

3500 Dx and 3500xL Dx Genetic Analyzers

Flexibility for clinical research applications with the Research Use Only (RUO) Mode

Key features supporting RUO applications

- Advanced thermal system design improves temperature control for demanding DNA fragment analysis applications
- Superior signal uniformity in fragment sizing applications from instrument to instrument, run to run, and capillary to capillary
- Exceptional application flexibility—one array and one polymer are used for most applications
- No consumable-based instrument hard stops, giving you control of how much and how long consumables are utilized

3500 Dx Series system specifications for RUO applications

Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers can perform a number of sequencing and high-resolution fragment sizing applications for research use, including but not limited to STR/microsatellite analysis, loss of heterozygosity (LOH), and SNP confirmation and screening, as well as *de novo* sequencing and resequencing (mutation profiling).

A full range of applications may be run using a single polymer (Applied Biosystems™ POP-7™ Polymer) and the 50 cm capillary array. For even greater application versatility, Applied Biosystems™ POP-4™ and POP-6™ Polymers and the 36 cm capillary array are also available.

Secondary analysis software for RUO applications

- Applied Biosystems™ Sequencing Analysis Software with KB™ Basecaller for sequence basecalling, editing, re-basecalling, reporting, and printing
- Applied Biosystems™ Variant Reporter™ Software for mutation detection, SNP discovery, comparative sequencing, resequencing, validation, and sequence confirmation
- Applied Biosystems™ SeqScape™ Software for resequencing applications with library identification
- Applied Biosystems™ GeneMapper™ Software for microsatellite, LOH, SNP, and t-RFLP analyses
- Applied Biosystems™ GeneMapper™ ID-X Software for analysis of human identification data using AmpF ℓ STR™ kits
- Applied Biosystems™ MicroSEQ™ ID Analysis Software for microbial sequence typing using MicroSEQ™ kits

Product	Cat. No.
Anode Buffer Container, CE-IVD	4393925
Capillary Array, 8-capillary, 36 cm, CE-IVD	4404682
Capillary Array, 24-capillary, 36 cm, CE-IVD	4404686
Capillary Array, 8-capillary, 50 cm, CE-IVD	4404684
Capillary Array, 24-capillary, 50 cm, CE-IVD	4404688
Cathode Buffer Container, CE-IVD	4408258
Conditioning Reagent, CE-IVD	4409543
POP-6 Polymer (960 samples), CE-IVD	4393711
POP-6 Polymer (384 samples), CE-IVD	4393716
POP-7 Polymer (960 samples), CE-IVD	4393713
POP-7 Polymer (384 samples), CE-IVD	4393709
POP-4 Polymer (960 samples)	4393710
POP-4 Polymer (384 samples)	4393715
Hi-Di Formamide (4 x 5 mL), CE-IVD	4404307
BigDye Terminator Sequencing Standard v1.1, CE-IVD	4462113
BigDye Terminator Sequencing Standard v3.1, CE-IVD	4404310
BigDye Terminator v3.1 Matrix Standards Kit, 3500/3500xL	4336974
BigDye Terminator v1.1 Matrix Standards Kit, 31xx and 3500	4336824
DS-33 Matrix Standard Kit (5-dye), CE-IVD	A25775
DS-33 GeneScan Install Standards, CE-IVD	A25793
DS-02 Matrix Standard Kit (5-dye, E5 dye set)	4323014
DS-32 Matrix Standard Kit (4-dye)	4345831
DS-36 Matrix Standard Kit (6-dye)	4425042
GeneScan 120 LIZ Size Standard	4322362
GeneScan 500 ROX Size Standard	401734
GeneScan 600 LIZ Size Standard v2.0, CE-IVD	A25794
GeneScan 1200 LIZ Size Standard	4379950



Table 1. Sequencing modules for RUO applications.

Run modules	Throughput ¹			Configuration		Performance		
	Average run time (minutes)	Average throughput, 3500xL Dx (samples/day)	Average throughput, 3500 Dx (samples/day)	Array separation distance (cm)	Polymer type	Resolution range in ≥90% of samples	Bases collected in 90% of samples	QV20 CRL ² in ≥90% of samples
ShortReadSeq50_POP7 ³	≤30	≥1,104	≥368	50	POP-7	40–400	≥325	≥300
RapidSeq50_POP7	≤40	≥840	≥280	50	POP-7	40–550	≥600	≥500
FastSeq50_POP7	≤65	≥504	≥168	50	POP-7	40–600	≥750	≥700
StdSeq50_POP7	≤125	≥264	≥88	50	POP-7	40–700	≥1,000	≥850
BDxShortReadSeq50_POP7	≤30	≥1,104	≥368	50	POP-7	40–400	≥325	≥300
BDxRapidSeq50_POP7	≤40	≥840	≥280	50	POP-7	40–550	≥600	≥500
BDxFastSeq50_POP7	≤65	≥504	≥168	50	POP-7	40–600	≥750	≥700
BDxStdSeq50_POP7	≤125	≥264	≥88	50	POP-7	40–700	≥1,000	≥850
RapidSeq50_POP6	≤65	≥504	≥168	50	POP-6	20–500	≥450	≥450
FastSeq50_POP6	≤90	≥368	≥122	50	POP-6	20–550	≥600	≥600
StdSeq50_POP6	≤135	≥240	≥80	50	POP-6	20–600	≥700	≥600
BDxRapidSeq50_POP6	≤65	≥504	≥168	50	POP-6	20–500	≥450	≥450
BDxFastSeq50_POP6	≤90	≥368	≥122	50	POP-6	20–550	≥600	≥600
BDxStdSeq50_POP6	≤140	≥240	≥80	50	POP-6	20–600	≥700	≥600
MicroSEQ ID 50_POP6	≤135	≥240	≥80	50	POP-6	20–600	≥700	≥600
FastMicroSEQ ID 50_POP6	≤105	≥312	≥104	50	POP-6	20–500	≥450	≥425

