DATA SHEET

Illumina DNA Prep with Enrichment Dx

An EU IVDR 2017/746–compliant and FDA-regulated library preparation and enrichment solution

- Validated IVDR and FDA-regulated solution for diagnostic library preparation and enrichment applications
- Flexible support for various content types, including fixed, custom, and exome panels
- Optimized performance on Illumina IVD platforms for highly accurate data generation

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

Introduction

Illumina DNA Prep with Enrichment Dx is a library preparation and enrichment solution that is compliant with European Union (EU) *In Vitro* Diagnostics Regulation (IVDR) 2017/746 and regulated by the Food and Drug Administration (FDA). It supports library preparation for a wide range of genomic DNA (gDNA) derived from human cells and tissue, including gDNA extracted from whole blood or formalin-fixed, paraffin-embedded (FFPE) tissue (Table 1). As part of a next-generation sequencing (NGS) workflow, Illumina DNA Prep with Enrichment Dx enables clinical laboratories to add targeted sequencing enrichment panels to their menu of diagnostic applications (Figure 1).

Table 1: Illumina DNA Prep with Enrichment Dx specifications

Parameter	Specification	
gDNA input type	Whole blood	FFPE tissue
DNA input verified[a]	50–1000 ng	
Required DNA input quality	260/280 ratio of 1.8–2.0	ΔCq value of ≤ 5
Pre-enrichment pooling[b]	12-plex	1-plex
Supported sequencing platforms	MiSeqDx, NextSeq 550Dx, and NovaSeq 6000Dx Instruments	
Total workflow time[c]	~ 7.0 hours	

a. DNA inputs outside these thresholds have not been validated and are considered off-label use .
b. gDNA from FFPE tissue is recommended exclusively for 1-plex enrichment reactions; gDNA from blood is recommneded exclusively for 12-plex enrichment reactions; nonstandard plexities may require additional optimization.
c. Includes library preparation, enrichment, and library normalization/pooling steps.

Simple library preparation and enrichment

Illumina DNA Prep with Enrichment Dx features innovative on-bead tagmentation, which uses bead-bound transposomes to mediate a uniform tagmentation reaction. When combined with a simplified, single hybridization step, tagmentation provides a rapid library preparation and enrichment solution (Table 1). Cleanup beads for library purification and sequencing indexes are included in the kit for added convenience and ease of use.

Flexible support for panel content

Illumina DNA Prep with Enrichment Dx supports both fixed and custom panels of varying sizes, including exome panels. The kit is compatible with Illumina and third-party enrichment DNA probe panels for increased flexibility (Table 2).

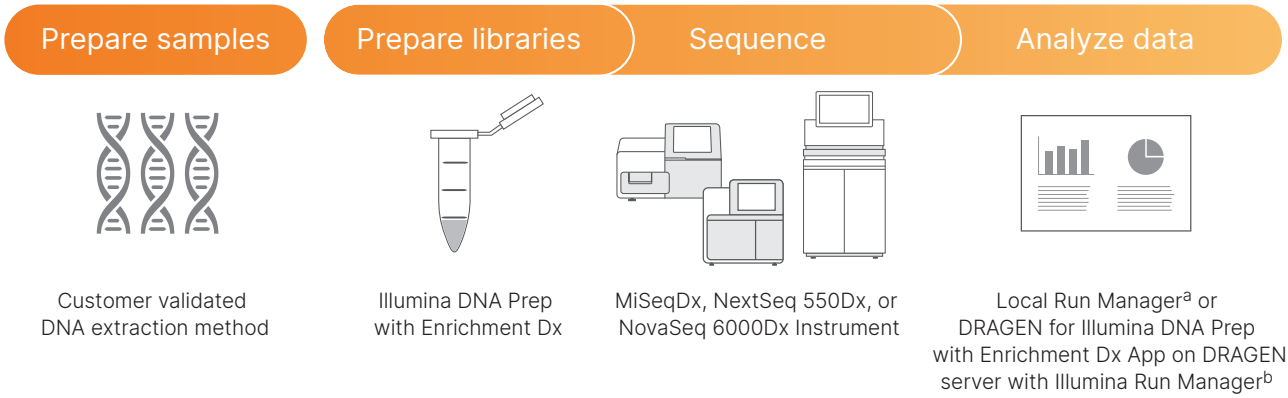

Figure 1: Illumina DNA Prep with Enrichment Dx workflow—After samples are prepared with a validated DNA extraction method, the Illumina DNA Prep with Enrichment Dx NGS workflow proceeds from library preparation to sequencing and data analysis for enrichment-based targeted sequencing applications.
a. Available on MiSeqDx and NextSeq 550Dx Instruments.
b. Available on NextSeq 550Dx and NovaSeq 6000Dx Instruments.

Table 2: Illumina DNA Prep with Enrichment Dx probe panel requirements

Parameter	Specification
Probe type	Single- or double-stranded DNA
Probe length	80 bp or 120 bp
Panel size	500–675,000 probes
Total probe input[a]	≥ 3 pmols

a. For enrichment at plexities from 1-plex to 12-plex.

Optimized performance on Illumina sequencing platforms

Illumina DNA Prep with Enrichment Dx is compatible with the MiSeq™Dx, NextSeq™ 550Dx, and NovaSeq™ 6000Dx Instruments (Figure 2). These FDA-regulated and Conformité Européene *in vitro* diagnostic (CE-marked IVD) platforms are designed specifically to bring the power of NGS to the clinical laboratory. Taking advantage of proven Illumina sequencing by synthesis (SBS) chemistry, these instruments provide highly accurate and reliable results for diagnostic testing.

