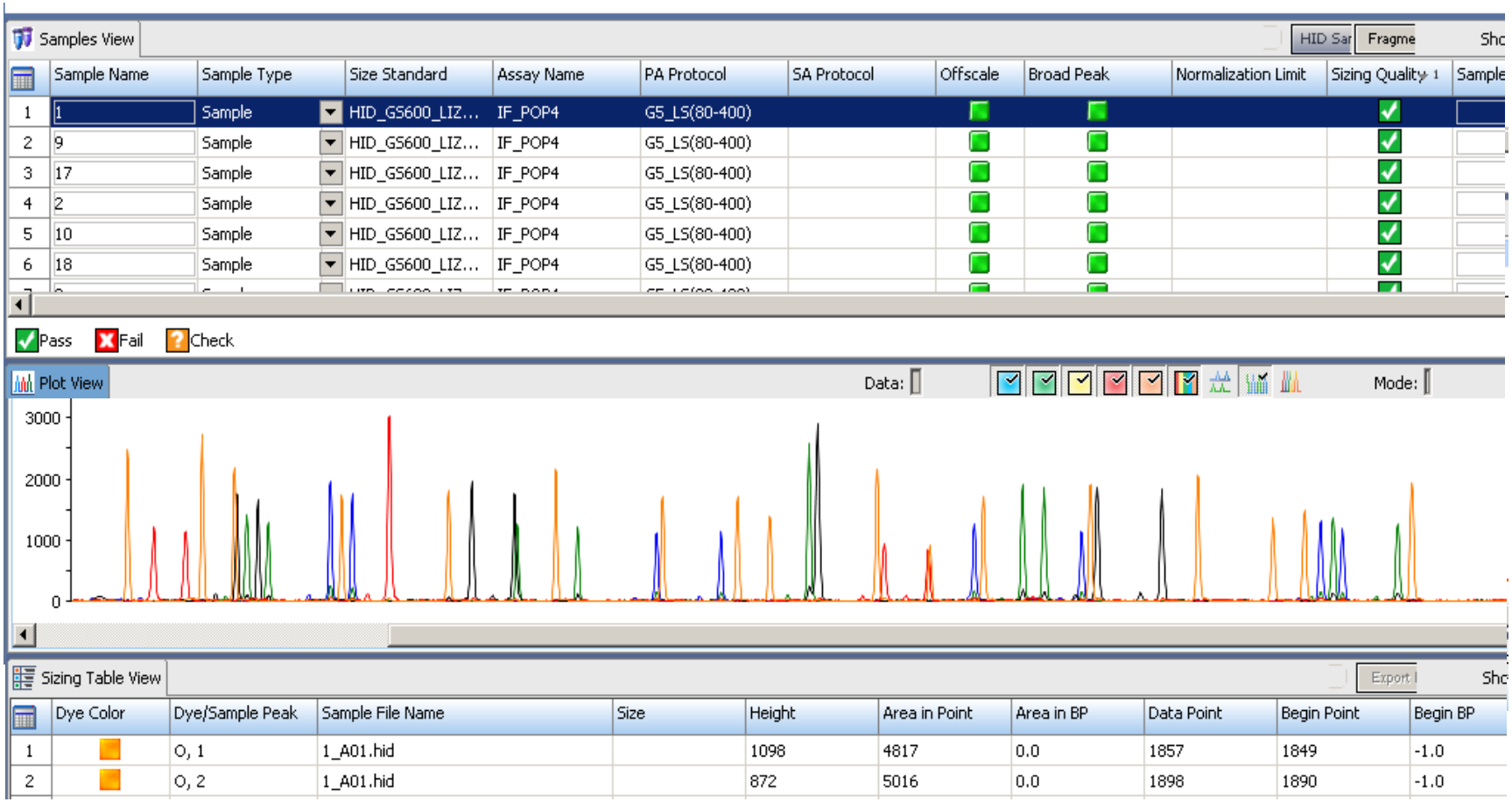


To quickly start a run, use a preconfigured HID plate template by selecting the "Create Plate from Template" button in the Dashboard Screen

