

Package Insert

FOR IN VITRO DIAGNOSTIC USE

Intended Use

The Illumina NovaSeq 6000Dx Reagent v1.5 Kit (300 cycles)(S2 or S4) and the Illumina NovaSeq 6000Dx Buffer Cartridge (S2 or S4) are reagents and consumables intended for sequencing of sample libraries when used with validated assays. The kit is intended for use with the NovaSeq 6000Dx instrument and analytical software.

Principles of Procedure

The Illumina NovaSeq 6000Dx S2 Reagent v1.5 Kit (300 cycles) and NovaSeq 6000Dx S4 Reagent v1.5 Kit (300 cycles) are single-use sets of reagents and consumables for sequencing on the NovaSeq 6000Dx Instrument. The Illumina NovaSeq 6000Dx S2 Reagent v1.5 Kit (300 cycles) and NovaSeq 6000Dx S4 Reagent v1.5 Kit (300 cycles) use libraries generated using validated assays. 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.

The S2 Buffer Cartridge and the S4 Buffer Cartridge are single-use sets of buffers and wash solution that are used on the instrument during the sequencing run.

The NovaSeq 6000Dx Instrument Package Insert provides instructions for performing sequencing on the NovaSeq 6000Dx.

Limitations of the Procedure

- For *in vitro* diagnostic use only.

Product Components

Table 1 NovaSeq 6000Dx Consumables

| Kit Name | Illumina Catalog Number |
|---|-------------------------|
| NovaSeq 6000Dx S2 Reagent v1.5 Kit (300 cycles) | 20046931 |
| NovaSeq 6000Dx S4 Reagent v1.5 Kit (300 cycles) | 20046933 |
| NovaSeq 6000Dx S2 Buffer Cartridge | 20062292 |
| NovaSeq 6000Dx S4 Buffer Cartridge | 20062293 |

Consumables

Table 2 NovaSeq 6000Dx S2 Reagent v1.5 Kit (300 cycles)

| Consumable | Quantity | Description |
|-------------------------------------|----------|--|
| NovaSeq 6000Dx S2 Flow Cell | 1 | Single-use, paired-end glass flow cell |
| NovaSeq 6000Dx S2 Cluster Cartridge | 1 | Clustering reagents |
| NovaSeq 6000Dx S2 SBS Cartridge | 1 | Sequencing reagents |

Table 3 NovaSeq 6000Dx S4 Reagent v1.5 Kit (300 cycles)

| Consumable | Quantity | Description |
|-------------------------------------|----------|--|
| NovaSeq 6000Dx S4 Flow Cell | 1 | Single-use, paired-end glass flow cell |
| NovaSeq 6000Dx S4 Cluster Cartridge | 1 | Clustering reagents |
| NovaSeq 6000Dx S4 SBS Cartridge | 1 | Sequencing reagents |

Table 4 NovaSeq 6000Dx S2 Buffer Cartridge

| Consumable | Quantity | Description |
|------------------------------------|----------|---------------------------|
| NovaSeq 6000Dx S2 Buffer cartridge | 1 | Buffers and wash solution |

Table 5 NovaSeq 6000Dx S4 Buffer Cartridge

| Consumable | Quantity | Description |
|------------------------------------|----------|---------------------------|
| NovaSeq 6000Dx S4 Buffer cartridge | 1 | Buffers and wash solution |

Storage and Handling

- Storage conditions are defined as follows.
 - Room temperature is 15°C to 30°C
 - Refrigerated is 2°C to 8°C
 - Frozen is -25°C to -15°C
- Reagent kit components are shipped under temperature control and are stable when stored at the indicated storage temperatures until the expiration date on the label.
- The NovaSeq 6000Dx S2 Reagent v1.5 Kit (300 cycles) and NovaSeq 6000Dx S4 Reagent v1.5 Kit (300 cycles) reagent cartridges are stable for up to 4 hours when thawed in a controlled 19°C to 25°C water bath following specified procedure in the NovaSeq 6000Dx Instrument Package Insert.

4. Changes in the physical appearance of the reagents can indicate deterioration of the materials. If changes in the physical appearance occur, such as obvious changes in reagent color, or cloudiness apparent with microbial contamination, do not use the reagents.

Equipment and Materials Required, Sold Separately

- NovaSeq 6000Dx, Illumina Catalog # 20068232
- NovaSeq 6000Dx Library Tube, Illumina Catalog # 20062290 (single) or Illumina Catalog # 20062291 (24 pack)

Lot Numbers

Each 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.

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 they practice, to use or order the use of the device.

- **Some components of reagents provided by Illumina for use with the NovaSeq 6000Dx Instrument contain 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.** For additional environmental, health, and safety information, refer to the Safety Data Sheets (SDS) at support.illumina.com/sds.html.
- Failure to follow the procedures as outlined can result in erroneous results or significant reduction in sample quality.
- 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 kit reagents. Wash hands thoroughly after handling specimens and kit reagents.
- Proper laboratory practices and good laboratory hygiene are required to prevent PCR products from contaminating reagents, instrumentation, and genomic DNA samples. PCR contamination can cause inaccurate and unreliable results.

- To prevent contamination, make sure that pre-amplification and post-amplification areas have dedicated equipment and consumables (eg, pipettes, pipette tips, heat blocks, vortexers, and centrifuges).
- Index to sample pairing requires matching the index plate layout exactly. The DNA Prep with Enrichment Application automatically populates the index primers associated with the sample names, when entered during run setup. The user is advised to verify the index primers associate with samples before starting the sequencing run. Mismatches between the sample and plate layout results in loss of positive sample identification and incorrect result reporting.
- Do not operate the NovaSeq 6000Dx with any of the panels removed. Operating the instrument with any of the panels removed creates potential exposure to line voltage and DC voltages.
- Do not touch the flow cell stage in the flow cell compartment. The heater in this compartment operates between 22°C and 95°C and can result in burns.
- The instrument weighs approximately 1059 lbs. and could cause serious injury if dropped or mishandled.

Instructions for Use

Refer to the *NovaSeq 6000Dx Instrument Package Insert* and applicable user documentation.

Performance Characteristics

Refer to the *NovaSeq 6000Dx Instrument Package Insert*.

Revision History

| Document | Date | Description of Change |
|--------------------------|-------------|-----------------------|
| Document # 200025483 v00 | August 2022 | Initial release. |

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Product Labeling

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