Figure 2: Optimized performance across validated platforms—These FDA-regulated, CE-marked IVD instruments offer user-friendly interfaces, enhanced security, and high-quality results for clinical applications.

Integrated system software

Local Run Manager in Dx mode offers a fully integrated onboard analysis option accessed through a user-friendly touch screen interface on the MiSeqDx or NextSeq 550 Dx Instruments. The software supports sequence run planning and tracking of libraries and runs with audit trails. Local Run Manager automatically starts primary analysis (FASTQ generation from base calls) after a sequencing run is completed with the GenerateFASTQ Dx Module.

While any software tool can be used for secondary analysis, the Illumina DNA Prep with Enrichment Dx application is available on a local DRAGEN™ server with Illumina Run Manager for the NextSeq 550Dx or NovaSeq 6000Dx Instruments. Illumina Run Manager provides intuitive configuration of sequencing runs in Dx mode. The DRAGEN for Illumina DNA Prep with Enrichment Dx app performs read mapping, alignment, and accurate and efficient variant calling.

Highly accurate data

Illumina DNA Prep with Enrichment Dx provides high coverage uniformity and padded read enrichment for whole exome panels, enabling accurate single nucleotide variant (SNV) and insertion/deletion (indel) recall and precision (Table 3).

Table 3: Assay performance with whole-exome panels[a]

Panel	Exome panel I (45 Mb)[b]	Exome panel T (36.8 Mb)[c]
Padded unique read enrichment	78.65%	93.29%
Uniformity of coverage	95.37%	97.50%
SNV recall[d]	96.11%	96.26%
SNV precision[e]	98.16%	99.34%
Indel recall[d]	89.84%	92.18%
Indel precision[e]	84.19%	90.27%

a. Coriell cell line gDNA NA12878, with a known truth set for germline variant detection (Coriell platinum genome). Libraries were sequenced on the NextSeq 550Dx Instrument with FASTQ files generated from base calls using the Generate-FASTQ Dx Module in Local Run Manager; custom scripts in the DRAGEN platform v3.8.4 were used for analysis.
b. Twenty-four technical replicates in two 12-plex enrichment reactions.
c. Twelve technical replicates in a single 12-plex enrichment reaction.
d. Recall = true positives/(true positives + false negatives).
e. Precision = true positives/(true positives + false positives).

Summary

Illumina DNA Prep with Enrichment Dx delivers an FDA-regulated and EU IVDR 2017/746–compliant solution for targeted sequencing enrichment applications, including fixed and custom panels. This kit enables clinical labs to add optimal targeted enrichment and exome sequencing to grow their range of diagnostic service offerings.

Learn more

Illumina DNA Prep with Enrichment Dx, illumina.com/idpedx

Ordering information

Product	Catalog no.
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
MiSeqDx Instrument	DX-410-1001
MiSeqDx Reagent Kit v3	20037124
NextSeq 550Dx Instrument	20005715
NextSeq 550Dx High-Output Reagent Kit v2.5 (300 cycles)	20028871
NovaSeq 6000Dx Instrument	20068232
NovaSeq 6000Dx S2 Reagent v1.5 Kit (300 cycles)	20046931
NovaSeq 6000Dx S4 Reagent v1.5 Kit (300 cycles)	20046933
Illumina DNA Prep with Enrichment Dx Training	20028457

Intended use statements

Illumina DNA Prep with Enrichment Dx

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 (United States)

Illumina DNA Prep with Enrichment Dx is a set of reagents and consumables used to prepare sample libraries from DNA extracted from peripheral whole blood and formalin-fixed, paraffin-embedded 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.

MiSeqDx Instrument

The MiSeqDx 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 for *in vitro* diagnostic (IVD) assays performed on the instrument. The MiSeqDx instrument is not intended for whole genome or *de novo* sequencing. The MiSeqDx instrument is to be used with registered and listed, cleared, or approved IVD reagents and analytical software.

NextSeq 550Dx Instrument (United States)

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 for *in vitro* diagnostic (IVD) assays performed on the instrument. The NextSeq 550Dx instrument is not intended for whole genome or *de novo* sequencing. The NextSeq 550Dx instrument is to be used with registered and listed, cleared, or approved, IVD reagents and analytical software.

NextSeq 550Dx instrument (United States)

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 for *in vitro* diagnostic (IVD) assays performed on the instrument. The NextSeq 550Dx instrument is not intended for whole genome or *de novo* sequencing. The NextSeq 550Dx instrument is to be used with registered and listed, cleared, or approved, IVD reagents and analytical software.

NextSeq 550Dx Instrument (European Union/other)

The NextSeq 550Dx instrument is intended for sequencing of DNA libraries when used with in vitro diagnostic (IVD) assays performed on the instrument. The NextSeq 550Dx instrument is to be used with specific registered, certified, or approved IVD reagents and analytical software.

NovaSeq 6000Dx Instrument (United States)

The NovaSeq 6000Dx 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 NovaSeq 6000Dx instrument is not intended for whole-genome or *de novo* sequencing. The NovaSeq 6000Dx instrument is intended for use with specific registered, certified, or approved IVD reagents and analytical software.

NovaSeq 6000Dx Instrument (European Union/other)

The NovaSeq 6000Dx instrument is intended for sequencing of DNA libraries when used with *in vitro* diagnostic (IVD) assays. The NovaSeq 6000Dx instrument is intended for use with specific registered, certified, or approved IVD reagents and analytical software.

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M-GL-00743 v3.0