Studies Confirm Rapid Phenotypic Susceptibility Results Enable Earlier Antimicrobial Intervention and Better Patient Outcomes

From IDWeek™, the annual meeting of the Infectious Diseases Society of America (IDSA) held in Washington, DC October 2 - 6.

TUCSON, Ariz., Oct. 3, 2019 /PRNewswire/ -- Accelerate Diagnostics, Inc. today announced presentation of full data from three outcome studies at IDWeek™ 2019. The full data being presented build upon the high-level findings that were first reported in the Company's September 18, 2019 press release.

"We are thrilled to see these data, which demonstrate conclusively that the Accelerate PhenoTest™ BC kit positively impacts clinical outcomes across a diverse set of institutions and patient populations. The studies show an improvement in antibiotic use, a necessary factor for lowering the risk of multidrug-resistant infections and in preserving the patient's vital functions, while also improving the hospital's bottom line by reducing patient length of stay," commented Dr. Romney Humphries, Chief Scientific Officer of Accelerate Diagnostics and former UCLA Section Chief for Clinical Microbiology.

The first of the studies is RAPIDS-GN (ClinicalTrials.gov # NCT03218397), a randomized controlled trial conducted at Mayo Clinic and UCLA**.** RAPIDS-GN focused on Gram-negative bacteremia and randomized patients to be tested by the BC kit or legacy methods. The study met the primary endpoint of therapy optimization, reporting time to first Gram-negative antibiotic change a full 24 hours sooner than legacy methods (17.4 hours vs. 42.1 hours, $p<0.01$) and time to any antibiotic change 6 hours sooner (8.6 hours vs. 14.9 hours, $p=0.02$).

"This study was a success. We believe that shortening the time from empiric to targeted antibiotic therapy by over 24 hours is a clinically significant difference as more rapid, actionable results can lead to better care for patients with sepsis," said Dr. Ritu Banerjee, PI of RAPIDS-GN and former Mayo Clinic MD PhD.

A prior study by the Mayo Clinic was unable to demonstrate any statistically significant differences in similar antibiotic use endpoints for patients with Gram-negative bacteremia when using a molecular ID-only test (BioFire™), highlighting the fact that both rapid ID and phenotypic AST are required for physicians to take early, and potentially life-saving, action to adjust antibiotics for these patients.

RAPIDS-GN also reported on secondary endpoints such as length of stay (LOS) and mortality but did not find statistically significant differences. "The study was not powered to detect differences in these outcomes," commented Dr. Banerjee. "Patients in the rapid testing arm were sicker than those in the control arm, which may have biased against seeing a benefit in these outcomes."

Mayo Clinic has among the lowest rates of Gram-negative resistant bacteria in the U.S., with a short baseline LOS of 7.1 days. UAMS, with a baseline LOS of 11.9 days as reported at IDWeek™ 2019, was able to reduce LOS for its patients by over two days to 9.5 days with the Accelerate Pheno™ system with no additional changes to their existing stewardship practices.

Following review of the data from RAPIDS-GN, Mayo Clinic purchased the Accelerate Pheno™ system, furthering its investment in antibiotic stewardship and its focus on improving patient care by reducing antibiotic overuse. Other institutions like UAMS and University of Iowa, which also reported data on the system at IDWeek™ 2019, also purchased the Accelerate Pheno™ system to bolster their antibiotic stewardship programs and help reduce hospital LOS.

Unlike RAPIDS-GN, the University of Iowa and UAMS studies evaluated patients with both Gram-positive and Gram-negative bloodstream infections. UAMS specifically reported the different impact of the system for Gram-positive and Gram-negative patient groups, showing a statistically significant decrease in time on broad-spectrum Gram-positive coverage (e.g., vancomycin) of 23.3 hours ($p=0.02$) and a decrease of time on broad-spectrum Gram-negative coverage (e.g., piperacillin-tazobactam) of 38.4 hours ($p<0.01$) with the Accelerate Pheno™ system. "I find the outcomes of the study to be very exciting. We continued to demonstrate an overall hospital length of stay reduction. Also, an important area for impact are the patients in whom we are already not expecting a long length of stay. Accelerate allows us to have good results early on, rapidly adjust to the appropriate antibiotics, and move towards discharge. We can provide safe, effective care, and minimize the patients' healthcare exposure," said Dr. Katherine Lusardi, Stewardship Pharmacist at University of Arkansas for Medical Sciences.

"Since implementing Pheno at our institution, we are able to obtain identification and susceptibility data much quicker, allowing us to provide more effective and safer patient care. I believe wholeheartedly that we're doing a better job and patients are benefiting," said Dr. Ryan Dare, Infectious Diseases MD at UAMS. "From a business

perspective, our hospital administration is aware of the program and has been thrilled with the reductions in length of stay due to Accelerate."

Similarly, data from the University of Iowa showed not only a de-escalation benefit, but also that 34% (95 out of 277 instances) of antibiotic stewardship interventions driven by Accelerate Pheno™ system results were escalations of antibiotic therapy. Dr. Bradley Ford, principal investigator for the study and laboratory director, commented, "This is the utility of phenotypic methods like Pheno: most cases are about narrowing or stopping therapy, not about high-level resistance. We've actually been surprised at how often we've had to broaden therapy."

Dr. Ford concluded, "The results of our study, combined with the others presented at IDWeek™, should give all institutions the confidence they need that adopting rapid ID and phenotypic AST methods will have a positive clinical impact on top of improved laboratory metrics."

For additional information about the authors, data, or presentation times, access the abstracts online:

Randomized Clinical Trial Evaluating Clinical Impact of RAPid IDentification and Antimicrobial Susceptibility Testing for Gram-Negative Bacteremia (RAPIDS-GN)

Impact of Accelerate Pheno Rapid Blood Culture Detection System with Real Time Notification versus Standard Antibiotic Stewardship on Clinical Outcomes in Bacteremic Patients

Real-World Impact of Accelerate Pheno Implementation with Antimicrobial Stewardship Intervention

About Accelerate Diagnostics, Inc.

Accelerate Diagnostics, Inc. (NASDAQ: AXDX) 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 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's infection—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, such as those, among others, about the company's projections as to when certain key business milestones may be achieved, the potential of the company's products or technology, the growth of the market, the company's estimates as to the size of its market opportunity and potential pricing, the company's competitive position and estimates of time reduction to results, and its future development plans and growth strategy. 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. The company's forward-looking statements could be affected by general industry and market conditions. 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.

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