

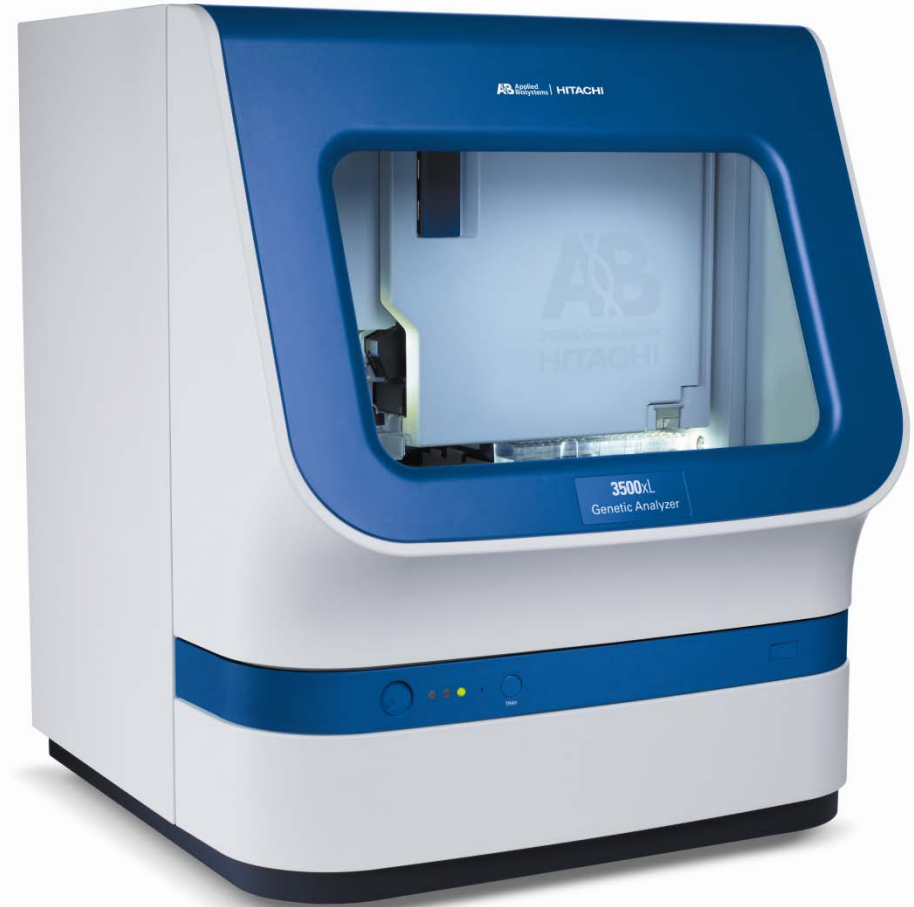


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# Next Generation Capillary Electrophoresis System: *The 3500 Series Genetic Analyzers*

