SPECIFICATION SHEET

NextSeq™ 550Dx Instrument

FDA-regulated, CE-marked, mid-throughput sequencing platform

- Support clinical and research demands with flexible read lengths and multiple output configurations
- Accelerate research studies with fast turnaround times and user-friendly data analysis
- Enable IVDR-compliant secondary analysis with optional paired, on-premises DRAGEN™ server and license (available in select countries)
- Access a growing pipeline of laboratory developed tests backed by Illumina science and expertise

illumina®

For *In Vitro* Diagnostic Use. Not available in all regions and countries.

Introduction

The NextSeq 550Dx instrument is a mid-throughput FDA-regulated, CE-marked platform designed to deliver the power of next-generation sequencing (NGS) to the clinical laboratory (Figure 1). Featuring dual boot functionality, the NextSeq 550Dx Instrument includes a Diagnostic Mode* and a Research Mode. These dual modes provide the flexibility to perform *in vitro* diagnostic (IVD) testing, laboratory developed tests (LDTs), and clinical research on a single instrument.† The NextSeq 550Dx Instrument offers a validated mid-throughput platform and provides access to an ever-expanding pipeline of clinical applications in the fields of oncology, reproductive health, and more.

The NextSeq 550Dx Instrument can generate up to 120 Gb of data in less than two days, while delivering the consistency required of a regulated platform, and includes fully integrated, onboard instrument and analysis software. In addition, running the instrument in Research Mode supports all currently available research applications, including exome sequencing, transcriptome profiling, customer-designed targeted panels, and microarray scanning. An optional, paired Illumina DRAGEN Server for NextSeq 550Dx Instruments‡ and DRAGEN license enables IVDR-compliant, accurate, and efficient secondary data analysis. With the NextSeq 550Dx Instrument, clinical laboratories can run in Diagnostic Mode for IVD testing or run in Research Mode on a single platform, accelerating clinical studies without sacrificing the speed and power of a mid-throughput sequencing system.

Figure 1: The NextSeq 550Dx Instrument—Leveraging SBS chemistry and user-friendly, regulated workflows, the NextSeq 550Dx Instrument delivers high-quality results for clinical and research applications.

Illumina SBS chemistry delivers exceptional accuracy

The NextSeq 550Dx Instrument provides exceptional accuracy for clinical tests and research applications. At the core of the instrument is proven Illumina sequencing by synthesis (SBS) chemistry. This reversible, terminator–based method detects single bases as they are incorporated into growing DNA strands and enables parallel sequencing of millions of DNA fragments. Illumina SBS chemistry employs natural competition among all four labeled nucleotides, which reduces incorporation bias and allows more robust sequencing of repetitive regions and homopolymers.[1]

Compared to capillary electrophoresis (CE)-based Sanger sequencing, NGS can detect a broader range of DNA variants, including low-frequency variants and adjacent phased variants, with a faster time to result and fewer hands-on steps.[2,3] Furthermore, NextSeq sequencing reagents deliver improved signal intensities and a lower number of false positives and false negatives.[4]

* Runs performed in Diagnostic Mode are in compliance with global regulatory standards including FDA and IVDR regulations.

† Contact an Illumina representative for more information about IVD development partnerships.

‡ DRAGEN Server for NextSeq 550Dx Instruments is available in select countries.

Easy, three-step workflow

Assays run on the NextSeq 550Dx Instrument follow a simple, three-step process that includes library preparation, sequencing, and data analysis (Figure 2).

Library preparation

Library preparation begins with the addition of primers to genomic DNA (gDNA) samples, generating indexed libraries for simultaneous capture and amplification of hundreds of targeted regions. For a range of clinical applications, the Illumina DNA Prep with Enrichment Dx library preparation kit supports user-defined oligo panels. This fast, efficient library prep kit requires just 50 ng gDNA or formalin-fixed, paraffin-embedded (FFPE) tissue–derived DNA to produce high-quality sequencing libraries in less than one day.

Sequencing on the NextSeq 550Dx Instrument

With prefilled reagent cartridges, starting a run on a NextSeq 550Dx Instrument is as easy as thaw, load, and go, taking roughly 30 minutes of total hands-on time. The intuitive user interface allows researchers to perform various sequencing applications with minimal user training or instrument set-up time. Furthermore, the NextSeq 550Dx Instrument performs cluster generation and SBS sequencing on a single instrument and offers a simple transition to onboard or cloud-based data analysis. As with the NextSeq 550 System, the NextSeq 550Dx Instrument delivers high-quality data with over 75% of bases sequenced yielding a quality score of Q30 or higher (Table 1).

