

## **Thermo Fisher Scientific Completes FDA Listing and Launches the Applied Biosystems QuantStudio 5 Dx Real-Time PCR System for In Vitro Diagnostic Use**

**Innovative qPCR platform simplifies molecular diagnostic workflows for infectious disease, oncology and COVID-19 testing**

CARLSBAD, Calif., March 25, 2021 /PRNewswire/ -- Thermo Fisher Scientific today announced the completion of the U.S. Food and Drug Administration (FDA) listing for the Applied Biosystems QuantStudio 5 Dx Real-Time PCR System. The innovative product enables clinical laboratories and assay developers to meet testing demands and enhance their molecular diagnostics workflows.

Clinical diagnostic and hospital laboratories across the United States have ramped up PCR testing over the last year in response to the global COVID-19 pandemic. These laboratories are now seeking solutions to continue to screen for COVID-19 after emergency use authorizations (EUAs) for SARS-CoV-2 assays expire.

"The COVID-19 pandemic has increased testing demands for laboratories exponentially, with a significant portion of the testing globally conducted on Thermo Fisher PCR instruments," said Mark Smedley, president of Genetic Sciences for Thermo Fisher Scientific. "As our customers' testing requirements grow, we are continuously innovating to meet their needs with our molecular diagnostic products. With the launch of the IVD QuantStudio 5 Dx, we can continue to support our customers around the world."

The high-performing qPCR system's simplified, efficient workflow minimizes steps to deliver quality results in as little as 30 minutes. The system has high sensitivity and specificity and offers up to six channels for multiplexing. The cost-effective and complete solution, including simplified software, enhanced security and a simple-to-use interface, comes in a compact footprint that can fit in any lab.

"Thermo Fisher is a valued partner, supporting us in the development of clinical trial assays and companion diagnostics," said Michael Sloan, global vice president of commercial operations at Almac Diagnostic Services. "Thermo Fisher's QuantStudio qPCR systems offer a seamless integration into our assay development workflows. Both the QuantStudio Dx and QuantStudio 5 Dx offer the flexibility of customizable solutions and provide high-quality data output for molecular diagnostic testing."

The QuantStudio 5 Dx Real-Time PCR System is listed with the FDA, includes the CE-IVD Mark under the self-certification process in the European Union, and has been certified and approved by the National Medical Products Administration (NMPA) in China. The system is currently registered in more than 50 countries.

For more information, please visit [www.thermofisher.com/quantstudio5dx](http://www.thermofisher.com/quantstudio5dx).

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Media Contact Information:

Mauricio Minotta

Phone: 760-805-5266

Email: [mauricio.minotta@thermofisher.com](mailto:mauricio.minotta@thermofisher.com)

Jen Heady

Phone: 617-275-6547

Email: [jheady@greenough.biz](mailto:jheady@greenough.biz)

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