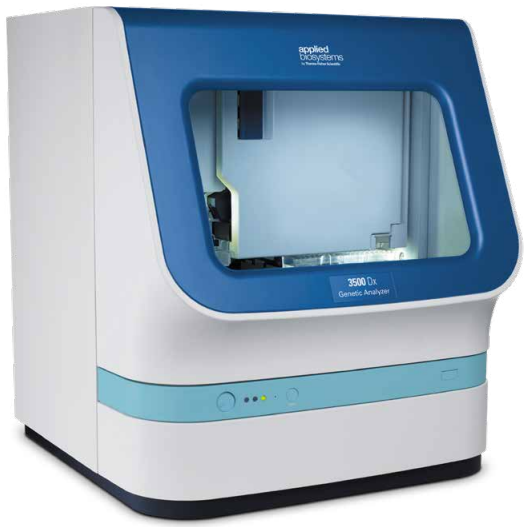
3500 Dx Genetic Analyzer
3500xL Dx Genetic Analyzer

Key features supporting *in vitro* diagnostic (IVD) applications

- 8-capillary Applied Biosystems™ 3500 Dx Genetic Analyzer and 24-capillary Applied Biosystems™ 3500xL Dx Genetic Analyzer
- Long-life, 505 nm solid-state laser—utilizes a standard power supply; requires no heat removal
- Flexible, dual-mode (diagnostic and test), integrated Applied Biosystems™ 3500 Dx Series Data Collection Software 3 IVD v3.0.1 supports both sequencing and fragment analysis, and provides real-time assessment of data quality
- Radio-frequency identification (RFID) technology tracks data for key consumables 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 Genetic Analyzer and 24-capillary 3500xL Dx Genetic Analyzer help you set the standard for Sanger sequencing and fragment analysis in the molecular diagnostic laboratory.

Intended use

The 3500 Dx Genetic Analyzer and the 3500xL Dx Genetic Analyzer are *in vitro* diagnostic devices intended for detection of fluorescently labeled human genomic deoxyribonucleic acid (DNA) nucleotides by capillary electrophoresis.

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IVD system components*

The 3500 Dx Genetic Analyzer and 3500xL Dx Genetic Analyzer are supplied as follows:

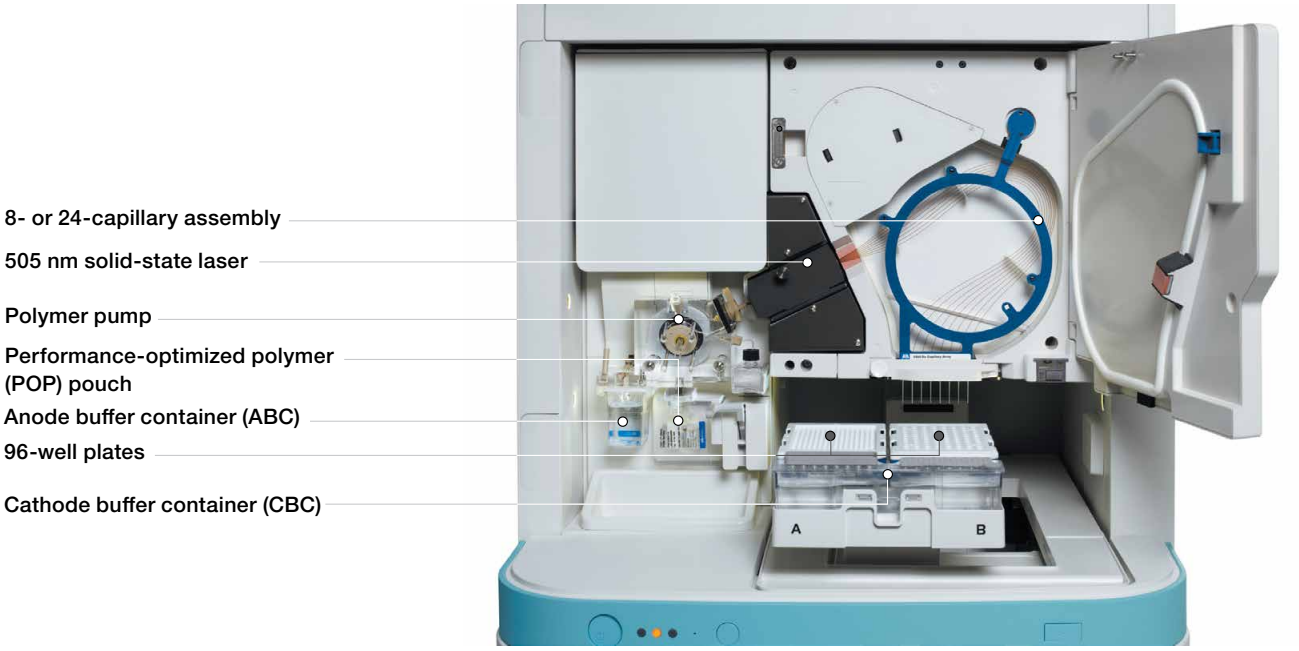
- 8-capillary (3500 Dx Genetic Analyzer) or 24-capillary (3500xL Dx Genetic Analyzer) array
- DNA sequencing and fragment analysis reagents and consumables
- Integrated, dual-mode software for instrument control, data collection, quality control, and auto-analysis of sample files for basecalling

