

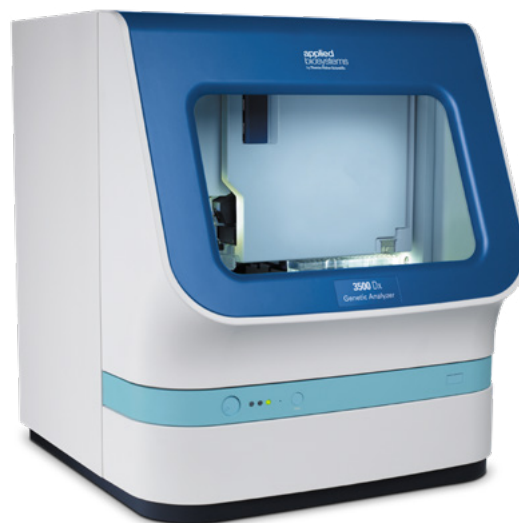
3500 Dx Genetic Analyzer

3500xL Dx Genetic Analyzer

Only available in the US.

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 v3.2 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.

The 3500 Dx Genetic Analyzer and the 3500xL Dx Genetic Analyzer are indicated for sequencing and fragment analysis using FDA-cleared or approved assays.

The 3500 Dx Genetic Analyzer and the 3500xL Dx Genetic Analyzer can be used with the Applied Biosystems™ SeCore™ HLA typing kits along with the uTYPE™ Dx Sequencing Analysis Software and the AmplideX™ Fragile X Dx & Carrier Screen Kit.

IVD-labeled 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-labeled 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.

Table 1. Sequencing throughput and specifications using the diagnostic mode.*

| Run module (diagnostic mode) | Throughput** | | | Configuration | | Performance | |
|-----------------------------------|------------------------|---|---|-----------------|--------------|--|-----------------------------|
| | Average run time (min) | Average throughput, 3500xL Dx (samples/day) | Average throughput, 3500 Dx (samples/day) | Array size (cm) | Polymer type | Median bases collected in 90% of samples | QV20 CRL† in 90% of samples |
| RapidSeq50_BDTv1.1_HLA_Assay-POP6 | ≤65 | ≥504 | ≥168 | 50 | POP-6 | ≥450 | ≥450 |
| FastSeq50_BDTv1.1_HLA_Assay-POP6 | ≤90 | ≥368 | ≥122 | 50 | POP-6 | ≥600 | ≥600 |

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

** 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).

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

- 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)



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 v3.2.

System software*

The 3500 Dx Genetic Analyzer and 3500xL Dx Genetic Analyzer include 3500 Dx Series Data Collection Software 3 IVD v3.2 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 | Main power voltage | 100–240 V ± 10% 50–60 Hz |
| Electrophoresis voltage | Up to 20 kV | Current | Maximum: 15 A |
| Oven temperature | Active temperature control from 18°C to 70°C | Maximum power dissipation | 417 VA, 371 W (approximate, not including computer and monitor) |
| Minimum computer requirements | Hardware: Dell™ OptiPlex™ XE2 Quad Core, 3.10 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 | Dimensions of electrophoresis unit | Width (closed-door): 61 cm Width (open-door): 122 cm Depth: 61 cm Height: 72 cm Weight: 82 kg (approximate) |
| Operating environment | Temperature: 15–30°C (room temperature should not fluctuate more than ±2°C during an instrument run) Humidity: 20–80% (noncondensing) | Service and warranty | 1-year limited warranty on parts and labor Service installation Basic instrument training available |

Ordering information

| Product | Cat. No. |
|--|----------|
| IVD-labeled instruments: | |
| include 3500 Dx Series Data Collection Software 3 IVD v3.2 for fragment analysis and sequencing | |
| Applied Biosystems 3500 Dx Genetic Analyzer (8-capillary) | A46344 |
| Applied Biosystems 3500xL Dx Genetic Analyzer (24-capillary) | A46345 |
| 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 | 4404307 |
| Sequencing Standard v1.1 | 4462113 |
| DS-30 Matrix Standard Kit (Dye Set D) | A35945 |
| DS-33 GeneScan Install Kit with GeneScan 600 LIZ Size Standard v2.0 | 4482975 |
| 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 |
| MicroAmp Fast Optical 96-Well GPLE Reaction Plates | 4481190 |
| MicroAmp EnduraPlate Optical 96-Well Clear GPLE Reaction Plates with Barcode | 4483348 |
| 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.



Find out more at thermofisher.com/3500dx

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