Accelerate Diagnostics Announces New FDA Clearance for Accelerate PhenoTest® Improvements

TUCSON, Ariz., Sept. 16, 2020 /PRNewswire/ -- Accelerate Diagnostics, Inc. (NASDAQ:AXDX) today announced that the Company has received U.S. Food and Drug Administration (FDA) clearance for a new suite of product enhancements to the Accelerate Pheno® system, which improve performance and expand the system's antimicrobial susceptibility testing (AST) menu for bloodstream infections.

The new product release, formally classified as FDA 510(k) Clearance No. K192665, features improvements in susceptibility testing performance for four important antibiotics used to treat *Pseudomonas aeruginosa,* as well as the addition of the combination of *P. aeruginosa* and aztreonam, an empiric antibiotic, to the Accelerate PhenoTest BC kit testing panel.

"These improvements to our PhenoTest BC kit will provide clinicians with an even wider array of results to inform highly tailored treatment options for patients with bacteremia and sepsis. We believe that these new tests will support improved patient outcomes and further strengthen the trust that laboratories place in our system," commented Shelley Campeau, Accelerate's Chief Scientific Officer.

Jack Phillips, Chief Executive Officer of Accelerate Diagnostics, stated, "I am thrilled to offer this latest release as part of our commitment to continuous improvement of the Pheno system and to expanding upon our leadership position in rapid AST. Further to this commitment, we have multiple new products moving through our development pipeline. We expect that our next FDA filing will be for clearance of the Accelerate PhenoAST BC GN kit, our AST-only testing solution for Gram-negative bacteremia. Our entire team is dedicated to delivering these lifesaving innovations as quickly as possible to laboratories, clinicians, and patients."

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. 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. The FDA cleared system and kit fully automate the sample preparation steps to report phenotypic antibiotic susceptibility results in approximately 7 hours direct from positive blood cultures. Recent external studies indicate the solution offers results 1–2 days faster than existing methods, enabling clinicians to optimize antibiotic selection and dosage specific to the individual patient days earlier.

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

Forward-Looking Statements
This press release contains forward-looking statements, which are subject to risks and uncertainties, including those described in our periodic reports and other filings with the U.S. Securities and Exchange Commission (the "SEC"). Forward-looking statements include projections, statements about our future and those that are not historical facts. Forward-looking statements may contain words such as "will," "may," "expect," "believe," "likely," "anticipate," similar expressions, and variations or negatives of these words. Forward-looking statements are made on the basis of management's views and assumptions regarding future events and business performance as of the time the statements are made. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Anticipated results only reflect information available to us at this time and may differ from actual results. Information about the risks and uncertainties faced by Accelerate Diagnostics is contained in the section captioned "Risk Factors" in the company's most recent Annual Report on Form 10-K, filed with the Securities and Exchange Commission on February 28, 2020, and in any other reports that we file with the Securities and Exchange Commission from time to time. Except as required by federal securities laws, we undertake no obligation to update or revise these forward-looking statements to reflect new events, uncertainties, or other contingencies.

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