Element Biosciences

Specification Sheet

AVITI Dx™ System

CE-marked Class A IVD benchtop sequencer with dual-boot mode

Highlights

- **CE-marked under the EU IVDR with sequencing with dual-boot mode for switching between IVD and RUO workflows**
- **Individually addressable lanes and direct loading of linear libraries built for the demands of a regulated laboratory**
- **Mid-throughput benchtop platform for clinical laboratories**

Introduction

The Element AVITI Dx System is a Class A IVD, CE-marked under the EU IVDR, and is a mid-throughput benchtop sequencing platform bringing the advantages of Avidite Base Chemistry™ (ABC™) to clinical laboratories.

AVITI Dx accepts linear libraries directly, without a separate circularization step before loading, simplifying sample prep ahead of a run. Each lane on the flow cell is individually addressable, so labs can run different samples or panels side-by-side on the same instrument without dedicating a full run to a single protocol. This lane-level control supports the day-to-day realities of a regulated lab, where different samples may need to move through distinct laboratory workflows on their own timelines.

AVITI Dx products are not available for sale in the U.S. and are available only in select countries, as confirmed by Element.

Novel ABC sequencing

The fundamentals of ABC technology leverage the unique properties of Avidites™ to execute an efficient sequencing reaction and yield highly accurate data. A strong signal-to-noise ratio that persists through high polony densities drives this accuracy.

When a run starts, the library molecules circularize by hybridizing to surface primers coating the flow cell. Rolling circle amplification (RCA) generates long concatemer DNA strands having repeat copies of complementary sequences of the original library molecule. The concatemers form tightly bound polonies. This PCR-free amplification workflow reduces index hopping and other PCR-induced errors.

During sequencing, the polonies bind sequencing primers, sequencing polymerases and fluorescent Avidites to form tight complexes that generate prominent signals for highly-accurate sequencing and reduced reagent consumption.

Dual-boot mode switching

AVITI Dx supports switching between RUO and IVD operating environments, enabling laboratories to maximize instrument utilization across research and clinical workflows. RUO consumables are only allowed to be run in RUO mode, while Dx consumables are only allowed to be run in IVD mode to support their respective intended uses. The separation of operating environments helps maintain distinct workflows, software configurations, and data management practices. This flexibility enables laboratories to expand their sequencing capabilities without requiring dedicated instruments for research and diagnostic applications.

Sequencing specifications*

Kit Configuration	Read Length	Read Count**	Run Time	Q30
High Output	2×150	≥1.2 B	≤40 hours	≥90%
	2×75	≥1.2 B	≤26 hours	≥90%
Low Output	2×150	≥300 M	≤40 hours	≥90%

* Specifications in this table are for the AVITI Dx in IVD mode. For specifications in RUO mode, please see the AVITI24™ sequencing specifications on the Cloudbreak™ Sequencing Kits Product Sheet.

** Performance metrics are based on sequencing Element libraries. Actual results may differ due to library type and preparation methods.

ISO 13485 quality management

AVITI Dx is manufactured under an ISO 13485 certified quality management system, supporting rigorous standards for medical device quality, safety, and reliability. Controlled manufacturing processes, comprehensive quality assurance procedures, and robust traceability help ensure consistent product performance and reproducibility. These quality practices support the stringent requirements of clinical laboratories and and help ensure consistent instrument performance.

Intended use statement

The AVITI Dx product family delivers precise, high-quality raw DNA sequencing data from a variety of biological samples. The product is intended solely as a data generation tool and does not provide diagnostic interpretations or direct clinical recommendations.

System specifications

Instrument Configuration	Dual flow cells In RUO mode: AVITI™ Operating Software In IVD mode: AVITI Dx Operating Software Ubuntu Core 20.04 LTS operating system
Operating Environment	Temperature: 18°C to 26°C Elevation: < 2000 m Sound level: ≤ 62 db at 3.3 ft
Dimensions	(H x W x D) 29.5 in x 37.6 in x 28.5 in Weight: 155.1 kg/342 lb
Power	Requirements 100–240 VAC at 50/60 Hz, 15 A. 550 W (average)

Ordering information

AVITI Dx System	880-00008
2×150 CB Freestyle Dx™ High Output	860-00052
2×150 CB Freestyle Dx Low Output	860-00053
2×75 CB Freestyle Dx High Output	860-00054

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