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AlloSure Featured in Journal of Applied Laboratory Medicine

Defines Cell-free DNA Levels in Stable Kidney Transplant Patients

BRISBANE, Calif., March 14, 2017 (GLOBE NEWSWIRE) -- CareDx, Inc. (Nasdaq:CDNA), a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant recipients, announces a publication in the *Journal of Applied Laboratory Medicine.* This report describes the biological variation and clinical reference intervals of donor-derived cell-free DNA (dd-cfDNA) in stable healthy renal transplant recipients.

Lead author Dr. Jonathan S. Bromberg, Vice Chair Research at the University of Maryland, School of Medicine, stated, "This report for the first time establishes the biological variation and reference intervals for the AlloSure® test in a population of clinically stable renal transplant recipients. The biological variability of the test in a reference renal transplant population is critical to the clinical interpretation of results in allograft recipients, who may undergo serial monitoring of dd-cfDNA to assess the status of the allograft."

Key Findings:

- Stable, healthy renal transplant recipients have a median AlloSure level of 0.21%.
- 96% of AlloSure results for stable, healthy renal transplant patients are below 1% dd-cfDNA.
- The reference change value RCV(%), for AlloSure is 61. This reference change value defines the relative change, between two sequential results from an individual that may be considered clinically significant.

This reference population was selected from the cohort of subjects enrolled in the DART study (Circulating Donor-Derived Cell-Free DNA in Blood for Diagnosing Acute Rejection in Kidney Transplant Recipients, NCT02424227) Rigorous demonstration of the assay analytical variation of the clinical-grade AlloSure assay used in this study was critical to these findings.

James P. Yee M.D., Ph.D., Chief Medical Officer at CareDx, Inc. said, "This report is important for the clinical interpretation of AlloSure test results as it assists clinicians to stratify their patients, and manage their care accordingly. The AlloSure level offers a new criterion that clinicians may consider in addition to other conventional factors used to make decisions regarding immunosuppressive medications in individual renal transplant patients."

The link to the publication: http://jalm.aaccjnls.org/content/early/2017/03/13/jalm.2016.022731

NOTES FOR CITATION OF PUBLICATION

"Biological Variation of Donor-derived Cell-free DNA in Renal Transplant Recipients: Clinical Implications" by Jonathan S. Bromberg, Daniel C. Brennan, Emilio Poggio, Suphamai Bunnapradist, Anthony Langone, Puneet Sood, Arthur J. Matas, Shikha Mehta, Asif Sharfuddin, Bernard Fischbach, Mohanram Narayanan, Stanley C. Jordan, David J. Cohen, Ziad S. Zaky, David Hiller, Robert N. Woodward, Marica Grskovic, John J. Sninsky, James P. Yee, and Roy D. Bloom. Accepted, in press in The Journal of Applied Laboratory Medicine Feb 2017. Published by American Association for Clinical Chemistry.

ABOUT *THE JOURNAL OF Applied Laboratory Medicine:*

The Journal of Applied Laboratory Medicine (*JALM*) is an international, peer-reviewed AACC publication that showcases clinically relevant laboratory topics in applied and translational research, and thoughtful commentary on the practice of clinical chemistry and laboratory medicine. Through *JALM* the AACC aims to provide a resource to laboratory professionals and the healthcare team for discovering new adaptive solutions for meeting patient care challenges and driving innovation in the field of laboratory medicine. *JALM* also aims to provide Laboratory professionals and the healthcare team with interpretive guidance so that patients receive the most effective care available. As such, *JALM* focuses on cutting edge research in applied and translational laboratory medicine. *JALM* will consider submissions for publication on laboratory methods, evidence-based laboratory medicine, flow cytometry, hemostasis, management, health economics, best practices, test utilization, critical care, and pediatric testing. Additionally, the journal will provide a forum for discussion of policy and

regulatory issues that impact the field.

About CareDx
CareDx, Inc., based in Brisbane, California, is a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value, non-invasive diagnostic surveillance solutions for transplant recipients. The Company has commercialized AlloMap®, a gene expression test that aids clinicians in identifying heart transplant recipients. CareDx is also pursuing the development of additional products for post-transplant monitoring of other solid organs that use a variety of technologies, including next generation sequencing, to detect donor-derived cell-free DNA to monitor the health of organs after transplantation.

CareDx, with its presence through Olerup, also develops, manufactures, markets and sells high quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs.

For more information, please visit: www.CareDx.com.

Forward Looking Statements
This press release contains forward-looking statements about our business, research, development and commercialization efforts including, but not limited to the development, commercialization, utility, performance and adoption of AlloSure. These forward-looking statements are based upon information that is currently available to us and our current expectations, speak only as of the date hereof, and are subject to numerous risks and uncertainties, including risk associated with successful research, development and planned commercialization of our technologies, that are described in our filings with the SEC, including the Annual Report on Form 10-K for the fiscal year ended December 31, 2015 filed by us with the SEC on March 29, 2016 and the Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2016 filed by us with the SEC on November 14, 2016. Any of these may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements. We expressly disclaim any obligation, except as required by law, or undertaking to update or revise any such forward-looking statements.

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Source: CareDx, Inc.