



NEWS RELEASE

CareDx Completes Analytical Validation of AlloSure: A Next-Generation Sequencing Test Measuring Donor-Derived Cell-Free DNA in Transplant Patients

Brisbane, CA — December 23, 2015—CareDx, Inc. (Nasdaq: CDNA), a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic surveillance solutions for transplant patients today announced the completion of analytical validation for AlloSure™, a proprietary next-generation sequencing (NGS) test that measures the percent of donor-derived cell-free DNA (dd-cfDNA) in solid organ transplant recipients.

AlloSure quantifies dd-cfDNA in transplant recipients without prior knowledge of the donor or recipient genotype. Samples used in the analytical validation included donor recipient pairs with unrelated as well as closely related family members. Plasma samples for AlloSure will be tested in the recently expanded purpose-built CLIA laboratory space at CareDx. AlloSure is now available for order through CareDx.

In 2015, CareDx presented preliminary data on the increase of dd-cfDNA prior to rejection and the decrease of dd-cfDNA following immunosuppressive therapy in heart and kidney transplant recipients at several professional society meetings. Multi-centered observational studies for heart and kidney transplant patients are underway to inform future clinical validity and utility. The company is building a valuable biorepository of well annotated blood samples in transplantation for further research and development.

“AlloSure is an innovative approach to better understand the underlying pathology of transplantation genomics,” says Peter Maag, PhD, CEO and President of CareDx. “It builds on our commitment and experience with AlloMap, our surveillance solution for heart transplant patients.”

The development of AlloSure has involved several best-in-class technology partners, including Horizon Discovery for analytical reference standards and DNAnexus for cloud platform computational analysis. CareDx used the National Institute of Standards and Testing (NIST) human reference genome in the validation to ensure that this new test is accurate, reproducible and establishes a reference for ongoing methods-based proficiency testing.

The use of NGS platforms for clinical testing has grown significantly in recent years. Several professional organizations such as the Association of Molecular Pathology (AMP) have issued guidelines on the quality and consistency of results when NGS based technology is used for sequencing. CareDx is a participant in the federal level creation of standards for NGS sequencing and has used these same standards in the analytical validation of AlloSure.

CareDx welcomes proposals for scientific collaborations using AlloSure.

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 diagnostic surveillance solutions for transplant patients. The company has commercialized AlloMap®, a gene expression test that aids clinicians in identifying heart transplant patients with stable graft function who have a low probability of moderate/severe acute cellular rejection. CareDx is also pursuing the development of additional products for transplant monitoring using a variety of technologies, including AlloSure, its next-generation sequencing-based test to detect donor-derived cell-free DNA after transplantation. For more information, please visit: www.CareDx.com.

Forward Looking Statements

This press release contains forward-looking statements including, but not limited to statements regarding the Company's expectations regarding future potential, development and commercial activities. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward looking statements are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in the forward looking statements, including CareDx's limited operating history and experience with developing new markets; risk relating to new partnerships and commercialization of those relationships, as well as other risks stated in CareDx's filings with the SEC located at www.sec.gov. CareDx disclaims any obligation to publicly update or revise any forward looking statements to reflect events that occur or circumstances that exist after the date on which they were made.

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AlloSure is not available for testing samples that originate in the State of New York.