



NEWS RELEASE

# CareDx Successfully Completes CLIA Validation of AlloMap Kidney in Preparation for Commercial Launch

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Completing AlloMap Kidney CLIA Validation Represents the Next Step to Offering a More Comprehensive, Multimodality Assessment of Organ Transplant Health

SOUTH SAN FRANCISCO, Calif., Jan. 06, 2022 (GLOBE NEWSWIRE) -- CareDx, Inc. (Nasdaq: CDNA) – The Transplant Company™ focused on the discovery, development, and commercialization of clinically differentiated, healthcare solutions for transplant patients and caregivers – today announced the successful completion of the Clinical Laboratory Improvement Amendments (CLIA) validation for AlloMap® Kidney, a blood-based gene expression classifier that identifies immune quiescence, an important biomarker needed to comprehensively assess immunological risk of rejection and allograft health.

In clinical validation, published in **Kidney360**, AlloMap Kidney demonstrated the ability to differentiate between rejection (both T-cell mediated rejection [TCMR] and antibody-mediated rejection [AMR]) and immune quiescence, and provide an assessment of immunological activity additive to the allograft injury information derived from AlloSure Kidney donor-derived cell-free DNA (dd-cfDNA), with a combined area under the curve (AUC) of 0.894.<sup>1</sup> Together, these two biomarkers offer a more comprehensive assessment of kidney health compared to the current standard of care. CareDx's AlloMap Kidney along with AlloSure Kidney forms KidneyCare, a multimodality solution that has been studied in the Outcomes of KidneyCare in Renal Allografts (OKRA) registry across 50 transplant centers.

“As the market leader in transplant and the company that consistently delivers innovations to improve outcomes for transplant recipients, we are excited that our first and best-in-class technologies, and expertise in multimodality



HeartCare, are being used in KidneyCare,” said Reg Seeto, CEO and President of CareDx. “We are pleased to have completed CLIA validation of AlloMap Kidney on schedule and to be moving a step closer to the commercialization of KidneyCare, a breakthrough multimodality solution that will help clinicians more comprehensively monitor the organ health of their kidney transplant patients.”

“Multimodality assessment of allograft health represents the next important step in the evolution of kidney transplant care. By adding an immune quiescence assessment to organ rejection monitoring, clinicians can tailor earlier therapeutic interventions that not only improve health outcomes, but ultimately improve overall quality of life by reducing the need for dialysis use,” said Enver Akalin, MD, at Montefiore Medical Center. “This CLIA validation brings us one step closer to being able to use AlloMap Kidney in our practice and I look forward to being able to incorporate it along with AlloSure Kidney for a more complete assessment of my patient’s organ transplant health.”

#### About CareDx – The Transplant Company

CareDx, Inc., headquartered in South San Francisco, 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 AlloMap Kidney, the CLIA validation for AlloMap Kidney, and KidneyCare, and the potential benefits and results that may be achieved through AlloMap Kidney, the CLIA validation for AlloMap Kidney, and KidneyCare. 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 the CareDx does not realize the expected benefits of the AlloMap Kidney, the CLIA validation for AlloMap Kidney, or KidneyCare; 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, 2020 filed by CareDx with the SEC on February 24, 2021, the quarterly report on Form 10-Q for the first quarter of 2021 ended on March 31, 2021 filed by CareDx with the SEC on May 5, 2021, the quarterly report on Form 10-Q for the second quarter of 2021 ended on June 30, 2021 filed by CareDx with the SEC on July 29, 2021, the quarterly report on Form 10-Q for the third quarter of 2021 ended on September 30, 2021, filed by CareDx with the SEC on October 28, 2021, 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.

CONTACTS:

CareDx, Inc.

Sasha King

Chief Marketing Officer

415-287-2393

**sking@CareDx.com**

Investor Relations

Ian Cooney

(415) 722-4563

**investor@CareDx.com**

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