Simplified Run Set Up:
Preconfigured HID Plate Template

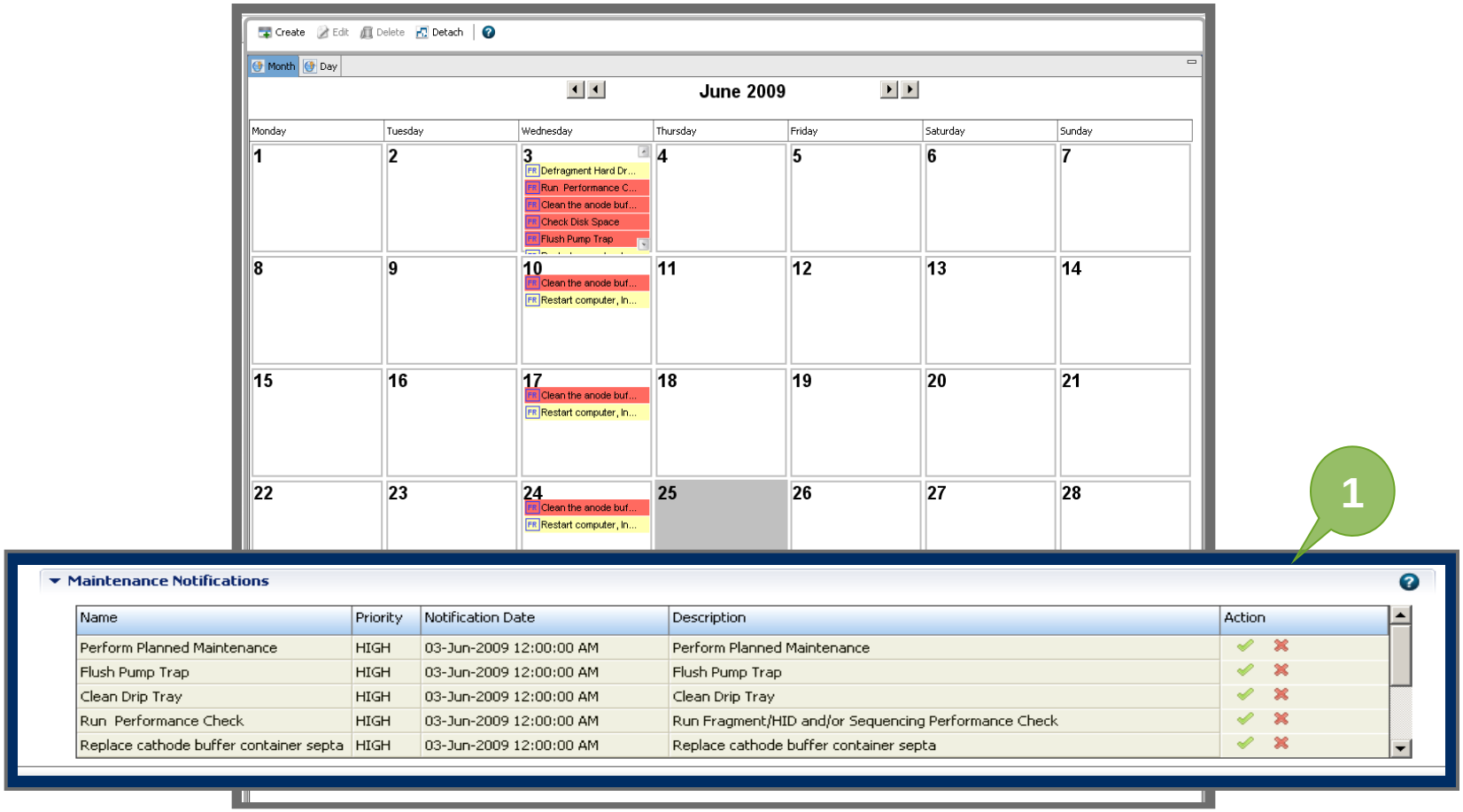


Preliminary Data or QC Analysis



QC Analysis Tools have been integrated to enable real-time preliminary data analysis. Review data quality flags, electropherograms and sizing tables to identify and select samples for reinjection or additional processing.

Maintenance Tools



A maintenance calendar automatically tracks maintenance tasks and notifies you in the Dashboard screen (1) of tasks that need to be performed

Reporting Tools

Applied Biosystems

Spatial Report

Report Created On: 28-Jun-2009 10:07:35 PM
3500 Data Collection Software Version 1.0.0

Signed In User: Administrator

Instrument

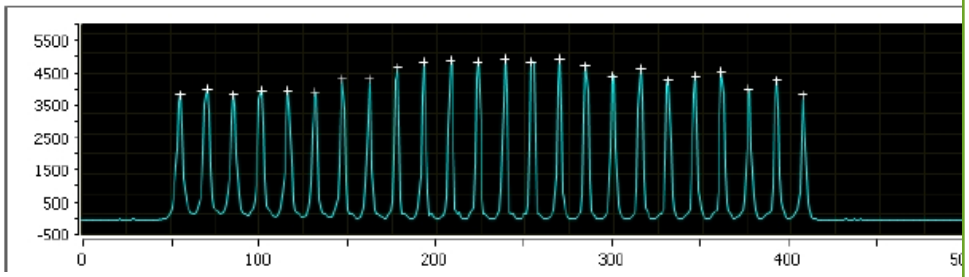
Name:	3500 Instrument
Serial Number:	13527-029

Capillary Array

Array Length:	36
Number of Capillaries:	24
Serial Number:	80K2450
Lot Number:	80K005
Installation Date:	25-Jun-2009
Expiration Date:	31-Dec-2009
Number of Injections Performed:	79

Spatial Calibration

Calibration Date: 03-Jun-2009 04:56:17 PM



Reporting and Printing Functionality has been introduced throughout the data collection for record keeping. Here is an example of the Spatial Calibration report.

Reporting Tools

Applied Biosystems

Report Created On: 28-Jun-2009 10:23:
3500 Data Collection Software Versio

Spectral Report

Signed In User: Administrator

Instrument

Name: 3500 Instrument
Serial Number: 13527-029

Polymer

Polymer Type: POP4
Lot Number: 51A007
Initial Installation Date: 26-Jun-2009
Expiration Date: 31-Dec-2009

Capillary Array

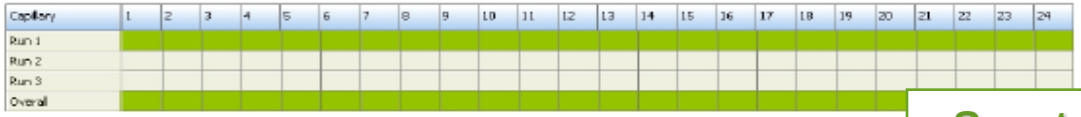
Array Length: 36
Number of Capillaries: 24
Serial Number: 80K2450
Lot Number: 80K005
Installation Date: 25-Jun-2009
Expiration Date: 31-Dec-2009
Number of Injections Performed: 80

Anode Buffer

Lot Number: 51-B-34007
Initial Installation Date: 24-Jun-2009
Expiration Date: 31-Dec-2009

Cathode Buffer

Lot Number: 8751-6TH-B
Initial Installation Date: 24-Jun-2009
Expiration Date: 31-Dec-2009



