

C. diff assay and PCR system, 9/13:78 (AACC)

Quidel Corp. and Life Technologies in March received FDA 510(k) clearances to market the Quidel Molecular Direct *C. difficile* assay with Life Technologies' QuantStudio Dx and 7500 Fast Dx Applied Biosystems real-time PCR instruments.

The *C. difficile* assay is part of Quidel's molecular diagnostic product line, which includes PCR reagent kits for molecular diagnostic laboratories including Life Technologies' QuantStudio Dx and 7500 Fast Dx. These reagents can be refrigerated instead of frozen, are convenient and ready to use, and provide a short time to result.

The Quidel Molecular Direct *C. difficile* assay kit includes an extraction-free, three-step sample preparation process that requires no heat step, no timed step, and no centrifugation. This fast, easy, and economical direct-to-amplification procedure allows the assay to generate a result in less than 70 minutes.

The QuantStudio Dx real-time PCR instrument's touchscreen, reagent and sample tracking, and LIMS interface make it easy to use, and a six-color feature allows for a multiplex of six targets in one reaction.

The 7500 Fast Dx is a five-color real-time PCR instrument that provides high-quality results in a 96-well format. The 7500 Fast Dx is also FDA cleared for diagnostic use with the Centers for Disease Control and Prevention's H1N1 assay and with the Quidel Molecular assays for influenza A and B and human metapneumovirus.

The QuantStudio Dx has an optional test-development mode, which allows the use of easily interchangeable thermal cycling blocks that accommodate 96- or 384-well plates and a proprietary qPCR microfluidics card, which can perform 48 tests on eight samples simultaneously without liquid-handling robots. The card can also be used to design and implement custom tests. In test-development mode, the QuantStudio Dx can perform pathogen detection, gene-expression analysis, SNP genotyping, copy-number analysis, mutation detection, microRNA and other noncoding RNA analysis, and high-resolution melt analysis.

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