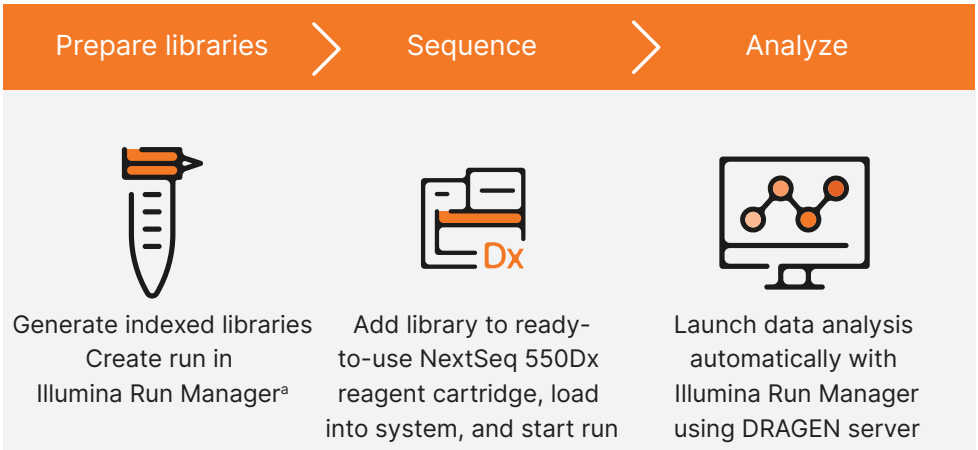

Figure 2: Three-step NextSeq 550Dx assay process—The NextSeq 550Dx Instrument is part of an integrated, three-step workflow. Detailed results reports are available with the Illumina DNA Prep with Enrichment Dx assay.

a. Illumina Run Manager is included with the purchase of a DRAGEN Server for NextSeq 550Dx Instruments.

Table 1: NextSeq 550Dx Instrument performance parameters—Diagnostic Mode[a,b]

Flow cell configuration	Read length	Output	Run time	Data quality[c]
High-Output flow cell	2 × 150 bp	90 Gb	< 35 hours	> 75% ≥ Q30

a. Libraries generated with the Illumina DNA Prep with Enrichment Dx library preparation kit.
b. For performance parameters in Research Mode, see the NextSeq 550 System specifications.
c. A quality score of Q30 corresponds to a 0.1% error rate in base calling.

The NextSeq 550Dx Instrument is easily configured, providing researchers with scalability to handle low- to high-throughput projects. In Research Mode, users can choose between two flow cell configurations (Mid-Output and High-Output), easily shifting from low-throughput to higher throughput as needed. With an expanding portfolio of IVD solutions, researchers can easily scale from the MiSeq™Dx Instrument to the NextSeq 550Dx Instrument.

Integrated system software

There are two software options for the NextSeq 550Dx Instrument: Illumina Run Manager (available with the Illumina DRAGEN Server for NextSeq 550Dx Instruments) or Local Run Manager.

Illumina Run Manager enables fast and highly accurate variant calling for diagnostic workflows using flexible Illumina DNA Prep with Enrichment Dx targeted library preparation. After a sequencing run is completed, Illumina Run Manager automatically starts data analysis using the application-specific analysis module selected during run setup. Illumina Run Manager employs various digital measures to ensure data security and privacy.

Accessing via instrument or remotely, users can plan and stagger multiple sequencing runs, track libraries with audit trails, and monitor run progress.

The advanced graphical user interface for Illumina Run Manager on the Illumina DRAGEN Server for NextSeq 550Dx Instruments enables user-friendly sequencing run setup and secondary data analysis. Additionally, the seamless integration with NextSeq 550Dx Instruments decreases the number of user interaction points and overall time to results (Figure 3, Table 2). This solution produces high-quality sequencing data and accurate detection of germline and somatic variants in diagnostic testing (Table 3).

Local Run Manager software supports planning sequencing runs, tracking libraries and runs with audit trails, and integration with onboard data analysis modules. While Local Run Manager runs on the instrument computer, users can monitor run progress and view analysis results from other computers connected to the same network. After a sequencing run is completed, Local Run Manager automatically starts data analysis to FASTQ using one of the application-specific analysis modules.