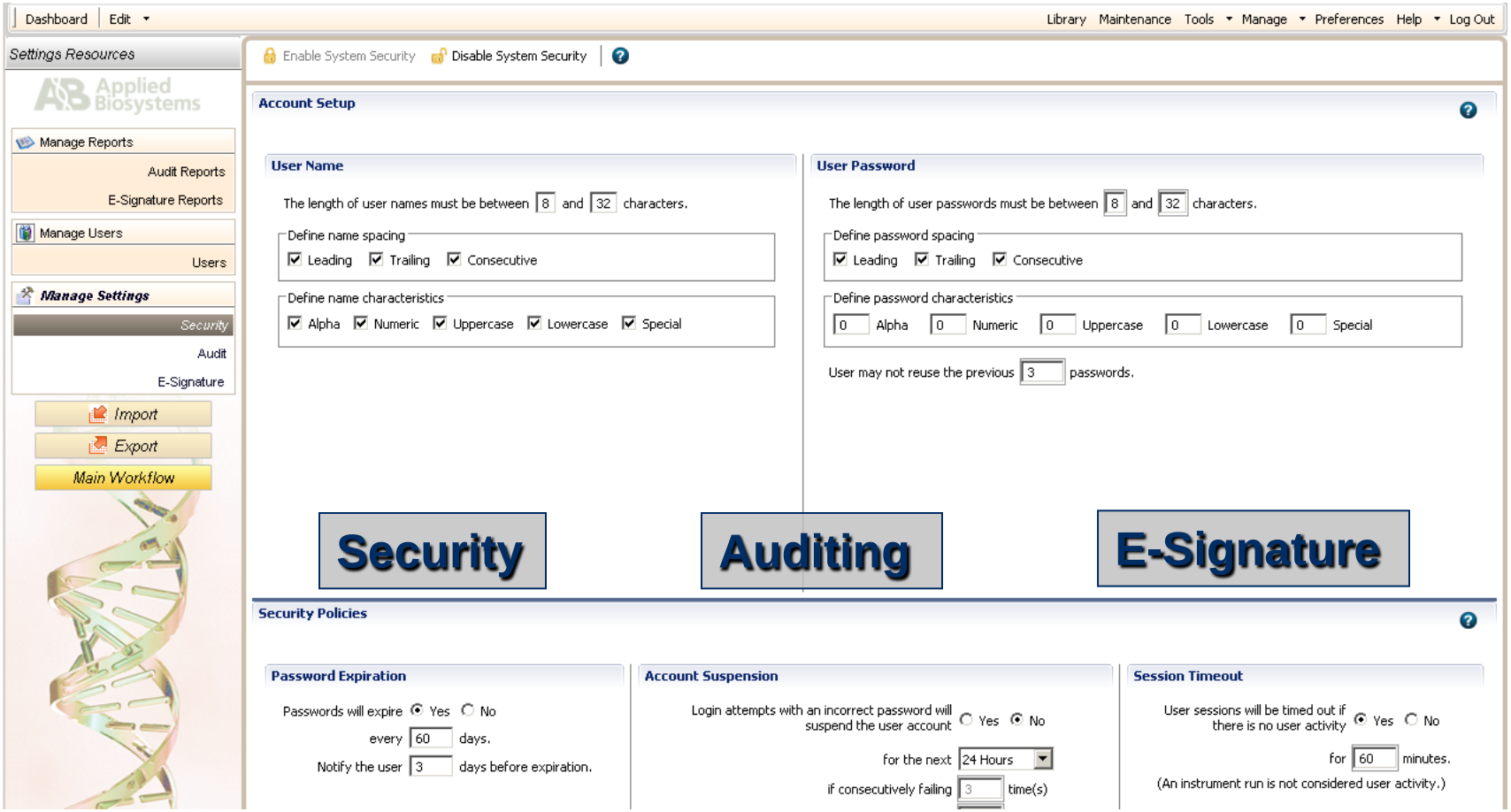
Legend: Passed Failed Borrowed Not Calibrated

Spectral Calibration report

Capillary Run Data

Capillary	Pass/Fail/Borrowed	q Value	Condition Number	Peak 1	Peak 2	Peak 3	Peak 4	Peak 5
1	Pass	0.996	10.089	16052	20541	26255	23411	18071
2	Pass	0.999	10.096	25768	33342	42869	37779	29278
3	Pass	0.998	10.137	20029	26087	33770	29919	22023

Data Chain of Custody



Similar to GMIDx, the data collection software carries user configurable security, auditing and e-signature functionality to maintain chain of custody over electronically generated data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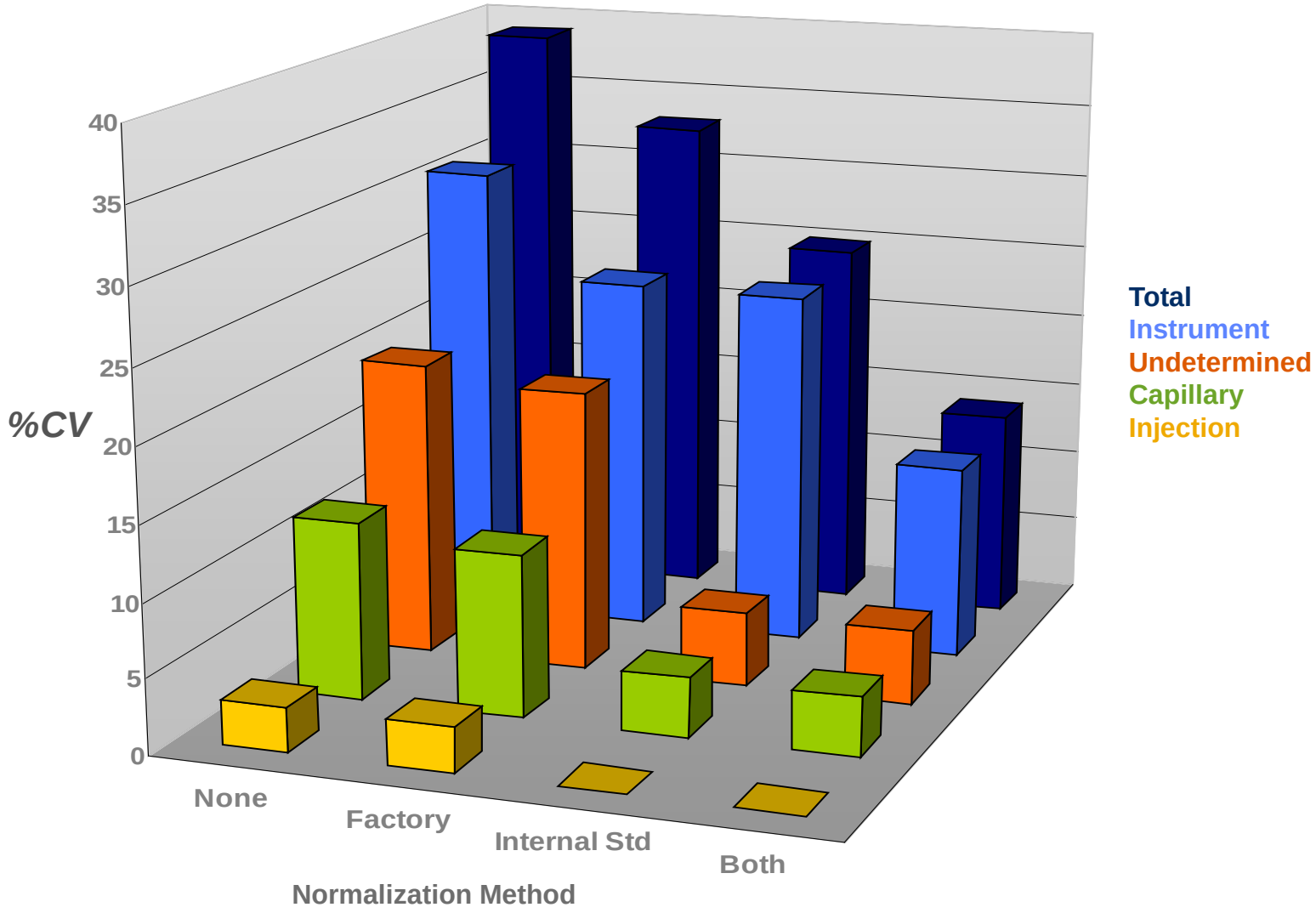
3500 Normalization Tools