# 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**

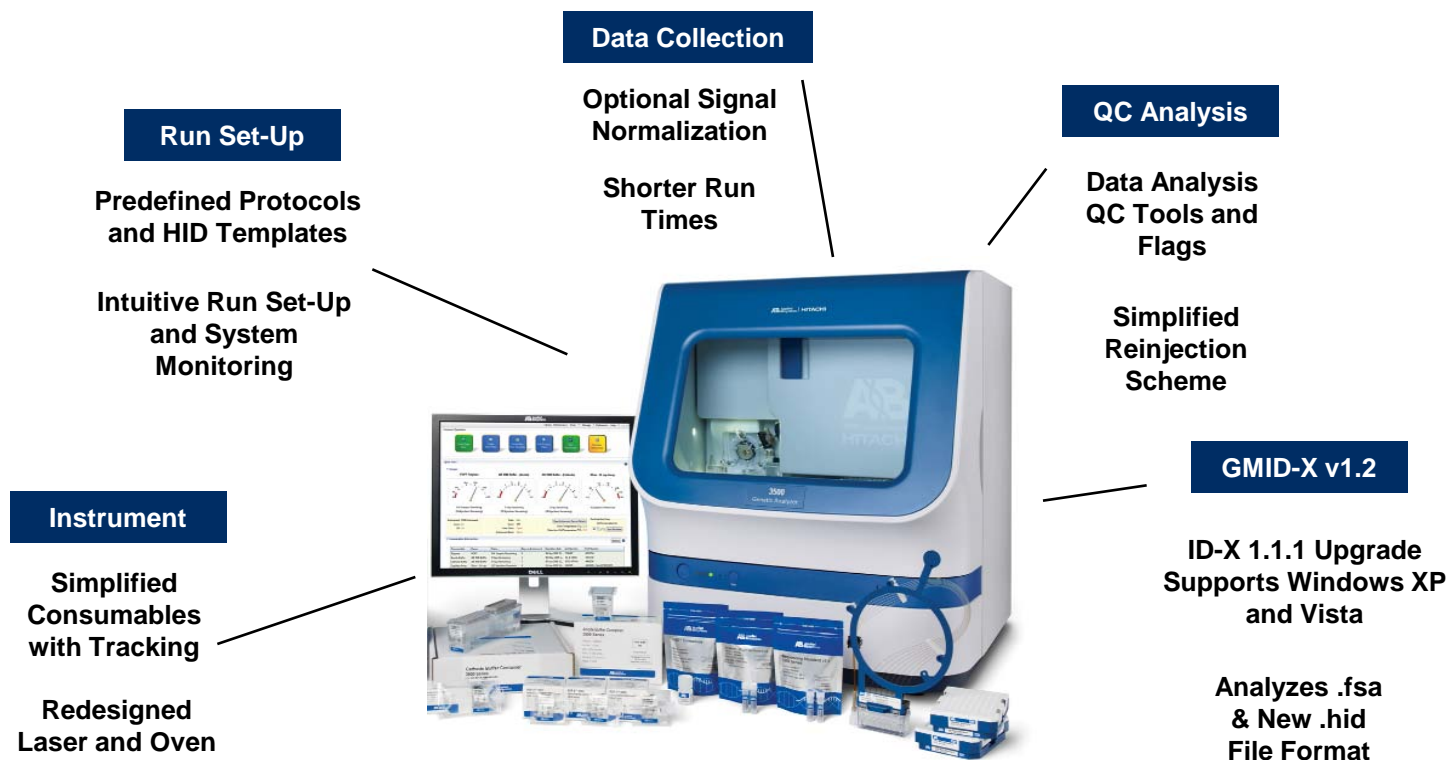


**3500xL**



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



**Instrument**

**Run Set-Up**

**Data Collection**

**QC Analysis**

**GMID-X v1.2**

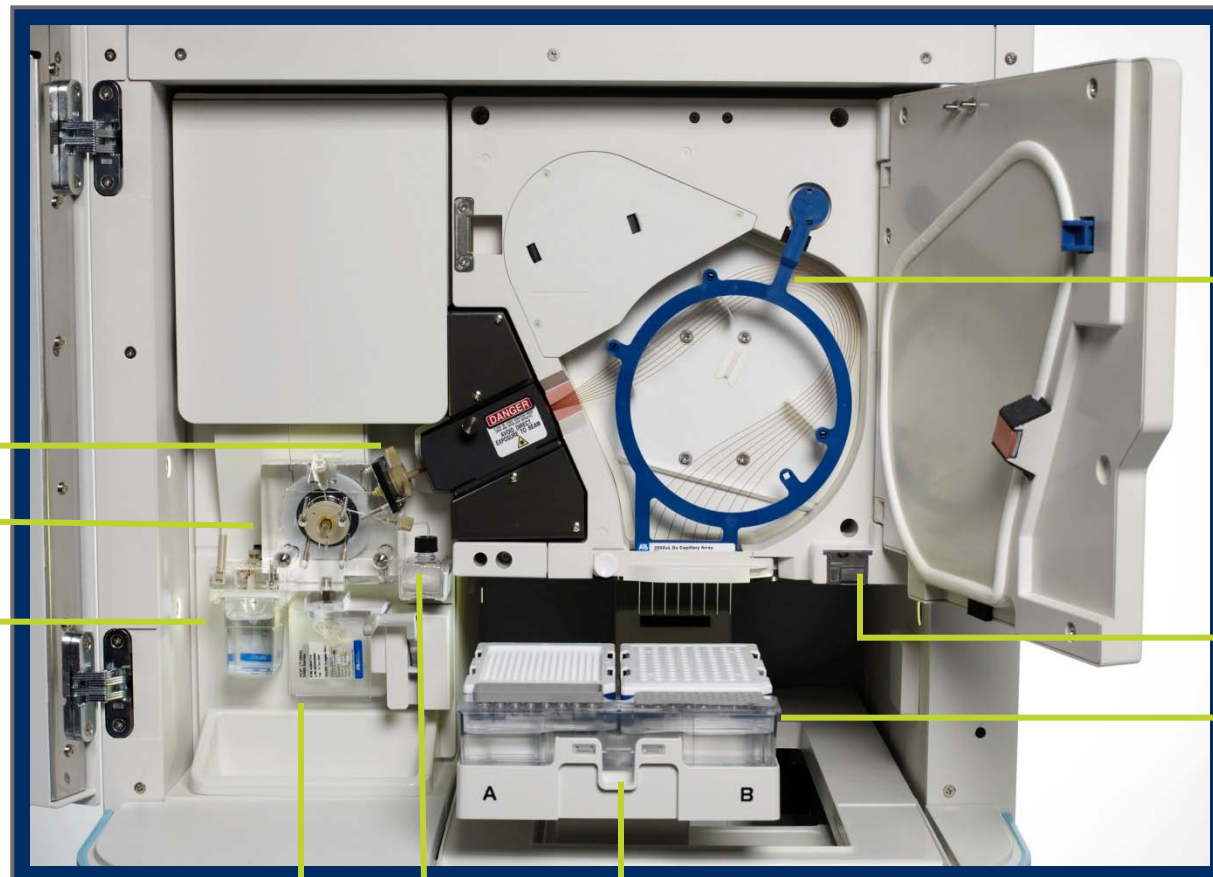




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# 3500 Series Hardware

# Instrument Interior



Array head lock  
mechanism

Pump Delivery System

Anode Buffer  
Container

Polymer pouch

Pump water  
overflow  
reservoir

Autosampler

Array +  
Array holder

Oven  
condensation  
reservoir

Cathode Buffer  
Container

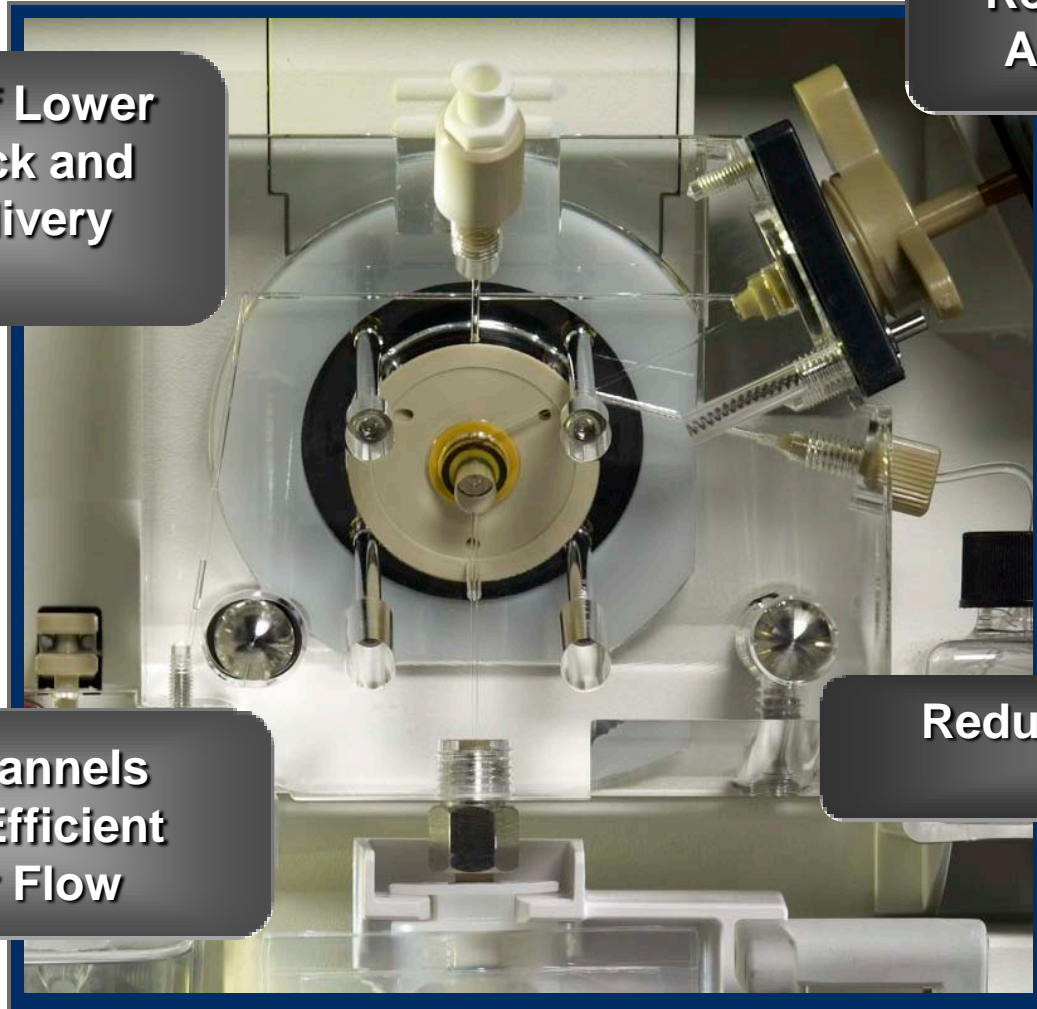
# Redesigned Polymer Pump

**Elimination of Lower  
Polymer Block and  
Polymer Delivery  
Tubing**

**Redesigned  
Array Port**

**Direct Channels  
Promote Efficient  
Polymer Flow**

**Reduced Polymer  
Waste**





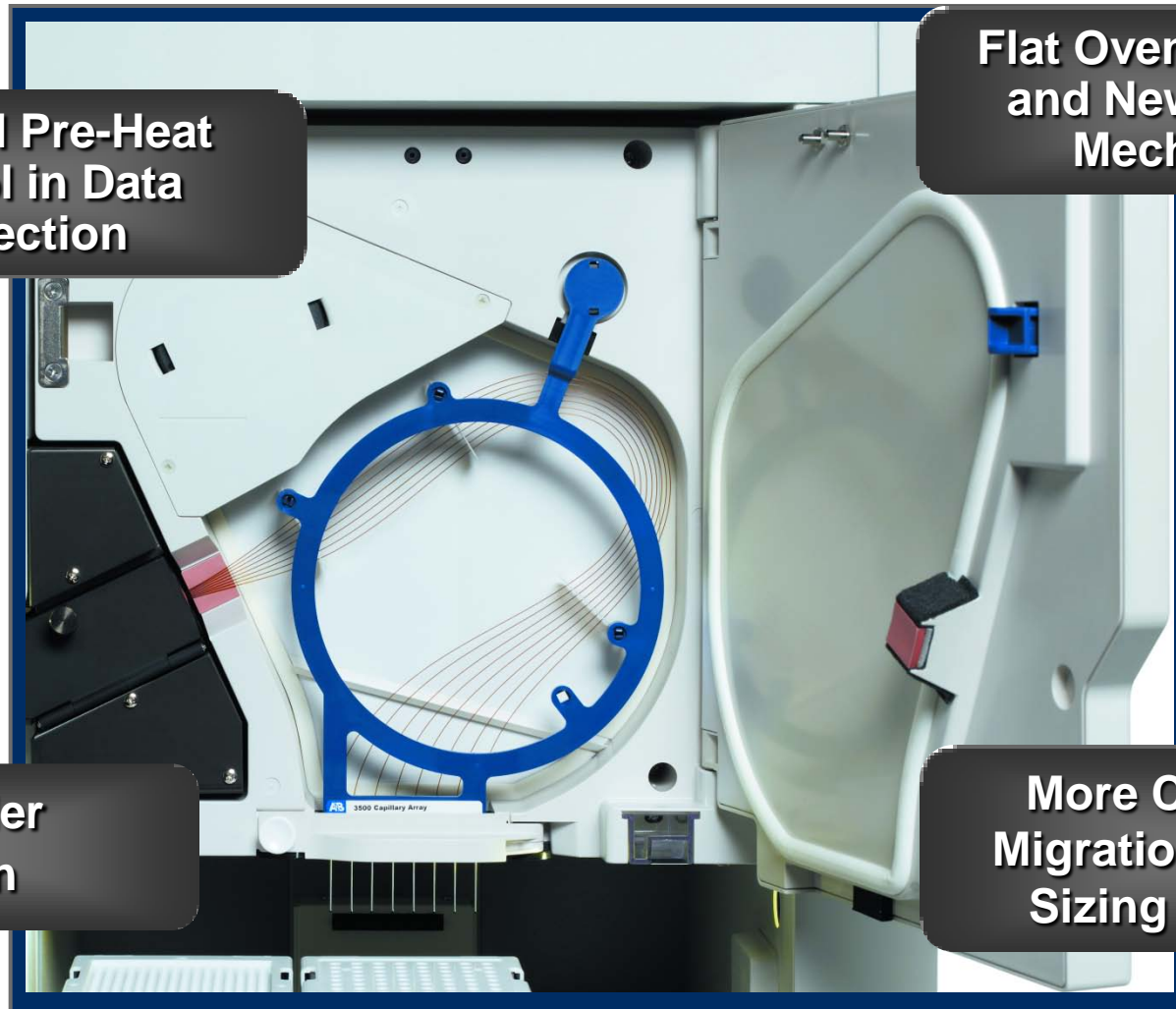
# Improved Temperature Control System

**Optional Pre-Heat  
Control in Data  
Collection**

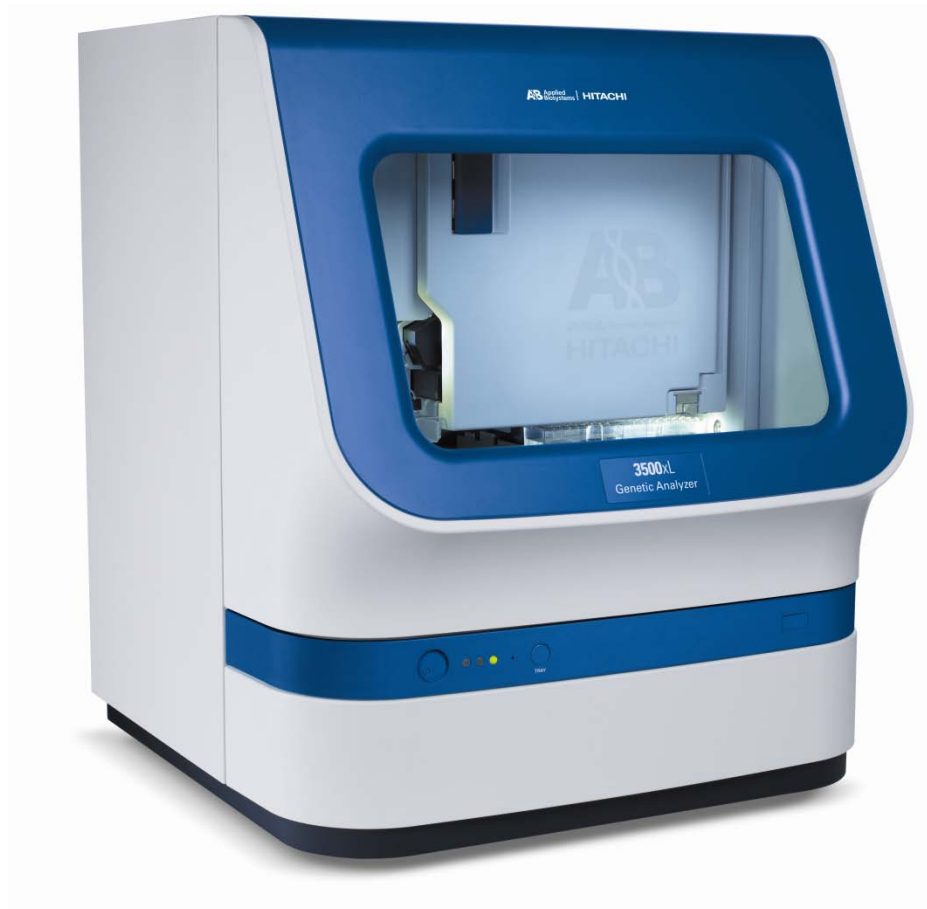
**Flat Oven Door Seal  
and New Locking  
Mechanism**

