



## CareDx Supports FDA Development of Next Generation Sequencing Guidelines, Offers Further Perspective on Clinical Grade Quality and Data

**BRISBANE, Calif., August 1, 2016:** CareDx, Inc. (CDNA), a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients, commends the FDA on the release of two draft guidance documents on the standards and the use of public databases for variant detection for Next Generation Sequencing (NGS). Both documents were further supported through a hosted webinar on July 27.

CareDx is an active stakeholder and has provided comments to develop these guidance documents at FDA NGS workshops held in November 2015 and February 2016. Most recently CareDx contributed to an article in *Medtech Insight* about how these new guidelines will encourage collaboration.

The draft standards guideline focuses on analytical validity and is consistent with guidelines and recommendations from several laboratory organizations, including the American College of Medical Genetics (ACMG), the Association of Molecular Pathology (AMP), the College of American Pathologists (CAP) and the New York State Clinical Laboratory Standards of Practice. While the draft standards guidance is not directed to NGS testing in transplantation, the development and validation of AlloSure<sup>®</sup>, an NGS test which measures organ injury associated with rejection through the detection of donor-derived cell-free DNA (dd-cfDNA) in transplant patients, meets or exceeds proposed recommendations.

The draft guideline on the use of variant databases provides specific comments on transparency and quality of scientific evidence for reporting sequence changes associated with inherited diseases. AlloSure was specifically designed to exclude inherited disease sequence variants in order to avoid the potential confusion of incidental findings for clinicians and patients.

This level of rigor and commitment to highest quality standards of molecular testing was first demonstrated through the company's submission and pioneering work to obtain 510(k) clearance for AlloMap<sup>®</sup>, a gene expression test to identify heart transplant recipients with stable allograft function who have a low probability of moderate/severe acute cellular rejection (ACR).

"We are proud to be able to contribute our recommendations to the regulatory oversight of this powerful technology and applaud the FDA on a clear and informative webinar describing the recent NGS guidance. This agency is breaking new ground in adopting flexible and adaptive regulatory oversight with this guidance document." commented Mitch Nelles, Ph.D., Chief Operations Officer at CareDx.

CareDx's application of NGS technology to organ transplant represents another example of the company's efforts to remain in the forefront of translational medicine for transplant patients. These efforts are aligned with President Obama's Precision Medicine Initiative to accelerate the translation of innovation to care and extend the lives of patients.

**About CareDx**

CareDx, Inc., headquartered in Brisbane, California, is a global molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients. CareDx offers AlloMap®, a gene expression test that aids clinicians in identifying heart transplant patients with stable graft function who have a low probability of moderate to severe acute cellular rejection (ACR). CareDx is developing additional products for transplant monitoring using a variety of technologies, including AlloSure®, a proprietary next-generation sequencing–based test to detect donor-derived cell-free DNA (dd-cfDNA) 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. Olerup SSP® is a set of HLA typing products used prior to hematopoietic stem cell/bone marrow transplantation and organ transplantation. XM-ONE® is the first standardized test that quickly identifies a patient's antigens against HLA Class I, Class II or antibodies against a donor's endothelium. For more information, please visit: [www.CareDx.com](http://www.CareDx.com).

**Forward Looking Statements**

This press release includes or implies forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that are subject to risks, uncertainties and other factors, including the risk that we may not be successful in our efforts to develop and commercialize AlloSure, a NGS diagnostic test based on sequencing cell-free DNA. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in CareDx's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, and Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to CareDx, and CareDx assumes no obligation to update any such forward-looking statements.

**Media Contact**

Molly Martell, CareDx, Inc.  
T: +1 415-728-6307  
[mmartell@caredx.com](mailto:mmartell@caredx.com)

**Investor Contact**

Jamar Ismail, Westwicke Partners  
T: +1 415-513-1282  
[jamar.ismail@westwicke.com](mailto:jamar.ismail@westwicke.com)