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

IVD system consumables*

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

- **Capillary arrays:** The internally uncoated capillaries are supplied in assemblies of 8 or 24 capillaries per array, with a 50 cm built-in frame for easy installation. The capillary arrays are specified for 160 injections.
- **Performance-optimized polymer (POP) pouches:** Applied Biosystems™ POP-6™ Polymer for sequencing and POP-7™ Polymer for fragment analysis are packaged in ready-to-use, load-and-run pouches. Each polymer is available in 2 sizes: 384 samples (a maximum of 60 injections for use with the 3500 Dx Genetic Analyzer or 20 injections for use with the 3500xL Dx Genetic Analyzer), and 960 samples (a maximum of 120 injections for use with the 3500 Dx Genetic Analyzer or 50 injections for use with the 3500xL Dx Genetic Analyzer). The pouches have adequate polymer to support the stated number of samples or injections, plus additional volume for initial setup and installation operations.
- **Buffer and conditioning reagent consumables:** The cathode buffer, anode buffer, and conditioning reagent for the 3500 Dx Series Genetic Analyzers 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 or to a maximum of 120 injections on the 3500 Dx Genetic Analyzer or 50 injections on the 3500xL Dx Genetic Analyzer, 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 or to a maximum of 120 injections on the 3500 Dx Genetic Analyzer or 50 injections on the 3500xL Dx Genetic Analyzer, whichever comes first.
  - **Conditioning reagent 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.



RFID labeling

The 3500 Dx Series Genetic Analyzers 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 Series Data Collection Software 3 IVD v3.0.1.

System software*

The 3500 Dx Genetic Analyzer and 3500xL Dx Genetic Analyzer include 3500 Dx Series Data Collection Software 3 IVD v3.0.1 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.

3500 Dx Series instrument 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: Dell™ OptiPlex™ XE3 Hex Core, up to 4.6 GHz Turbo processor
Operating system: Windows™ 10 IoT 64-bit
Installed RAM: 16 GB
Hard drive: 2 x 500 GB SATA 3.0 Gb/s
Operating environment
Temperature: 15–30°C (room temperature should not fluctuate more than ±2°C during an instrument run)
Humidity: 20–80% (noncondensing)

Main power voltage
100–240 V ± 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

applied
biosystems

Ordering information

Product	Cat. No.
IVD-labeled instruments: include 3500 Dx Series Data Collection Software 3 IVD v3.0.1 for fragment analysis and sequencing	
3500xL Dx Genetic Analyzer (8-capillary)	A27772
3500xL Dx Genetic Analyzer (24-capillary)	A27856
IVD-labeled reagents, consumables, and accessories for 3500 Dx Series Genetic Analyzers*	
POP-6 Polymer, for sequencing (960 samples)	4393711
POP-6 Polymer, for sequencing (384 samples)	4393716
POP-7 Polymer, for fragment analysis (960 samples)	4393713
POP-7 Polymer, for fragment analysis (384 samples)	4393709
Anode Buffer Container	4393925
Cathode Buffer Container	4408258
Conditioning Reagent	4409543
Hi-Di Formamide, 3500 Dx Series	4404307
Hi-Di Formamide, 3500 Dx Series, 4 x 5 mL	4440752
Sequencing Standard v1.1	4462113
Sequencing Standard v3.1	4404310
DS-33 GeneScan Install Kit Dx with GeneScan 600 LIZ Size Standard v2.0 Dx	A25793
DS-33 Matrix Standard Kit (Dye Set G5)	A25775
GeneScan 600 LIZ Size Standard v2.0	A25794
8-Capillary Array, 50 cm	4404684
24-Capillary Array, 50 cm	4404688
Septa Cathode Buffer Container	4410716
Retainer and Base Set (Standard), 96-Well	4410227
Retainer and Base Set (Fast), 96-Well	4410229
Septa, 96-Well	4410700
Polymer Pouch Cap	4462785
Pump Cleaning Kit	4461875

* 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.

CE IVD

Find out more at **thermofisher.com/3500dx**

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