**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

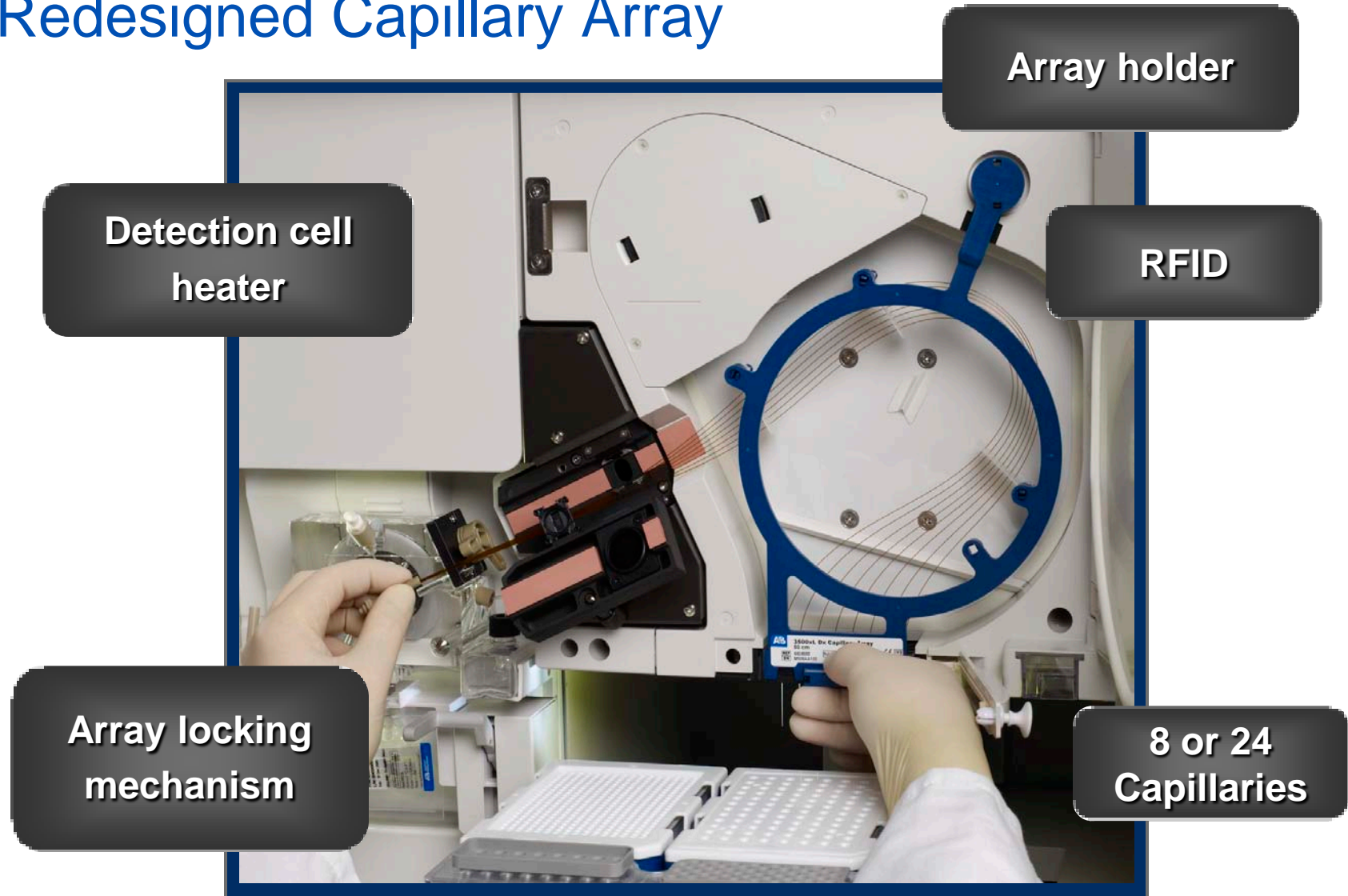
Simplified Instrument Setup and Consumable Tracking

# 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 ( $\frac{1}{4}$  turn)
- Easier bubble flush





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# 3500 Data Collection Software

# Dashboard

## Key Operations

### Common Operations



## Consumable Gauges

### Quick View

#### Gauges

#### POP4 Polymer



509 Samples Remaining  
(40 Injections Remaining)

#### AB 3500 Buffer - (Anode)



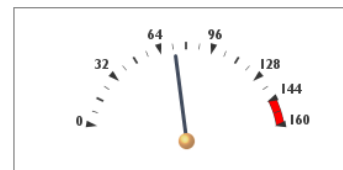
3 Days Remaining  
(45 Injections Remaining)

#### AB 3500 Buffer - (Cathode)



3 Days Remaining  
(45 Injections Remaining)

#### 36cm - 24 cap Array



72 Injections Performed

## Instrument Status

Instrument: 3500 Instrument

Laser: On

EP: On

State: Idle

Oven: Off

Oven Door: Open

Instrument Door: Close

[View Instrument Sensor Details](#)

Oven Temperature (°C): 53.5

Detection Cell Temperature (°C): 23.5

Pre-Heat the Oven

Set Temperature to:

60 (°C) [Start Pre-Heat](#)

### Consumables Information

[Refresh](#)

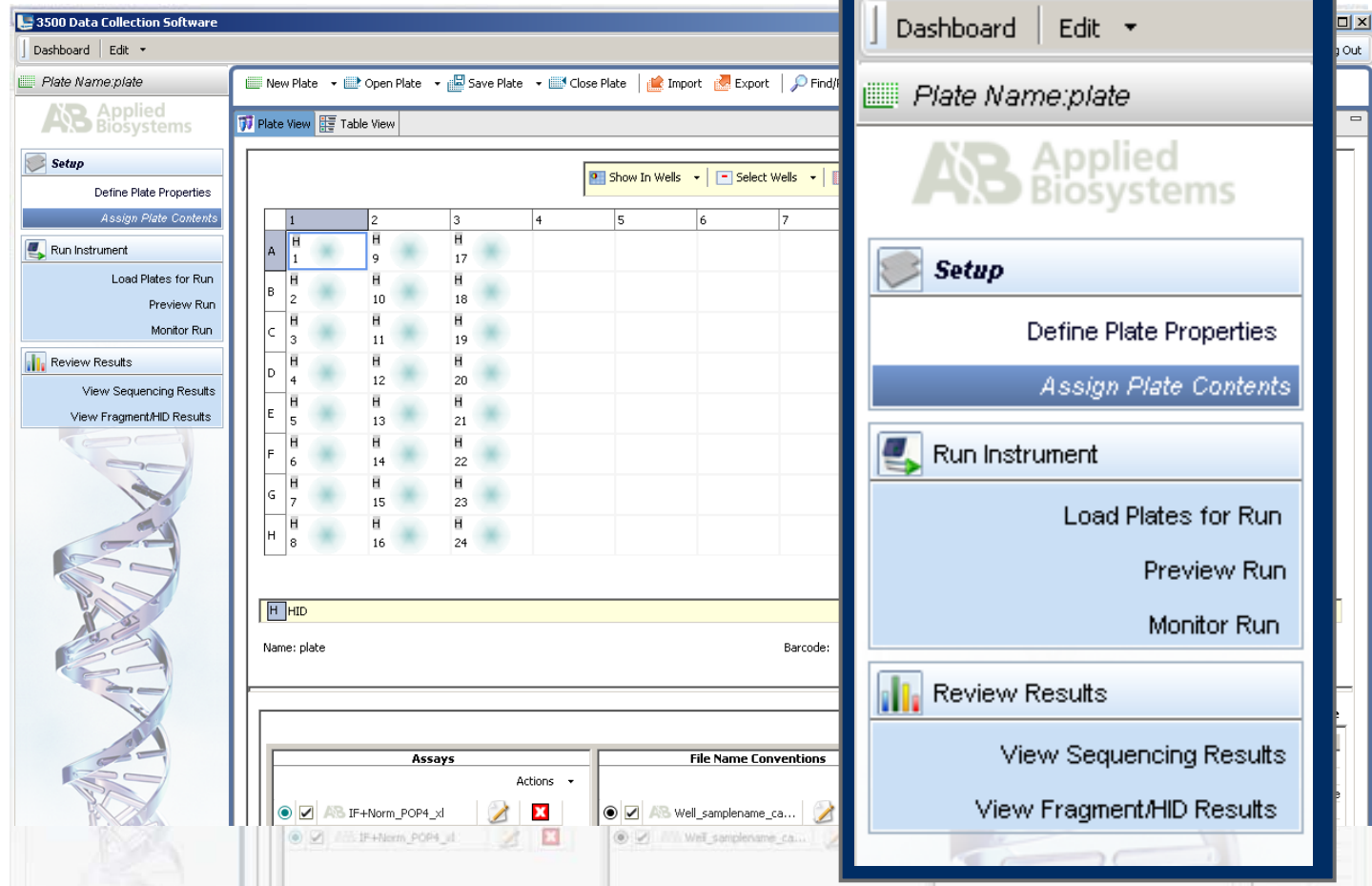
### Maintenance Notifications

Name	Priority	Notification Date	Description	Action
Perform Planned Maintenance	HIGH	03-Jun-2009 12:00:00 AM	Perform Planned Maintenance	✓ ✗
Flush Pump Trap	HIGH	03-Jun-2009 12:00:00 AM	Flush Pump Trap	✓ ✗
Clean Drip Tray	HIGH	03-Jun-2009 12:00:00 AM	Clean Drip Tray	✓ ✗