Improved Signal Consistency

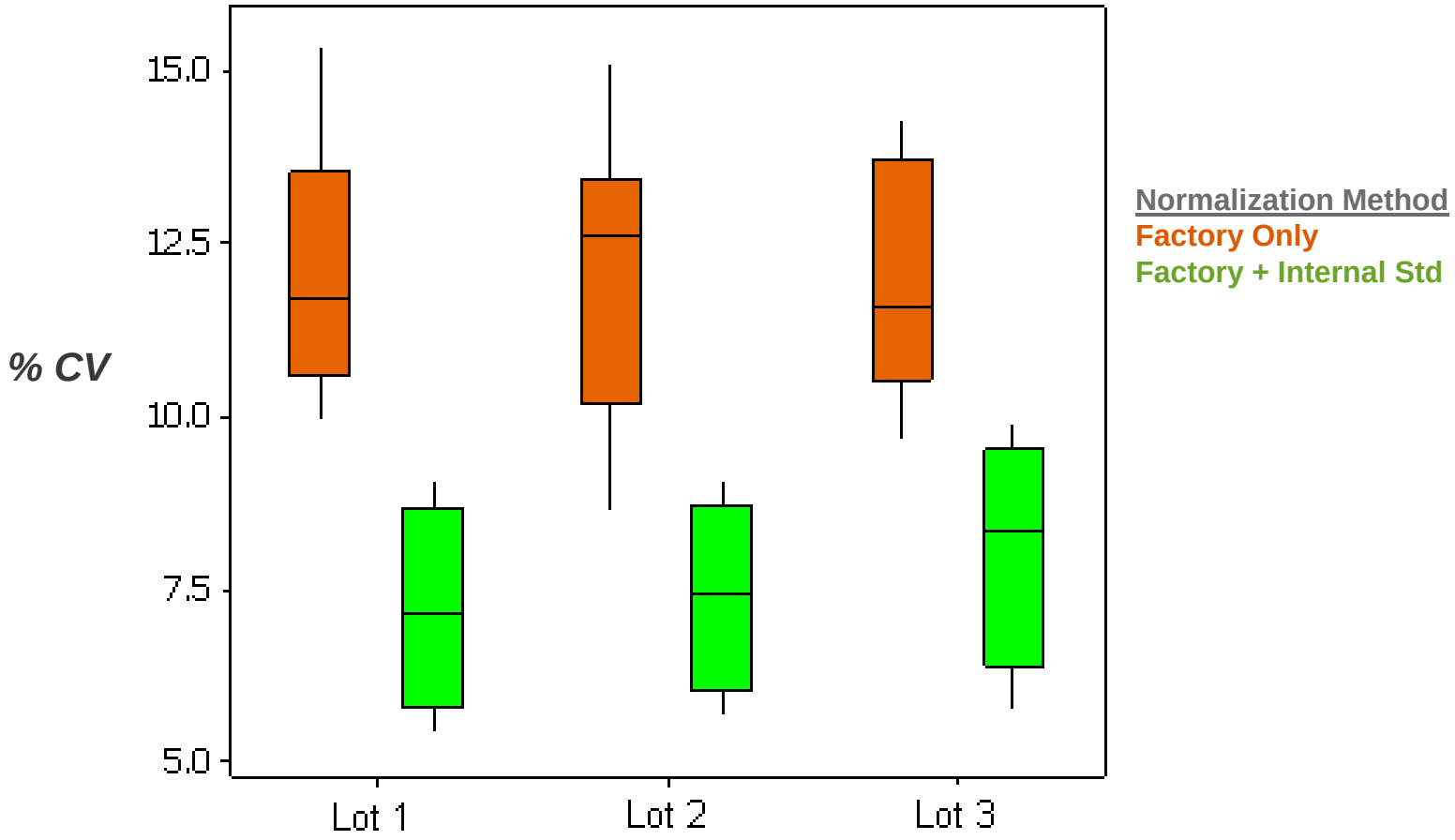
- **Factory Standardization:** Hardware-based calibration for more consistent instrument to instrument performance

- **Internal Standard (Internal Std.) Normalization:** Chemistry and software based method for more consistent signal across injections and instruments
  - User enabled
  - Utilizes re-designed GS600 LIZ Size Standard
  - Sample peak heights are scaled relative to the intensity of the co-injected size standard compared to an optimized average size standard peak height (Normalization Target)

