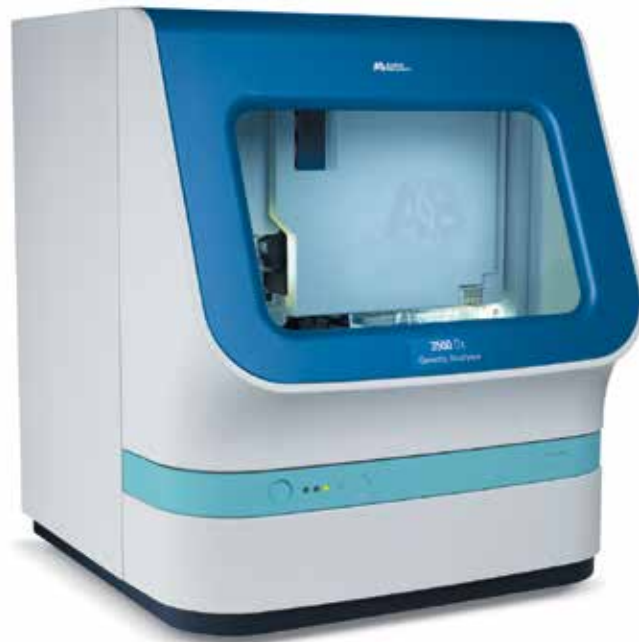


3500 Dx and 3500xL Dx Genetic Analyzers CS2

Key features supporting *in vitro* diagnostic applications

- 8-capillary 3500 Dx System and 24-capillary 3500xL Dx System
- Single-line 505 nm, solid-state long-life laser—utilizes a standard power supply; requires no heat removal
- Powerful, integrated data collection and primary analysis software provide real-time assessment of data quality
- Radio frequency identification (RFID) technology tracks key consumables data and records administrative information
- Simple setup, operation, and maintenance—easy to run and easy to own



Overview

Proven through decades of results—including sequencing of the first human genome—Applied Biosystems™ genetic analyzers are trusted for Sanger sequencing. Specifically designed for regulated and clinical environments, the 8-capillary 3500 Dx and 24-capillary 3500xL Dx Genetic Analyzers help you set the standard for Sanger sequencing in the molecular diagnostic laboratory.

The Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers CS2 with 3500 Dx Series Software 2011 (v1) are *in vitro* diagnostic devices intended for the sequencing (detection and identification) of fluorescently labeled DNA by capillary electrophoresis.

This capability is demonstrated by using the 3500 Dx or 3500xL Dx System and the associated IVD-labeled SeCore™ HLA typing kits along with uTYPE™ Dx Sequencing

Analysis Software, and verified by generating sequencing information from the primary control material, the Applied Biosystems™ BigDye™ Terminator Sequencing Standard v1.1. Each tube of the sequencing standard contains a PCR-amplified sequencing reaction with a sample of a known sequence, the *hsp69* gene of the fugu genome, contained within an artificial plasmid template.

IVD-labeled system components*

The Applied Biosystems 3500 Dx and 3500xL Dx Genetic Analyzers CS2 are supplied as follows:

- 8-capillary (3500 Dx instrument) or 24-capillary (3500xL Dx instrument) array
- DNA sequencing reagents and consumables, along with Applied Biosystems™ POP-6™ Polymer
- Integrated software for instrument control, data collection, quality control, and auto-analysis of sample files for basecalling

Note: Also included is a Dell™ computer workstation with a flat-screen monitor.

IVD-labeled system consumables*

The following consumables are available for use on the 3500 Dx Series instruments:

- **Capillary arrays:**
The internally uncoated capillaries are supplied in assemblies of 8 or 24 capillaries per array, with a built-in frame for easy installation. The 50 cm array is optimized for sequencing applications when used with POP-6 Polymer and specific run modules. The capillary arrays are specified for 160 injections.

- **POP-6 Performance-Optimized Polymer:** Dx POP-6 Polymer is packaged in ready-to-use, load-and-run pouches. POP-6 Polymer is available in two sizes, for 384 samples (a maximum of 60 injections for use with the 3500 Dx instrument or 20 injections for use with the 3500xL Dx instrument), and for 960 samples (a maximum of 120 injections for use with the 3500 Dx instrument or 50 injections for use with the 3500xL Dx instrument).

The pouch has adequate polymer to support the stated number of samples or injections, plus additional volume for initial setup and installation operations.

- **Buffers and conditioning reagent consumables:** The cathode buffer, anode buffer, and conditioning reagent for the 3500 Dx Series instruments are also designed for ready-to-use, load-and-run installation. Consumables containers should be disposed of when the maximum number of samples have been processed.

- **Cathode Buffer Container (CBC):**
Prefilled container with 1X buffer to support all electrophoresis applications.

The container has two separate compartments: the left side contains the cathode buffer for electrophoresis, and the right side contains spent polymer waste from the capillary wash between injections. The CBC is specified to be used on the instrument system for up to 7 days after first installation (to a maximum of 120 injections on the 3500 Dx instrument, or 50 injections on the 3500xL Dx instrument, whichever comes first).

- **Anode Buffer Container (ABC):**
Prefilled container with 1X buffer to maintain a source of ions and the correct pH for electrophoresis. The ABC is specified to be used in the system for up to 7 days after first installation (to a maximum of 120 injections on the 3500 Dx instrument, or 50 injections on the 3500xL Dx instrument, whichever comes first).
- **Conditioning pouch:**
Prefilled pouch with a conditioning reagent used for priming the polymer pump, and washing the pump between polymer type changes and during instrument shutdown. The pouch has a sufficient volume for one-time use.

