



NEWS RELEASE

# New ISHLT Guidelines Support Use of CareDx's HeartCare Solutions, AlloMap and AlloSure, in Routine Monitoring of Heart Transplant Patients

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ISHLT Guidelines Recommend Earlier Use of AlloMap Heart Starting 2 Months Post-Transplant Based on Strength of Clinical Studies

ISHLT Guidelines Recommend Remote Use of GEP and dd-cfDNA Heart Transplant Surveillance, as in HeartCare, May be Used to Reduce the Need for Biopsies and Hospital Visits

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 the publication<sup>1</sup> of new guidelines by the International Society for Heart and Lung Transplantation (ISHLT) supporting the use of CareDx's non-invasive molecular surveillance portfolio.

The new ISHLT guidelines support the use of CareDx's cardiothoracic portfolio, AlloMap® Heart, AlloSure® Heart, and HeartCare® (AlloMap Heart and AlloSure Heart). Specifically, the guidelines:

- Support the earlier use of AlloMap Heart starting at two months to five years post-transplant versus starting at six months based on strength of clinical studies.<sup>2-4</sup>
- Support AlloMap gene-expression profiling (GEP) and donor-derived cell-free DNA (dd-cfDNA) for routine post-transplant monitoring, which is new in the current guidelines and reflects increased adoption of non-invasive molecular testing in clinical practice. This includes dd-cfDNA which is new in the current guidelines.
- Support remote use of GEP and dd-cfDNA heart transplant surveillance, as in HeartCare, as it may be used to

reduce the need for biopsies and hospital visits, which is new in the current guidelines, and as evidenced during the recent COVID pandemic.

“We applaud ISHLT and the sub-committee for their recognition of the value and importance of innovative, non-invasive solutions, such as AlloSure, AlloMap, and HeartCare, in managing post-heart transplant patients,” said Reg Seeto, CEO and President of CareDx. “We are proud to be the leader in this space by delivering meaningful clinical utility data and for the recognition by the global transplant community through broad adoption of these ongoing innovations.”

The new ISHLT guidelines were discussed during the April ISHLT 2022 meeting and have now been finalized, published and available online in the Journal of Heart and Lung Transplantation [JHLT].<sup>1</sup> These guidelines are an update from the 2010 guidelines.

“A lot of innovation has occurred over the past decade with the introduction of AlloMap and AlloSure, both which have influenced clinical practice, and these are now reflected in the new ISHLT guidelines,” said Dr. Eugene DePasquale, Medical Director of Heart Failure, Heart Transplant and MCS Program at the University of Southern California. “I look forward to the long-term impact on outcomes through the incorporation of both AlloMap gene-expression profiling and AlloSure dd-cfDNA as the new standard of care, which will reduce the need for invasive biopsies with its associated risks for the benefit of patients.”

AlloMap and AlloSure Heart are used in more than 90 percent of the nation’s heart transplant centers and in more than 1 in 2 newly transplanted patients.<sup>5</sup>

“One of the key changes in the new ISHLT guidelines is incorporating donor-derived cell-free DNA, such as AlloSure,” said Dr. Kiran Khush, Professor of Cardiovascular Medicine and Director of Heart Transplant Research, Stanford University. “The importance of routine scheduled biomarker testing has now been captured in the new guidelines and reflects what we saw as a paradigm shift to non-invasive monitoring instead of biopsies in the heart transplant community during the COVID-pandemic.”

## 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 AlloSure, AlloMap, HeartCare, and the recommendation of the use of CareDx non-invasive molecular surveillance portfolio by the new ISHLT guidelines (the “Recommendation”). 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, AlloMap, HeartCare, and the Recommendation; 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:

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5. CareDx data on file.

Media Relations

Anna Czene

818-731-2203

**aczene@caredx.com**

Investor Relations

Ian Cooney

(415) 722-4563

**investor@CareDx.com**

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