Accelerate Diagnostics submits 510(K) application to FDA for Gram-negative menu expansion and breakpoint updates for the Accelerate PhenoTest® BC kit

TUCSON, Ariz., Dec. 19, 2022 /PRNewswire/ -- Accelerate Diagnostics, Inc. (NASDAQ: AXDX) today announced that the Company has submitted a 510(k) application to the FDA for Gram-negative menu expansion and breakpoint updates for the Accelerate PhenoTest® BC kit. Included in the submission are additional escalation and de-escalation agents for Gram-negative organisms, additional antibiotics for *Acinetobacter baumannii*, and breakpoint updates. These updates add oral de-escalation antibiotic options for clinicians to use, which can assist with expediting patient discharge plans.

Jack Phillips, Chief Executive Officer of Accelerate Diagnostics, stated, "We are very excited to offer this updated PhenoTest panel, which adds meaningful new antibiotic choices for clinicians to minimize time to optimal therapy for patients with bloodstream infections. These additions and improvements will increase the value of the Pheno system in hospitals across the country, enhancing the clinical value labs have been experiencing for the past several years. We continue to innovate to provide laboratories with lifesaving technology for patients with serious infections."

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

Certain of the statements made in this press release are forward looking or may have forward looking implications. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. 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 March 14, 2022, and in any other reports that the company files with the Securities and Exchange Commission. The company's forward-looking statements could be affected by general industry and market conditions, and regulatory approvals. 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.

SOURCE Accelerate Diagnostics, Inc.

For further information: For further information: Investor Inquiries & Media: Laura Pierson, Accelerate Diagnostics, +1 520 365-3100, investors@axdx.com

---

https://ir.axdx.com/2022-12-19-Accelerate-Diagnostics-submits-510-K-application-to-FDA-for-Gram-negative-menu-expansion-and-breakpoint-updates-for-the-Accelerate-PhenoTest-R-BC-kit