Signal Consistency Study

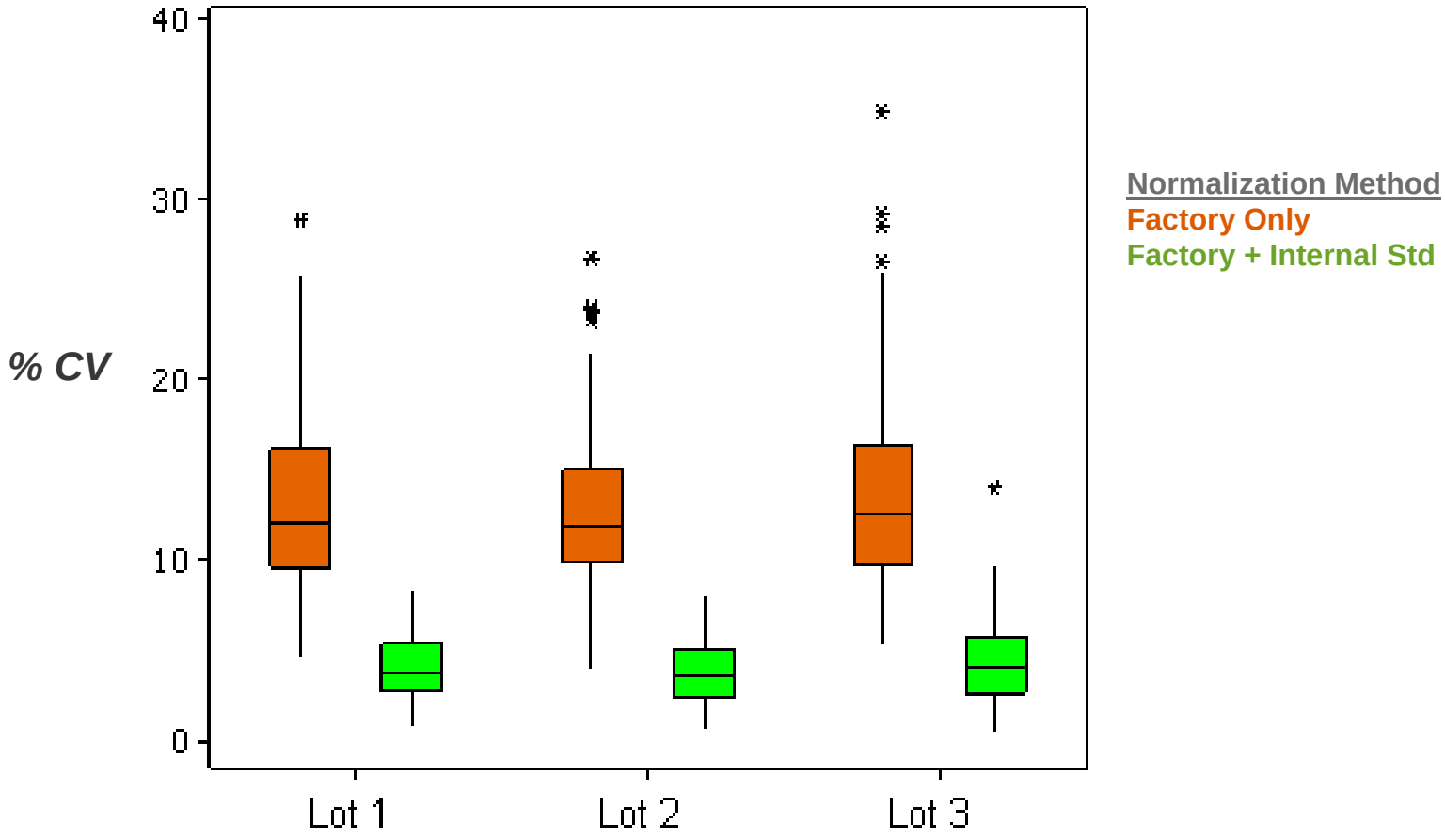


Internal Standard Normalization:
Instrument to Instrument Peak Height Consistency