## Maintenance Alerts

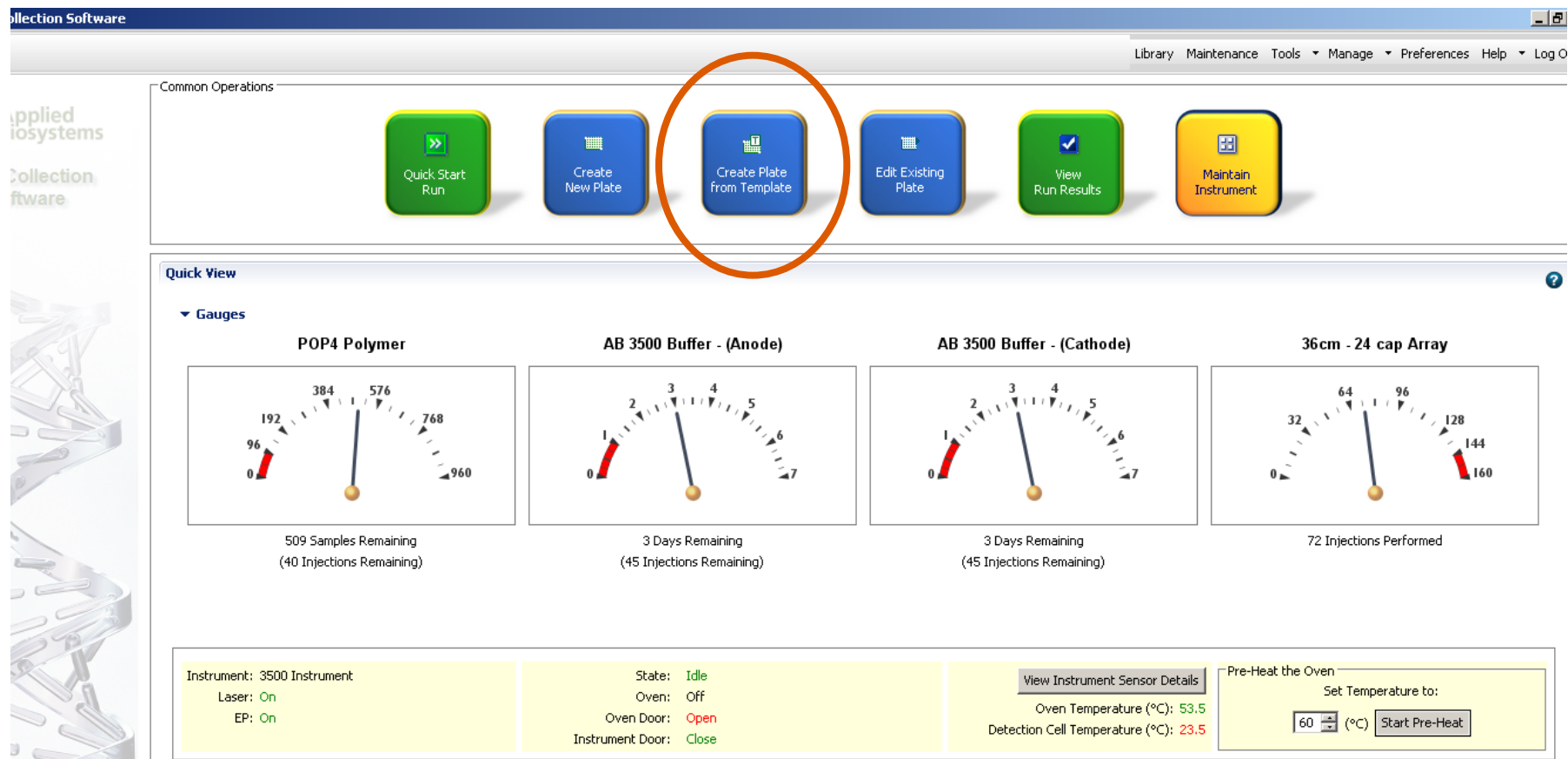
The Dashboard screen provides current instrument and consumable information and direct access to key functionality to quickly perform common tasks

# 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

**1**

In the HID Plate Template, simply enter or import sample names (1) and assign the instrument protocol from the preconfigured list of Assays (2)

	1	2	3	4	5	6
A	H 1	H 9	H 17	H 25		
B	H 2	H 10	H 18	H 26		
C	H 3	H 11	H 19	H 27		
D	H 4	H 12	H 20	H 28		
E	H 5	H 13	H 21	H 29		
F	H 6	H 14	H 22	H 30		
G	H 7	H 15	H 23	H 31		
H	H 8	H 16	H 24	H 32		

**2**

**Assays**

	Actions
<input checked="" type="checkbox"/> IF+Norm_POP4_xl	[Edit] [Delete]
<input type="checkbox"/> MF+Norm_POP4_xl	[Edit] [Delete]
<input type="checkbox"/> SEF+_+Norm_POP4_xl	[Edit] [Delete]
<input type="checkbox"/> YF+Norm_POP4_xl	[Edit] [Delete]
<input type="checkbox"/> CO_POP4_xl	[Edit] [Delete]
<input type="checkbox"/> IF_POP4_xl	[Edit] [Delete]
<input type="checkbox"/> MF_POP4_xl	[Edit] [Delete]

**File Name Conventions**

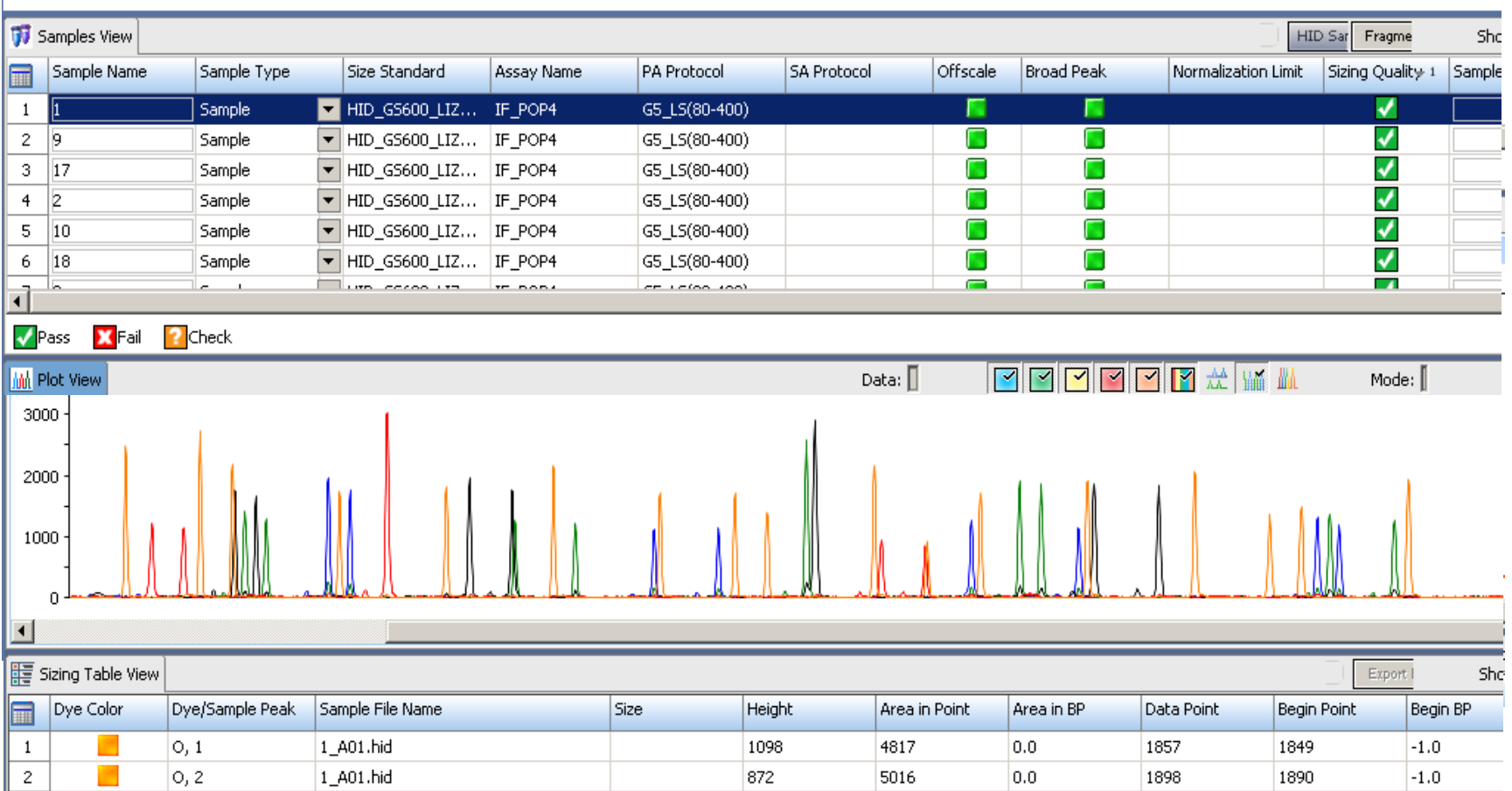
	Actions
<input checked="" type="checkbox"/> Samplename_well_capillar...	[Edit] [Delete]
<input type="checkbox"/> Well_samplename_capillar...	[Edit] [Delete]
<input type="checkbox"/> AB My_FVC	[Edit] [Delete]

**Results Groups**

	Actions
<input type="checkbox"/> PN_Infolder_RG	[Edit] [Delete]
<input checked="" type="checkbox"/> PN_RG	[Edit] [Delete]
<input type="checkbox"/> PN_IFassay_RG	[Edit] [Delete]
<input type="checkbox"/> PN_MFassay_RG	[Edit] [Delete]
<input type="checkbox"/> PN_YFassay_RG	[Edit] [Delete]

