



NEWS RELEASE

CareDx Launches Two Expanded Indications for AlloSure Testing Services

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AlloSure Heart is Now Validated and Commercially Available for Pediatric Heart Transplant Patients Under 15

AlloSure Kidney is Now Validated and Commercially Available for Simultaneous Pancreas-Kidney Transplant Patients

BRISBANE, Calif.--(BUSINESS WIRE)-- CareDx, Inc. (Nasdaq: CDNA) – The Transplant Company™ – a leading precision medicine company focused on the discovery, development, and commercialization of clinically differentiated, high-value healthcare solutions for transplant patients and caregivers – today announced that AlloSure® is now commercially available for pediatric heart transplant patients of all ages and patients who have received a simultaneous pancreas-kidney (SPK) transplant.

Both indications are approved by the New York State Clinical Laboratory Evaluation Program, demonstrating that AlloSure has met the most rigorous validation standards for laboratory developed tests (LDTs).

AlloSure Heart, available for patients aged 15 years and older since 2020, is now clinically validated and commercially available for use in pediatric patients under 15, including infants. Studies have shown that AlloSure Heart can detect biopsy proven Acute Cellular Rejection (ACR) and AMR (Antibody Mediated Rejection) in all ages of pediatric heart transplant patients, consistent with its performance in adults.¹⁻⁴ In a prospective study, the use of AlloSure dd-cfDNA for surveillance monitoring in pediatrics demonstrated an 81% reduction in surveillance endomyocardial biopsies (EMB).¹

"The availability of AlloSure dd-cfDNA for all pediatric heart transplant patients is a major development. Our goal is

for every one of our patients, including our youngest heart transplant recipients, to thrive with their transplanted heart. With molecular surveillance we can monitor organ health while avoiding the inconvenience and discomfort of unnecessary biopsies,” said Dr. Brian Feingold, Medical Director, Pediatric Heart Transplantation, UPMC Children’s Hospital of Pittsburgh. “We consider the use of surveillance biopsies outside of the first 2 or 3 months after transplantation to be outdated now that AlloSure is available for every pediatric heart transplant recipient.”

Simultaneous pancreas-kidney (SPK) transplants are known to improve the quality of life and long-term survival of patients with insulin dependent diabetes and advanced renal disease.⁵ As with other organ transplants, the organs are at risk of rejection. AlloSure Kidney has been clinically validated to identify rejection and graft injury in SPK patients.⁶⁻⁷ AlloSure Kidney can improve the management of SPK patients by differentiating those at increased risk of rejection, who are otherwise stable, from patients at low likelihood of rejection.

“It is an honor to have led some of the early studies and to see that AlloSure Kidney is now clinically validated and commercially available for use in patients who have undergone simultaneous pancreas-kidney transplantation,” said Dr. Dolamu Olaitan, MBBS, Transplant Surgeon, Rush University Medical Center. “I have witnessed firsthand the significant benefits for patients with diabetes and kidney failure of receiving a pancreas and kidney transplant. Now, we have a well-validated, non-invasive tool to monitor organ rejection and injury, which has the potential to improve their quality of life and long-term outcomes.”

“We are thrilled to introduce two new expanded indications of AlloSure, addressing critical needs in transplant patient care. Until now, children under 15 who received a heart transplant could only be tested by exception, but now they can receive routine AlloSure Heart testing. Additionally, for patients who have undergone a simultaneous pancreas-kidney transplant, we have a solution to meet their needs,” said Robert N. Woodward, CareDx Chief Scientific Officer.

In 2024, over 4,500 heart transplants were performed in the U.S. with about 10 percent under the age of 18.⁸ Additionally, in 2024 more than 700 patients received an SPK transplant.⁸

About CareDx – The Transplant Company

CareDx, Inc., headquartered in Brisbane, California, is a leading precision medicine solutions company focused on the discovery, development, and commercialization of clinically differentiated, high-value healthcare solutions for transplant patients and caregivers. CareDx offers testing services, products, and digital healthcare solutions along the pre- and post-transplant patient journey and is the leading provider of genomics-based information for transplant patients. For more information, please visit www.caredx.com.

Forward Looking Statements

This press release includes forward-looking statements related to CareDx, Inc., including statements regarding the potential benefits and results that may be achieved with AlloSure Heart and AlloSure Kidney. These forward-looking statements are based upon information that is currently available to CareDx and its current expectations, speak only as of the date hereof, and are subject to numerous risks and uncertainties, all of which are difficult to predict and many of which are beyond CareDx's control, that could cause actual results to differ materially from those projected, including risks that CareDx does not realize the expected benefits of AlloSure Heart and AlloSure Kidney. These statements are also subject to general economic and market factors, and global economic and marketplace uncertainties, among other risks discussed in CareDx's filings with the Securities and Exchange Commission (the "SEC"), including, but not limited to, the Annual Report on Form 10-K for the fiscal year ended December 31, 2024 filed by CareDx with the SEC on February 28, 2025, and other reports that CareDx has filed with the SEC. Any of these may cause CareDx's actual results, performance, or achievements to differ materially and adversely from those anticipated or implied by CareDx's forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements. CareDx expressly disclaims any obligation, except as required by law, or undertaking to update or revise any such forward-looking statements, whether as a result of new information, future events or otherwise.

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