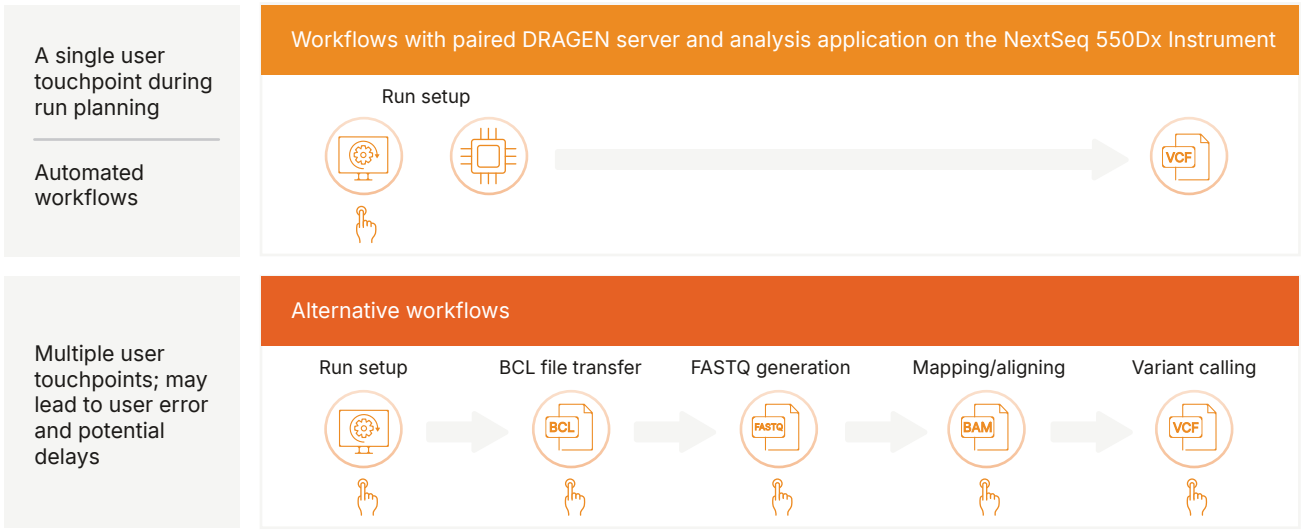

Figure 3: Single-touch workflow minimizes delays and user error—Workflows paired with DRAGEN Server for NextSeq 550Dx Instruments and analysis applications are automated to only require a single user touch point during run planning, compared to alternative workflows that require multiple touchpoints.

Table 2: Analysis time using DRAGEN for Illumina DNA Prep with Enrichment Dx app on Illumina DRAGEN Server for NextSeq 550Dx Instruments

	Analysis time[a]
DRAGEN for Illumina DNA Prep with Enrichment Dx app, compressed with ORA	5.82 min
DRAGEN for Illumina DNA Prep with Enrichment Dx app	4.98 min

a. Average run rime for gernline analysis of eight samples. Sequencing data was generated using a 42.5 Mb exome panel with a read depth of 200×.

Table 3: Comparison of germline variant calling accuracy in Diagnostic Mode[a]

Pipeline	SNV precision	SNV recall	SNV F1	Indel precision	Indel recall	Indel F1
BWA-GATK[b]	97.36%	93.95%	95.62%	65.29%	79.83%	71.78%
DRAGEN for Illumina DNA Prep with Enrichment Dx app	99.14%	95.85%	97.46%	90.12%	85.43%	87.70%

a. Variant calling accuracy comparison based on genomic DNA extracted from Coriell Institute reference samples. Variant calling accuracy was assessed with the Illumina Variant Calling Assessment Tool (VCAT 4.1.0) by comparing each sample to a truth set. SNV, single nucleotide variant; Indel, insertion–deletion variant.
b. For comparison, sequencing data were aligned with BWA-MEM (0.7.17), processed with SAMtools (1.15.1) and Picard (2.27.5), and analyzed with GATK 4.3.0.

Available IVD applications on Illumina Run Manager

In Diagnostic Mode, the NextSeq 550Dx Instrument supports applications performed with the Illumina DNA Prep with Enrichment Dx assay. With library preparation from FFPE-derived gDNA, the DRAGEN for Illumina DNA Prep with Enrichment Dx app can produce somatic variant calling with a limit of detection (LoD) of 0.05. The instrument supports up to 192 multiplexed samples on the NextSeq 550Dx Instrument.