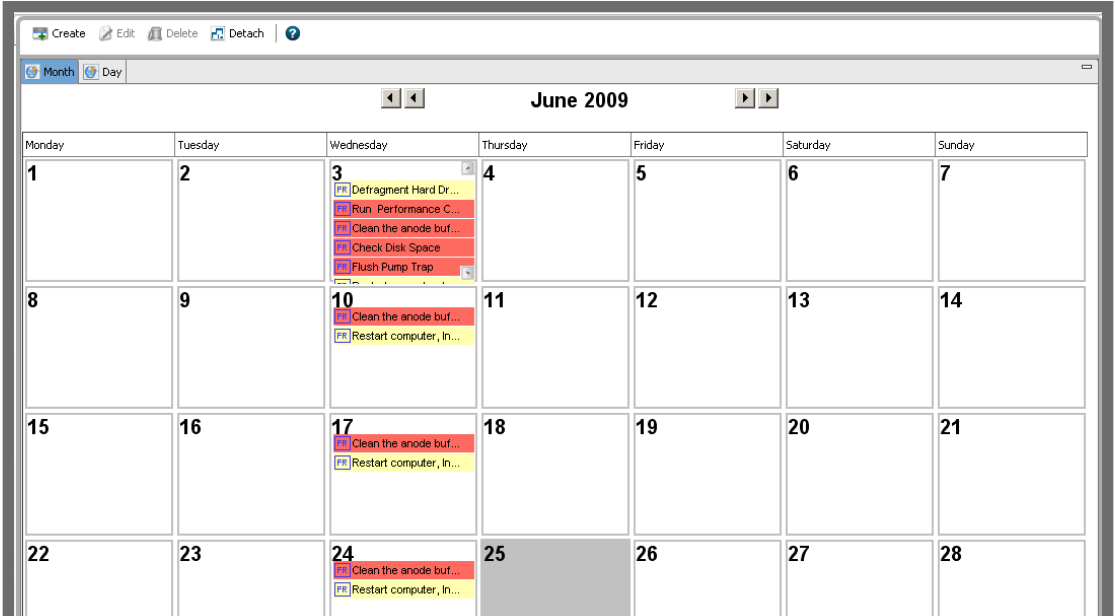
Customize Sample Info

# 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



The screenshot displays a maintenance calendar for June 2009. The calendar is organized by days of the week (Monday to Sunday). Maintenance tasks are listed for specific dates: Wednesday, June 3rd; Wednesday, June 10th; Wednesday, June 17th; and Wednesday, June 24th. Each task entry includes a priority icon (a red 'P' in a square) and a description. A green callout bubble with the number '1' points to the 'Maintenance Notifications' panel at the bottom of the screen.

**Maintenance Notifications**

Name	Priority	Notification Date	Description	Action
Perform Planned Maintenance	HIGH	03-Jun-2009 12:00:00 AM	Perform Planned Maintenance	✓ ✗
Flush Pump Trap	HIGH	03-Jun-2009 12:00:00 AM	Flush Pump Trap	✓ ✗
Clean Drip Tray	HIGH	03-Jun-2009 12:00:00 AM	Clean Drip Tray	✓ ✗
Run Performance Check	HIGH	03-Jun-2009 12:00:00 AM	Run Fragment/HID and/or Sequencing Performance Check	✓ ✗
Replace cathode buffer container septa	HIGH	03-Jun-2009 12:00:00 AM	Replace cathode buffer container septa	✓ ✗

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

# Reporting Tools



## 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

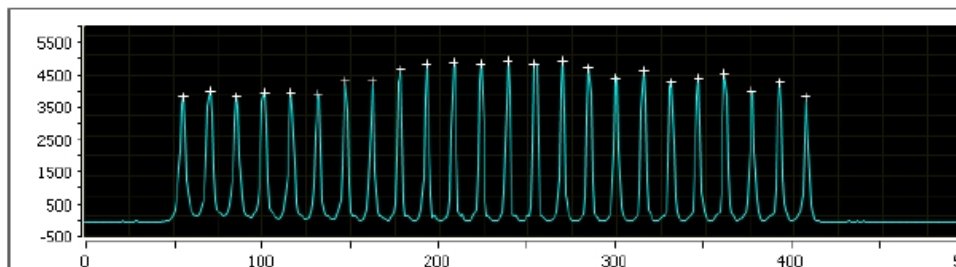
Name: 3500 Instrument  
Serial Number: 13527-029

### 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



## Spectral Report

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

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

Capillary	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Run 1																								
Run 2																								
Run 3																								
Overall																								

Legend: ■ Passed ■ Failed ■ Borrowed □ Not Calibrated

### 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

**Spectral Calibration  
report**



# Data Chain of Custody

Dashboard | Edit | Library | Maintenance | Tools | Manage | Preferences | Help | Log Out

Settings Resources

Applied Biosystems

Manage Reports

Audit Reports

E-Signature Reports

Manage Users

Users

Manage Settings

Security

Audit

E-Signature

Import

Export

Main Workflow

Enable System Security Disable System Security ?

## Account Setup

### User Name

The length of user names must be between 8 and 32 characters.

Define name spacing

☒ Leading ☒ Trailing ☒ Consecutive

Define name characteristics

☒ Alpha ☒ Numeric ☒ Uppercase ☒ Lowercase ☒ Special

### User Password

The length of user passwords must be between 8 and 32 characters.

Define password spacing

☒ Leading ☒ Trailing ☒ Consecutive

Define password characteristics

Alpha  Numeric  Uppercase  Lowercase  Special

User may not reuse the previous 3 passwords.

## Security Auditing E-Signature

### Security Policies

#### Password Expiration

Passwords will expire ☒ Yes ☐ No

every 60 days.

Notify the user 3 days before expiration.

#### Account Suspension

Login attempts with an incorrect password will suspend the user account ☐ Yes ☒ No

for the next 24 Hours

if consecutively failing 3 time(s)

#### Session Timeout

User sessions will be timed out if there is no user activity ☒ Yes ☐ No

for 60 minutes.

(An instrument run is not considered user activity.)

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



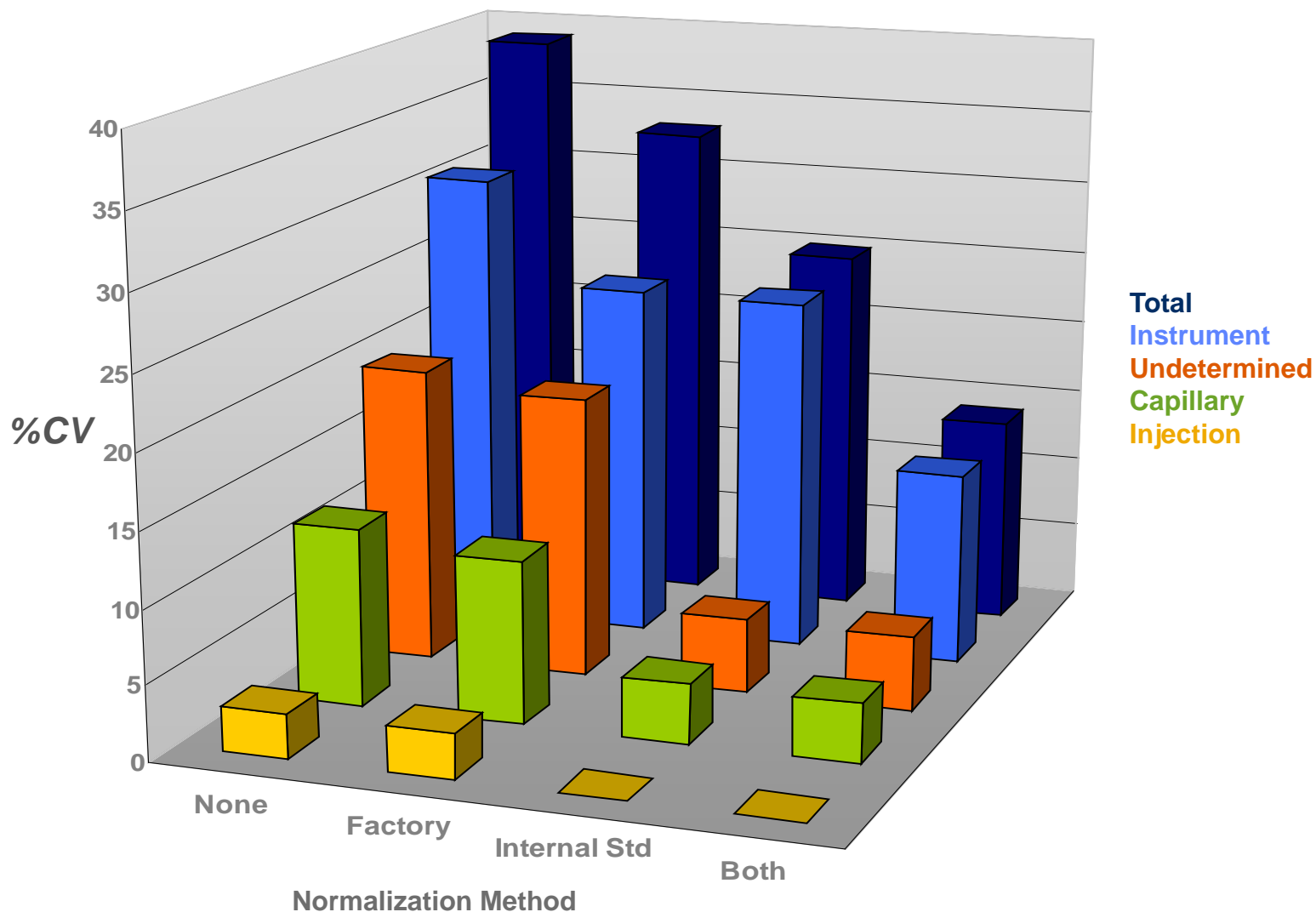
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# 3500 Normalization Tools