GS600 Peak Height consistency across 6 instruments and 3 lots of GS600 v2.0

Internal Standard Normalization:
Injection to Injection Peak Height Consistency



GS600 Peak Height Consistency · 6 instruments · 3 lots of GS600 v2.0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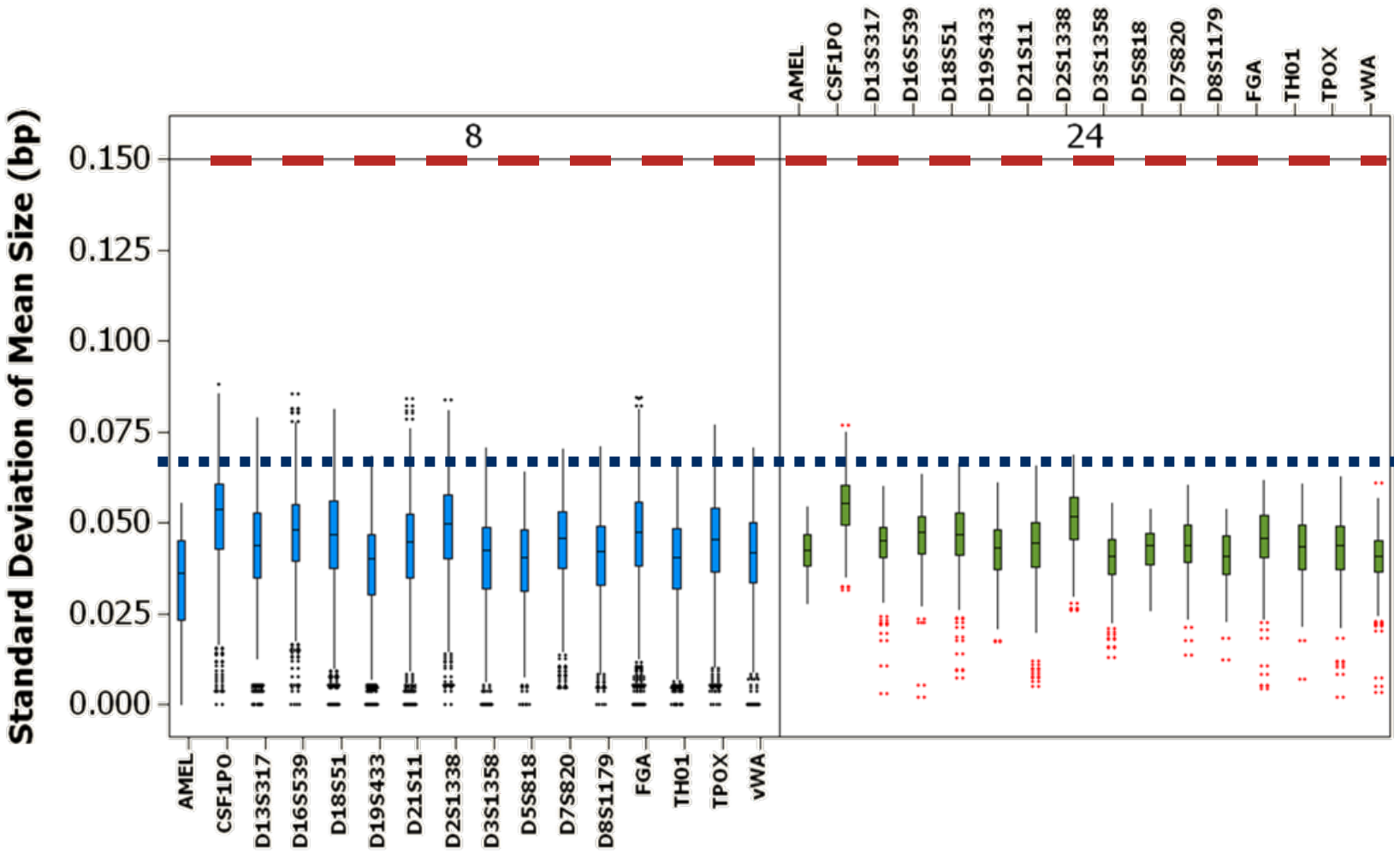
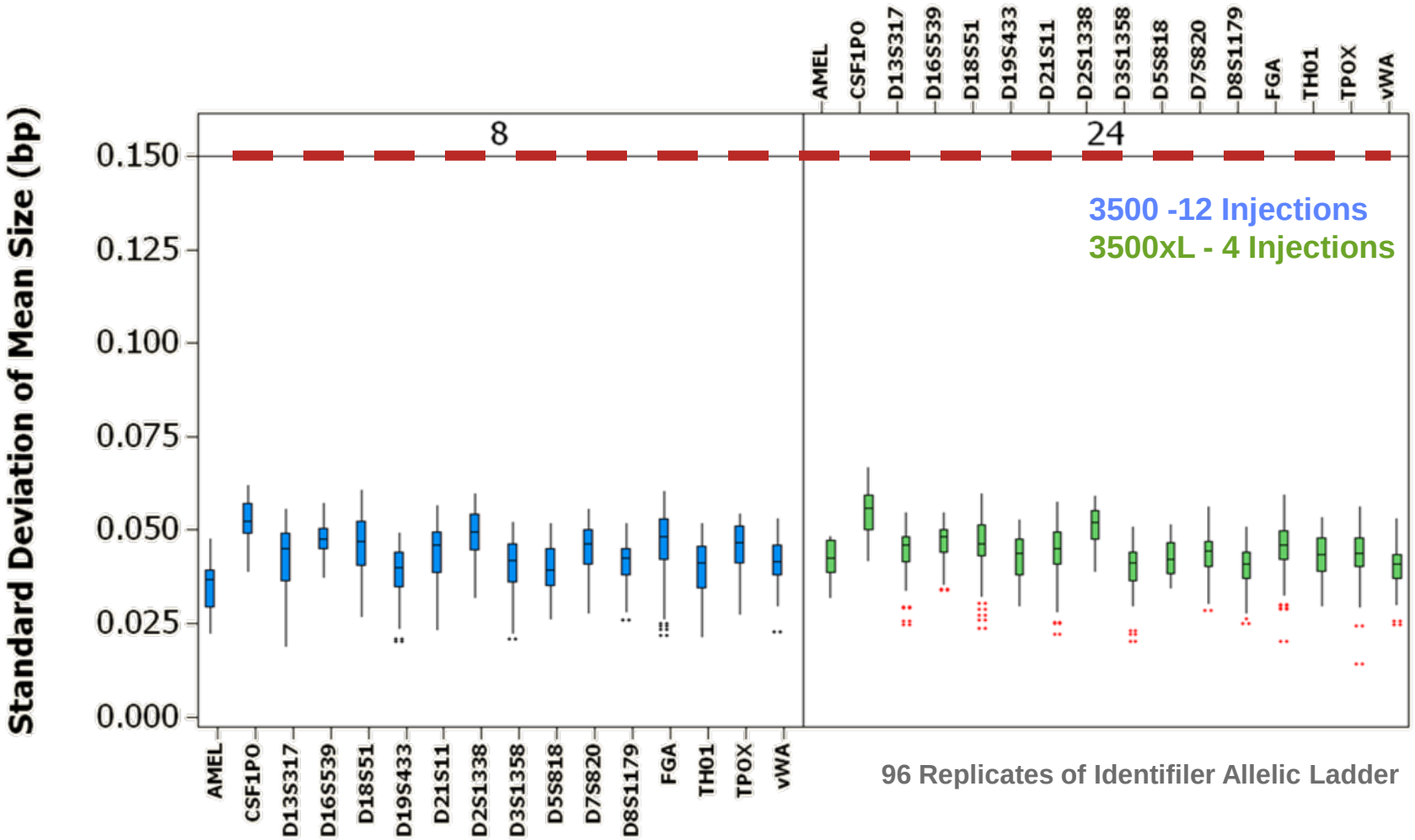
3500 System HID Validation