Accurate, IVDR-compiant variant calling using the Illumna DRAGEN Server for NextSeq 550Dx Instruments application note

DRAGEN for Illumina DNA Prep with Enrichment Dx on NextSeq 550Dx Application User Guide

Array scanning in Research Mode

In Research Mode, the NextSeq 550Dx Instrument enables experimental flexibility by supporting both sequencing and microarray scanning of Illumina BeadChips.§ With microarray scanning, researchers have instant access to a highly complementary technology for measuring copy number variants and DNA methylation (Table 4). The integrated DNA-to-data workflows enable rapid sequencing of exomes, targeted sequencing panels, and transcriptomes with Mid-Output or High-Output run configurations. For more information about the broad range of sequencing and microarray applications supported by the NextSeq 550Dx Instrument in Research Mode, see the NextSeq 550 System Specification sheet.[5]

§ The NextSeq 550Dx Instrument in Research Mode supports microarray scanning of the Infinium™ MethylationEPIC BeadChip and Infinium HumanCytoSNP-850K BeadChip.

Table 4: NextSeq 550Dx Instrument array scanning parameters in Research Mode

BeadChip	Scan time per BeadChip	Scan time per sample
Infinium MethylationEPIC BeadChip	40 min	5 min
Infinium HumanCytoSNP-850K BeadChip	40 min	5 min

Summary

The NextSeq 550Dx Instrument brings mid-throughput NGS capabilities to the clinical lab for research and diagnostic applications. This transformative platform features an easy three-step workflow leveraging proven Illumina sequencing and an optional, paired DRAGEN server. The NextSeq 550Dx Instrument delivers access to rapid, regulated workflows for somatic and germline variant calling applications and a growing menu of NGS-based clinical assays. The NextSeq 550Dx Instrument offers customers the flexibility to deliver time-sensitive IVD data or pursue the latest questions in clinical research.

Learn more

NextSeq 550Dx Instrument

NextSeq 550Dx applications

Illumina DRAGEN Server for NextSeq 550Dx Instruments

Illumina DNA Prep with Enrichment Dx

Ordering information

Product	Catalog no.
NextSeq 550Dx Instrument	20005715
NextSeq 550Dx High-Output Reagent Kit v2.5 (75 cycles)[a]	20028870
NextSeq 550Dx High-Output Reagent Kit v2.5 (300 cycles)[a]	20028871
Illumina DRAGEN Server for NextSeq 550Dx[b]	20086130
Illumina DNA Prep with Enrichment Dx with UD Indexes Set A (16 samples)	20051354
Illumina DNA Prep with Enrichment Dx with UD Indexes Set A (96 samples)	20051352
Illumina DNA Prep with Enrichment Dx with UD Indexes Set B (16 samples)	20051355
Illumina DNA Prep with Enrichment Dx with UD Indexes Set B (96 samples)	20051353
NextSeq Air Filter	20063988

a. Class I sequencing consumables have single lot shipment, kit lot testing, advance change notification, and a Certificate of Analysis available for each lot. Reagents are developed under design control principles, manufactured under current good manufacturing practices (cGMP), and verified to ensure specification compliance.
b. DRAGEN Server for NextSeq 550Dx Instruments is available in select countries.

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References

1. Bentley DR, Balasubramanian S, Swerdlow HP, et al. Accurate whole human genome sequencing using reversible terminator chemistry. *Nature*. 2008;456(7218):53-59. doi:10.1038/nature07517
2. Shokralla S, Porter TM, Gibson JF, et al. Massively parallel multiplex DNA sequencing for specimen identification using an Illumina MiSeq platform. *Sci Rep*. 2015;5:9687. doi:10.1038/srep09687
3. Precone V, Monaco VD, Esposito MV. Cracking the Code of Human Diseases Using Next-Generation Sequencing: Applications, Challenges, and Perspectives. *Biomed Res Int*. 2015;161648. doi:10.1155/2015/161648
4. Eberle MA, Fritzilas E, Krusche P, et al. A reference data set of 5.4 million phased human variants validated by genetic inheritance from sequencing a three-generation 17-member pedigree. *Genome Res*. 2017;27:157-164. doi:10.1101/gr.210500.116
5. Illumina. NextSeq 550 System Specification Sheet. illumina.com/content/dam/illumina/gcs/assembled-assets/marketing-literature/nextseq-550-system-spec-sheet-m-gl-01298/nextseq-550-system-spec-sheet-m-gl-01298.pdf. Published 2017. Updated 2022. Accessed May 20, 2024.

