



NEWS RELEASE

# Transplant Patients Experience Less Pain and Fewer Adverse Events with CareDx Non-Invasive Testing Solutions

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Study Reaffirms Benefits of AlloMap, the Industry's Only Gene-Expression Profiling Blood Test, for Heart Transplant Rejection Surveillance

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 a new peer-reviewed publication showing that AlloMap®, the industry's only gene-expression profiling (GEP) blood test to non-invasively assess graft rejection by monitoring immune quiescence in heart transplant patients,<sup>1</sup> resulted in less pain and fewer adverse events compared to heart biopsy.<sup>2</sup> The study also highlights that the associated AlloMap blood test draw can be performed in the patient's home to help reduce the risk of exposure to infection.

In an independent, prospective study performed at Baylor University Medical Center, forty-three heart transplant patients undergoing surveillance with a protocol that included both routine cardiac biopsy and AlloMap testing, reported significantly less pain and experienced fewer adverse events (no bleeding or swelling) with AlloMap than with biopsy.<sup>2</sup>

"We are extremely proud to offer patients AlloMap, the only test of its kind to non-invasively assess graft rejection by monitoring immune quiescence in heart transplant patients," said Reg Seeto, CEO and President of CareDx. "Our dedication to improving the transplant patient journey is at the core of our mission and AlloMap improves patients' quality of life by helping to reduce the pain and adverse events associated with an invasive biopsy procedure."

These study results are consistent with the finding of improved patient satisfaction from the groundbreaking IMAGE (Invasive Monitoring Attenuation through Gene Expression) clinical utility trial published in the New England Journal of Medicine.<sup>3</sup>

"These real-world findings reiterate the value of using this non-invasive test in heart transplant patients. For these patients, an invasive heart biopsy procedure, which is more painful and fraught with potential adverse events is often not necessary, especially for asymptomatic surveillance," said Shelley Hall, MD, Chief of Transplant Cardiology and Mechanical Support/Heart Failure, Baylor University Medical Center. "It's great to have this reminder because often traditional biopsies are used when a less invasive test may be a much better option for many heart transplant patients."

CareDx non-invasive heart transplant solutions, including AlloSure® and AlloMap, have made transplant surveillance a less painful experience for patients. Gwen Chambers and Vang Her, both heart transplant recipients, share their experiences.

"I found biopsies very uncomfortable and scary because I'm awake and only mildly sedated while it's happening, which causes me a lot of anxiety," Gwen said. "If I had the option of AlloMap, that's hands-down my choice over biopsy to monitor my heart's status because it's a much less invasive and traumatic alternative. Hopefully, studies like this one will result in more patients having access to these tests so they can be spared the discomfort, trauma and anxiety resulting from invasive biopsies."

Vang Her added, "For me, biopsies involve painful catheterization through the neck or groin, which have left me bruised, stiff and sometimes with dangerous blood clots, including one in my heart, which took weeks to recover from. With CareDx testing, I receive a simple blood draw and experience no pain and no downtime, which means I can work without interruption, enjoy activities with my wife and kids, and train for the Iron Man competition."

AlloMap became commercially available in 2005 and has the distinction of being the only gene-expression profiling test that has been FDA cleared for use in heart transplant patients,<sup>1</sup> incorporated in International Society for Heart and Lung Transplantation guidelines, and covered by Centers for Medicare & Medicaid Services (CMS) both individually and for multimodality assessment using AlloSure donor-derived cell-free DNA. AlloMap is used in more than 90 percent of the nation's heart transplant centers and in more than 1 in 2 newly transplanted patients.<sup>4</sup> In 2020, CareDx launched HeartCare, which includes both AlloMap and AlloSure, to provide a comprehensive view of organ rejection by assessing immune quiescence and graft injury, and currently accounts for over 90 percent of AlloMap use.<sup>4</sup>

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 non-invasive testing solutions, including AlloMap and AlloSure, and the new study on AlloMap performed at Baylor University Medical Center (the "Study"). 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 its non-invasive testing solutions, including AlloMap and AlloSure, or the Study; risks that the results of the Study 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, 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. AlloMap Testing is intended to aid in the identification of heart transplant recipients with stable allograft function who have a low probability of moderate/severe acute cellular rejection (ACR) at the time of testing in conjunction with standard clinical assessment.
2. Jamil AK, Tecson KM, Ganz TT, et al. Heart transplant Recipients' perspectives on invasive versus Non-invasive graft failure surveillance Methods. *Heart Lung*. 2022 Aug 23; 57:41-44. doi: 10.1016/j.hrtlng.2022.08.003. Epub ahead of print. PMID: 36027738.
3. Pham MX, Teuteberg JJ, Kfoury AG, et al. S IMAGE Study Group. Gene-expression profiling for rejection surveillance after cardiac transplantation. *N Engl J Med*. 2010 May 20;362(20):1890-900. doi: 10.1056/NEJMoa0912965. Epub 2010 Apr 22. PMID: 20413602.
4. CareDx data on file, September 15, 2022.

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