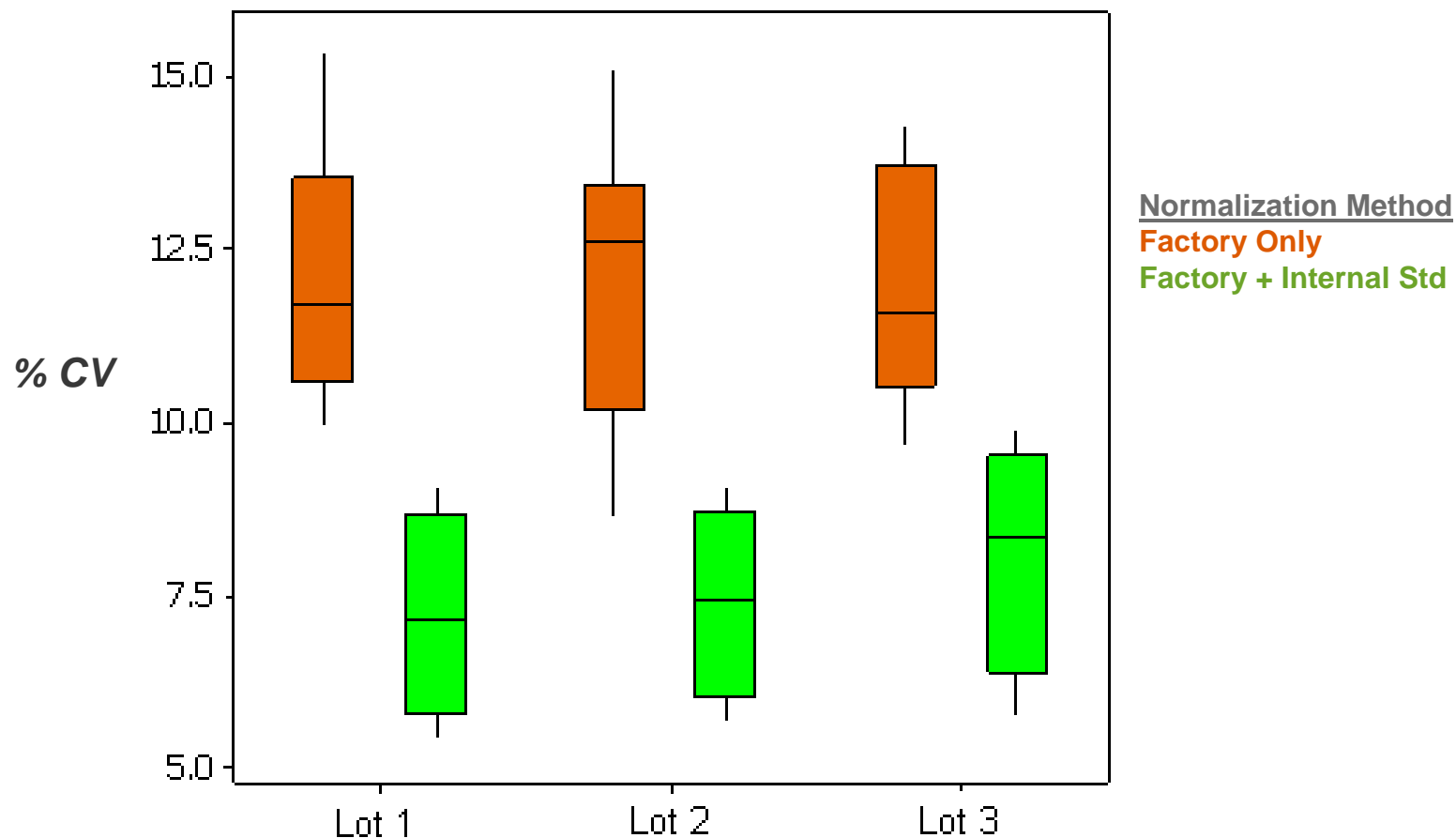
## Improved Signal Consistency

- **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



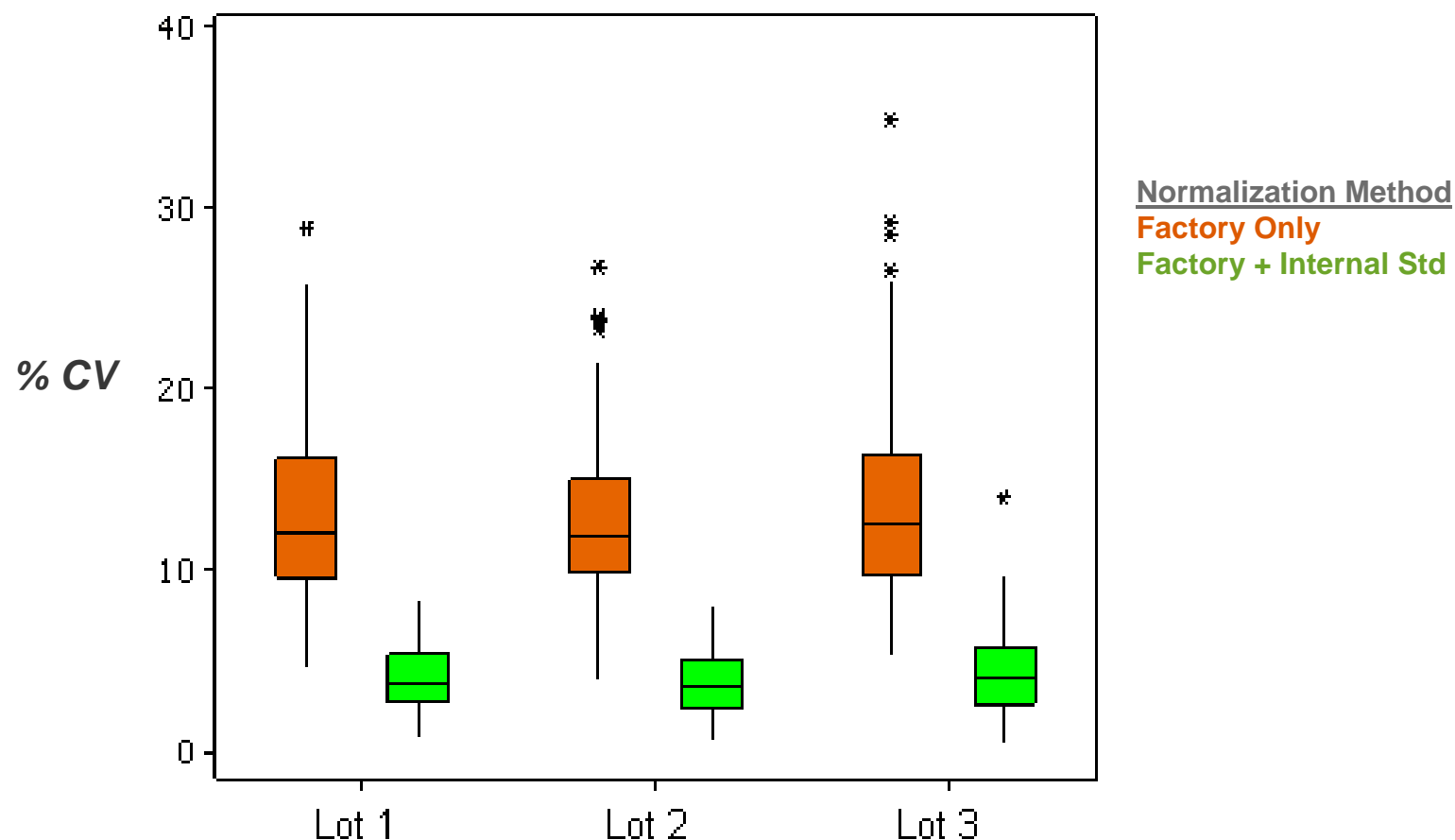
## Internal Standard Normalization: Instrument to Instrument Peak Height Consistency



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



## Internal Standard Normalization: Injection to Injection Peak Height Consistency



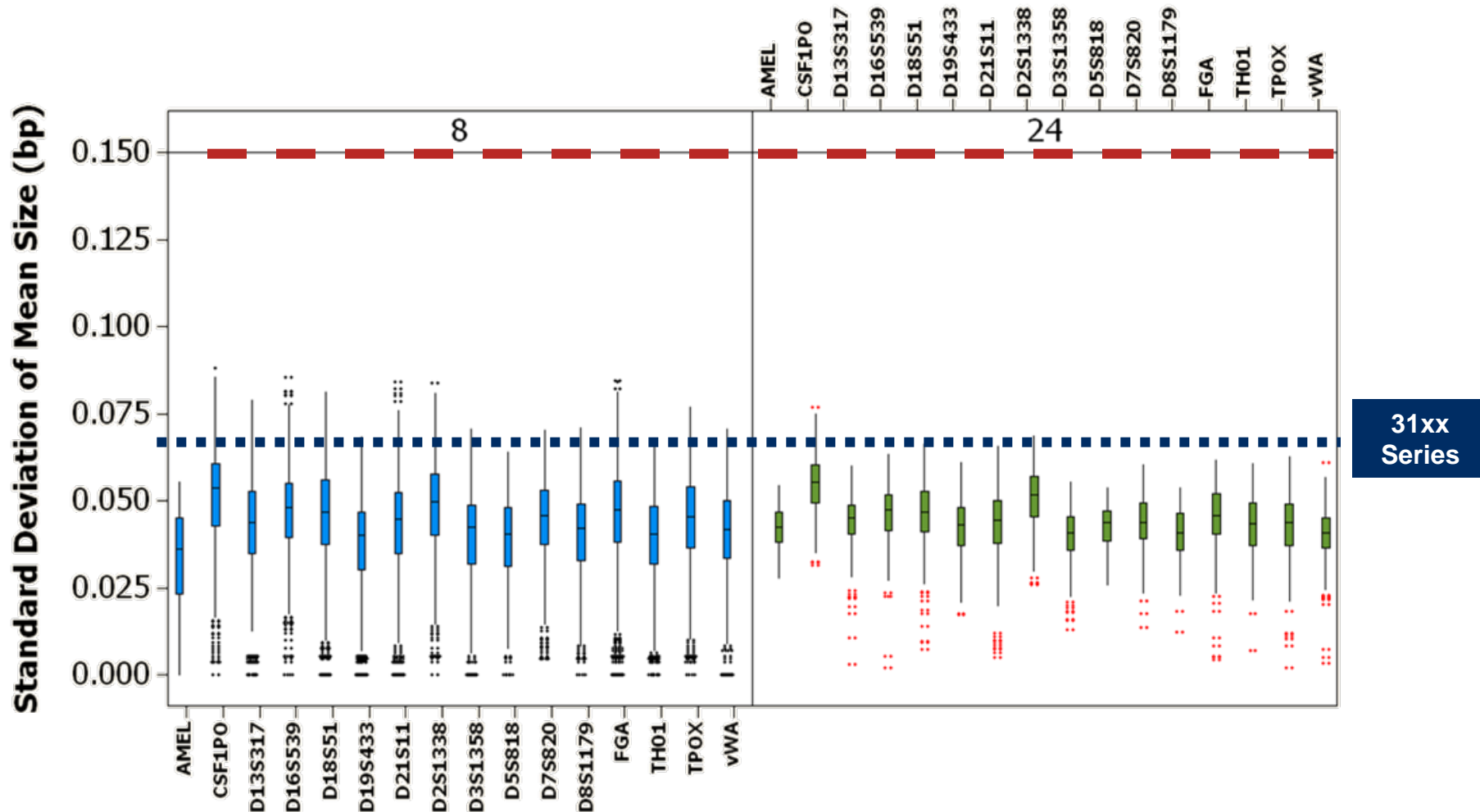
GS600 Peak Height Consistency - 6 instruments - 3 lots of GS600 v2.0



