



Twist Bioscience Launches IVDR-compliant Precision Dx Products for Whole Exome Sequencing

March 5, 2024

Precision Dx Products are CE-marked and compliant with EU IVDR 2017/746 regulations

Precision Dx Products include Twist Precision Prep and Enrichment Dx Kit, Twist Precision Exome Dx Panel and Twist Precision Exome Dx Kit

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Mar. 5, 2024-- [Twist Bioscience Corporation](#) (NASDAQ: TWST), a company enabling customers to succeed through its offering of high-quality synthetic DNA using its silicon platform, today announced European Union (EU) in vitro diagnostic regulations (IVDR) compliant [Twist Precision Dx](#) next-generation sequencing (NGS) Products.

In accordance with the IVD regulations put in place by the EU to ensure the safety and quality of in vitro diagnostic medical devices, Twist's Precision Dx Products are CE-marked and compliant with EU IVDR 2017/746 regulations demonstrating the quality of kit materials. The Precision Dx products are designed to enable panel sequencing within a clinical setting.

The suite of our CE-marked Products includes:

- The Twist Precision Prep and Enrichment Dx Kit¹ (Reagents for enzymatic fragmentation, library preparation, and target enrichment), which is panel-agnostic²
- The Twist Precision Exome Dx Panel¹ (Targeted capture probes for exome enrichment)
- Twist Precision Exome Dx Kit¹ (Reagents for enzymatic fragmentation, library preparation, and target enrichment along with targeted capture probes for exome enrichment; IVDR compliant workflow)

The Twist Precision Prep and Enrichment Dx Kit and the Twist Precision Exome Dx Panel can be used individually within existing workflows or as a combined solution known as the Twist Precision Exome Dx Kit. In addition, as an added service to customers, Twist is collaborating with Platomics to enable laboratories to efficiently generate documentation on Platomics' multi-stakeholder platform for workflows incorporating the Twist Precision Exome Dx Kit, and to help automate regulatory processes and accelerate compliance for laboratories and manufacturers.

"The Twist Precision Dx products are our first NGS product line specifically developed to be included within regulated customer products. With IVD regulation in place and an expanding customer base in EMEA, we've launched one of the first comprehensive, fully-validated whole exome library preparation and target enrichment workflows to enable our customers to seamlessly obtain IVDR certification for their diagnostic tests," said Emily M. Leproust, Ph.D., CEO and co-founder of Twist Bioscience. "By taking the steps to have our exome workflow IVDR certified ahead of the transition deadline for existing tests, we continue to support our current customers in Europe developing clinical tests using Twist NGS tools while also expanding our market opportunity to include regulated test workflows. With multiple CE-marked Products, we can support our European customers in several ways, either by providing panel-agnostic library prep and target enrichment for their existing panels, an exome workflow for their existing workflows or a combined solution for an IVDR-compliant workflow."

The Precision Dx workflow enables comprehensive coverage with more than 98% of target bases covered at 30x as well as reliable performance with uniform enrichment and consistent yield from high-complexity libraries. The Precision Dx Products are intended for use with high-quality genomic DNA derived from human cells and allow for flexibility within workflows.

Twist Precision Prep and Enrichment Dx Kit

The Twist Precision Prep and Enrichment Dx Kit¹ is a reagent kit that includes enzymatic fragmentation, library preparation, and targeted capture. It utilizes Twist's expertise in enzymatic DNA fragmentation and library preparation to enable reliable access to target DNA for NGS. The kit's streamlined workflow combines library preparation steps into a single-tube reaction which, alongside a high on-target rate and Twist's highly uniform target enrichment workflow, translates into an enhanced quality library preparation and sequencing result. The kit can be used to target specific regions of the genome with DNA panels supplied by users or with a Twist DNA panel, such as the Twist Precision Exome Dx Panel, for NGS applications.

Twist Precision Exome Dx Panel

The Twist Precision Exome Dx Panel¹ is a qualified Twist DNA panel that can be used in conjunction with the Twist Precision Prep and Enrichment Dx kit to produce exome-enriched libraries compatible for NGS applications. The panel expands exonic coverage to include the mitochondrial genome as well as additional clinically relevant loci, providing efficient and comprehensive exome sequencing for improved coverage of target sequences.

Twist Precision Exome Dx Kit

Twist Precision Exome Dx Kit¹ utilizes the qualified Twist Precision Exome Dx Panel along with the Twist Precision Prep and Enrichment Dx Kit to produce exome-enriched libraries compatible for NGS applications.

1 For in vitro diagnostic use. Not available in all regions and countries.

2 Panels supplied by users must meet Twist specifications, available upon request.

About Twist Bioscience Corporation

Twist Bioscience is a leading and rapidly growing synthetic biology and genomics company that has developed a disruptive DNA synthesis platform to industrialize the engineering of biology. The core of the platform is a proprietary technology that pioneers a new method of manufacturing synthetic DNA by “writing” DNA on a silicon chip. Twist is leveraging its unique technology to manufacture a broad range of synthetic DNA-based products, including synthetic genes, tools for next-generation sequencing (NGS) preparation, and antibody libraries for drug discovery and development. Twist is also pursuing longer-term opportunities in digital data storage in DNA and biologics drug discovery. Twist makes products for use across many industries including healthcare, industrial chemicals, agriculture and academic research.

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Twist Bioscience Legal Notice Regarding Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts contained herein are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding our ability to help customers seamlessly obtain IVDR certification for their diagnostic tests and the usefulness of Platomics’ multi-stakeholder platform for automating regulatory processes, documentation generation and compliance. Forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause Twist Bioscience’s actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the ability to achieve the expected benefits of Twist Bioscience’s restructuring activities and reduced investments in DNA data storage; the ability to attract new customers and retain and grow sales from existing customers; the ability of Twist Bioscience to achieve sufficient revenue to achieve or maintain positive cash flow from operations or profitability in any given period; risks and uncertainties of rapidly changing technologies and extensive competition in synthetic biology that could make the products Twist Bioscience is developing obsolete or non-competitive; uncertainties of the retention of significant customers; the ability of Twist Bioscience to successfully integrate acquired companies and to achieve expected benefits from acquisitions; supply chain and other disruptions; risks of third party claims alleging infringement of patents and proprietary rights or seeking to invalidate Twist Bioscience’s patents or proprietary rights; and the risk that Twist Bioscience’s proprietary rights may be insufficient to protect its technologies. For a description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Twist Bioscience’s business in general, see Twist Bioscience’s risk factors set forth in Twist Bioscience’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on February 2, 2024 and subsequent filings with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and Twist Bioscience specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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