



NEWS RELEASE

# JACC Publication Guides Use of CareDx's HeartCare Transplant Rejection Surveillance in Clinical Practice

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Guide Helps Transplant Centers Continue the Evolution from Endomyocardial Biopsies to Noninvasive Surveillance Using AlloMap GEP and AlloSure dd-cfDNA

BRISBANE, Calif.--(BUSINESS WIRE)-- CareDx, Inc. (Nasdaq: CDNA) – The Transplant Company™ focused on the discovery, development, and commercialization of clinically differentiated, high-value healthcare solutions for transplant patients and caregivers – today announced that the Journal of the American College of Cardiology (JACC): Heart Failure has published a **detailed guide**<sup>1</sup> to help clinicians transition from routine invasive endomyocardial biopsy (EMB) to a less invasive acute rejection monitoring protocol in clinical practice.

The publication<sup>1</sup> reviews the clinical evidence for noninvasive surveillance, much of which evaluates the multicenter study data demonstrating the clinical utility of AlloMap® gene-expression profiling (GEP) and AlloSure® donor-derived cell-free DNA (dd-cfDNA). The authors also discuss the complementary role of GEP and dd-cfDNA and review the data suggesting that the tests can be used together for effective noninvasive rejection surveillance in heart transplant patients.

“CareDx is very proud to have helped clinicians shift their reliance on invasive EMBs to non-invasive solutions for routine heart transplant surveillance. We’ve led the way by delivering an extensive body of clinical evidence in support of our HeartCare® testing services, AlloMap and AlloSure,” said Reg Seeto, CEO and President of CareDx. “I am delighted to see the publication of the JACC: Heart Failure guide on the heels of the new International Society for Heart and Lung Transplantation guidelines<sup>2</sup> that support the routine use of both GEP and dd-cfDNA.”

Key Highlights:



- Rejection surveillance using GEP and dd-cfDNA, such as AlloMap and AlloSure is noninferior to endomyocardial biopsy.
- The use of multimodal solutions including GEP to assess immune quiescence and dd-cfDNA to identify graft injury, offers a robust strategy for the surveillance of heart transplant recipients.
- AlloSure and AlloMap have been tested and validated for acute rejection surveillance in numerous multicenter studies.
- Non-invasive surveillance indicators of rejection can precede pathological rejection diagnosis.

“Much innovation has occurred over the past decade and there is strong evidence for using noninvasive rejection surveillance. By using both GEP and dd-cfDNA, it is conceivable that transplant programs could perform noninvasive surveillance for a growing number of heart transplant recipients,” said Luise Holzhauser, MD, lead author, Assistant Professor of Clinical Medicine at University of Pennsylvania Advanced Heart Failure and Transplant Cardiology. “We are at the precipice of evolving to a new standard of care in heart transplant surveillance, from routine endomyocardial biopsies to noninvasive surveillance, using GEP and dd-cfDNA, and I am proud to have worked with a fantastic group of co-authors to develop this practical guide to help make this evolution possible.”

Since the introduction of AlloMap Heart in 2005 and AlloSure Heart in 2020 as part of HeartCare, many leading heart transplant centers across the U.S. have independently established their own HeartCare surveillance testing protocols in their clinical practice based on the extensive published literature and their own experience of the services’ clinical value. HeartCare is used in more than 90 percent of the nation’s heart transplant centers and in more than 1 in 2 newly transplanted patients.

## 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](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 CareDx’s HeartCare, including AlloSure and AlloMap testing services, and JACC publication’s support of the use of AlloSure and AlloMap. 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, AlloSure and AlloMap; risks that the JACC publication's review on the use of AlloSure and AlloMap may not be accurate; general economic and market factors; and other risks discussed in CareDx's filings with the SEC, including the Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed by CareDx with the SEC on February 24, 2022, the quarterly report on Form 10-Q for the quarter ended March 31, 2022 filed by CareDx with the SEC on May 5, 2022, the quarterly report on Form 10-Q for the quarter ended June 30, 2022 filed by CareDx with the SEC on August 4, 2022, the quarterly report on Form 10-Q for the quarter ended September 30, 2022 filed by CareDx with the SEC on November 3, 2022, 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. Holzhauser L, DeFilippis E, Nikolova A, et al. The End of Endomyocardial Biopsy? J Am Coll Cardiol HF. null2023, 0 (0).<https://doi.org/10.1016/j.jchf.2022.11.002>
2. Velleca A, Shullo MA, Dhital K, et al. The International Society for Heart and Lung Transplantation (ISHLT) Guidelines for the Care of Heart Transplant Recipients. Journal of Heart and Lung Transplantation. S1053-2498(22)02185-4. <https://doi.org/10.1016/j.healun.2022.10.015>

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