The specifications are reported using the BigDye Terminator v3.1 Sequencing Standard. BDx classified run modules are optimized with the 3500 Dx Series systems to obtain more usable data when sequencing reactions are purified using the BigDye XTerminator Purification Kit.

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).
2. QV20 CRL is defined as the longest uninterrupted segment of bases with an average of QV ≥20, calculated over a sliding window of 21 base pairs.
3. The fast ShortReadSeq module collects 300 bp in 30 minutes for operations requiring short verification of sequence content (e.g., clone QC verification).

Table 2. Fragment analysis modules for RUO applications.

Module name	Throughput ¹			Configuration		Performance							
	Average run time (minutes)	Average throughput, 3500xL Dx (samples/day)	Average throughput, 3500 Dx (samples/day)	Array length (cm)	Polymer type	General		Sizing precision ³ of 100% of alleles in ≥90% of samples			Multirun sizing ⁴ of 100% of alleles in ≥90% of samples		
						Resolution range ² in ≥90% of samples	Largest fragment collected in ≥90% of samples	50–400 bp	401–600 bp	601–1,200 bp	50–400 bp	401–600 bp	601–1,200 bp
FragmentAnalysis36_POP7	≤30	≥1,104	≥368	36	POP-7	60–400	>420	<0.15	NA	NA	<1 bp	NA	NA
Fragment Analysis36_POP4	≤35	≥936	≥312	36	POP-4	60–400	>420	<0.15	NA	NA	<1 bp	NA	NA
FragAnalysis50_POP7	40	≥840	≥280	50	POP-7	40–520	≥600	<0.15	<0.30	NA	<1 bp	<2 bp	NA
FragAnalysis50_POP6	100	≥336	≥112	50	POP-6	20–550	≥600	<0.15	<0.30	NA	<1 bp	<2 bp	NA
LongFragAnalysis50_POP7	125	≥264	≥88	50	POP-7	40–700	≥1,200	<0.15	<0.30	<0.45	<1 bp	<2 bp	<3 bp
HID36_POP4	35	≥936	≥312	36	POP-4	60–400	≥420	<0.15	NA	NA	<1 bp	NA	N/A
SNaPshot50_POP7	30	≥1,104	≥376	50	POP-7	40–120	≥120	<0.50	NA	NA	<1 bp	NA	NA



NA = specification not applicable for this parameter.

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).
2. Resolution range is defined as the range of bases over which the peak spacing interval divided by the peak width at half peak height is greater than 1.
3. Sizing precision is the standard deviation of sizes for a given allele size across all capillaries in the same run.
4. Multirun sizing is a measure of the precision of the 3500 Series across multiple runs. For example, it would be expected that a 200 bp allele across 3 runs would have an average deviation of <1 bp in 90% of all samples.

Find out more at thermofisher.com/3500dx

Certificate of Analysis

POP-7 Polymer (960 Samples) 3500 Dx Series

REF 4393713
LOT 2411153
 2024-12-02
 2025-04-28

TEST	RESULT
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VISUAL INSPECTION
NOTE The polymer is particulate free at room temperature, but upon refrigeration, urea may precipitate out of solution.

Clear, particulate free, viscous solution at room temperature	Pass
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FLUORESCENCE TEST
The ratio of the background fluorescence intensity of the polymer to that of water is measured for each bulk lot to ensure conformance to manufacturing specifications

Fluorescence Ratio	Pass
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RESOLUTION TEST
Resolution is evaluated by measuring separations and widths of peaks in a multi-fragment DNA standard on a multi-capillary Genetic Analyzer

Resolution	Pass
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Manufactured in compliance with our ISO 13485 certified quality management system and 21 CFR 820 quality system regulations.

Made in USA

Life Technologies Holdings Pte Ltd
Block 33, Marsiling Industrial Estate Road 3 #07 - 06
Singapore 739256
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For inquiries, contact us at cofarequests@thermofisher.com



Kim Kheav
Quality Assurance
Issued 03DEC2024

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

MarqMetrix
2157 North Northlake Way
Suite 240
Seattle
Washington
98103
USA

Holds Certificate No:

FM 705363

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The Design, Development, Manufacture and test of Raman spectroscopy systems and accessories for commercial distribution.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2019-05-07

Effective Date: 2022-05-07

Latest Revision Date: 2022-04-01

Expiry Date: 2025-05-06

Page: 1 of 1



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