Table 1. Sequencing throughput and performance specifications using the diagnostic mode¹.

Run module (diagnostic mode)	Throughput ²			Configuration		Performance	
	Average run time (minutes)	Average throughput, 3500xL Dx (samples/day)	Average throughput, 3500 Dx (samples/day)	Array size (cm)	Polymer type	Median bases collected in 90% of samples	KB QV20 CRL ³ in 90% of samples
RapidSeq50_POP6	≤65	≥504	≥168	50	POP-6	≥450	≥450
FastSeq50_POP6	≤90	≥368	≥122	50	POP-6	≥600	≥600



8- or 24-capillary assembly

505 nm solid-state laser

Polymer pump

Performance-optimized polymer (POP) pouch

Anode Buffer Container (ABC)

96-well plates

Cathode Buffer Container (CBC)

Radio frequency identification (RFID) labeling

The 3500 Dx Series instruments incorporate RFID labels on all capillary arrays, polymer pouches, buffer containers, and conditioning pouches. These labels allow for tracking and reporting of consumables usage, lot and part numbers, expiration dates, and on-instrument lifetime. The tracked consumables data are stored and retrievable from the 3500 Dx Data Collection Software.

Validated reagents and accessories*

The IVD-labeled reagents available for the 3500 Dx Series Genetic Analyzers include:

- BigDye Terminator Sequencing Standard v1.1
- Applied Biosystems™ Hi-Di™ Formamide, 5 mL tubes

The IVD-labeled accessories available for the 3500 Dx Series Genetic Analyzers include:

- 96-well retainer and base, standard set
- 96-well septa plate

3500 Dx Series operating specifications

Laser

Long-life, single-line 505 nm, solid-state laser excitation source

Electrophoresis voltage

Up to 20 kV

Oven temperature

Active temperature control from 18°C to 70°C

Minimum computer requirements

Hardware: OptiPlex™ XE Duo
3 GHz processor

Operating system: Windows™ 7

Installed RAM: 4 GB

Hard drive: >500 GB 7200 RPM SATA
3.0 GB/s

Operating environment

Temperature: 15°C–30°C (room temperature should not fluctuate more than $\pm 2^\circ\text{C}$ during an instrument run)

Humidity: 20%–80% (noncondensing)

Main power voltage

100–240 V \pm 10%

50–60 Hz

Current

Maximum: 15 A

Maximum power dissipation

417 VA, 371 W (approximate, not including computer and monitor)

Dimensions of electrophoresis unit

Width (closed-door): 61 cm

Width (open-door): 122 cm

Depth: 61 cm

Height: 72 cm

Weight: 82 kg (approximate)

Service and warranty

1-year limited warranty on parts and labor

Service installation

Basic instrument training available

System software*

The Applied Biosystems 3500 Dx and 3500xL Dx Genetic Analyzers CS2 include Data Collection Software with a simple user interface and clean design for easy display of consumables and array usage information, quick-start functionality, system maintenance reminders, and several other convenient features. Basecalling or primary analysis functionalities are performed within the primary Data Collection Software for real-time data evaluation. Also included are security, audit, and electronic signature features.

Ordering information

Product	Cat. No.
3500 Dx Series Genetic Analyzers	
3500 Dx Genetic Analyzer CS2 (8-capillary)	4461450
3500xL Dx Genetic Analyzer CS2 (24-capillary)	4461447
IVD-labeled system consumables, reagents, and accessories	
3500 Dx 8-Capillary Array (50 cm)	4404684
3500xL Dx 24-Capillary Array (50 cm)	4404688
POP-6 Polymer, 3500 Dx Series (960 samples)	4393711
POP-6 Polymer, 3500 Dx Series (384 samples)	4393716
Anode Buffer Container (ABC), 3500 Dx Series	4393925
Cathode Buffer Container (CBC), 3500 Dx Series	4408258
Septa Cathode Buffer Container, 3500 Dx Series	4410716
Conditioning Reagent, 3500 Dx Series	4409543
Hi-Di Formamide, 5 mL bottle	4404307
BigDye Terminator Sequencing Standard v1.1, 3500 Dx Series	4462113
96-Well Septa, 3500 Dx Series	4410700
96-Well Retainer and Base Set, 3500 Dx Series	4410227

1. The specifications are reported using Sequencing Install Standard—BigDye Terminator Sequencing Standard v1.1.

2. Throughput (samples/day) is determined by the total number of samples that can be run in 23 hours (allows time for sample preparation, instrument maintenance, and warm-up).

3. QV20 CRL is defined as the longest uninterrupted segment of bases with an average QV \geq 20, calculated over a sliding window of 21 base pairs.

* Only system components, consumables, software, reagents, and accessories that have been verified for use with the 3500 Dx Series systems and marked for *In Vitro* Diagnostic Use should be used when operating the 3500 Dx Series instrument in IVD Mode.

Find out more at thermofisher.com/3500-dxCS2

ThermoFisher
SCIENTIFIC

For *In Vitro* Diagnostic Use. The 3500 Dx and 3500xL Dx Genetic Analyzers CS2 and accessories meet the requirements for IVD instrumentation in the United States and Canada. © 2015 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. Dell and OptiPlex are trademarks of Dell, Inc. Windows is a trademark of Microsoft Corporation.

CO016137 0715