

Chinese FDA premarket clearance, 8/15

Hangzhou Berry Genomics, a subsidiary of Berry Genomics, has received premarket clearance from the Chinese Food and Drug Administration for the NextSeq CN500, a high-throughput sequencing instrument developed with Illumina to meet Chinese clinical needs. Hangzhou Berry Genomics also received premarket clearance for its noninvasive prenatal testing detection kit for trisomies 13, 18, and 21.

The NextSeq CN500 uses Illumina's sequencing by synthesis technology and was designed for operations in a clinical setting. Complementary with NextSeq CN500, Berry Genomics' NIPT kit is based on a proprietary PCR-free protocol, which simplifies the complex NIPT sample preparation process to a two-step workflow in a single tube. The system can process up to 96 samples per instrument run.

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