3500 Sizing Precision Study:
Within an Injection of Identifiler Allelic Ladder



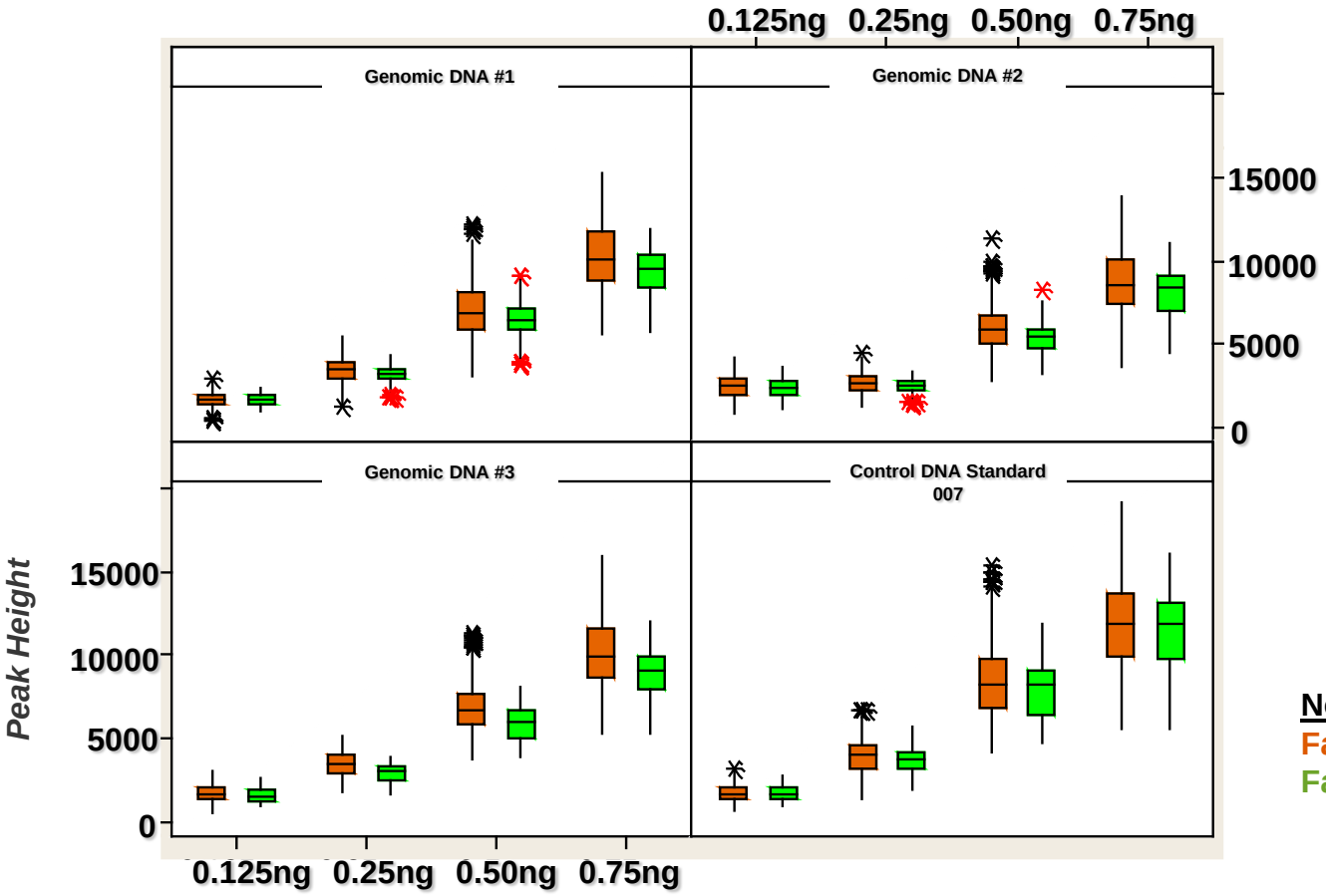
31xx Series

3500 Sizing Precision Study:
Across Multiple Injections of Identifiler Allelic Ladder Samples



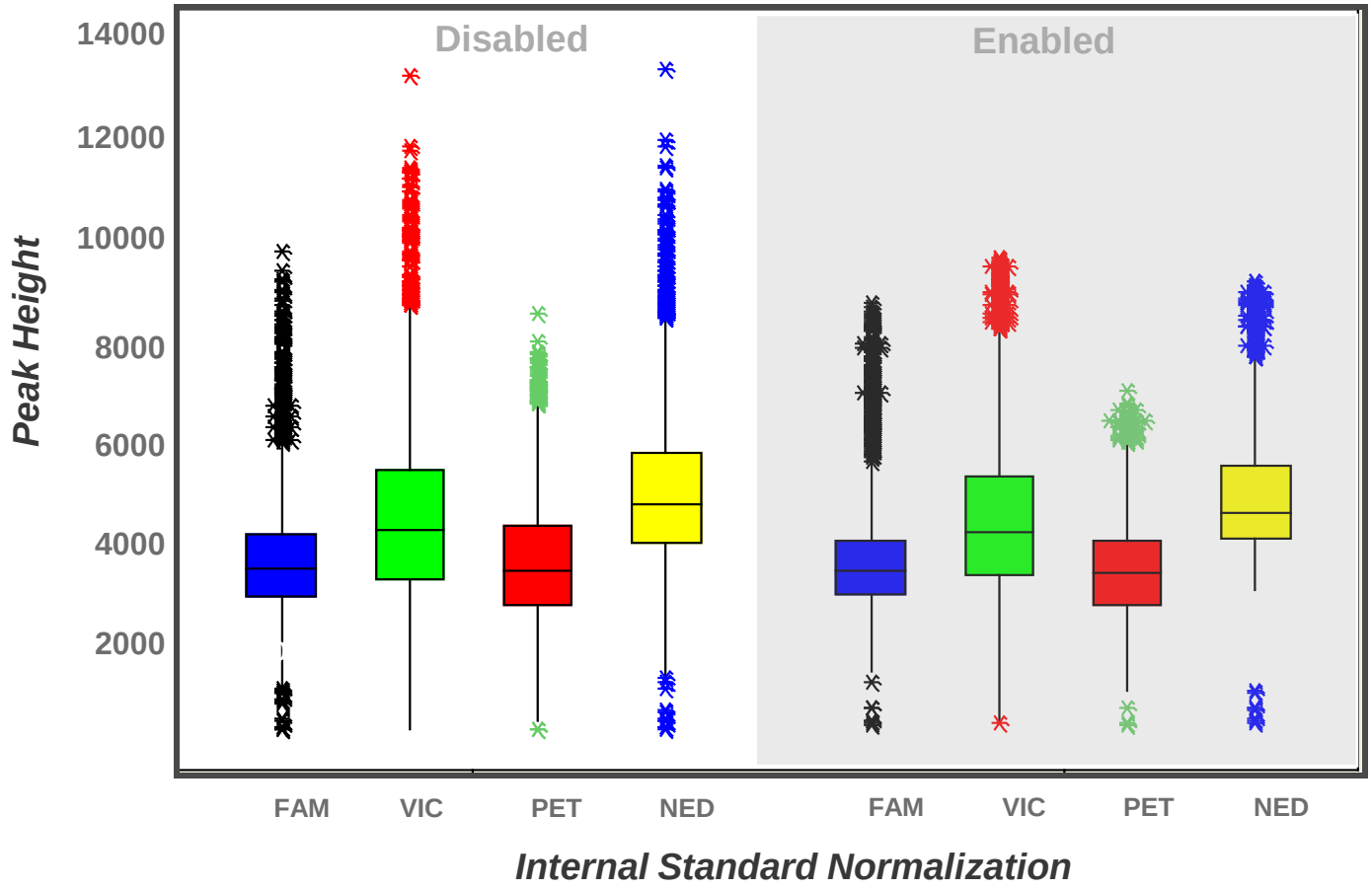
Sensitivity Study:

Average Peak Height across a Range of DNA Input Amounts AmpFℓSTR® MiniFiler™ PCR Amplification Kit