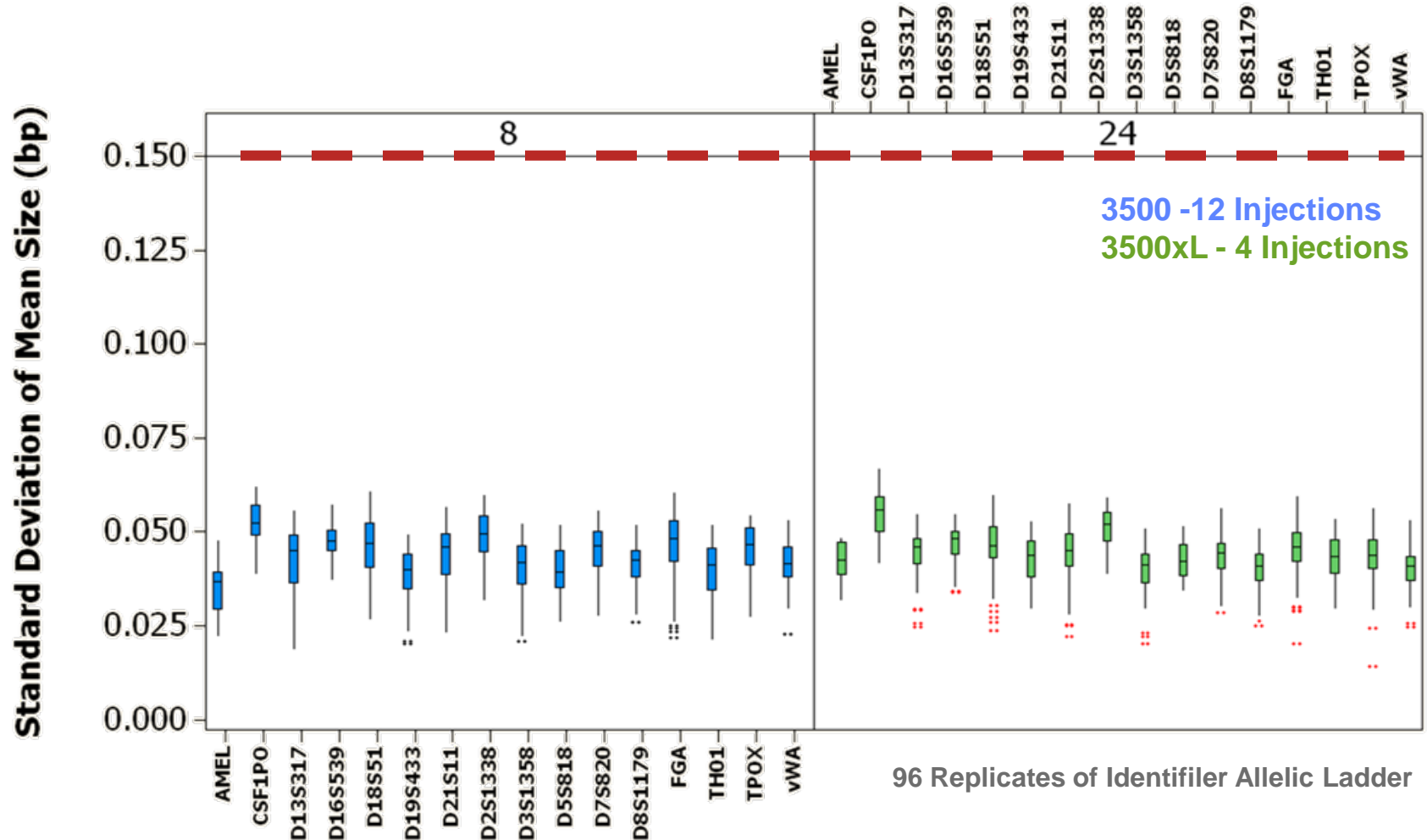
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# 3500 System HID Validation

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



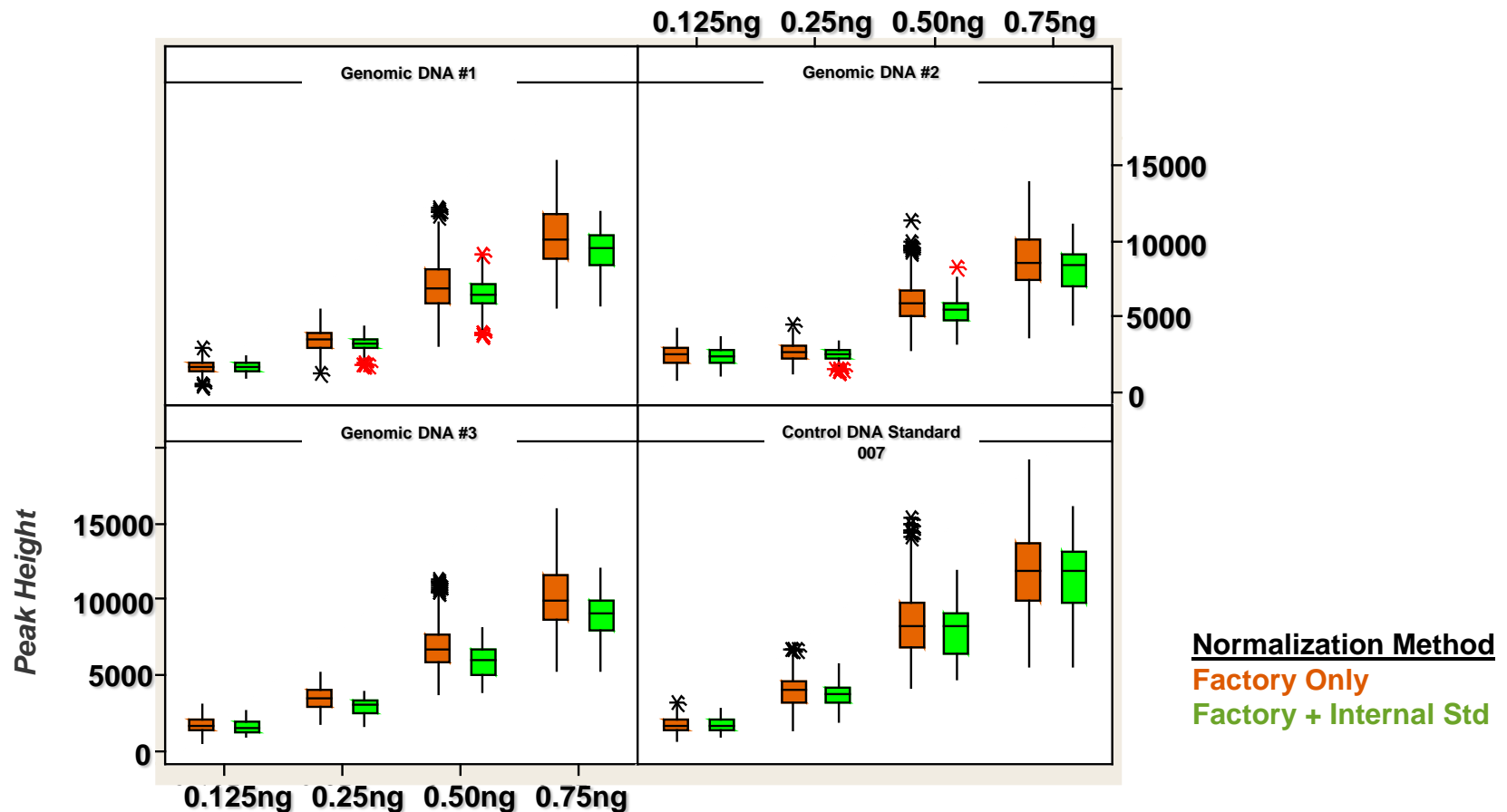
# 3500 Sizing Precision Study: Across Multiple Injections of Identifiler Allelic Ladder Samples



