Accelerate Diagnostics Announces FDA Emergency Use Authorization for COVID-19 Antibody Testing System

TUCSON, Ariz., Aug. 18, 2020 /PRNewswire/ -- Accelerate Diagnostics, Inc. (NASDAQ: AXDX) and BioCheck, Inc., a privately-held San Francisco-based company focused on *in vitro* diagnostics, today announced that the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the BioCheck SARS-CoV-2 IgM and IgG Combo Test and fully-automated MS-Fast instrument.

In accordance with the previously disclosed commercial supply and collaboration agreement, Accelerate Diagnostics will market, commercialize, and support this serology-based testing platform. The MS-Fast system and BioCheck SARS-CoV-2 chemiluminescence tests are capable of processing human serum samples in 30 minutes to detect antibodies that indicate recent or prior COVID-19 infection.

"The BioCheck SARS-CoV-2 IgM and IgG Combo Test targets the S1 protein, which is the major antigen of the novel coronavirus," stated Shelley Campeau, Accelerate Diagnostics' Clinical Trials Manager. "The S1 protein has the fewest similarities to other coronaviruses, which allows for a lower probability of false positives due to cross reactivity. The S1 protein is also the primary target for the leading COVID-19 vaccines candidates, which are being developed to neutralize antibodies that can block the virus from infecting healthy cells. Several other EUA approved tests target the nucleocapsid (N) protein, but we believe the S1 protein antibodies are more likely to be protective against infection and are thus a more clinically relevant marker."

Jack Phillips, Accelerate Diagnostics' Chief Executive Officer, also commented, "This EUA will allow for more widespread adoption of the MS-Fast serology-based COVID-19 antibody testing platform. Serology testing is an important tool in the fight against COVID-19, as it enables the demographic and geographic surveillance necessary to guide an appropriate response to the current pandemic. Today's announcement represents the next phase of our commercialization efforts to make a simple-to-use, scalable platform for COVID-19 serology testing available to all laboratories."

Dr. Amy Zhang, Vice President and General Manager of BioCheck, stated, "This EUA is a strong testament to the performance of our tests. Through our partnership with Accelerate Diagnostics, we believe that the MS-Fast instrument and BioCheck SARS-CoV-2 IgM and IgG Combo Test will provide a fast and reliable platform for COVID-19 serology testing across the globe."

For further information regarding the BioCheck SARS-CoV-2 IgM and IgG Combo Test and fully-automated MS-Fast instrument, please visit our Accelerate Diagnostic Inc.'s website at http://acceleratediagnostics.com/sars-cov-2.

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.

The "ACCELERATE DIAGNOSTICS" and "ACCELERATE PHENO" and "ACCELERATE PHENOTEST" and diamond shaped logos and marks are trademarks or registered trademarks of Accelerate Diagnostics, Inc.

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

About BioCheck, Inc.

Since 1997, biotechnology company BioCheck, Inc. has been engaged in the development and manufacturing of high-quality*in vitro* diagnostic test kits for the worldwide biomedical, pharmaceutical, and scientific research markets under cGMP and ISO 13485 standards. BioCheck is commercializing the MS-FAST analyzer (automated chemiluminescent immunoassay system) and associated Covid-19 and other cytokine, metabolic, and cardiovascular test kits to allow convenient, instant, and accurate diagnosis of disease markers with a bench top instrument. In addition, the company also develops ultra-sensitive assays using Simoa™ technology (single molecule array), a powerful tool for detecting low-abundance biomarkers.

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"). Such forward-looking statements include our expected performance and accuracy of the MS-Fast system and BioCheck SARS-CoV-2

chemiluminescence test, and our anticipated more widespread adoption and commercialization of the MS-Fast system and BioCheck SARS-CoV-2 chemiluminescence test following FDA EUA approval. 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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