NEWS RELEASE

# Landmark Study Shows CareDx's HeartCare Outperforms dd-cfDNA Alone in Identifying Rejection and Patients Experienced Excellent Outcomes with Fewer Biopsies

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HeartCare Results Effectively Stratified Patients at Highest Risk for Acute Cellular Rejection

Cardiologists Performed the Fewest Biopsies After Dual Negative HeartCare Results Compared to Single or Dual Positive Results

Two-Year Clinical Outcomes Data Demonstrate Excellent Survival and Allograft Function

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 findings from the SHORE (Surveillance HeartCare Outcomes Registry) study, one of the largest heart transplant studies of its kind, published in **The Journal of Heart and Lung Transplantation**.

The prospective observational study demonstrates that HeartCare® which combines AlloSure® Heart donor-derived cell-free DNA (dd-cfDNA) and AlloMap® Heart gene-expression profiling (GEP), identifies acute cellular rejection in heart transplant patients better than dd-cfDNA testing alone and is associated with fewer biopsies and excellent clinical outcomes.[1]

## Key Findings from the SHORE Study Publication[1]:

- Dual-positive HeartCare results are associated with the highest incidence (9.2%) of acute cellular rejection (ACR), whereas dual-negative HeartCare results are associated with the lowest incidence (1.5%) of ACR.
- Follow-up endomyocardial biopsies (EMB) are performed at the lowest rate (8.8%) following a dual-negative HeartCare result, and at the highest rate (35.4%) following a dual positive HeartCare result.
- The rate of biopsies performed in response to a single positive result is 56% lower than dual-positive HeartCare results.
- Clinician behavior to HeartCare results changed over time as centers gained experience with the testing. By the end of the study cardiologists performed 10% fewer biopsies in the first year post-transplant and 40% fewer in the second year post-transplant despite an increase in follow-up biopsy rates for dual positives.
- Excellent clinical outcomes were observed in patients managed with HeartCare including fewer follow-up endomyocardial biopsies, 95% survival and 97% with normal allograft function at two years post-transplantation.

“This large, prospective, multicenter study demonstrates that HeartCare significantly improves clinicians’ ability to assess acute cellular rejection risk and its use is associated with lower biopsy rates and excellent clinical outcomes two-years post-transplant,” said John W. Hanna, CareDx President and CEO.

“The SHORE study confirms the superior performance of dual molecular testing, combining donor-derived cell-free DNA and gene-expression profiling for acute cellular rejection surveillance in optimizing care for heart transplant patients. This approach allows for refined patient selection for surveillance biopsies, leading to fewer invasive procedures over time while maintaining vigilant ACR monitoring, and achieving excellent clinical outcomes,” said Kiran Khush, MD, MAS, Cardiologist, Professor of Cardiovascular Medicine, Stanford Medicine.

One of the largest heart transplant studies of its kind, SHORE is a prospective 67-center, observational study of over 2,700 heart transplant patients in the United States receiving non-invasive molecular testing with AlloSure Heart dd-cfDNA and AlloMap Heart GEP or HeartCare. Together, these different molecular tests offer a more comprehensive evaluation of a patient’s heart transplant status by assessing both allograft health and immune system activity. The published study was designed to evaluate the utility of combined molecular testing using HeartCare for acute cellular rejection (ACR) surveillance.

To read the publication, go **here**.

## 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 HeartCare, which combines AlloSure Heart donor-derived cell-free DNA (dd-cfDNA) and AlloMap Heart gene-expression profiling (GEP). 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 risks and uncertainties that could cause actual results to differ materially from those projected, including risks that CareDx does not realize the expected benefits of HeartCare, which combines AlloSure Heart donor-derived cell-free DNA (dd-cfDNA) and AlloMap Heart gene-expression profiling (GEP); risks that the findings in the SHORE study supporting the data may be inaccurate, general economic and market factors; and 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, 2023 filed by CareDx with the SEC on February 28, 2024, the quarterly report on Form 10-Q for the quarter ended March 31, 2024 filed by CareDx with the SEC on May 9, 2024 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. CareDx expressly disclaims any obligation, except as required by law, or undertaking to update or revise any such forward-looking statements.

## References:

1. Khush K, Hall S, Kao A, et al. Surveillance with Dual Non-invasive Testing for Acute Cellular Rejection After Heart Transplantation: Outcomes from the Surveillance HeartCare Outcomes Registry (SHORE). The Journal of Heart and Lung Transplantation. Published online May 15, 2024. DOI: **https://doi.org/10.1016/j.healun.2024.05.003**

## CareDx, Inc.

Media Relations

Anna Czene

818-731-2203

**aczene@caredx.com**

Investor Relations

Greg Chodaczek

**investor@caredx.com**

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