# Sensitivity Study:

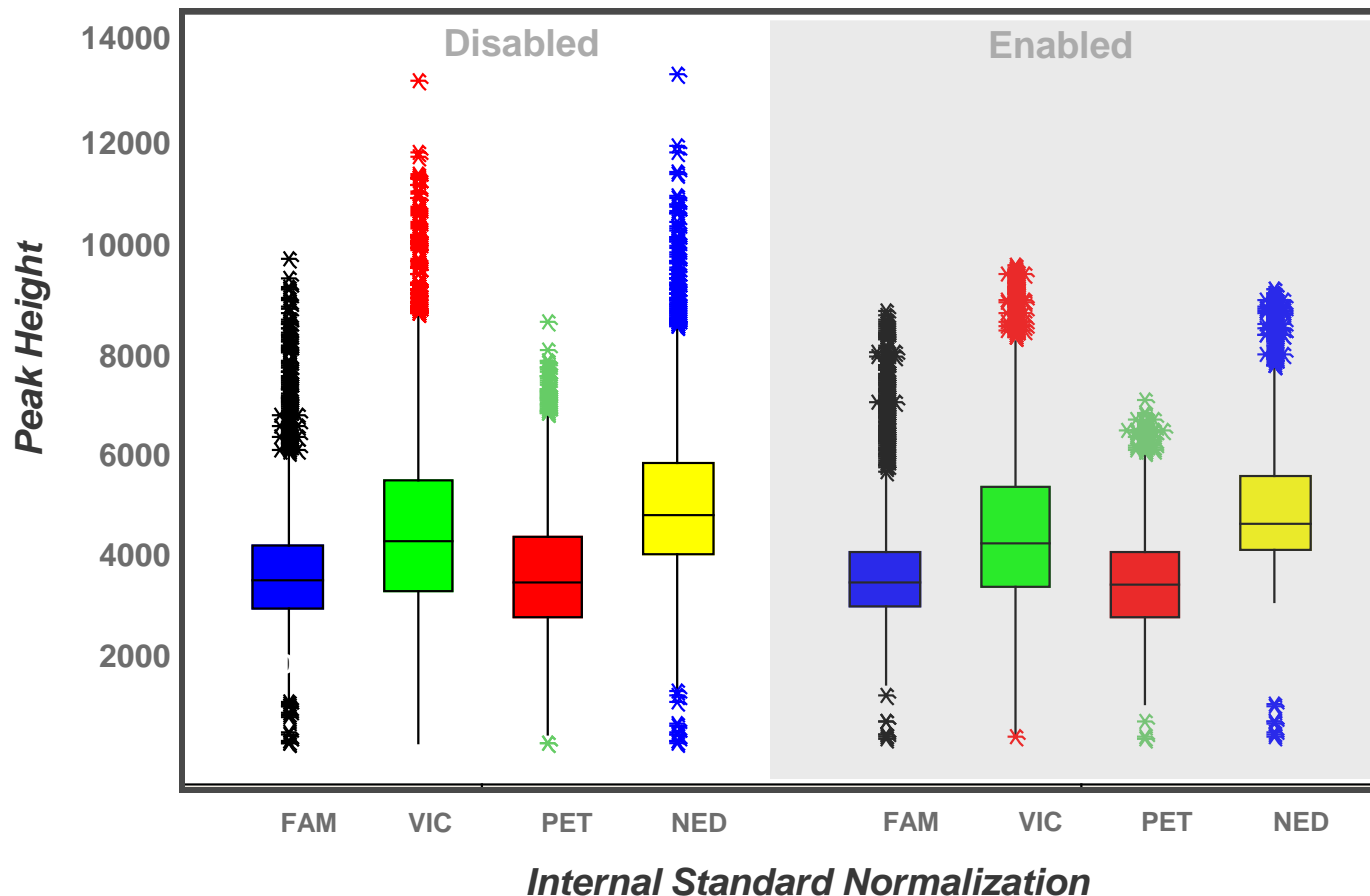
## Average Peak Height across a Range of DNA Input Amounts

### AmpF $\ell$ STR® MiniFiler™ PCR Amplification Kit



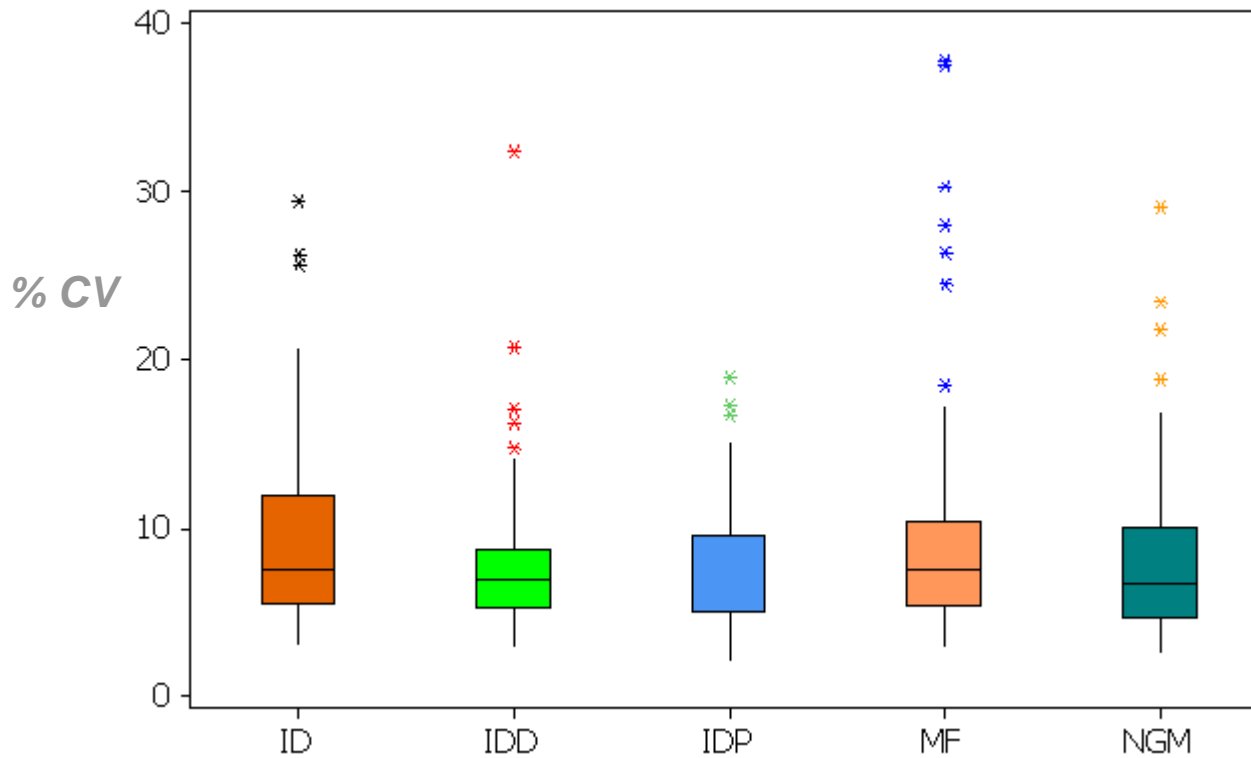
# 3500 Sensitivity Study:

## Average Peak Height by Dye for 1ng DNA Input AmpF lSTR® Identifiler® PCR Amplification Kit





# GS600 v2.0 Peak Height Consistency Study: %CV for 5 Different AmpF $\ell$ STR® Kits



GS600 Peak Height Consistency - 5 Different AmpF $\ell$ STR® Kits - 3 Lots of GS600v2



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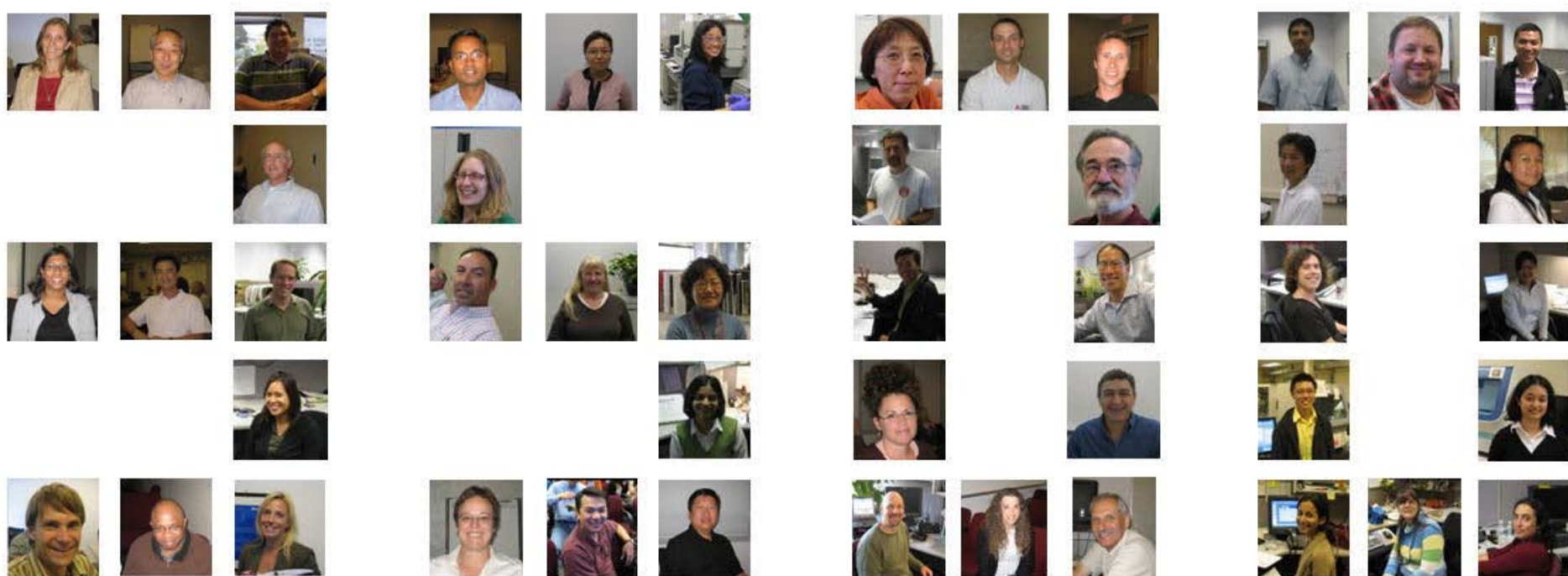
# Product Information and Availability

## 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](http://www.appliedbiosystems.com/3500HID)**



# 3500 Core Development Team



# Legal

- **Research Use Only**
- The purchase of this product conveys to the purchaser the limited, non-transferable right to use the purchased amount of the product only to perform internal research for the sole benefit of the purchaser. No right to resell this product or any of its components is conveyed expressly, by implication, or by estoppel. This product is for internal research purposes only and is not for use in commercial applications of any kind, including, without limitation, quality control and commercial services such as reporting the results of purchaser's activities for a fee or other form of consideration. For information on obtaining additional rights, please contact [outlicensing@lifetech.com](mailto:outlicensing@lifetech.com) or Out Licensing, Life Technologies, 5791 Van Allen Way, Carlsbad, California 92008.



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# Thank you!

[www.appliedbiosystems.com/3500HID](http://www.appliedbiosystems.com/3500HID)