NextSeq 550Dx Instrument specifications

Parameter	Specification
Instrument configuration	RFID tracking for concumables
Instrument control computer	Processor: Dual Intel Xeon E5-2648L v3 1.8 GHz CPU, Memory: 128 GB Hard Drive, Diagnostic Mode: 2 × 2 TB (RAID 1) Hard Drive, Research Mode: 2 × 2 TB (RAID 1) Operating System: Windows 10
Operating environment	Temperature: 19°C to 25°C (22°C ± 3°C) Humidity: Noncondensing 20%–80% relative humidity Altitude: 0-2000 m (6500 ft) Ventilation: Up to 2048 BTU/hr @ 600 W For Indoor Use Only
Light emitting diode (LED)	Green 510-525 nm, Red 645-655 nm; Laser diode: 780 nm, Class IIIb
Dimensions	W × D × H: 54 cm × 69 cm × 58 cm Weight: 186 lbs, Crated Weight: 360 lbs
Power requirements	100–120 VAC 15 A, 220–240 VAC 10 A
Radio frequency identifier (RFID)	Frequency: 13.56 MHz Power: Supply current 120 mA, RF output power 200 mW
Product safety and compliance	NRTL certified IEC 61010-1 CE marked FCC/IC approved

Intended Use statements

NextSeq 550Dx Instrument intended use (CE-IVD)

The NextSeq 550Dx Instrument is intended for sequencing of DNA libraries when used with *in vitro* diagnostic assays. The NextSeq 550Dx Instrument is to be used with specific registered, certified, or approved *in vitro* diagnostic reagents and analytical software.

NextSeq 550Dx Instrument intended use (United States and Canada)

The NextSeq 550Dx instrument is intended for targeted sequencing of DNA libraries from human genomic DNA extracted from peripheral whole blood or formalin-fixed, paraffin-embedded (FFPE) tissue when used with *in vitro* (IVD) diagnostic assays. The NextSeq 550Dx instrument is not intended for whole genome or de novo sequencing. The NextSeq 550Dx instrument is to be used with specific registered, certified, or approved *in vitro* diagnostic reagents and analytical software.

Illumina NextSeq 550Dx High Output Reagent Kit v2.5 (75 Cycles) intended use

The Illumina NextSeq 550Dx High Output Reagent Kit v2.5 (75 Cycles) is a set of reagents and consumables intended for sequencing of sample libraries when used with validated assays. The kit is intended for use with the NextSeq 550Dx instrument and analytical software.

Illumina NextSeq 550Dx High Output Reagent Kit v2.5 (300 Cycles) intended use

The Illumina NextSeq 550Dx High Output Reagent Kit v2.5 (300 Cycles) is a set of reagents and consumables intended for sequencing of sample libraries when used with validated assays. The kit is intended for use with the NextSeq 550Dx instrument and analytical software.

Illumina DNA Prep with Enrichment Dx intended use (CE-IVD)

The Illumina DNA Prep with Enrichment Dx Kit is a set of reagents and consumables used to prepare sample libraries from genomic DNA derived from human cells and tissue to develop *in vitro* diagnostic assays. User-supplied probe panels are required for the preparation of libraries targeting specific genomic regions of interest. The generated sample libraries are intended for use on Illumina sequencing systems. The Illumina DNA Prep with Enrichment Dx includes software for sequencing run setup, monitoring, and analysis.

Illumina DNA Prep with Enrichment Dx intended use (United States)

Illumina DNA Prep with Enrichment Dx Kit is a set of reagents and consumables used to prepare sample libraries from DNA extracted from peripheral whole blood and formalin-fixed, paraffin-embedded (FFPE) tissue. User-supplied probe panels are required for the preparation of libraries targeting specific genomic regions of interest. The generated sample libraries are intended for use on Illumina sequencing systems.

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1.800.809.4566 toll-free (US) | +1.858.202.4566 tel
techsupport@illumina.com | www.illumina.com

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