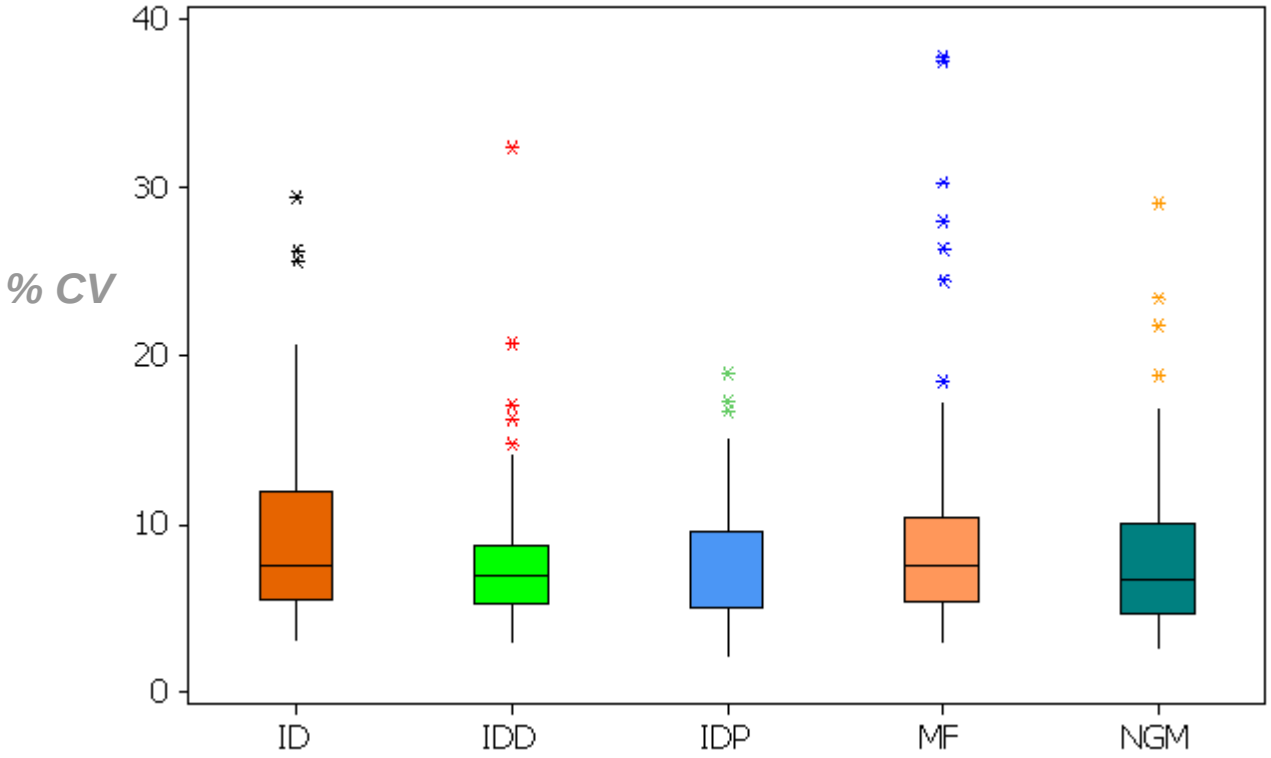


Normalization Method
Factory Only
Factory + Internal Std

3500 Sensitivity Study:
Average Peak Height by Dye for 1ng DNA Input AmpFℓSTR® Identifiler® PCR Amplification Kit



GS600 v2.0 Peak Height Consistency Study:
%CV for 5 Different AmpFℓSTR® Kits



GS600 Peak Height Consistency · 5 Different AmpFℓSTR® Kits · 3 Lots of GS600v2

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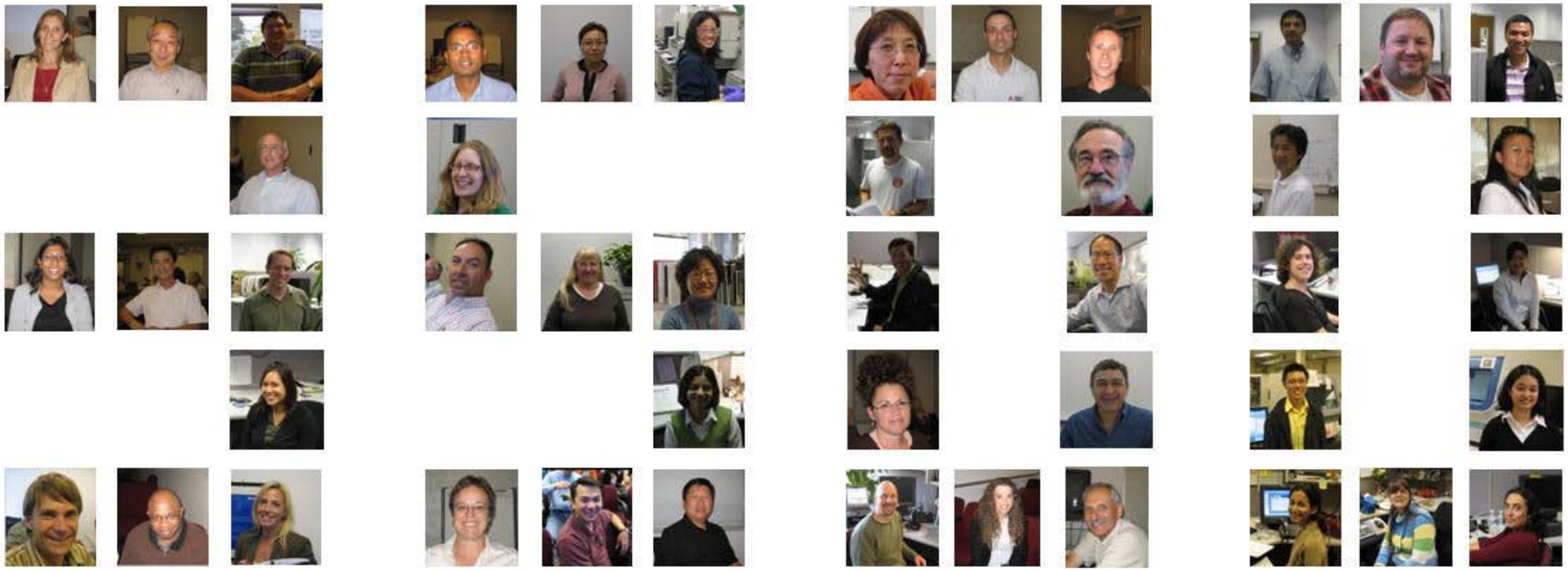
Product Information and Availability

Product Information

- **Developmental Validation is complete - *Validation User Bulletin to Follow***
- **The 3500 Series Genetic Analyzer is *Now Available* for Human Identification**
- **To learn more…Go to: www.appliedbiosystems.com/3500HID**

3500 Core Development Team



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Thank you!

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