



NEWS RELEASE

# CareDx Announces Largest Landmark Study of Its Kind on Antibody Mediated Rejection in Heart Transplantation Published in Journal of the American College of Cardiology: Heart Failure

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Second SHORE Study Validates AlloSure Heart, an Integral Component of HeartCare, as a Reliable Biomarker for Antibody-Mediated Rejection in Heart Transplant Recipients

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- CareDx, Inc. (Nasdaq: CDNA) – 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 the publication of the second study from Surveillance HeartCare Outcomes Registry (SHORE) in the Journal of the American College of Cardiology: Heart Failure. It is the largest prospective analysis of antibody-mediated rejection (AMR) in heart transplantation, including 2,240 patients across 59 U.S. transplant centers and analyzing 24,768 biopsies, 8,851 paired donor-derived cell-free DNA (dd-cfDNA) samples measured using AlloSure® Heart, and 136 AMR-positive biopsies paired with dd-cfDNA results. AlloSure, in combination with AlloMap, form HeartCare – a non-invasive and clinically validated approach to heart transplant surveillance.

“SHORE is a landmark in heart transplantation, validating AlloSure Heart as a reliable biomarker for antibody mediated rejection and enabling more precise, context-driven decision-making,” said Amit Alam, MD, Assistant Professor, Department of Medicine at NYU Grossman Long Island School of Medicine and author of the publication. “This study empowers clinicians to further reduce surveillance biopsies and improve patient care.”

The second SHORE study established a new benchmark in transplant diagnostics as the largest published dataset

for molecular testing in AMR and demonstrated that AlloSure Heart results  $\geq 0.50\%$  were highly specific (92.8%) for AMR diagnosis.

## Key Findings

- AlloSure Accurately Identified AMR: Elevated AlloSure Heart levels were strongly associated with biopsy-proven AMR, with higher values correlating with more severe grades of rejection.
- HeartCare Enabled Context-Dependent Thresholds: Different AlloSure thresholds were established based on clinical context. For patients with low pre-test probability (no DSA, normal graft function), higher thresholds ( $\geq 0.50\%$ ) may safely reduce unnecessary biopsies and modest elevations (0.2-0.49%) should only trigger biopsies if AlloMap is positive indicating a risk of ACR.
- Treatment Response Monitoring: AlloSure Heart levels declined following presumed treatment for AMR, supporting its use as a marker for therapeutic response.

"SHORE provides compelling evidence that HeartCare, which includes AlloMap and also AlloSure Heart, can optimize biopsy utilization and clinical decision-making in heart transplant care," said Robert Woodward, Chief Scientific Officer of CareDx. "With the largest AMR molecular dataset to date, CareDx continues to set the standard for data-driven non-invasive testing."

The full publication is available online at: [www.sciencedirect.com/science/article/pii/S2213177925006468](http://www.sciencedirect.com/science/article/pii/S2213177925006468)

## About CareDx

CareDx, Inc., headquartered in South San Francisco, is a precision medicine company focused on the discovery, development, and commercialization of clinically differentiated, high-value healthcare solutions for transplant patients and caregivers. For more information, visit [www.caredx.com](http://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, AlloMap, and HeartCare. 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 AlloSure Heart, AlloMap, and HeartCare, 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, 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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