

## Package Insert

FOR IN VITRO DIAGNOSTIC USE.

## Intended Use

The Illumina® NovaSeq™ 6000Dx Library Tubes (single tube or 24 pack) are intended to hold sample libraries for sequencing with NovaSeq 6000Dx S2 or S4 reagent v1.5 kits and validated assays. The library tube is intended for use with the NovaSeq 6000Dx instrument.

## Principles of Procedure

The Illumina NovaSeq 6000Dx Library Tubes (single tube or 24 pack) are intended to hold sample libraries for sequencing with NovaSeq 6000Dx S2 or S4 reagent kits, S2 and S4 buffer cartridges, and validated assays.

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

Kit Name	Illumina Catalog Number
NovaSeq 6000Dx Library Tube	20062290
NovaSeq 6000Dx Library Tube, 24 Pack	20062291

## Storage and Handling

1. Storage conditions are defined as follows.
  - Room temperature as 15°C to 30°C.
2. Library tubes do not have an effective expiration date. The placeholder expiration date (set far in the future) encoded by the RFID is intended for system functionality only.
3. Library tubes are stable at room temperature.
4. Changes in the physical appearance of the library tube can indicate damage to the material. If physical damage is observed, do not use the library tube.

# Equipment and Materials Required, Sold Separately

- NovaSeq 6000Dx, Illumina Catalog # 20068232
- NovaSeq 6000Dx S2 Reagent v1.5 Kit (300 cycles), Illumina Catalog # 20046931
- NovaSeq 6000Dx S4 Reagent v1.5 Kit (300 cycles), Illumina Catalog # 20046933
- NovaSeq 6000Dx S2 Buffer Cartridge, Illumina Catalog # 20062292
- NovaSeq 6000Dx S4 Buffer Cartridge, Illumina Catalog # 20062293

## 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](http://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.
- Immediately report any serious incidents related to this product to Illumina and to the Competent Authorities of the member states in which the user and the patient are established.

## 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 # 200025484 v01	October 2024	Clarified Storage and Handling information to indicate that the library tubes do not have an expiration date. Added new Warnings and Precautions information instructing users to report incidents relating to the product to the appropriate parties. Added S2 and S4 buffer kits to Principles of Procedure.
Document # 200025484 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](http://support.illumina.com) on the *Documentation* tab for your kit.