

NextSeq™ 550Dx High Output Reagent Kit v2.5 (75 Cycles)

FOR IN VITRO DIAGNOSTIC USE

Catalog # 20028870

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 from human genomic DNA extracted from peripheral whole blood or formalin-fixed, paraffin-embedded (FFPE) tissue when used with validated assays. The kit is intended for use with the NextSeq 550Dx instrument and analytical software.

Principles of Procedure

The NextSeq 550Dx High Output Reagent Kit v2.5 (75 Cycles) is a single-use set of reagents and consumables for sequencing on the NextSeq 550Dx instrument. For its input, the NextSeq 550Dx High Output Reagent Kit v2.5 (75 Cycles) uses libraries generated from DNA where sample indexes and capture sequences are added to targets. Sample libraries are captured on a flow cell and sequenced on the instrument using sequencing by synthesis (SBS) chemistry. SBS chemistry uses a reversible-terminator method to detect fluorescently-labeled single nucleotide bases as they are incorporated into growing DNA strands. The number of sample libraries depends on the multiplexing supported by the upstream library preparation method.

Limitations of the Procedure

- 1 For *in vitro* diagnostic use.
- 2 The NextSeq 550Dx High Output Reagent Kit v2.5 (75 Cycles) is only compatible with the NextSeq 550Dx instrument. The Reagent Kit is not compatible with the NextSeq 550 instruments.
- 3 When used with the NextSeq 550Dx instrument in a 2 x 38 base pair (bp) run configuration, the NextSeq 550Dx High Output Reagent Kit v2.5 (75 Cycles) can deliver:
 - ▶ Sequencing output \geq 22.5 gigabases (Gb)
 - ▶ 80% of bases with Phred scale quality scores \geq 30

Reagent Kit Components

Each component of the NextSeq 550Dx High Output Reagent Kit v2.5 (75 Cycles) is provided in a separate box. Promptly store components at the indicated temperature to ensure proper performance. The following is a list of reagent kit components.

Table 1 Reagent Kit Components

Component	Quantity	Fill Volume	Description	Storage*
NextSeq 550Dx High Output Reagent Cartridge v2 (75 cycles)	1 each	Various	Clustering and sequencing reagents	-25°C to -15°C
NextSeq 550Dx Buffer Cartridge v2 (75 cycles)	1 each	Various	Buffers and wash solution	15°C to 30°C

Component	Quantity	Fill Volume	Description	Storage*
NextSeq 550Dx High Output Flow Cell Cartridge v2.5 (75 cycles)*	1 each	N/A	Single-use, paired-end, glass flow cell	2°C to 8°C
NextSeq 550Dx Accessory Box (75 cycles)	1 tube	12 ml	Library dilution buffer	-25°C to -15°C

*The NextSeq 550Dx High Output Flow Cell Cartridge v2.5 (75 cycles) is shipped at ambient temperature.

Lot Numbers

The reagent kit has a single lot number, which is referred to as the reagent kit lot number. Each box in the reagent kit is printed with the reagent kit lot number. Reagent kit components that are inside the boxes are printed with component-specific lot numbers that are different from the reagent kit lot number. Keep sequencing consumables stored in their boxes until ready for use to maintain kit lot association. See the Certificate of Analysis of the reagent kit for details about reagent part numbers and lot numbers.

Storage and Handling

- 1 Room temperature is defined as 15°C to 30°C.
- 2 Reagent kit components are stable when stored at the indicated storage temperatures until the expiration date on the label.
- 3 The NextSeq 550Dx Accessory Box and NextSeq 550Dx Reagent Cartridge are stable for a maximum of one thaw to room temperature before the specified expiration date. The reagent cartridge is stable for up to 6 hours when thawed in a room temperature water bath. Alternatively, the reagent cartridge may be thawed at 2°C to 8°C for up to 5 days before use.
- 4 Changes in the physical appearance of the reagents can indicate deterioration of the materials. If changes in the physical appearance occur after mixing, such as obvious changes in reagent color, or cloudiness apparent with microbial contamination, do not use the reagents.

Equipment and Materials Required, Sold Separately

- ▶ NextSeq 550Dx Instrument, Catalog # 20005715

Warnings and Precautions



CAUTION

Federal law restricts this device to sale by or on the order of a physician or other practitioner licensed by the law of the State in which he/she practices, to use or order the use of the device.

- 1 The NextSeq 550Dx High Output Reagent Kit v2.5 (75 Cycles) contains potentially hazardous chemicals. Personal injury can occur through inhalation, ingestion, skin contact, and eye contact. Wear protective equipment, including eye protection, gloves, and laboratory coat appropriate for risk of exposure. Handle used reagents as chemical waste and discard in accordance with applicable regional, national, and local laws and regulations.
- 2 For environmental, health, and safety information, see the safety data sheet (SDS) at support.illumina.com/sds.html.
- 3 Failure to follow the procedures as outlined may result in erroneous results or significant reduction in sample quality.
- 4 Use routine laboratory precautions. Do not pipette by mouth. Do not eat, drink, or smoke in designated work areas. Wear disposable gloves and laboratory coats when handling specimens and assay reagents. Wash hands thoroughly after handling specimens and assay reagents.
- 5 Proper laboratory practices and good laboratory hygiene are required to prevent PCR products from contaminating reagents, instrumentation, and genomic DNA samples. PCR contamination may cause inaccurate and unreliable results.

- To prevent contamination, ensure that pre-amplification and post-amplification areas have dedicated equipment (eg, pipettes, pipette tips, vortexer, and centrifuge).

Instructions for Use

See the *NextSeq 550Dx Reference Guide (document # 100000009513)* and applicable user documentation.

Performance Characteristics

The Illumina NextSeq 550Dx High Output Reagent Kit v2.5 (75 Cycles) is a set of reagents and consumables intended for the sequencing of sample libraries when used with validated assays. There are no performance characteristics associated with this product. For assay specific performance, see relevant library preparation documentation.

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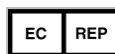
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Product Labeling

For a complete reference to symbols that may appear on product packaging and labeling, refer to the symbol key at support.illumina.com on the *Documentation and Literature* tab for your kit.