NEWS RELEASE

Waters Announces FDA 510(k) Clearance of BD BACTEC FXI Culture System, Enabling Broader Access to Bloodstream Infection Diagnostics

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- FDA 510(k)-cleared BD BACTEC™ FXI Culture System now available to U.S. market, enabling broader access to confident bloodstream infection diagnostics.
- Achieves a 3-hour faster time to detection (~15% reduction) versus the prior-generation system, per clinical study data, enabling earlier targeted sepsis prevention.
- Fully automated solution delivers an industry-leading 50% increase in vial loading and up to 960-vial per module capacity, maximizing walk-away time.

MILFORD, Mass., June 3, 2026 /PRNewswire/ -- Waters Corporation (NYSE: WAT) today announced that the BD BACTEC FXI Culture System has received U.S. Food and Drug Administration (FDA) 510(k) clearance. This clearance enables commercialization in the U.S. and provides a new option for laboratories seeking a fully automated blood culture system designed to improve the speed, consistency, and accuracy of sepsis and bloodstream infection diagnostics in modern microbiology laboratories.

Clinical study data[1] showed that the BD BACTEC FXI Culture System reduced mean time to detection by approximately three hours (~15%) compared with the previous-generation BD BACTEC™ FX Blood Culture System (17 hours vs. 20 hours). Faster detection enables earlier pathogen identification and more timely targeted antimicrobial therapy for patients with suspected bloodstream infections and sepsis. Because each hour of delayed sepsis treatment increases mortality by 3.6% to 9.9%,[2] faster diagnostic workflows are critical in acute care settings.

"Recent evidence-based laboratory guidelines document the beneficial clinical impact of rapid laboratory results for the detection of bloodstream infections; therefore, advancing the science of automated blood culture instruments

is critical to further speed results," said Donna M. Wolk, MHA, Ph.D., D(ABMM), Division Chief, Molecular and Microbial Diagnostics and Development, Geisinger Medical Laboratories. "Reducing the time to detection for positive results is key to improving the availability of Gram stain and other tests, on which treatment decisions are based. The faster, the better."

The BD BACTEC FXI Culture System features a first-of-its-kind capability in a blood culture platform – an automated gravimetric measurement of individual blood culture vial volume. By objectively confirming blood volume in each vial, the system reduces pre-analytical variability and supports more consistent diagnostics and adherence to recommended collection practices.

"Waters is proud to bring the BD BACTEC FXI Culture System to the U.S. market, delivering an important advancement in bloodstream infection diagnostics," said Jianqing Bennett, Senior Vice President, Waters Advanced Diagnostics, Waters Corporation. "This innovation reflects the scientific expertise and commitment of the Waters team to improve patient care. The system helps laboratories support earlier clinical decisions for patients with suspected sepsis and bloodstream infections when every hour matters."

Designed for high-throughput microbiology labs, the BD BACTEC FXI Culture System fully automates vial loading, unloading, incubation, and detection alerts, with an industry-leading automated loading capacity of up to 60 vials at a time,[3] 50% more vials than the leading competitior.[4] Available in 480- and 960-vial configurations,[3] the BD BACTEC FXI Culture System delivers scalable efficiency while reducing manual intervention and increasing staff walk-away time.

The BD BACTEC FXI Culture System was recently CE marked under the European Union's In Vitro Diagnostic Regulation (IVDR) and licensed by the Japan Pharmaceuticals and Medical Devices Agency (PMDA) for availability in Europe[5] and Japan.[6]

Additional Resources:

The BD BACTEC FXI Culture System and BD BACTEC™ Blood Culture Vials are manufactured by Becton, Dickinson and Company or one of its affiliates or subsidiaries.

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About Waters Corporation:

Waters Corporation (NYSE: WAT) is a global leader in life sciences and diagnostics, dedicated to accelerating the

benefits of pioneering science through analytical technologies, informatics, and service. With a focus on regulated, high-volume testing environments, our innovative portfolio harnesses deep scientific expertise across chemistry, physics, and biology. We collaborate with customers around the world to advance the release of effective, high-quality medicines, ensure the safety of food and water, and drive better patient outcomes by detecting diseases earlier, managing routine infections, and combating antibiotic resistance. Through a shared culture of relentless innovation, our passionate team of ~16,000 colleagues turn scientific challenges into breakthroughs that improve lives worldwide. For more information, please visit **www.waters.com/aboutus**.

Disclaimer:

The BD Biosciences and BD Diagnostic Solutions businesses have been acquired by Waters Corporation ("Waters"). Becton, Dickinson and Company or one of its affiliates or subsidiaries ("BD") remains the legal manufacturer of Biosciences and Diagnostic Solutions products until all required regulatory transfers are completed. During this interim period, BD maintains full responsibility for all regulatory obligations of the legal manufacturer. Product information provided here is supplied under BD's regulatory authority. To learn more about the relationship between Waters and BD during this transition period, please see our detailed summary: **www.waters.com/bdtransaction**.

References:

Data on file BD, Clinical Performance Study Report IDS-23BACT002. Overall faster mean time to detection 2.8-hrs – 3.2-hrs compared to BD BACTEC FX Blood Culture System for BD BACTEC™ Plus Aerobic media and BD BACTEC™ Lytic Anaerobic media, respectively.
Kumar A, Roberts D, Wood KE, et al. Duration of hypotension before initiation of effective antimicrobial therapy is the critical determinant of survival in human septic shock. Crit Care Med. 2006;34(6):1589-96. PMID 16625125.
Specification Data on File, Becton, Dickinson and Company 2026.
Specification data from BACT/ALERT® VIRTUO® 510(k) Substantial Equivalence Determination Decision Summary (K161816); page 5, Table J3.
Waters Press Release, April 15, 2026: **https://www.prnewswire.com/news-releases/waters-announces-ce-mark-for-next-generation-fully-automated-bd-bactec-fxi-culture-system-for-bloodstream-infection-diagnosis-302743121.html**.
Japan Pharmaceuticals and Medical Devices Agency (PMDA), License No. 13B1X10407.

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