Accelerate Diagnostics Submits WAVE System and Gram-Negative Positive Blood Culture Menu to the FDA for 510(k) Clearance

TUCSON, Ariz., March 21, 2025 /PRNewswire/ -- Accelerate Diagnostics, Inc. (Nasdaq: AXDX), an innovator in rapid in vitro diagnostics for microbiology, today announced the submission of its Accelerate WAVE™ system and positive blood culture gram-negative test kit to the U.S. Food and Drug Administration (FDA) for 510(k) clearance.

The Accelerate WAVE system is designed to provide rapid antimicrobial susceptibility testing (AST) directly from positive blood culture bottles and bacterial isolate colonies. The WAVE system is designed to deliver accurate results in an average of 4.5 hours, enabling same shift targeted antimicrobial therapy for patients with serious infections.

With a user-friendly workflow, high throughput capacity, and scalable design, once approved by the FDA, the WAVE system will offer microbiology laboratories a comprehensive AST solution to meet a wide range of testing demands and hospital formulary needs.

According to the World Health Organization, sepsis affects an estimated 49 million people globally each year, resulting in approximately 11 million deaths.[1] Of those, around 1.32 million deaths[2] are attributed to bacterial antimicrobial resistance. Sepsis also represents the most significant cost burden to the U.S. healthcare system, with an estimated annual expense of $62 billion.[3]

By delivering rapid AST results, the WAVE system is designed to support earlier, targeted antimicrobial therapy—improving patient outcomes, reducing hospital costs, and helping combat antimicrobial resistance.

References:

1. Rudd KE, Johnson SC, Agesa KM, Shackelford KA, Tsoi D, Kievlan DR, Colombara DV, Ikuta KS, Kissoon N, Finfer S, Fleischmann-Struzek C, Machado FR, Reinhart KK, Rowan K, Seymour CW, Watson RS, West TE, Marinho F, Hay SI, Lozano R, Lopez AD, Angus DC, Murray CJL, Naghavi M. Global, regional, and national sepsis incidence and mortality, 1990-2017: analysis for the Global Burden of Disease Study. Lancet. 2020 Jan 18;395(10219):200-211. doi: 10.1016/S0140-6736(19)32989-7.

2. Murray CJ. Global Burden of Bacterial Antimicrobial Resistance in 2019: A Systematic Analysis. The Lancet. 2022;399(10325):629-655. doi:https://doi.org/10.1016/S0140-6736(21)02724-0.

3. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7017950/)

About Accelerate Diagnostics, Inc.

Accelerate Diagnostics, Inc. is an in-vitro diagnostics company dedicated to providing solutions for the global challenges of antibiotic resistance and sepsis. Accelerate Diagnostics' current portfolio of FDA-cleared platforms include the Accelerate Pheno system and Accelerate PhenoTest® BC kit as well as the Accelerate Arc™ system and BC kit. The Accelerate Pheno system and Accelerate PhenoTest® BC kit combine several technologies aimed at reducing the time clinicians must wait to determine the most optimal antibiotic therapy for deadly infections. This system fully automates sample preparation, identification and phenotypic antibiotic susceptibility testing in approximately seven hours directly from positive blood cultures. Recent external studies indicate this solution offers results 1-2 days faster than existing methods, enabling clinicians the ability to optimize antibiotic selection and dosage specific to the individual patient days earlier. Further, the Accelerate Arc™ system and BC kit provide a novel, automated positive blood culture sample preparation platform for use with Bruker's MALDI Biotyper® CA System (MBT-CA System) and MBT-CA Sepsityper® software extension. Designed for clinical laboratories, the Accelerate Arc system has a simple workflow that automates positive blood culture sample preparation for direct downstream microbial identification using Bruker's MBT-CA System. This innovation eliminates the need for overnight culture methods, reducing the wait time for microbial identification results, which is critical in the fight against sepsis.

For more information about the company, its products and technology, or recent publications, visit axdx.com.

Forward-Looking Statements

Certain statements made in this press release and the related conference call are forward-looking or may have forward-looking

implications within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the company intends that such forward-looking statements be subject to the safe harbors created thereby. These forward-looking statements, which can be identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "estimate," or "continue," or variations thereon or comparable terminology, include but are not limited to, statements about: the WAVE system's expected performance, effectiveness, hospital and patient benefits, market interest, and eventual commercialization; FDA approval for the WAVE system, including our ability to fund operations through the commercial launch of the Wave system. Actual results or developments may differ materially from those projected or implied in these forward-looking statements due to significant risks and uncertainties, including, but not limited to: difficulties in resolving the company's continuing financial condition and ability to obtain additional capital to meet its financial obligations; and the company's ability to obtain any regulatory approvals in a timely manner. Other important factors that could cause the company's actual results to differ materially from those in its forward-looking statements include those discussed in the company's filings with the Securities and Exchange Commission (the "SEC"), including in the "Risk Factors" sections of the company's most recently filed periodic reports on Form 10-K and Form 10-Q and subsequent filings with the SEC. Except as required by federal securities laws, the company undertakes no obligation to update or revise these forward-looking statements to reflect new events, uncertainties or other contingencies. Forward-looking statements speak only as of the date they are made and should not be relied upon as representing the company's plans and expectations as of any subsequent date.

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For further information: Laura Pierson, lpierson@axdx.com
